Health Technology Assessment Report 3

Prevention of relapse in alcohol dependence


With significant contributions from the Topic Specific Group (Appendix 1)

Prevention of relapse in alcohol dependence
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1 EXECUTIVE SUMMARY

1.1 Background

1. The 1998 Scottish Health Survey included questions to estimate the scale of alcohol dependence in Scotland. It recorded that 10% of male drinkers and 3 – 4% of female drinkers replied affirmatively to one or more of three questions designed collectively to identify alcohol dependence. All three questions were answered affirmatively by 1% of male drinkers but less than 0.5% of female drinkers.

2. Untreated alcohol dependence results in levels of drinking which substantially increase the risk of stroke, cirrhosis of the liver, brain damage and several forms of cancer and are associated with increased mortality.

3. Following initial detoxification of people with alcohol dependence, a longer-term programme of treatment is required to prevent relapse into heavy drinking and dependence. A number of different psychosocial and pharmacological interventions are available to prevent relapse. These are the focus of this Health Technology Assessment.

4. The Plan for Action on Alcohol Problems was published in January 2002 (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) and covers a wide range of social, economic and clinical aspects of the misuse of alcohol in Scotland, including chronic heavy drinking. This Health Technology Assessment provides policy makers, planners and those working in the field of prevention of relapse in alcohol dependence with information required to implement a part of the plan. Local Alcohol Action Teams should take account of this advice when preparing the local strategies to be published in April 2003, that are required by the Plan for Action.

5. People with established alcohol dependence are likely to require treatment mainly within Tier 3 (for people with more complex needs) or Tier 4 (for people with highly specialised needs) of the Scottish Executive’s Alcohol Problems Support and Treatment Framework. Thus, this Health Technology Assessment will be of primary interest to those concerned with these specialist tiers. However, aspects of prevention of relapse may happen in Tier 1 (services for the whole community) or Tier 2 (local services that identify and respond to people with alcohol problems). In 2003, the Scottish Intercollegiate Guidelines Network (SIGN) will publish a guideline on the management of harmful drinking and alcohol dependence in primary care.

6. There is no single definition of alcohol dependence used by clinical trial investigators, although certain basic features tend to be shared. Rigid adherence to any single criterion would have forced many studies to be discarded and so in this Health Technology Assessment, when possible, the pragmatic criterion that any process of detoxification had been undergone was preferred.
1.2 Objectives of this Health Technology Assessment

The objectives of this Health Technology Assessment were to answer the following questions:

1. Which treatment or combination of treatments (pharmacological and psychosocial) will yield the maximum maintenance of recovery amongst the population of those with alcohol dependence who have undergone detoxification?

2. What is the most effective and efficient approach to delivering the individual interventions (or combination of interventions) taking into account the different risk groups, locations, durations of treatment, etc?

1.3 Health Technology Assessment evidence

1. This Health Technology Assessment used systematic literature searching to identify evidence published in scientific literature. It also used evidence submitted by professional groups, patient groups, manufacturers, other interested parties and experts and commissioned primary research with patients to elicit their views and preferences.

2. For clinical effectiveness, a number of comprehensive reviews of treatment for alcohol problems and reviews of specific interventions were consulted. Studies particularly relevant to people with alcohol dependence were extracted from these reviews. Additional relevant studies were identified and an analysis was carried out to estimate the effects of treatment in a form suitable for input to the Health Technology Board for Scotland economic model.

3. The patient issues component used published scientific literature, materials from Alcoholics Anonymous, and a qualitative study of patient attitudes commissioned by the Health Technology Board for Scotland.

4. The economic evaluation critically appraised the economic models contained in the literature. The Health Technology Board for Scotland developed a simple, transparent model to combine the clinical effectiveness and epidemiology data with the costs of therapies and diseases in order to inform the cost effectiveness estimates of four psychosocial and three pharmacological therapies to prevent relapse in people who are alcohol dependent.

5. The current provision of services for prevention of relapse in alcohol dependence in Scotland was assessed by two postal surveys. One of these was targeted at National Health Service specialist services and the other at non-National Health Service providers.

1.4 Clinical effectiveness

1. A number of psychosocial interventions were found to be of value in preventing relapse in alcohol dependence. The total combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between six months and beyond one year), in trials of those psychosocial treatments judged effective, was 42% for patients in the intervention groups and 26% for those receiving control
treatments. In common with clinical trials in many other areas of medicine, these may overestimate the absolute benefits attainable in everyday clinical practice.

2. The Health Technology Board for Scotland meta-analysis suggested similar, statistically significant, beneficial effect sizes for four types of psychosocial treatment. The odds ratios for abstinence or controlled drinking at the end of the clinical trial compared with patients offered control treatments were: Behavioural Self-Control Training (odds ratio=1.75, 95% confidence interval 1.02, 3.02); Motivational Enhancement Therapy (odds ratio=1.88, 95% confidence interval 1.28, 2.77); Marital/Family Therapy (odds ratio=1.94, 95% confidence interval 1.37, 2.73); and Coping/Social Skills Training (odds ratio=2.11, 95% confidence interval 1.53, 3.92).

3. Behavioural Self-Control Training showed benefit when compared with control interventions. However, the only trial which focused on the unique defining features of Behavioural Self-Control Training and controlled for the more general features of Cognitive Behavioural Therapy did not show a benefit. Thus, there is no proof of superiority over other Cognitive Behavioural Therapy based approaches.

4. There is mixed evidence for Motivational Enhancement Therapy. It shows efficacy over ineffective controls. However, it was slightly less effective than Alcoholics Anonymous based treatment in outpatients in Project MATCH. This may be due to the short course of treatment given. It is suggested that Motivational Enhancement Therapy might be provided first, if such a relatively low intensity approach has not already failed, and more intensive therapy then given if necessary.

5. Although Marital/Family Therapy has shown a beneficial effect it should be recognised that this approach is only usually feasible in those with relatives willing to invest substantial effort in the treatment and with the consent of the patient. Thus, it is an option for treatment of only some patients. An exception to this is the Community Reinforcement Approach, which has been shown to be effective when a contractual element with non-family members has been tested.

6. Trials of Brief Interventions have failed to show any benefit in patients with established alcohol dependence.

7. Acamprosate and naltrexone are pharmacological treatments intended to reduce relapse. The meta-analysis suggested statistically significant beneficial effects for both treatments: acamprosate (odds ratio=1.73, 95% confidence interval 1.36, 2.20); and naltrexone (odds ratio=1.46, 95% confidence interval 1.12, 1.90). The combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between three months and one year), in trials of these treatments was 34% for treated patients and 25% for those receiving placebo treatments. These may overestimate absolute benefits attainable in clinical practice.

8. Disulfiram, which causes unpleasant symptoms when taken with alcohol, was found to be ineffective if taken without supervision to ensure compliance. One good clinical trial and some substantiating evidence supports the use of supervised oral disulfiram.
9. All the evidence for effectiveness of pharmacological treatments is obtained from studies in which they were adjuncts to ‘counselling’. Thus, the psychosocial treatment should preferably be organised prior to starting medication.

10. Within a specialist unit, protocols should be available for all treatment options to ensure standardised and consistent treatment. These protocols should be closely based on methods that have proven effective in clinical trials.

11. Evidence suggests that practical help with problems such as housing, debt and claiming benefits is likely to contribute to control of alcohol problems. Thus, close liaison with local authority services such as social work and housing and groups able to deliver such help is essential.

12. Encouragement to attend Alcoholics Anonymous meetings has been shown to have benefit. Explanation of the aims and philosophy of Alcoholics Anonymous during treatment will allow patients to make an informed choice. For benefit to be obtained from Alcoholics Anonymous, as with other psychosocial treatment approaches, people with alcohol dependence should not be pressurised to attend.

13. The effectiveness of interventions for prevention of relapse delivered by the Councils on Alcohol, and some other non-statutory services, has not been tested in clinical studies. Where counsellors are practising treatments that have been shown to be effective in other settings there is likely to be benefit.

1.5 Patient issues

1. Method of treatment, treatment awareness and access, involvement in choice of treatment and follow up were identified as key patient issues.

2. It is important that both the person who is alcohol dependent and his or her doctor understand and agree the purpose of treatment and review this understanding.

3. In reply to the Health Technology Board for Scotland survey, only 36% of National Health Service specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. It is recommended that such information should be available for all interventions.

4. A qualitative study has been undertaken for the Health Technology Board for Scotland, to explore patients’ treatment preferences and also to elicit factors which were felt to prevent relapse to drinking. The aim was to describe the experiences and preferences of individuals for pharmacological or psychosocial interventions, or a combination of both, for the treatment for alcohol dependence. This was achieved by undertaking in-depth one-to-one interviews with 45 patients in three Trusts in NHSScotland.

5. Issues to emerge from this qualitative research include:

- participation in residential or day case relapse services may currently depend on the way services are structured locally, rather than patient choice.
• lack of understanding of terms such as Cognitive Behavioural Therapy and Motivational Enhancement Therapy need to be recognised in communication with service users
• participants valued activities such as coping skills training, assertiveness training, anger management, stress/anxiety management, relaxation exercises and rehearsing difficult situations within a safe environment.
• views about pharmacological interventions differed greatly. Some people identified a role for acamprosate in providing confidence about not being tempted to drink, while others doubted whether acamprosate reduced the sense of craving. However, those who felt the benefits were convinced.
• most people who had no experience of taking disulfiram said this was because they would not trust themselves not to drink while taking it.
• all who took these pharmacological interventions believed that the pharmacological and psychosocial interventions were complementary.
• women who had experienced ‘women only’ group work had a preference for women only groups, but conversely men may have a preference for mixed sex group work.
• individual therapy sessions may be valued for the depth of work they enable.
• flexibility of times and venues was valued.
• a Helpline number given to people when they were discharged from inpatient treatment in one Trust was valued.
• all participants in this sample of National Health Service attenders recognised that Alcoholics Anonymous works well for many people, but most of them felt that it was not suitable for them.
• awareness of services other than Alcoholics Anonymous may be low and may require better promotion.

6. Additionally, the study, the literature and consultation comments indicate that awareness of different services and treatments may be low among health professionals and service users and require better promotion and discussion to identify treatment preferences. A shared understanding and mutual agreement regarding the purpose of treatment is important between a person who is alcohol dependent and his or her doctor.

7. Letters from services users of residential 12-step settings tended to emphasise the benefits of residential treatment and Alcoholics Anonymous.

8. It is clear from the results of clinical studies that all interventions are of limited effectiveness. It is therefore worth providing a range of options of proven efficacy. Treatment should be individualised taking account of patients’ expectations, needs and wishes with the understanding that these needs may change and the treatment plan should adapt to this.

1.6 Economic evaluation

1. The economic evaluation compared the costs and consequences of seven therapies in comparison to a standard care package. The relevant outcomes were disease states, these being alcohol dependence, alcoholic psychosis (including alcohol-related brain damage), liver cirrhosis, epilepsy, chronic pancreatitis, cancer, stroke and death.
2. For each therapy, the costs and consequences for 1000 patients complying with the therapy were modelled and compared with the costs and consequences for 1000 patients receiving a standard care package. This involved:

- defining and costing each intervention
- applying the clinical effectiveness odds ratio for the intervention to the epidemiology for the cohort, to calculate the number of patients likely to be in the various disease states
- calculating the costs to NHSScotland of the disease states
- calculating an incremental cost or saving per additional abstinent patient.

3. The results show that each of the four psychosocial interventions (Coping/Social Skills Training, Behavioural Self-Control Training, Motivational Enhancement Therapy and Marital/Family Therapy) and acamprosate produce net savings per incremental abstinent patient. This means that the cost of the intervention is less than the savings it affords to NHSScotland. These savings arise because the improved abstinence rate results in a lower incidence of diseases, thereby saving inpatient hospital stays and other disease-related costs.

4. Naltrexone and unsupervised oral disulfiram have a net cost per abstinent patient but are judged to be cost effective in comparison to standard care. Sensitivity analysis shows that the ranking of therapies is robust.

5. A limitation of the model is the absence of data on relapse rates beyond the relatively short trial periods. There are also concerns about generalising from trials to treating patients in a Scottish setting. Further research and evidence is therefore needed to give more definitive estimates of the long-term effectiveness of all the therapies in a Scottish setting.

6. The financial implications of implementing the recommendations presented in the organisational and patient issues sections of this Assessment Report amount to £2.5 million per annum.

1.7 Organisational issues

1. Randomised controlled trials testing matters related to the organisation of specialist alcohol services are scarce. Thus, recommendations with regard to organisational issues also take account of clinical expert judgement, economic evaluation, patients’ needs and preferences, surveys of existing services and relevant policy documents.

2. Alcohol dependence is a relapsing condition and the need for ongoing treatment, even after a number of unsuccessful interventions, should be recognised.

3. Alcohol services are highly suited to ‘joint working’, as recommended by the Joint Futures Group, involving specialist mental health and social work addiction services and non-statutory agencies with joint resourcing and management of community care services.
4. Certain subgroups such as young people, the homeless and those with comorbid mental health problems, have special service needs and providers should ensure that the service is accessible to all and responsive to differences in users’ needs.

5. NHS specialist alcohol services should be multidisciplinary community (and day hospital) based services with the option of specialist inpatient/residential care. Consolidation of services may be necessary to allow for a concentration of expertise and resources for inpatient services for example.

6. Specialist services must make themselves aware of mutual help (Alcoholics Anonymous) and non-statutory agencies operating in their area and coordinate their approach, making this information available to individuals within their care. Informing patients about Alcoholics Anonymous and non-statutory agencies should be part of the overall strategy for prevention of relapse.

7. In specialist settings it will usually be the case that abstinence will be the goal for severe dependence, where controlled use is rarely sustainable and especially when there is evidence of alcohol-related organ damage. Controlled use of alcohol may be an appropriate treatment goal for those with less severe alcohol problems. If controlled use or harm minimisation is the considered preferred goal of the individual, there must still be options for intervention e.g. referral to a non-statutory agency or outpatient motivational sessions.

8. The National Health Service survey identified gaps in the core provision of services for inpatient/residential facilities and for staffing. In addition to the core services, it is good practice for specialist services to make arrangements for continuing care of service users. For example, service users value follow up, such as a phone call, when they miss appointments.

9. An improved information collection system is required. Information and Statistics Division is currently developing the National Alcohol and Information Resource for use by those who plan and provide services. Local services should liaise with Information and Statistics Division regarding methods of recording and collecting information.

10. A regularly updated comprehensive directory of alcohol services including residential treatment would be beneficial. This should be useable by all participating agencies and where available provide accurate outcome data as well as a greater understanding of progress through the treatment system.

1.8 Discussion

1. This Assessment Report addresses the problems of prevention of relapse in people who are alcohol dependent and have undergone detoxification and are newly abstinent.

2. The focus of this Assessment Report is the service delivered by NHS specialist staff and the evidence reviewed is largely drawn from studies carried out in a specialist setting. Extrapolation from any of the Health Technology Assessment conclusions to other settings should be undertaken with caution. Advice on
management of alcohol problems by primary care professionals is available from the Scottish Intercollegiate Guidelines Network (SIGN).

3. This Health Technology Assessment views alcohol dependence from a health perspective. However, no effective service can ignore the societal aspects of drinking alcohol. The existence of a spectrum of drinking from the socially acceptable, and even encouraged, to the socially unacceptable and dangerous necessitates an unbiased self-assessment by the person before treatment will even be sought. Thus, judgmental attitudes concerning alcohol dependence may delay some people in seeking help. In consequence, weight has been given in this Health Technology Assessment to perceptions of service users and the message that any alcohol treatment service must be approachable cannot be emphasised too highly.

4. The long-term health consequences of harmful drinking have been reviewed using sources drawn from published literature. This analysis revealed the extensive damage caused to the health of people who drink beyond defined limits. The increased risk of several types of cancer, liver disease, brain damage and of death from many causes show clearly the importance of identifying and effectively treating alcohol dependence at an early stage.

5. The quality of evidence regarding effectiveness of interventions is not high. Most studies of psychosocial interventions are performed by skilled enthusiasts. Furthermore they generally involve small, and necessarily unblinded, trials. The assumption that other specialists can consistently achieve similar results in everyday practice is not obviously justifiable. Hence, very stringent criteria have been imposed in the cost-effectiveness analyses to test the robustness of the Health Technology Assessment conclusions on this point. Similar remarks apply to acamprosate and naltrexone which show unexpected variations in efficacy between studies.

6. The concern that it might be difficult to reproduce in clinical practice the effectiveness seen in clinical trials has led to several conclusions with respect to the importance of therapist training, access to expert psychological advice and the existence of robust quality assurance measures. It is stressed that the complex nature of psychosocial interventions and the important role of therapist qualities in their delivery make these measures an essential element in ensuring a consistent and effective service.

1.9 Recommendations

1. Behavioural Self-Control Training, Motivational Enhancement Therapy, Marital/Family Therapy and Coping/Social Skills Training are clinically and cost-effective psychosocial interventions and are recommended treatment options for the prevention of relapse in alcohol dependence.

2. Brief Interventions are not recommended, as trials in people with alcohol dependence have failed to show any benefit. However, the Scottish Intercollegiate Guideline Network (SIGN) will recommend Brief Interventions for hazardous drinkers (a less severely affected group than those who are considered to be alcohol dependent).
3. Other psychosocial interventions are not recommended as their clinical effectiveness is unproven.

4. Acamprosate and supervised oral disulfiram are treatment options recommended as adjuncts to psychosocial interventions. Naltrexone does not have a Marketing Authorisation for the treatment of alcohol dependence in the United Kingdom and is not recommended for routine use in NHSScotland.

5. Alcohol services should aim to reduce the delay between detoxification and interventions for the prevention of relapse. This would be facilitated by joint working between specialist mental health services, primary care, social work addiction services and non-statutory agencies, as recommended by the Joint Futures Group.

6. Acamprosate or supervised oral disulfiram should usually be initiated by a specialist service. The specialist service will: ensure that the patient meets the criteria for suitability; ensure the assessment of the motivation and ability of the patient to use the medication correctly; monitor efficacy; and ensure that adjunctive psychosocial treatment is organised. Usage should be in accordance with the Summary of Product Characteristics, and should also be reviewed regularly during the first 12 weeks after initiation of treatment, at which stage transfer of prescribing to the general practitioner may be appropriate, even though specialist care may continue (shared care).

7. Introduction to Alcoholics Anonymous and non-statutory agencies such as local Councils on Alcohol (Alcohol Focus Scotland) should be part of the overall strategy of specialist NHS services for the prevention of relapse. As with other psychosocial treatments, attendance is most likely to be beneficial if it is an informed voluntary decision.

8. People who are alcohol dependent should be informed about treatment choices. Their needs, preferences and social circumstances should be considered. As a result, the choice of interventions should be a shared decision between the health professional and the patient.

9. NHS specialist services should contact people who drop out of treatment programmes and offer them another appointment.

10. Health professionals should provide patient information, including leaflets, which should be used to support discussion between health professionals and patients about the most appropriate treatment option.

11. Written information about the range of available services should be readily accessible to people with alcohol problems, their families, carers and to health professionals, especially general practitioners. Alternative formats such as cartoons or audio-visual material should be used to support discussions with people who have low reading skills or poor concentration. Alcohol Action Teams could coordinate information requirements.
12. A regularly updated comprehensive directory of alcohol services and accommodation should be developed for the benefit of NHSScotland staff, patients and their families, friends and carers.

13. Shorter, less intensive interventions (such as Motivational Enhancement Therapy) might be provided first, following the principle of ‘stepped’ care, if the history suggests that such a relatively low intensity approach has not already failed. Non-response will indicate the need to move to more intensive treatment.

14. Recurrent relapse should not be a barrier to re-referral. If a particular intervention is unsuccessful for an individual, it is important to recognise that other treatments may be more suitable and that further options should be explored.

15. Core services should provide the full spectrum of treatment options, including access to beds for NHS inpatient or private/non-statutory residential treatment. This might be achieved economically by sharing of services across Trusts and Boards provided that access is carefully considered.

16. To ensure equity of access for the heterogeneous group of people with alcohol dependence, the provision and standard of alcohol services should be consistent throughout NHSScotland.

17. Specialist NHS services should make provision for the continuing care of each individual.

18. Certain subgroups of people with alcohol dependence such as those in rural communities, young people, the homeless, those with comorbid mental health problems and those in the criminal justice system can encounter unique difficulties in accessing specialist services. Providers should make reasonable efforts to ensure that the needs of every alcohol-dependent person can be accommodated somewhere within the spectrum of service provision.

19. Providers should develop services for the relatives, carers and dependants of people with alcohol dependence.

20. Joint training of staff from NHS and non-statutory services is recommended to help ensure that all staff are trained to uniform standards and equipped with the necessary skills to deliver the recommended interventions.

21. Interventions should be carried out in accordance with standardised protocols by staff trained to agreed national standards.

22. Measures should be in place to ensure that psychosocial treatments are delivered to consistently high standards over time. The delivery of these interventions should be as similar as possible to that which has been shown effective in clinical trials. As these have involved delivery by clinical psychologists, the skills of such professionals should be used at least in supervision of treatment delivery and in training in methods of delivery.

23. The Plan for Action (Scottish Advisory Committee on Alcohol Misuse, 2002) requires each Alcohol Action Team to draw up, publish by April 2003, and
subsequently implement, a local strategy covering at least three years. These strategies should take account of these recommendations.

24. An improved information collection system is required to ensure that the requirements of these recommendations are fulfilled. Development of the National Alcohol and Information Resource (NAIR), currently being undertaken by the Information and Statistics Division, should take these requirements into account.

25. In order to assess the long-term clinical course of alcohol dependence following treatment in Scotland, measurement of simple, verifiable outcomes such as further detoxification over a period of, for example, five years would prove useful. Long-term treatment success rates in terms of abstinence or controlled drinking should be reported.

26. More research is needed regarding the benefits of different settings for psychosocial interventions in order to determine the most effective and efficient approach to delivering the interventions. It has not been established whether group therapy is more effective than individual therapy, or whether an inpatient, outpatient or day unit setting is most conducive to treatment success. It is unclear if there is a correlation between the effectiveness of interventions and the length, frequency or intensity of treatment. In particular, the impact on effectiveness of multiple psychosocial treatments for one individual is not established.

27. Acamprosate (and naltrexone) have given unusually variable results in clinical trials in specialist settings, with some trials having shown no treatment effect. Possible explanations have been suggested but these require corroboration by prospective studies. Given the variability of effect even in specialist settings, any extrapolation to use in primary care requires new clinical trial evidence of effectiveness.

28. A trial of supervised oral disulfiram has shown a convincing reduction in drinking while on the drug but no study has demonstrated that this results in an increased likelihood of ongoing abstinence or controlled drinking. Such a study is needed to inform clinical practice.
2  INTRODUCTION AND OBJECTIVES

2.1  Introduction

The document titled ‘Our National Health: a plan for action, a plan for change’ (Scottish Executive Health Department, 2000) made a clear commitment relating to alcohol misuse. In particular it stated that ‘we will develop a plan for action on alcohol misuse, bringing together what needs to be done by all concerned, including the Executive. Prevention and services for people with alcohol problems will lie at the heart of the plan.’.

This Plan for Action on Alcohol Problems was published in January 2002, by the Scottish Advisory Committee on Alcohol Misuse (SACAM, 2002) and covers a wide range of social, economic and clinical aspects of the misuse of alcohol in Scotland. The Plan notes that ‘Two current exercises will add in the next year or two to our understanding of how best to address the whole range of alcohol problems, including chronic heavy drinking. These are work by the Scottish Intercollegiate Guidelines Network (SIGN) on the management of alcohol problems by primary care professionals and by the Health Technology Board for Scotland (HTBS) on prevention of relapse.’. This Assessment Report fulfils the second of these commitments.

This HTBS Health Technology Assessment (HTA) assesses interventions to prevent relapse in those who are alcohol dependent (Section 3.5) and have undergone detoxification. It will link in closely to the Scottish Executive Health Department (SEHD) initiative, particularly in terms of organisation of services.

The prevention of relapse therapies studied in this HTBS HTA are mainly given in secondary care settings and so this HTA will complement the SIGN guideline on management of alcohol dependence in primary care (due to be completed early in 2003 – see Appendix 2).

HTBS uses the internationally recognised definition of HTA (INAHTA, 2000) describing it as a multidisciplinary field of policy analysis that studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology.

This HTA follows a modification of the process published by HTBS (Health Technology Board for Scotland (HTBS), 2001). This involves the submission of evidence from a wide variety of sources, expert staff to undertake the analyses, a multidisciplinary expert Topic Specific Group (TSG) to collect and critique evidence and analyses, quality assurance (QA) by the HTBS Governance Board and wide-ranging open consultation and expert review.

In this HTA, national and international evidence is critically appraised, taking account of Scottish circumstances, so that clear, practical recommendations can be made to the National Health Service in Scotland (NHSScotland). Two other summary documents have been produced based on this HTA. The Advice to NHSScotland is aimed at policy makers, NHS Board decision makers and health care professionals. An Understanding HTBS Advice document has also been published explaining to
patients, carers and the public how the evidence was reviewed and the reasons for the HTBS recommendations.

2.2 Objectives

The objective of this HTA is to answer the following questions:

1. Which approach or combination of approaches will yield the maximum maintenance of recovery amongst the population of those with alcohol dependence who have undergone detoxification?

2. What is the most effective and efficient approach to delivering the individual interventions (or combination of interventions) taking into account the different risk groups, locations, duration of treatment, etc.?

The health interventions considered fall into two categories: pharmacological and psychosocial. This latter category covers a wide range from the purely psychological to those that attempt to intervene practically in many areas of social welfare and functioning.

A number of subsidiary questions were identified by our expert advisers, during the planning phase of this HTA. These were used to focus on the selection of literature and the review process. These questions are included as Appendix 3.

2.3 What is in this document?

This document presents a critical appraisal and detailed presentation of the analysis of evidence gathered to inform the four components of the HTA as identified in Figure 2-1: clinical effectiveness, cost effectiveness, patient issues and organisational issues. A final discussion and recommendations bring together the key aspects from each section.

2.4 What is the aim?

This Assessment Report seeks to inform decision making and policy.

2.5 Who should use it?

It is intended that this document should be used by those involved with the planning and running of specialist alcohol services. Local Alcohol Action Teams (AATs) should take account of the report when preparing the local strategies, required by the Plan for Action (SACAM, 2002) to be published in 2003.

2.6 Who produced the document?

The Assessment Report was produced by a multidisciplinary team of HTBS staff and consultants, guided by the TSG and the Health Technology Board. Many people contribute to HTBS HTAs to facilitate understanding and implementation of the report. Wide public consultation is used to ensure that all views are taken into consideration.
In January 2003, HTBS will become part of a new body called NHS Quality Improvement Scotland which will aim to promote the highest quality of patient care in NHSScotland by contributing to best practice in clinical care and ensuring effective clinical governance.
Figure 2-1  Health Technology Assessment (HTA) process

Topic proposal & filtration

Selection by HTBS Board: definition of the policy question(s) & objective

Determination of background information

Planning: scoping & protocol development

Definition of evidence question(s)

Assessment Report

Working with evidence

Clinical effectiveness

Epidemiology

Organisational issues

Patient issues

Economic evaluation

Scottish interpretation with TSG

Board and external review including open consultation

Conclusions & recommendations

Final Assessment Report

Dissemination of Report, Advice, Understanding

Implementation of HTA by NHS Boards

Review of the HTA by HTBS
3 BACKGROUND

3.1 Alcohol misuse in Scotland

Scotland has a significant alcohol misuse problem. This has been highlighted in the Scottish Executive’s Plan for Action on Alcohol Problems (SACAM, 2002) referred to henceforth as the ‘Plan for Action’. Planning services for treatment of alcohol problems requires an understanding of the existing treatment services and a prediction of the volume of service required, in addition to knowledge of the clinical and cost effectiveness of treatments. This HTA addresses the particular problems of prevention of relapse in that subgroup of drinkers who are alcohol dependent. Service planning for these patients is complicated by the difficulty of defining the group of patients who want, or would benefit from, interventions for the prevention of relapse.

The misuse of alcohol can lead to a wide range of physical, psychological and social problems and places a significant burden on the workload of the NHS. This burden results from damage not only to the harmful or problem drinker but also to third parties affected by the excessive drinking. The Plan for Action estimates that alcohol problems cost Scotland at least £1 billion each year. Much of this is accounted for by reduced productivity and human costs. The direct costs of alcohol problems (£449 million annually) to health, social work and criminal justice systems are more than drug misuse (£382 million), Alzheimer’s disease (£155 million), schizophrenia (£121 million) or stroke (£118 million). Alcohol problems therefore impose a substantial financial burden on Scottish society, the considerable costs to statutory agencies draining resources from other priorities.

There is no single culture surrounding drinking in Scotland. It extends across age groups, genders, ethnic and religious groups, urban and rural areas. This heterogeneity must be borne in mind when planning services and interpreting clinical and cost-effectiveness reviews. In addition, problems, such as access to appropriate and sensitive services, that may be experienced by groups including homeless people, older people, users of illegal drugs, minority ethnic groups, disabled people and people in rural areas must be identified and addressed.

The association between alcohol and drug misuse should be recognised both in treatment approaches and overall service planning. The similarities and differences between alcohol and drug problems are discussed in the Plan for Action, with some approaches to treatment being applicable to both. It is noted that the number of people misusing alcohol in Scotland far exceeds the number using illegal drugs.

The links between severe problem drinking, homelessness and imprisonment are also acknowledged and are important factors in assessment of services for the prevention of relapse.

The Plan for Action has highlighted worrying trends in alcohol use in Scotland against which the current initiatives are set. The following are statistics taken from the Plan for Action:

- 44% of all men and 26% of all women are drinking more than twice the recommended daily benchmarks (less than eight units for men and less than six units for women) on their heaviest drinking day each week
• alcohol-related death rates for women have doubled in the last decade (from 13.4/100 000 in 1990 to 31.2/100 000 in 2000)
• in 1990, alcohol-related deaths accounted for one in 100 deaths in Scotland. By 1999, this had risen to one in 40. These figures might in part reflect altered recording although there is evidence from liver deaths that this is not the explanation. More than two thirds of alcohol-related deaths are in men.

3.2 Treatment strategy and settings

Treatment for alcohol dependence may usually be considered to have two distinct but interrelated arms. Firstly, helping the individual to stop or reduce alcohol use. This may require supervised detoxification. The second arm of treatment is to help the individual live a life of abstinence or controlled drinking depending on the goal of treatment, the ethos of the service and the individual’s preference. This understanding that detoxification is only the start of the journey in the treatment of alcohol dependence is of major importance to all agencies involved in health care. Long-term benefit relies on the development of life skills and methods that enable individuals to maintain the desired changes in their use of alcohol. It is this second arm of treatment under the title of prevention of relapse that will be the focus of this HTA.

Detoxification and prevention of relapse, although distinct processes, have an important relationship in terms of timing (Prochaska et al., 1992). Detoxification may only improve long-term outcome if the individual has reached a crucial point in their attitude toward drinking. The early transition from detoxification, whether inpatient or outpatient, to adapting to life without alcohol may be a crucial period for long-term outcome. This may be the point where pharmacological interventions have the greatest role.

Prevention of relapse may involve psychosocial (a combination of psychological and social) and pharmacological interventions. It is characteristically most intensively carried out in the few weeks immediately following detoxification, and may also be part of a longer-term intervention aimed at reducing overall harm caused by alcohol. The main aims of psychosocial interventions are to support, motivate and encourage effective coping skills. Introduction to other agencies in the treatment ‘system’ can be part of the overall strategy for the prevention of relapse.

Agencies carrying out interventions for the prevention of relapse will be described later in this section of the report (Section 3.18). However, it should be mentioned here that the interventions described are, for the most part, carried out by specialist alcohol services. Generalist interventions (e.g. as carried out by general practitioners [GPs], general medical and even general psychiatric wards) are usually limited to ‘opportunistic’ interventions. These latter interventions involve screening for alcohol problems, identifying hazardous or harmful drinkers and offering minimal (brief) interventions, aimed at reducing drinking to low risk levels. More seriously impaired or dependent individuals may be referred on to specialist services although some generalists feel more able to offer intensive treatments. Other interventions, which are currently usually initiated in a specialist service, e.g. acamprosate, may be best continued in a generalist setting with ongoing monitoring by the specialist service. This ‘shared care’ is a current area of development in substance misuse managements generally. The NHS Executive (1995) defines shared care as ‘the joint participation of
specialists and GPs (and other agencies as appropriate) in the planned delivery of care for patients with a drug (alcohol) misuse problem, informed by an enhanced information exchange beyond routine discharge and referral letters. It may involve the day-to-day management by the GP of the patient’s medical needs in relation to his or her drug (alcohol) misuse. Such arrangements would make explicit which clinician was responsible for different aspects of the patient’s treatment and care.’

3.3 Health consequences of high levels of drinking

The health consequences of drinking beyond the recommended daily levels are many and varied. Harmful alcohol use (see Section 3.20.3 for definition) often persists over many years, although some drinkers may have intermittent periods of prolonged sobriety. Those with a pattern of harmful alcohol use may present as dependent, seeking help, intoxicated, in withdrawal, with physical or psychiatric comorbidity, in the wake of an accident, with social problems or having infringed the law.

Prolonged harmful alcohol use often leads to serious health disorders affecting the nervous system (Wernicke’s encephalopathy, Korsakoff’s syndrome, alcoholic dementia, peripheral neuropathy), the liver (cirrhosis, alcoholic hepatitis), the gastrointestinal system (opharyngeal cancer, gastritis, upper gastrointestinal bleeding, pancreatitis), the cardiovascular system (cardiomyopathy, hypertension), the respiratory system (laryngeal cancer), and the haematological system (anaemia, bleeding disorders). In addition, the risk to the fetus in a pregnant alcohol misuser is well recognised.

A recent study of the incidence of Korsakoff’s syndrome in East Glasgow (Ramayya & Jauhar, 1997) highlighted a sharp increase in presentation in recent years, rising from 12.5 per million in 1990 to 81.25 per million in 1995. This is amongst the highest incidence reported anywhere in the world.

Harmful alcohol use is commonly associated with psychiatric illness. Harmful drinking may be a response to underlying depressive illness or may itself precipitate depressive illness. It can cause, or sometimes develop alongside, anxiety disorders. Alcohol is associated with a high proportion of completed and attempted suicides. Harmful drinkers can present with erectile impotence and decreased libido. Dependent drinkers (see Section 3.5 for definition) in withdrawal may develop delirium tremens. Alcoholic hallucinosis/psychosis may occur secondary to prolonged heavy alcohol use.

A quantitative discussion of the long-term health expectations of heavy drinkers is given in Section 3.20.

3.4 Social and economic consequences of problem drinking

The Plan for Action highlighted many problems which may accompany alcohol dependence. It often leads to severe social and economic consequences for individuals and their families. Harmful alcohol use is associated with violence (domestic and otherwise), family stress, problems at work (including loss of job), financial strain and social isolation. The social exclusion that may result from problem drinking may lead to homelessness and offending behaviour. There is an association with theft and other crimes (including homicide) committed under the influence of alcohol. Alcohol
contributes to road accidents due to intoxicated pedestrians as well as intoxicated drivers.

3.5 The definition and prevalence of alcohol dependence

Standard definitions of dependence are given in full in Appendix 4. The definition commonly used, and upon which hospital discharge data and mortality data are coded, uses the International Classification of Disease (ICD-10) (World Health Organisation, 1992) diagnostic categories. This requires the presence of three or more of the following for a diagnosis of dependence:

1. a strong desire or sense of compulsion to take alcohol
2. impaired capacity to control alcohol taking behaviour
3. a physiological withdrawal state
4. evidence of tolerance to the effects of alcohol
5. preoccupation with alcohol use (to the detriment of alternative pleasures or interests)
6. persistent alcohol use despite clear evidence of harmful consequences.

The true prevalence of alcohol dependence, according to this definition, is difficult to estimate. This is because dependent individuals will not necessarily present for medical treatment. However, various estimates have been made from concomitant evidence.

A high proportion of the Scottish population currently drinks. Only 7% of men and 12% of women aged 16 – 74 said that they did not currently drink (Shaw et al., 2000). At the 2001 census there were 1 823 000 men and 1 940 000 women of age 16 – 74 years in Scotland. This suggests a population of slightly more than 1.7 million male and 1.7 million female drinkers.

The Scottish Health Survey 1995 (Dong & Erens, 1997) estimated that the numbers of Scottish adults exceeding the weekly recommended limits of 21 units for men and 14 units for women were 33% of men and 13% of women. In the same year, 8% of men were drinking above 50 units per week and 1% of women were drinking above 35 units per week. These levels are known to have a harmful effect on the drinkers’ health. In absolute terms they represent about 146 000 men and 19 000 women drinking at harmful levels.

Drinking at a harmful level does not necessarily mean the drinker is alcohol dependent. The Scottish Health Survey 1998 (Shaw et al., 2000) contained three statements designed to assess dependence: ‘There have been occasions when I felt unable to stop drinking’; ‘I have had a drink first thing in the morning to steady my nerves or get rid of a hangover’; and ‘I have found that my hands were shaking in the morning after drinking the previous night’.

Looking at the three items on physical dependence, 90% of current male drinkers said none of the three items applied to them, 7% said one applied, 2% two items and 1%
all three items. Among current female drinkers, the corresponding figures were 96% none, 3% one item. Precise figures are not given for two and three items but they are noted as being less than 0.5%: An average ‘dependence score’ of 0.05 is given for women which would suggest that about 0.3% answered three items affirmatively\footnote{If the highest value for two items (0.5\%) is assumed, 0.03x1+0.005x2+Yx3=0.05 and hence Y=0.0033.}. The likelihood of agreeing with one or more of these three items was highest among 16 – 24 year olds in both sexes, and then decreased with age. These figures suggest that 180 000 men and 34 000 women might answer one or more items affirmatively. However, 18 000 men and 5700 women would answer all three of these dependence items affirmatively.

Self-reported information on drinking must always be interpreted with caution. Cross-sectional surveys have been found to underestimate per capita consumption judged from alcohol sales figures. However, the preceding figures would appear to give reasonable bounds on the size of patient group that might benefit from specialist alcohol services. Assuming that it includes all those who would answer affirmatively to the three dependence items but would not exceed the numbers drinking harmfully, the number of men lies between 18 000 and 146 000 and the number of women between 5700 and 19 000.

The number who might use services will not necessarily equal the number who might benefit. Some measure of current usage of inpatient services can be gauged from Information and Statistics Division (ISD) hospital discharge figures for 1999 – 2000, which show 3268 discharges from psychiatric hospitals and 4398 discharges from non-psychiatric hospitals with a diagnostic code of F10.2, alcohol dependence syndrome (not necessarily as primary diagnosis). This total of 7666 does not include the numbers undergoing detoxification in the community and receiving other treatments not involving hospital admission. These may constitute significant numbers.

The Plan for Action gives the following rates:

- in 1999, one in 40 (or 1595) deaths were reported as alcohol related. The majority of these have a diagnosis of alcohol dependence and alcoholic liver disease: 51% alcoholic liver disease; 44% alcohol dependence; 13% acute intoxication; and 1% alcoholic psychosis. It is believed that alcohol is often omitted as a factor on the death certificate in deaths where alcohol was only a contributing factor, such as deaths from haemorrhagic stroke, cancer of the head and neck, suicide, burns, drowning or injuries.
- an estimated 0.7\% (107 685) of all GP consultations in Scotland were for alcohol-related diagnoses in 2000; of these, 69% were due to alcohol dependence, 21% due to alcohol intoxication, 5% due to physical/organ damage (including alcoholic liver disease), 3% due to alcoholic psychosis and 2% due to unspecified problem drinking/excess consumption
- three in 100 of acute hospital inpatient admissions had an alcohol-related diagnosis of which 28.5% were diagnosed as acute intoxication, 26.2\% (8618) as alcohol dependence, 24.7\% as alcohol problems, 17.1\% as organ damage
(including liver), 11% as alcohol poisoning (many of which were linked to overdoses) and 1% as alcoholic psychosis.

- 15% (4432) of all psychiatric hospital admissions had an alcohol-related diagnosis. Over two thirds of these (71.4%) had a diagnosis of alcohol dependence and the remaining diagnoses were: 20% (885) alcohol problems; 7.5% (332) alcoholic psychosis, (including alcohol-related brain damage); 2.6% (113) acute intoxication; 0.9% (40) other; 0.2% (9) organ damage including liver; and 0.02% (1) alcohol poisoning.

- men are twice as likely as women to be admitted to an acute or psychiatric hospital for alcohol-related problems.

### 3.5.1 Temporal trends

Official statistics on alcohol dependence over time are currently limited. However, the General Register Office has published figures for alcohol-related death which showed a steady rise from below 700 in 1990 to 1600 in 1999. Such figures must be interpreted with caution as recording practices may have changed during the decade both in the way particular disease codes are used and in willingness to attribute death to alcohol. However, the suggestion is clear that alcohol represents an important and increasing cause of mortality. It is probable that this rise in mortality is a product of a similar rise in excessive drinking and the figures from the General Register Office for recent years suggest that this trend may be continuing.

### 3.6 Special subgroups

A number of subgroups within the alcohol-dependent population may present special problems in treatment. These include those with comorbid mental illness, those with a dual alcohol and other substance misuse problem, those presenting through the Criminal Justice System, homeless alcohol misusers and those people, often quite young, whose memory and judgement are impaired as a result of brain damage. In addition, slightly different presentations may exist in different ethnic groups.

#### 3.6.1 Comorbidity

Surveys show that about a third of acute psychiatric inpatients with severe and enduring mental health problems also have an alcohol problem (SACAM, 2002). Such a ‘dual diagnosis’ adds to an individual’s difficulties, complicates their treatment and may well delay their recovery. The Greater Glasgow Alcohol Strategy (Greater Glasgow Health Board, 2000) notes that consultant psychiatrists from all parts of Glasgow report an increase in the proportion of patients in psychiatric hospitals where schizophrenia or depressive illness are complicated by alcohol misuse.

#### 3.6.2 Dual substance dependence

There is evidence of people misusing alcohol along with drugs, both street-purchased and prescribed, such as benzodiazepines or methadone, with unpredictable short and long-term consequences. The Plan for Action notes that in 1999/2000, one in 10 of those attending drug services reported use of alcohol as a problem in addition to their drug problem (Scottish Drug Misuse Database ISD 2001).
3.6.3 Alcohol problems in offenders

Over 50% of male prisoners in the United Kingdom (UK) were drinking hazardously in the year before coming into prison (Singleton et al., 1998). In a survey of 50% of all untired prisoners in Scotland in 1993, 22% of the prisoners had alcohol-related problems (Greater Glasgow Health Board, 2000). In a review of the medical history of all 906 men admitted to Barlinnie Prison during January 1998, 10% were suffering from serious withdrawal symptoms on admission.

The Scottish Prison Service (SPS) assesses all prisoners on admission for addictions using a general screening questionnaire and, for those screened positive, using its Common Addictions Assessment Tool. Thereafter a treatment and care plan is developed for each prisoner. Although a significant proportion of prisoners on admission have alcohol problems, there is no access to alcohol in prison and hence there is no use of acamprosate, disulfiram or naltrexone. Treatment includes detoxification and psychosocial interventions including the 12-step approach (see Section 3.11). Alcoholics Anonymous (AA) has a presence in 11 out of 16 SPS establishments, with structured programmes in three establishments using the 12-step approach.

3.6.4 Homelessness and alcohol problems

Scotland has over 5000 homeless people. Studies among ‘rough sleepers’ show that 50% are alcohol dependent. More than half of a sample of homeless people in Greater Glasgow in 1999 were drinking hazardously, increasing from 37% of 16 – 24 year olds to 63% of those aged 55 and over; men (60%) more than women (16%) (Kershaw et al., 2002).

In Greater Glasgow, a multidisciplinary Homelessness Addiction Team with representation from Greater Glasgow Primary Care Trust (PCT), social work and housing (Glasgow Problem Drug Service and the Alcohol and Drug Directorate) has been formed. Particular problems that they have identified in dealing with homeless people include:

- a proportion of people who do not wish any help
- limited access to services and a lack of facilities specifically for the homeless
- ensuring referrals are appropriate
- considerable comorbidity.

3.6.5 Alcohol versus drug misuse

The Plan for Action points out the similarities and differences between drug and alcohol problems. Links noted are the influence on both of a wide range of overlapping social and cultural factors, the fact that many children who drink or smoke also try illegal drugs and that many adult drug users also have alcohol problems. However, the numbers of people both using and misusing alcohol in Scotland far exceeds the number using illegal drugs. In 1997, there were 82 drug-related deaths recorded by the Registrar General in Greater Glasgow compared with 351 alcohol-related deaths, although both are likely to be under reported. From 1991 to 1995, there were 3857 drug-related emergency hospital admissions compared with 19 296 alcohol-related emergency hospital admissions. Alcohol continues to
have a much greater negative impact on health than misuse of illegal drugs (Greater Glasgow Health Board, 2000). Although there are probably neurochemical and psychological overlaps between dependence on all psychoactive substances, and there are many similarities between the psychosocial ‘first-line’ treatments, the range of problems experienced by people who misuse alcohol differ in many respects from those experienced by drug misusers, as do the effects on society and on their families. People with drug and alcohol problems may need different types of services, particularly at the more specialised end of the spectrum.

3.7 Organisation of NHSScotland

NHSScotland, like the NHS in other parts of the UK, provides comprehensive health care for its citizens, and is free at the point of use. It is funded mainly by direct taxation in the form of income tax and national insurance contributions, with a small proportion of funding coming from patient charges, such as for dental care and prescriptions. A key advantage of the UK’s funding system is its fairness, providing maximum separation between an individual’s financial contributions and their use of health care. After social security payments, health is the biggest single component of public expenditure (Wanless, 2001).

Mortality and morbidity rates are higher in Scotland than in England, reflecting differences in their populations and environmental and socio-economic factors. However, alongside these greater health needs, Scotland has more health care resources. Funding per head, the number of hospital beds and professional health care staff are all above the levels in England (Wanless, 2001). NHSScotland has core aims of improving the health of the population and reducing inequalities in health. There are currently five priority topics: coronary heart disease/stroke, cancer, mental health, children and young people, and older people (Scottish Executive Health Department, 2000).

In 1998, the UK health expenditure per capita was £1510 or 6.8% of the gross domestic product (5.7% publicly funded and 1.1% privately funded). The European Union (EU) weighted average figures were £1824 and 8.4% of the gross domestic product (6.4% publicly funded and 2.1% privately funded) (Wanless, 2001). Scotland has higher public health service expenditure per capita than the UK average (Wanless, 2001).

NHSScotland has around 132,000 staff, including more than 63,000 nurses, midwives and health visitors and over 8,500 doctors. There are also more than 7,000 general practitioners, including doctors, dentists, opticians and community pharmacists, who are independent contractors providing a range of services within the NHS in return for various fees and allowances (www.show.scot.nhs.uk/public/publicindex.htm).

The SEHD leads the central management of NHSScotland. It oversees the work of 15 NHS Boards responsible for planning health services for people in their area and, through the boards, the activities of the 28 acute and primary care NHS Trusts responsible for providing services to patients and the community (www.show.scot.nhs.uk/public/publicindex.htm). PCTs have been developing Local Health Care Cooperatives (LHCCs), which initially involved only general practitioners but are now evolving into multiprofessional organisations. The aim of
LHCCs is to allow local decision making (with involvement of local communities) to improve health and health care (Hopton & Hill, 2001).

A number of special health boards also exist which have Scotland-wide remits for specific functions. For example, NHS Education for Scotland commissions education and training for some NHS staff and HTBS provides advice on the clinical and cost effectiveness of new and existing health technologies.

The Joint Future Group report ‘Community Care: a Joint Future’ was published in December 2000. This put joint working (involving relevant staff in predominantly the NHS and social work departments of local authorities but also the non-statutory sector when appropriate) at the heart of community care and applies to services for people with alcohol problems. The key features of the Joint Futures approach are to have better outcomes for service users and their carers, better use of resources, decisions which are transparent and according to shared priorities, better management of services, and better systems with less bureaucracy and clear responsibilities.


3.8 Structure and aims of current services

NHS specialist services engaging in prevention of relapse for alcohol dependence are part of the local mental health services which are incorporated in PCTs. The other statutory services focusing particularly on interventions for the prevention of relapse are those provided by social work services through local authorities. In addition, non-statutory services provide considerable assistance to people with severe alcohol problems and their families, to the extent that the statutory services could not cope in their absence. For example, in Glasgow they make an indispensable contribution to the overall provision of services (Greater Glasgow Health Board, 2000).

There has been progress in the treatment of alcohol problems over the years with improvement in the range of options available for prevention of relapse. This is probably secondary to positive changes in the attitudes of the medical profession and increased recognition of the harm caused by alcohol-related problems in the UK. However, local service development in Scotland has been extremely varied probably as a result of local funding policies rather than on the basis of objective needs assessment. Development of training and research resources has also been patchy and generally limited.

It is clear that no one agency can meet the needs of people experiencing alcohol problems. A combined and coordinated treatment ‘system’ (so termed by Heather, 1995) is required, recognising the contribution of statutory and non-statutory services and guiding individuals appropriately through the care pathway. The Treatment Framework of the Plan for Action (Scottish Executive Health Department, 2002) should guide local agencies on strategic development. Attention should be paid to adequate services at all tiers of service and to avoiding duplication of effort between agencies and diversion of scarce resources from vital areas of care. For example, it is important that the development of the primary care based tier does not reduce the number of trained staff available in specialist tiers delivering prevention of relapse to
those with established alcohol dependence. Joint planning across social work, health and non-statutory sectors should take account of such possibilities.

Specialist agencies may be able to increase efficiency by focusing their efforts on delivering existing treatments of proven effectiveness and attempting to minimise duplication and overlap with programmes offered by other agencies involved in the same individual’s care. Prevention of relapse should not be seen as a treatment in isolation but should be a component part of all treatment programmes (Raistrick & Heather, 1998). As indicated in Section 3.5, in addition to using specialist agencies, problem drinkers seek the services of a range of other NHS facilities.

Non-specialist NHS services, therefore, also need to remain aware that detoxification or treating the presenting alcohol-related physical disease is only one part of the process of treating alcohol dependence and clear understanding of how to access the care pathway (treatment system) for alcohol dependence is necessary. This understanding of the care pathway integrating specialist and non-specialist, statutory and non-statutory agencies is relevant to all agencies within and accessing the treatment system.

With respect to specific treatment options there is a need for a balanced response to alcohol misuse. Those at risk of becoming dependent on alcohol but not yet experiencing serious problems may respond well to minimal interventions, according to the draft SIGN guideline (Scottish Intercollegiate Guidelines Network (SIGN), 2002), the final version of which is due to be published in 2003. Those with established dependence on alcohol require a more intensive approach.

Details of the nature and extent of services for treatment of alcohol dependence in Scotland were collected by HTBS in two surveys in 2001. Results of these surveys are given in Section 3.18.

3.8.1 Measuring success in clinical practice

Establishing reliable processes to obtain outcome measures for the effectiveness of available treatments is a problem. Laboratory investigations, corroborative histories and self-reporting questionnaires are currently used patchily throughout Scotland with no standardised approach. Definition of relapse is a key issue in outcome measurement. The consumption of eight units for a man or six units for a woman in a single day is a commonly agreed research definition of relapse for someone in treatment for alcohol dependence. Different considerations would apply to those not meeting the criteria for dependence, where the treatment goal may be harm-free drinking.

3.9 The Alcohol Problems Support and Treatment Services Framework

The Plan for Action requires each local AAT to draw up, publish by April 2003, and subsequently implement, a local strategy covering at least three years. The Framework (Scottish Executive Health Department, 2002) focuses on the support and treatment elements of local AAT plans. It provides a template for needs assessment planning to meet those needs.

The Framework proposes a four-tier model of services. The tiers are:
Tier 1 – services for the whole community. Services concerned with local approaches to alcohol problems, the promotion of positive health and well-being generally, and enabling people to make decisions about their use of alcohol with the assistance of information, delivered through a range of media.

Tier 2 – local services that identify and respond to people with alcohol problems. These services will meet the treatment and support needs of the majority of people with an alcohol problem. They generally operate at the level of primary health care teams or local social work teams.

Tier 3 – services for people with more complex needs. These provide a range of specialist diagnostic assessment, treatment and rehabilitative services for people with alcohol problems.

Tier 4 – services for people with highly specialised needs. These provide services for relatively small numbers of people with severe or complex alcohol-related problems. They may be based in a research or academic unit, as part of a clinical network.

This HTA relates primarily to people provided for in Tier 3 and Tier 4 of the Framework. It adds to the Framework in that it identifies those with established alcohol dependence as a high-risk group requiring specialist attention even in the absence of any additional social or coexisting health problem.

3.10 HTBS surveys of Scottish services

In order to evaluate the nature and range of services for prevention of relapse provided in Scotland, two postal surveys were carried out. The first of these addressed the services within NHSScotland and was sent to all major specialist alcohol units. Twenty-seven questionnaires were sent out of which four questionnaires were mistakenly sent to different individuals within the same service and the number of questionnaires expected to be returned was therefore reduced to 23. Of these, 22 were completed and returned including at least one from each NHS Board. Limited data on the one service, which did not complete the questionnaire was obtained via telephone contact. The questionnaire is shown in Appendix 5 and narrative and tabular results are in Appendices 7 and 8.

The second survey attempted to assess the provision of services for the prevention of relapse by non-NHSScotland care providers. This was a briefer questionnaire and is shown in Appendix 6. One hundred and fourteen questionnaires were sent out and 39 returned. Compiling a full listing of such providers is not an easy task and it was decided to risk inappropriate, or possibly multiple, contacts with some providers in order to maximise appropriate contacts. Thus it is difficult to interpret these response rates in terms of coverage of services.

The figures given for Scottish service provision in the following sections are based on the data obtained from these surveys.
3.11 Psychosocial interventions

Psychosocial interventions for the prevention of relapse\(^2\) are based around ‘talking therapies’, which can involve one-to-one, couple, family or group approaches and encourage self-help as part of the treatment and support options. These interventions are numerous, having more than 40 different ‘brand names’, although certain ingredients are common to almost all (e.g. the therapeutic alliance). A clear and distinct definition of each therapy has proved extremely difficult to produce. However, certain elements contribute to many therapies and are used in combination or as stand-alone interventions.

These elements are aimed at:

- building motivation
- cognitive restructuring
- developing coping skills.

A conceptually rather different approach is involved in those interventions based on the 12-step approach and this is described separately.

Effective **motivation building** in alcohol-dependent patients is based on Motivational Enhancement Therapy (MET) or Motivational Interviewing (MI). The goal of MET/MI is to elicit the individual’s intrinsic motivation for change (Miller & Rollnick, 1991) and involves certain therapeutic strategies. These include expressing empathy, avoiding argument, detecting and ‘rolling with’ resistance, highlighting discrepancies between the individual’s goals/values and their current behaviour. This approach, utilising the individual’s own skills and resources, is shared generally by client centred approaches e.g. Solution Focused Therapy (Miller *et al.*, 1992).

Measures aimed at **cognitive restructuring** are based on Cognitive Behavioural Therapy (CBT) (as opposed to behavioural coping strategies), and form an element of Skills Training (see the following text for more detail). Cognitive restructuring aims to help service users identify, examine and change negative thoughts and underlying assumptions; the overall aim being to develop more adaptive thinking styles and make positive behavioural responses due to these changes in thinking. It is the core element of the cognitive behavioural approach which underpins many of the treatments for alcohol problems.

Measures aimed at **developing coping skills** often focus on general ‘life’ skills, however, these would tend to be within the context of the addictive behaviour. The overall aim being to avoid a relapse to abusive drinking. For example:

- Skills Training/Coping Skills Training aims to teach the individual techniques to allow them to deal more effectively with high-risk for drinking situations. Treatment is likely to focus on a wide range of skills including coping with anxiety and depression, managing anger and developing assertiveness. Learning

\(^2\) It should be noted that the term ‘Relapse Prevention’ is used as a technical and specific one by practitioners delivering a distinct type of psychosocial intervention based on the original model by Marlatt & Gordon (1985) and this can cause confusion.
to cope with positive/pleasant experiences without resorting to alcohol use is also considered to be an essential aspect of skill development. Avoidance of high-risk drinking situations is encouraged as an early coping strategy, however, during the course of treatment, an individual is encouraged to enter into increasingly riskier situations through a process of graded exposure. Achieving ‘mastery’ in what was previously a high-risk for drinking situation, is thought to result in an increase in self-efficacy. High levels of self-efficacy (i.e. an individual’s confidence in his/her ability to perform a certain behaviour), have been shown to be associated with a reduction in the likelihood of relapse (Annis et al., 1996).

- Social Skills Training aims to help service users increase social support and improve their ability to establish rewarding interpersonal relationships. The content of training will focus on a range of areas including body language, listening skills and assertiveness.

- The Community Reinforcement Approach (CRA) (Azrin et al., 1982), focuses on changing the individual’s social environment by developing rewarding employment, leisure activities and relationships that do not involve alcohol. Partners, family and friends are viewed as crucial collaborators in the treatment process and their roles may include supervising disulfiram, being partners in marital counselling, active agents in re-socialisation and reinforcement programmes, and anticipating relapse or other problems.

- Behavioural Self-Control Training (BSCT), involves the use of simple, self-contracted goals and self-rewards for their achievement.

- Behavioural Marital/Couples/Family Therapy emphasise the teaching of skills to improve communication and behaviour change negotiation. The overall aim is to increase the level of positive reinforcement exchanged within the relationship(s) involved. Other marital or family therapy approaches draw on systems theory in both formulating the hypothesis about distress and planning interventions.

The 12-step approach is based on the philosophy of AA. This involves self-help or mutual support group sessions, and is distinct from the above categories in that it is not delivered by a therapist. The 12 steps refer to the stages of growth through which the individual must progress in order to achieve and maintain sobriety (see Section 3.13.1 and Appendix 9). The individual is expected to acknowledge the need for help and aim for complete abstinence (http://www.alcoholics-anonymous.org/).

One further type of intervention which is not adequately covered by any of the above groupings is that of Brief Intervention (BI). This is a time-limited intervention which may occur opportunistically e.g. when an individual presents at a hospital or GP clinic for something other than specific alcohol dependence problems. The precise content of BIs vary, and they are mainly used to reduce alcohol consumption in people drinking above recommended levels but who are not dependent.

It should be noted that care is needed in interpreting the published literature as psychosocial interventions described within it do not necessarily match those delivered in practice, despite sharing the same name.
3.12 Psychosocial interventions within NHSScotland

Psychosocial interventions used in NHS specialist services in Scotland, based on the HTBS survey, are shown by NHS Board in Table 3-1. One or more of these is offered in 90% of specialist services.

Table 3-1 Psychosocial interventions in NHS secondary care

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<tr>
<th>NHS Board</th>
<th>Motivational Interviewing</th>
<th>Cognitive Behavioural Therapy</th>
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<th>Behavioural Marital/Couples Therapy</th>
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* No specialist services in Shetland

In the NHS, among specialist services offering psychosocial interventions for alcohol problems, MI and Coping Skills Training appear to be universally used.

For MI, the number of sessions offered ranged from 2 – 10, or up to three weeks depending on the service and the individual. About 20% of services using the therapy acknowledged having protocols for this. MI was usually carried out on a one-to-one basis and in a non-residential setting. Very few services attempted to audit the intervention. Staff carrying out the therapy were most often internally trained but external training had occurred in the past. Only in a few cases was it declared that staff had no training in the technique.

For Coping Skills Training, the number of sessions offered ranged from 4 – 10 or up to four weeks, with over half of the services noting that this varied depending on the individual. About 15% of the services carrying out this therapy reported having protocols. Coping Skills Training was carried out in one-to-one and group settings, usually non-residentially. Very few services attempted to audit the intervention. Staff were most often internally trained but external training did occur.

Stress Management was used in 95% of specialist services offering psychosocial interventions. The number of sessions, setting and training of staff were as for Coping
Skills Training. About 10% of the services carrying out this therapy acknowledged having protocols.

BIIs were used in 89% of services offering psychosocial interventions. The number of sessions ranged from 1 – 10, with over half of the services noting that this varied depending on the individual. Over a third of services carrying out this therapy reported having protocols. Although this intervention may have been expected to be carried out entirely on a one-to-one basis, some services noted using the technique in a group setting. Although mostly carried out non-residentially, there was some use of BI in residential settings which may suggest an ‘opportunistic’ application (e.g. by specialist staff liasing to general wards). Only one service appeared to audit interventions of this sort. Both internal and external training took place.

CBT was used in 84% of specialist services offering psychosocial interventions. The number of sessions ranged from 4 – 10, or up to four weeks, but was noted to be variable in over half of the services. About 20% of the services carrying out this therapy acknowledged having protocols. CBT was most commonly carried out on a one-to-one basis and usually in a non-residential setting. Very few services attempted to audit the intervention. Most staff training was external but additional internal training did occur.

Social Skills Training was used in 79% of specialist services offering psychosocial interventions. The number of sessions, setting and training of staff were as for Coping Skills Training. About 20% of services carrying out this therapy reported having protocols.

Other less common interventions included:

- Community Reinforcement Therapy (acknowledged by 42% of the specialist services offering psychosocial interventions)
- Couples Therapy (37%)
- Behavioural Marital/Couples Therapy (BMCT) (26%)
- Family Therapy (21%)
- ‘Relapse Management’ (26%)
- 12-step approach (11%)

Non-specific counselling was noted to take place in 37% of these NHS services.

Relapse Prevention groups were acknowledged in 47% of services offering psychosocial interventions. Some, if not all, have written protocols. Greater Glasgow NHS Board, for instance, uses a standardised protocol with patient manual based on the Marlatt model (Larimer et al., 1999) throughout its four centres.

Various other psychosocial interventions were acknowledged including Anger Management, Assertiveness Training, Solution Focused Therapy, Anxiety Management, Alcohol Education Groups, Supportive Counselling and Relaxation and Exercise Groups.

A number of services offered tailored groups e.g. women’s groups.
For each of these interventions a number of outcome measures are cited as being used, these varying from service to service, presumably in terms of frequency as well as form. Outcome measures used included laboratory investigations (gamma glutamyl transferase [GGT], Mean Cell Volume [MCV], Liver Function Tests [LFT]), diaries, self-report, rating scales and questionnaires (self-report and therapist), timeline follow back and collateral information. The rating scales and questionnaires cited were Drug-Taking Confidence Questionnaire 8, readiness to change questionnaires, the Christo Inventory, the Alcohol-Related Problems Questionnaire, service user satisfaction questionnaires and CBT rating scales.

Eleven percent of NHS specialist services carrying out psychosocial interventions did not use routine outcome measures.

Only 36% of NHS specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. These are included as Appendix 10.

### 3.13 Psychosocial interventions in non-NHS services

In the non-NHS day services surveyed, of those responding to the questionnaire 42% carried out non-specific counselling, 25% used person-centred counselling, 21% used Social Skills Training, 21% offered support and advice, 17% used MI and 17% used some form of group therapy. Other interventions included psychodynamic counselling, Stress Management, Assertiveness Training, Solution Focused Therapy, Complementary Therapy, Couples Therapy and Family Therapy.

Although counsellors from the Councils on Alcohol are usually centrally trained by Alcohol Focus Scotland (AFS) using a CBT based approach, the Councils on Alcohol responding to the survey acknowledged a range of approaches: a CBT based approach (47%), non-specific/eclectic counselling (41%), person-centred counselling (23%), Social Skills Training (18%), MI (19%), Stress Management (6%) as well as support and advice, couples, family and group work.

Social work services responding to the questionnaire were few in number. The information obtained from those responding would suggest that a range of validated psychosocial interventions might be offered including CBT, MI and Social Skills Training as well as non-specific counselling. Responses to the consultation document (Slattery et al., 2002) clarified that social work services aim to provide a range of interventions, both therapeutic and practical.

Of non-NHS residential rehabilitation services surveyed the returned information suggests that a range of interventions is being offered including non-specific counselling, CBT based counselling, person-centred counselling, task-centred counselling, Positive Modelling, Social Learning Theory, Anger Management and group work.

Of non-NHS residential homelessness services surveyed only 46% acknowledged offering psychosocial interventions for alcohol dependence. Interventions most commonly offered included support and advice, non-specific counselling, 12-step approach and Social Skills Training. Less frequently offered interventions included

Private care facilities (e.g. Priory and Castle Craig) were not sent the survey questionnaire. Details of the services provided are given in Section 3.18.9.

### 3.13.1 Alcoholics Anonymous

Founded in 1935, AA has a long history of providing confidential support and advice to those with alcohol problems (http://www.alcoholics-anonymous.org.uk/).

AA is organised by and for people with a drinking problem. The only requirement for membership is a desire to stop drinking. There are numerous local groups throughout Scotland who may be contacted directly. There is an unofficial website which is useful in locating these groups (http://www.aa-uk.org.uk/)

HTBS did not survey Alcoholics Anonymous facilities or meetings. However, a large quantity of information was submitted from AA as evidence.

The trustees of the AA General Service Board decided in 1968 to begin conducting anonymous surveys of the membership. These surveys are repeated at three-year intervals and provide a continuing view of the demographic changes in alcohol-related problems over the last 34 years.

The 1968 survey clarified the need for AA to work more closely with professionals in the field, and culminated in the formation of a Professional Relations Committee (now Cooperation With the Professional Community). Succeeding surveys have underlined the importance of outside help in pointing dependent people toward AA and in providing additional help during sobriety. In 1998, 34% of members were introduced to AA through treatment facilities, 11% by court order, and 17% by a counselling agency or health care provider. Before coming to AA, 60% of members received some type of treatment or counselling, and 75% of those members said it played an important part in directing them to AA. After coming to AA, 62% of members received some type of treatment or counselling, and 83% of those believe it was important to their recovery. As in the past several surveys, 75% report that their doctors know they are in AA.

There are numerous branches of AA in Scotland. There are 228 weekly meetings in Glasgow alone and 934 over the whole of Scotland.

The philosophy and approach of AA is well documented in numerous publications. In particular, AA consider that alcohol dependence, once established, is a permanent condition which can only be controlled by complete abstinence. The 12-step facilitation programme is designed to help achieve this objective (Appendix 9).

### 3.14 Pharmacological interventions

Pharmacological interventions used in alcohol dependence for prevention of relapse include deterrent medication, such as disulfiram (Antabuse®), which induces unpleasant symptoms if the individual consumes alcohol, acamprosate (Campral®), an N-methyl-D-aspartate (NMDA) receptor modulator, specifically designed to prevent
alcoholic relapse through a claimed action on craving, and naltrexone (Revia®), an opioid antagonist believed to work through an effect on reward mechanisms.

3.14.1 Disulfiram

Oral disulfiram is indicated as an adjunct in the treatment of carefully selected and cooperative patients with drinking problems. It should be combined with appropriate supportive treatment, which although not defined explicitly, implies some form of psychosocial therapy. It is supplied as 200 mg tablets and the manufacturers recommend an initial dose of four tablets, which is reduced by one tablet daily to a maintenance dose of one or half a tablet continuing for up to six months. The individual taking disulfiram regularly in sufficient dose will, on consuming alcohol, experience an unpleasant reaction (flushing of the face and upper body, throbbing headache, palpitation, dyspnoea, tachycardia, nausea, vomiting and with large amounts of alcohol, arrhythmias, hypotension and collapse). The reaction occurs about 10 minutes after ingestion of alcohol and may last several hours. The severity of this reaction shows a great deal of individual variation and, rarely, the reaction can be life threatening. Conversely some individuals have no or mild reactions on standard doses and higher doses may be required. Even small amounts of alcohol can lead to unpleasant systemic reactions and therefore care must be taken when using other medicinal products and toiletries. It is advisable for patients to carry a card warning of the danger of administration of alcohol. The patient is told the nature of the reaction prior to prescription of the drug.

There are several contraindications to using disulfiram including cardiac failure, coronary artery disease, previous history of cerebrovascular accident, hypertension, pregnancy, breast feeding, severe personality disorder, suicidal risk or psychosis (which is thought may be exacerbated by the action of disulfiram on dopamine β-hydroxylase). Additional caution is required in renal failure, hepatic or respiratory disease, diabetes mellitus, epilepsy and the concurrent use of anticonvulsant, anticoagulant and antihypertensive medication.

Side effects may include drowsiness, fatigue, nausea, halitosis and reduced libido. The manufacturer’s Summary of Product Characteristics (SPC) reports that psychotic reactions occur rarely and that allergic dermatitis, peripheral neuritis and hepatic cell damage have been reported.

The medication is recommended to be administered daily, but can also be given twice or thrice weekly (at 3 – 4 day intervals) as the action lasts for about seven days after the last dose. This may be of practical importance if administration is supervised e.g. at a day hospital, by a workplace nurse, community psychiatric nurse (CPN) or practice nurse. Disulfiram has also been tested as a slow release sub-cutaneous implant but this form is not licensed in the UK.

Disulfiram is described as an adjunct to psychosocial intervention (not specified) and is not, for instance, intended for use as a monthly repeat prescription with minimal doctor/patient interaction.
3.14.2 Acamprosate

Acamprosate has been licensed in the UK since 1995 for abstinence maintenance therapy for up to one year in motivated alcohol-dependent patients. Its chemical structure is similar to the naturally occurring amino acid neuromediators, taurine and gamma aminobutyric acid (GABA) and it is believed that it may act by binding to NMDA receptors in the brain, modulating the up-regulation of NMDA receptors which occurs on alcohol withdrawal, enhancing GABA inhibitory neurotransmission and antagonising glutamate excitation, thus suppressing putative biochemically based craving in response to learned cues (e.g. feeling stressed, passing a bar or being in the company of others drinking alcohol).

The recommended dosage is two 333 mg tablets three times per day over a one-year treatment period. The dosage is reduced to four tablets per day (two morning, one midday, one night) in those weighing less than 60 kg. It is licensed only for patients between 18 and 65 years of age.

Pharmacokinetic studies showed very large inter-subject variations in bioavailability. Mean bioavailability was reduced by about 20% when tablets were taken with food. It appears to be excreted primarily via the kidneys and is contraindicated in renal dysfunction (serum creatinine over 120 micromols/L). Other contraindications are hypersensitivity, severe hepatic failure (Childs Pugh Classification C), pregnancy and breast feeding.

Adverse effects are usually mild and transient and are predominantly gastrointestinal (diarrhoea, nausea, vomiting, abdominal pain) and dermatological (pruritis, occasional maculopapular rash and rare cases of bullous skin reactions have been reported).

As it takes 5 – 7 days to reach therapeutic levels (elimination half-life 18 hours), acamprosate should be started soon after detoxification.

As with disulfiram, acamprosate is currently recommended to be combined with counselling.

3.14.3 Naltrexone

Naltrexone, an opioid antagonist, is not licensed in the UK for use in alcohol dependence. It has been licensed for this use in the Republic of Ireland and several other EU countries since 1996, as part of a comprehensive treatment programme for alcohol dependence to reduce the risk of relapse to heavy drinking, support abstinence and reduce alcohol craving. It may act by breaking the desire for the next drink by blocking the pleasure or ‘high’ which would normally result from sampling alcohol. It is reviewed in this HTA because it is used off-licence in five Scottish NHS Boards (see Table 3-2).

The recommended dosage is one 50 mg tablet per day. An initial treatment period of three months is suggested but longer-term treatment can be considered.

Serious side effects of naltrexone are rare but the most commonly reported side effects include nausea (9.8%), headache (6.6%), dizziness (4.4%), nervousness (3.8%), fatigue (3.6%), difficulty sleeping (3.0%), vomiting (2.6%), anxiety (2.0%),
and somnolence (2.0%). The incidences were estimated over 12 weeks by Croop et al. (1997).

Contraindications are acute hepatitis, liver failure, current dependence on opiates, current use of opioid containing medication and hypersensitivity.

### 3.15 Pharmacological interventions in NHS specialist services in Scotland

The Greater Glasgow ‘shared care’ protocol for the use of acamprosate and the Lothian protocol for the use of naltrexone can be found in Appendix 11 and Appendix 12, respectively.

In the HTBS survey of NHS specialist alcohol services, all used acamprosate and disulfiram. In addition five services prescribed naltrexone (see Table 3-2). No other medications are routinely used in Scotland for prevention of relapse in alcohol dependence. Combinations of acamprosate and disulfiram are used in 57% of services. Combinations of naltrexone and disulfiram are used in one service. There was no noted use of combinations of naltrexone and acamprosate.

#### Table 3-2 Pharmacological treatments in NHS secondary care

<table>
<thead>
<tr>
<th>NHS Board</th>
<th>acamprosate</th>
<th>disulfiram</th>
<th>naltrexone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayrshire and Arran</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Borders</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Dumfries and Galloway</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Fife</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Forth Valley</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Grampian</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Greater Glasgow</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Highland</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Lanarkshire</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Argyll and Clyde</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Lothian</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Orkney</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Shetland*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tayside</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Western Isles</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>

* No specialist services in Shetland

In the majority of NHS specialist services, medical staff of all grades (senior house officer to consultant) prescribed acamprosate and disulfiram. In the services without medical staff, as well as many of those with medical staff, GPs would prescribe these medications on the advice of the team or in coordination with the team, if local NHS Board prescribing arrangements permit.

In services prescribing naltrexone, this was always done by consultant medical staff attached to the specialist team.

#### 3.15.1 Disulfiram

Fifty-two percent of specialist services used supervised administration if required. Supervision may be by a CPN/practice nurse/alcohol unit nursing staff or relatives (18% of services using supervision acknowledged this method – see Appendix 13 for
useful information for the patient, partner/supervising person and supervising doctor (Lothian NHS Board), place of work or the community pharmacy.

Most of the services commence disulfiram in both inpatient and outpatient settings with initial proposed duration varying between services from one month to one year (41% of services considered the proposed duration to be variable/indefinite depending on factors such as patient response).

Protocols exist for the use of disulfiram in 9% of services.

All services noted that psychosocial interventions were used in combination with disulfiram but, for instance, one service commented that this was simply the ‘normal clinic regime’. The most commonly acknowledged interventions to be used in combination with disulfiram were CBT and MI. Also noted were Relapse Prevention (RP) groups, group work, counselling, abstinence maintenance and ‘specific Antabuse® adjunctives’.

The outcome measures most commonly used were derived from laboratory tests (28% of services), self-report (19% of services) and diaries (14% of services) with cumulative abstinence duration (CADs), collateral information and alcometer readings also used. One service used no outcome measures.

Only one service (Forth Valley) noted auditing the use of disulfiram.

3.15.2 Acamprosate

Nine percent of services acknowledged enlisting a third party to supervise administration of the medication.

Most services commenced the use of acamprosate in both an inpatient and outpatient setting.

The initial proposed duration of treatment varied between services from one month to one year (47% of services answering the question cited one year).

Protocols exist for the use of acamprosate in 48% of services (see Appendix 11 for shared care protocol from Greater Glasgow).

All NHS specialist services used psychosocial interventions in combination with acamprosate, the most commonly acknowledged being MI, RP Therapy, CBT and group work. Also noted were ‘counselling’, Social Skills Training, abstinence maintenance, ‘specific acamprosate adjunctives’ and one service noted using the ‘normal clinic regime’.

Sixty-five percent of services cited abstinence as the goal of treatment, 15% of services cited either abstinence or controlled drinking as the goal, and 20% of services cited controlled drinking as the goal.

The most commonly used outcome measures were laboratory investigations (38% of services), including GGT, MCV, LFTs, self-report (19%), diaries (14%) and CADs (14%).
Twenty-eight percent of services audited the use of acamprosate.

3.15.3 Naltrexone

Of the five services using naltrexone, two services set no special condition for administration, one service insisted on regular consultant review, and two services used some form of supervision of treatment.

Four out of the five services commenced naltrexone on both an outpatient and inpatient basis. One service commenced naltrexone on an outpatient basis only.

The initial proposed duration was reported as six months to one year in one service, one year in one service and indefinite in two services.

Lothian has a protocol for prescribing naltrexone for alcohol dependence (Appendix 12).

All services prescribing naltrexone used psychosocial interventions in combination with the medication although the type of intervention was not specified.

Two services cited abstinence as the goal of treatment. One service cited either abstinence or controlled drinking as the goal of treatment.

The outcome measures used were laboratory tests (four services), self-report (two services) and diaries (one service).

The use of naltrexone is not audited by these services.

3.16 The care pathway

For the psychosocial and pharmacological interventions described, it should be noted that in most services these are not carried out in isolation but as part of an ongoing relationship with individuals in contact with the service. Examples of care pathways were provided by a number of services (Appendix 14) and perhaps illustrate more similarities than differences in the care of individuals from the moment of their referral to the alcohol problems service. The use of non-statutory agencies in the treatment system is well illustrated.

The minimum continuing care package offered to most individuals on discharge from hospital following alcohol detoxification varies from service to service, with one service suggesting that there may be no continuing care package, and others offering a follow-up appointment by the keyworker (CPN, day hospital nursing staff, Community Addiction Team, medical staff) at the base alcohol unit or at home depending on geographical factors. Others offer an increasingly intense continuing care package with outpatient clinic appointments and CPN visits, immediate (next day) follow up by the home detox team and regular follow up thereafter for several weeks (e.g. every two days for six weeks), day hospital attendance for a prevention of relapse programme or referral to the waiting list for the RP group, one-to-one psychological intervention, periodic MI sessions (e.g. 8 – 10 weekly), ongoing drop-in facility, referral to other agencies e.g. social work, if requested, and consideration of antirelapse agents e.g. acamprosate.
The Argyll and Bute service (within the Argyll and Clyde NHS Board area) offers respite admissions as well as the availability of 24-hour contact with the unit and outreach clinic appointments if geographically suitable.

Areas without NHS statutory alcohol services will advise individuals to utilise local non-statutory services e.g. counselling/befriending services, social work alcohol support groups, AA and Councils on Alcohol.

There seems to be no standardised approach to continuing care with many of the above elements/options being employed in various combinations presumably tailored to the need of the individual and local resources.

The external agencies most frequently used by NHS specialist services when arranging continuing care are AA, social work day services and Councils on Alcohol with non-statutory residential rehabilitation services being used more moderately and the least used agencies being residential homelessness services and private care.

3.17 Default, non-adherence and recurrent relapse

One issue worth considering is that of default or non-adherence with interventions offered. About 25% of services report that their approach to this may include discharge back to GP care. Other reports involve various degrees of assertive outreach including offering 1 – 2 follow-up appointments or contacting the patient by letter to ascertain their desire for further contact, perhaps individuals with more severe problems having more aggressive follow up.

In the case of recurrent relapse, almost all services reported either continued contact or at least no restriction on re-referral.

Miller (1985) notes that a simple handwritten note or telephone call after the first visit, or after a missed visit, can double or triple the likelihood that a service user will return. This ‘active’ interest in the individual with alcohol problems appears to be reflected in most of the services surveyed.

3.18 Services available for alcohol-related problems

The provision of services for individuals with alcohol-related problems can be categorised into non-specialised (GPs and other primary care staff, accident and emergency [A&E] departments, general hospitals, general psychiatric services, social services and criminal justice services and employment-related schemes) and specialised (statutory [NHS and social work], non-statutory and private). Non-specialised workers are routinely encountering individuals with alcohol problems in their day-to-day work with perhaps only the most seriously affected being referred on to specialist services. Statutory NHS specialist alcohol services may range from a single CPN with an alcohol remit to a fully integrated residential and community based addiction service.

3.18.1 NHS specialist services

The Plan for Action (SACAM, 2002) states that ‘the general perception is that service coverage in Scotland is patchy and fragmented and there is disparity in support and treatment available across Scotland’. The HTBS survey of specialist services confirms
that some gaps in the service exist. There is also an apparent deficit in formal staff training and accreditation. The variability in service provision may reflect historical factors and the enthusiasms of individual consultants and other service developers rather than regional differences in morbidity.

In recent years the emphasis has shifted from inpatient to outpatient treatment. Inpatient services continue to exist, sometimes with dedicated beds for alcohol/addiction problems, sometimes using general adult psychiatry beds and occasionally using general medical beds. Inpatient care may be restricted to the more complex cases, for instance those with a lack of social support, the homeless, those with comorbid psychiatric or severe physical illness, those at risk of suicide and those with a dual dependence.

As shown in the HTBS survey, there is wide regional variation in NHS specialist service provision, with areas such as Shetland offering no specialist NHS alcohol services and areas such as Greater Glasgow, Ayrshire and Arran and Lanarkshire having a relatively large service, though these need to be seen in the context of local needs.

At the most specialised end of the spectrum (referred to as ‘Tier 4’ in the Plan for Action Treatment Services Framework) there is an assumption that the individuals with the most complex needs are seen. Most people with alcohol problems are not in this category and will be seen at lower tiers of service, with GPs often being the first and only source of advice for a substantial proportion of those with alcohol problems. It is estimated that ‘less than one in ten individuals with alcohol-related problems are in contact with a specialist agency’ (Unnithan et al., 1994).

### 3.18.2 Inpatient services

Only certain areas provide specialist inpatient-based services. From the survey, those areas with no acknowledged specialist inpatient beds at all were Grampian, parts of Lanarkshire covered by Hairmyres Hospital and Shetland. Forth Valley, Fife and Orkney use a very limited number of general adult psychiatry, or general medical beds (Orkney – one bed) for alcohol problems if necessary. South Glasgow and Western Isles have no dedicated beds for alcohol problems but provide inpatient care using general adult psychiatry beds. All other areas have dedicated beds for patients with alcohol problems (61% of all services surveyed).

From the survey, there are approximately 100 inpatient beds specifically dedicated to alcohol problems in NHS specialist services in Scotland (see Table 3-3).

Of these services with dedicated alcohol beds, 50% have nursing staff specifically trained in alcohol/substance misuse care to cover these beds.

Sixty-one percent of services use adult psychiatric acute admission beds for alcohol problems, including 63% of the services which did not acknowledge any form of inpatient based service, and 53% of the services which were considered to have inpatient based alcohol services (including South Glasgow and Western Isles as noted previously).
The results of the survey indicate that there are approximately 30 general adult psychiatry acute admission beds in Scotland used specifically for care of patients with alcohol problems at any one time (see Table 3-3).

### Table 3-3 Breakdown of NHS bed usage per NHS Board

<table>
<thead>
<tr>
<th>NHS Board</th>
<th>Dedicated alcohol beds</th>
<th>General adult psychiatric beds (in use at one time)</th>
<th>Total beds (in use at one time)</th>
<th>Population</th>
<th>Beds per 100 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayrshire and Arran</td>
<td>6(+6)b</td>
<td>0</td>
<td>12</td>
<td>374545</td>
<td>4.81</td>
</tr>
<tr>
<td>Borders</td>
<td>1.5</td>
<td>0.8</td>
<td>2.3</td>
<td>106389</td>
<td>2.16</td>
</tr>
<tr>
<td>Dumfries and Galloway</td>
<td>4a</td>
<td>2</td>
<td>6</td>
<td>147280</td>
<td>4.07</td>
</tr>
<tr>
<td>Fife</td>
<td>0</td>
<td>4.4</td>
<td>4.4</td>
<td>348214</td>
<td>1.26</td>
</tr>
<tr>
<td>Forth Valley</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>275806</td>
<td>0.76</td>
</tr>
<tr>
<td>Grampian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>532110</td>
<td>0</td>
</tr>
<tr>
<td>Greater Glasgow</td>
<td>19 – 21</td>
<td>6</td>
<td>25 – 27</td>
<td>897053</td>
<td>2.90</td>
</tr>
<tr>
<td>Highlands</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>210418</td>
<td>2.85</td>
</tr>
<tr>
<td>Lanarkshire</td>
<td>7</td>
<td>8</td>
<td>15</td>
<td>559150</td>
<td>2.68</td>
</tr>
<tr>
<td>Argyll and Clyde</td>
<td>25c</td>
<td>4</td>
<td>29</td>
<td>426046</td>
<td>6.81</td>
</tr>
<tr>
<td>Lothian</td>
<td>12</td>
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<td>12</td>
<td>774528</td>
<td>1.55</td>
</tr>
<tr>
<td>Orkney</td>
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<td>1</td>
<td>1</td>
<td>19794</td>
<td>5.05(as above)</td>
</tr>
<tr>
<td>Shetland</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>22855</td>
<td>0</td>
</tr>
<tr>
<td>Tayside</td>
<td>12</td>
<td>0a</td>
<td>12</td>
<td>391397</td>
<td>3.07</td>
</tr>
<tr>
<td>Western Isles</td>
<td>0</td>
<td>1 – 2 (probably)</td>
<td>1 – 2</td>
<td>28476</td>
<td>3.51(only used for alcohol problems if needed)</td>
</tr>
</tbody>
</table>

General Adult Psychiatry (GAP) beds recorded are those used specifically by the specialist team for their patients for treatment of alcohol problems

a Dumfries and Galloway has four dedicated beds for either alcohol or substance misuse

b Ayrshire and Arran has ‘six beds for alcohol detoxification and 12 beds for residential dual diagnosis services which at any one time are used by approximately 50% alcohol users (and also drug users)” (C.Lind, Consultant Psychiatrist, personal communication, 13 March 2002)

c Renfrewshire and Inverclyde have 11 dedicated beds but those in Inverclyde (seven beds) are in daytime use only with severely unwell patients, including those at risk of seizures, being admitted to GAP beds

d There are approximately 300 alcohol-related admissions/year to GAP beds in Tayside. An average length of stay of 12 days would lead to 10 GAP beds in use for primary alcohol problems at any one time.

e Grampian has three non-NHS residential rehabilitation centres

### 3.18.3 Alcohol liaison in general hospitals

In earlier decades at least a quarter of Scottish general hospital inpatients reported drinking in the risk range (Chick et al., 1991), (Watson, 1999). For each level of drinking above 21 units per week, a Scottish male is at progressively greater risk of being admitted to a medical ward of a general hospital (Chick et al., 1986). More recently, Butler et al. (2001) found that, in Paisley, alcohol-related conditions (19%) and respiratory conditions (19%) were the most common reasons for acute medical admission. In Edinburgh, 10.8% of surgical admissions had an alcohol-related complaint, of whom half were dependent (Aarvold & Crofts, 2002).
Interventions targeted directly at alcohol dependence are a) the safe management of withdrawal and b) interventions aimed at helping the patient reduce or stop his/her habitual intake. There is a separate set of studies on patients seen as outpatients or in accident and emergency but not admitted. These have been reviewed, with draft recommendations, by SIGN (Scottish Intercollegiate Guidelines Network (SIGN), 2002), the final of which will be published in 2003.

a) The management of alcohol withdrawal in the general hospital

Alcohol withdrawal seizures, Wernicke’s encephalopathy and delirium tremens are life-threatening conditions. Rapid identification, so that prophylactic benzodiazepines and parenteral thiamine are prescribed, is the key to management. CRAG (1998) produced a Good Practice Statement, recommending that hospitals should have protocols in place. Specialist alcohol liaison nurses have been helpful in training, promulgating protocols and supporting staff (Leslie & Learmonth, 1994), (Hillman et al., 2001).

b) Interventions aimed at helping patients reduce or stop habitual intake

Controlled studies have tested whether one session with a doctor, nurse or psychologist, opening up the issue of alcohol, is associated with a reduction in drinking or alcohol-related problems in the coming year, compared to an assessment interview only. Most studies which showed efficacy (Chick et al., 1985) (Elvy et al., 1988) (Heather et al., 1996) had excluded alcohol-dependent patients. Elvy et al. (1988) offered slightly more than one session: the study included a nurse screening and, for the intervention group, referral to a counsellor who would also offer one appointment after discharge.

Two positive studies included dependent drinkers, and also tested several, not just one, sessions of motivational intervention. Antti-Poika et al. (1988), with injured patients admitted to hospital, gave one to three nurse interviews about alcohol during and after discharge, resulting in a reduction of consumption at six months compared to a no-intervention control group (follow-up data was obtained by nurses who had conducted the intervention and this could have biased the result). Gentilello et al. (1999) also studied patients admitted to trauma wards without excluding dependent patients. One session of MI with a specialist psychologist (plus a follow-up letter to the patient after one month) was associated with a greater reduction in consumption at the 12-month point than in the randomly allocated control group, and a greater reduction was also shown in an objective measure: future hospital record of injuries.

Testing whether a very minimal intervention has an effect after screening, Watson (1999) could not show that an advice session was associated with greater reduction in drinking at follow-up than simply giving health education literature, nor was there an additive effect; however, the study may not have had sufficient statistical power to show a difference. Forsberg et al. (2000) studied patients admitted to an emergency surgical ward who screened positive for alcohol problems (dependent patients were not excluded) and who were then randomised to either a brief assessment followed by feedback about risky alcohol consumption conducted by a nurse, psychologist or a surgeon or, the same assessment procedure conducted by a psychologist and followed by a second session lasting from one to two and a half hours of feedback and counselling. No differences in effect were found between the interventions.
Welte et al. (1998), in a quasi-experimental study, compared outcomes of problem drinkers from a hospital which had a screening and intervention service. Full intervention included a referral to treatment. Outcomes were compared across three groups: those who received a full intervention, those who received a risk-reduction intervention, and a comparison group of similar patients from four hospitals where that was not available. Full intervention was effective in increasing the probability of abstinence, reducing the number of heavy drinking days, and encouraging patients to accept referral to treatment. Risk-reduction intervention was effective in reducing alcohol consumption and consequences, but only for those patients who had some signs of dependence at the first interview.

Marshall et al. (2002) found no effect of a single session of counselling on the general medical wards having excluded dependent drinkers, while in a gastroenterological ward, Kuchipudi et al. (1990) likewise found no effect in patients, including dependent drinkers, in comparison with a non-intervention control condition. A quasi experimental comparison, among excessive drinkers on hospital wards, of screening and feedback by computer with or without computer advice plus self-help manual showed no advantage to adding on the computer advice and manual (Daniel et al., 1992).

In recent years, a few Scottish hospitals have introduced an alcohol liaison service in which a nurse with a specialist alcohol remit, is available to provide BI for newly identified non-dependent problem drinkers (Leslie & Learmonth, 1994), for which there is some, albeit limited, evidence of effect. Other roles of these nurses are to assess excessive drinkers in the medical and surgical wards with regard to post-discharge treatment for the prevention of relapse or referral to specialist services (Holloway, 2000), and to provide information and support to members of the acute medical and nursing team, particularly with advice on management of alcohol withdrawal (Hillman et al., 2001).

3.18.4 Outpatient services

Outpatient services can be divided into community, day hospital and outpatient based services. The following text summarises outpatient services in Scotland:

- 22% of services surveyed have no community based alcohol service
- 22% of services surveyed have no outpatient based alcohol service
- 61% of services surveyed have no day-patient based services
- 17% of services are solely community based – Borders, Orkney, parts of Fife and Lanarkshire
- there are no services which are solely inpatient based
- the staffing of these services varies widely (see Table 3-4)
- 74% of services have a consultant psychiatrist in or leading the team
- 26% of services do not have any medical staff
- 33% of services have psychology staff of some kind
- 33% of services have occupational therapy staff
- 14% of services have additional social work staff.
Table 3-4 Staff numbers per NHS Board area (whole time equivalent posts)

<table>
<thead>
<tr>
<th>Area</th>
<th>Consultant psychiatrists</th>
<th>Other medical staff</th>
<th>Nursing staff</th>
<th>Psychology staff</th>
<th>Occupational therapy staff</th>
<th>Social work staff</th>
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<td>21.5</td>
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<td>Tayside</td>
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</tbody>
</table>

3.18.5 NHS generalist services

Specialist services are resourced to meet the needs of only the small percentage of those most severely affected by alcohol-related problems. Generalist services provide the bulk of treatment work. They may be divided into primary care and non-specialist hospital care. These two components interact through, for example, specialist staff offering clinics in primary care; joint work systems such as home detoxification; or delivery of training programmes for primary care staff.

The Plan for Action notes ‘GPs are often the first source of advice about alcohol problems. They play a vital role in identifying and tackling such problems and referring patients for appropriate help’. The Greater Glasgow Health Board (GGHB) Alcohol Strategy Consultation document (Greater Glasgow Health Board, 2000), notes that in a randomised survey of 227 GGHB GPs, many GPs had large numbers of patients with serious alcohol-related problems. Very few of these GPs had a special interest in alcohol problems. Seventy percent of GPs said they employed BI techniques, almost 90% employed home detoxification and over 60% employed some form of counselling technique (not specified). Few had access to nursing or counselling staff trained in the management of alcohol-related problems. Work reviewed later in Chapter 5 of this report shows that effective specialist psychosocial and pharmacological treatments are available for alcohol-dependent patients and that BI is not sufficient for those with established alcohol dependence. Thus, clear evidence based decision processes for referral to specialist services and greater accessibility of these services would allow GPs to offer a more complete service.

The HTBS survey did not assess the capacity of generalist services for treating alcohol problems, but in the case of this HTA, it could be assumed that the bulk of generalist intervention (not including input from Councils on Alcohol to GP
surgeries) is BI, ‘support and advice’ and the prescribing of medication (e.g. benzodiazepines for detoxification and acamprosate for prevention of relapse).

A&E departments have a role in recognising alcohol-related problems and can be appropriate settings in which to offer help, for instance through the use of BI techniques for less severe cases or by referral on to an appropriate agency within the ‘treatment system’.

Significant numbers of admissions to general hospital medical wards and other wards (e.g. surgical) have current alcohol-related problems. ‘There is little evidence that most problem drinkers entering hospital are having their drinking problem recognised, assessed and appropriate action then taken’ (Greater Glasgow Health Board, 2000). Intervention may be limited to the immediate management of alcohol withdrawal. There may be, however, the opportunity for some psychosocial intervention on medical wards, perhaps more so than in the primary care setting, given the lengthier period of time in contact with the individual. It is not clear to what extent this may be occurring.

A liaison psychiatrist, when available, can advise and educate not only on the immediate management of alcohol withdrawal but also on appropriate subsequent referral to specialist agencies.

Specialist alcohol liaison nurses are few in number but may provide useful support to general hospital wards in terms of both the management of alcohol-related problems and the education and training of generalist health care professionals. Lothian and East Glasgow currently provide this alcohol liaison nurse service.

General psychiatric services see a large proportion of the alcohol misusers referred to the psychiatric services overall, including the specialist addiction services. Additionally, many patients have a dual diagnosis of alcohol dependence coupled with a psychiatric illness. Therefore, many problem drinkers are admitted to acute psychiatric beds with few of the supervising consultants or nursing staff having a specialist addiction training.

### 3.18.6 Non-NHS services

Table 3-5 shows the distribution of non-NHS services which have at least some role in the care of individuals with alcohol problems. This does not take into account the numerous AA meetings, which occur throughout Scotland on a daily basis (Section 3.13.1).
### Table 3-5 Non-NHS services

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<tr>
<th></th>
<th>Argyll and Clyde</th>
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<th>Borders</th>
<th>Dumfries and Galloway</th>
<th>Fife</th>
<th>Forth Valley</th>
<th>Grampian</th>
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<td></td>
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</table>

| Residential rehabilitation facilities |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| Social work |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| City council |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| Church of Scotland |                  |                   |         |                       | 1    | 1            | 1        | 1             | 1        |             |         |        |         |         |               |
| Salvation Army |                  |                   |         |                       |      |              | 1        |               |          |             |         |        |         |         |               |
| Other non-statutory |                  |                   |         |                       |      |              | 2        | 2             | 2        |             |         |        |         |         |               |

| Residential homelessness facilities |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| Social work |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| City council |                  |                   |         |                       | 4    | 2            |          |               |          |             |         |        |         |         |               |
| Church of Scotland |                  |                   |         |                       |      |              |          |               |          |             |         |        |         |         |               |
| Salvation Army |                  |                   |         |                       |      |              | 1        |               |          |             |         |        |         |         |               |
| Other non-statutory |                  |                   |         |                       |      |              | 2        | 10            | 5        |             | 7       |        |         |         |               |
| TOTAL |                  |                   |         |                       | 21   | 8             | 2        | 4             | 4        | 14          | 47      | 13     | 6       | 27      | 1           | 22      | 13  | 2         | 30      | 2         |

| Number per 100,000 | 7 | 2 | 2 | 1 | 1 | 2 | 3 | 5 | 6 | 1 | 4 | 5 | 9 | 3 | 7 |

Areas with five or more services per 100 000 of population are Greater Glasgow, Lomond and Argyll, Renfrewshire and Inverclyde, Highland, Orkney, Shetland and Western Isles. Areas with two or less are Ayrshire and Arran, Borders, Dumfries and Galloway, Fife, Forth Valley and Lanarkshire. These figures do not take account of differences in demand or difficulties in accessing the services. They also do not give any indication of the size and workload of individual facilities.
Day facilities (which, in this Assessment Report, include all non-residential facilities irrespective of hours of opening, intensity of workload, type of intervention etc.) make up the bulk (71%) of non-NHS services (even excluding AA from these statistics) – largely through the numerous facilities provided by Councils on Alcohol (52% of day facilities); social work services make up the next largest group (24%) of facilities (Community Alcohol Teams are not included in these figures).

Residential homelessness services provide 21% of non-NHS facilities identified (excluding AA) through various charitable organisations including Cyrenians (19% of residential homelessness facilities) and, in Glasgow, the Talbot Association (16%), as well as city councils (16%).

Many of the homelessness facilities identified do not have a special remit for dealing with alcohol problems and over 50% of facilities returning the questionnaire did not offer any psychosocial interventions to deal with these problems. Nonetheless, people with alcohol problems seem to account for a significant proportion of individuals using those facilities.

Greater Glasgow has most in the way of residential homelessness facilities (42%), with Edinburgh and Lothian (25%), Tayside (19%), Renfrewshire and Inverclyde (8%) and Grampian (6%) making up the rest of identified facilities of this nature.

A large proportion of homeless people have evidence of severe alcohol-related problems. There is an apparent lack of availability of specialist addictions services for homeless people with alcohol problems, although the Rough Sleepers Initiative (RSI) and in Glasgow the development of the Homeless Addictions Team is a step towards tackling this issue. The GGHB Alcohol Strategy Consultation Document (Greater Glasgow Health Board, 2000) recognised that liaison between statutory addiction services and hostels was poor. Glasgow Council on Alcohol hold regular weekly surgeries at Glasgow city council hostels.

Residential rehabilitation facilities are few in number (14 facilities, 9 – 10% of identified non-NHS facilities). Five (36%) are provided by the Church of Scotland, with two (14%) provided by the Salvation Army and only one (7%) provided by social work services. The facilities are in Greater Glasgow, four (29%), Edinburgh and Lothian, three (21%), Grampian, three (21%), and one (7%) each in Highland, Renfrewshire and Inverclyde, Lomond and Argyll and Lanarkshire.

### 3.18.7 Social work services

The social services are in an ideal position to recognise and assess individuals with alcohol problems through their contact with many ‘at risk’ groups as part of the work of child and family teams, community care teams and prison social work teams. In addition, the specialist addiction social work services provide intervention in terms of advice, information, counselling, advocacy, support and care planning. They are also involved in purchasing services such as rehabilitation.

Expansion of Tier 3 (Scottish Executive Health Department, 2002) may create a greater resource for outpatient care but there is concern that this could result in redistribution of staff from NHS specialist Tier 4 services.
The survey of existing non-NHS alcohol facilities included 14 social work facilities making up 13% of non-NHS facilities surveyed. A further 17 facilities were identified post-survey from SACAM information taking the total to 31 facilities identified (18% of the total non-NHS facilities eventually identified). Ninety-three percent of these were day facilities with one residential rehabilitation facility and one residential homelessness facility. The social work facilities are mostly to be found in Greater Glasgow (42%), with other facilities located in Lanarkshire, Grampian, Tayside, Lomond and Argyll, Renfrewshire and Inverclyde, Lothian, Fife and Ayrshire and Arran.

It appears that a range of validated psychosocial interventions (e.g. MI, Social Skills Training) may be offered by social work services.

3.18.8 Non-statutory facilities

Non-statutory services may have charitable or independent status. The Plan for Action points to the ‘strong contribution already made by non-statutory organisations in providing prevention, education, treatment and support services’ and notes their good value for money. Non-statutory services may better meet the needs of marginalised subgroups and communities than statutory services.

The contribution of AA to non-statutory services in Scotland was not assessed in the survey but they are discussed separately in this Assessment Report (Section 3.13.1, 5.8.1 and 6.5.4).

Eighty-seven non-statutory facilities were surveyed. An additional 32 Council on Alcohol sub offices and 10 other facilities identified post-survey from SACAM information were not surveyed. A total of 129 non-statutory facilities (not including AA) were identified.

Sixty-seven percent of those surveyed are day facilities, mostly Councils on Alcohol (72%), 10% are residential rehabilitation facilities, largely Church of Scotland (38%), and 23% are residential homelessness facilities.

The Scottish Executive provides core funding for AFS, which, in turn, has the function of supporting local Councils on Alcohol. Councils on Alcohol appear to be the largest non-NHS service in the field of alcohol problems identified in the survey, with a rigorous selection and training process resulting in counsellor accreditation. The psychosocial intervention termed ‘alcohol counselling’ by many of the facilities is a CBT based approach. On average, 24 service users engaged or re-engaged in a month per facility. Service users remain engaged in the service for a variable period of time taking individual needs into account but the average length of treatment/contact is probably about 3 – 4 months.

Services provided by the Church of Scotland Board of Social Responsibility may vary from facility to facility. The Board has five residential rehabilitation facilities plus a day service centre responding to a range of alcohol related challenges. The counselling methods used are person-centred, along similar lines to MI with psychodynamic approaches also employed. The following is a description of the residential centres (Mr D. Kellock, Deputy Director of social work (Operations), Church of Scotland, personal communication, 10 August 2001):
• Victoria View is a residential rehabilitation facility in Glasgow with seven staff, where 12 – 16 beds are provided for alcohol problems. The mean length of stay is 26 weeks. Psychosocial interventions include intensive group therapy, family therapy and individual counselling. Funding is through social work and local authority.

• Ronachan House is a residential rehabilitation facility in Argyll and Clyde area, with eight staff, offering 6 – 8 month stays [depending on need] for up to 20 residents. Psychosocial interventions include work programme, group work, individual counselling, educational input and leisure activities.

• Malta House is a rehabilitation unit in Edinburgh, with nine staff, offering six-month programmes for up to 15 residents with drug/alcohol dependence. Psychosocial interventions include group work, counselling, physical work and activities.

• Deeford House was a rehabilitation unit in Grampian region with seven full time and two part time staff, offering an average stay of approximately 12 weeks for up to 17 service users [four in a satellite house]. Psychosocial interventions included group meetings, one-to-one counselling and anger management. However, this facility has been closed during the time since the information regarding non-statutory residential facilities was provided to HTBS.

• Beechwood House is a rehabilitation unit in the Highland area, with 22 staff, providing a four-week intensive assessment and intervention programme with optional access to a further 10-week programme for individuals seeking support in re-establishing a pattern of alcohol-free living.

3.18.9 Private care

Private care facilities (e.g. The Langside Priory and Castle Craig) were not sent the survey questionnaire but submitted evidence in response to the consultation procedures during the HTA. The Langside Priory offers a service which includes detoxification as an inpatient or outpatient aimed at achieving abstinence, CBT, problem solving, family therapy, couple therapy, post-treatment planning, weekly continuing care and self-help group meetings within the hospital (continuing care is provided free of charge for as long as required). Castle Craig adopts a 12-step approach in a residential setting and aims for abstinence. The treatment program includes group therapy, individual therapy, didactic lectures, video films, individual readings and written assignments. Funding, in Glasgow for example, is via social work and subcontracted with GGHB; in Highland region, NHS Board funding occurs for the first six-week intensive period and thereafter social work funding is required. There is a similar smaller facility in Aberdeen.

3.18.10 Services for alcohol dependent offenders

Prison services have not been addressed although the SACAM survey identified prison liaison facilities involving collaboration between social work or Councils on Alcohol and the SPS.

3.19 Demand versus service distribution

In the consultation process prior to publication of the Plan for Action, ‘patchiness’ in service provision throughout Scotland was noted. This perception was borne out by
the HTBS survey of specialist alcohol services (Section 3.10). Services appear fragmented, perhaps leaving some people without access to what should be minimum care. This is particularly noticeable in certain rural areas. It may also be that different populations have different needs and, for instance, rural communities may face specific circumstances and difficulties when providing treatment for alcohol problems: distance; geographical location; lack of social support; fear of stigma etc. may constitute barriers to treatment and complicate rehabilitation and follow-up procedures.

Some services appear to be comparatively well provisioned but may, nonetheless, be working beyond their capacity, with pressure on resources and long waiting lists. For instance, 84% of the most deprived people in Scotland live in Greater Glasgow area (Greater Glasgow Health Board, 2000). The rates of general hospital and psychiatric admissions for alcohol-related diagnoses are 10 times greater for people in the most deprived, compared with the most affluent areas. The greater levels of socio-economic deprivation in Glasgow mean that the area probably has higher rates of some alcohol-related problems than any other health authority in the UK (Greater Glasgow Health Board, 2000). The Plan for Action (2002) notes that men living in the most deprived areas of Scotland are seven times more likely to die an alcohol-related death than those in the least deprived areas (although there may be significant regional variations in this figure).

3.20 Long-term health expectation in alcohol dependence

3.20.1 Effects of chronic and acute exposure to alcohol

The economic evaluation of interventions for the prevention of relapse in this HTA relates the costs of the interventions to the benefits obtained from a reduction in the adverse effects of alcohol on health. In order to do this, it is necessary to evaluate the impact of alcohol on the health of alcohol-dependent patients.

Drinking large amounts of alcohol alters the chance of developing many diseases and is also associated with increased risks of accidents and suicide. Some of these effects appear to be related to chronic heavy drinking while others may be related to acute intoxication. However, whether the nature of these effects differs in alcohol-dependent individuals from those who drink similar quantities without developing dependence is unclear. For the purposes of this HTA, it seems reasonable to assume that the risks of diseases associated with chronic excessive drinking are similar whether or not dependence is present and also that alcohol-dependent individuals are likely to be drinking in quantities which carry a risk similar to the highest levels of risk seen in the population in general. However, whether dependent drinkers account for a high proportion of events associated with acute intoxication is less clear. This is because many such events may be experienced by occasional heavy drinkers. For this reason, it seems reasonable to restrict the consideration within the economic model to illness associated with chronic drinking. However, it must be recognised that any benefit of treatment will only reflect a part of the potential benefit to the health service of treatment of alcohol dependence since alcohol-dependent drinkers will also experience the heightened risks associated with acute intoxication, for example accidents. The possible extent of this underestimation can be roughly gauged from the following discussion of the Australian National Alcohol Indicators Project (NAIP) (Chikritzhs et al., 2000).
3.20.2 The Australian National Alcohol Indicators Project

The Australian National Drug Research Institute published a report on alcohol-caused deaths and hospitalisations as part of the NAIP (Chikritzhs et al., 2000). The report used relative risks of disease comparing high alcohol intake with low or moderate drawn from a paper by English (1995), subsequently updated by Gutjahr et al. (2001). From these, combined with information on the drinking levels in Australia and the total disease burden, the amount of disease attributable to drinking was calculated. These figures are of considerable relevance because they show which of the many diseases affected by alcohol are likely to have the biggest clinical and economic impact. The report identifies 19 events/conditions associated with acute intoxication and 15 conditions associated with chronic drinking as partially or wholly attributable to high-risk alcohol consumptions. An additional two conditions, stroke and suicide, are classified as ‘mixed’ since they are associated with both acute and chronic drinking. The relative impacts of these classes of health events can be judged from the total alcohol-caused deaths, person-years lost, hospitalisations and bed-days associated with them.

Table 3-6 Impact on health of acute and chronic drinking (Australia)

<table>
<thead>
<tr>
<th></th>
<th>Acute intoxication (19 conditions)</th>
<th>Chronic drinking (15 conditions)</th>
<th>Mixed (2 conditions)</th>
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</thead>
<tbody>
<tr>
<td><strong>Males</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>695</td>
<td>1061</td>
<td>540</td>
</tr>
<tr>
<td>Person-years lost</td>
<td>22743</td>
<td>15675</td>
<td>10076</td>
</tr>
<tr>
<td>Hospitalisations</td>
<td>31366</td>
<td>14670</td>
<td>3463</td>
</tr>
<tr>
<td>Bed-days</td>
<td>156476</td>
<td>95049</td>
<td>25115</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>218</td>
<td>328</td>
<td>449</td>
</tr>
<tr>
<td>Person-years lost</td>
<td>6246</td>
<td>5309</td>
<td>2933</td>
</tr>
<tr>
<td>Hospitalisations</td>
<td>13517</td>
<td>6165</td>
<td>3122</td>
</tr>
<tr>
<td>Bed-days</td>
<td>60865</td>
<td>41052</td>
<td>25238</td>
</tr>
</tbody>
</table>

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From this it can be seen that the adverse health effects of acute intoxication represent a considerable burden to the health service. Just over 50% of total bed-days attributable to alcohol were taken up by such events. Hence it is conceivable that health service benefits from effective treatments could be twice as large as we estimate from our model. However, this would only be under the unlikely circumstance that almost all of the acute drinking events were in alcohol-dependent people.

The impact of each chronic and ‘mixed’ event can be judged from Table 3-7 which shows them in descending order of total bed-days in the NAIP report.
Table 3-7  Total bed-days from diseases associated with chronic or ‘mixed’ drinking patterns (Australia)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Deaths</th>
<th>PVLL</th>
<th>PYLL</th>
<th>Hospitalisation</th>
<th>Bed-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol dependence</td>
<td>257</td>
<td>4335</td>
<td>13043</td>
<td>85294</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>726</td>
<td>4019</td>
<td>4716</td>
<td>43247</td>
<td></td>
</tr>
<tr>
<td>Alc. Liver cirrhosis</td>
<td>683</td>
<td>11108</td>
<td>3222</td>
<td>25654</td>
<td></td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>13</td>
<td>151</td>
<td>1516</td>
<td>8377</td>
<td></td>
</tr>
<tr>
<td>Suicide</td>
<td>264</td>
<td>8985</td>
<td>1868</td>
<td>7105</td>
<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td>31</td>
<td>794</td>
<td>1730</td>
<td>6453</td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal cancer</td>
<td>55</td>
<td>637</td>
<td>395</td>
<td>3708</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>38</td>
<td>216</td>
<td>417</td>
<td>1836</td>
<td></td>
</tr>
<tr>
<td>Female breast cancer</td>
<td>51</td>
<td>715</td>
<td>371</td>
<td>1810</td>
<td></td>
</tr>
<tr>
<td>Oesophageal cancer</td>
<td>54</td>
<td>532</td>
<td>225</td>
<td>1670</td>
<td></td>
</tr>
<tr>
<td>Laryngeal cancer</td>
<td>31</td>
<td>300</td>
<td>182</td>
<td>1485</td>
<td></td>
</tr>
<tr>
<td>Oesophageal varices</td>
<td>2</td>
<td>28</td>
<td>473</td>
<td>1205</td>
<td></td>
</tr>
<tr>
<td>Liver cancer</td>
<td>65</td>
<td>659</td>
<td>161</td>
<td>1158</td>
<td></td>
</tr>
<tr>
<td>Alc. Cardiomyopathy</td>
<td>109</td>
<td>1481</td>
<td>146</td>
<td>873</td>
<td></td>
</tr>
<tr>
<td>Alc. poly neuropathy</td>
<td>0</td>
<td>0</td>
<td>32</td>
<td>240</td>
<td></td>
</tr>
<tr>
<td>Psoriasis</td>
<td>0</td>
<td>0</td>
<td>40</td>
<td>122</td>
<td></td>
</tr>
<tr>
<td>Cholelithiasis(a)</td>
<td>-1</td>
<td>-6</td>
<td>-1118</td>
<td>-3784</td>
<td></td>
</tr>
<tr>
<td>Sub-total</td>
<td>2378</td>
<td>33954</td>
<td>27419</td>
<td>186453</td>
<td></td>
</tr>
</tbody>
</table>

\(a\) Alcohol is protective for cholelithiasis \(b\) Person-years of life lost

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The only beneficial effect of very heavy drinking appears to be an effect on gall bladder stones (cholelithiasis). The risk at the highest levels of consumption appears to be about half that at low levels. Clinically this is not a benefit comparable to the harm since cholelithiasis is very rarely a fatal condition. However, the NAIP report shows a saving in hospital bed-days, which may be economically important. Ignoring adverse effects of alcohol will tend to undervalue treatment for dependence while ignoring benefits will do the opposite. Thus the decision to ignore this effect should be carefully considered. However, there are several small but proven adverse associations which can be reasonably disregarded as minor effects but which roughly counterbalance the bed-days gained through any protective effect on cholelithiasis. Hypertension, oesophageal varices and psoriasis have been disregarded.

3.20.3 Categorisation of drinking by associated risk

In the study by Gutjahr et al. (2001) the relative risks for each disease are estimated from meta-analysis of published studies. Three levels of drinking are considered relative to abstinence. These are described as low, hazardous and harmful, but definitions of these are not given in the report. The UK Medical Council on Alcohol (http://www.medicouncilalcol.demon.co.uk/handbook/glossary.htm) defines these terms as follows:

- low risk – intake unlikely to be associated with the development of alcohol-related harm if taken over seven days (males <21 units/week, females < 14 units/week)
- hazardous drinking – intake likely to increase the risk of developing alcohol-related harm (males 22 – 50 units/week females 15 – 35 units/week)
- harmful drinking – a pattern of drinking associated with the development of alcohol-related harm (males >50 units/week females >35 units/week)
One unit corresponds approximately to 8 g of pure ethanol and hence these figures translate to:

- **low risk** (males =24 g/day, females =16 g/day)
- **hazardous drinking** – probable dependence forming level – (males 25 – 57 g/day, females 17 – 40 g/day)
- **harmful drinking** (males >57 g/day, females >40 g/day)

### 3.20.4 Concordance between epidemiological studies

The risk ratios (RR) calculated by Gutjahr et al. (2001) between harmful and low-risk drinking for the diseases partially explained by chronic drinking are compared in Table 3-8 with those quoted by other meta-analytic reports. These other reports are discussed in the text which follows.

**Table 3-8 Comparison of reported relative risk from harmful drinking from three sources**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Gutjahr 2001</th>
<th>Bagnardi (95% CI) 2001</th>
<th>Mazzaglia 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>7.72f 1.79m</td>
<td>3.0 Haemorrhagic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3 Ischaemic</td>
<td></td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td>7.52f 6.83m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal cancer</td>
<td>5.39</td>
<td>6.01 (5.5, 6.6)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.79f 2.05m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female breast cancer</td>
<td>1.66f</td>
<td>2.71 (2.3, 3.1)</td>
<td></td>
</tr>
<tr>
<td>Oesophageal cancer</td>
<td>4.36</td>
<td>4.23 (3.9, 4.6)</td>
<td></td>
</tr>
<tr>
<td>Laryngeal cancer</td>
<td>4.93</td>
<td>3.95 (3.4, 4.6)</td>
<td></td>
</tr>
<tr>
<td>Oesophageal varices</td>
<td>9.54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver cancer</td>
<td>3.60</td>
<td>1.86 (1.5, 2.3)</td>
<td></td>
</tr>
</tbody>
</table>

f=female, m=male

a Relative risks are not given for chronic pancreatitis but the attributable fraction is estimated as 0.84.

The figures of Bagnardi et al. (2001) are for alcohol consumption greater than 100 g/day. There are appreciable differences between the two sources in estimates for female breast cancer and for liver cancer. Bagnardi also identifies five additional cancers as increased by alcohol intake greater than 100 g/day. These are stomach (RR=1.32, 95% CI 1.2, 1.5), colon and rectum (RR=1.38, 95% CI 1.3, 1.5), lung (RR=1.08, 95% CI 1.0, 1.2), ovary (RR=1.53, 95% CI 1.0, 2.3), and prostate (RR=1.19, 95% CI 1.0, 1.4). Alcohol increases the risk of each of these rather less than the cancers included in the NAIP report. However, the contribution that each cancer makes to the total burden of alcohol-related morbidity will depend on the relative risk, the proportion of heavy drinkers and on the absolute risk. The Scottish Health Statistics (Information and Statistics Division National Health Service in Scotland, 2000) give numbers of registration for 1996 which can be used to assess this impact. This is a rough calculation performed for a population of which 8% are heavy drinkers. It also ignores the raised risks at intermediate levels of alcohol consumption. However, the relative impact of these cancers for men or women is insensitive to these assumptions.
Table 3-9 Estimates of Scottish cancers attributable annually to heavy drinking

<table>
<thead>
<tr>
<th>Cancer</th>
<th>RR (95% CI) - Bagnardi</th>
<th>N (1996)</th>
<th>Attributable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oropharyngeal cancer</td>
<td>6.01 (5.5, 6.6)</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>Female breast cancer</td>
<td>2.71 (2.3, 3.1)</td>
<td>3295</td>
<td>397</td>
</tr>
<tr>
<td>Oesophageal cancer</td>
<td>4.23 (3.9, 4.6)</td>
<td>840</td>
<td>172</td>
</tr>
<tr>
<td>Laryngeal cancer</td>
<td>3.95 (3.4, 4.6)</td>
<td>351</td>
<td>67</td>
</tr>
<tr>
<td>Liver cancer</td>
<td>1.86 (1.5, 2.3)</td>
<td>252</td>
<td>16</td>
</tr>
<tr>
<td>Stomach cancer</td>
<td>1.32 (1.2, 1.5)</td>
<td>993</td>
<td>25</td>
</tr>
<tr>
<td>Colon and rectum</td>
<td>1.38 (1.3, 1.5)</td>
<td>3567</td>
<td>105</td>
</tr>
<tr>
<td>Lung</td>
<td>1.08 (1.0, 1.2)</td>
<td>4806</td>
<td>31</td>
</tr>
<tr>
<td>Ovary</td>
<td>1.53 (1.0, 2.3)</td>
<td>615</td>
<td>25</td>
</tr>
<tr>
<td>Prostate</td>
<td>1.19 (1.0, 1.4)</td>
<td>2027</td>
<td>30</td>
</tr>
</tbody>
</table>

From this simple calculation it appears that the five additional cancers identified by Bagnardi each add more to the disease burden than either liver or oropharyngeal cancer. They also add 216 attributable cases to the 659 from the other cancers. Hence all ten cancers have been included when calculating the economic impact of alcohol.

Mazzaglia defined heavy drinking to be more than 40 g/day when calculating estimates of the risk of stroke with alcohol (Mazzaglia et al., 2001). The report included one cross-sectional study, 15 case-control and nine cohort studies in the investigation of chronic drinking and stroke incidence. The report does not attempt to meta-analyse the results and hence is difficult to interpret. There is inconsistent evidence concerning ischaemic stroke. All seven case-control studies for which odds ratios are reported found raised risks, which were between 2.4 and 15.3. Three studies yielded values around 2.9. However, three prospective cohort studies yielded relative risks of 0.4, 0.8 and 2.0, the former being significantly less than one and the latter significantly greater. Random effects inverse variance weighted mean results (HTBS calculation) for these figures gives an odds ratio (OR) of 2.3, 95% CI 0.8, 6.75. Thus the effect is not statistically significant but suggests some increase in incidence. By contrast, all but one of ten studies (four case-control, six cohort) gave significantly raised risks for haemorrhagic stroke. The inverse variance weighted mean OR was 3.0, 95% CI 1.1, 8.6. There was considerable heterogeneity between studies for both ischaemic and haemorrhagic stroke. In the latter case this was almost entirely due to a single study (Berger et al., 1999) which found a reduction in stroke. The finding of a marked difference in additional risk between men and women (NAIP) is not supported in this study, most studies in only men returning relative risks close to the mean. The NAIP report included the large, anomalous study by Berger, which was in male physicians from the United States of America (USA) and it is likely that this will have strongly skewed the comparison of males and females. The NAIP authors note that the position with respect to alcohol and stroke is currently being reviewed in Australia – which suggests some uncertainty about the results used in the report. Thus preference has been given to the evidence from Mazzaglia as presented previously.

### 3.20.5 Suicide

Relative risks for suicide are difficult to determine. There is a good discussion of this in the International Guide for Monitoring Alcohol Consumption and Harm (World Health Organisation, 2000) in which it is recommended that `Relative Risk estimates be based upon well-conducted studies from, ideally, the country to which they are to be applied, or at least from culturally and economically similar countries.’ This World
Health Organisation publication includes suicide as an effect of acute drinking rather than 'mixed' and the economic modelling in this Assessment Report will not include suicide but note that this may be an additional conservative element in the analysis.

### 3.20.6 Alcoholic cardiomyopathy and polyneuropathy

As shown in the NAIP report, alcoholic cardiomyopathy and polyneuropathy – although specifically associated with alcohol – are not major contributors to clinical costs. Cardiomyopathy contributes to alcohol-associated mortality and hence would be of interest in an analysis which costed lost life-years. Alcoholic polyneuropathy is a rare condition. Hence neither is explicitly accounted for in the economic analysis for this report.

### 3.20.7 Alcoholic psychosis

Alcoholic psychosis, which was one of the main outcomes considered in the report on which the economic model for this HTA is based (Schadlich & Brecht, 1998) was classified by NAIP to be primarily a result of acute episodes of heavy drinking and hence does not appear in Table 3-7. However, this is potentially misleading as it appears to be a result of amalgamating several different conditions including ICD-10 F10.0 (Acute intoxication) F10.4 (Withdrawal state with delirium) F10.5 (Psychotic disorder) F10.6 (Amnesic syndrome) and F10.7 (Residual and late-onset psychotic disorder). The latter four categories are predominantly associated with chronic drinking and are included in this HTBS HTA.

Specific relative risks were not found for the above conditions but their impact was estimated using Scottish data on hospital episodes (Information and Statistics Division National Health Service in Scotland, 2000) compared with hospital episodes for cirrhosis. This is a fairly crude procedure for accounting a complex mixture of psychiatric diseases and it is important to note that a subgroup of patients will have chronic debilitating psychiatric problems that have substantial clinical and economic costs and are not acknowledged in the model.

### 3.20.8 Alcohol associated diseases accounted in the HTBS model

Thus the total disease impact of chronic drinking, considered in this Assessment Report includes the following:

- alcohol dependence
- stroke
- alcoholic liver cirrhosis
- cancer
  - oropharyngeal
  - female breast
  - oesophageal
  - laryngeal
  - liver
  - stomach
  - colon and rectum
  - lung
  - ovary
- prostate
- chronic pancreatitis
- epilepsy
- alcoholic psychosis including organic brain damage.

These conditions fall into two categories, which are handled differently in the analysis. Cancer, stroke and cirrhosis are major events likely to be fatal or, if survived, have appreciable downstream effects upon the patients. For these, the proportion of patients likely to suffer a first event of each type has been calculated. Chronic pancreatitis, epilepsy and alcoholic psychosis are likely to cause ongoing problems and the likely burden of each illness in a patient until the occurrence of one of the severe events considered in the preceding text or death has been calculated.

### 3.20.9 Disease incidence

To calculate the probability that a person develops any one of the partially attributable conditions when exposed to a hazardous level of alcohol exposure, it is necessary to know the probability of doing so at low alcohol exposure and the relative risks as discussed previously. If the proportion of cases attributable to alcohol is not great, the population incidence may be taken as reflecting the baseline risk with only second order errors in calculation of risk to hazardous drinkers. If this assumption is not credible then a correction based on the prevalence of hazardous drinking should be used.

#### 3.20.9.1 Cancer

Incidence figures for all forms of cancer are routinely collected but other, non-notifiable, disease incidences must be estimated from other sources. The cancer incidences for the Scottish population have been taken from the Scottish Health Statistics (Information and Statistics Division National Health Service in Scotland, 2000). They are based on observations made in 1996.

#### 3.20.9.2 Stroke

Warlow et al. (1996) quoted eleven different studies of stroke incidence. The averaged age specific incidences per 100 000 are presented in Table 3-10.

<p>| Table 3-10 Estimates of the age specific annual incidence of stroke per 10 0000 |</p>
<table>
<thead>
<tr>
<th>Age (years)</th>
<th>0 – 44</th>
<th>45 – 54</th>
<th>55 – 64</th>
<th>65 – 74</th>
<th>75 – 84</th>
<th>85+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence</td>
<td>13</td>
<td>96</td>
<td>278</td>
<td>664</td>
<td>1409</td>
<td>2089</td>
</tr>
</tbody>
</table>

These figures include ischaemic stroke, primary intracerebral haemorrhage, and subarachnoid haemorrhage. The same source reports that in seven incidence studies of first ever stroke, about 80% of strokes were ischaemic, 10% were primary intracerebral haemorrhage, 5% were subarachnoid haemorrhage and 5% were of unknown aetiology. For the purpose of this HTA it has been assumed that the unclassified strokes were predominantly ischaemic and that the age distribution was roughly similar for ischaemic and haemorrhagic strokes.

Hart et al. (2000) followed a cohort of Scottish residents aged between 45 and 64 years for twenty years and estimated stroke incidence. They found strokes in
472 (6.7%) of 7052 men and in 557 (6.7%) of 8354 women. This can be roughly compared with the figures from Warlow et al., (1996). Over twenty years the chance of stroke in a 55 year old would be \([1-(1-278/100 \,000)^{10} \times (1-664/100 \,000)^{10}] \times 100\% = 9\%\). This is somewhat higher than the 6.7% observed by Hart, however it is strongly dependent on age; the chance in a 45 year old can be calculated to be 3.7% while that in a 65 year old would be 18.2% (ignoring competing mortality). Thus it appears that the two sources of data give similar results.

The very simple model of disease being used in the HTBS economic assessment (Chapter 7) requires some mean stroke risk and a time horizon to be chosen. A 20-year horizon has been used as have baseline risks for people aged 45 at the start of this period.

3.20.9.3 Liver disease and cirrhosis

Becker et al. (1996) followed 13 285 subjects age 30 to 79 years over 12 years in Copenhagen. Self-reported drinking levels, which were not independently verified, were compared with the incidence of liver disease and cirrhosis.

A very steep increase in both liver disease and cirrhosis with alcohol intake was found in both sexes. The baseline risk was that in the lowest, non-abstinent, group (12 – 72 g/week of ethanol). Relative to this group, men and women who fulfilled the ‘harmful drinking’ criterion had greater than seven times the risk of cirrhosis and four times the risk of any alcohol-related liver disease. The highest levels of drinking observed (>120 g/day for men and between 48 and 70 g/d for women) carried relative risks of around 17 for cirrhosis and eight for any liver disease.

Table 3-11 presents a rough estimate of the baseline risks from the figures given in the paper.

| Table 3-11  Estimates of population baseline risks of liver disease |
| --- | --- | --- |
| Any alcohol-related liver disease | Men per 1000 per year | Women per 1000 per year |
| Cirrhosis | 1.5 | 0.76 |
| Cirrhosis | 0.52 | 0.23 |

Any age variation in these rates could not be calculated from the information supplied.

The very large variation in risk with alcohol intake complicates the use of these figures in predicting rates for an alcohol-dependent population. In the population from the Copenhagen City Heart Study discussed in the paper the mean relative risk for the 5% of the population with the highest drinking rate was 16.5 in men while the relative risk of any liver disease was 8.1. These figures were not calculable for women but the similarity of relative risks in men and women at their respective levels of ‘harmful drinking’ suggests using the same relative risks in each group. In the absence of information based on a Scottish population, these figures have been used in the present calculations.
3.20.10 Mortality in harmful drinkers

In order to calculate the expected pattern of alcohol-related disease in a cohort of harmful drinkers, it is necessary to have some information about the likelihood of dying without developing such a disease. Some studies of heavy drinkers have suggested that this is much higher than in the population in general. However, a major difficulty with this calculation is that no studies have been found of a continuously drinking population. All studies were of treated populations and some will presumably have been successfully treated.

Chen et al. (2001) followed up 418 alcohol-dependent patients detoxified within a psychiatric hospital in Taiwan. The mean age of the patients was 39.4 years and 91% were male. The total follow up was 1268 person years during which 83 deaths were observed. Life table estimates suggested that only 50% survived for 10 years (mean survival 9.9 years). Sixty-three deaths were non-violent and of these 34% were gastrointestinal (predominantly liver disease) and 18% were cardiovascular.

Table 3-12 The numbers and causes of death (Chen et al., 2001)

<table>
<thead>
<tr>
<th>Violent deaths</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accident</td>
<td>16</td>
</tr>
<tr>
<td>Suicide</td>
<td>2</td>
</tr>
<tr>
<td>Homicide</td>
<td>2</td>
</tr>
<tr>
<td>Non-violent deaths</td>
<td>63</td>
</tr>
<tr>
<td>Cancer</td>
<td>6</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>15</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>28</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2</td>
</tr>
<tr>
<td>Others/unknown</td>
<td>12</td>
</tr>
</tbody>
</table>

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Denison et al. (1995) followed up 1123 male alcoholics in Sweden for one year following detoxification in a psychiatric hospital. The mean age was 46.5 years. Ninety-seven (8.6%) of these patients died – this compares with 6% in the first year of the Taiwan study, possibly reflecting the older age.

Table 3-13 The numbers and causes of death (Denison et al. 1995)

<table>
<thead>
<tr>
<th>Violent deaths</th>
<th>23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td>10</td>
</tr>
<tr>
<td>Intoxication</td>
<td>13</td>
</tr>
<tr>
<td>Non-violent deaths</td>
<td>74</td>
</tr>
<tr>
<td>Cancer</td>
<td>5</td>
</tr>
<tr>
<td>Cardiovascular (ischaemic heart disease)</td>
<td>20</td>
</tr>
<tr>
<td>Liver cirrhosis</td>
<td>6</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>5</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>5</td>
</tr>
<tr>
<td>Others/unknown</td>
<td>33</td>
</tr>
</tbody>
</table>

The authors note that ethanol was the sole agent in eight of the 13 intoxication deaths and was involved in three others. One of these three and the two cases not involving ethanol appear to have been suicide.

An interesting finding in both these studies is the rather low proportion of deaths which were attributed to somatic diseases, which are accepted as frequently alcohol
related. In the Swedish study, only 16% of deaths were due to cirrhosis, malignancy or stroke. The proportion in the Taiwanese study may have been higher (up to 37%) however, all liver disease was amalgamated and hence it cannot be determined exactly. From the point of view of this HTA, it is important to know this proportion as, in calculating the incidence of these conditions, all other deaths are taken as ‘censoring’ events. For the calculation, the proportion has been assumed to be 20%.

In calculating the burden of these alcohol-related diseases in men, a mortality rate amounting to 50% over 10 years has been assumed. Of course, this information does not define the entire relationship of mortality to age. Thus a proportional hazards model based on the empirical hazards from Scottish life tables has been assumed and the hazard ratio calculated, which gives a 50% chance of dying from any cause over 10 years to a 45 year old man. This gives a relative hazard of death of 12.1 for an alcohol-dependent man compared with the general population.

A number of other researchers have studied mortality in treatment-seeking, alcohol-dependent populations. Large studies have been done by Berglund (1984) and Barr (1984). Berglund found lower mortality over a longer period, 18 years, with a continuous fall in the ratio of observed to expected deaths with age. However, it is very difficult to draw conclusions about mortality in a continuously drinking population from the data given because older deaths will happen in those with good survival prospects, who are likely to be those who have successfully stopped drinking. In a population of 503 with a mean age of 41.6 years, Barr observed 40 deaths (8%) in a two-year period. However, of particular relevance to this HTA, the results were analysed separately for those who were still misusing alcohol at follow up and those who were not. The 302 misusers accounted for 35 of the deaths giving a ratio of 7.9 observed to expected deaths. This therefore gives a direct estimate of the mortality in current alcohol dependence. However, 8% of people in this study were lost to follow up and they were assumed alive. Thus the estimate of excess mortality is likely to be conservative.

In different studies the estimates of mortality vary considerably. A likely cause of this is variable success in treating alcohol dependence. Since this HTA is interested in estimating mortality among those who continue to drink heavily, the higher estimate from the studies, a relative risk of 12.1, has been selected for calculations.

Very little information concerning mortality in alcohol-dependent women is contained in the studies discussed in the preceding paragraphs. The study in Taiwan included 9% of women who accounted for three of the 83 deaths. Thus the relative risk for a woman compared with a man was (3/9)/(80/91)=0.38. However, no information is given about the age distribution in the male and female groups. In this study it has been assumed that the relative risk of death for an alcohol-dependent woman compared with an alcohol-dependent man would be the same as that for a non-alcohol-dependent woman compared with a non-alcohol-dependent man. This is also calculated from Scottish life table data.

3.21 Mortality in the Scottish population

The health consequence attributable to harmful drinking can only be seen in comparison with the incidences of the same diseases in a non-alcohol-dependent population. These can be calculated in a similar fashion but require an estimate of the
(much lower) mortality rate in moderate drinkers. This is because the lower risk of disease is partially compensated by the higher life expectancy allowing more time for disease to develop. Age and sex specific death rates for Scotland in 1998, as reported in Scottish Health Statistics 1999, were used. In this, predominantly non-alcohol-dependent group it is assumed that the proportion of mortality due to alcohol-related diseases may be ignored.

3.21.1 Calculation of life-time probabilities of severe alcohol-related disease

3.21.1.1 Method

The health prospects of a typical non-alcohol-dependent person are assumed to be reflected in the official Scottish health statistics (Information and Statistics Division National Health Service in Scotland, 2000). Initially the probability of developing one of the alcohol-related cancers, stroke or liver cirrhosis have been calculated using age and sex specific cancer and mortality rates from Scottish Health Statistics 1999 and stroke and cirrhosis rates as described previously. For these major events only first occurrences are calculated. Thus each event is considered as censoring for all others. Events in each five-year period were calculated and then added to get the total events in this period – i.e. assuming non-overlapping disease groups. The disease-free survivors for the following period was then calculated as the initial group minus the total events.

The same calculation was performed for the alcohol-dependent group with two differences. Firstly the incidence rates for each disease were the rates used previously multiplied by the appropriate risk ratio from the epidemiological studies. Secondly not all death was considered censoring. This was because a larger proportion of deaths in these patients might be expected to occur after the alcohol-related events which were being estimated. Hence this second order effect could not be ignored.

Rates of hospitalisation for less serious events were then calculated using proportions relative to cirrhosis. These were derived either from Scottish Health Statistics 1999 or, failing this, from the Australian NAIP report. An important potential source of underestimation in this calculation is that each case of cirrhosis was taken as a single hospitalisation. Thus these estimates are believed to be conservative.

For inclusion in the primary economic analysis all events were discounted at 6%. No timings could be estimated for hospitalisations, therefore the discounting was approximated using the same factor as the cirrhosis.

3.21.1.2 Men

A base case of a 45 year old man is compared with the health profile of the general male population. Table 3-14 presents the major events predicted in 1000 individuals during twenty years.
Table 3-14 Expectations of stroke, cancer, or cirrhosis in men

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent (discounted at 6% p.a.)</th>
<th>Non-alcohol dependent (discounted at 6% p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>936</td>
<td>188</td>
</tr>
<tr>
<td>Stroke (all types)</td>
<td>43 (26)</td>
<td>33 (18)</td>
</tr>
<tr>
<td>Cancer</td>
<td>88 (53)</td>
<td>97 (50)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>102 (72)</td>
<td>10 (6)</td>
</tr>
</tbody>
</table>

As listed in Table 3-9

The hospitalisations would be expected in addition are presented in Table 3-15.

Table 3-15 Expectations of hospitalisation for other disease in men

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent (discounted at 6% p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic psychoses</td>
<td>571 (403)</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>44 (31)</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>41 (29)</td>
</tr>
<tr>
<td>Alcohol dependence</td>
<td>814 (575)</td>
</tr>
</tbody>
</table>

As listed in Table 3-9

Table 3-17 presents the hospitalisations which would be expected in addition.

Table 3-17 Expectations of hospitalisation for other disease in women

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent (discounted at 6% p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic psychoses</td>
<td>160 (107)</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>32 (22)</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>50 (34)</td>
</tr>
<tr>
<td>Alcohol dependence</td>
<td>260 (175)</td>
</tr>
</tbody>
</table>

As listed in Table 3-9

Table 3-16 Expectations of stroke, cancer, or cirrhosis in women

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent (discounted at 6% p.a.)</th>
<th>Non-alcohol dependent (discounted at 6% p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>785</td>
<td>114</td>
</tr>
<tr>
<td>Stroke (all types)</td>
<td>53 (31)</td>
<td>33 (18)</td>
</tr>
<tr>
<td>Cancer</td>
<td>146 (93)</td>
<td>125 (73)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>52 (35)</td>
<td>4 (3)</td>
</tr>
</tbody>
</table>

As listed in Table 3-9

Table 3-17 presents the hospitalisations which would be expected in addition.

Table 3-17 Expectations of hospitalisation for other disease in women

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent (discounted at 6% p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic psychoses</td>
<td>160 (107)</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>32 (22)</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>50 (34)</td>
</tr>
<tr>
<td>Alcohol dependence</td>
<td>260 (175)</td>
</tr>
</tbody>
</table>

As listed in Table 3-9

3.21.1.3 Women

A base case of a 45 year old woman is compared with the health profile of the general female population. Table 3-16 presents the major event in 1000 individuals during twenty years, predicted by the model.
There is also calculated to be an additional burden of non-cirrhotic liver disease, estimated to be an extra 24 cases (18 discounted at 6% p.a.) per 1000 alcohol-dependent population for men and 22 cases (16 discounted at 6% p.a) for women.

The figures in this section and Section 3.21.1.2 are used to calculate costs to NHSScotland of continued harmful drinking among those for whom treatment proves ineffective. This economic model is presented in Chapter 7.
4 SOURCES OF EVIDENCE

The HTAs undertaken by the HTBS use international evidence from a range of sources: published literature, grey literature (e.g. academic and government reports, website publications, conference abstracts) and information submitted from a variety of interested parties.

The following interested parties were invited to submit evidence for the Assessment:

Professional/Specialist Groups

Church of Scotland Board of Social Responsibility
Centre for Alcohol & Drug Studies, University of Paisley
Scottish Association of Health Councils
Royal College of Physicians Edinburgh
Royal College of Physicians London
Strathclyde University
Royal College of Nursing Scottish HQ
Royal College of Physicians & Surgeons Glasgow
Centre for Drug Misuse Research, University of Glasgow
Fife Alcohol Advisory Service
British Psychological Society (Scottish Branch)
The Medical Council on Alcohol
Association of Directors of Social Work
Royal College of General Practitioners
Community Psychiatric Nurses Association
Royal College of Psychiatrists Scottish Division
Intercollegiate Group on Alcohol Problems
Royal Free and University College Medical School
Scottish Executive Health Department
Alcohol Concern
Alcohol Focus Scotland

Patient Groups

Alcoholics Anonymous
Beechwood House
Phoenix House
Renewal Clinics Ltd (Castle Craig)
The Priory Hospital Glasgow

Manufacturers

Alpharma AS
Merck Pharmaceuticals
DuPont Pharmaceuticals Ltd

Systematic literature searches to inform the clinical and cost-effectiveness sections of this Assessment Report were undertaken. Smaller scale literature searches were carried out as required to provide additional costing information and to input to the patient and organisational issues sections. All searches are detailed in the appropriate
parts of the Assessment Report. Efforts were made to capture both published and unpublished literature, and the help of the TSG was enlisted to ensure that all relevant studies were retrieved.

Two surveys of Scottish service provision have been undertaken by HTBS (Section 3.10).

A consultation report (Slattery et al., 2002) was distributed widely and made available on the HTBS website. The response to this was substantial and comments on the report were received from a wide range of interested parties, including service users and health professionals. These comments have all been taken into consideration for this final Assessment Report.
5 CLINICAL EFFECTIVENESS

Summary

- Four broadly defined psychosocial interventions with effectiveness in the prevention of relapse in alcohol dependence, supported by good quality published reviews, were selected for evaluation.

- A preliminary review of acamprosate, naltrexone and disulfiram was based on published reviews and information supplied by pharmaceutical manufacturers.

- A meta-analysis was carried out to estimate the benefit of the four psychosocial and three pharmacological treatments in increasing the proportion of patients who had achieved abstinence or controlled drinking.

- The meta-analysis suggested similar, statistically significant, beneficial effect sizes for Behavioural Self-Control Training (odds ratio=1.75, 95% confidence interval 1.02, 3.02), Motivational Enhancement Therapy (odds ratio=1.88, 95% confidence interval 1.28, 2.77), Marital/Family Therapy (odds ratio=1.94, 95% confidence interval 1.37, 2.73) and Coping/Social Skills Training (odds ratio=2.11, 95% confidence interval 1.53, 2.92). Control treatments varied and, since some control treatments may have been effective, these estimates may be conservative.

- Brief Intervention was not selected for detailed evaluation as published reviews show it to be of unproven efficacy in alcohol-dependent patients and recent evidence suggests it is ineffective. Many other psychosocial interventions were identified but were unsupported by good clinical studies.

- Both acamprosate and naltrexone have extensive clinical trial data, which show that, when used according to the clinical trial procedures, they can add value to a programme of psychosocial treatment. The meta-analysis suggested statistically significant beneficial effects for both treatments: acamprosate (odds ratio=1.73, 95% confidence interval 1.36, 2.20), naltrexone (odds ratio=1.46, 95% confidence interval 1.12, 1.90).

- Trials of both acamprosate and naltrexone show statistically significant unexplained heterogeneity in effect sizes. Some large pragmatic trials have not shown an effect. This suggests that differences in the method of use may materially affect the effectiveness. Further studies are needed to ensure that the full benefits of these treatments are achieved in practice.

- One well-conducted randomised study of supervised oral disulfiram has found a benefit and it seems likely that it can contribute beneficially to a prevention of relapse programme. No strong evidence exists for the use of unsupervised oral disulfiram.

- The Project MATCH study showed that an introductory programme based on 12-step approach combined with encouragement to attend Alcoholics Anonymous meetings helps to prevent relapse.
Randomised studies have shown that practical help with problems such as housing, debt, and claiming benefits appear likely to contribute to control of alcohol problems.

5.1 Literature search

A scoping search was undertaken to gauge the quantity and quality of the existing literature, with particular attention being paid to finding studies by other HTA organisations, systematic reviews and research in progress. Following this, the decision was made to undertake a systematic literature review. Given the large quantities of literature on this topic, this was mainly restricted to material published after 1990 and to randomised controlled trials (RCTs), although RCTs of good methodology published before 1990 were included. The list of databases searched is given in Appendix 15. No language restrictions were applied.

To cover all aspects of the topic, the search was carried out in four parts. The first two parts looked at the population in question, in combination with either pharmacological or psychosocial interventions. A third part looked at the population again but this time in combination with general terms for the intervention, hence retrieving records concerning interventions which might not have been specified in the previous two parts of the search. Finally a fourth part combined the population with the outcome of treatment, thereby retrieving records where the individual recovered without treatment and also relevant records not retrieved in the previous three parts of the search. The searches were performed using the available subject headings (e.g. MeSH, EMTREE) and free text terms. Members of the TSG provided assistance in identifying interventions and their synonyms. Use was also made of the National Institute on Alcohol Abuse and Alcoholism thesaurus (http://etoh.niaaa.nih.gov/AODVol1/Aodthome.htm).

A copy of the strategy used to search the Medline database is given in Appendix 16. This strategy was adapted to search the other databases. A complete listing of all strategies can be obtained by contacting HTBS. Also contained with Appendix 16 is a flow chart showing the number of studies identified as potentially suitable for meta-analysis and then included in each stage of the process.

Additional studies, in particular grey literature, were identified by the TSG, or were submitted to HTBS as evidence.

5.2 Issues related to assessment of interventions to prevent relapse

Therapists helping patients to overcome alcohol dependence have two quite different sets of clinical interventions open to them: psychosocial methods and pharmacological treatments. In addition to these measures, it may also be necessary or desirable to have purely social facilities available, such as accommodation or advice and practical help with other aspects of the service user’s life which may have been disrupted by alcohol or contribute to continued use of alcohol. All these aspects of a comprehensive alcohol service have been tested in clinical trials.

The psychosocial interventions present very special difficulties for HTA. The literature obtained from the searches described previously contained RCTs of more than forty nominally distinguishable psychosocial methods, each of which generally
included several different components whose precise application would require a detailed written protocol. This apparent diversity of interventions is handled by specialists through classification into broad categories based both on the underlying conceptual model of alcohol dependence and on familiarity with the practical details of the way interventions are delivered. Appropriate use of such classifications requires considerable in-depth knowledge and hence it is necessary to rely on expert judgments as exercised in published reviews of individual treatment models. The decision concerning which treatment trials to group has been guided by the decisions made in previous treatment-specific reviews. Thus, this clinical effectiveness discussion is organised according to a hierarchy of evidence ordered by comprehensiveness. Initially, major extensive reviews were appraised, then specific treatment models were reviewed and lastly, when additional information was required, the individual clinical studies were evaluated.

Although this HTA relies on published expert reviews for decisions about grouping of clinical trials, other approaches are possible. The conceptual models, while providing a useful framework for presentation of a treatment programme, may not be the best basis for systematic statistical analysis of psychosocial treatments. The component parts of an intervention, for example ‘an analysis of factors which characterise high-risk situations for relapse’ or ‘practising responsible drinking skills’, may form elements in many different treatment approaches and may cut across the boundaries between conceptual models. Furthermore, even treatments grouped within one conceptual model may contain some quite striking differences in terms of their component parts. Thus analysis based on multiple regressions using such component parts as explanatory variables might prove informative. However, this does assume that some independent effect is attributable to these parts – i.e. that primary effects due to components tend to outweigh those due to interactions between components. It appears that this approach has not been tried even within such dedicated alcohol research facilities as the Mesa Grande project (Section 5.4.1).

Clinical trials of some treatment attributes have been undertaken. For instance there have been investigations of particular interventions delivered to groups or to individuals, as outpatient or as inpatient treatment, or with abstinence as a chosen objective compared with controlled drinking.

This HTA has had to be selective. The focus has been on studies in alcohol dependence but, even so, many tested treatments for prevention of relapse would not be likely to form part of a conventional NHS service. Examples of these are lysergic acid diethylamide (LSD), electric shocks, acupuncture and intercessory prayer. Only products aimed at reduction of alcohol intake, not at comorbid conditions which may be associated with alcohol problems, were considered. Therefore, more conventional pharmacological interventions, such as antidepressants, have been excluded.

The population to whom results of studies discussed in this chapter apply is difficult to define precisely. Almost all trials of pharmacological treatment enrolled patients who had undergone detoxification. This therefore corresponds with the population stated in the primary HTA questions in Section 2.2. However, trials of psychosocial treatments are generally less selective. Studies were selected when patients were described as ‘alcohol dependent’ or ‘alcoholic’. They were not selected if patients were described as ‘problem drinkers’ only or were obtained through population screening. It was hoped in this way to select trials of patients at the more severe end
of the spectrum of alcohol problems. The setting of many of these studies within specialist centres for treatment of alcohol problems may itself add a pragmatic element to the patient selection. The patients in these studies will be those who are referred to specialist centres and hence all the more appropriate to this HTA.

By contrast with psychosocial interventions, the investigation of pharmacological interventions is relatively straightforward. Acamprosate and naltrexone have been extensively tested in conventional clinical trials over the last few years. The clinical position regarding disulfiram is more complex. This drug has been used for more than forty years and many of the effectiveness studies come from an earlier era of clinical research when a lower standard of proof of efficacy was required for pharmaceutical licensing. Furthermore, the use of social contracts between the patient and a partner to reinforce the taking of disulfiram has been incorporated as an element into several psychosocial treatment programmes. Thus, studies that test disulfiram under conditions where treatment compliance is most likely, tend to confound its effects with other components of a treatment programme.

5.3 Methods used to assess clinical effectiveness

Preliminary assessment of psychosocial interventions was undertaken by critical appraisal of published reviews and other HTAs. The purpose of this work was to identify those therapies with strong empirical support for effectiveness and to obtain expert opinions concerning which, nominally different, therapies might be grouped for assessment purposes. Pharmacological interventions were selected on the basis of common usage in NHSScotland for prevention of relapse in alcohol dependence (Section 3.15). A preliminary assessment of these was done using published reviews and information supplied by pharmaceutical manufacturers.

A major purpose of the clinical effectiveness analysis within a HTA is to provide input to the cost-effectiveness analysis. The most appropriate clinical outcome measure for assessing the impact of treatment on future health appears to be the success rates by patient in achieving lives free of alcohol problems, in other words in which drinking alcohol is either controlled and safe or avoided. Not all studies and no reviews have presented this outcome in a manner which allows estimates to be applied to economic models. Thus, for this outcome only, it was necessary to extract data from studies and perform a meta-analysis. Rather than include this essentially separate analysis under reviews of specific interventions, it is included as a self-contained section (Section 5.6).

The aim of treatment in the studies was abstinence or controlled drinking. In some studies the aim was predetermined, in others it was decided by agreement between the clinician and the patient.

Treatment effects were expressed as the odds of one of these successful outcomes compared with patients treated with control treatments. Control treatments were often judged to have only placebo effects.

More detail of the methodology used for this meta-analysis is given in Section 5.6 and in Appendix 17.
5.4 Previous Health Technology Assessments and comprehensive reviews

5.4.1 The Mesa Grande project

The Mesa Grande project (Miller et al., 1995); (Miller et al., 1998); (Miller & Wilbourne, 2002) is a long-term and ongoing systematic review of the RCTs in treatments for alcohol problems. The results of ranking 87 alternative treatments on the basis of 361 separate studies have been presented. Each study was given an overall score based on methodological quality and the number of studies supporting a beneficial effect compared with the number not doing so.

A criticism of this method of ranking is that interventions are given weight on the basis of a positive benefit relative to a comparator, irrespective of the nature of the comparator or the size of the benefit. A more sophisticated model might give more weight to a positive result relative to a comparator which itself had been shown to be effective.

The major strength of the Mesa Grande project is the immense effort that has been put into identifying and interpreting RCTs in interventions for alcohol problems. Its methodology leads directly to a ranking of these interventions and hence it forms a natural starting point for any investigation of relative effectiveness. It provides a good basis for differentiating promising interventions from unpromising ones and hence for focusing further research and reviews of specific comparisons. It also reveals the wide range of interventions which have been studied for alcohol problems. Thus it is worth presenting the ranking of interventions on the basis of the Mesa Grande scoring system in full (see Appendix 18).

From the point of view of the present review there are some difficulties in interpreting the Mesa Grande results. Notably, the database covers studies across a much wider range of patients and problems than is the remit of this HTA (i.e. those with alcohol dependence) and the ranking table does not include information concerning the type of patient in each study. Hence studies in severely dependent patients may be ranked alongside those studying drinkers with less severe problems. A particular example of this is the primacy of place achieved by BI in the ranking when others have found it ineffective in alcohol-dependent patients (see Section 5.5.1.3). The outcome measure is also not uniform across studies and thus the nature of the effect of each treatment is unclear. Hence for clinical applications targeting particular types of patient and with clinically relevant estimates of treatment effect, it is necessary to seek more focused reviews.

5.4.2 Raistrick and Heather

A UK review of effectiveness of interventions in alcohol dependence has been produced by members of the Alcohol Commissioning Guidance Steering Group (Raistrick & Heather, 1998).

Estimates of the extent of alcohol problems in England are presented. Eight percent of English males and 4% of females are estimated to have definite problems and moderate dependence while 1.5% of the population may have definite problems and severe dependence.
The report includes many recommendations for organisation of a comprehensive UK service for treatment of alcohol problems. Some of these are based on evidence and some are based on logistical or clinical considerations. A summary of those which are of particular relevance to this HTA is included in Appendix 18.

Discussion is also made of initial assessment of the patient, training of therapists, dealing with psychiatric comorbidity and measurement of outcomes in clinical practice.

A chapter is devoted to intensive alcohol-focused interventions. Social Skills Training, Community Reinforcement, Behaviour Contracting, Aversion Therapy, Cognitive Behavioural Marital Therapy and BSCT are discussed on the grounds that all get good ratings in the Mesa Grande assessment. It is noted that about two thirds of service users will relapse within six months (Marlatt & Gordon, 1985). Continuing care is discussed and a number of reasons for it are listed. Some evidence for efficacy of continuing care is noted.

The authors note that all the treatments which they found to be effective are based on a cognitive behavioural approach. They note that drinking is a learned response, which can be modified by learning through rehearsal of new behaviours. There is also a social element to most of the interventions.

The final chapter presents the authors’ view of a comprehensive service for treatment of alcohol problems. Much of the discussion is very general but specific suggestions are made about the treatment programmes that a health district might need. A ‘stepped care’ model of treatment is discussed. The need for training is highlighted and general proposals made for research and development.

5.4.3 Swedish (SBU) Health Technology Assessment

In 2001, the Swedish national HTA agency (SBU) published a two-volume report covering the treatment of alcohol and drug abuse (Andreason et al., 2001). The full report has not yet been translated into English but the conclusions of the report have been reviewed.

The report was compiled by a panel of 11 experts and it is noted that the Medline search found 23 000 studies on alcohol problems from between 1950 and 2000. Six hundred and forty-one relevant studies, mostly RCTs, were selected (presumably this includes studies in alcohol and other drugs of abuse).

The main questions addressed include assessment of both absolute (compared with no treatment) and relative efficacy. Subgroup effect, setting (inpatient or outpatient) and concomitant mental illness are mentioned. Cost effectiveness is also an area of investigation.

Three subjects relating to alcohol are covered: detection of hazardous drinking before dependence develops, treatment of alcohol dependence and alcohol withdrawal. One hundred and thirty-nine studies in psychosocial treatment of alcohol dependence were found, 14 of which compared with no treatment. One hundred and twenty RCTs of medications for alcohol dependence were found.
The report covers a much wider area than this HTA and it has not been possible to review the evidence base as the report is in the process of translation but conclusions are listed in Appendix 18.

5.5 Treatment specific reviews and clinical studies

In addition to the ongoing work of the Mesa Grande project (Miller & Wilbourne, 2002) the comprehensive review by Raistrick & Heather (1998) and the HTA by the SBU (Andreasson et al., 2001), there have been a number of reviews focused on specific interventions for prevention of relapse. These reviews generally cover a range of severities of alcohol problems. The approach in this HTA has been to review these sources of evidence and ask how well they apply to the group of alcohol-dependent patients which is the concern of this HTA and also whether additional evidence can be added to the reviews or subsets abstracted appropriate to the primary HTA question (Section 2.2).

5.5.1 Psychosocial treatments

Many treatment strategies exist which might be classed as psychosocial therapies (Section 3.11). Most of these are based on conceptual models of addiction, which involve several components, each of which is addressed by a facet of the strategy. Different models frequently contain common themes and hence common elements to the treatment. Thus, a challenge in summarising the evidence for the effectiveness of these treatments is deciding when two treatments are substantially the same and should be combined, or have important differences and should not be combined. The following sections report reviews by other authors of a number of interventions commonly used in Scotland.

5.5.1.1 Cognitive Behaviour Therapy (CBT) in alcohol dependence

CBT provides a conceptual model, which has been widely adapted to treatment of drug and alcohol abuse. Many of the interventions discussed in this HTA report borrow ideas from it. However, this very ubiquity makes it difficult to identify any clear set of therapies, which should contribute to a meta-analysis of CBT in alcohol therapy. The Mesa Grande project (Miller & Heather, 1998) does not allot a unique category to CBT. By contrast, Project MATCH (Project MATCH Research Group, 1993), possibly the largest clinical trial of alcohol treatments, includes a treatment option labelled CBT.

CBT in Project MATCH was designed to help patients understand their thoughts and feelings and how these trigger behaviours. The goal was to provide service users with coping skills in high-risk situations that could contribute to relapse. This included management of anger, depression and interpersonal difficulties. A similar approach has been classified by others (Wolwer, 2001) as Coping Skills Training.

Morgenstern & Longabaugh (2000) reviewed CBT for alcohol dependence with the specific objective of investigating its hypothesised mechanism of action. CBT is described as care packages which ‘use a standard set of skills that include identification of specific situations where coping inadequacies occur, and the use of instruction, modelling, role plays and behavioural rehearsal’. These authors considered CBT to be similar in nature to Social Skills Training. They included
interventions labelled as Relapse Prevention\(^3\), Social Skills Training or cognitive behavioural approaches.

Interestingly, the authors of this study conclude that, although CBT clearly is effective, the studies provide no evidence to support its hypothesised mechanism.

From the discussion on CBT, it can be concluded that in the studies mentioned, CBT does not, for the purposes of systematic review, constitute a single intervention. Rather it is a model underlying many of the psychosocial interventions.

### 5.5.1.2 Behavioural Self-Control Training (BSCT)

Walters (2000) reviewed trials of BSCT for problem drinkers. The author investigated the subgroup of patients judged to be alcohol dependent. The inclusion of a trial required that three quarters of the study population met one of the criteria: Diagnostic and Statistical Manual (DSM)-III-R/IV diagnosis of dependence; traditional classification of gamma alcoholism (Jellinek, 1960); significant alcohol withdrawal symptoms; or hospitalisation for alcoholism.

The technique of BSCT aims at controlled drinking rather than abstinence. This is achieved by teaching service users to drink more slowly and increase intervals between drinks and choose less alcoholic drinks. They are also taught to recognise high-risk situations and to set personal goals.

The literature search identified English language studies from the PsycLIT database between 1984 and 1997 and was extended from reference sections of study reports. This found 17 RCTs. Seven studies were of alcohol-dependent patients.

Several comparisons were made. BSCT was compared with controls receiving no intervention, with alternative non-abstinent controls and with abstinent controls.

A fixed effects meta-analysis was performed on standardised measures of outcome differences between groups in the studies. This gave a highly significant positive treatment effect. However, these results combined trials in patients judged to be alcohol dependent with those classed as problem drinkers. Table 5-1 presents the results from this paper restricted to studies of alcohol-dependent patients.

A wide range of outcome measures were found in the studies and hence the analysis combined disparate effects.

\(^3\) This is a technical use of the term ‘Relapse Prevention’ to refer to a specific intervention rather than the broad class of interventions covered by this assessment
Table 5-1  Randomised control studies on BSCT for dependent drinking: continuous outcome measures (Walters, 2000)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Outcome Measure</th>
<th>Length of Follow Up</th>
<th>Mean Scores</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>BSCT</td>
<td>Control</td>
</tr>
<tr>
<td>Sobell &amp; Sobell (1976)</td>
<td>20 Alcoholics receiving BSCT 19 Alcoholics trained in abstinence</td>
<td>% days functioning well</td>
<td>24 months</td>
<td>83.1</td>
<td>40.7</td>
</tr>
<tr>
<td>Caddy et al. (1978)</td>
<td>13 Alcoholics receiving BSCT 14 Alcoholics trained in abstinence</td>
<td>% days functioning well</td>
<td>36 months</td>
<td>94.8</td>
<td>74.9</td>
</tr>
<tr>
<td>Baker et al. (1975)</td>
<td>29 Alcoholics receiving BSCT 9 Alcoholics receiving standard programme</td>
<td>% days sober</td>
<td>6 months</td>
<td>56.7</td>
<td>47.3</td>
</tr>
<tr>
<td>Volger et al. (1975)</td>
<td>23 Alcoholics receiving BSCT 19 Alcoholics receiving standard programme</td>
<td>Monthly consumption</td>
<td>6 months</td>
<td>37.0</td>
<td>78.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 months</td>
<td>38.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 months</td>
<td>38.7</td>
</tr>
<tr>
<td>Stimmel et al. (1983)</td>
<td>17 Alcoholics receiving BSCT 16 Alcoholics trained in abstinence 2</td>
<td>2- day alcohol consumption 3</td>
<td>2.5 years</td>
<td>-1.5</td>
<td>+1.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.5 years</td>
<td>-1.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 months</td>
<td>72.4</td>
</tr>
</tbody>
</table>

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When combined, these results give a non-significant trend in favour of BSCT (effect size=0.21, p=0.09). The heterogeneity is highly significant $X^2(6)=22.6, \ p<0.001$. The major contributor to this is clearly the marginally significant adverse effect noted in the study by Foy.
Table 5-2  Randomised control studies on BSCT for dependent drinking: discrete outcome measures (Walters, 2000)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Outcome Measure</th>
<th>Length of Follow Up</th>
<th>BSCT</th>
<th>Control</th>
<th>d</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sobell &amp; Sobell (1976)</td>
<td>20 Alcoholics receiving BSCT, 19 alcoholics trained in abstinence</td>
<td>Rates improved by collateral</td>
<td>24 month</td>
<td>85.0</td>
<td>42.1</td>
<td>+1.13</td>
<td>0.39</td>
</tr>
<tr>
<td>Caddy et al. (1978)</td>
<td>13 Alcoholics receiving BSCT, 14 alcoholics trained in abstinence</td>
<td>Continuous drunk days</td>
<td>36 month</td>
<td>38.5</td>
<td>71.4</td>
<td>+0.76</td>
<td>0.46</td>
</tr>
<tr>
<td>Volger (1975)</td>
<td>23 Alcoholics receiving BSCT, 19 Alcoholics receiving standard programme</td>
<td>Abstinent/control drinking</td>
<td>12 month</td>
<td>65.2</td>
<td>57.9</td>
<td>+0.17</td>
<td>0.24</td>
</tr>
<tr>
<td>Pomerleau et al. (1978)</td>
<td>18 Alcoholics receiving BSCT, 14 Alcoholics trained in abstinence</td>
<td>Abstinent/improved</td>
<td>12 month</td>
<td>72.0</td>
<td>50.0</td>
<td>+0.52</td>
<td>0.41</td>
</tr>
<tr>
<td>Stimmel (1983)</td>
<td>42 Alcoholics receiving BSCT, 42 Alcoholics trained in abstinence</td>
<td>Undesirable departure</td>
<td>2.5 year</td>
<td>26.2</td>
<td>33.3</td>
<td>+0.19</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>42 Alcoholics receiving BSCT, 43 Alcoholics receiving standards programme</td>
<td>Undesirable departure</td>
<td>2.5 year</td>
<td>26.2</td>
<td>37.2</td>
<td>+0.28</td>
<td>0.26</td>
</tr>
</tbody>
</table>

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When combined these results give a significant result in favour of BSCT (effect size=0.40, p<0.005). The heterogeneity is not significant. Note that the study by Foy, which was negative for the continuous outcomes in Table 5-1, did not contribute to this analysis.
It is worth commenting that the one trial which gave significant negative results for BSCT (Foy et al., 1984) tested simply those parts of the strategy aimed at controlled drinking: blood alcohol discrimination; responsible drinking skills; and social drinking practice sessions. Both treatment groups received broad-spectrum behavioural treatment. Furthermore, there was a major imbalance between treatment groups with the pre-treatment abusive days being 22% higher in the BSCT group (201.6) compared with the control group (164.6). When corrected for this imbalance, the change in abusive days over 12 months was identical in the two treatment groups. Thus it seems likely that this trial suggests that the three elements listed may add little to the overall programme but does not suggest that BSCT has a net negative effect.

This review generally appears to support the effectiveness of the BSCT approach in promoting controlled drinking.

5.5.1.3 Brief Intervention (BI)

Wilk et al. (1997) undertook a review of studies of BI in heavy alcohol drinkers. These BIs were less than one hour in duration.

The literature search of Medline and PsychLIT covered 1966 to 1995 and did not exclude dependence. Thus studies relevant to this HTA should have been identified. However, most of the trials had ‘dependence’ as a specific exclusion criterion.

The odds ratio for moderation of drinking with BI compared with no intervention was estimated to be 1.95, 95% CI 1.66, 2.30. However, the authors note that ‘generalisability of our results must be limited to less severely affected drinkers who exhibit little or no alcohol dependence’.

A further meta-analysis of BI was carried out by Poikalainen (1999). Two additional studies (Fleming et al., 1997); (Nilssen, 1991) were identified and three, included in the study by Wilk, were excluded on the basis that they included some hospital patients (Babor & Grant, 1992); (Chick et al., 1985); (Antti-Poika et al., 1988).

Oddly, since the excluded studies would seem likely to contain more severely affected patients, Poikalainen (1999) estimated smaller treatment effects than Wilk et al. (1997). He noted only that BI decreased alcohol consumption in women.

These studies seem to provide no evidence for or against the use of BI in dependent patients.

Currently the most comprehensive review of BI (Moyer et al., 2002) identified a total of 56 studies including all those in the Wilk et al. (1997) and Poikalainen (1999) studies. Thirty-four studies were in people whose alcohol problems were identified via screening programmes or because they responded to invitations to participate in treatment programmes (non-treatment-seeking patients) and 22 in people who actively sought clinical help (treatment-seeking patients). Of the 22 studies in treatment-seeking subjects, 20 compared with a more extensive intervention and 10 of these did not exclude alcohol-dependent patients.
The distinction between non-treatment-seeking and treatment-seeking patients is important because the latter group is likely to contain those with severe alcohol problems.

The authors’ primary finding in respect of these groups is stated as ‘Brief interventions were effective compared with control conditions in studies where more severely affected individuals were excluded; brief interventions were not more effective than control conditions in studies where more severely affected persons were not excluded. This finding suggests that, at least during this period in the post-treatment course (3 – 6 months), such interventions – which usually consist of a single session of advice, often accompanied by feedback and delivered in a health care setting – are useful only for patients with less severe drinking problems’.

Almost all studies in treatment-seeking subjects compared BI with the longer interventions. This therefore is a more severe test than the no-treatment comparisons often made in less severely affected subjects. However, there is a suggestion that BI was less effective than these longer interventions. The alcohol consumption was significantly higher in the BI group after 3 – 6 months of follow up (p<0.01) and a composite drinking-related outcome showed an adverse trend (p=0.072). These are the only outcomes reported.

This study added appreciably to the previous reviews in that it showed not only that BI is unsupported in treatment of alcohol-dependent patients, but that it is significantly less effective than other measures.

5.5.1.4 Motivational Enhancement Therapy (MET)

Motivational Enhancement Therapy and Motivational Interviewing (MI) are terms which are often used interchangeably. For the purposes of this Assessment Report, MET is the preferred term, however when describing previous studies, the terminology used in each individual study has been retained.

Dunn et al. (2001) investigated the MI method described by Rollnick & Miller (1995). This analysis was not restricted to alcohol dependence but 17 studies were in substance abuse and seven of these included dependent patients and measured an alcohol-related outcome. Only four studies included dependent patients alone. Although very short interventions were included, there appears to be no overlap with the studies in the reviews of BI by Wilk et al. (1997) and Poikolainen(1999).


The authors recorded both the time taken to deliver MI and, when available, the time taken to train staff to deliver MI. The latter averaged 15 hours.
### Table 5-3  Drinking-related outcomes in studies of Motivational Interviewing (Dunn et al., 2001)

<table>
<thead>
<tr>
<th>Study</th>
<th>Time</th>
<th>Outcomes</th>
<th>Control</th>
<th>Effect size (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL DEPENDENT PATIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bien (1993) N=31</td>
<td>3 months</td>
<td>Drinks per week</td>
<td>Inactive</td>
<td>0.72 (-0.07, 1.52)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percentage of days abstinent</td>
<td>Inactive</td>
<td>0.30 (-0.47, 1.08)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Composite index</td>
<td>Inactive</td>
<td><strong>0.83 (0.03, 1.63)</strong>^a</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>Drinks per week</td>
<td>Inactive</td>
<td>0.35 (0.43, 1.12)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days abstinent (%)</td>
<td>Inactive</td>
<td>-0.20 (-0.97, 0.58)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Composite index</td>
<td>Inactive</td>
<td>0.14 (-0.63, 0.91)</td>
</tr>
<tr>
<td>Project MATCH</td>
<td>9 months</td>
<td>Drinking consequences</td>
<td>CBT</td>
<td>-0.09 (-0.28, 0.11)</td>
</tr>
<tr>
<td>(Project MATCH Research Group, 1997) N=1726</td>
<td></td>
<td>Drinking consequences</td>
<td>TSF^b</td>
<td><strong>-0.30 (-0.49, -0.12)</strong>^a</td>
</tr>
<tr>
<td></td>
<td>15 months</td>
<td>Drinking consequences</td>
<td>CBT</td>
<td>-0.01 (-0.20, 0.19)</td>
</tr>
<tr>
<td></td>
<td>(outpatient arm)</td>
<td>Drinking consequences</td>
<td>TSF</td>
<td>-0.18 (-0.37, 0.01)</td>
</tr>
<tr>
<td></td>
<td>9 months</td>
<td>Drinking consequences</td>
<td>CBT</td>
<td>-0.02 (-0.23, 0.20)</td>
</tr>
<tr>
<td></td>
<td>(continuing care)</td>
<td>Drinking consequences</td>
<td>TSF</td>
<td>-0.02 (-0.24, 0.19)</td>
</tr>
<tr>
<td></td>
<td>15 months</td>
<td>Drinking consequences</td>
<td>CBT</td>
<td>0.09 (-0.13, 0.31)</td>
</tr>
<tr>
<td></td>
<td>(continuing care)</td>
<td>Drinking consequences</td>
<td>TSF</td>
<td>0.16 (-0.05, 0.38)</td>
</tr>
<tr>
<td>Wertz (1994) N=42</td>
<td>1 month</td>
<td>Days in treatment</td>
<td>Inactive</td>
<td>-0.08 (-0.68, 0.53)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number standard drinks</td>
<td>Inactive</td>
<td>0.43 (-0.44, 1.30)</td>
</tr>
<tr>
<td><strong>SOME DEPENDENT PATIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentilello (1999) N=762</td>
<td>6 months</td>
<td>Drinks per week</td>
<td>Inactive</td>
<td>-0.08 (-0.26, 0.11)</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>Drinks per week</td>
<td>Inactive</td>
<td>0.09 (-0.12, 0.31)</td>
</tr>
<tr>
<td>Handmaker (1999) N=42</td>
<td>2 months</td>
<td>Total alcohol consumption</td>
<td>Inactive</td>
<td>0.03 (-0.64, 0.71)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Abstinent days</td>
<td>Inactive</td>
<td>0.38 (-0.30, 1.05)</td>
</tr>
<tr>
<td>Heather (1996) N=174</td>
<td>6 months</td>
<td>Drinks per week</td>
<td>Inactive</td>
<td>0.16 (-0.29, 0.60)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drinks per week</td>
<td>SG</td>
<td>0.35 9-0.07, 0.76</td>
</tr>
<tr>
<td>Schneider (1999) N=89</td>
<td>3 months</td>
<td>Alcohol Addiction Severity Index</td>
<td>Inactive</td>
<td>0.24 (-0.17, 0.66)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Standard drinks past 30 days</td>
<td>Inactive</td>
<td>-0.09 (-0.51, 0.31)</td>
</tr>
<tr>
<td></td>
<td>9 months</td>
<td>Alcohol Addiction Severity Index</td>
<td>Inactive</td>
<td>0.42 (0.00, 0.84)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Standard drinks in 30 days</td>
<td>Inactive</td>
<td>-0.01 (-0.43, 0.41)</td>
</tr>
</tbody>
</table>

^a Statistically significant results are in bold type
^b TSF = Twelve Steps Facilitation

The authors note that the best evidence for MI effectiveness found by this review was when it was used as an enhancement to more intensive substance abuse treatment.

In the context of the present HTA, in which the effects for alcohol-dependent patients are of interest, it may be appropriate to be cautious. Only two statistically significant effects were observed in trials that included a substantial majority of such patients. A study of 42 patients found a benefit in terms of a composite drinking index (Bien et al., 1993) and Project MATCH found a significant adverse effect in outpatients on ‘drinking consequences’ at nine months relative to a TSF approach. The outpatient group in Project MATCH included 952 people and the p-value for differences between the treatment arms in drinking consequences at nine months was 0.006. However, the TSF approach was clinically effective and hence this does not show that MI was ineffective.

This review and the meta-analysis conducted in this HTA (see Section 5.6) supports MI as an effective part of more extensive psychosocial treatment. However the results of Project MATCH suggest that it should not be used as a short stand-alone treatment in the manner of that study (four sessions).
5.5.1.5  Skills Training

Training in coping skills and social skills forms a significant part of many psychosocial therapies. Indeed, these often appear to be the major elements linking interventions which are described as generic CBT rather than one of the derivatives of CBT. As such it seems reasonable to focus on Skills Training as an intervention in its own right. No specific systematic review was identified for Skills Training but Social Skills Training is identified as a discrete intervention in the Mesa Grande project (Miller & Heather, 1998); (Miller & Wilbourne, 2002) in which it ranked as the sixth most effective treatment.

A combination of Cue Exposure Therapy (CET) and Communication Skills Training (CST) has been advocated by Monti (1993) (2001) and tested in three clinical trials. These studies and four others with interventions judged to be similar are included in the HTBS analysis. This analysis of Skills Training, which appears effective in alcohol-dependent people, is included in Appendix 17 and Section 5.6.

5.5.1.6  Marital/Family Therapy


Twenty-two relevant studies were identified. The literature search methods are not reported but it is noted that studies were included if spouses and/or other family members were involved in the treatment of an alcoholic adult. This term appears to imply alcohol dependence. Trials were divided into those in which the alcoholic adults were unwilling to seek treatment and those in which they had sought help. In the former, the outcome measures were either family coping or initiation of change and in the latter, they were generally measures of reduction in drinking. All trials included a randomised control group, which was either ‘wait-list’, i.e. deferred treatment, or another intervention without family involvement.

The review combined the results of the studies in a meta-analysis. Outcome measures, although differing in nature between studies, were grouped by underlying theme (see Table 5-4). Statistically significant benefits of family involvement compared with wait-list controls or individual therapy were reported in each outcome.

Table 5-4  Effect of family involvement in treatment (O’Farrell, 2001)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of studies</th>
<th>Subjects</th>
<th>Median r</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol use</td>
<td>16</td>
<td>692</td>
<td>0.30</td>
<td>2x10^{-10}</td>
</tr>
<tr>
<td>Treatment attendance</td>
<td>3</td>
<td>106</td>
<td>0.32</td>
<td>0.007</td>
</tr>
<tr>
<td>Couple/family adjustment</td>
<td>11</td>
<td>413</td>
<td>0.17</td>
<td>0.035</td>
</tr>
<tr>
<td>Patient adjustment</td>
<td>10</td>
<td>309</td>
<td>0.21</td>
<td>2x10^{-5}</td>
</tr>
<tr>
<td>Spouse/family member adjustment</td>
<td>6</td>
<td>348</td>
<td>0.26</td>
<td>2x10^{-5}</td>
</tr>
</tbody>
</table>

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The use of Pearson’s $r$ as an outcome measure and the absence of data from individual studies tend to obscure the clinical meaning of these results. The authors give a rule of thumb ($r=0.1$ is small, $r=0.3$ is medium, $r=0.5$ is large) however this appears quite arbitrary. They also note that the effect size in the Physicians Health Study of aspirin was only $r=0.03$. 

5-14
A number of different interventions were included under the term ‘Family Therapy’. The paper also examined the efficacy with respect to persuading reluctant patients to seek treatment. The authors noted that the only form of Family Therapy that does not appear to increase engagement in treatment programmes is the Johnson Institute Intervention, which involves training family members to confront the patient. This may be because the family member will often decide against the planned confrontation.

There are a number of difficulties with respect to O’Farrell’s analysis. Although overall results are presented, there is only a narrative discussion of the individual studies and the measures used as input for the meta-analysis are not presented. Despite the common factor of involvement of a family member or other third party in the treatment, the selection of studies may have resulted in the combination of qualitatively different interventions varying from the highly intensive CRA to the simple addition of a disulfiram contract to individual therapy.

While there appears to be some support for inclusion of family members in treatment, the nature of their involvement and the clinical significance of any benefit is left unresolved.

O’Farrell’s own study (1993) of couples relapse prevention is of particular interest because it studied long-term effects. Couples were started on the treatment after an initial five months of Behavioural Couples Therapy. The results suggested that useful treatment effects were sustained at 18 months. Thus long-term treatment may be an important aspect of prevention of relapse.

5.5.1.7 Intensive case management

Many interventions combine psychological interventions with practical help in other areas of the service user’s lifestyle. For instance, the CRA may involve helping the service user find a job, find a home and also to achieve a more rewarding social life. The literature suggests that some interest surrounds the question of the extent to which alcohol dependence behaviour can be modified purely by altering the environment of the people affected.

Cox et al. (1998) examined the effect of an ‘intensive case management (CM)’ strategy for people with an extensive history of alcohol abuse and treatment failures. This involved practical social support focused on improving welfare. The aims were to stabilise the patients financial condition and housing status and to encourage reduction of substance use. One hundred and fifty subjects were randomised to CM and 148 to control.

Follow up was at six-month intervals for two years. The primary analysis was based on repeated measures and required complete follow-up data. This limited the analysable group to 193 of the randomised 298 (65%).

Statistically significant improvements between groups were noted in the three primary variables (public income \(p=0.043\), own residence \(p=0.04\), days of drinking \(p=0.009\)). There were also changes over time in own residence and days of drinking which suggest a gradual improvement.
Table 5-5  Group means for dependent variables for subjects who had 6-, 12- and 18-month follow ups (Cox et al., 1998)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Baseline</th>
<th>6-month</th>
<th>12-month</th>
<th>18-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIMARY DEPENDENT VARIABLES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Income (dollars)in last 30 days (benefits claimed from the State)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>84</td>
<td>218</td>
<td>198</td>
<td>262</td>
<td>269</td>
</tr>
<tr>
<td>CM</td>
<td>105</td>
<td>238</td>
<td>343</td>
<td>303</td>
<td>358</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nights in own residence in last 60 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>83</td>
<td>7.1</td>
<td>10.3</td>
<td>17.8</td>
<td>21.7</td>
</tr>
<tr>
<td>CM</td>
<td>108</td>
<td>9.5</td>
<td>19.4</td>
<td>24.0</td>
<td>25.4</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days of drinking (any alcohol use) in last 30 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>85</td>
<td>23.8</td>
<td>17.8</td>
<td>14.8</td>
<td>15.3</td>
</tr>
<tr>
<td>CM</td>
<td>108</td>
<td>23.6</td>
<td>14.6</td>
<td>12.3</td>
<td>11.3</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SECONDARY DEPENDENT VARIABLES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days using alcohol since last interview</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>83</td>
<td>NA</td>
<td>123</td>
<td>97</td>
<td>99</td>
</tr>
<tr>
<td>CM</td>
<td>105</td>
<td>NA</td>
<td>102</td>
<td>78</td>
<td>70</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td>-21</td>
<td>-19</td>
<td>-29</td>
<td></td>
</tr>
<tr>
<td>Detox admissions in prior six months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>85</td>
<td>8.1</td>
<td>11.5</td>
<td>5.7</td>
<td>5.1</td>
</tr>
<tr>
<td>CM</td>
<td>107</td>
<td>8.8</td>
<td>9.1</td>
<td>3.6</td>
<td>2.4</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td>-0.7</td>
<td>-2.4</td>
<td>-2.1</td>
<td>-2.7</td>
</tr>
<tr>
<td>Days alcohol problems in last 30 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>80</td>
<td>22.6</td>
<td>15.8</td>
<td>16.3</td>
<td>16.3</td>
</tr>
<tr>
<td>CM</td>
<td>105</td>
<td>22.4</td>
<td>15.3</td>
<td>14.8</td>
<td>12.7</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td>-0.2</td>
<td>-0.5</td>
<td>-1.5</td>
<td>-3.6</td>
</tr>
<tr>
<td>Troubled or bothered by alcohol problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>85</td>
<td>2.9</td>
<td>2.4</td>
<td>2.1</td>
<td>2.1</td>
</tr>
<tr>
<td>CM</td>
<td>107</td>
<td>2.7</td>
<td>2.2</td>
<td>2.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Difference</td>
<td></td>
<td>-0.2</td>
<td>-0.2</td>
<td>-0.1</td>
<td>-0.5</td>
</tr>
</tbody>
</table>


The imbalance in numbers followed up is clear from Table 5-5. This is a weakness of the analysis.

The authors note that their intervention is expensive – one case manager was assigned to 15 patients – but also appears effective.

Far simpler CM techniques have also been tested (Hilton et al., 2001). Stout et al. (1996) tested a low-cost, long-term procedure for maintaining contact with dependent people during periods when they are at elevated risk for relapse. The intervention involved telephone contacts on a tapering schedule for two years. Three hundred and forty-two patients were randomised and the follow-up rate was 80%. Follow-up data and health cost data were collected for three years. There was a statistically significant (p<0.05) treatment effect on percentage of days of heavy drinking during the third year. The frequency of heavy drinking was twice as high in the controls (mean=24%) as in the case-monitored subjects (mean=12%).

While these studies only constitute limited evidence, they suggest that practical social interventions, whether to keep service users housed and aid with appropriate use of the welfare system or simple contact over time, may have a beneficial effect on
alcohol intake. Some supporting evidence for this is supplied by the good performance of the CRA, ranked seventh in the Mesa Grande table of interventions (Section 5.4.1), which has substantial elements of social intervention.

5.5.2 Pharmacological interventions

The commonly accepted view, reflected in their indications (Section 3.14.1, Section 13.4.2 and Section 3.14.3), of the role of pharmacological interventions in the prevention of relapse in alcohol dependence is that they are subsidiary to the psychosocial interventions. Thus they should not be considered as alternative therapies and any treatment programme will contain a psychosocial element but may have an additional pharmacological component. The question, which needs to be addressed in assessing the pharmacological intervention, is whether, for the targeted group of patients, additional net benefit is obtained above that from the psychosocial treatment.

This HTA covers only those pharmacological products which are currently in widespread use for the specific indication of ‘prevention of relapse’. This includes two products with UK marketing authorisations, acamprosate and disulfiram, but also naltrexone about which there is extensive literature and which has marketing authorisations both in the USA and in some EU member states, and while not licensed for use in the UK appears to be prescribed in some areas (Section 3.15).

Much of the work to demonstrate the effectiveness of pharmacological interventions comes from clinical trials aimed at providing information for marketing authorisation (licensing) applications and has been either designed or sponsored by manufacturers. Thus each manufacturer was given the opportunity to submit evidence regarding their products.

5.5.2.1 Acamprosate

Medication with acamprosate appears to decrease craving and counter the reinforcing properties of alcohol. Although sometimes referred to as a GABA agonist, the mechanism by which it affects the use of alcohol is not known.

5.5.2.1.1 Information submitted by Merck Pharmaceuticals

An expert report previously supplied to UK regulatory authorities and dated 1994 was supplied (Sass, 1994). The author, Professor Sass, was the principal investigator in a clinical trial of acamprosate, the Prevention of Relapse with acamprosate in the Management of Alcoholism (PRAMA) study.

The expert report lists two phase II and 10 phase III double-blind, placebo-controlled trials of acamprosate. In these trials, 1839 patients were allocated Campral® (acamprosate) at the licensed dosage for treatment periods between 90 and 360 days. Sixteen hundred and one patients were allocated placebo. All patients entering the studies had undergone a detoxification programme. Patients in these studies generally received psychosocial interventions in addition to the randomised treatment. It is not clear which psychosocial interventions were used.
A number of measures of relapse were collected for assessment of efficacy. These included total abstinence at each visit, time to irrevocable failure, and cumulative abstinence. In three studies (PRAMA, BENELUX, Pelc II), outcome data were confirmed by breathalyser, urine analysis or evidence from relatives.

High drop-out rates were a problem in all studies. At 90 days, 64% of the patients randomised to placebo and 67% of those randomised to acamprosate were followed up. By 180 days, the figures had fallen to 49% and 56%. Intention-to-treat (ITT) analyses, which assumed failure in non-attenders were carried out.

Failure to attend for follow up is a problem in most studies of alcohol-dependent subjects. If all patients who do not attend for assessment are taken as having relapsed, it is impossible to tell the difference between a relapse preventing agent and one which increases the probability of presenting. Any treatment, which had a benefit – say an antidepressant effect – might increase the probability of presenting. Thus it is important that analysis of attenders should agree qualitatively with the ITT analysis. The assumption that ‘Did Not Attend’ was equivalent to relapse should also be checked.

In addition to the expert report some reports of individual studies were also supplied. A brief description is given in the text which follows but results of these studies are presented in the HTBS analysis (Appendix 17).

The PRAMA study (Schadlich & Brecht, 1998);(Sass, 1996b) enrolled 272 newly detoxified (14 – 28 days) alcohol-dependent patients in Germany. They were randomised to 48 weeks of either acamprosate or placebo and then followed up for a further 48 weeks. Patients with psychiatric problems were excluded. All patients received weekly counselling or psychotherapy for a mean period of 18 weeks and then met in fortnightly contact groups. Dosage was 1998 mg/d (2 x 333 mg three times daily) with a two thirds dose for those with body weight less than 60 kg. Assessment was every four weeks for 12 weeks and then every 12 weeks. Drinking status was checked by breath testing and GGT. The primary outcome was abstinence. The primary analysis was performed using the ITT population but a per-protocol (PP) analysis was also performed. The drop-out rate was high, 134 (49.3%) of patients remained in the study at one year. The drop-outs were not balanced between treatments: 57 acamprosate, 81 placebo.

An uncontrolled study of 614 Belgian patients on acamprosate was also supplied to describe the demography and concomitant treatments used over 24 months (Ansoms et al., 2000). Measures of outcome were also recorded and drinking episodes were classified as lapse, binge or relapse. Patients included had no other major illness and were actively drinking within the seven days before study inclusion. Only 517 of 614 patients (84%) eventually fulfilled the study inclusion criteria. A further 174 dropped out over the study period.

It is difficult to extrapolate the data from this study. Many patients in clinical practice would not satisfy the entry criteria. However, rough estimates of drinking behaviour can be obtained from the paper.

A brief digest of evidence concerning acamprosate from the British Journal of Clinical Governance (Earl-Slater, 1999) was also supplied. Effectiveness data are
based on three RCTs (Paille et al., 1995); (Whitworth et al., 1996); (Sass, 1996a). This is not a meta-analysis but a checklist of issues related to the use of acamprosate in alcohol dependence.

The Lancet report of a study by Whitworth et al. (1996) was also supplied. Data from this and PRAMA have been extracted and are included in the main effectiveness analysis for the economic model inputs (see Section 5.6).

A review of the pharmacological treatment of alcohol dependence by Garbutt et al. (1999) covers acamprosate, naltrexone and disulfiram in addition to selective serotonin reuptake inhibitors (SSRIs), lithium, buspirone and ondansetron. RCTs in alcohol-dependent patients were included but so were other forms of controlled study and review articles. Nine studies of acamprosate, nine of disulfiram (four oral, five implanted), and three of naltrexone are assessed. Meta-analysis or other modelling to combine trial results was not attempted. The reviewers consider that acamprosate and naltrexone had consistent proof of efficacy compared with placebo. Disulfiram had inconsistent evidence from sufficient data. This was based on positive evidence that disulfiram reduced the number of drinking days but mixed results for other outcomes. The total drop-out rates in the trials are tabulated but the way that drop-outs are accounted for in the analysis is not reported. Relative drop-out rates are not reported. The time period for the naltrexone trials was only 12 weeks and longer-term evidence would have been desirable.

Another review by Mason and Ownby (2000) assesses only trials of acamprosate. It includes all the trials reviewed by Garbutt et al. (1999) with the exception of a small, four-week study by Gerra (1992). Six additional placebo-controlled trials and a trial of acamprosate combined with disulfiram are included. It is noted that a large USA study was still to report and data could not be included. The statement of interest notes that Dr Mason is a consultant to the manufacturer of acamprosate. Missed visits in these studies were counted as non-abstinence and biological markers and collateral reports were preferred to self-reports in the case of discrepancies. A meta-analysis of 15 European RCTs is referred to but not described or the results reported. The summary notes that 14 of 16 placebo-controlled RCTs found positive treatment effects for acamprosate (exceptions were Roussaux et al. (1996); Chick et al. (2000)). The authors suggest that delays in initiating treatment following detoxification in the study by Chick may have contributed to the lack of treatment effect.

A further review by Mason was published in 2001. This collated but did not meta-analyse all the available European trials of acamprosate.

A summary, an abstract and a report by Soyka (Soyka & Sass, 1994) describe an observational study (Integral) of various psychosocial interventions with acamprosate. Patients given individual psychotherapy (242), group psychotherapy (183), CBT/coping strategy (122) and BI (204) were found to have almost identical results for complete abstinence – about 55% at 24 weeks. PP cumulative abstinent days were also the same for each intervention – about 127 days. Time to first relapse in the ITT population was 74.5 days. Conflicting results for PP time to first relapse are provided, a graph shows about 128 days but the abstract gives 159 days.
These data do not contain comparative information on acamprosate but provide estimates for effects under conditions closer to clinical practice than those in a clinical trial. The quality of reporting was judged to be poor.

5.5.2.1.2 Evidence from literature search

There appear to be 17 controlled trials of acamprosate in alcohol dependence for which rates of controlled drinking or abstinence are currently available. The large USA multicentre study of acamprosate has finished and some results were released in abstract form in 2001 (Mason, 2001a). Although the study report is yet to be published the results have been submitted in an application for a marketing authorisation in the USA. These are available on the website of the USA Food and Drug Administration (FDA).

http://www.fda.gov/ohrms/dockets/ac/02/Slides/3857S1_08_FDA-Winchell/sld001.htm.

HTBS effectiveness calculations are reported in Section 5.6.

5.5.2.2 Disulfiram

Disulfiram is an antidipsotropic agent. In other words it induces adverse reactions when alcohol is taken.

5.5.2.2.1 Submission from Alpharma

Alpharma has supplied some general commentary and literature on the efficacy of disulfiram. They note that, in general, modern controlled trials are not available.

A literature review by Brewer (1992) discusses several studies, often of an uncontrolled nature. It is concluded that supervised disulfiram can be effective but that unsupervised disulfiram is of no proven benefit.

One controlled study discussed by Brewer is that by Fuller et al. (1986) This was a three-arm study in which 605 men received either 250 mg of unsupervised disulfiram (202), 1 mg of unsupervised disulfiram (204), or no disulfiram (199) for one year. The patients were unblinded to whether they received disulfiram but did not know that they might receive an ineffective dose. Single patients were excluded, as social support was considered important for the trial. Follow up was for one year. No differences in total abstinence or time to first drink were found. However, among those who did drink, a reduced frequency of drinking was noted in the 250 mg disulfiram group.

A paper by Besson et al. (1998) reported a placebo-controlled randomised trial of acamprosate in which the (unrandomised) use of disulfiram (the paper did not specify whether or not this was supervised) was also recorded. It was concluded that the concomitant use of disulfiram improved the effectiveness of acamprosate. Results from a single unrandomised study would not generally be considered sufficiently convincing to warrant recommendation about clinical practice.
5.5.2.2 Evidence from literature search

A discussion of the use of disulfiram is given by O'Farrell et al. (1995). These authors remark that various methods have been used to reinforce compliance with a disulfiram regimen. They note that disulfiram implants have not been found to be effective because of inadequate levels of disulfiram release and adverse effects. Various incentives to persevere with disulfiram have also been tried and generally found, to some extent, to work. However, the most common and extensively researched method has been a formally and publicly agreed contract, between the patient and a significant other – usually the wife or husband. Such contracts have also been tried within the context of a CRA (Hunt & Azrin, 1973). This has been tested in Azrin (1976) and Azrin et al. (1982). This latter study suggested that, for married subjects, the contract alone is as good as the contract with CRA. However, CRA appeared to be important for single patients. The authors conclude by noting that previous research has failed to differentiate the effect of recommending disulfiram from the effect of reinforcing compliance through contracts and they recommend further research which includes a double-blind factorial trial of disulfiram (clinical versus nominal dose) and compliance enhancement (present versus absent).

It is difficult to see how compliance enhancement could be double-blind and it is not clear that blinded use of disulfiram is appropriate since the treatment effect appears to be due to fear of an adverse reaction from drinking. This fear will still be present if the subjects think themselves to be taking disulfiram and hence the appropriate clinical effect can be measured only in an open treatment trial. Any effect found in a blinded trial can only be due to unblinding caused by exposure to alcohol or some other uncontrolled effect of the drug.

The HTBS analysis of effectiveness is reported in Section 5.6

5.5.2.3 Naltrexone

Naltrexone is an opioid antagonist, which is administered to reduce drinking and craving. It is not currently licensed in the UK for this indication. It is licensed in the Republic of Ireland for use within a comprehensive treatment programme for alcohol dependence to reduce risk of relapse, support abstinence and reduce alcohol craving.

5.5.2.3.1 Submission from Dupont Pharma

Naltrexone was initially developed for use in opioid addiction but then found to reduce alcohol craving. As a consequence of its effect on opioid receptors, current dependence on opioids must be ruled out before use in alcohol dependence.

The SPC discusses two 12-week randomised placebo-controlled trials (Volpicelli et al., 1992); (O'Malley et al., 1992). A combined analysis of the two efficacy trials authored by O'Malley, Volpicelli and three employees of Dupont (O'Malley et al., 1995) is included in the submission. The combined results showed statistically significant benefits in favour of naltrexone in time to first drink (p=0.002) and time to first episode of heavy drinking (p<0.001). During 12 weeks, 75% of naltrexone treated patients and 48% of placebo treated patients did not have an episode of heavy drinking. Fifty-four percent of naltrexone treated patients and 31% of placebo treated patients were abstinent. An interesting finding of these studies was that patients who
were non-abstinent were at significantly lower risk of heavy drinking when on naltrexone. This was not a prespecified hypothesis of either study. Both the percentage of drinking days and craving scores also showed significant benefit in favour of naltrexone.

These were fairly small (combined n=186) and short-term studies. However, they are well reported and appear well conducted.

5.5.2.3.2 Evidence from literature

There has been considerable recent interest in testing naltrexone for alcohol dependence and there appear to be 25 clinical trials, of which 24 are published. Seventeen of these studies give information on rates of abstinence or controlled drinking at the end of the study.

Analysis of data from the trials is reported in Section 5.6.

5.5.2.4 Comparison of acamprosate and naltrexone

A meta-analysis by Kranzler and Van Kirk (2001) was motivated by the absence of direct comparative studies of naltrexone and acamprosate. They thus attempted to collate and contrast the evidence from placebo-controlled trials of each treatment.

Nine naltrexone and 11 acamprosate studies were included. All outcome measures were assessed in ITT analyses. Two further acamprosate studies, Lhuintre et al. (1985) and Lhuintre et al. (1990), were omitted because of methodological concerns.

The measures combined across studies were differences in proportions of successes between groups. When continuous measures were reported, the standardised mean difference was used.

Comparisons were made of the percentage of patients abstinent at the end of the study, the CADs, and the percentage retention. These comparisons did not show differences between the performance measured in the acamprosate studies and that measured in the naltrexone studies. Both treatments had highly statistically significant benefits in these measures relative to placebo.

Heterogeneity was noted in the estimates of the effect of naltrexone on the percentage of drinking days and the effect of acamprosate on CADs. These effects were found to be significantly correlated with recency of study for naltrexone (effects fell with time) and proportion of males for acamprosate (the effect was greater in females).

The authors conclude that both treatments have small but significant benefits in alcohol dependence.

This review appears to be a systematic and comprehensive assessment of the published RCTs for acamprosate and naltrexone. The comparison between acamprosate and naltrexone is not randomised. Furthermore, absence of a statistically significant difference does not imply absence of a difference – confidence intervals would be useful rather than p-values. A difficulty, which is not addressed, is that the length of follow up in each study is not reported and the work performed for this HTA (see Appendix 17) shows that it varies systematically between trials of acamprosate.
and of naltrexone. Thus, differences in effectiveness are confounded with differences in trial procedures.

### Table 5-6  Outcome measures and mean effect sizes for naltrexone and acamprosate (Kranzler & Van Kirk, 2001)

<table>
<thead>
<tr>
<th>Measure</th>
<th>K</th>
<th>N</th>
<th>Effect size (SD)</th>
<th>Effect p-value</th>
<th>Heterogeneity p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Subjects abstinent</td>
<td>8</td>
<td>781</td>
<td>0.122 (0.066)</td>
<td>&lt;0.001</td>
<td>0.88</td>
</tr>
<tr>
<td>% Drinking days</td>
<td>8</td>
<td>650</td>
<td>-0.191 (0.195)</td>
<td>&lt;0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Drinks/drinking day</td>
<td>5</td>
<td>439</td>
<td>-0.067 (0.126)</td>
<td>0.081</td>
<td>0.14</td>
</tr>
<tr>
<td>% Relapse to heavy drinking</td>
<td>7</td>
<td>549</td>
<td>-0.161 (0.107)</td>
<td>&lt;0.001</td>
<td>0.36</td>
</tr>
<tr>
<td>Retention (%)</td>
<td>7</td>
<td>529</td>
<td>0.005 (0.132)</td>
<td>0.45</td>
<td>0.10</td>
</tr>
<tr>
<td>Acamprosate outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Subjects abstinent</td>
<td>11</td>
<td>3204</td>
<td>0.114 (0.073)</td>
<td>&lt;0.001</td>
<td>0.06</td>
</tr>
<tr>
<td>CAD</td>
<td>10</td>
<td>3077</td>
<td>0.129 (0.088)</td>
<td>&lt;0.001</td>
<td>0.003</td>
</tr>
<tr>
<td>Retention (%)</td>
<td>10</td>
<td>3077</td>
<td>0.074 (0.071)</td>
<td>&lt;0.001</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Positive effect sizes indicate higher means for active medication group; negative effects sizes indicate higher means for placebo group
K = number of studies contributing effect sizes
N = total number of subjects contributing to calculation of effectiveness

### 5.6 Meta-analysis of clinical effectiveness

The economic model used in the cost-effectiveness section of this report compares costs of treatment with the long-term health consequences of any treatment-related changes in drinking behaviour. Only limited information is available on the epidemiology of drinking-related disease and, in particular, on the relationship between different patterns, quantities and duration of alcohol consumption and risk of disease. Thus, a very simple assumption is made that, following treatment, a subject will either be in a controlled (possibly abstinent) state, in which disease risks are reduced to that of the general population, or will be in an uncontrolled state with high risk of alcohol-related disease.

The nature of the model requires that information be available from clinical studies regarding the proportion of patients in each treatment group who are considered treatment successes – i.e. controlled – and those who are failures. Unfortunately, many studies do not make this distinction on a patient-by-patient basis but report other drinking outcomes, for instance percentage of heavy drinking days in the whole treatment group. In particular, none of the systematic reviews of psychosocial treatments have reported success rates in this fashion. Consequently the individual studies have been reviewed and these data extracted when possible.

Some difficulties are inherent in extracting this type of information. Different points in time are chosen for outcome measurements in different studies. The choice of success measure may also vary with some studies reporting only abstinence, others only controlled drinking and with different definitions of controlled drinking. Studies where subjects are given the choice of aiming for either an abstinent or controlled state may simply report a combined success rate. In analysis, outcome measures around one year after treatment have been chosen as far as possible however, if these were not available, the closest time point was used. Absolute success rates are likely
to vary considerably with time, so analyses are carried out in terms of odds ratios for success between treated and untreated groups. A further complication is the drop-out rate during follow up in these studies. The view that the most reasonable assumption is that those lost to follow up are likely to be treatment failures has been adhered to and ITT estimates have been used when sufficient information is available. However, it is also recognised that interventions of very different intensity or duration may induce different drop-out rates for reasons unrelated to treatment failure and that this methodological difficulty introduces an element of uncertainty into the calculations which will not be reflected in confidence intervals.

The method of analysis used was to fit a random effects logistic regression using the GLIMMIX macro in SAS (Computer Program. Version 8.1. Available from SAS Institute Inc CMU.)

The choice of interventions which have been analysed has been guided by the preceding effectiveness discussion. In particular, interventions which do not seem effective in dependent patients on the basis of more extensive reviews, have been excluded. Only unsupervised disulfiram is analysed, as the outcome of abstinence or controlled drinking has not been reported in a well-conducted trial of supervised disulfiram.

More details of the calculations, including variations in follow-up period and treatment of missing data, are given in Appendix 17. However, for ease of comparison with the other effectiveness results, the main results are reproduced in the following table.

Table 5-7  Results of meta-analysis for rates of abstinence or controlled drinking
(see Appendix 17)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Treated Total N</th>
<th>Control Total N</th>
<th>Odds Ratio (95% CI)</th>
<th>Heterogeneity p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training a</td>
<td>875</td>
<td>353</td>
<td>2.11 (1.53, 2.92)</td>
<td>NS</td>
</tr>
<tr>
<td>BSCT a</td>
<td>141</td>
<td>135</td>
<td>1.75 (1.02, 3.02)</td>
<td>NS</td>
</tr>
<tr>
<td>MET a</td>
<td>596</td>
<td>96</td>
<td>1.88 (1.28, 2.77)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>362</td>
<td>380</td>
<td>1.94 (1.37, 2.73)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>2347</td>
<td>2182</td>
<td>1.73 (1.36, 2.20)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1171</td>
<td>942</td>
<td>1.46 (1.12, 1.90)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Unsupervised oral disulfiram</td>
<td>245</td>
<td>241</td>
<td>1.31 (0.26, 6.70)</td>
<td>NS</td>
</tr>
</tbody>
</table>

*aData from Project MATCH also included for these interventions
NS=not significant

The results indicate a similar statistically significant beneficial effect for each of the psychosocial interventions. The same is true for two of the pharmacological interventions, acamprosate and naltrexone. Only unsupervised disulfiram could be included in this analysis and this did not demonstrate any benefit.

5.6.1  Conclusions on psychosocial interventions

In the preceding sections, a number of psychosocial interventions were found to be of value in preventing relapse in alcohol dependence. These included MET, Marital/Family Therapy, BSCT and Coping/Social Skills Training.
Many different outcomes are used in trials of these therapies and meta-analyses identified in the literature have used generalised outcome measures without clear clinical interpretation. A meta-analysis of success rates – either abstinence or controlled drinking – at the end of the study shows no clear differences in effect size between these treatments. Systematic searching has not found adequate proof of effectiveness for the many other psychosocial treatments.

Even effective treatments will fail in around half the patients. The total combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between six months and beyond one year), in trials of those psychosocial treatments judged effective was 42% for treated patients and 26% for those receiving control treatments.

Trials of BIs in alcohol-dependent patients have failed to show any benefit.

The efficacy of purely social interventions (Section 5.5.1.7) has some support, which suggests that this may form an important component of a comprehensive service.

5.6.2 Conclusions on pharmacological interventions

Acamprosate and naltrexone were both found to be effective as adjuncts to psychosocial interventions. The combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between three months and one year), in trials of these treatments was 34% for treated patients and 25% for those receiving placebo treatments. However, it should be noted that there are marked differences between the figures for acamprosate (26% versus 18%) and naltrexone (51% versus 41%) which may reflect the systematic differences in primary outcome and duration of follow up between studies of the two treatments (Appendix 17).

Use of unsupervised oral disulfiram was not supported by evidence but limited evidence suggests that supervised oral disulfiram may be an effective treatment for prevention of relapse.

5.7 Safety of interventions for the prevention of relapse

There does not appear to be any literature on adverse effects associated with psychosocial interventions. If any exist they are only reflected in this HTA in so far as they impinge on the effectiveness of treatment.

Use of acamprosate, disulfiram or naltrexone carries some associated risk of adverse effects. Those which have been observed in clinical trials or identified by national spontaneous reporting systems are documented in the SPC for the products. A clinically relevant discussion is given in the International Handbook of Alcohol Dependence and Problems (Chick, 2001). The most common adverse effect of acamprosate (around 10%) is diarrhoea and abdominal discomfort. Clinical trials of naltrexone have consistently revealed a higher level of nausea when compared with placebo treated patients and headache, dizziness and weight loss may also be experienced. Disulfiram may cause drowsiness, headache, bad breath or skin rashes. Very rare serious adverse reactions such as liver hypersensitivity (one in 25 000) and psychosis have been reported.
5.8 Other Issues

5.8.1 Effectiveness of Alcoholics Anonymous

AA is a self-funding organisation outside the NHS and, as such, not an easy treatment option to test in clinical trials. However, the limited evidence which does exist has been reviewed by other researchers (Kownacki & Shadish, 1999).

This review included both randomised and unrandomised studies comparing AA treatment with either active or inactive control treatments. The nature of the active control treatments is unclear. Treatments were compared in terms of a standardised mean difference to allow combination over different outcome measures. All outcome measures were alcohol related.

Ten randomised studies were identified which fell into three groups. Three studies randomised to AA meetings, two examined inpatient treatment based on AA principles, and five examined only selected facets of the AA approach. The comparisons in these groups gave different results. The comparison of AA meetings with either active or inactive control treatments estimated a statistically significant adverse effect of AA meetings. The comparison of AA based inpatient treatment with other inpatient treatments suggested no difference between the two. However, the individual facets examined (Communication Skills to do AA steps versus discussion, recovered alcoholics as counsellors versus non-alcoholic counsellors, senior abstinent patient-led group versus therapist-led group, honest inventory milieu versus hypnotherapy) gave an overall significant benefit for the treatments based on AA principles.

The authors note that the three studies which gave the adverse estimate of AA meeting efficacy only enrolled subjects who were coerced into treatment. They argue that AA meetings, compared with other forms of treatment, may provoke more negative responses in those forced to attend them. Thus the correct interpretation of these trials is that patients should not be coerced into attending AA.

An argument is strongly put for more and better quality randomised trials of AA.

The paucity of data concerning the actual effects of AA as an organisation does not extend to the effectiveness of the AA treatment philosophy. This formed one of the three arms of the Project MATCH study (Project MATCH Research Group, 1993) and was, perhaps, the most successful of the treatment arms. As already noted, Project MATCH found a significant beneficial effect for the 12-step approach in outpatients on ‘drinking consequences’ at nine months relative to MI. The outpatient group in Project MATCH included 952 persons and the p-value for differences between the treatment arms in drinking consequences at nine months was 0.006. The effects of the 12-step approach were found to be similar to the CBT approach used in the third arm. Although this was not a direct test of AA itself it is worth noting that the overall goal of the 12-step programme in Project MATCH was to promote the active participation in ‘traditional fellowship activities of AA’. To this end, the intervention emphasised the beliefs of AA that alcoholism is a chronic and progressive illness without cure for which total abstinence is the only solution. Hence the trial was a direct test of the acceptability and effectiveness of the AA model of alcohol dependence. A further
finding of Project MATCH was that the 12-step approach was more effective than CBT in patients ‘without support for abstinence in their environment’.

### 5.8.2 Treating drug and alcohol-dependent patients together

Beidler (1991) randomised 450 people with either primary drug (206) or alcohol (244) problems to either be treated together or in segregated groups. Subgroups of subjects were examined to try to find any in whom these strategies might be particularly good or particularly poor. Treatment consisted of a number of coordinated psychosocial approaches. Follow up was for eight months.

Of the 212 people assigned to combined treatment, 53 (25%) had problems with both alcohol and drugs. In the separate treatment group (238), only 29 (12.2%) had problems with both. This is an odd and highly statistically significant (p<0.001) imbalance.

No differences in changes in dependence levels, criminality, suicidal tendencies or employment levels were seen for either those with primary alcohol or primary drug problems between the two treatment options.

This study is broadly supportive of combined treatment as an option. However, the power to detect problems for particular subgroups is not discussed and the imbalance in multiple abuse may suggest problems with randomisation.

### 5.8.3 Minimising pre-treatment drop out

Stasiewicz & Stalker (1999) report a RCT of measures to minimise failure to attend for first appointments at substance abuse clinics. They compared a group given appointments within 48 hours with groups given appointments after 48 hours but with (1) a reminder call 24 hours before the appointment (2) an appointment card and clinic brochure in the post or (3) no additional reminder. They found that those given appointments within 48 hours were substantially more likely to keep the appointment than those in the other groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients attending for first appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intake within 48 hours</td>
<td>23/32 (72%)</td>
</tr>
<tr>
<td>Phone call</td>
<td>16/32 (50%)</td>
</tr>
<tr>
<td>Appointment card/brochure</td>
<td>16/32 (50%)</td>
</tr>
<tr>
<td>No contact</td>
<td>17/32 (53%)</td>
</tr>
</tbody>
</table>

This suggests that a prompt response to requests for help with alcohol-related problems is important. Minimising the delay in obtaining treatment has also been picked out as a matter of concern to patients by the SIGN patient focus groups in the draft SIGN guideline (Scottish Intercollegiate Guidelines Network (SIGN), 2002)[Draft], the final of which will be published in 2003.
5.8.4 Inpatient and outpatient care

Rychtarik et al. (2000) randomised 192 individuals with a score of nine or more on the Alcohol Use Disorders Identification Test (Babor & Grant, 1989) to (1) a residential, abstinence oriented, alcoholism treatment facility (2) a specialist outpatient clinic with intensive treatment or (3) a specialist outpatient clinic with standard treatment. The intention of the study was to test treatment-matching hypotheses with respect to drinking problem severity and to social support for drinking. Patients with high levels of either variable were expected to benefit from inpatient or intensive outpatient treatment.

Drinking outcomes were obtained in each month following treatment by the timeline follow-back method, which reconstructs daily drinking via a calendar. The primary outcomes were the percentage of voluntarily abstinent days and the number of drinks per drinking day.

There was no overall difference between the groups in primary outcomes over 18 months of follow up. However, a relationship was found between drinking problem severity and the treatment allocation. This did not follow the hypothesised pattern in that, although severely affected patients benefited more from inpatient treatment, there seemed to be a negative association with intensive outpatient treatment and no significant association with standard outpatient treatment.

Although this relationship was not as expected, and hence might be regarded as hypothesis generating, it suggests that inpatient care may be important for those with more severe alcohol problems.

No interaction was found with social support for drinking.

Several evaluations of the benefits of inpatient and outpatient care are reviewed by Finney & Moos (1998). The evidence concerning effectiveness for all patients does not show clear superiority for either option. However, the authors note that there is a group of patients with few social resources and/or environments that are serious impediments to recovery for whom residential options should be available and that inpatient treatment options should be available for those with serious medical/psychiatric conditions. Other authors (Mattick & Jarvis, 1994) have noted that inpatient care may also be suitable for sub-groups requiring close supervision of detox.

5.8.5 Matching of treatment to patient

A primary objective of some recent studies (Mattson et al., 1994) has been to investigate ‘matching’ in treating alcohol dependence. In other words the intention was to evaluate differences in effectiveness of treatments between subgroups of patients. Studies aimed at investigating such questions are still designed as RCTs but one or more patient characteristics are prespecified and the primary hypothesis is concerned with the interaction between the characteristics and treatment rather than with the difference in the effect of treatment between randomised groups. In general, the success of this approach has been questionable and no widely accepted clinically useful conclusions have been drawn from it. As yet it is unclear whether this is because no clinically important interactions exist or because trials have been
inadequately designed to find them. Whichever may be the case, the evidence does not yet exist to allow matching hypotheses to be systematically addressed in this HTA.

The most extensive and rigorous test of matching hypotheses was that provided by the clinical trial in Project MATCH (Project MATCH Research Group, 1993). In this study, 952 outpatients and 774 inpatients were randomised to either CBT, a 12-step approach or MET. A number of patient characteristics were measured at baseline and 10 \textit{a priori} primary service user-treatment matching hypotheses were pre-specified. These failed to find any interaction effects that had an impact on drinking throughout the treatment phase. Despite the size of this trial, no convincing subgroup differences in treatment effects were discovered (Longabaugh \textit{et al.}, 1998).

5.9 Conclusions

The following points relate to psychosocial treatments:

- the meta-analysis suggested similar, statistically significant, beneficial effect sizes for BSCT (OR=1.75, 95\% CI 1.02, 3.02), MET (OR=1.88, 95\% CI 1.28, 2.77), Marital/Family Therapy (OR=1.94, 95\% CI 1.37, 2.73) and Coping/Social Skills Training (OR=2.11, 95\% CI 1.53, 2.92). Treatment of control groups varied and, since some control treatments may have been effective, these estimates may be conservative.
- BSCT appears to show benefit when compared with ineffective controls. However, the only trial that focused on the unique defining features of BSCT and included the more general features in both patient groups did not show a benefit. BSCT is aimed solely at promoting controlled drinking rather than abstinence and this may limit its applicability in practice.
- MET shows efficacy over ineffective controls. However, it was slightly less effective than AA based treatment in outpatients in Project MATCH. This may be due to the short course of treatment given. It is suggested that MET form an important initial element in a course of psychosocial treatment but should not be the sole intervention.
- Marital/Relationship Therapy has shown a beneficial effect. However, it is usually only feasible in those with relatives willing to invest substantial effort in the treatment and with the consent of the patient. Thus, it can only form an option for treatment of some patients. An exception to this is the CRA in which the contractual element with non-family members has been tested.
- BI was not selected for detailed evaluation as published reviews show it to be of unproven efficacy in alcohol-dependent patients and recent evidence suggests it is likely to be ineffective. Many other psychosocial interventions were identified but were unsupported by good clinical studies.
- lack of standardisation of psychosocial treatments in clinical trials often leaves doubt as to how a treatment shown to be effective in a meta-analysis should be delivered in clinical practice. A pragmatic approach is to adopt a protocol which has been detailed in a report from a trial included in the meta-analysis and with a larger than average effect size.
- encouragement to attend AA meetings has been shown to have benefit, however patients should not be pressurised to attend. Explanation of the aims and philosophy of AA during treatment will allow patients to make an informed
choice. As with other psychosocial treatment approaches, agreement upon rather
than pressure to enrol in AA treatment appears essential for benefit to be obtained.
• therapists will need to be able to give informed and unbiased advice regarding AA
and other non-NHS services. This ability may be facilitated by regular liaison
between NHS staff and the other services.
• within a specialist unit, protocols should be available for all available treatment
options to ensure standardised and consistent treatment. These protocols should be
closely based on methods that have been proven effective in clinical trials.
• practical help with problems such as housing, debt and claiming benefits also
appears likely to contribute to control of alcohol problems. Thus, close liaison
with social work services and groups able to deliver such help is essential.

The following points relate to pharmacological treatment:
• pharmacological treatments have been tested and licensed as additional to
psychosocial treatment, not as alternative therapy
• both acamprosate and naltrexone have extensive clinical trial data, which show
that, used according to the clinical trial procedures, they can add value to a
programme of psychosocial treatment. The meta-analysis suggested statistically
significant beneficial effects for both treatments: acamprosate (OR=1.73, 95% CI
1.36, 2.20), naltrexone (OR=1.46, 95% CI 1.12, 1.90).
• trials of both acamprosate and naltrexone show statistically significant
unexplained heterogeneity in effect sizes. Some large pragmatic trials have not
shown an effect. This suggests that differences in the method of use may
materially affect the effectiveness. Further studies are needed to ensure that the
full benefits of these treatments are achieved in practice.
• the additive value of acamprosate and disulfiram in combination has not been
specifically studied in well designed trials and so cannot be recommended
• the effect size estimated for naltrexone is smaller than that for acamprosate. There
are major differences in the way these products were evaluated which make a
direct comparison difficult but this fact, in combination with the unlicensed status
of naltrexone, would suggest that acamprosate should be the current preferred
choice between these two medicines.
• no strong evidence exists for the use of unsupervised disulfiram
• much of the evidence for supervised use of oral disulfiram arises from
observational studies and is hence potentially biased. Most of the evidence from
RCTs confounds supervised disulfiram with other interventions. However, one
randomised unconfounded study has found a benefit and it seems likely that
supervised oral disulfiram can contribute beneficially to a prevention of relapse
programme.

The following points relate to delivery of treatment:
• although a clear benefit for inpatient compared with outpatient treatment has not
been demonstrated, the literature suggests, and clinical opinion supports, the
existence of groups of patients who require residential or inpatient treatment.
These include those with few social resources and/or environments that are
serious impediments to recovery and those with serious medical/psychiatric
conditions.
• an increased rate of failure to attend associated with delay between referral and start of treatment has been demonstrated. This underlines the importance of minimising such delays.
6 PATIENT ISSUES: THE VIEWS OF SERVICE USERS

Summary

- The patient issues reported have been identified primarily by the findings of a qualitative study commissioned by the Health Technology Board for Scotland to explore service users’ treatment preferences, patient information leaflets, a study entitled ‘Attitudes Towards Alcohol: Views of the General Public, Problem Drinkers, Alcohol Service Users and their Families and Friends’ (Lancaster & Dudleston, 2002) and comments from service users submitted during consultation. Issues to emerge were in relation to method of treatment, treatment awareness and access, involvement in choice of treatment and follow up.

- Participants valued activities such as Coping Skills, Assertiveness Training (Section 3.11) and rehearsing difficult situations within a safe environment, anger management, stress/anxiety management and relaxation exercises.

- Views about pharmacological interventions differed greatly: some doubted they would work; others found they gave them confidence; and some did not trust themselves not to drink while taking them.

- All who took these pharmacological interventions believed that the combination of the pharmacological and psychosocial interventions were complementary.

- Group therapy and individual therapy was valued. Women who had experienced ‘women only’ group work had a preference for women only groups, but conversely men may have a preference for mixed group work.

- Awareness of different services and treatments may be low among health professionals and service users and require better promotion and discussion to identify treatment preferences.

- The survey of National Health Service specialist services indicated that only 36% of those carrying out psychosocial interventions had patient information sheets or leaflets for any of these interventions.

- Terms such as Cognitive Behaviour Therapy and Motivational Enhancement Therapy need to be communicated to service users in easy-to-understand language in discussions with health professionals and in written information for patients.

- Shared understandings and mutual agreements regarding the purpose of treatment need to be formed between a person who is alcohol dependent and his or her doctor and reviewed regularly.

- Participants thought it was appropriate, rather than intrusive, for the health service to contact them and offer another appointment when they default. Service users value flexible times and locations. Additionally, a Helpline number given to people when
they were discharged from inpatient treatment in one Trust was valued by these service users.

6.1 Introduction

Perhaps more than any other field of medicine, the treatment of alcohol dependence involves the risk of important differences between the goals of the patient and the aims perceived as desirable by the doctor. Thus, it is very important for both parties to understand and agree the purpose of treatment.

The intention of the patient issues section of a HTA is to ensure that needs and preferences of service users are taken into consideration when developing treatment services and also to identify issues which may only affect a minority of service users but, in those few cases, may profoundly impinge on the benefit which an individual can derive from the service.

Obtaining accurate information about patient concerns regarding alcohol treatment services can present major difficulties. Several methods have been used by HTBS. A limited Medline search has been carried out to identify published literature on patient preferences. HTBS has commissioned a qualitative study focused on the service users within the Scottish services for the prevention of relapse. HTBS also contacted certain organisations that interact with subgroups of service users, in particular the criminal justice system.

The TSG included a representative from the Council on Alcohol. AA in Glasgow also generously gave time to explain its views on a variety of issues and submitted a substantial evidence base.

6.2 Literature search

A search of Medline from 1990 to the present time was undertaken to ascertain the usefulness of searching for general patient issues and concerns in relation to this topic. Approximately 500 abstracts were retrieved, but few were found to address the specific area of interest. It was therefore decided not to continue searching in other databases.

Part of the evidence presented in support of the Scottish Executive’s Plan for Action was a study entitled ‘Attitudes Towards Alcohol: Views of the General Public, Problem Drinkers, Alcohol Service Users and their Families and Friends’ (Lancaster & Dudleston, 2002). The study included an analysis of the perceptions of service provision by current and past problem drinkers of their needs and the extent to which they were being met. As a consequence of recruitment problems, which were outside the control of the researchers, the participants were mainly derived from urban areas. The report primarily focuses on alcohol misuse rather than dependence.
6.3 **Design and conduct of the qualitative patient issues study commissioned by HTBS**

The design of this study involved interviews with service users of the Scottish services for the prevention of relapse in three Trusts. This was not a formal questionnaire based interview but was intended to explore service users’ treatment preferences and to elicit factors which prevent relapse to drinking. The full protocol for this study is included as Appendix 19.

This project sought the experiences of individuals who have received treatment for alcohol dependence. The study aimed to identify people’s preferences for psychosocial or pharmacological interventions, or a combination of both, according to their own particular experiences. A qualitative approach was adopted using in-depth, one-to-one interviews with a sample of individuals from urban, rural and semi-urban areas in Scotland who have had relevant personal experience.

6.4 **Method and analysis**

Approval was granted by each of the three Local Research Ethics Committees, which govern research within the participating Trusts. Consultants responsible for the care of the participating service users also gave approval for access. On recruitment to the study all participants were assured that their confidentiality would be respected. The conditions of the Data Protection Act (Great Britain, 1998) were observed.

The sample was recruited and comprised individuals who had used the alcohol treatment services of three geographically distinct areas in Scotland within the past year. Posters were displayed in prominent positions within treatment facilities and information about the study was made available to anyone who expressed interest in participating. In addition, nurse managers wrote to a random sample of service users who had attended for treatment during the past year, seeking volunteers for the study and suggesting that those interested should contact the researcher. In this way the anonymity of service users was protected until they agreed to volunteer. Moreover, since the study involved an element of service evaluation, the process of randomly selecting the sample recruited via the nurse managers ensured that bias in the selection was minimised.

There were no exclusions with regard to gender, age, social class or employment status. All participants had been required to undergo detoxification either prior to, or as part of NHS treatment for alcohol dependence. Some had done so themselves, either unsupervised or with chlordiazepoxide prescribed by their GP, whereas for others this had been assisted detoxification either at home or, less commonly, as an inpatient.

Qualitative research does not attempt to produce generalisable results that are derived objectively. Instead it aims to describe people’s experiences which are unique and context related. Therefore, the findings of this study are not statistically representative of the entire population of people in Scotland who are alcohol dependent. The results are of personal significance to the participants who told their stories.
One-to-one in-depth interviews were conducted during which the participants were asked to recount their experiences of treatment and their preferences for pharmacological and psychosocial interventions. They were also asked to discuss the factors which they perceived as contributing to the experience being either positive or negative, and to reflect on the reasons for their preferences. The interview guide, which was used to ensure that all relevant topics were addressed, is included as Appendix 19. Prompts were used for clarification when necessary, and to encourage further disclosure. The interviews were conducted at a variety of locations to meet the preferences of the participants and to minimise inconvenience incurred by them. The venues included the researcher’s office, service users’ own homes, health service facilities and accommodation within the premises of one of the Councils on Alcohol.

The duration of the interviews ranged from 30 minutes to one and three quarter hours. All except one were audio-tape recorded. The reason for the exception was that the participant was reluctant to be recorded, so hand-written notes were taken instead.

The interviews were transcribed prior to analysis. Burnard’s framework for thematic analysis of qualitative data was used to search for themes and patterns in the data (Burnard, 1991). As a means of ensuring rigour in the process, a sample of the transcriptions were analysed independently by a colleague of the researcher with experience of undertaking qualitative research. Points of divergence were discussed and agreement reached for the final analysis. The participants were invited to comment on a summary of the findings as part of the validation process for qualitative research (Sandalowski, 1993);(Whittemore et al., 2001).

### 6.5 Findings of patient issues study

A total of 45 participants were interviewed. The gender distribution and age range of participants are shown in Table 6-1, and Table 6-2 shows the number of participants who had, at some time in their lives, experienced some form of psychosocial or pharmacological treatment for alcohol dependence.

#### Table 6-1 Gender distribution and age range of participants

<table>
<thead>
<tr>
<th>Trust 1 (n=15)</th>
<th>Male</th>
<th>Female</th>
<th>Age range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10</td>
<td>5</td>
<td>30 – 71 years</td>
</tr>
<tr>
<td>Trust 2 (n=15)</td>
<td>12</td>
<td>3</td>
<td>26 – 72 years</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>6</td>
<td>31 – 71 years</td>
</tr>
</tbody>
</table>

#### Table 6-2 Treatment experiences

<table>
<thead>
<tr>
<th>Trust 1</th>
<th>NHS individual therapy</th>
<th>NHS group therapy</th>
<th>Disulfiram</th>
<th>Acamprosate</th>
<th>Councils on Alcohol</th>
<th>AA</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>15</td>
<td>5</td>
<td>7</td>
<td>10</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Trust 2</td>
<td>15</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Trust 3</td>
<td>15</td>
<td>15</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>9</td>
</tr>
</tbody>
</table>
All participants were asked to describe their drinking history and to recount the kinds of treatment they had experienced for alcohol dependence. It was most common for individuals to have sought help for an alcohol problem in the first instance through their GP, with much smaller proportions being referred through other health services such as general hospitals, psychiatric services or occupational health services. Seven people had sought help in the first instance from AA, compared with three who had attended one of the Councils on Alcohol before approaching any other service.

One participant described having been referred to a specialist NHS alcohol service following an admission to a medical ward after a collapse. His referral had come about as a result of a discussion between his family and the medical ward staff during which his relatives asked about what help was available for the treatment of alcohol dependence. It appeared that one member of the nursing staff was aware of specialist provision within the area, but only because of the personal experience of a member of her own family. The patient was subsequently referred and has been abstinent and attending the service for six months. This highlights the need for staff in secondary care to be aware of specialist provision so that appropriate referrals can be made.

The following section summarises the views of the participants as regards their preferences for different treatment modalities for alcohol dependence and the prevention of relapse to drinking.

6.5.1 Organisation of care within the three participating areas

6.5.1.1 Trust 1

This Trust serves a rural and semi-urban area.

An initial episode of four weeks duration as an inpatient was described. This stay comprised detoxification, a structured programme of group work, and individual therapy with members of the nursing team. Following completion of the programme, a phased continuing care programme of a one-week inpatient stay was offered, with the interval between episodes lengthening over a two-year period. Service users who live in one geographic area within this Trust’s catchment area are offered follow-up outpatient appointments in satellite clinics. Those who live within the same Trust area, but who live outside the specified area, have no such opportunity. The view was expressed that this represented unequal provision.

6.5.1.2 Trust 2

This Trust serves an urban area.

Different patterns of care are available to service users who live in different areas within the Trust’s catchment area. For example, in one area, a four-week structured day programme is offered and, in another, an inpatient stay of approximately two weeks is available with periodic follow-up outpatient appointments arranged on discharge from hospital. However, more data are required from the Trust to verify the situation, and it may be that differences in service provision reflect differences in local need.
6.5.1.3 Trust 3

This Trust serves a mixed rural and semi-urban area.

The participants’ descriptions of their treatment indicated services available to those attending included a three-week inpatient stay during which time detoxification was available, followed by a structured programme of group work, led by members of the nursing staff, and individual therapy. Continuing care provision included the opportunity to attend a group on a weekly or twice-weekly basis. The opportunity exists for these service users to attend as and when they feel necessary and appropriate, rather than as obligatory attendance on each occasion that the group meets. This group is therefore open to some extent. One of the options within this service is for a ‘women’s only’ group, which has led, by default, to the formation of a men’s group. Some people in this area also talked of having been referred to an organisation which offered aspects of community reinforcement in the form of training and support in seeking employment.

6.5.2 Residential versus day-patient care

The decision about whether treatment would be offered on a residential, day-patient, or outpatient basis was generally made by the consultant and appeared to depend on the basis of how care delivery was organised. An additional factor, in one area in particular, was that the geographic distance from the communities where the majority of service users lived made residential treatment essential.

Most service users valued the sense of asylum which residential care brought. However, most recognised that, as inpatient users, they were protected from the environmental stressors which they normally experienced. They talked of feeling ‘cocooned’, and ‘in a bubble’. In one Trust, they were required to return home from the unit at weekends and this was generally felt to be a useful time for preparing for discharge and practicing new skills learned. This sense of trepidation about leaving the relative safety of the hospital was also reported by Lancaster & Dudleston (2002).

Several participants at the Trust where the residential programme seemed to be most structured found the combined effect of group work, individual therapy, and paper-and-pencil (used in the evenings and over the weekends) tiring. However, the majority found it very worthwhile. This level of activity contrasts with reports of residential care in which the users of the services complained of boredom and a lack of structured activity in another area in Scotland (Lancaster & Dudleston, 2002). This could reflect variation in the philosophy of care in the two areas, or perhaps in the level of resources available.

Sobell & Sobell (2000) argue that decisions regarding care of those with alcohol problems should be individualised, evidence-based, and ‘stepped’ in intensity or quantity according to service user need. They suggest that self-change or natural recovery is the first step, requiring initiatives at the public health approach and the use of self-help groups, such as AA. BIs delivered within primary care may be appropriate at the next level, with more intensive interventions, which could involve admission to a residential
programme, being preserved for those with more complex problems. Included within this latter group would be individuals who are alcohol dependent. Such an approach to care could be readily incorporated into the tiered framework for service provision which is outlined in the Scottish Executive’s document, Alcohol Problems Support and Treatment Services Framework (Scottish Executive Health Department, 2002).

6.5.3 Psychosocial interventions

All participants had experienced psychosocial interventions as part of treatment offered by NHS specialist services. None were able to identify what was meant by the terms ‘Behavioural Self-Control Training’, ‘Cognitive Behaviour Therapy’ or ‘Motivational Enhancement Therapy’, although one patient who had recently completed a psychology course was able to identify retrospectively different approaches, which he had experienced:

‘Now I’ve done the psychology course, I can recognise that the doctors take the biological approach, and the cognitive approach, and you can see the client-centred approach in the one-to-ones. I didn’t see it while I was there, obviously.’ (Interview 19, male, Trust 1)

Others described the content of the psychosocial interventions and, in doing so, identified elements of MET, BSCT and Coping Skills Training:

‘Coping skills…anxiety management and exercises, and …complementary therapy.’ (Interview 20, male, Trust 1)

‘We talk about money problems, family problems, health problems and, of course, your drink problems.’ (Interview 42, female, Trust 2)

‘… relapse prevention, talking about the cues and triggers, you know, as well as all the educational information. I don’t know if that would fit into what ye’re asking aboot [MET, CBT, RP] You know it’s very informative. There was role play, and you know, a lot of group work’. (Interview 7, female, Trust 3)

‘Like, you do the cost/benefits, and how to avoid risky situations, and the high risk situations. Well, we talk about voluntary work and other things to get you into, to try and pass your time. I mean, it’s not the cure all and be all, but it does give you the tools and the help to put you on the road and you can say well if this person can do it, then so can I.’ (Interview 2, female, Trust 3)

In general psychosocial interventions were described as being very helpful. It was acknowledged that all such interventions could be delivered in either a group or an individual format.
6.5.3.1 Group work within NHS facilities

Activities highlighted as beneficial by several participants included Coping Skills, Assertiveness Training and rehearsing difficult situations within a safe environment, anger management, stress/anxiety management and relaxation exercises.

The majority of those who had experience of group work described it as being of value for some of the following reasons:

‘I would say that for me, coming here [to the open group] is the key. It’s hard to say how they work, but they do work for me. It’s good to come along and see the same people. And you get benefit from other people, knowing that other people have been through the same thing.’ (Interview 6, male, Trust 3)

‘How does it help? Well I don’t know – but we’re a’ the same. Emm, you can get things off yer chest, and if you relapse or whatever, and yer heed sterts [starts], and ye get things blown up out of all proportion, and at least coming to meetings you get a chance to air it, and you might not get an answer – often you don’t, but it does work, and ye go awa’ hame the calmer.’ (Interview 7, female, Trust 3)

For one individual, attending groups was the preferred treatment of choice, although he did recognise the value of individual sessions too, but felt that the approach may become more directive within the individual situation:

‘I think the groups can be more empowering [than one-to-one sessions]. Probably if I think about it, Dr X did say “do this” or “don’t do that”, and cracks the whip!’ (Interview 1, male, Trust 3)

Group work may be difficult for people who are still drinking. All but one of the minority of service users who were still drinking found the groups difficult. One described discharging himself from treatment because he said that he was on the brink of having a fight with one of the group members. During another episode of care, the same patient discharged himself again because he found the attitude of a staff member objectionable. He described how, on this occasion, the staff member had instructed him to attend the group and then interrupted him as he was about to speak and told him to be quiet. He could not give a reason for this. Two of the other participants expressed resentment as they described incidents where they felt that the staff had treated them like children in the groups.

Several of the women who were interviewed made the point that one of the weekly groups which they attended was for women only. The majority of the women who had experienced these groups valued this, expressing the view that they felt less inhibited in such an environment. One person said that she could discuss issues, which seemed trivial but were sources of irritation, which could have developed into a trigger for drinking. These findings echo those of Lancaster & Dudleston (2002) but are at odds with the recommendations of an expert seminar on women and alcohol, published by the Health Education Board for Scotland, which advocates the provision of ‘gender sensitive’, rather than ‘gender specific’ services on the grounds of current limited resources (Plant & Haw,
In the study reported here, those women who had no experience of women’s only groups had no strong feelings. However, all of the men felt that mixed groups were preferable.

The benefits of group therapy that the participants described related to reflecting, learning from each other and feeling good about being able to contribute positive experiences to the group so that others could learn from them. The following quote illustrates this point:

‘I hope I can give somebody else the hope it can be better, somebody just starting off. I know what it’s like, sat in the corner feeling terrible while everybody else seems to be feeling a bit better.’ (Interview 27, Male, Trust 1)

6.5.3.2 Individual therapy sessions within NHS facilities

This was also found to be helpful by most participants, and most people expressed the view that they enabled problem-solving approaches to be addressed at greater depth. The individual therapy sessions were regarded as important for discussing issues which people felt were too personal to discuss within the groups. The opportunity to discuss issues which were pertinent to them as individuals, as opposed to problems which were common to members of the group was also valued.

‘The one-to-ones are good, because there’s some things that, eh…, there can be so many people speaking at the one time in the groups, that you can’t explain, whereas in the one-to-one, although you have a set time for the one-to-one, they’ll always make time for you, day or night.’ (Interview 17, male, Trust 1)

‘And the one-to-ones, even though they were total strangers, you could just talk away to them no problem just as though you’d known them all your life. You were a bit strange to begin with, but that might have been the alcohol still working, and all the lies you tell when you’re on heavy drinking, like. But after the first couple and I’d done my detox and all that, it was just brilliant. You could talk about everything, whatever troubles you’ve got, or if you’re doing well, even. Just whatever you want to talk about.’ (Interview 25, male, Trust 1)

‘It’s directed to your own individual circumstances, it only works if you are honest with them and you are honest with yourself.’ (Interview 15, male, Trust 1)

‘The one-to-ones were more beneficial for me because I could let go more and I could tell more than I could in a group. There’s a lot of underlying reasons that you wouldn’t share with a group but you need the one-to-ones to open up about them.’ (Interview 20, male, Trust 1)

One participant felt that he could not cope with individual sessions since he was:

‘Too paranoid to benefit – not ready.’ (Interview 11, male, Trust 3)
6.5.3.3 Service users preferences for group or individual therapy

Most participants who had experience of both formats felt that group and individual therapies were complementary and most were reluctant to commit themselves to either as a preference.

‘It has definitely got to be a combination.’ (Interview 15, Male, Trust 1)

‘I think one is as important as the other.’ (Interview 12, Male, Trust 3)

6.5.3.4 Couples therapy

None of the participants had experienced formal couples therapy (discussed elsewhere in this Assessment Report as Behavioural Couples Therapy and Family/Marital Therapy), although a few said that spouses/partners had attended joint consultations in the early stages of treatment. These were regarded as helpful, but not as of central importance to their overall treatment.

6.5.4 Alcoholics Anonymous

Most participants had attended at least one meeting of AA. All said that they recognised that AA works well for many people, but most of them felt that it was not suitable for them. This may, however, have been an artefact of the recruitment strategy which selected participants to the study from referrals to the NHS. Those who found it beneficial, although in a minority, seemed to gain considerable support. The flexibility of the times and venues of meetings was valued for a range of reasons, as illustrated by the following quotations:

‘It doesn’t matter how often you come and go, you’re always welcome – more than welcome. People are rooting for you and they want you to do well. There’s always a meeting while she’s [daughter] at school.’ (Interview 7, female, Trust 3)

Some participants found the experience intimidating:

‘I was really nervous at the AA because you had to stand up in front of people and it’s just the way it’s done. I know it works for a lot of people you know, but I found when I went it wasn’t right for me at that time. I’ll maybe give it another go some time…..’

(Interview 13, female, Trust 1)

‘I didn’t take to it at all, although I went hundreds of times. … I wasn’t one for standing up and speaking in front of the crowd, a group of people. … I think was the biggest downfall for me was that I am too quiet I just couldn’t do it, that was a lot to do with it.’

(Interview 33, Male, Trust 2)

Others seemed to derive benefit from attending AA at different times in their lives:

‘I used to be scared to go to AA because that was a definite commitment that you didn’t want to drink, you know. And saying I was an alcoholic in front of other people, I used to
say, oh I’m not quite wanting to go as far as that, you know. I’m never going to say, no, you know, I’ll never say I’ll never drink again. But I have been and I have stood up. … I mean it doesn’t bother me, you know. It didn’t bother us to say it. And I still go to AA maybe once, twice a fortnight. Because you get a different perspective on it.’ (Interview 12, Male, Trust 3)

‘Certainly for somebody that’s starting off and trying to get sober it’s actually very, very useful’. (Interview 22, Female, Trust 2)

Some people felt that members of AA tended to replace their dependence on alcohol with a dependence on involvement with AA, which they thought represented limited progress towards achieving a fulfilled life.

No-one had completed a programme utilising the 12-step approach, the closest reached was one person who had completed nine of the steps. One participant had asked for a sponsor to work through the programme with her, but it had not been possible to find people who had completed the programme themselves. Another had made two attempts to work through the programme and had found both of his sponsors to be very good. However, he felt that it was a mistake to rely too much on the sponsor because, as he said:

‘It’s nothing to do with sponsorship, it’s all to do with me, you know.’ (Interview 16, male, Trust 1)

6.5.5 Councils on Alcohol

Several of the participants had experienced the services offered by the Council on Alcohol. Some valued the opportunity for one-to-one counselling and for complementary therapies, such as aromatherapy. Others felt that the philosophy of the Councils was that controlled drinking was a feasible option, which many of the participants felt was inappropriate for their own situation.

Some participants said that they felt that they had attended the Council at an inappropriate time in their drinking careers. For example:

‘I used to go and see, it was Mary [a pseudonym]. But I think when I first went to see her, I was still very resistant to change, you know. I was still a bit in denial.’ (Interview 12, male, Trust 3)

The availability of the service was important to one participant who described a recent incident when she felt close to drinking:

‘A couple of weeks ago I was really desperate for a drink, it was a really severe craving, and I thought to myself, “I can go down to the shop and get a carry out,” and then I thought, “No I’m going to talk to somebody”. So I went down to the Council on Alcohol and spoke to somebody and stayed there for a couple of hours, and was speaking to other people that have been there and had the cravings, you know, that you’re going through, kind of thing and it really helped me. I’ve found like even just going down to the Council
on Alcohol and speaking to people, it was just an informal chat basically, you know, but that helped settle me down and you get a game of cards and stuff.’ (Interview 13, female, Trust 1)

### 6.5.6 Pharmacological interventions

Participants were asked about their experiences of taking pharmacological preparations as prevention of relapse to drinking. The particular preparations of interest were disulfiram, acamprosate and naltrexone.

#### 6.5.6.1 Disulfiram

All participants had heard of disulfiram as Antabuse® and approximately a third had experience of taking it. Three of the sixteen service users who had taken disulfiram had experienced skin rashes as a reaction to wearing perfume or aftershave which contained alcohol.

A few people described the very unpleasant effects they had experienced as a result of drinking while taking disulfiram:

‘Yes, but I actually drank on it and was very ill, and even that didn’t deter me. I even drank on it again, knowing how ill I’d be.’ (Interview 7, female, Trust 3)

Despite knowing about these effects, this person said he was unable to resist alcohol. Another explained his feelings at the time as follows:

‘I ended up in A&E one time. It was quite strange, because I’d got to the point where I’d got to the stage that I didn’t really care. I knew I wasn’t safe to be taking drink but I had a whole bottle of single malt in the house, and I thought, well, it doesn’t really matter what happens. For a day there was really no reaction at all, and then, it just massively hit. Apparently it must have been some sort of heart problem, because when I was in the hospital I was on a heart monitor all the time.’ (Interview 6, male, Trust 3)

Of those who had no experience of taking disulfiram, most said that this was because they would not trust themselves not to drink while taking it.

‘I wouldn’t trust myself on Antabuse®. I’ve heard a lot of horror stories about Antabuse®. I think there’s a good possibility that I would drink while I was on it and I wouldn’t like to risk it.’ (Interview 20, male, Trust 1)

Some of the participants said that they took disulfiram but were concerned that this should only provide support until they were able to manage without it, for example:

‘I wouldn’t be learning how to cope with it [abstinence]. You know I’d never feel the sense of accomplishing something if I kept on it.’ (Interview 16, male, Trust 1)

However, for some others, taking disulfiram was an important supplement to other forms of treatment:
'For me it is the backbone – it just strengthens my resolve.' (Interview 27, male, Trust 1)

'I had seen these leaflets about Antabuse®, so I said, “I want to go on it”, and he said, “Well are you sure?” And I said, “Yes it’s the only way, I cannot go back out there [home at Christmas and New Year] and say I won’t drink”. So they started me on it and I haven’t had a drink since [December 2000] actually.' (Interview 21, female, Trust 1)

Later this participant explained that she used disulfiram to reinforce the effects of the psychosocial support she had received while in hospital, in combination with ongoing support she received from a CPN. Indeed, all who had found disulfiram of benefit felt that it was the combination of interventions which was effective for them.

6.5.6.2 Acamprosate

Nineteen participants had taken acamprosate with reports of varying success. Some people noticed no reduction in craving and felt that it was of no benefit, whereas others felt unable to discern whether a reduced sense of craving had resulted from their improved coping skills, the medication, or a combination of both:

'I did try that once but it didn’t work for me. I’m not very good at taking tablets anyway, and that’s three times a day dose and they’re quite big tablets, and it didn’t seem to affect my desire to drink. I have to take a lot of tablets anyway because of other health problems.' (Interview 6, male, Trust 3)

On the other hand, approximately half of the participants did report that they were finding that taking acamprosate was effective in that, although they still experienced a craving for alcohol, that it was less severe and this they attributed to the drug:

'I think if you take it along with your own self will power it gives you a wee backup system, I found they worked because, with walking into a shop, the first thing you see is the drink. All the bottles of drink are in front of you in a shop I have never felt the urge, I just walk by it now.' (Interview 25, Male, Trust 1)

One participant, who had not been prescribed either disulfiram or acamprosate felt that NHS staff should provide more information about these drugs so that they could reach an informed choice about what treatments could be available to them.

6.5.6.3 Naltrexone

None of the participants had been prescribed naltrexone.

6.5.7 Community reinforcement

Only a few people had experience of attending organisations, which offered support regarding training and continuing education or assistance with housing. Those who did, valued the opportunities which this afforded in terms of building self esteem and life skills:
‘I’ve done my higher psychology and I’m going to do a computing course next year. I’ve thoroughly enjoyed the experience and I’ve met so many people. It’s opened so many doors I don’t have time to think about drink’. (Interview 19, male, Trust 1)

‘Once you have been sober for a while, they do a three-month training programme to try and get you into work or a college.’ (Interview 3, male, Trust 3)

‘I’m with an organisation called Rehab Scotland. It actually helps people with mental illness – with depression and all that, and I’m finding that a great deal of support, and they can pull all the strings for you for to get you back into employment.’ (Interview 20, male, Trust 1)

6.5.8 Relapse stressors

Participants reported a range of factors, which had contributed to their relapsing. These most often involved stressors. Stressors included moving house, family problems, disappointment related to failed job applications and emotional anniversaries. However, some could not explain why they had relapsed and others described circumstances such as receiving relatively large sums of money, which was quickly spent on alcohol. A few talked of continuing to use alcohol as a reward for periods of abstinence and described how it took several relapses to realise the irony of such actions. High-risk precipitating factors therefore, for this sample, appear to include both ‘interpersonal’ and ‘intrapersonal’ determinants as described by Cummings et al. (1980).

Those who were experiencing the longest periods of sobriety reflected that the ‘time had been right’. When pressed to describe what was different about the ‘time’ and how they knew this, explanations were elusive. These findings are in keeping with those of Isenhart (1997) whose study of the relationship between pre-treatment stages of change and outcome indicated that service users who experience less ambivalence about their drinking are more likely to acknowledge the existence of a problem and become more willing to take action to address the problem. Similar findings were reported by Hu et al. (1997).

Service users described several courses of action, which they had taken to prevent relapse. Several people in a Trust had used a local Helpline, which the NHS service had made available to people being discharged from inpatient treatment, and some had contacted AA or the Council on Alcohol. Others said that they rehearsed the exercises which they had learned, such as relaxation techniques, or found some meaningful way of occupying their time, such as tackling some chore or going for a walk, cycle, run, or workout.

Others talked about continuing efforts to maintain sobriety so that relapse was less likely, as this person described:

‘Well what I’m doing now, going to xx [nurse therapist] every two weeks and coming here [NHS group] every Thursday and just making the effort to come. Keeping it going and it’s far, far too easy to get lapsed and, you know and coming here especially is a great reminder that I can’t do it, can’t go down that road.’ (Interview 11, male, Trust 2)
Some people talked about using AA meetings in this way, whereas others valued the chance to return for a week’s inpatient stay, for example:

‘I think that respite for me was terribly important. I think I could have fell off the rails if I hadn’t had that. I would say you learn something different every time.’ (Interview 17, male, Trust 1)

However, continuing care, although available in the longer term, was not always timely, as described here:

‘You need follow up. I was in [as an inpatient in hospital] for four weeks, then waited five weeks for an appointment with my follow-up worker. That’s a long time, and you could undo all the good that’d been done’. (Interview 32, male, Trust 2)

The view was also expressed that some facilities served too wide an area, and the suggestion was made that satellite resources should be available. Some participants also felt that some GPs were unsympathetic and lacked understanding and knowledge of alcohol problems. In discussing his experience of using acamprosate, one participant recounted the following:

‘It’s the GP I got it [acamprosate] from. I actually went to see, actually because I had been sober for six weeks he said, “Well if you have managed six weeks I think eh. . . .” I said, “Well I managed six weeks, but the six weeks have been sheer hell, it’s been dragging minute by minute, I have heard of this [acamprosate] and I want to give it a try.” . . . It was like dragging teeth to get them but at least I have got them now . . . They do help.’ (Interview 3, male, Trust 3)

Although some participants did feel that their GPs lacked sympathy and could appear ill-informed about the nature of alcohol dependence, many recounted very positive experiences where their GP had been very supportive and helpful. Several of them acknowledged that they had sometimes been ‘difficult patients’.

Given that many participants reported that one of the consequences of relapse was that they were likely to disengage with treatment agencies, the interviews sought to explore this issue further. Participants were asked what would happen if they missed an appointment for NHS treatment. All replied that they could telephone or write for another. Most said that the hospital would send another appointment or telephone them. However, a patient from one Trust described having walked out during a treatment session and required to be re-referred by his GP. In two of the Trusts, the referral system appeared to be open, whereas in the other referral seemed to be through the patient’s GP.

Participants were asked if they would regard receiving a reminder appointment or telephone call as intrusive. All participants said they felt that such actions on behalf of the service would be appropriate. Some did acknowledge that relapse could be a reason for non-attendance.
6.6 Views of service users obtained during consultation

The Assessment Report was subject to a period of open consultation (Slattery et al., 2002) and during this time views from service users, other than those included in the study commissioned by HTBS, were submitted.

Most of these service users had received treatment at a private residential facility in Scotland. Residential treatment was generally considered effective by these individuals: the support, discipline, one-to-ones, companionship in adversity and regular nutritious meals were all viewed as key aspects of residential care. There was concern regarding the length of wait for admission to such facilities and that the needs of service users with dependants should be considered. While residential treatment can be beneficial, it was recognised that it is not necessarily the only successful means of treatment.

Many people thought it was difficult for people who are alcohol dependent and their families to obtain information about available services. GPs were widely thought to regard alcohol dependence as a personal weakness rather than a ‘disease’ and as such were not thought to offer sufficient information to allow the service user to make an informed treatment choice.

Varying opinions were expressed regarding the effectiveness of disulfiram and acamprosate. Opinion also differed as to whether or not people with an addiction to drugs should be treated together with people who are dependent on alcohol.

There was perceived to be a stigma associated with people who are alcohol dependent. Some service users felt that this was exacerbated by the fact that alcohol treatment services are linked to mental health services. Others believed that it is appropriate to treat alcohol dependence within mental health services due to the underlying problems that can exacerbate the condition e.g. depression.

Appendix 20 summarises the responses to consultation questions pertaining to patient issues.

6.7 Range of treatment options

It is clear from the clinical studies that all interventions are of limited effectiveness or only work for a minority of patients. It is thus worth providing a range of options of proven efficacy. Treatment should be individualised taking account of service users’ expectations, needs and wishes with the understanding that these needs may change and the treatment plan may need to adapt to this. Flexibility is important in retaining engagement in the treatment system.

Improving the engagement of the individual in the treatment process is likely to lead to better completion rates and outcomes and can be facilitated by involving individuals in planning their own treatment programme and making treatment plans clear and explicit. Other factors such as engendering a positive relationship with the therapist and practical measures such as provision of transport to those who would otherwise not attend may improve engagement, although evidence is lacking in this area.
Keaney et al. (1995) reported the impact of interviewing service users prior to starting a programme for the prevention of relapse. The purpose of the interview was to provide information about the programme and to ask if they felt that it was likely to address their needs. The authors reported that this resulted in a highly statistically significant reduction in attrition. However, the results should be regarded with caution since there was no control group, and no mention of training to ensure consistency in interviewing techniques.

6.8 Awareness of alcohol-related services

There may be a lack of awareness of the range of services for people with alcohol-related problems in Scotland. Lancaster & Dudleston (2002) found there were low levels of awareness of organisations that provide help or advice for people with alcohol-related problems and even lower awareness of services for the families and friends of drinkers. They found that in most cases awareness and knowledge improved once contact had been made with the service.

This lack of awareness resulted in the local GP being most commonly named as a source of help and advice, and referral to counselling and psychologists, although many GPs are unaware of available sources of help (e.g. Councils on Alcohol). Additionally, Lancaster & Dudleston (2002) found most people were aware of AA, although their knowledge of its aims and the type of service it provided was limited. Only a few people were aware of other specific services.

Lancaster and Dudleston (2002) also reported a perception among the public in Scotland that there were more services for drug misuse than services for alcohol problems and that the drug misuse services were better promoted.

6.9 Communicating with patients

In reply to the HTBS survey, only 36% of NHS specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. This is mirrored in the views of service users (Section 6.6). It is recommended that such information should be available for all interventions to support discussions between service users and health professionals where appropriate.

AFS publish a variety of information leaflets for people concerned about their drinking and their family and friends, as well as a drink diary and self-help guide. The leaflets are distributed through the Councils on Alcohol and do not differentiate between dependence and misuse. They provide information to help people understand sensible drinking, identify if they have a problem or their drinking is harmful and promote sources of support and advice. Issues addressed include: women and alcohol; alcohol and older people; what children can do if they feel their parents drink too much; dual diagnosis; stress and how alcohol affects behaviour and the body. Examples are included in Appendix 10.

AA has numerous leaflets explaining its ethos and how it works and material has been developed to support those seeking abstinence. Some of these are aimed at specific
subgroups such as young people, prisoners and the armed forces. Additionally, Al-Anon, an organisation designed to complement AA by providing support to those close to problem drinkers, provides a variety of leaflets and books for the families, friends and carers of people who are alcohol dependent.

Written communication may not meet the needs of people with low reading skills or poor concentration. Information presented in cartoons or audio-visual format offer an alternative way of reinforcing and clarifying discussions between health professionals and these service users.

6.10 Conclusions

The patient issues reported have been identified primarily by the findings of a qualitative study commissioned by HTBS to explore service users’ treatment preferences, patient information leaflets, and a study entitled ‘Attitudes Towards Alcohol: Views of the General Public, Problem Drinkers, Alcohol Service Users and their Families and Friends’ (Lancaster & Dudleston, 2002). Additionally, feedback from service users during consultation on this report has highlighted key issues.

The key issues to emerge were in relation to method of treatment, treatment awareness and access, involvement in choice of treatment and follow up. Participants in the qualitative study valued activities such as Coping Skills, Assertiveness Training, rehearsing difficult situations within a safe environment, anger management, stress/anxiety management and relaxation exercises. Both group therapy and individual therapy were valued, the latter was especially valued for the depth of work it enables. Women who had experienced ‘women only’ group work had a preference for women only groups, but conversely men may have a preference for mixed group work.

Views about pharmacological interventions differed greatly. Some people identified a role for acamprosate in providing confidence about not being tempted to drink, while others doubted whether acamprosate reduced the sense of craving. However, those who felt the benefits were convinced. Most of the people who did not have experience of taking disulfiram said that this was because they would not trust themselves not to drink while taking it. Some people were concerned about the safety of pharmacological interventions and all who took these pharmacological interventions believed that pharmacological and psychosocial interventions were complementary.

All participants in the survey commissioned by HTBS recognised that AA works well for many people, but most of them felt that it was not suitable for them. However, AA was valued and used by some of the service users who contacted HTBS during consultation. Many of the service users who submitted comments during consultation especially valued residential services, while the qualitative study indicated that participation in residential or day case relapse services may currently depend more on the way services are structured locally, than patient choice.

A lack of awareness of different treatment and service providers among health professionals, potential service users and their families may hinder access to treatments.
Service users and their carers indicated that it was difficult to find out about different treatment options and Lancaster & Dudleston (2002) found that there was a low level of awareness of providers other than AA. Additionally, the qualitative study found that participants were unaware of terms such as Cognitive Behaviour Therapy and Motivational Enhancement Therapy. Access to services may also be increased through flexible opening times and a choice of venues. Additionally, study participants from one Trust area valued access to a local Helpline number that was offered to people when they were discharged from inpatient treatment.

A shared understanding and mutual agreement regarding the purpose of treatment is needed between a person who is alcohol dependent and his or her doctor. Greater awareness of treatments may help people with alcohol dependence and their doctors locate the most appropriate treatment option and, in turn, foster concordance. Regular review of this may be beneficial.

Finally, participants thought it was appropriate, rather than intrusive, for the health service to contact them and offer another appointment.
7 ECONOMIC EVALUATION

Summary

- An economic model shows that acamprosate, naltrexone and four psychosocial therapies are cost effective in comparison to a control treatment.

- Unsupervised oral disulfiram appears cost effective under base case assumptions but very wide confidence intervals for clinical effectiveness, including the possibility that it is not effective, make any decision on cost effectiveness unreliable.

- Supervised oral disulfiram reduces intake of alcohol. However, it is not known how this may relate to controlled drinking or abstinence and hence cost effectiveness could not be determined.

- The cost of a course of treatment is estimated to be £385 for each of the psychosocial therapies, £607 for acamprosate, £454 for naltrexone and £407 for supervised oral disulfiram.

- The results show that the four psychosocial therapies (Coping/Social Skills Training, Behavioural Self-Control Training, Motivational Enhancement Therapy and Marital/Family Therapy) each produce net savings of around £1600 per incremental abstinent patient. This means that adopting the intervention saves the NHSScotland £1600 per additional abstinent patient. These savings arise because the improved abstinence rate results in a lower incidence of diseases, thereby saving inpatient hospital stays and other disease-related costs. Further societal savings will also be realised, thereby further increasing the cost effectiveness of the therapies.

- Acamprosate is also cost saving, with a net saving of around £820 per incremental abstinent patient. Naltrexone has a small net cost per incremental abstinent patient of £1520 and oral supervised disulfiram would have a net cost of £4060 if it only achieved the mean estimated effectiveness of unsupervised disulfiram (a conservative assumption). All the therapies are therefore judged to be cost effective under the base case assumptions. Sensitivity analyses also show that the economic evaluation is robust to reasonable assumptions concerning treatment costs and effectiveness.

- A limitation, modelled in the sensitivity analysis, is the absence of data on relapse rates beyond the period of the clinical trials (3 – 12 months) and on different combinations of interventions. There are also concerns about generalising from trials to treating patients in Scottish settings. Further research is needed to give more definitive estimates of the long-term effectiveness of all the therapies in Scottish settings.

- The costing of the disease endpoints is limited because Scottish disease-related costs are not available. Using average functional costs may understate the cost of alcohol-related diseases and thus the cost effectiveness of the therapies. Moreover, research suggests there is under-reporting of the incidence of alcohol-related diseases, which could also result in an under-reporting of the total costs of alcohol-induced diseases.
7.1 Framework for an economic evaluation

Several guidelines for economic evaluations of health technologies are available, for example, Busse et al. (2002), Drummond et al. (1997) and Gold et al. (1996). HTBS has reviewed these and produced its own ‘Guidance to Manufacturers’ (Health Technology Board of Scotland, 2002) that highlights the main methodological issues to be addressed in the economic evaluations performed within the HTBS HTA framework.

Best practice recommends that economic evaluations adopt a societal perspective (Drummond & McGuire, 2001). Adopting a societal perspective means all changes in resource use, that is all changes to costs and outcomes, should be included in the economic evaluation. However, HTBS recognises that in an economic evaluation it may not be possible to quantify all the consequences or resources associated with such a wide perspective. Consequently, the base case of the economic evaluation should assess changes from the stance of NHSScotland, patients, families and carers, with quantification of other costs and consequences as far as possible (Health Technology Board of Scotland, 2002).

In October 2001, Scottish Executive published a comprehensive report prepared by Catalyst Health Economics Consultants Ltd (Catalyst Health Economics Consultants Ltd, 2001) that estimated the total societal costs associated with alcohol misuse in Scotland to be £1071 million, of which £96 million are health care costs. These costs are discussed in Section 7.4.1.

The target population for this HTA is people with alcohol dependence who have undergone detoxification and are newly abstinent. This group will give rise to some of the societal costs estimated in the Catalyst report. However, HTBS cannot quantify the societal costs identified in that report attributable to this subgroup. Rather, the economic evaluation models future health care and patient costs only, while noting that these costs are considerably lower than the costs to society.

7.2 Objectives

The objectives of the economic evaluation are to:

- review the existing literature on economic evaluations of individual therapies, or combination of therapies, that have the aim of reducing relapse in alcohol-dependent patients
- extract from the literature, data from studies that inform on possible economic models and the costs and outcomes of therapies
- develop a simple model that is valid for the Scottish population and health care system and to populate that model with Scottish cost and outcome data
- run the model to inform on the cost effectiveness of different therapies
- make due allowance for uncertainty in the model inputs and in the structure of the model by adopting sensitivity analysis
- interpret the results, to include the outcomes from the sensitivity analysis, in the context of answering the original HTA question.
7.3 Literature search

7.3.1 Search strategy

In 2001, the Centre for Reviews and Dissemination (CRD) in York undertook a search of electronic databases for the period 1990 to 2000 for cost-effectiveness literature. All economic evaluations were included and all identified studies were quality assessed using a standard checklist. The literature search was used to inform the section on the cost effectiveness of prevention of relapse in ‘Cost-effective Measures to Reduce Alcohol Misuse in Scotland’ (Ludbrook et al., 2001).

HTBS updated the CRD York database by searching the same range of databases and, where possible, starting from entries added to the databases from January 2000. To date, only one additional paper has been identified (Palmer et al., 2000), a modelling study reviewed in Section 7.4.6.

The list of databases is shown in Appendix 21. It includes the NHS Economic Evaluation Database (NHS EED), Health Economic Evaluations Database (HEED) and the web sites of leading health economics units.

A copy of the strategy used to search the Medline database is given in Appendix 22. This strategy was adapted to search the other databases. A complete listing of all strategies can be obtained by contacting HTBS.

7.3.2 Criteria for inclusion and exclusion of studies

The following exclusion criteria were applied when reviewing the economic literature search results:

- review articles not containing data on costs, outcomes or models
- studies not carried out in a population that might be broadly relevant to Scotland
- studies where it is not possible to disaggregate results of alcohol treatment from other addiction treatments.

7.3.3 Data extraction

Two main types of economic studies were identified in the review. First, some studies have attempted to collect data on costs and effectiveness concurrently. These studies have focused on short-term economic consequences, such as changes in health care costs before and after treatment. In this first category, most studies fail even a minimum quality criterion (Ludbrook et al., 2001) and are not considered further in this Assessment. The second type of economic study has used modelling techniques drawing data from a number of sources to estimate the longer-term consequences of alcohol-related problems, for example, the development of liver cirrhosis.
The three key studies used in the economic modelling are of this second type and are described in the following sections, with formal data extractions for each presented in Appendix 23.

7.4 Economic model of prevention of relapse for alcohol patients

7.4.1 Overview of the cost to society of alcohol misuse: in Scotland

There is substantial evidence that alcohol-related ill health gives rise to considerable costs to the NHS (Mckenna et al., 1996). Moreover, considerably greater costs fall on society as a result of alcohol misuse. In October 2001, Catalyst Health Economics Consultants Ltd quantified the annual societal cost of alcohol misuse in Scotland to be £1071 million (Catalyst Health Economics Consultants Ltd, 2001).

This sum comprised costs to NHSScotland (£96 million), costs to the social work services and associated organisations (£86 million), costs to the criminal justice system and emergency services (£268 million), wider economic costs from absenteeism and premature mortality but not reduced productivity in the workplace (£404 million) and premature mortality in the non-working population (£217 million). Thus, health care costs are estimated to form only 9% of the costs to society arising from alcohol misuse.

Table 7-1 reproduces the analysis of health service resource use in Scotland from the Catalyst document (Catalyst Health Economics Consultants Ltd, 2001).
### Table 7-1 Annual NHSScotland costs of alcohol misuse at 2001/2002 prices
(Reproduced with permission of Catalyst Health Economics Consultants Limited)

<table>
<thead>
<tr>
<th>Health service resource use associated with:</th>
<th>Annual resource use</th>
<th>Annual cost (£ million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP consultations</td>
<td>211,516</td>
<td>3.6</td>
</tr>
<tr>
<td>GP-prescribed drugs</td>
<td>6% of drugs prescribed by GPs for substance dependence</td>
<td>0.2</td>
</tr>
<tr>
<td>Consultations with practice and district nurses and health visitors</td>
<td>No information currently recorded. Unable to quantify</td>
<td></td>
</tr>
<tr>
<td>Laboratory tests</td>
<td>147,256</td>
<td>1.8</td>
</tr>
<tr>
<td>Hospitalisation days</td>
<td>275,775</td>
<td>54.3</td>
</tr>
<tr>
<td>Accident and emergency attendances</td>
<td>187,951</td>
<td>9.6</td>
</tr>
<tr>
<td>Outpatient visits</td>
<td>93,999</td>
<td>8.1</td>
</tr>
<tr>
<td>Day hospital attendances</td>
<td>44,800</td>
<td>3.1</td>
</tr>
<tr>
<td>Community psychiatric team visits</td>
<td>8% of total community psychiatric team expenditure</td>
<td>4.0</td>
</tr>
<tr>
<td>Ambulance journeys</td>
<td>64,382</td>
<td>9.1</td>
</tr>
<tr>
<td>Health promotion/prevention by Health Education Board for Scotland (HEBS)</td>
<td>HEBS, Drinkwise, Alcohol Development Officers</td>
<td>1.2</td>
</tr>
<tr>
<td>NHS Board expenditure to alcohol-related voluntary organisations</td>
<td>Funding to 25 organisations</td>
<td>0.6</td>
</tr>
<tr>
<td>Total for NHS Scotland</td>
<td></td>
<td>95.6</td>
</tr>
</tbody>
</table>

In summary, the Catalyst report showed that 57% of the NHSScotland costs of alcohol misuse arise from the occupation of hospital beds to treat alcohol-related diseases, with a further 20% arising from ambulance journeys and attendance at A&E units.

A similar view of the cost of alcohol misuse for the health service is provided in the July 2000 GGHB consultation document on its alcohol strategy (Greater Glasgow Health Board, 2000). The document noted that alcohol misuse accounts for probably 8 – 15% of attendances at A&E units and about 13% of acute psychiatric admissions. The document also noted that alcohol-related admission rates to general hospitals had risen by 278% between 1981 and 1997.

A study of the economic costs of alcohol misuse in the Lanarkshire NHS Board area in 1999 (Brown et al., 2001) identified, measured, and where possible valued, the cost of alcohol misuse in Lanarkshire. The results indicated that in 1999 between 128 and 200 alcohol-specific deaths occurred and that the total cost of alcohol misuse in Lanarkshire was between £31 million and £49 million, of which £6 million to £10.5 million arise from health and social services costs. Approximately 11% of the Scottish population live in Lanarkshire.

In a response to the HTBS consultation document (Slattery et al., 2002), Dr Bell from the Argyll and Clyde NHS Board (Dr D. Bell, Consultant in Public Health Medicine (Addictions) with NHS Argyll & Clyde NHS Board, personal communication, September 2002) noted that a study by that Board indicated the costs to NHSScotland might be understated in the Catalyst study. The Board’s study of the costs of dealing with alcohol...
problems in NHSScotland Argyll and Clyde hospitals and the ambulance services only, in the year 2000, was estimated at £19 million (Director of Public Health, 2002). Note that 8.3% of the Scottish population live in the Argyll and Clyde NHS Board area.

The response suggested a prime reason for the understatement of costs in the Catalyst study could be the use of average costs by speciality function. For example, when costing inpatient episodes of alcoholic liver disease, Catalyst applied an average medical inpatient cost per day of but this may not be appropriate for patients in liver wards. Using these average functional costs is necessary in the absence of disease-related costs.

Argyll and Clyde offered to give HTBS access to discharge data in order to quantify this effect. This has not proved possible to do in the timescale but would be a very worthwhile exercise. Section 9.2 of this document recommends research is undertaken to make available Scottish disease-related costs.

7.4.2 Overview of the economics of prevention of relapse: international studies

International studies have shown that other countries including Germany, Sweden and USA also face considerable costs to their societies from abuse of alcohol. (National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism, 1998);(Brecht et al., 1996);(Andreasson et al., 2001). For example, the National Institute on Drug Abuse in the USA undertook a major review of the economic costs of alcohol and drug use in the States in 1992 (National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism, 1998). The study concluded that in 1992 the costs of treatment for health problems attributable to alcohol abuse were $13.2 billion, rising to $18.8 billion with the inclusion of treatment costs for alcohol dependence, representing 13% of the economic costs to society from alcohol abuse.

These studies also show that the benefits in terms of future costs avoided from successful alcohol treatment extend beyond the initial improvements in health and quality of life for patients. For example, successfully treated patients have also been shown to reduce their utilisation of health care resources in general (Parthasarathy et al., 2001). The study reviewed existing published studies and noted that these estimated a reduction in the use of health care resources, following treatment of patients with alcohol disorders, ranging from 26% – 69%, with a median of 40%. The reduction in health care costs ranged from $0.41 – $1.10 for every dollar spent on treatment. The paper also noted that the research informing these results had several limitations, including that most research was conducted prior to the widespread change from inpatient to outpatient treatment.

The Parthasarathy et al. (2001) study analysed the use that 1011 patients made of outpatient and inpatient health care services 18 months before and 18 months after entering the Chemical Dependency Recovery Programme at the Sacramento Kaiser Permanente facility. Costs for the provision of the services were mainly from an internal accounting system.
The results of the analysis were that, following treatment, there was a 26% reduction in total medical costs, with a 35% and 39% reduction in inpatient and emergency unit costs, respectively.

Other older studies are summarised in Ludbrook et al. (2001).

7.4.3 Economic evaluation technique

Economic evaluation has been defined as ‘the comparative analysis of alternative courses of action in terms of both their costs and consequences’ (Drummond & McGuire, 2001). An economic evaluation thus requires the identification, measurement, valuation and comparison of the costs and outcomes of the alternatives being considered, from a stated perspective and over a relevant time horizon. In the following sections, costs and benefits are evaluated from the perspective of the relevant health care system and the patient.

The outcome under review is prevention of relapse, measured in terms of patients who are abstinent or have controlled drinking, consistent with the definition applied for clinical effectiveness (Section 5.6) No robust estimates of the utility values of health states to apply to people who are alcohol dependent have been found from the literature. It is thus not possible to use a utility-based outcome such as quality adjusted life years (QALYs).

7.4.4 Published and submitted economic models

The literature search revealed that two forms of economic model have been used to model the cost effectiveness of strategies for the prevention of relapse in alcohol dependence. The first form is a static decision tree model as adopted by Schadlich and Brecht (1998). This model is based on a cohort of patients entering treatment and then experiencing a range of endpoints with different probabilities. Those who were successfully abstinent at the end of treatment were assumed to be free of the risk of alcohol-related diseases. Those unsuccessful at the end of treatment were assumed to have a fixed probability of various alcohol-related disease endpoints.

The second form of model is a dynamic Markov model, used by Annesmans et al. (2000). In this model, patients move between different alcohol-related treatment regimes across time in a fashion determined by transition probabilities.

The identified studies are reviewed in Sections 7.4.5, 7.4.6, 7.4.7 and 7.4.8 in terms of their model structure and the data employed.

7.4.5 Schadlich and Brecht model

The original Schadlich and Brecht model (1998) investigated the incremental costs per additional abstinent patient from taking acamprosate compared with standard care. The economic evaluation was a cost-effectiveness analysis from the perspective of the German health care system, concentrating on the disease costs. The analysis excluded health care treatment costs arising from accidents and all productivity costs were also excluded.
The clinical effectiveness data came from a RCT study of patients at 12 outpatient centres in Germany (Sass, 1996b). All patients in the trial met at least five of the DSM criteria for alcohol dependence and had to be completely abstinent from any alcohol consumption for 14 to 28 days before entry into the trial. In the trial, patients received acamprosate or placebo for 48 weeks in addition to routine counselling. The patients were followed up for a further 48 weeks without medication.

The measured health outcome was abstinence in the 48-week follow-up period but there was no reported definition of abstinence. The analysis stated that at the end of the 48-week medication-free period, 39.9% of the 136 acamprosate-treated patients and 17.3% of the placebo-treated patients had remained abstinent.

The model included epidemiology data, to incorporate frequency of disease events per person, obtained from records of the disease course of patients with alcohol dependence in West Germany, and expert opinion. The medical and rehabilitation inpatient days and associated costs were obtained from official sources.

The model used a three-stage decision tree analysis and is reproduced in Figure 7-1 for a sample of 1000 patients. The first step was to model the relapse and abstinence rates for two cohorts of patients, one group having had acamprosate in conjunction with the standard care and the second group having the standard care only. The second stage of the model was to calculate the disease events for patients in each of the two cohorts. Five disease states were considered: alcoholic psychoses; alcohol dependence syndrome; alcohol fatty liver; acute alcoholic hepatitis and liver cirrhosis. The third stage of the model was to cost the treatments for each cohort, to include the cost of acamprosate and to compare the costs of the two cohorts to derive the incremental costs avoided from using acamprosate.

The results, based on 1000 hypothetical patients, are presented in Table 7-2.

**Table 7-2 Cost savings of acamprosate (per 1000 patients)**

<table>
<thead>
<tr>
<th></th>
<th>DM 000s</th>
<th>£000s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment cost for acamprosate group</td>
<td>7333</td>
<td>2317</td>
</tr>
<tr>
<td>Treatment cost for placebo group</td>
<td>10090</td>
<td>3188</td>
</tr>
<tr>
<td>Cost of acamprosate</td>
<td>2170</td>
<td>685</td>
</tr>
<tr>
<td>Cost saving of acamprosate</td>
<td>587</td>
<td>186</td>
</tr>
<tr>
<td>Cost saving per marginal abstinent patient</td>
<td>2.6</td>
<td>0.823</td>
</tr>
</tbody>
</table>

*Number of additional abstinent patients in acamprosate group = 226

The total cost avoided per additional abstinent patient in the acamprosate group (obtained by dividing the cost savings from using acamprosate £186 000, by the number of additional abstinent patients 226) was £823.
Figure 7-1 Decision tree for evaluation of acamprosate

1000 patients

Adjuvant acamprosate therapy

p=0.399
399 patients abstained

p=0.601
601 patients relapsed

ICD 291
Alcoholic psychoses
90 cases

p=0.15
10 years

ICD 303
Alcohol dependence syndrome
601 cases

p=1
4 years

ICD 571.0
Alcoholic fatty liver
301 cases

ICD 571.1
Acute alcoholic hepatitis
150 cases

p=0.5
5 years

ICD 571.2
Alcoholic liver cirrhosis
75 cases

p=0.5
10 years

p=0.5
3 years

1000 patients

p=0.5

ICD 571.0
Alcoholic fatty liver
414 cases

ICD 571.1
Acute alcoholic hepatitis
207 cases

p=0.5
5 years

ICD 571.2
Alcoholic liver cirrhosis
103 cases

p=0.5
10 years

p=0.5
3 years

ICD 571.0
Alcoholic fatty liver
173 patients abstained

ICD 571.1
Acute alcoholic hepatitis
827 patients relapsed

ICD 571.2
Alcoholic liver cirrhosis
124 cases

p=0.15
4 years

p=0.173
827 cases

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7.4.6 Palmer Model

Palmer et al. (2000) developed the Schadlich and Brecht model to include both a wider range of disease states and also mortality from these diseases. The model consisted of a number of submodels to model the specific disease costs and the mortality from the different diseases. The model tested whether using acamprosate in conjunction with standard counselling would reduce the incidence and progression of diseases arising from alcoholism and be cost effective in comparison with the standard care package.

The Palmer et al. (2000) model applied incremental cost-effectiveness analysis for a German male cohort with an average age of 41 years. The model assumed that 80% of the cohort presented with fatty liver, 15% with cirrhosis, 22% with pancreatitis and 1% with alcoholic cardiomyopathy when entering the model. Disease progression was modelled using a Markov chain with probabilities of progression/regression between the states being derived from a literature search. Only direct medical costs were considered.

Palmer et al. developed a separate Markov model for each major disease state (liver disease, gastrointestinal, alcoholic cardiomyopathy and other complications to include suicide and accidental death). The results in Table 7-3 show lifetime costs per patient of £15,244 for the acamprosate group, saving £524 per patient in comparison with the placebo group.

Table 7-3: Lifetime costs per patient

<table>
<thead>
<tr>
<th></th>
<th>DM</th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group with acamprosate</td>
<td>48,245</td>
<td>15,244</td>
</tr>
<tr>
<td>Placebo group</td>
<td>49,907</td>
<td>15,768</td>
</tr>
<tr>
<td>Difference</td>
<td>1,662</td>
<td>524</td>
</tr>
</tbody>
</table>

From a base case of 41 years, life expectancy increased from 14.70 to 15.90 years with acamprosate, a life year gain of 1.2 years (undiscounted), or 0.52 life years gained when discounted at 5% per annum.

7.4.7 Annemans et al. model

Annemans et al. (2000) used a Markov model to investigate flows of patients through different alcohol-related treatments, and compared the cost effectiveness of acamprosate in preventing alcohol relapse with no pharmacological treatment, over a 24-month period and from the Belgian health care perspective. Only direct medical costs were used and these were sourced from official statistics and a survey of GPs.

A Markov model was developed to model the movement of patients between six different health states. The six states were:

- community follow up after detoxification
- community detoxification
- hospital detoxification
- hospital follow up after detoxification
• lost to follow up
• death.

Relapse rates were taken from a placebo-controlled prospective trial of 448 patients in Belgium, while details of treatment following relapse were taken from an unpublished Belgian study. Effectiveness of inpatient and outpatient detoxification was taken from Hayashida (1989) who compared 87 outpatient and 77 inpatient detoxifications, which showed a 66% success rate for outpatients compared with 81% for inpatients.

The data were entered into the Markov model and the costs of treatment and future health care costs applied. The model then predicted how the average patient would progress over 24 months.

In the Annemans model, the expected cost of the acamprosate strategy in Belgian Francs (BEF), to include drug costs, was 211,986 BEF (£3193) compared with 233,287 BEF (£3514) for the no acamprosate treatment arm. Although the cost of acamprosate treatment over the 24-month period was 34,712 BEF (£522) compared with the placebo-treated population, cost savings through a lower rate of acute hospitalisation, lower long-term hospitalisation and fewer liver complications resulted in a net cost saving from treatment of around 213,100 BEF (£320) per patient.

The sensitivity analysis included adjusting several of the unit costs. The authors reported that the cost of acute hospitalisation would need to be 50% lower than in the model before the acamprosate treatment ceased to be cost saving.

The authors conclude that if 30% of patients reporting to their GPs with an alcohol problem were to be detoxified and started on acamprosate, the total net saving would be 220 million BEF, equivalent to £3314 139 over two years.

7.4.8 Merck model

pH Consulting developed a hybrid of the Schadlich and Brecht and Annemans et al. models to investigate the effectiveness of managing alcohol abuse through acamprosate. Dr A Walker added Scottish cost data to the pH Consulting model and the resulting model is referred to as ‘the Merck model’ (Walker, 2001).

The Merck model adapted some of the data inputs applied in the Schadlich and Brecht model for Scottish conditions. For example, Scottish hospital bed costs were applied to German hospital bed stay days for the four diseases of alcoholic psychoses, alcohol dependence syndrome, acute alcoholic hepatitis and liver cirrhosis. The Merck model removed any resource costs for inpatient rehabilitation because, according to the author, a Scottish patient care pathway seldom makes provision for such care. The author also noted that German epidemiological data were used because no Scottish epidemiological data were available.
The Merck model applied abstinence rate data from one German and one Austrian study (Whitworth et al., 1996); (Sass, 1996a). The abstinence rates applied are presented in Table 7-4.

### Table 7-4 Abstinence rates after 24 months

<table>
<thead>
<tr>
<th></th>
<th>Acamprosate (%)</th>
<th>Placebo (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sass ( (n=104)^* )</td>
<td>39</td>
<td>17</td>
</tr>
<tr>
<td>Whitworth ( (n=148) )</td>
<td>11.9</td>
<td>4.9</td>
</tr>
</tbody>
</table>

*This study is also used by Schadlich and Brecht in their model.*

The Merck model did not include data from the UK trial on acamprosate undertaken by Chick et al. (2000). The UK trial did not find any difference in abstinence rates following the use of acamprosate in comparison with standard care. The Merck report stated that the UK trial was not included because patients were given acamprosate with some delay following detoxification, which is inconsistent with the protocol. The latter specifies that the drug should be used as soon as possible after detoxification.

The Merck model allowed for short-term savings from reduced community and hospital follow up and reduced detoxification costs, adapting the different care pathways from the Annemans et al. study of a Belgian trial of 448 patients (Annemans et al., 2000).

The results of the Merck model are presented in Table 7-5.

### Table 7-5 Mean cost effectiveness of acamprosate (1000 patients)

<table>
<thead>
<tr>
<th></th>
<th>£000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of acamprosate</td>
<td>373.7</td>
</tr>
<tr>
<td>Short-term savings from reduced detoxification</td>
<td>(186.6)</td>
</tr>
<tr>
<td>Long-term savings from avoided disease conditions</td>
<td>(537.0)</td>
</tr>
<tr>
<td>Net cost saving</td>
<td>(349.9)</td>
</tr>
<tr>
<td>Cost saving per marginal abstinent patient *</td>
<td>1.841</td>
</tr>
</tbody>
</table>

*Number of additional abstinent patients = 190

The Merck model concluded that, under the base case assumptions, to include the clinical effectiveness of acamprosate, there would be cost savings to the NHS of using the drug. These cost savings, resulting from avoided repeat detoxifications and fewer incidences of liver and mental health diseases, exceeded the initial cost of prescribing the drug.

### 7.5 Summary of results

The results of the four models are summarised in Table 7-6.
Table 7-6 Summary of results from economic models

<table>
<thead>
<tr>
<th>Study</th>
<th>Cost saving per patient from acamprosate £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schadlich and Brecht</td>
<td>823</td>
</tr>
<tr>
<td>Merck</td>
<td>1841</td>
</tr>
<tr>
<td>Annemans</td>
<td>320</td>
</tr>
<tr>
<td>Palmer</td>
<td>524</td>
</tr>
</tbody>
</table>

The Merck model realised the greatest savings because it aggregated the effects found by Schadlich and Brecht and Annemans and assumed all the benefits could be attributed to one application of the drug.

7.6 Model limitations

Models can be validated by considering how well each model performs in respect of three major groups of attributes; these being structure, data and validation (ISPOR, 2001). The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) set out 13 attributes concerning model structure, 17 concerning data identification, data modelling and data incorporation and six validation attributes. This economic evaluation has not rigorously examined each model for each key attribute. Rather the limitations notified by the original authors and by others critiquing the studies, for example in the Scottish Executive report on alcohol misuse (Ludbrook et al., 2001), have been noted.

The limitations that apply to all the aforementioned models include:

- the assumption that abstinence rates are maintained at the value observed at the end of the trial period
- lack of clarity about the definition of the abstinence outcome
- model specification of ‘lost to follow up’ and incomplete disease and treatment states
- use of average costs determined for insurance or administration purposes
- absence of opportunity costs and non-medical costs relating to community care, crime, accidents, productivity etc.
- application of data from different sources and often different countries into the same model with no correction for these differences
- absence of probability distributions around costs and epidemiology data
- exclusion of trial data that show no difference in the abstinence rates following the adoption of acamprosate (Chick et al., 2000) and (Roussaux et al., 1996)
- absence of any revealed preference data.

More research is needed in particular to provide more definite estimates of:

- long-term effectiveness of all the therapies
- incidence and prevalence of alcohol-related diseases
- relevant Scottish costs of these diseases.
7.7 HTBS economic model

The HTBS economic evaluation adopts the Schadlich and Brecht model as a basis, as this provides a simple but useful approach to structuring the evidence on clinical and economic outcomes.

The Schadlich and Brecht model only sought to measure the marginal costs and outcomes of adopting acamprosate as an adjunct to counselling or psychotherapy according to the routine practices of the participating centres. This HTBS economic evaluation extends the analysis to consider the changes to costs and outcomes following the adoption of the following pharmacological and psychosocial therapies:

- acamprosate
- naltrexone
- disulfiram
- Coping/Social Skills Training
- BSCT
- MET
- Marital/Family Therapy.

The HTBS model also adopts more disease endpoints than the Schadlich and Brecht model. However, the model still has many of the limitations identified in Section 7.6. The implications of these limitations are addressed in Section 7.14. In particular, the costings will be from an NHSScotland and patient viewpoint rather than a societal perspective (see Section 7.2). This limitation has, in part, been addressed by the quantification of the societal costs from the Catalyst Economics report for the Scottish Executive (Catalyst Health Economics Consultants Ltd, 2001). However, the assumption will result in an understatement of costs, omitting to capture disease-related costs incurred in private sector hospitals, nursing homes, and social work costs, to include rehabilitation services and residential care.

Most costs in the economic model are average costs collected for administrative purposes and thus include components such as overheads. The model adopts a 20-year time horizon. Given the long-term horizon of the economic evaluation, the average costs may be a reasonable approximation to long run incremental costs (see Section 7.8).

No utility data are available to enable the model to be enhanced to measure outcomes in terms of QALYs. Thus, in the absence of observed or estimated data on utilities for people who are alcohol dependent, it will not be possible to include utility measures or QALYs within this economic evaluation. The model will adopt the clinical effectiveness measure of outcome, that being the number of patients who have abstained or have controlled drinking.

A study by Patience et al. (1997) did report data from a study of 212 patients who had contacted an alcohol problem clinic 12 months previously. The report explained that the results of an Alcohol-Related Problem Questionnaire could be used to map drinking
behaviour onto a quality of life score (Short Form [SF]-36) and act as a marker for quality of life.

The Merck submission noted that a literature search found no utility measurements for alcohol-related health states (Walker, 2001). The author attempted to infer utility scores from the available SF-36 information obtained from the study by Patience et al. This approach has some shortcomings including that neither the alcohol questionnaire nor the SF-36 score measures individuals’ preferences. Brazier et al. (2002) published a potential technique to move from observed SF-36 scores to utility scores, but as the paper notes, this research is at a very early stage.

7.8 Costings for the economic model

Costing for economic evaluations should identify, measure and value all resource changes that occur as a certain health intervention is carried out. The categories of costs identified by Brouwer, Rutten and Koomanschap in Chapter 4 of the book by Drummond & McGuire, (2001) are:

- medical resources directly needed for the intervention
- non-medical resources needed for the intervention
- patient time, including productivity changes
- time of informal caregivers and other costs of informal care
- future medical costs that are a consequence of the intervention.

Due to the perspective adopted, a subset of the cost groups identified in Brouwer, Rutten and Koomanschap is quantified:

- resources directly needed to pay for the intervention
- future changes to NHSScotland medical costs that are a consequence of the intervention
- cost of patient travel.

Brouwer et al. (2001) explain that the decision on whether to use marginal or average cost depends on the research question. They note that when longer-term cost consequences are being considered then average costs may be more appropriate because many cost items that are fixed in the short term may become variable in the long term. The authors also state that, in general, the resources used should be valued at their opportunity costs, being the value of their best alternative use. This will usually be the observed price where there are competitive markets, however in health care there is often no market price that reflects the opportunity cost.

This economic model requires two major categories of costs: the costs of the psychosocial and pharmacological therapies for the prevention of relapse in alcohol dependence and the disease-related costs. The following sections explain the method used to estimate each category.
7.8.1 Cost of psychosocial interventions

Following discussions with a TSG member (Dr C Keogh, Consultant Clinical Psychologist, personal communication, 17 April 2002) and Ms M O’Sullivan, (Ms M O’Sullivan, Day Hospital Manager, Alcohol and Drug Directorate, Parkhead Hospital, Personal communication, 13 May 2002) it was decided that the costs of delivering a programme for psychosocial therapies vary with the structure and duration of the course, rather than according to the type of psychosocial therapy.

The costings shown in Table 7-7 for psychosocial therapies have thus been developed for three different, but commonly used courses:

- a group course with a six-week duration, consisting of one two-hour session per week with follow-up
- a group course over four weeks with daily sessions of one and a half hours duration with follow-up
- ten hourly one-to-one sessions.

An allowance for supervision is included in the costings for all the courses since such a function is regarded as essential to ensure standards are maintained and the courses comply with ‘best practice’ as defined for that location.

The first course format is used in several parts of Scotland and is based on a programme devised by Annis et al. (1996). This course is delivered at weekly two-hour sessions (one and a half hours of group work plus 30 minutes for one-to-one work), for invited groups of 9 – 14, for six weeks, with three-month and six-month follow up. Not all invitees complete the course. The costs assume a range of 6 – 9 attendees.

The costed staff input is: one psychologist (although other parts of Scotland use different levels of professional input), one Grade G CPN and one trainee/student for three hours on a weekly basis. Staff costs are calculated assuming average staff costs plus 40% on-costs, averaged over 1760 annualised hours. No costs are included for the trainee/student who usually attends as an observer as part of a therapy programme. Time is allowed for set up, travelling, administration and a supervisory element per session. The accommodation costs are assumed to be £15 per session to hire a community hall for three hours plus £5 administration costs.

The second course costed is over four weeks, providing one and a half hours of group work plus a 30 minute set-up, administration and supervision time (i.e. two hours) per day, five days a week, with two further follow-up periods of the same duration. This course is delivered to a similar group size by two staff, coming from a mix of staff to include F and E grade nurses, a senior occupational therapist, together with consultant-level support. Staff costs are calculated using scale midpoints, 40% on-costs and 1760 annualised hours. The accommodation costs of £550 per course are calculated by applying the relevant rates from ‘Scottish Health Service Costs’ to an area of 100 m².
The third option costed is a one-to-one therapy session for ten hours, (15 hours, including preparation, administration time and some supervisory element) with a grade G nurse. No marginal accommodation costs are included for this option because it is assumed accommodation provided for other purposes will be usable at nil additional cost.

All course materials are assumed to cost £10,000 to produce and to be used for five years. This has been annualised using the 6% financial discount rate, to yield a cost per person of £10. Administration costs are assumed to be £10 per invited attendee.

The costs per course for the three models are summarised in Table 7-7.

<table>
<thead>
<tr>
<th></th>
<th>Model A £</th>
<th>Model B £</th>
<th>Model C £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>1040</td>
<td>1800</td>
<td>250</td>
</tr>
<tr>
<td>Accommodation (non-residential)</td>
<td>160</td>
<td>550</td>
<td>0</td>
</tr>
<tr>
<td>Administration and manual</td>
<td>350</td>
<td>290</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>1550</td>
<td>2640</td>
<td>280</td>
</tr>
<tr>
<td>Cost per attendee</td>
<td>175 – 260</td>
<td>295 – 440</td>
<td>280 (one attendee)</td>
</tr>
</tbody>
</table>

These costs are all reasonably similar, with the main determinant being number of attendees and the drop-out rate. To avoid spurious accuracy, all the psychosocial course delivery modes have been assumed to have a mean cost of £300 per person. This value is similar to the cost estimate of £270 per person per intervention provided by a PCT, (personal communication in confidence, 18 September 2002).

In addition, it is assumed that each attendee has a 30-minute consultation with a specialist. The Scottish Health Services Costs 2000/01 (Information and Statistics Division National Health Service in Scotland, 2001) provides a net cost of £57 per attendance with a clinical psychologist in 2000/01 prices, which is equivalent to £60 per attendance in 2002 prices.

The attendee will incur costs to attend the course. These are assessed at an average cost per service user of £2 per visit, using public transport, with an average of 12 visits per course. The total cost is thus £300 for the intervention plus £60 for a consultation plus £24 per person for travelling expenses, or rounded to £385 per person.

7.8.1.1 Sensitivity analysis

Sensitivity analysis is necessary to test the sensitivity of the results to uncertainty arising from the use of single point estimates for each key cost and health outcome measure. The central cost estimate of these therapies thus needs to be augmented by high and low values.
The high cost estimates are calculated on the basis recommended by Ms B Graham, ISD, in her response to the consultation document (Slattery et al., 2002). The respondent noted that the Scottish Health Services Costs 2000/01 (Information and Statistics Division National Health Service in Scotland, 2001) reported costs relevant to this economic evaluation. For example, the reported cost of a visit from a member of the community psychiatric team was £74 per contact.

The high cost estimates are calculated using these reported costs, updated by 5% for intervening inflation. The resultant average cost per service user of the three courses ranges from £500 for course A, assuming nine attendees, to £1280 for course B with six attendees. The mean cost is £900 per service user and this has been adopted. In addition, travel time and an initial consultation cost are added, to give a total cost of £980 per attendee.

A low estimate of £250 has been used. This is equivalent to delivering a course with one staff member with some support and supervision. It has been assumed that it is improbable that effective courses can be delivered at a cost lower than this. No travel cost is assumed for the low cost but an initial consultation cost of £60 is added to the base case costs.

The costs used in the model for psychosocial therapies are:

- low £310 per service user
- mean £385 per service user
- high £980 per service user.

**7.8.2 Cost of pharmacological therapies**

The patient pathways for the treatment programmes of acamprosate and supervised oral disulfiram are presented in Figure 7-2 and Figure 7-3 and were provided by the Alcohol and Drug Directorate South and Alcohol and Drug Directorate West, respectively. TSG members advised on the naltrexone patient pathway (TSG meeting, 10 June 2002).

The resource units, unit costs and total costs of the three drug treatment programmes are contained in Table 7-8, Table 7-9 and Table 7-10. The resources used are derived from the patient pathways. All patients receiving any drug are assumed to have a 30-minute specialised consultation.
Table 7-8  Resource uses and costs: acamprosate 12 months treatment per patient
May 2002 prices

<table>
<thead>
<tr>
<th>Resource</th>
<th>Unit cost £</th>
<th>Total costs £</th>
<th>Source of costings</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-minute specialist NHS consultation</td>
<td>60.00</td>
<td>60.00</td>
<td>Scottish Health Service Costs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2000/2001 Clinical Psychology £57 per attendance plus inflation.</td>
</tr>
<tr>
<td>First consultation</td>
<td>20.15</td>
<td>20.15</td>
<td>Dr 15 mins and CPN 15 mins at salary of £24370, times 1.4 divided by 1760 hours</td>
</tr>
<tr>
<td>Second consultation</td>
<td>15.05</td>
<td>15.05</td>
<td>Dr 10 mins and CPN 15 mins and Dr 15 mins and CPN 15mins</td>
</tr>
<tr>
<td>Third consultation</td>
<td>20.15</td>
<td>35.20</td>
<td>Dr 10 mins and CPN 15 mins and Dr 15 mins and CPN 15mins</td>
</tr>
<tr>
<td>Monthly consultation CPN then Dr</td>
<td>4.85</td>
<td>65.05</td>
<td>CPN 15 mins and Dr 10 mins</td>
</tr>
<tr>
<td>90% at six tablets per day</td>
<td></td>
<td>410.67</td>
<td>BNFb 43 –7% +95p per prescription + 10 mins GP visit alternate months</td>
</tr>
<tr>
<td>10% at four tablets a day</td>
<td></td>
<td>293.80</td>
<td></td>
</tr>
<tr>
<td>Total costs assuming 90% on six tablets</td>
<td></td>
<td>579</td>
<td>14 visits at £2 each</td>
</tr>
<tr>
<td>Plus service user travel time</td>
<td></td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Grand total</td>
<td></td>
<td>607</td>
<td></td>
</tr>
</tbody>
</table>

a A clinical psychologist has been costed; if in some areas a psychiatrist delivers this service then the equivalent cost from the same source is £75 per attendance.


If patients fail to respond to the drug intervention then doctors will cease prescribing the drug. The average cost for a cohort of 1000 patients is thus not £607 x 1000 but rather is profiled as people drop out. The economic evaluation assumes patients drop out of pharmacological treatments monthly, until, by the end of the 12-month treatment period, only the number of patients implied by the clinical effectiveness plus 20% remain. The 20% margin is used to allow for non-compliance rates. Under this assumption, the average cost of acamprosate over a year is £385 per patient.
Table 7-9: Resource uses and costs: disulfiram for six months treatment per patient
May 2002 prices

<table>
<thead>
<tr>
<th>Resource</th>
<th>Unit cost (£)</th>
<th>Total costs (£)</th>
<th>Source of costings</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-minute specialist NHS consultation</td>
<td>60.00</td>
<td>60.00</td>
<td>Scottish Health Service Costs 2000/2001 Clinical Psychology £57 plus inflation</td>
</tr>
<tr>
<td>Medical and bloods</td>
<td>30+15.30</td>
<td>45.30</td>
<td>NHSScotland</td>
</tr>
<tr>
<td>Week 1 visits to Alcohol Problems Treatment Unit (APTU)</td>
<td>4.85</td>
<td>33.95</td>
<td>As above</td>
</tr>
<tr>
<td>Six monthly visits to keyworker</td>
<td>4.85</td>
<td>29.08</td>
<td>As above</td>
</tr>
<tr>
<td>Blood test + check up month 1</td>
<td>30+15.30</td>
<td>45.30</td>
<td>As above</td>
</tr>
<tr>
<td>Five monthly GP visits</td>
<td>15.30</td>
<td>76.50</td>
<td>NHSScotland</td>
</tr>
<tr>
<td>25 weeks of three per week 10-minute supervision at APTU 15% supervised</td>
<td>1.59</td>
<td>22.02</td>
<td>Assumes supervision cost of £12 000 multiplied by 1.4 per annum and 1760 hours</td>
</tr>
<tr>
<td>25 weeks of six tablets per week + one week of eight tablets</td>
<td>18.38 for 50</td>
<td>54.93</td>
<td>BNF 43 –7% +95p per prescription + 6 10 mins GP visit</td>
</tr>
<tr>
<td>Total costs</td>
<td></td>
<td>367</td>
<td>20 journeys at £2 each</td>
</tr>
<tr>
<td>Plus service user travel time</td>
<td></td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Grand Total</td>
<td></td>
<td>407</td>
<td></td>
</tr>
</tbody>
</table>

Phasing out the use of disulfiram and other monthly costs as patients relapse gives an average cost per patient of £358 over six months. This includes supervision costs of about £18 per patient and assumes that 15% of patients are supervised at a NHSScotland unit three times weekly for 25 weeks.

Note there are only clinical effectiveness data for the abstinence/controlled drinking effectiveness of unsupervised disulfiram, so it has not been possible to model the use of supervised oral disulfiram. However, in this model the costs for the unsupervised disulfiram treatment include some element of supervision. This is because in the Scottish setting most oral disulfiram use is supervised.

Table 7-10: Resource uses and costs: naltrexone for six months treatment per patient May 2002 prices

<table>
<thead>
<tr>
<th>Resource</th>
<th>Unit cost (£)</th>
<th>Total costs (£)</th>
<th>Source of costings</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-minute specialist NHS consultation</td>
<td>60.00</td>
<td>60.00</td>
<td>Scottish Health Service Costs 2000/2001 General psychiatry cost per attendance of £71 plus 5%</td>
</tr>
<tr>
<td>Six monthly visits to keyworker</td>
<td>4.85</td>
<td>29.08</td>
<td>As above</td>
</tr>
<tr>
<td>Five monthly GP visits</td>
<td>15.30</td>
<td>76.50</td>
<td>NHSScotland</td>
</tr>
<tr>
<td>Drug costs 26 weeks at 50 mg per day</td>
<td>42.51 for 28</td>
<td>262.73</td>
<td>BNF 43 –7% +95p per prescription + 6 10 mins GP visit</td>
</tr>
<tr>
<td>Total costs</td>
<td></td>
<td>428</td>
<td>13 journeys at £2 each</td>
</tr>
<tr>
<td>Plus service user travel time</td>
<td></td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Grand total</td>
<td></td>
<td>454</td>
<td></td>
</tr>
</tbody>
</table>

Similarly, phasing out the use of naltrexone in line with relapse rates reduces the average cost per patient to £381 over six months.
High and low values are similarly required for these pharmacological costs. The high cost has been derived by costing visits to key workers at £74 per visit, being the cost reported in The Scottish Health Service Costs Book for 2000/01 for a visit from a member of the community psychiatric team, updated for inflation. The low cost is the mean value less patient travel time.

In addition, to be consistent with the trials, it is assumed that all service users undertaking pharmacological treatments are also benefiting from a psychosocial course. Although, in practice, while a psychosocial intervention is recommended, not all patients receiving pharmacological intervention attend such a course.

However, the cost of a psychosocial course is not included in the costs for the pharmacological treatments in the economic model. This is because the psychosocial costs are common to standard care and the pharmacological treatments (see Section 7.13) and it is only the incremental costs of the drugs treatment that are included as a cost.

The total costs, excluding psychosocial therapies are presented in Table 7-11.

**Table 7-11: Total costs for three drug treatments per patient**

<table>
<thead>
<tr>
<th>Average phased drug therapy cost</th>
<th>Low (£)</th>
<th>Central (£)</th>
<th>High (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acamprosate: 12-month treatment period</td>
<td>368</td>
<td>385</td>
<td>702</td>
</tr>
<tr>
<td>Supervised oral disulfiram: 6-month treatment period</td>
<td>325</td>
<td>358</td>
<td>1227</td>
</tr>
<tr>
<td>Naltrexone: 6-month treatment period</td>
<td>360</td>
<td>381</td>
<td>734</td>
</tr>
</tbody>
</table>
Figure 7-2 Patient pathway: acamprosate – 12-month treatment programme

- GP
- Psychiatrist
- Psychologist
- CPN Home Detox
- CPN/OT Outreach Clinic

New patient appointment
Specialist NHS consultation

ACAMPROSATE CLINIC

First appointment
- 15 minutes CPN
- 15 minutes doctor
- Pharmacy
- Hospital
- One-month script

Two months
- 15 minutes CPN
- 10 minutes doctor
- Pharmacy
- Hospital
- One-month script

Three months
- 15 minutes CPN
- 15 minutes doctor
- Pharmacy
- Hospital
- One-month script

Monthly appointments alternating CPN and doctor
- Script transferred to GP
- Monthly scripts

OT Occupational therapist
In addition to the NHSScotland costs, there may be patient costs to include travel and incidental costs of supervision for disulfiram users. Such costs have been excluded in the base case but are modelled in the sensitivity analysis.
7.8.3 Costs of different settings

Several respondents to the HTBS consultation document (Slattery et al., 2002) and interviewees in the HTBS commissioned patient research, noted the value of inpatient settings and the importance of having a choice of community or residential rehabilitation settings available to the clinician and the service user. Such settings may be necessary to provide stepped care where community-run courses prove ineffective or impractical (e.g. in large sparsely populated areas).

There is considerable variability in the provision of such residential settings in Scotland. For the purposes of this model, two settings have been costed. The first is an intensive six-week care programme that provides extensive intervention, medical support and full residential care. This is similar to the programme length for the care pathway at Castle Craig, assuming a patient does not require further support before moving back to the community. The NHS cost of this service has been estimated from several sources to be about £7500 (personal communication in confidence, 30 September 2002). For example, the gross cost of a general psychiatric bed for one week in 2000/01 was £1171 (Information and Statistics Division National Health Service in Scotland, 2001) which updated for inflation equates to almost £7400 for a six-week stay.

The second residential option used in the model is for an average length of stay of ten days. Ten days has been selected because it is the average of the length of inpatient stays for therapy after detoxification advised by two PCTs. Using the average cost of a general psychiatric bed of £171 per week from Scottish Health Service Costs 2000/01 plus 5% inflation provides an indicative cost for this setting for 10 days of £150. This cost includes an allowance for nursing costs of £780 and pharmacy costs of under £70, with almost all other costs being indirect allocated costs.

It is not possible to judge whether these costs are, or are not, a good surrogate for the cost of inpatient treatment for patients with alcohol dependence. However, in the absence of better treatment specific data, the model will include two additional sensitivity tests. The first will assume a service user requires inpatient treatment to control alcohol dependence at a cost of £1750 and the second that a more intensive course is necessary at a cost of £7500.

None of the literature identified using the search strategy detailed in Section 5.1 used to inform the clinical effectiveness analysis provided evidence to demonstrate that one setting was likely to be more effective than another. Thus, the same abstinence/controlled drinking rates will be assumed for all settings.

7.8.4 Costs of disease

The epidemiology of alcohol-dependent patients and the resultant incremental disease cases, in comparison with the general population, has been discussed in Section 3.20. For a cohort of 45-year-old men and women who are alcohol dependent the health consequences over 20 years are compared with the general male and female population (Table 7-12 and Table 7-13).
Table 7-12: Estimated disease cases – men

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent</th>
<th>Non-alcohol dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>936</td>
<td>188</td>
</tr>
<tr>
<td>Stroke</td>
<td>43</td>
<td>33</td>
</tr>
<tr>
<td>Cancer</td>
<td>88</td>
<td>97</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>102</td>
<td>10</td>
</tr>
<tr>
<td>Alcoholic psychoses</td>
<td>571</td>
<td>-</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>44</td>
<td>-</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>41</td>
<td>-</td>
</tr>
<tr>
<td>Alcohol dependence syndrome</td>
<td>814</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 7-13: Estimated disease cases - women

<table>
<thead>
<tr>
<th></th>
<th>Alcohol dependent</th>
<th>Non-alcohol dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>785</td>
<td>114</td>
</tr>
<tr>
<td>Stroke</td>
<td>53</td>
<td>33</td>
</tr>
<tr>
<td>Cancer</td>
<td>146</td>
<td>125</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>52</td>
<td>4</td>
</tr>
<tr>
<td>Alcoholic psychoses</td>
<td>160</td>
<td>-</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>32</td>
<td>-</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>50</td>
<td>-</td>
</tr>
<tr>
<td>Alcohol dependence syndrome</td>
<td>260</td>
<td>-</td>
</tr>
</tbody>
</table>

The economic evaluation uses these diseases as endpoints for the economic model. The model attributes costs to treat each of the disease endpoints. No cost to NHS Scotland is attributed to death. However, it is important to note that avoidance of death is the major benefit from preventing relapse. No financial benefit has been attributed to the outcome of avoidance of death, although as these tables show, moving from alcohol dependence to non-alcohol dependence greatly improves life expectancy.

The cost of each disease has been estimated using data extracted from the Scottish medical records held by ISD on a linked database. ISD provided:

- mean length of stay, measured in bed days, per inpatient in Scottish non-psychiatric hospitals, mental illness hospitals and psychiatric units for each relevant disease, for the period 01 April 1997 to 31 March 2001
- mean cost per patient for such inpatient stays in Scottish non-psychiatric hospitals, mental illness hospitals and psychiatric units for each relevant disease cost, for the same period
- mean cost of day cases discharged for the same relevant diseases over the same period.

In addition to these costs, it was assumed that all patients would have six GP appointments, thereby adding almost £90 to the disease costs.

No rehabilitation costs are included in the disease costs. The same assumption was used in the Merck model because in Scotland there is little provision for such rehabilitation services (Dr PJ Jauhar, Clinical Director/Consultant Psychiatrist, Alcohol & Drug Directorate, Parkhead Hospital, personal communication, 2002).
The uncertainty around the costs is expressed in a sensitivity analysis. High and low costs for each disease were obtained using semi-interquartile values of the relevant speciality cost as reported in the Scottish Health Care Scottish Health Service Costs 2000/01.

Table 7-14 shows the:

- mean inpatient days per episode for each relevant disease
- mean, high and low cost per episode, comprising the costs of inpatient care, outpatient and GP appointments for each episode for each relevant disease.

The original ISD data, to include a total cost per annum for inpatient and day case discharges for these diseases and relevant subgroups are contained in Appendix 24.

Table 7-14: Inpatient days and costs by disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>Inpatient days</th>
<th>Low</th>
<th>Mean</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol dependence syndrome</td>
<td>21</td>
<td>3190</td>
<td>3600</td>
<td>4480</td>
</tr>
<tr>
<td>Alcohol-related brain damage (psychosis)</td>
<td>52</td>
<td>7669</td>
<td>8651</td>
<td>10765</td>
</tr>
<tr>
<td>Liver disease</td>
<td>20</td>
<td>4853</td>
<td>5451</td>
<td>6328</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>4</td>
<td>933</td>
<td>1048</td>
<td>1217</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td>8</td>
<td>2766</td>
<td>3107</td>
<td>3607</td>
</tr>
<tr>
<td>Cancer weighted average: Men</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol dependent</td>
<td>18</td>
<td>5346</td>
<td>7356</td>
<td>11308</td>
</tr>
<tr>
<td>Non-alcohol dependent</td>
<td>18</td>
<td>4958</td>
<td>6823</td>
<td>10556</td>
</tr>
<tr>
<td>Cancer weighted average: Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol dependent</td>
<td>11</td>
<td>4117</td>
<td>5665</td>
<td>8764</td>
</tr>
<tr>
<td>Non-alcohol dependent</td>
<td>11</td>
<td>4086</td>
<td>5623</td>
<td>8699</td>
</tr>
<tr>
<td>Stroke*</td>
<td>21</td>
<td>5520</td>
<td>6200</td>
<td>7200</td>
</tr>
</tbody>
</table>

Note the cost of stroke is from unlinked data, plus GP cost and estimated day care costs

The cohort used in the modelling assumes a ratio of four males to every one female in the population. This ratio was observed in the Copenhagen City Heart Study (Becker et al., 1996) discussed in Section 3.20.

As explained in Section 3.20.7, alcoholic psychosis aggregates several separate conditions to include withdrawal, psychotic disorder and amnesic syndrome due to the use of alcohol (ICD codes F103 to F107). Two ICD codes, F106 alcoholic amnesic syndrome and F107 residual and late onset psychotic disorder, to include alcoholic dementia and chronic alcoholic brain syndrome, account for just 12% of patients discharged in this group but around 85% of the related inpatient stays. Indeed in 2000/01 the mean stay per patient coded to F106 as a primary diagnosis was over 433 days, associated with an average cost of over £70 000. This itself is likely to be an underestimate of average length of stay and thus of costs per patient because the trigger for the generation of a length of stay record is a discharge form. Patients who have been admitted since April 1997 and not discharged will not be captured in the length of stay data. This effect could be important. For example, one report produced
by ISD for HTBS using unlinked data sets showed one patient had been in a mental illness hospital or psychiatric unit for 28 years before discharge.

### 7.8.5 Alcohol-related brain damage

There is some unpublished evidence (Chiang, 2002) to suggest that there may be under-reporting of certain chronic alcohol induced conditions, in particular the Wernicke-Korsakoff syndrome. Following observation that patients suffering from long-term psychological problems that prevent discharge into the community use some psychiatric beds, a researcher in Argyll and Clyde undertook a survey to estimate the numbers of people in that NHS Board area with Wernicke-Korsakoff syndrome.

The analysis identified that there could be about 300 people in that area with this disease, of whom 65 were inpatients in the Acute and Primary Care Trusts, with the remainder in a mix of care homes, hostels and the community. In comparison, ISD record 28 inpatients in Scotland with Wernicke syndrome and 158 with amnesic syndrome, which includes Korsakoff’s.

The Chiang report noted that until 1997, Argyll and Clyde had the highest prevalence of Wernicke-Korsakoff syndrome in Scotland. In 1997, the most recent period for which data were provided, the prevalence in Argyll and Clyde dipped below the Scottish average. It is thus not possible to say if Argyll and Clyde is or is not representative of other parts of Scotland. If it is representative, then aggregating its data to Scotland level suggests that patients with severe alcohol-related brain damage could occupy over 700 inpatient beds in Scotland. This is three times greater than the rate reported from the morbidity returns.

Dr Chiang identified that there are several reasons why patients may not be given an alcohol-related code. For example, using an alcohol-related code for a patient might give rise to difficulties in placing the patient on leaving the hospital setting. This can be avoided by using a more general descriptor such as dementia. Other clinicians have also noted there is a reluctance to code explicitly to alcohol-related codes.

Any such under-reporting may give rise to inappropriate treatment for people with the disease and inappropriate decisions on resource allocation. Moreover given the pressure on beds, the opportunity cost of using beds may exceed the accounting derived average cost. Thus, using a simple average cost is likely to under-estimate the costs to NHSScotland of providing care to this group of patients.

### 7.9 Other costs

The model has not attempted to cost the resource use in general practice from patients presenting with mental and behavioural disorders due to misuse of alcohol. ISD Continuous Morbidity Recording (CMR) system collected data for 60 practices in 2001, with a population of 370 600 records and almost 4500 consultations by 1870 patients. Grossing this prevalence rate up to a Scotland-wide level and applying a cost per consultation of £15.30 indicates general practice costs could be around £0.95 million.
However, these again may understate the actual costs. For example, the CMR system records 33 alcohol detoxifications in the 60 practices in 2001. Grossing this up to Scotland-wide level suggests some 450 detoxifications per annum. Separate figures from one PCT show it detoxes 155 service users in the community, suggesting over 2200 service users are being detoxed in Scotland each year in the community. The same source states the average number of detoxes per person is three to four, but no other data on this aspect have been found.

The marginal cost of a community detoxification is estimated to be around £350 assuming the initial assessment, drawing up a contract and facilitation of the detoxification takes two hours and a further eight visits each of one hour are required; allowing for travel time, this amounts to 16 hours. Variations in practice across different NHS Boards will alter the costs. For example, the costs fall to £230 per detoxification assuming each detoxification takes 10 hours rather than 16 hours.

Applying the cost of £350 per service user to the extrapolated number of 2200 suggests that detoxification services could thus be costing NHSScotland over £0.75 million per annum.

No allowance for detoxification costs avoided has been included in the model because of uncertainties on the number of service users being detoxified and the number of detoxes per person. Based on the Trust’s data of three to four detoxes per service user, the economic model could understate the benefits, in terms of avoided detoxifications, by up to £1000 per person who does not remain abstinent. Improved recording of effectiveness will enable this aspect to be quantified with greater certainty.

7.10 Discounting

Individuals and society exhibit behaviour that indicates they have a positive rate of time preference (Drummond et al., 1997). Thus, most people prefer to have benefits today rather than at a later date and to defer costs for as long as possible. It is important in economic evaluation to adjust the cash flows associated with costs and benefits over time to take account of this time preference effect. This enables decision makers to compare alternative treatments over any time horizon.

In line with HTBS’s Guidance to Manufacturers (Health Technology Board of Scotland, 2002), costs and financial benefits to include the savings from avoided diseases are discounted according to the UK Treasury discount rate which is currently 6.0%.4

7.11 Effectiveness results for alcohol interventions

Analysis of the cost effectiveness of interventions for prevention of relapse in alcohol requires estimates of the proportions of patients in whom therapies will be effective. As discussed in previous sections, the estimates of the effectiveness of pharmacological treatments are based on placebo-controlled or no

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4 The model includes health benefits such as number of additional disease-free years but these indicators are not included in this Assessment. These health benefits are discounted at 1.5%, the social time preference rate, in accordance with HTBS’s Guidance.
treatment-controlled trials. The evaluations of psychosocial interventions are based on a more methodologically diverse selection of trials. Most of these included a treatment arm in which the intervention was thought likely to have little or no effect and this is used as the comparator arm when available. However, other trials included interventions thought to be less effective but not necessarily ineffective. These have also been included and thus it may be that psychosocial intervention effects are somewhat underestimated. However, other factors such as the tendency for investigators in psychosocial studies to be skilled enthusiasts and the impossibility of blinding may introduce an opposing bias, tending to overestimate what is likely to be achieved in clinical practice.

The proportions of patients in whom treatment is successful may be expressed either as those in a controlled drinking state or as those totally abstinent. Furthermore these figures are reported at different time points in different studies. Thus combination of these outcomes can be difficult. The approach has been to use figures for controlled drinking where presented and figures for abstinence otherwise. The analysis used in this HTA works in terms of odds ratios – in the hope that these will vary less than absolute values over time – and chooses times of follow up as close to one year as possible. However, due to the limited duration of many trials, this may often be only three months.

In order to use the effectiveness figures to calculate the rates of success that might be expected in clinical practice, it is necessary to have an estimate of the success which might have been achieved without the use of the interventions being evaluated. This does not mean the rate of spontaneous recovery in patients who are not treated at all. Rather it is the success rate in groups treated in ways which the effective treatments might replace and it is therefore reasonable to base an estimate of this effect on the observed responses in the groups allocated to the control comparator in clinical trials. Such groups generally receive some treatment for the same period of time as those allocated to the intervention under test. Thus, they will certainly benefit from a placebo effect and, in some studies, may also get an active treatment. For instance, in trials of pharmacological interventions all patients generally received some form of counselling.

A range of success rates was observed in clinical trials. Combining all the control groups from the studies of pharmacological and psychosocial interventions and adjusting for variations in time of follow up gives a success rate among controls at 12 months of 19%. Discussion with TSG members suggests that this is likely to be an overestimate of the true effect. Irrespective of allocated treatment, patients in clinical trials tend to do better than those not in trials. It therefore seems reasonable to use a slightly reduced rate of 15% for the base-case control effectiveness.
Table 7-15: Estimated outcome of single episode of treatment with a 15% recovery rate for patients treated with control interventions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Odds Ratio (95% CI)</th>
<th>Success per 1000</th>
<th>Failed per 1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control intervention</td>
<td>1.0</td>
<td>150</td>
<td>850</td>
</tr>
<tr>
<td><strong>Psychosocial</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>2.11 (1.53, 2.92)</td>
<td>272</td>
<td>728</td>
</tr>
<tr>
<td>BSCT</td>
<td>1.75 (1.02, 3.02)</td>
<td>236</td>
<td>764</td>
</tr>
<tr>
<td>MET</td>
<td>1.88 (1.28, 2.77)</td>
<td>249</td>
<td>751</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>1.94 (1.37, 2.73)</td>
<td>255</td>
<td>745</td>
</tr>
<tr>
<td><strong>Pharmacological</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>1.73 (1.36, 2.20)</td>
<td>234</td>
<td>766</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1.46 (1.12, 1.90)</td>
<td>205</td>
<td>795</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>1.31 (0.26, 6.70)</td>
<td>188</td>
<td>812</td>
</tr>
</tbody>
</table>

Some points which should be borne in mind in applying these figures are:

1. the figures for disulfiram are obtained from studies of oral unsupervised disulfiram only and it has been noted that the effectiveness of disulfiram may depend strongly on the degree of supervision exercised over those taking it.

2. in most studies of pharmacological interventions, patients in both arms of the trial received the same form of counselling.

3. psychosocial and pharmacological interventions should not be treated as competing. The design of the trials of pharmacological interventions gives every reason to believe that some additional effect can be obtained by adding pharmacological interventions to psychosocial.

**7.11.1 Alternative assumptions for control group effectiveness and more than one episode of treatment**

It is believed that the assumed base case rate of recovery of 15% is likely to be quite close to the true value. However, it is clearly important to investigate the robustness of the cost-effectiveness conclusions to this assumption. To do this, the expected outcomes for patients in clinical settings have been calculated where recovery was likely for 10% and 20% of patients not treated with the therapies which have been shown to be effective. These are shown in Table 7-16.
Table 7-16: Expected outcome of single episode of treatment for 1000 patients when recovery rate with control interventions is 10% or 20% in each episode

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Odds Ratio</th>
<th>10% Success</th>
<th>Fail</th>
<th>20% Success</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control intervention</td>
<td>1.0</td>
<td>100</td>
<td>900</td>
<td>200</td>
<td>800</td>
</tr>
<tr>
<td><strong>Psychosocial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>2.11</td>
<td>190</td>
<td>810</td>
<td>345</td>
<td>655</td>
</tr>
<tr>
<td>BSCT</td>
<td>1.75</td>
<td>163</td>
<td>837</td>
<td>304</td>
<td>696</td>
</tr>
<tr>
<td>MET</td>
<td>1.88</td>
<td>173</td>
<td>827</td>
<td>320</td>
<td>680</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>1.94</td>
<td>177</td>
<td>823</td>
<td>327</td>
<td>673</td>
</tr>
<tr>
<td><strong>Pharmacological</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>1.73</td>
<td>161</td>
<td>839</td>
<td>302</td>
<td>698</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1.46</td>
<td>140</td>
<td>860</td>
<td>267</td>
<td>733</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>1.31</td>
<td>127</td>
<td>873</td>
<td>247</td>
<td>753</td>
</tr>
</tbody>
</table>

It is clear from the preceding tables that a single episode of treatment is unlikely to be effective. From clinical practice data, it is known that patients frequently return for subsequent courses of treatment. No evidence is available for the effectiveness of repeat therapies. However, the clinical trials generally include patients who have undergone previous treatment and thus the effectiveness results will be averaged over patients with a range of previous therapeutic experiences. To approximate the likely maximum effect of courses of treatment involving repeated episodes of the same psychosocial therapy, it has been assumed that each episode has the same chance of success for each patient independently of previous treatment history. Table 7-17 illustrates the potential number of successes from repeated courses, the clinical effectiveness of courses being cumulative. This is felt likely to give an upper bound to the effectiveness of psychosocial therapies.

Table 7-17: Maximum outcome of six episodes of treatment with a 15% recovery rate for patients treated with control interventions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Number of courses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Control</td>
<td>150</td>
</tr>
<tr>
<td><strong>Psychosocial</strong></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>272</td>
</tr>
<tr>
<td>BSCT</td>
<td>236</td>
</tr>
<tr>
<td>MET</td>
<td>249</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>255</td>
</tr>
</tbody>
</table>

7.12 Economic model

The economic model is a simple treatment model constructed in Microsoft Excel. The effect of each therapy is calculated for a cohort of 1000 patients. Figure 7-4 shows how the range of treatments is compared with the standard care package, with costs and consequences associated with each.
Figure 7-4 A basic economic evaluation

The results are presented as an incremental cost-effectiveness analysis of the treatment over and above the ‘standard treatment’ scenario. The pharmacological therapies used in the model are provided as an adjunct to the standard treatment, for example acamprosate is provided in addition to a standard care package, to include a psychosocial treatment.

The incremental cost-effectiveness ratio (ICER) is calculated as follows:

\[
\text{ICER} = \frac{\text{Costs}_A - \text{Costs}_B}{\text{Consequences}_A - \text{Consequences}_B}
\]

Patients are assumed to enter one of two arms of a basic decision tree following compliance with the treatment programme. The ‘successes’ become non-alcohol dependent while the ‘failures’ continue as alcohol dependent. This is shown in Figure 7-5.

Figure 7-5 Alcohol dependent and non-dependent outcomes in the model

Patients then experience a range of disease endpoints: death; stroke; cancer; cirrhosis; alcoholic psychoses; chronic pancreatitis; epilepsy and alcohol dependence syndrome (see Section 7.8.4).

7.13 Results

As indicated in Table 7-15, the effectiveness of standard treatment is taken as 150 successes and 850 failures per 1000 patients, and therefore the effectiveness of each intervention is calculated by examining the number of successes over and above that of standard treatment.
For each intervention, the cost of treating 1000 people is calculated. Then the number of disease endpoints is multiplied through by the disease costs per case for both the intervention and the standard treatment package. The difference between these gives the net savings in disease-related costs from undertaking the intervention. Finally, the net savings in disease-related costs is deducted from the cost of intervention to give the net costs or savings from the intervention. The figures for each intervention are provided in Table 7-18.

An estimate of the additional patients abstinent when each treatment is compared with standard care is combined with these estimated costs to calculate the cost per additional abstinent patient. Estimates of the number of deaths averted are also presented in Table 7-18. It should be noted from the table that a negative cost represents a cost saving.

The four therapies (Coping/Social Skills Training, BSCT, MET and Marital/Family Therapy) demonstrate net health care cost savings ranging from £274 008 (Coping/Social Skills Training) to £80 452 (BSCT) for a cohort of 1000 people. These are calculated by subtracting the cost of intervention for a cohort of 1000 people from the net savings in disease-related treatment cost for this group in comparison with a cohort of 1000 people receiving standard care.

For the pharmacological therapies, there is a net economic saving associated with using acamprosate for a cohort of 1000 of £68 928 and net economic costs of using naltrexone of £83 432, rising to £153 189 for a cohort using unsupervised oral disulfiram. Acamprosate is the most cost effective of the pharmacological therapies.

Also presented are the net health care costs per death averted. These range from -£3073 (a net saving per death averted) for Coping/Social Skills Training to £5536 for unsupervised oral disulfiram. Assuming that each death averted only saved one life year (a very conservative assumption), the costs per life year saved for all therapies are lower than the cost per QALY of many of the recent products approved for use in the NHS. Indeed all the psychosocial therapies and acamprosate actually show a net saving per life year gained.
Table 7-18: Results summary (costs discounted at 6%) for a cohort of 1000 people

<table>
<thead>
<tr>
<th>Base case</th>
<th>Coping/Social Skills Training (£)</th>
<th>BSCT (£)</th>
<th>MET (£)</th>
<th>Marital/Family Therapy (£)</th>
<th>Acamprosate (£)</th>
<th>Naltrexone (£)</th>
<th>Unsupervised disulfiram (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total intervention cost</td>
<td>385 000</td>
<td>385 000</td>
<td>385 000</td>
<td>385 000</td>
<td>385 337</td>
<td>380 526</td>
<td>357 709</td>
</tr>
<tr>
<td>Change in health care costs over 20 years</td>
<td>-659 008</td>
<td>-465 452</td>
<td>-536 723</td>
<td>-568 795</td>
<td>-454 265</td>
<td>-297 094</td>
<td>-204 520</td>
</tr>
<tr>
<td>Net health care cost over 20 years</td>
<td>-274 008</td>
<td>-80 452</td>
<td>-151 723</td>
<td>-183 795</td>
<td>-68 928</td>
<td>83 432</td>
<td>153 189</td>
</tr>
<tr>
<td>Additional patients abstinent from standard</td>
<td>122</td>
<td>86</td>
<td>99</td>
<td>105</td>
<td>84</td>
<td>55</td>
<td>38</td>
</tr>
<tr>
<td>Reduction in deaths from standard</td>
<td>-89</td>
<td>-63</td>
<td>-73</td>
<td>-77</td>
<td>-61</td>
<td>-40</td>
<td>-28</td>
</tr>
<tr>
<td>Cost per Additional Abstinent Patient</td>
<td>-2252</td>
<td>-936</td>
<td>-1531</td>
<td>-1750</td>
<td>-822</td>
<td>1521</td>
<td>4056</td>
</tr>
<tr>
<td>Net Health Care Cost per Death Averted</td>
<td>-3073</td>
<td>-1278</td>
<td>-2089</td>
<td>-2388</td>
<td>-1122</td>
<td>2076</td>
<td>5536</td>
</tr>
</tbody>
</table>

(Negative costs are a cost saving)
7.14 Sensitivity analysis

The impact of uncertainty should always be explored in an economic evaluation (Health Technology Board for Scotland, 2002) to assess how the results change when different values for the input parameters are used. For the individual cost parameters, measures of dispersion around the base case value are not available and hence it is not possible to provide probability distributions. The cost parameters have been expressed as mean, high and low values only.

The following analysis is based on incremental discounted cost per additional abstinent patient, with the increment being the costs and consequences over and above standard care. The sensitivity tests measure the impact on the results of uncertainty about the:

- effectiveness of therapies
- cost of therapies
- disease cost consequences and the choice of discount rates.

7.14.1 Sensitivity analyses: clinical effectiveness

Table 7-19 to Table 7-24 test the sensitivity of the economic evaluation to assumptions relating to the treatment effectiveness. Table 7-19 shows the effect of using the 95% confidence limits for the effectiveness estimates. The confidence intervals for disulfiram are very wide and cross 1.0, being 0.26 to 6.70. The results are thus highly variable and so conclusions on the cost effectiveness of disulfiram may be unreliable.

The lower confidence interval for BSCT approaches 1.00, being 1.02. At this level, the effectiveness is virtually the same as the effectiveness of standard care, with a resultant very high cost per additional abstinent patient. BSCT effectiveness is thus subject to more uncertainty than the remaining therapies.

Table 7-19: 95% confidence limits of effectiveness: cost per additional abstinent patient

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Lower 95% confidence limit (£)</th>
<th>Base case (£)</th>
<th>Upper 95% confidence limit (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>735</td>
<td>-2252</td>
<td>-3389</td>
</tr>
<tr>
<td>BSCT</td>
<td>146 018</td>
<td>-936</td>
<td>-3467</td>
</tr>
<tr>
<td>MET</td>
<td>5822</td>
<td>-1531</td>
<td>-3256</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>3199</td>
<td>-1750</td>
<td>-3217</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>3086</td>
<td>-822</td>
<td>-2311</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>19 590</td>
<td>1521</td>
<td>-1597</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>standard care dominates</td>
<td>4056</td>
<td>-4429</td>
</tr>
</tbody>
</table>

Table 7-16 shows how the clinical effectiveness odds ratios change by varying the base case effectiveness of standard care from 15% to 10% and 20%. Table 7-20 shows the resultant change in cost effectiveness. Again the rankings remain virtually the same and all the psychosocial therapies, except BSCT, show savings in net health care costs. BSCT has a small cost if standard care has an effectiveness rate of 10%.
Naltrexone and disulfiram show net health care costs for all the standard care effectiveness scenarios, with a maximum value of £7622 per additional abstinent patient recorded for disulfiram at the 10% standard care effectiveness rate. Acamprosate is cost saving at the 15% and 20% effectiveness rate but has a small cost at the 10% effectiveness rate.

Table 7-20: Sensitivity to effectiveness of standard care: cost per additional abstinent patient

<table>
<thead>
<tr>
<th>Intervention</th>
<th>10% standard care (£)</th>
<th>15% standard care (£)</th>
<th>20% standard care (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills</td>
<td>-1147</td>
<td>-2252</td>
<td>-2774</td>
</tr>
<tr>
<td>BSCT</td>
<td>716</td>
<td>-936</td>
<td>-1725</td>
</tr>
<tr>
<td>MET</td>
<td>-126</td>
<td>-1531</td>
<td>-2199</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-436</td>
<td>-1750</td>
<td>-2374</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>433</td>
<td>-822</td>
<td>-1384</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>4004</td>
<td>1521</td>
<td>341</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>7622</td>
<td>4056</td>
<td>2346</td>
</tr>
</tbody>
</table>

In the base case, the clinical effectiveness estimated for a single episode of intervention is assumed to be maintained for the next 20 years. In Table 7-21, patients are assumed to relapse from the base case level at two different rates. Under the first case (relapse 1), 25% of people who are initially abstinent after intervention relapse after two years, rising to 50% after five years. Under the second case (relapse 2) a further 25% relapse after ten years.

Table 7-21: Relapse rates

<table>
<thead>
<tr>
<th>Relapse 1 (%)</th>
<th>Relapse 2 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 2 years</td>
<td>25</td>
</tr>
<tr>
<td>After 5 years</td>
<td>50</td>
</tr>
<tr>
<td>After 10 years</td>
<td>50</td>
</tr>
</tbody>
</table>

The effect of this upon downstream disease treatment costs can be approximated by applying the alcohol-dependent downstream disease treatment costs to those who relapse rather than the downstream treatment costs that apply to the non-alcohol dependent.

Table 7-22 shows how this affects the cost effectiveness, reported as the cost per abstinent patient prior to any patient relapsing. This tends to turn the net cost savings of the psychosocial interventions into net costs, though the cost per additional abstinent patient is still below £2000 even under the more pessimistic relapse rate assumption. The effect upon the cost effectiveness of the pharmacological interventions is also not marked, the highest cost per abstinent patient being for disulfiram at £6227 under the first relapse assumption and £6929 under the second relapse assumption.

Reporting cost effectiveness per additional abstinent patient prior to any relapse may be seen as misleading, given that the number of additional abstinent patients falls as relapse occurs. However, even reporting this as the additional abstinent patient at five years would only tend toward doubling the cost effectiveness ratios. Moreover, that approach would ascribe no benefit to the five years of abstinence among those who
relapse at five years. It should also be borne in mind that those who do not relapse within the five years would experience additional gains in terms of years of abstinence and alcohol diseases avoided.

Table 7-22: Relapse rates: cost per additional abstinent patient

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Base case (£)</th>
<th>Relapse 1 (£)</th>
<th>Relapse 2 (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Psychosocial</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>-2252</td>
<td>-80</td>
<td>621</td>
</tr>
<tr>
<td>BSCT</td>
<td>-936</td>
<td>1235</td>
<td>1937</td>
</tr>
<tr>
<td>MET</td>
<td>-1531</td>
<td>641</td>
<td>1342</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-1750</td>
<td>422</td>
<td>1123</td>
</tr>
<tr>
<td><strong>Pharmacological</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>-822</td>
<td>1349</td>
<td>2051</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1521</td>
<td>3693</td>
<td>4393</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>4056</td>
<td>6227</td>
<td>6929</td>
</tr>
</tbody>
</table>

Evidence from two PCTs (personal communication in confidence, 18 September 2002 and 12 September 2002) is that people who are dependent on alcohol frequently have more than one course of intervention. One Trust advised that the average number of therapies per individual was five, from a range of courses similar to those considered in this HTA (for example CBT, MI, Coping/Social Skills Training and couples and family work). A second Trust advised the average number of therapies per service user is eight.

There are no data on the clinical effectiveness of repeat treatments but two scenarios have been investigated corresponding to pessimistic and optimistic assumptions:

- only some patients will respond to treatment and they respond immediately. Hence the subsequent treatments are futile and only the effect of a single treatment episode is achieved despite multiple episodes.
- each patient has the same chance of responding at each episode. Hence the success rate rises asymptotically to 100% with further treatments.

If it is assumed that there are no drop outs between courses, the first scenario implies that the therapy cost of psychosocial interventions is a multiple of the number of courses required and effectiveness remains as in the base case. Assuming that six courses are used, this would affect the cost as shown in Table 7-23. Thus, if in the pragmatic setting people are having six courses of intervention before relapse is prevented then the cost effectiveness rises to about £13 560 per additional abstinent patient for Coping/Social Skills Training. This cost-effectiveness measure does not capture any value from the resultant deaths avoided nor measure the savings in societal costs from increased abstinence.
Table 7-23: Cost per additional abstinent patient: six psychosocial courses, non-cumulative effectiveness

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Base case: one course (£)</th>
<th>Six courses: non-cumulative (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coping/Social Skills Training</td>
<td>-2252</td>
<td>13 566</td>
</tr>
<tr>
<td>BSCT</td>
<td>-936</td>
<td>21 459</td>
</tr>
<tr>
<td>MET</td>
<td>-1531</td>
<td>17 891</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-1750</td>
<td>16 577</td>
</tr>
</tbody>
</table>

Under the second scenario of cumulative effectiveness, the number of additional abstinent patients, relative to standard care with a base case effectiveness of 15% per course, is as in Table 7-24.

Table 7-24: Abstinent patients with cumulative clinical effectiveness, 1000 initial patient cohort

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Number of courses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Abstinent Patients</td>
<td></td>
</tr>
<tr>
<td>Standard Care</td>
<td>150</td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>272</td>
</tr>
<tr>
<td>BSCT</td>
<td>236</td>
</tr>
<tr>
<td>MET</td>
<td>249</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>255</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Abstinent Patients Relative to Standard Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coping/Social Skills Training</td>
</tr>
<tr>
<td>BSCT</td>
</tr>
<tr>
<td>MET</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
</tr>
</tbody>
</table>

As would be expected, with repeated courses the cumulative effect of the more effective therapies is greater than that of the less effective therapies. This applies in particular to the standard care against which the additional numbers of abstinent patients is measured. But there remains considerable uncertainty as to the cumulative effect of standard care and of the psychosocial therapies, since trial data does not consider this aspect.

As a consequence, the total number of abstinent patients from six courses of psychosocial therapies may indicate an upper bound on their effectiveness. However, the net effect is felt to be too uncertain to attach meaningfully a cost figure, and incremental cost effectiveness ratios have not been derived given the inherent risk of misinterpretation.

7.14.2 Sensitivity analyses: cost of therapies

Varying the cost of the therapies alters the cost effectiveness. Table 7-25 shows the high and low costs for each intervention (see Section 7.9) and the results are presented in Table 7-26. Taking the low cost of intervention, which excludes any patient costs, gives a range of cost per additional abstinent patient from £1151 to £3202 for naltrexone and disulfiram respectively while acamprosate and all of the psychosocial interventions show increased net cost savings.
Table 7-25: Low and high intervention costs

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Low (£)</th>
<th>Base case (£)</th>
<th>High (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial</td>
<td>310</td>
<td>385</td>
<td>980</td>
</tr>
<tr>
<td>Acamprosate</td>
<td>368</td>
<td>385</td>
<td>702</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>360</td>
<td>381</td>
<td>734</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>325</td>
<td>358</td>
<td>1227</td>
</tr>
</tbody>
</table>

Taking the high therapy costs shows a range of costs per additional abstinent patient of £2955 for acamprosate, £7954 for naltrexone, rising to £27 060 for unsupervised disulfiram and £2638 to £5986 for the psychosocial interventions.

Table 7-26: Low and high treatment costs: cost per additional abstinent patient

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Low intervention costs (£)</th>
<th>Base case (£)</th>
<th>High intervention costs (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>2868</td>
<td>-2252</td>
<td>2638</td>
</tr>
<tr>
<td>BSCT</td>
<td>-1809</td>
<td>-936</td>
<td>5986</td>
</tr>
<tr>
<td>MET</td>
<td>-2287</td>
<td>-1531</td>
<td>4472</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-464</td>
<td>-1750</td>
<td>3915</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>-1028</td>
<td>-822</td>
<td>2955</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1151</td>
<td>1521</td>
<td>7954</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>3202</td>
<td>4056</td>
<td>27 060</td>
</tr>
</tbody>
</table>

The cost effectiveness of adopting residential care for the psychosocial therapies is shown in Table 7-27. The results are obtained by substituting the mean cost of £385 for a psychosocial intervention by:

- £1750 for 10 days residential care
- £7500 for six weeks of residential care.

Table 7-27: Psychosocial therapies: more intensive scenarios coupled with higher disease costs – cost per additional abstinent patient

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Base case (£)</th>
<th>10 days residential: £1750 (£)</th>
<th>6 weeks residential: £7500 (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coping/Social Skills Training</td>
<td>-2252</td>
<td>7675</td>
<td>54 923</td>
</tr>
<tr>
<td>BSCT</td>
<td>-936</td>
<td>13 655</td>
<td>80 550</td>
</tr>
<tr>
<td>MET</td>
<td>-1531</td>
<td>10 952</td>
<td>68 964</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-1750</td>
<td>9956</td>
<td>NA</td>
</tr>
</tbody>
</table>

No evidence was found on the clinical effectiveness of residential and non-residential settings. The model thus uses the base case effectiveness assumptions for each setting. As residential therapies may be more likely to be given to those with a longer or...
worse history of alcohol abuse, the higher disease costs as reported in Table 7-14 have been applied. It is assumed Marital/Family therapy is not provided in the six-week residential option because the care setting is likely to be distant from the family home.

Under these care setting assumptions, Coping/Social Skills Training is the most cost effective, although the cost per abstinent patient is particularly high under the six-week residential setting option (range £54,923 – £80,550). However, it may be that patients considered for such settings have much more serious medical damage than the average and so the avoided medical costs may be materially higher than the costs used in this analysis.

7.14.3 Sensitivity tests: disease costs

In Table 7-28, the disease costs are varied between low and high cost assumptions. The cost-effectiveness estimates are not very sensitive to these upper and lower bounds, principally because the upper and lower estimates are relatively close together but also because any net difference in cost only applies to a subset of patients being those additionally abstinent relative to standard care.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Low disease costs (£)</th>
<th>Base case (£)</th>
<th>High disease costs (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>-1629</td>
<td>-2252</td>
<td>-3541</td>
</tr>
<tr>
<td>BSCT</td>
<td>-313</td>
<td>-936</td>
<td>-2225</td>
</tr>
<tr>
<td>MET</td>
<td>-908</td>
<td>-1531</td>
<td>-2820</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-1127</td>
<td>-1750</td>
<td>-3039</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>-199</td>
<td>-822</td>
<td>-2111</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>2144</td>
<td>1521</td>
<td>231</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>4679</td>
<td>4056</td>
<td>2767</td>
</tr>
</tbody>
</table>

7.14.4 Discount rates

Section 7.10 explained that discount rates are necessary to capture timing effects. The base case has discounted financial costs and benefits using a 6% discount rate. Two sensitivities are presented in Table 7-29. These apply a 0% and 1.5% discount rate to financial cost and savings. The effect of using lower discount rates is to increase the value of the future health savings and thus increase the net saving from each intervention.
Table 7-29 Cost per abstinent patient using 6%, 1.5% and 0% discount rates

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Discount rates:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6% base case (£)</td>
<td>1.5% (£)</td>
<td>0% (£)</td>
</tr>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping/Social Skills Training</td>
<td>-2252</td>
<td>-3789</td>
<td>-4441</td>
</tr>
<tr>
<td>BSCT</td>
<td>-936</td>
<td>-2474</td>
<td>-3125</td>
</tr>
<tr>
<td>MET</td>
<td>-1531</td>
<td>-3068</td>
<td>-3720</td>
</tr>
<tr>
<td>Marital/Family Therapy</td>
<td>-1750</td>
<td>-3287</td>
<td>-3939</td>
</tr>
<tr>
<td>Pharmacological</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acamprosate</td>
<td>-822</td>
<td>-2360</td>
<td>-3011</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1521</td>
<td>-16</td>
<td>-668</td>
</tr>
<tr>
<td>Unsupervised disulfiram</td>
<td>4056</td>
<td>2518</td>
<td>1867</td>
</tr>
</tbody>
</table>

### 7.14.5 Summary of sensitivity analysis

The odds ratio for each intervention is the parameter that has the greatest impact on cost effectiveness and the ranking of therapies. The evidence used to calculate the odds ratios has been explained in Section 5.6 and is primarily from reported RCTs. Whilst unsupervised oral disulfiram appears cost effective under base case assumptions, the very wide confidence intervals for the odds ratio include the possibility that it is not cost effective. The lower 95% confidence interval for BSCT approaches one, suggesting there is also some uncertainty about its effectiveness. Thus, the recommended research focuses on collecting robust effectiveness data.

The disease costs are calculated using inpatient length of stay in NHSScotland hospitals as the prime measure of resource use. This understates resource use because it does not capture rehabilitation provided in the community, or the use of long-stay private homes by psychiatrically damaged patients who are discharged there and paid for by NHSScotland. The sensitivity tests show that using the higher disease cost increases the cost effectiveness per additional abstinent patient by around £1300.

The costings are also limited to the NHSScotland perspective. They do not capture the societal costs that could be avoided by preventing relapse. The Catalyst report (Catalyst Health Economics Consultants Ltd, 2001) indicated that health care costs are less than 10% of the costs that alcohol imposes on society. While the ratio may be different for this subgroup of people with established alcohol dependence, taking the narrow health care perspective will undoubtedly lead to an understatement of the benefits from reducing relapse. For example, if the savings in disease costs increase tenfold to capture societal savings, then the cost effectiveness improves to a saving of around £50 000 per abstinent person from the psychosocial therapies and acamprosate, £47 220 for naltrexone and £44 700 for oral unsupervised disulfiram.

The sensitivity analysis is limited to univariate analysis because there is insufficient relevant information in the literature or evidence from the PCTs, to enable multi-variate probability distributions to be assigned to the model inputs.

### 7.14.6 Interpretation of results

The economic evaluation shows that Coping/Social Skills Training, MET, Family/Marital Therapy, BSCT and acamprosate all result in positive net economic benefits; that is the cost of the therapy is more than offset by subsequent savings in...
alcohol-related disease treatment costs. Naltrexone and unsupervised oral disulfiram have a net cost per abstinent patient of £1521 and £4056. All seven therapies are cost-effective in comparison to standard care.

The economic evaluation has ranked interventions in terms of the incremental cost per abstinent patient. This approach assumes the psychosocial interventions can be neatly categorised using the definitions applied within the HTA, which may not always be possible. This approach could also be misinterpreted since it fails to recognise that different people will respond better to different interventions and it is thus important that a range of interventions is offered. For example, not all patients, and possibly very few, can take advantage of a Marital/Family Therapy. Note the pharmacological treatments are not an alternative to psychosocial therapy but an additional therapy.

The costings did not indicate a systematic difference in the cost per person of providing group or individual training and the effectiveness is assumed to be the same under either approach. However, this should not be interpreted as suggesting the courses are identical in terms of outcomes for individual patients; rather individual preferences will still be important when deciding whether a course should be on a one-to-one basis or in a group setting.

Similarly the clinical effectiveness analysis did not find evidence of difference between residential and non-residential settings. This is probably not true and it should be reviewed once robust data are available.

The model has not sought to value death although the epidemiology indicates that reducing the death rate would be the biggest benefit from reducing alcohol relapse. Other government departments, in particular the Department of the Environment and Transport have developed a methodology that values a life at about £800 000. The economic model could be extended to include an annual saving per death avoided based on this capital sum. However, this approach would be inconsistent with adopting the NHSScotland perspective and would raise issues of generalisability.
8 ORGANISATIONAL ISSUES

Summary

• Randomised controlled trials testing matters related to the organisation of specialist alcohol services are scarce. Thus recommendations with regard to organisational issues also take account of clinical expert judgement, economic evaluation, patients’ needs and preferences, surveys of existing services, and relevant policy documents such as the Alcohol Problems Support and Treatment Services Framework (Scottish Executive Health Department, 2002).

• Alcohol dependence is a relapsing condition and the need for ongoing treatment, even after a number of unsuccessful interventions, should be recognised.

• Most services for prevention of relapse in alcohol dependence relate to Tiers 3 (services for people with more complex needs) and 4 (services for people with highly specialised needs) of the Scottish Executive’s Alcohol Problems Support and Treatment Framework.

• Alcohol services are highly suited to ‘joint working’, as recommended by the Joint Futures Group (Scottish Executive, 2001), involving specialist mental health and social work addiction services and non-statutory agencies with joint resourcing and management of community care services.

• Certain subgroups such as young people, the homeless and those with comorbid mental health problems, have special service needs and providers should ensure that the service is accessible to all and responsive to differences in users’ needs.

• National Health Service specialist alcohol services should be multidisciplinary community (and day hospital) based services with the option of specialist National Health Service inpatient/private or non-statutory residential care. Consolidation of services may be necessary to allow for a concentration of expertise and resources e.g. inpatient care. It is good practice for specialist services to make arrangements for continuing care of service users.

• Specialist services must make themselves aware of mutual help (Alcoholics Anonymous) and non-statutory agencies operating in their area and coordinate their approach, making this information available to individuals within their care. Informing patients about Alcoholics Anonymous and non-statutory agencies should be part of the overall strategy for prevention of relapse.

• An improved information collection system is required. Information and Statistics Division are currently developing the National Alcohol and Information Resource for use by those who plan and provide services. Local services should liaise with Information and Statistics Division regarding methods of recording and collecting information.

• A regularly updated comprehensive directory of alcohol services including residential treatment would be beneficial. This should be useable by all participating agencies and provide accurate outcome data (as recorded and
analysed) as well as a greater understanding of progress through the treatment system.

8.1 Introduction

Recommendations regarding the organisation of alcohol services in this section have taken account of the clinical effectiveness and cost-effectiveness evidence base, patients’ needs and preferences, expert knowledge, surveys of existing services and policy documents such as the Alcohol Problems Support and Treatment Services Framework (Scottish Executive Health Department, 2002). In particular, there has been considerable input from the experts on the TSG, who have provided much of the information in this chapter.

This section aims to assist NHS Boards, NHS Trusts and AATs in organising services for the prevention of relapse.

8.1.1 Alcohol dependence

Alcohol dependence is a potentially relapsing condition and the need for ongoing treatment, even after a number of unsuccessful interventions, should be recognised. Recurrent relapse should not be a barrier to re-referral and the HTBS survey of specialist services suggest that this is generally accepted. The condition should be approached like other relapsing medical conditions with long-term monitoring and intermittent or continuous care (O’Brien & McLellan, 1996). Services for prevention of relapse are part of the overall care pathway of people with alcohol dependence. Staff need to be aware of the needs of service users before and after accessing services for the prevention of relapse.

Staff in non-specialist NHS services (Tier 1 – services for the whole community, and Tier 2 – local services that identify and respond to people with alcohol problems [Section 3.9]) need to remain aware that detoxification or treating the presenting alcohol-related physical disease is only one part of the process of treating alcohol dependence. This awareness can be stimulated by improved liaison between general hospitals and specialist services.

8.1.2 Provision of services (including the Alcohol Problems Support and Treatment Services Framework)

Most services for prevention of relapse in established alcohol dependence relate to Tiers 3 (services for people with more complex needs) and 4 (services for people with highly specialised needs) of the Framework but there will also be an impact on Tiers 1 and 2. The composite care pathway (Figure 8-1) encompasses Tiers 3 and 4 although the exact provision and configuration of services, including making best use of the available resources, will be an issue for the bodies noted. NHS Boards, NHS Trusts and AATs will need to consider whether specialist services need to be consolidated, including across Trusts and Board areas, to allow for a concentration of expertise and resources such as inpatient beds. The main aims of prevention of relapse are to support, motivate and encourage effective coping skills – medication is an adjunct to these.
In the organisation of services for substance abuse, the practical consideration of whether, and to what extent, services for people who abuse alcohol can be combined with those for people who abuse drugs, may arise. Given that there are certain shared principals in strategies aimed at tackling both sorts of problem, it would seem sensible to take account of the efficiency gains coming from addiction teams being able to advise on both alcohol and drug abuse in Tiers 1 and 2 of the intervention hierarchy. However, as the severity and complexity of the abuse problems increase, it is likely that separate specialist streams will be required.

The complex and varied nature of the problems faced by people with alcohol dependence means that many agencies might be involved in their care. A high level of integration must exist between statutory health, mental health and social work services and the non-statutory agencies. Development of clear lines of communication and referral from one service to another are required to avoid duplication of services. More specifically, single shared assessments as noted in the Framework document and shared care protocols, based on national policy but locally determined, should be developed between specialists, primary care (including LHCCs), social work teams, and the non-statutory sector.

Alcohol services are particularly suited to ‘joint working’, as recommended by the Joint Futures Group, involving specialist mental health and social work addiction services and non-statutory agencies with joint resourcing and management of community care services.

People with alcohol dependence should have a clear understanding of how to access the care pathway/treatment system when they need to. Individuals accessing the ‘treatment system’ want continuity in terms of those managing their care and therefore transition through the treatment system should ideally be managed retaining such continuity as far as possible. This may also encourage the avoidance of overlap in information gathering and interventions offered.

Certain subgroups such as young people, the homeless, those with comorbid mental health problems, and those in the criminal justice system have particular needs in accessing specialist services and providers should ensure that the service is accessible to all. Services for relatives, carers and dependent children of people with alcohol dependence also need to be developed.

As noted in Section 3.6.3, the SPS provides a treatment and care plan to those identified as in need of help. Prisoners might benefit from referral to NHS services during the period of renewed exposure to alcohol immediately after release. Thus, agreed procedures for routine referrals between the SPS and NHS services convenient to the prisoner might provide significant benefits.

Rural communities may have different needs from the urban communities. There may be greater need for inpatient detoxification and prevention of relapse due to geographical factors, which prevent effective community interventions. The non-statutory agencies are noted to be a valuable resource in the rural setting.
Figure 8-1 Example care pathway

GP (or general psychiatrist/CPN/social work/non-statutory agency)
Problem identified - follow SIGN guidelines
Refer if multiple relapse/concurrent psychiatric illness/
potential need for residential rehabilitation

NHS specialist alcohol service

Emergency
(assess level risk/withdrawal)

Non-urgent

Allocation meeting

CPN/alcohol day unit/
outpatient (medical/nursing)

Assessment

Specialist help
not required

Help required

Not accepted
(provide information)

Accepted:
dependence defined

Dependent

Non-dependent: identify
goal of treatment

Abstinence

Abstinence or
controlled drinking

Assess risk - detox waiting list
(Motivational Interviewing)

Non-statutory
agency
(e.g. Councils on
Alcohol)

Home detox/day hospital detox/inpatient detox

Prevention of relapse: psychosocial interventions (MET/Social Skills/CRA/
BMCT or BSCT group/individual/+/- acamprosate/supervised disulfiram

Programme complete (review continuing needs)

Purchased services
Medical/
General psychiatry
General medical
etc residential rehab.
nursing
outpatient

8-4
8.1.3 **NHS specialist alcohol services**

NHS specialist alcohol services (Section 3.18) should be multidisciplinary community (and day hospital) based services with the opportunity of access to specialist residential care. They require a highly skilled team that sees the most severe end of the spectrum of alcohol problems. They should also, if appropriate, provide supervision and training to professionals in less specialised tiers of service.

Acute hospital staff, identified for developing a special interest in alcohol problems, (e.g. ‘alcohol liaison nurses’)) may be able to counsel patients as a preparatory step to specialist care, develop knowledge about locally available non-statutory agencies and link up with liaison psychiatry and specialist alcohol services. Such acute hospital staff with this special interest may be able to educate and increase the knowledge of their co-workers.

NHS specialist alcohol services should have the core principles of: confidentiality; accessibility; ongoing contact rather than time limited; holistic care; a supportive/non-judgemental approach; the ability to tailor the approach to the individual; coordination with different agencies involved in helping those with alcohol problems (mental health, general medical, social, forensic); addressing the needs of other family members. The specialist service should create the opportunity for individuals to engage in social and occupational activities.

Services should offer a comprehensive package of help whether through their own actions or integration with other agencies, such as those dealing with debt counselling, employment or housing issues. Early liaison with these services may help in capitalising on the gains achieved through detoxification.

8.1.4 **Non-NHS specialist alcohol services**

NHS specialist services must make themselves aware of mutual help (AA) and non-statutory agencies operating in their area (Section 3.18) and make this information available to individuals under their care. Introduction to AA and non-statutory agencies should be part of the overall prevention of relapse strategy.

Those non-statutory agencies funded by statutory agencies, which carry out ‘counselling’, should deliver interventions of known clinical and cost effectiveness. The HTBS survey of these services suggests that much of the non-NHS specialist alcohol services sector appears to offer well validated and probably effective interventions. For instance AA is the origin of the now validated process called 12-step facilitation and the Councils on Alcohol can access training in a CBT/MET approach through the AFS training scheme which is accredited at Edinburgh University.

However gaps exist in services provided by the non-statutory sector. For example, over 50% of the homeless facilities that HTBS contacted did not provide psychosocial interventions despite a large proportion of their clientele having alcohol problems. There may be opportunity for training the staff in these facilities in community reinforcement therapy, which has been shown to be effective in this group.
8.2 Implications of clinical effectiveness and cost-effectiveness analysis for service provision for prevention of relapse in alcohol dependence

8.2.1 Psychosocial interventions

An evidence-based assessment of the clinical effectiveness of psychosocial interventions is included in Chapter 5 of this report. Further discussion of these, including comments on patient issues and cost effectiveness, is given in Chapter 6 and Chapter 7, respectively. With respect to the implementation of these findings, a number of recommendations are generally accepted on the basis of the clinical and cost-effectiveness evidence, expert opinion and experience from clinical practice:

- the role of clinical psychology staff is important, as much of the clinical evidence for psychosocial interventions is based on the provision of these interventions by clinical psychologists
- shorter less intensive interventions (MET) should be offered first, bearing in mind the principles of ‘stepped’ care
- when the patient has not responded to less intense intervention, increasing the intensity is appropriate
- disengaged individuals and/or those showing a high degree of anger are probably more likely to benefit from MI/MET than from other approaches
- there are common therapist factors and characteristics which appear to be important whatever the intervention used, including: the ability to form a therapeutic alliance; taking a non-judgemental empathic approach; using reflective listening. These factors may be crucial to the successful completion of treatment. Therapist empathy and expertise is as important as experience and in this respect adequate training and audit of therapist competencies is recommended.
- clear and acceptable guidelines should be used locally, to agreed national standards, for each psychosocial intervention employed
- monitoring of adherence to protocols and ensuring that what is delivered under the name of a specific intervention is the intervention as more widely recognised, will be an important factor in auditing the effectiveness of these approaches
- ensuring that the treatment delivered corresponds to that which has been demonstrated to be effective requires continuing clinical supervision of therapists, which must be accompanied by continuing opportunities for skill enhancement.

8.2.2 Pharmacological interventions

Discussion of the clinical effectiveness and cost effectiveness of pharmacological interventions is included in Chapter 5 and Chapter 7, respectively. The following points relate to the use of these interventions and are generally accepted:

- pharmacological interventions should only be used as an adjunct to psychosocial interventions. The circumstances in which adjunctive pharmacological interventions may be useful include early in treatment if craving is a major factor, or just after detoxification if psychosocial interventions alone have failed previously.
- in using pharmacological interventions, note should be taken of individual needs and expectations as well as contraindications, cautions and interactions
• shared care protocols (examples of which are provided within Appendix 11) should be drawn up for the use of both acamprosate and disulfiram
• acamprosate should be commenced immediately after successful completion of alcohol detoxification
• compliance with acamprosate should be monitored in the first month and the medication should be discontinued if compliance and/or the clinical result is poor
• review of acamprosate and supervised oral disulfiram usage should take place regularly in the first 12 weeks at which stage transfer of prescribing to the GP may be appropriate. Ongoing monitoring in shared care with the GP should continue thereafter. Monitoring ideally should include information from the family or other closely involved party, and/or GGT, MCV, as well as assessment of CADs.
• at present, acamprosate is licensed to be used for up to one year. However, there is no evidence to show that continuing the prescription for 12 months is superior to discontinuing it after, for example, six months.
• for disulfiram, patients should be told of the nature and dangers of the alcohol reaction prior to prescription of the drug and should carry a card warning of the danger of administration of alcohol
• daily, supervised administration of oral disulfiram is recommended. Twice or thrice weekly administration may be more logistically practical if supervision is by a day hospital, CPN, a practice nurse, or an occupational health worker or deputy.
• information sheets for the nominated supervising agent (e.g. spouse, family member, practice nurse, workplace nurse) should be available (an example of an information sheet is shown in Appendix 13)
• it is recommended that adherence to disulfiram and ongoing benefit from its use be reviewed on a monthly basis by the specialist service for the first three months, and thereafter two monthly by a physician alert to rare adverse effects of the drug such as neuropathy, or potential drug interactions
• naltrexone is not authorised for treatment of alcohol dependence in the UK and so is not recommended for routine use
• the additive value of acamprosate and disulfiram in combination has not been specifically studied in trials and so cannot be recommended.

8.3 Continuing care

While there has been a dearth of trials comparing different intensities of long-term contact, there is some evidence that even low-intensity continuing contact may have a beneficial effect (Hilton et al., 2001) (Section 5.5.1.7). Consequently, it is good practice for specialist services to make special arrangements for the continuing care of each individual.

If, during continuing care, other psychiatric problems persist such as anxiety or depression at three weeks post-detoxification, these should be treated appropriately e.g. with psychological therapy (CBT) or antidepressant medication, in accordance with the draft guideline from SIGN (2002)\(^5\), but without drawing the patient’s attention away from the primacy of the drinking goal.

\(^5\) Final guideline due to be published in 2003.
The HTBS patient study also identified that a Trust in Scotland provided out of hours telephone support for service users discharged from inpatient treatment. Several participants had used the Helpline which the NHS had made available. These service users valued this service.

8.4 Recording and collection of information

The difficulty in estimating the prevalence of alcohol dependence highlights the importance of recording contacts by service users with alcohol services. There is also a need to collect information routinely on what happens to individuals once they have left the service, either through default or completion of a programme. ISD, on behalf of the Scottish Executive, is setting up a National Alcohol Information Resource (NAIR) for use by those who plan and provide alcohol services.

Local services should liaise with ISD regarding methods of recording and collecting information so that local information systems can be coordinated with the national information system. For example Greater Glasgow Alcohol and Drug Directorate has designed, and are currently piloting, a computerised information system specifically developed to record useful clinical information on patients throughout their contact with the Directorate. In addition, Greater Glasgow social work addiction services already have an outcome monitoring system for recording information on the progress of their service users in contact with relevant services. However, the information on individuals once they have stopped using these services, through default or completion of a programme, is not collected. Consequently no information is available about the longer-term impact of contact with these services. Such information systems may help gain greater understanding of the demands on, and effective organisation of services.

A regularly updated comprehensive directory of alcohol services and accommodation would be beneficial for staff, service users and their relatives, and the public. This should be useable by all participating agencies and where available provide accurate outcome data as well as a greater understanding of progress through the treatment system.

8.5 Screening, audit and research

While screening tools such as the Family Addiction Screening Tool (FAST – an abbreviated version of AUDIT) as used in primary care settings (Scottish Intercollegiate Guidelines Network (SIGN), 2002) may not be as appropriate to the specialist setting, the use of comprehensive single shared assessments between agencies would be of much greater value in sharing information.

There is need for the auditing and monitoring of the ‘treatment system’ locally, with the facility to modify the system as the need to change is highlighted. Local systems should have the scope for incorporating evidence-based changes in treatment, and be able to audit these changes in its services.

The HTBS survey (Section 3.10) shows that, currently, audit of psychosocial and pharmacological interventions is minimal, and in some areas is not occurring at all. Audit of interventions should include: locally (and nationally) agreed outcome measurements (e.g. percentage of completed sessions, blood tests, patient self-report,
CADs); checking that interventions are delivered according to recognised methodology and standards; audit of therapist accreditation and supervision; ensuring that local protocols are being followed.

The improvement in information systems noted previously, including progress through the service and the longer-term outcomes, is essential for the audit and evaluation of services. National audit and evaluation should be coordinated to avoid the ‘evaluation overkill’ noted by workers in both statutory and non-statutory agencies.

In addition, research and development are essential components of improving the current system of care. Further research is needed regarding the benefits of different settings for psychosocial interventions e.g. group versus individual, inpatient versus outpatient versus day unit, intensity, length and frequency of sessions etc. Research is also required into models of treatment of Tier 3 services in the NHS which may provide evidence for transferring some treatment to lower tiers such as primary care.

8.6 Staff training and continuing professional development

The Framework document (Scottish Executive Health Department, 2002) highlights the role of Scottish Training on Drugs and Alcohol (STRADA) in providing training, while noting that Healthwork UK is developing a UK-wide set of competencies for staff working in alcohol and drug services. In addition to STRADA, there are training courses run by AFS, Drug Issues Scotland, Castle Craig and other private organisations.

Commissioners and providers of services should consider this when assessing the training and continuing professional development needs of their staff. Consequently, planning and funding of training for staff involved in the prevention of relapse in alcohol dependence requires a strategic approach to ensure that all staff have the skills to provide appropriate psychosocial and other services. This should involve joint training of staff from the statutory and non-statutory sectors.

As noted previously, the role of clinical psychology staff is important in psychosocial interventions, however clinical psychologists are involved in some of the services surveyed but not others. It is likely that services in all areas will require some input from clinical psychologists but they are a scarce resource. It may be appropriate for the NHS Education Scotland to consider how clinical psychologists should best be used in alcohol services, for example training and supporting other staff undertaking psychosocial interventions. This would include ensuring the ongoing maintenance of skills of other staff, and the supervision of the psychosocial services offered by them. Consequently, a clinical psychologist would see only those individuals with severe or complex problems.

8.7 Quality assurance

Services in different areas need to be consistent and equitable, be provided to accredited standards and as part of agreed protocols, have equity of access for the heterogeneous group of alcohol-dependent patients, train staff to agreed national standards, and use single shared assessments and agreed outcome measures. It is
essential to have a longer-term measurement of quality and effectiveness including measurements of outcome covering longer periods post-intervention.

This Assessment Report endorses the quality standards to which services should be delivered noted in the Framework document (Scottish Executive Health Department, 2002). The Scottish Executive has also published National Care Standards (Scottish Executive, 2002) for residential care of people with alcohol and drug problems. Finally, the Framework notes other sets of quality standards that set out key characteristics of services such as Quality in Alcohol and Drugs Services (QUADS).

8.8 Core services for prevention of relapse in alcohol dependence

The HTBS surveys of NHS specialist services (Section 3.10) highlighted that availability of treatment is unevenly distributed throughout Scotland, leaving some without access to what should be considered core services for individuals with alcohol dependence. Some areas may appear to be comparatively well serviced but may actually be unable to meet the needs of their population.

The core services required to offer a flexible and comprehensive package of care and thus form an integral part of developing alcohol services more generally in response to the Alcohol Problems Support and Treatment Services Framework (Scottish Executive Health Department, 2002) include:

1. the facility for inpatient/residential detoxification, if necessary
2. as a minimum, some members of staff covering this inpatient/residential facility should have a special interest and additional training in alcohol misuse
3. the facility for outpatient/day-patient detoxification (which may solely consist of a specialist CPN working in liaison with the GP who is taking responsibility for the prescription of medication)
4. CPNs who should be able to carry out prevention of relapse work including MET, Coping/Social Skills Training, Marital/Family Therapy or BSCT, and be able to offer ongoing follow up. Prevention of relapse should be available in outpatient, day-patient and residential settings.
5. access to appropriate mental health services for patients with psychiatric comorbidity.

As part of shared care and working in liaison with the specialist team, GP’s:

- may need to be able to carry out assessment of need/risk and refer as necessary for inpatient or outpatient detoxification
- may need to be able to assess individuals for the suitability of prescribing acamprosate or disulfiram (supervised e.g. by CPN, relative or community pharmacy)
- will be required, on prescription of such medication, to monitor outcomes, arrange appropriate psychosocial treatment, and carry out appropriate blood testing etc. The GP might have psychosocial treatment arranged through his/her practice, or
via a non-statutory agency, or with the local CPN, if available.

Non-statutory agencies may also be able to offer efficacious psychosocial interventions and may take on the bulk of preventive work when the specialist service is small. However, this raises questions about the resources available to these agencies which are beyond the scope of this report.

The non-statutory agencies may also take on the bulk of individuals for whom controlled drinking is the goal.

8.9 Potential resource impact for NHSScotland

This chapter makes several recommendations for effective service delivery. Facilitating these recommendations is likely to require additional funding within NHSScotland. This section considers the main recommendations and their potential financial consequences.

8.9.1 Use of interventions

Section 8.2 identifies that alcohol dependence requires treatment even after a number of unsuccessful interventions. However, there are sparse data on the current level of provision of interventions and the potential demand for such services. Some very broad-brush assumptions are therefore made to give indicative costs of providing services to those who need them.

The starting point for these estimates is existing data from two PCTs. This is combined with estimates of the prevalence of people with alcohol dependence in Scotland to derive an estimate of the additional number of interventions that may be required to meet demand.

8.9.1.1 Existing data from Primary Care Trusts

Data from the two PCTs, covering 15% of the Scottish population, indicate that these provide in total 800 drug and psychosocial interventions per annum (some patients may receive more than one intervention per annum), with the vast majority being psychosocial. If these Trusts are typical of other Trusts in Scotland, then the figures suggest 5225 service users per annum may be receiving a psychosocial therapy in Scotland. Applying a unit cost of £300 (see Section 7.8.1) per psychosocial therapy gives an estimated expenditure by the NHSScotland of around £1.6 million per annum. This is the best estimate of current expenditure on these therapies by NHSScotland.

8.9.1.2 Scotland-wide demand for therapy

Assuming a prevalence of 23 700 people (18 000 male and 5700 females) with alcohol dependence in Scotland, being the bottom range of the estimates provided in Section 3.5 of this Assessment Report, and that a third of these may be suitable for psychosocial therapy, as reported by Schadlich and Brecht (1998), then there may be demand for 7820 people to receive a therapy per annum. This is about 2600 more than the estimated 5225 presently receiving therapy (see Section 8.9.1.1). The cost of providing the additional therapies are £0.94 million, assuming that all the additional
interventions are psychosocial and have a cost of £300 per therapy and each requires an initial specialist consultation costing £60 each.

However, at the initial specialist consultation, the outcome of the shared decision making process is likely to be that some of these additional 2600 people also receive a pharmacological treatment. The cost of these courses of treatment, excluding the cost of the specialist consultation, is £520 per patient for acamprosate, £307 per person for supervised oral disulfiram and £368 per person for naltrexone.

It is not possible to forecast the mix of treatments that will be provided. A range of cost estimates can nonetheless be provided. The highest cost arises if all 2600 people receive acamprosate. This will increase NHSScotland costs by a further £1.35 million. If, for example, 20% of the additional 2600 people receive acamprosate and supervised oral disulfiram in equal numbers, then the additional cost will be some £0.21 million. The cost summary has adopted this lower figure. The total cost of the additional psychosocial and pharmacological therapies is thus estimated to be £1.15 million (£0.94 million plus £0.21 million).

8.9.2 Joint Working Framework

No specific additional costs have been attributed to the recommendation to adopt ‘joint working’ (Section 8.1.2), itself recommended by the Joint Futures Group. Service redesign to facilitate this is already underway in many Boards and social work departments.

8.9.3 NHS and non-NHS specialist alcohol services

Section 8.1.3 notes that NHS specialist alcohol services must be multi-disciplinary and community based services, delivered by highly skilled staff. No specific additional NHS funding is included to develop the services in this way.

The HTA also recommends that NHS specialist staff inform themselves of services available in the non-statutory sector and pass such information on to service users. Again, no specific additional NHS funding is judged to be required to implement this recommendation.

8.9.4 Continuing care

Section 8.3 recommends that all service users receive additional continuing care. Assuming this to be limited to three hours additional contact per service user, with a similar amount of organisational time, then to service 7820 service users per annum could cost around £0.91 million. This assumes a CPN is providing the care and uses an annualised hours approach.

8.9.5 Recording and collection of information

Section 8.4 makes recommendations on the management of information. These accord with initiatives being taken forward by the Scottish Executive. Such initiatives are underway and thus no additional money should be required as a direct result of this HTA recommendation.
8.9.6 Screening, audit, research and quality assurance

Introducing the recommendations in Sections 8.5 and 8.7 to audit and monitor the effectiveness of services and undertake research into improving the current care systems may involve additional information technology (IT) and staff costs. The former has been one aspect of the discussions with the Scottish Executive on IT systems but it is not clear that provision for additional staff costs has been made.

No forecast of the potential number of staff to undertake this work is available. If one staff member is assumed for each Board with a population of over 500 000 and 0.5 of a staff member for other Boards, with the Islands sharing a staff member then this suggests that between 9 and 10 additional staff could be required. Assuming an average cost of £20 000 per annum, then the additional staff costs for audit could be around £180 000 – £200 000 direct costs, or £252 000 – £280 000 with 40% overheads.

It is assumed that such staff could also undertake any QA-related work.

8.9.7 Staff training and continuing professional development

Section 8.6 recommends a strategic approach be adopted to plan and fund the training of staff involved in the prevention of relapse in alcohol dependence. This recommendation is not an easy one to cost. In order to get an indicative figure it is assumed that all existing NHS staff, as identified in Table 3-4, receive an additional one-week training course at a cost of £325 per course (Dr C Keogh, Clinical Psychologist, personal communication, September 2002). This gives an additional cost of around £87 200 and assumes no additional overtime or travel costs are incurred by staff covering for the trainee.

Training nursing staff in the acute sector will be additional to this cost, suggesting an additional training budget provision of around £100 000.

8.9.8 Patient leaflets

It is assumed that all people who are alcohol dependent and a carer or family member will each require a leaflet, suggesting 50 000 leaflets as a minimum are required. However, targeting such leaflets will not be easy and a one in 10 success rate is assumed. This suggests around 0.5 million additional leaflets need to be produced at £0.05 each, giving a cost of £25 000 per annum.

8.9.9 Core services for prevention of relapse in alcohol dependence

Section 8.8 recommends the core services required to offer a flexible and comprehensive package of care. It also states that the HTBS surveys of NHS specialist services (Table 3-3 and Table 3-4) highlight the uneven distribution of treatment throughout Scotland, leaving some individuals without access to core services.

Without knowing how individual NHS Boards will manage this requirement, it is difficult to provide helpful estimates of the potential additional costs that could arise from reducing the variability of services throughout Scotland. For example, the provision of services could be facilitated by consolidation across Trusts and Boards,
using Managed Clinical Networks, provided that access is carefully considered. It has therefore not been possible to present a resource impact for the provision of satisfactory core services throughout NHSScotland.

### 8.9.10 Summary

No robust financial forecasts can be provided of the total cost of implementing the HTA recommendations because of the absence of good baseline data on current expenditure on preventing relapse in people who are alcohol dependent. Furthermore, it has not been possible to quantify the cost of providing core services uniformly throughout NHSScotland.

An estimate of the incremental costs necessary to implement the remaining recommendations of this HTA is presented in Table 8-1.

#### Table 8-1: Estimate of annual additional cost to implement HTA recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Total £(000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional interventions</td>
<td>1151</td>
</tr>
<tr>
<td>Continuing care</td>
<td>910</td>
</tr>
<tr>
<td>Audit, screening, QA</td>
<td>280</td>
</tr>
<tr>
<td>Training</td>
<td>100</td>
</tr>
<tr>
<td>Patient leaflets</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2466</strong></td>
</tr>
</tbody>
</table>

In summary, an additional £1.15 million is required to increase the provision of effective interventions, (from an estimated base of £1.6 million [Section 8.9.1.1]) and £0.9 million to provide continuing care services. The remaining £0.4 million is required for additional training and audit, quality assurance and research.

The total impact of £2.47 million is about 2.5% of the annual cost to NHSScotland of alcohol misuse at 2001/2002 prices as identified by Catalyst Health Economics Consultants Limited (2001).

The cost savings identified in this HTA accrue only to the annual expenditure of £1.15 million on additional psychosocial and pharmacological therapies. Assuming that the effectiveness of the interventions is as modelled, then there will be resultant savings of around £1.6 million (discounted at 6%) realised over 20 years, arising from a reduction of an additional 209 in the number of people who are alcohol dependent.

The HTA has not quantified any other direct savings from incurring the remaining £1.32 million expenditure but this investment will improve the planning and delivery of good quality services in dedicated alcohol units in NHS Boards across Scotland. The HTA has also not quantified the savings to society or attributed a benefit to the deaths avoided as a result of reducing the rate of relapse in patients who are alcohol dependent. These savings and benefits are likely to be substantial.
9 DISCUSSION AND CONCLUSIONS

9.1 Principal findings on clinical and cost effectiveness

In this Assessment Report, four components of prevention of relapse in people who are alcohol dependent, have undergone detoxification and are newly abstinent have been examined. These are the clinical effectiveness of the interventions, the cost effectiveness, patient perspectives of treatment and a number of issues related to organisation of treatment services. The intention has been to produce an account which will inform policy aimed at improving the planning and running of specialist services for prevention of relapse and, with this in mind, it is clear that some interpretive discussion of the report findings is necessary.

9.1.1 Findings from the four HTA components

9.1.1.1 Clinical effectiveness

Clinical effectiveness evidence demonstrates that BSCT, MET, Marital/Family Therapy and Coping/Social Skills Training are of benefit in preventing relapse in alcohol dependence. The meta-analysis suggested that the beneficial effects were statistically significant and similar for each treatment.

BI, although commonly used, is not supported by evidence in alcohol-dependent patients.

There is evidence that acamprosate, supervised oral disulfiram, or naltrexone is of clinical benefit when given in addition to psychosocial interventions. The meta-analysis suggested statistically significant and broadly similar effects for acamprosate and naltrexone, while the results of one well conducted randomised study of supervised oral disulfiram indicate that it can contribute beneficially to a prevention of relapse programme.

The Project MATCH study showed that an introductory programme based on the 12-step approach combined with encouragement to attend AA meetings helps to prevent relapse.

Randomised studies have shown that practical help with problems such as housing, debt and claiming benefits appear likely to contribute to control of alcohol problems.

9.1.1.2 Patient issues

This HTA views alcohol dependence as a health problem. However, no effective service can ignore the sociological aspects of drinking alcohol. The existence of a spectrum of drinking from socially acceptable, and even encouraged, to socially unacceptable and dangerous necessitates an unbiased self assessment of the service user’s drinking before treatment can even be sought. Thus, judgemental attitudes concerning alcohol dependence may delay some people in seeking help. In consequence, some weight has been given in this HTA to the perceptions of service users and the message that any alcohol treatment service must be approachable cannot be emphasised too strongly.
Service users identified a variety of different preferences related to the treatment of alcohol dependence. The range of preferences emphasised the importance of offering a range of services that can meet the individual needs of the people who will require them. Service users were able to identify the value of group therapy, individual therapy, residential and outpatient care, and pharmacological interventions. The experience of many service users often indicated a journey of care that included a lack of awareness of the range of available treatments and trying treatments they found inappropriate. Difficulties in obtaining information about available services were perceived. For example, GPs were widely thought to regard alcohol dependence as a personal weakness rather than a ‘disease’ and as such were not thought to offer sufficient information to allow the service user to make an informed treatment choice.

The study of people attending NHS services (see Chapter 6) shows that most patients valued group therapy, which provided an opportunity to share experience with other people who really understood the situation. Women with experience of single sex groups preferred these groups, whereas men tended to prefer mixed groups. Those still drinking found the group work more difficult. Those who felt coerced into attending AA meetings did not continue with them, but others were positive about AA meetings and valued the flexibility of times and venues available. Most service users also found one-to-one therapy helpful to discuss a wide range of issues in depth and in a suitable manner to meet the individual’s needs. Some interviewees had attended a Council on Alcohol, mainly after being referred by an employer. Some valued the counselling and alternative interventions, but others felt that the ‘controlled drinking’ philosophy of the Councils was not a feasible approach for them. The availability of the service from the Councils at times of crisis was appreciated. Overall, it was clear from the responses that breadth of choice is very important.

In one of the Trusts included in the study, service users who live in a particular geographic area within the Trust’s catchment area are offered follow-up outpatient appointments in satellite clinics, however those who live outside the specified area have no such opportunity. This highlights the existing inequity of access.

Feedback during consultation from service users with experience of residential care indicated that it was valued for the support, discipline, one-to-ones, companionship in adversity and regular nutritious meals, all of which were viewed as key aspects of residential care. However, there was concern about the length of the waiting time for places in residential care.

The low level of awareness of services available to treat alcohol dependence was a key issue identified by Lancaster & Dudleston (2002), by research commissioned by HTBS for this assessment, and by service users during assessment consultation. GPs were identified as a critical source of this information. This information gap may prevent or delay access to treatments. In addition, a GP or patient’s lack of knowledge of the range of treatment options may result in a patient failing to find treatments that meet their individual needs and expectations. This may have implications for completion of treatment and patient trust in GPs.

9.1.1.3 Organisational issues

The HTBS survey indicates that there is considerable variation in the provision of alcohol services in Scotland. Services for prevention of relapse in alcohol dependence
throughout Scotland need to be consistent and equitable, be provided to accredited standards and as part of agreed protocols, have equity of access for the heterogeneous group of people with alcohol dependence, train staff to agreed national standards, and use single shared assessments and agreed outcome measures. Service users need to be able to access a flexible and comprehensive package of care such as detoxification services (including inpatient or residential care when appropriate), shared care and continuing care.

Joint training of staff from NHS and non-statutory services will help ensure that all staff are trained to uniform standards and equipped with the necessary skills to deliver the interventions recommended. This is demonstrated by the fact that psychosocial treatments need to be delivered to consistently high standards over time, and for these interventions to be as similar as possible to those which have been shown effective in clinical trials.

Non-NHS services treating alcohol-dependent patients use a wide range of psychosocial techniques. Some of these are not adequately supported by clinical trial evidence. Concentration on a few techniques closely based on those with proven benefits would be likely to increase the effectiveness of these services. Other approaches should be tested in formal randomised trials before being adopted as standard procedures.

9.1.1.4 Economic evaluation

An HTBS economic model over a 20-year time horizon showed that BSCT, MET, Marital/Family Therapy and Coping/Social Skills Training are cost-effective psychosocial interventions compared with standard care.

When combined with psychosocial interventions, acamprosate and naltrexone are also cost effective. The odds ratio for each intervention is the parameter that has the greatest impact on cost effectiveness and the ranking of therapies. The evidence used to calculate the odds ratios has been explained in Section 5.6 and is primarily from reported RCTs. Whilst unsupervised oral disulfiram appears cost effective under base case assumptions, the very wide confidence intervals for the odds ratio include the possibility that it is not cost effective. The lower 95% confidence interval for BSCT approaches one, suggesting there is also some uncertainty about its effectiveness. Thus, the recommended research focuses on collecting robust effectiveness data.

It was not possible to assess the cost-effectiveness of supervised oral disulfiram because, while this is known to significantly reduce intake of alcohol, it is not known how this may relate to controlled drinking or abstinence.

9.1.2 Assumptions, limitations and uncertainties

This report addresses the problems of the relatively small but significant subgroup of people who find themselves, at some stage, unable to control their drinking. This group is qualitatively different from others in the continuity of their exposure to alcohol and the consequent effects it may have on all aspects of their lives and in particular on their health. The profound adverse influence, which high levels of alcohol have on many aspects of morbidity and also on life expectancy, has been investigated in numerous epidemiological studies some of which are reviewed in this
Assessment Report. From these studies, HTBS has attempted to construct a profile of the health and life expectations of an untreated alcohol-dependent person and contrast it with the expectations of the general population. Such calculations are fraught with difficulties, some of which are described in the appropriate subsections of this discussion. However, the general message appeared to be that, while the burden of ill health is high in alcohol dependence, the biggest impact of heavy drinking is in raising mortality. Two studies, one in Taiwan (Chen et al., 2001) and the other in Sweden (Denison et al., 1995), observed death rates which were around 12 times that of the Scottish population. This effect could not be explained by national differences in mortality; the life expectancy at birth in Sweden being slightly higher than in Scotland based on 1997 figures from Statistics Sweden (http://www.scb.se/indexeng.asp). Furthermore, the majority of the excess mortality did not arise from somatic diseases generally linked with alcohol. Thus, it would be unwise to concentrate on too narrow a group of alcohol-associated illnesses and disregard the general message that alcohol dependence should itself be seen as a life-threatening condition.

Use of the results of either clinical trials or reviews of research as the basis of a practical effective clinical service is not a trivial undertaking. This is so even with conceptually simple interventions such as medicines that will have been tested according to carefully specified protocols, which should be reflected in the SPC in a way which makes it reasonable to suppose that the efficacy measured in trials will be similar to the effectiveness achieved in clinical practice. For psychosocial interventions the difficulties are much greater. There is rarely a single agreed protocol for delivery of these treatments and the setting and duration of the treatment and the personal qualities of the therapist may all play a part in determining the effectiveness. In addition to this, trials of nominally similar treatments may have involved substantively different procedures. It is generally the responsibility of each service provider to be acquainted with the practical details of what has been proven effective in research and to decide how it can be delivered locally. A pragmatic approach to this problem is to choose treatments which have been shown to perform well in meta-analyses and then to select trials from these meta-analyses of interventions which estimate treatment effects towards the higher end of the distribution of results – preferably statistically significant in their own right – and examine the nature of the intervention in more detail by consulting original research reports. A good example of this procedure is provided by Finney and Moos (1998) who pick out Social Skills Training, Community Reinforcement and Behavioural Marital Therapy as examples of effective interventions and discuss the possible elements of a service based on these interventions. The results of the meta-analyses in this report would agree with Finney’s general approach.

The results of the HTBS analysis also suggest that the combination of Coping/Social Skills Training and MET offered by many Scottish specialist care units provides a good foundation for treatment. However, very few of these interventions are delivered according to standardised protocols. This makes it difficult to be certain that the treatments correspond to those proven effective in clinical trials.

The lack of effectiveness of BI in alcohol-dependent people contrasts strongly with its beneficial effect in problem drinking in non-dependent people. This conclusion may at first seem at odds with much perceived wisdom but the predominance of
non-dependent patients in studies of BI and the substantively different nature of the problems faced by dependent drinkers provides a background against which this conclusion appears more compelling. Finney & Moos, (1998) have some comments on the way that BI has been assessed which shed further light on this issue.

Both acamprosate and naltrexone appear to be effective additions to ‘counselling’. Although the meta-analysis results suggest a slightly larger effect for acamprosate, the confidence intervals overlap by a substantial margin and no firm conclusion can be drawn about the relative efficacy of the treatments. A concern is that there is appreciable heterogeneity between trial results for both acamprosate and naltrexone. This suggests that there are genuine differences in efficacy possibly associated with trial procedures or types of patient. Two large pragmatic studies of acamprosate (Chick et al., 2000) (Mason, 2001b) have now produced negative results and this must raise the possibility that the effectiveness could be low in routine clinical practice.

It has been hypothesised that the absence of efficacy for acamprosate in the pragmatic studies may result from a number of causes. Mason (Mason & Ownby, 2000) suggests that failure in the European study may have been due to a delay between detoxification and commencing acamprosate. Alternatively Lesch et al.(2001) has suggested that acamprosate may only be effective in certain types of patient who were poorly represented in the study. Similarly, unlike most European studies, the US study (Mason, 2001a) recruited patients who were not required to cease drinking at the start of acamprosate treatment or to have undergone detoxification and many were taking drugs other than alcohol. However, these are no more than observations concerning the differences between these studies and other studies which demonstrated a benefit for acamprosate. Such differences between studies will always exist and provide potential but unproven explanations of differences in observed efficacy.

The deliberations of the USA FDA concerning the results of the US multicentre study of acamprosate and three of the positive European studies (Pelc et al., 1997);(Sass, 1996b);(Paille et al., 1995) resulted in a refusal of the application for a US marketing authorisation. The FDA re-examined the analysis of these studies and were critical of elements of the outcome ascertainment in the European studies. However, the FDA analysis did not materially change the conclusions concerning the treatment effect upon the proportion of patients achieving abstinence. Since this is the only outcome upon which the HTBS analysis is based, the results are not affected.

With regard to Scottish usage of acamprosate and naltrexone, it is stressed that only acamprosate currently holds a UK marketing authorisation. A licence to market naltrexone in the UK for prevention of relapse has previously been applied for but refused by the licensing authority on the advice of the Committee on Safety of Medicines (CSM). The CSM reviewed full evidence for the efficacy, safety and quality of the product at the time of application. Medicines can be given outside the provisions of their UK licence but the responsibility for this action lies solely with the prescribing physician. The manufacturers, Dupont, are currently deciding whether to make a further application. Naltrexone is already marketed in the UK for the treatment of opioid addiction. It has licences for use as an adjunct treatment in preventing alcohol relapse in a number of countries including the Republic of Ireland and the USA. Consequently, naltrexone cannot be recommended for routine use in alcohol dependence in Scotland.
The evidence reviewed in this report does not support the unsupervised administration of oral disulfiram. However, one well-designed clinical trial (Chick et al., 1992) and diverse supporting evidence have suggested that oral disulfiram is effective when it is appropriately supervised. The single trial did not report long-term success rates in terms of abstinence or controlled drinking. It is therefore not possible to express this effect in a manner comparable to the effects of the other treatments reviewed and thus allow its assessment in the economic evaluation.

The studies of pharmacological interventions reviewed in this report have considered the use of acamprosate, naltrexone and disulfiram used in conjunction with ‘counselling’ in centres of expertise. The important issue of how or whether these treatments should be used in other settings has not been addressed. Advice on the management of alcohol problems by primary care professionals is available from SIGN, however some clinically important areas such as GP prescribing of acamprosate are not extensively covered by this HTA or by SIGN.

The economic evaluation shows that the odds ratio for each therapy is the parameter that has the greatest impact on cost effectiveness and the ranking of therapies. Thus, the key issues emerging relate to the quality of evidence on the clinical effectiveness of each therapy and whether it can be generalised to a Scottish setting. These issues have been discussed in Section 9.3.

The other issues emerging from the discussion on the economic evaluation included whether the assumptions underlying the epidemiology are robust. Section 3.20 of this document explained that the economic evaluation has included illnesses associated with chronic drinking which in a way may understate the potential benefit to NHSScotland of treating alcohol dependence.

The disease incidences used in the economic evaluation combine probabilities extracted from various international studies with incidences from the Scottish population taken from the Scottish Health Statistics (Information and Statistics Division National Health Service in Scotland, 2000) and other sources. These sources are combined to provide a forecast number of disease cases for a cohort of alcohol-dependent and non-alcohol-dependent men and women. The model is particularly sensitive to the incidence of alcohol dependence syndrome and alcoholic psychosis, two diseases that were not well covered in the literature. Moreover the model assumes that abstinent patients have the same health as non-alcohol dependents. Evidence on both these points would be beneficial.

The remaining major issue for the economic evaluation is the absence of Scottish disease related costs. These have been approximated by obtaining data from ISD on length of stay by disease and applying the average inpatient cost for a general function. For example, in the case of cirrhosis, ISD advised that the average length of inpatient stay was almost 20 days and so a daily cost based on published cost for a ‘medical’ inpatient day was applied. It is not possible to say whether this average cost overstates or understates the costs of managing patients with cirrhosis.

9.2 Need for further research

A HTA requires collection of data relating to clinical effectiveness and safety of interventions, a full description of the long-term prognosis for patients and the
variation in prognosis with different treatments and also detailed knowledge of costs of treatments and of disease states. These data come from a variety of sources and it is frequently necessary to combine these sources using a model employing many assumptions. In the process of collecting the data it is often clear that they could be more complete and more directly informative. Thus, one of the outputs of an HTA is a set of recommendations concerning how better data might be obtained.

The epidemiology input to the cost-effectiveness calculations has relied on many diverse observational studies of disease and mortality among alcohol-dependent people. It would be very desirable for this, and many other HTAs, to have access to complete clinical life-event histories collected on a patient-by-patient basis for the Scottish population. This would permit the direct assessment of the interactions between different disease states associated with alcohol and the effects which current alcohol treatments have on these states. In recent years the linkage of different clinical datasets has allowed the first moves towards making such information available. Access to such data would both speed up and increase the accuracy of HTA.

Data collection in order to assess the long-term clinical course of alcohol dependence following treatment in Scotland is needed. Measurement of simple outcomes such as further detoxification over a period such as five years would provide useful long-term outcome data. Demonstration that a high quality of clinical service is being provided is strongly dependent on the availability of such measures and they also provide a way of assessing potential improvements to the service.

As noted previously, large scale pragmatic clinical trials of pharmacological interventions for prevention of relapse would increase confidence in the effectiveness of these treatments. Long-term treatment success rates in terms of abstinence or controlled drinking should be reported. Post-hoc rationalisations of negative results cannot provide satisfactory guidance on which to base clinical practice. Hence a large phase IV study using acamprosate according to procedures achievable in clinical practice – which should be recommended by the manufacturer – would do much to strengthen confidence in the treatment. This comment also applies to naltrexone in so much as a very large recent study (Krystal et al., 2001) produced rather disappointing results and a truly pragmatic study with a positive result would do much to increase confidence in the treatment generally.

The prescription of two or more of the pharmacological interventions simultaneously does not appear to have any supporting evidence of effectiveness or safety. However, the HTBS survey shows that acamprosate and disulfiram are used together in 57% of Scottish services and this is clearly an area for reflection and further study.

The quality of trials of psychosocial treatments is generally not high. In this HTA, studies which were not randomised have occasionally been included if the treatment allocation appeared to have no element of discretion. However, there is no good reason for not including an element of randomisation – either at the individual or group level – in any clinical trial. Complete blinding is not possible in studies of psychosocial treatments and hence biases due to clinician or patient enthusiasms for particular treatments may be difficult to avoid. Consideration should be given to ensuring treatments are delivered in an unbiased fashion and that outcomes are assessed by clinicians blinded to treatment. The results of Project MATCH may have lessened enthusiasm for performing studies with primary hypotheses expressed in
terms of matching patients to treatments. Whether this is so or not, the sample size calculations for such studies should be appropriate to the nature of the hypothesis. In addition the trial results by randomised group (ignoring the matching variables) should be clearly presented.

Finally, the availability of Scottish disease-related costs would inform the forecast savings to NHSScotland of avoiding relapse in people who are alcohol dependent.

9.3 Challenges for implementation

The psychosocial interventions which the HTBS analysis shows to have empirical support are Coping/Social Skills Training, BSCT, Marital/Family Therapy and MET. However, there are some practical limitations in the use of any of these methods and any one treatment is unlikely to suit every situation. These limitations are discussed in the following text.

Three of the clinical trials of Coping Skills included in the HTBS analysis are based on the work of Monti (2001) who investigated a combination of Cue Exposure Therapy (CET) with urge-specific Coping Skills Training, and Communication Skills Training (CET/CST) and compared them with educational discussions and relaxation training. These interventions were delivered as adjuncts to an intensive two-week partial hospital programme involving six hours per day of group, individual and marital treatment based on learning principles and the 12-step approach. This comparison was not randomised, patients being allocated according to month of admission. Each CET/CST session took 90 minutes a day and a total of five coping strategies and eight communication skills were taught. Burtscheidt (2001) used Monti’s treatment techniques in an outpatient treatment programme with 26 group sessions of 100 minutes over six months. There were six or less patients per group. The comparator was a standard outpatient programme, also with weekly meetings. The two very different patterns of delivery in these studies do not provide a clear guide to therapists wishing to use these techniques. The greatest estimated treatment effect was in Monti (2001) when CET/CST was used as an adjunct to another therapy. The study by Allsop et al. used Skills Training which involved written material, verbal instruction, modelling and role play. The authors have given more detailed descriptions of the intervention in other reports (Allsop & Saunders, 1991; Saunders & Allsop, 1991). This study also involved a motivational enhancement stage which may have contributed an additional effect. A third component was to present the view that a lapse does not lead to inevitable relapse. An HTBS meta-analysis, not detailed in this report but previously presented in the consultation version (Slattery et al., 2002), has shown that this final element is of unproven effectiveness. Furthermore, another review claiming to support its efficacy was methodologically flawed (Irvin et al., 1999). As it is easy to envisage conceptual models under which the lapse/relapse distinction might either be beneficial (allowing service users to put lapses behind them and progress with treatment) or harmful (giving the impression that occasional drinking is of little consequence and hence leading to treatment failure), this element should probably be avoided until justified in well designed clinical trials.

BSCT is a complete treatment package. It is primarily aimed at controlled drinking. The review by Walters (2000), and most of the studies included in it, investigate controlled drinking. Some components of the technique, for instance drinking rate control, are only applicable to this aim but other aspects such as goal setting and
identification of high-risk situations are applicable to either aim. The meta-analysis of success rates presented in this HTA is based on Walter’s selection of studies and restricted to those whom he judged as ‘alcoholic’ rather than problem drinkers. Consequently, it is also restricted to subjects seeking a controlled drinking outcome. It may thus be appropriate to use it in this fashion in clinical practice.

It has already been noted that the brief form of MET used in Project MATCH did not perform as well as the more intensive 12-step approach. This suggests the qualification that it may not be a sufficient stand-alone therapy but should be a precursor to other treatments or, possibly, an early component of a stepped care programme. It is notable that Sellman et al. (2001) excluded patients with ‘severe dependence’ or for whom abstinence might be advised from his study. However, it is not clear whether he considered four sessions of MET inappropriate for such patients or just the ‘no further counselling’ option. Bien et al. (1993) used only a single session of MET but as a precursor to standard outpatient treatment, much in the manner recommended in this Assessment Report.

Many interventions involving spouses, partners or contracts with other individuals have been tested and the twelve trials, which provided appropriate outcome data for the HTBS analysis, are rather diverse. Finney and Moos (1998) picked out the studies of the CRA as figuring prominently in several league tables of effective treatments, and the contribution of CRA (Hunt & Azrin, 1973); (Smith et al., 1998) to increasing the estimated treatment effect of relationship interventions is clear (Appendix 17). It is notable that the trial reported by Smith et al. enrolled homeless patients and, for the most part, the relationship involved a contract with the project nurse for supervision of disulfiram. Other standard elements of CRA such as a job club and social club reinforcing non-drinking recreational activities were also used. Non-CRA relationship interventions generally tended to show positive, if less impressive, results but the only study in which a statistically significant effect was estimated on treatment success rates was that by Corder et al. (1972). This study involved the wives of patients in an intensive four-day workshop at the end of a three-week daily treatment programme. The control group received a four-week daily programme without involvement of wives. Although the intervention appears to have been successful the result should be regarded with some caution as allocation was unrandomised and confounded by time period – all the control group were recruited first. Combined with the general positive trend in other marital interventions, this suggests that involvement of spouses in treatment, when acceptable to both patient and partner, is an option to be considered. However, this acceptability may prove a limiting factor in practice.

A concern with regard to the CRA treatment may be that the social elements involve substantial organisation and time. However, these elements could be run by staff without clinical expertise and the good clinical trial results suggest that such a strategy might be worth serious consideration.

9.4 Summary and conclusions

Inappropriate use of alcohol is a cause of many important problems in Scottish society. A broad picture of these has been given in the Plan for Action on alcohol problems (SACAM, 2002). The adverse consequences of alcohol are apparent in health, criminal justice, road traffic, employment and productivity. To a substantial extent, however, these problems arise through drinking in individuals who are not
dependent upon alcohol and who may not be considered either by themselves or most others to have an alcohol-related problem.

Due to the extensive damage caused to the health of people who drink beyond defined limits, the importance of identifying and effectively treating alcohol dependence at an early stage cannot be too greatly stressed.

An effective armamentarium for prevention of relapse in alcohol dependence is an essential feature of any alcohol treatment service. This HTA has addressed the problem of how a programme of treatment within NHSScotland can be constituted and maintained in a manner which will ensure that effective, consistent and efficient interventions are delivered in a way which will meet the needs and wishes of service users.

On balance, four psychosocial and two pharmacological interventions have been proven effective in clinical studies and together provide a versatile response to a range of needs.

MET may be used as a preliminary treatment in ‘stepped care’ to be followed if necessary by more intensive Coping/Social Skills Training. Marital/Family Therapy allows supportive family members or others close to the service users to contribute effectively to their recovery. BSCT provides an option particularly appropriate for any service users who choose to aim for controlled drinking but not abstinence. Either acamprosate or supervised oral disulfiram appear to be of value as adjuncts to psychosocial interventions. A partner who can help ensure that the alcohol-dependent person complies with the disulfiram regime should be found. A close friend, spouse or other family member, a supervisor or nurse at the workplace or a nurse at a clinic might be ‘the partner’.

The cost-effectiveness calculations have concentrated on cost and benefits to NHSScotland and, even in this limited area, cost savings have been shown for psychosocial interventions and for acamprosate. This HTA has accounted for many health costs not addressed in previous cost-effectiveness assessments in this area. However, there are still many health costs for which data are not available and numerous social costs which are likely to equal or exceed the health costs. Thus it is clear that expenditure on relapse prevention in alcohol dependence not only improves health but is socially and economically beneficial.

9.5 Recommendations to NHSScotland

1. BSCT, MET, Marital/Family Therapy and Coping/Social Skills Training are clinically and cost-effective psychosocial interventions and are recommended treatment options for the prevention of relapse in alcohol dependence.

2. BIs are not recommended, as trials in alcohol-dependent people have failed to show any benefit. However, the SIGN guideline will recommend BIs for hazardous drinkers (a less severely affected group than those who are considered to be alcohol dependent).

3. Other psychosocial interventions are not recommended as their clinical effectiveness is unproven.
4. Acamprosate and supervised oral disulfiram are treatment options recommended as adjuncts to psychosocial interventions. Naltrexone does not have a Marketing Authorisation for the treatment of alcohol dependence in the UK and is not recommended for routine use in NHSScotland.

5. Alcohol services should aim to reduce the delay between detoxification and interventions for the prevention of relapse. This would be facilitated by joint working between specialist mental health services, primary care, social work addiction services and non-statutory agencies, as recommended by the Joint Futures Group.

6. Acamprosate or supervised oral disulfiram should usually be initiated by a specialist service. The specialist service will: ensure that the patient meets the criteria for suitability; ensure the assessment of the motivation and ability of the patient to use the medication correctly; monitor efficacy; and ensure that adjunctive psychosocial treatment is organised. Usage should be in accordance with the SPC and reviewed regularly during the first 12 weeks after initiation of treatment, at which stage transfer of prescribing to the GP may be appropriate, even though specialist care may continue (shared care).

7. Introduction to AA and non-statutory agencies such as local Councils on Alcohol (AFS) should be part of the overall strategy of specialist NHS services for the prevention of relapse. As with other psychosocial treatments, attendance is most likely to be beneficial if it is an informed voluntary decision.

8. People who are alcohol dependent should be informed about treatment choices. Their needs, preferences and social circumstances should be considered. As a result, the choice of interventions should be a shared decision between the health professional and the patient.

9. NHS specialist services should contact people who drop out of treatment programmes and offer them another appointment.

10. Health professionals should provide patient information, including leaflets, which should be used to support discussion between health professionals and patients about the most appropriate treatment option.

11. Written information about the range of available services should be readily accessible to people with alcohol problems, their families, carers and to health professionals, especially GPs. Alternative formats such as cartoons or audio-visual material should be used to support discussions with people who have low reading skills or poor concentration. AATs could coordinate information requirements.

12. A regularly updated comprehensive directory of alcohol services and accommodation should be developed for the benefit of NHSScotland staff, patients and their families, friends and carers.

13. Shorter, less intensive interventions (such as MET) might be provided first, following the principle of ‘stepped’ care, if the history suggests that such a
relatively low intensity approach has not already failed. Non-response will indicate the need to move to more intensive treatment.

14. Recurrent relapse should not be a barrier to re-referral. If a particular intervention is unsuccessful for an individual, it is important to recognise that other treatments may be more suitable and that further options should be explored.

15. Core services should provide the full spectrum of treatment options, including access to beds for NHS inpatient or private/non-statutory residential treatment. This might be achieved economically by sharing of services across Trusts and Boards provided that access is carefully considered.

16. To ensure equity of access for the heterogeneous group of people with alcohol dependence, the provision and standard of alcohol services should be consistent throughout NHSScotland.

17. Specialist NHS services should make provision for the continuing care of each individual.

18. Certain subgroups of people with alcohol dependence such as those in rural communities, young people, the homeless, those with comorbid mental health problems and those in the criminal justice system can encounter unique difficulties in accessing specialist services. Providers should make reasonable efforts to ensure that the needs of every alcohol-dependent person can be accommodated somewhere within the spectrum of service provision.

19. Providers should develop services for the relatives, carers and dependants of people with alcohol dependence.

20. Joint training of staff from NHS and non-statutory services is recommended to help ensure that all staff are trained to uniform standards and equipped with the necessary skills to deliver the recommended interventions.

21. Interventions should be carried out in accordance with standardised protocols by staff trained to agreed national standards.

22. Measures should be in place to ensure that psychosocial treatments are delivered to consistently high standards over time. The delivery of these interventions should be as similar as possible to that which has been shown effective in clinical trials. As these have involved delivery by clinical psychologists, the skills of such professionals should be used at least in supervision of treatment delivery and in training in methods of delivery.

23. The Plan for Action (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) requires each AAT to draw up, publish by April 2003, and subsequently implement, a local strategy covering at least three years. These strategies should take account of these recommendations.

24. An improved information collection system is required to ensure that the requirements of these recommendations are fulfilled. Development of the NAIR, currently being undertaken by ISD, should take these requirements into account.
25. In order to assess the long-term clinical course of alcohol dependence following treatment in Scotland, measurement of simple, verifiable outcomes such as further detoxification over a period of, for example, five years would prove useful. Long-term treatment success rates in terms of abstinence or controlled drinking should be reported.

26. More research is needed regarding the benefits of different settings for psychosocial interventions in order to determine the most effective and efficient approach to delivering the interventions. It has not been established whether group therapy is more effective than individual therapy, or whether an inpatient, outpatient or day unit setting is most conducive to treatment success. It is unclear if there is a correlation between the effectiveness of interventions and the length, frequency or intensity of treatment. In particular, the impact on effectiveness of multiple psychosocial treatments for one individual is not established.

27. Acamprosate (and naltrexone) have given unusually variable results in clinical trials in specialist settings, with some trials having shown no treatment effect. Possible explanations have been suggested but these require corroboration by prospective studies. Given the variability of effect even in specialist settings, any extrapolation to use in primary care requires new clinical trial evidence of effectiveness.

28. A trial of supervised oral disulfiram has shown a convincing reduction in drinking while on the drug but no study has demonstrated that this results in an increased likelihood of ongoing abstinence or controlled drinking. Such a study is needed to inform clinical practice.
10 ACKNOWLEDGEMENTS

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12. APPENDICES

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### Appendix 1

**TOPIC SPECIFIC GROUP MEMBERS**

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<tr>
<th>Name</th>
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Appendix 2
SIGN GUIDELINE: KEY QUESTIONS ON ALCOHOL DEPENDENCE

Alcohol Dependence Guideline Development Group

Key Questions  June 2002

Detection and assessment
1. What evidence is there on the use of CAGE, AUDIT, history taking, liver function tests, and aspects of the physical examination in the detection of harmful drinking and alcohol dependence in A & E and the primary care setting?
2. What evidence is there on the sensitivity and specificity of the above methods?
3. What evidence is there on detection rates of harmful drinking and alcohol dependence by the courts, A & E, schools, homeless services, antenatal services, services for the elderly, police, social workers, new employee assessment, new patient assessment?
4. What evidence is there that training general practitioners, practice nurses, community nurses, social workers, and A & E staff in the detection of harmful drinking or alcohol dependence improves detection rates?

Early Intervention for hazardous and harmful alcoholism
Interventions by general practitioners, practice nurses, community nurses, social workers, and health visitors

5. What evidence is there that advice and information on safe levels of alcohol consumption on one or two occasions (minimum intervention) will (a) reduce hazardous drinking (b) reduce harmful drinking or (c) prevent harmful or hazardous drinking progressing to alcohol dependence?
6. What evidence is there on assessing a patient’s readiness to change his or her drinking habits?
7. What evidence is there on how the subject of alcohol consumption should be discussed with patients?
8. What evidence is there on the accuracy of self-assessment of alcohol consumption by counting units of alcohol?
9. What evidence is there on who should be given counselling or who should be referred to specialist addiction wards, or general psychiatric wards, or specialised alcohol services?

Detoxification
10. What evidence is there on the criteria (gender, age, alcohol consumption, associated morbidity such as cardiovascular disease, liver disease, or mental illness) that should be used when considering where detoxification should be carried out (i.e. in-patient versus community, specialist versus primary care)?
11. What evidence is there on the criteria (gender, pregnancy status, age, alcohol consumption, alcohol dependence symptoms, associated morbidity such as cardiovascular disease, liver disease, or mental illness) that should be used when considering whether pharmacological detoxification is required and if so which drugs and with which dosing schedules are appropriate (e.g. chlordiazepoxide, diazepam, variable vs fixed dosage, amount, length of drug treatment)?
12. What evidence is there on how different treatment settings (general psychiatric wards, specialist addiction wards, medical wards, general practice, nurse prescribing, home detoxification services, day units, alcohol clinics, and prisons) affect detoxification outcome?

13. What evidence is there on the role of vitamin supplements in detoxification?

14. What evidence is there on which is the preferred setting to which the general practitioner should refer (medical ward, psychiatric ward, detoxification unit) a patient with delirium tremens?

Specialist care and relapse prevention in primary care (including treatment for comorbidity)

15. What evidence is there that the AA reduces alcohol dependence or harmful drinking, and how should health care facilitate the patient’s utilisation of the AA?

16. What evidence is there that other lay services reduce alcohol dependence, harmful or hazardous drinking, and how should primary care facilitate the patient’s utilisation of these services?

17. What evidence is there regarding the effectiveness of antidepressants/anxiolytics in alcohol dependence, in relieving depression and anxiety disorders and/or preventing relapse?

18. What evidence is there that alternative therapies help prevent relapse/maintain abstinence? (shiatsu, aromatherapy, reflexology, massage)?

19. What evidence is there that involving family members (family therapy, couples therapy, Al-Anon) improves quality of life, drinking habit, and compliance to treatment regime? (Primary care aspects of this question are to be covered by SIGN)

20. What evidence is there on how schizophrenia, learning disability, bipolar disorder and substance abuse affect the management of harmful drinking and alcohol dependence?
Appendix 3

HTBS PLANNING QUESTIONS

HTBS ASSESSMENT OF
PREVENTION OF RELAPSE IN ALCOHOL DEPENDENCE

The HTA questions

1. Which approach or combination of approaches will yield the maximum maintenance of recovery amongst the population of those with alcohol dependence who have undergone detoxification?

2. What is the most clinically and cost effective approach to delivering the individual interventions, or combination of interventions, taking into account the different risk groups, locations, duration of treatment, concomitant medications, etc?

HTBS Evidence Questions

1. Relapse
   Q1a. What definitions of relapse are in current use?
   Q1b. Are different definitions appropriate to different individuals?
   Q1c. Are different definitions comparable?

2. Population
   Q2a. How are individuals identified for alcohol relapse prevention?

3. Service capacity and demand
   Q3a. What is the current service capacity for inpatient and outpatient care?
   Q3b. What is the current service demand for inpatient and outpatient care, as indicated by those presenting for treatment?
   Q3c. How is healthcare use distributed between primary vs specialist care?

4. Effectiveness and Delivery of psychosocial interventions – current practice
   Q4a. What psychosocial interventions are in current use for relapse prevention?
   Q4b. Who is delivering psychosocial therapies?
   Q4c. Where are psychosocial therapies being provided?
   Q4d. For what time period are psychosocial therapies being provided (no. of sessions and length of treatment period).
   Q4e. For which of the psychosocial interventions are there protocols/manuals?
   Q4f. If a psychosocial intervention has no manual/protocol can it be sufficiently well characterised for an HTA to be performed?
   Q4g. Are pharmacological interventions used as a standard adjunct to psychosocial therapies?
5. **Effectiveness and Delivery of psychosocial interventions – evidence base**

Q5a. What is the evidence base for the effectiveness of each psychosocial method (including objective evaluations of relapse using blood, breath or other formal test)?
Q5b. Who should deliver psychosocial therapy?
Q5c. What evidence exists on the effectiveness of inpatient versus outpatient delivery of treatment?
Q5d. What evidence exists on the optimal duration for the provision of psychosocial therapies?
Q5e. What are the training, competency, accreditation and supervision requirements for the therapists?
Q5f. Are there groups of individuals at whom psychosocial therapies are best targeted (e.g. treatment matching)?
Q5g. Should pharmacological interventions be given with psychosocial therapies?
Q5h. What evidence is there that the AA helps to reduce relapse and how should healthcare services facilitate access of individuals to the AA?

6. **Effectiveness and delivery of pharmacological interventions – current practice**

Q6a. What pharmacological interventions are in current use for relapse prevention?
Q6b. Who is prescribing and administering these therapies?
Q6c. Where are pharmacological therapies being provided?
Q6d. For what time period are pharmacological therapies being prescribed?
Q6e. Do established protocols exist for delivery of these interventions?
Q6f. What are the safety issues with these pharmacological interventions – particularly interaction issues with Antabuse?
Q6g. What adjunct psychosocial therapies are being given with pharmacological interventions?

7. **Effectiveness of pharmacological interventions – evidence base**

Q7a. What is the evidence base for the effectiveness of each medication (including objective evaluations of relapse using blood, breath or other formal test)?
Q7b. Who should deliver pharmacological therapy?
Q7c. What evidence exists on the optimal location for the commencement and subsequent provision of pharmacological therapies?
Q7d. What evidence exists on the optimal duration of treatment with pharmacological therapies?
Q7e. Should pharmacological therapies be targeted at groups of individuals?
Q7f. Should adjunct psychosocial therapies be given with pharmacological interventions?

8. **Important concomitant substances**

Q8a. What other medications do individuals use for the treatment of alcohol or alcohol related problems in addition to those prescribed for relapse prevention?
Q8b. Is the success of either psychosocial or pharmaceutical interventions in relapse prevention affected by the use of other medications?
Q8c. Does the presence of concomitant disease or substance abuse affect the choice of interventions for relapse prevention?

9. **Combining treatment**

Q9a. Are combinations of psychosocial and pharmacological interventions more effective in relapse prevention than either approach given alone?

10. **Patient Issues**

Q10a. What are the best methods to support and encourage individuals through the treatment programme?

Q10b. What are the patient preferences for treatment?

Q10c. What are the issues involved in relapse prevention in alcohol dependent individuals who have been involved in the criminal justice system?

11. **Healthcare system use**

Q11a. Following relapse, what proportion of individuals leave the healthcare system and what proportion remain undergoing further detoxification and relapse prevention?

Q11b. What are the current courses of action when a patient relapses?

Q11c. Is there any evidence for continued repetitions of the detoxification and relapse prevention treatment programme, following failure?
Appendix 4
DEFINITIONS OF DEPENDENCE

DSM-IV Criteria for Substance Dependence
(source: http://www.psych.org/clin_res/pg_substance_2.cfm)

The Diagnostic and Statistical Manual (DSM-IV) of the American Psychiatric Association (American Psychiatric Association, 2000) defines substance dependence as:

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

1. Tolerance, as defined by either of the following:
   a. a need for markedly increased amounts of the substance to achieve intoxication or desired effect.
   b. Markedly diminished effect with continued use of the same amount of the substance.

2. Withdrawal, as manifested by either of the following:
   a. The characteristic withdrawal syndrome, for the substance (refer to Criteria A and B of the criteria sets for Withdrawal from the specific substances).
   b. The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.

3. The substance is often taken in large amounts or over a longer period than was intended.

4. There is a persistent desire or unsuccessful efforts to cut down or control substance use.

5. A great deal of time is spent in activities necessary to obtain the substance (e.g. visiting multiple doctors or driving long distances) use the substance (e.g. chain-smoking), or recover from its effects.

6. Important social, occupational, or recreational activities are given up or reduced because of substance use.

7. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have caused or exacerbated by the substance (e.g. current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption.

Specify if:
With Physiological Dependence: evidence of tolerance or withdrawal (i.e. either Item 1 or 2 is present).
**Without Physiological Dependence**: no evidence of tolerance or withdrawal (i.e. neither Item 1 nor 2 is present).

*Course specifiers* (See text for definitions):

- **Early Full Remission**
- **Early Partial Remission**
- **Sustained Full Remission**
- **Sustained Partial Remission**
- **On Agonist Therapy**
- **In a Controlled Environment**

ICD-10 criteria for substance dependence

A diagnosis of dependence should usually be made only if three or more of the following have been experienced or exhibited at some time during the previous year.

- (a) A strong desire or sense of compulsion to take the substance.
- (b) Difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use.
- (c) A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by the characteristic withdrawal syndrome for the substance, or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms.
- (d) Evidence of tolerance such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses.
- (e) Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects.
- (f) Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.
Appendix 5

HTBS SURVEY OF NHS SECONDARY CARE IN SCOTLAND - QUESTIONNAIRE

Health Technology Board for Scotland

The Current Provision of Services for Alcohol Relapse Prevention
In Secondary Care

Name of Respondent: __________________________________________

Occupational Title and Grade: _______________________________

Work Address: ______________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

Name and Address of Employer: _______________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

Name / Title of the Service Covered in this Questionnaire: 
_________________________________________________________________

Geographical Area / Sector Covered by the Service: 
_________________________________________________________________

Name of the Consultant / Other (Please give designation) in Charge of the Service: 
_________________________________________________________________

Date of Completion of Questionnaire: __________________________

May we contact you to clarify details regarding your response to this questionnaire? YES / NO
Telephone no. ___________________________
E-mail address ___________________________
A INVENTORY OF ALCOHOL SERVICES

1. Do you have any specialist alcohol workers / services?       YES / NO
   Go to Q.A2 Section B

2. Is the service:
   Please ‘X’ all that apply
   - community based   ___
   - outpatient based   ___
   - day hospital based ___
   - inpatient based   ___
   - other (please specify) ________________________________

3. With respect to inpatient alcohol services:
   - do you have dedicated beds for alcohol patients?       YES / NO ___
     if yes, are the nursing staff covering these beds dedicated to or specifically trained in alcohol / substance misuse nursing? YES / NO
     Please give an estimate of
     - no. in use at any onetime
   - do you use general adult psychiatric acute admission beds? YES / NO ___
4. Please complete details of the specialist alcohol workers in the community / outpatient / day hospital based service as well as inpatient staff solely dedicated to alcohol/substance misuse services.

<table>
<thead>
<tr>
<th>Position</th>
<th>Please ‘X’ all that Apply</th>
<th>Permanent Whole Time Equivalent Posts</th>
<th>Temporary Whole Time Equivalent Posts</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Example-staff grade psych.)</td>
<td>X</td>
<td>0</td>
<td>1 x 0.6</td>
</tr>
<tr>
<td>Consultant psychiatrist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff grade psychiatrist</td>
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<td></td>
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<tr>
<td>Senior house officer</td>
<td></td>
<td></td>
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<tr>
<td>Other medical-please specify</td>
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<tr>
<td>Other medical-please specify</td>
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</tr>
<tr>
<td>Community / staff nurse (I)</td>
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<tr>
<td>Community / staff nurse (H)</td>
<td>*</td>
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<tr>
<td>Community / staff nurse (G)</td>
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<tr>
<td>Community / staff nurse (F)</td>
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<tr>
<td>Community / staff nurse (E)</td>
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<tr>
<td>Community / staff nurse (D)</td>
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<tr>
<td>Community / staff nurse (C)</td>
<td>*</td>
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<tr>
<td>Nursing assistant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other nursing staff-please specify</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other nursing staff-please specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant clinical psychologist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical psychologist</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Trainee psychologist</td>
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<tr>
<td>Assistant psychologist</td>
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<tr>
<td>Occupational therapist</td>
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<td></td>
<td></td>
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<tr>
<td>Other-please specify</td>
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<td></td>
<td></td>
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<tr>
<td>Other-please specify</td>
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</tbody>
</table>

*Please indicate whether nursing staff are RGN or RMN
**B ALCOHOL RELAPSE PREVENTION – PSYCHOSOCIAL INTERVENTIONS**

1. Does your service offer psychosocial interventions for alcohol relapse prevention?
   
   Yes ☐       No ☐ (If No go to section C)

2. Which psychosocial intervention does your service provide for relapse prevention?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Motivational interviewing</td>
</tr>
<tr>
<td>B</td>
<td>Cognitive Behaviour Therapy</td>
</tr>
<tr>
<td>C</td>
<td>Brief intervention</td>
</tr>
<tr>
<td>D</td>
<td>Twelve step facilitation therapy</td>
</tr>
<tr>
<td>E</td>
<td>Behavioural marital/couples therapy</td>
</tr>
<tr>
<td>F</td>
<td>Couples therapy</td>
</tr>
<tr>
<td>G</td>
<td>Family therapy</td>
</tr>
<tr>
<td>H</td>
<td>Community reinforcement approach/therapy</td>
</tr>
<tr>
<td>I</td>
<td>Social skills training</td>
</tr>
<tr>
<td>J</td>
<td>Coping skills training</td>
</tr>
<tr>
<td>K</td>
<td>Stress management</td>
</tr>
<tr>
<td>L</td>
<td>Non-specific counselling (please give details below*)</td>
</tr>
<tr>
<td>M</td>
<td>Other (please specify below*)</td>
</tr>
</tbody>
</table>

*____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

3. Please give codes (A-M above) of those interventions with written protocols in place.

____________________________________________________________________
(It would be helpful if copies of protocols could be enclosed with the questionnaire)

4. Please give codes (A-M above) of those interventions with patient information leaflets.

____________________________________________________________________
(It would be helpful if copies of patient information leaflets could be enclosed)
5. For each of the interventions marked in question 1 above please give the following details

**Note:** If there are more than 4 interventions used please photocopy this page and attach to the completed questionnaire.

<table>
<thead>
<tr>
<th>Code (A-M above)</th>
<th>Individual/group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(If applicable)</td>
</tr>
<tr>
<td>Residential (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Proposed duration/ number of sessions</td>
<td></td>
</tr>
<tr>
<td>Aim of intervention</td>
<td>e.g. abstinence, increase in CAD</td>
</tr>
<tr>
<td>Outcome measures used?</td>
<td>e.g. timeline follow back, collateral info, diary, laboratory investigations (specify)</td>
</tr>
<tr>
<td>Process audited? (If known give no. seen/year)</td>
<td></td>
</tr>
<tr>
<td>Accredited staff</td>
<td>e.g. discipline, grade, no.</td>
</tr>
<tr>
<td>Non-accredited staff carrying out therapy.</td>
<td>e.g. discipline, grade, no.</td>
</tr>
<tr>
<td>What training does staff receive?</td>
<td>e.g. internal or external and from which body/organisation etc</td>
</tr>
<tr>
<td>Does this result in accreditation?</td>
<td></td>
</tr>
</tbody>
</table>
### ALCOHOL RELAPSE PREVENTION – PHARMACOLOGICAL INTERVENTIONS

1. Please complete details of the pharmacological interventions offered for relapse prevention

<table>
<thead>
<tr>
<th></th>
<th>Acamprosate</th>
<th>Naltrexone</th>
<th>Disulfiram</th>
<th>Other (*specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please ‘X’ if used</td>
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<td></td>
<td></td>
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<tr>
<td>Start as in/outpatient/both?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Which staff prescribe this medication?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of review?</td>
<td></td>
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<tr>
<td>Initial proposed duration?</td>
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<tr>
<td>Are psychological interventions usually used in combination? (Please specify)</td>
<td></td>
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<tr>
<td>Are special conditions of administration employed? e.g. CPN supervision (Please specify)</td>
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<tr>
<td>What outcome measures are used? e.g. timeline follow back, collateral info, diaries, lab. Investigations (Please Specify)</td>
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</tr>
<tr>
<td>What is the goal / aim of the treatment e.g. abstinence inc. in CAD</td>
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<tr>
<td>Is the process audited? (if possible enter no. seen / yr)</td>
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</tbody>
</table>

*___________________________________________________________________________________________________________*

2. Are combinations of pharmacological interventions regularly used for relapse prevention? Please specify.

_________________________________________________________________________________________________________

3. For which of the pharmacological interventions are there protocols in place?

_________________________________________________________________________________________________________

(It would be helpful if copies of protocols could be enclosed with the questionnaire)
D APPROACH TO TREATMENT ADHERENCE, DEFAULT, RECURRENT RELAPSE

1. What is your approach to non-adherence / default from psychosocial intervention? ____________________________________________________
________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________

2. What is your approach to non-adherence / default from pharmacological intervention? _________________________________________________
________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________

3. What measures would you continue to offer in the case of recurrent relapse if each of the aforementioned interventions has already been used?
________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________

E USE OF OTHER AGENCIES

1. Which agencies do you ‘make use of’ / integrate in the aftercare of patients?

<table>
<thead>
<tr>
<th>Agency</th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>REGULARLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social work</td>
<td></td>
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</tr>
<tr>
<td>Alcoholics Anonymous</td>
<td></td>
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</tr>
<tr>
<td>Alanon (carer / family support)</td>
<td></td>
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<tr>
<td>Council on Alcohol</td>
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<tr>
<td>Voluntary hostels</td>
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<tr>
<td>Private care e.g. Priory, Castle Craig</td>
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<tr>
<td>Non-statutory rehabilitation units e.g. Church of Scotland</td>
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<tr>
<td>Other secondary care (e.g. GI clinic – please specify)</td>
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<tr>
<td>Other primary care (e.g. practice nurse – please specify)</td>
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<tr>
<td>Other (please specify)</td>
<td></td>
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</tr>
</tbody>
</table>
F OTHER ASPECTS OF CURRENT SERVICE

1. With respect to your service, what is the standard **minimum** aftercare package offered to most individuals on discharge from hospital care following alcohol detoxification? (Please only answer if relevant to your service)

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

2. Are there other features of your service which are important in relation to relapse prevention which are not covered in this questionnaire? If so please comment.

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Appendix 6

HTBS SURVEY OF OTHER PROVIDERS IN SCOTLAND - QUESTIONNAIRE

Health Technology Board for Scotland

SERVICES FOR PREVENTION OF RELAPSE IN ALCOHOL DEPENDENCE IN SCOTLAND

Name of Respondent

Designation (Occupational title and grade)

Name of Service / Unit

Address of Service / Unit

Parent Body

Date of Questionnaire Completion

A.1 Please give the approximate no. of staff in your service. ____

B.1 Do you have dedicated beds for individuals with alcohol dependence/problems? YES / NO ____

Please add any additional explanatory comments if required ________________________________

B.2 Please describe on what basis these beds are allocated to individuals and the length of time individuals would be expected to occupy these beds. ________________________________

C.1 Does your service offer psychosocial interventions / counselling for alcohol dependency / alcohol relapse prevention? YES / NO

C2 Please describe what forms of psychosocial intervention are offered (e.g. CBT, social skills training, non-specific counselling) ________________________________

C.3 Please describe the training that staff receive to carry out these interventions. ________________________________

Delete as appropriate
C.4 Does the training result in accreditation? YES / NO

D.1 Please estimate how many individuals with alcohol problems are newly engaged or re-engaged (e.g. in treatment programs, counselling etc.) with your service in an average month. _______

D.2 On average, what would be the usual proposed length of treatment / ongoing contact with individuals engaged with your service? (Please add any additional comment if required). _______
Appendix 7

NARRATIVE SUMMARY OF RESULTS OF SURVEYS BY NHS BOARD

NHS SPECIALIST SERVICES QUESTIONNAIRE

(A specimen questionnaire can be found in Appendix 5)

- Twenty-seven survey questionnaires were sent to identified individuals who were either known to be leading NHS specialist alcohol teams or, in the case of NHS Board areas without such teams, individuals who would have information regarding specialist services for the treatment of alcohol problems in their area.

- The questionnaires covered all NHS Board areas.

- Telephone enquiry prior to sending the questionnaires could not identify any further NHS specialist service specifically involved in the treatment of alcohol problems which may have been overlooked.

- After the questionnaires had been sent out, it was clarified that Lanarkshire NHS Board had three main centres with base hospitals at Hairmyres, Hartwood and Monklands. Five questionnaires had been sent to Lanarkshire with a resultant overlap in the services covered. In addition both Lothian Health Board and Western Isles Health Board were sent two questionnaires each with only one respondent answering for the whole area. The number of questionnaires expected to be returned was therefore reduced to 23.

- Only one questionnaire out of the 23 remaining questionnaires was not returned. Additional information was obtained on telephone enquiry from that particular service covering basic staffing and service data.

- The returned questionnaires were almost universally completed to a high standard in terms of quality and detail of information.

- Additional protocols for psychosocial interventions, pharmacological interventions and other aspects of aftercare were submitted by respondents from Orkney, Lothian, East Glasgow, South Glasgow, Lomond and Argyll, Dumfries and Galloway and Renfrewshire & Inverclyde.

- The collated information has been checked for accuracy using written follow-up contact with all respondents.
NON NHS SERVICES QUESTIONNAIRE
(A sample questionnaire can be found in Appendix 6)

- Survey questionnaires were sent out to all voluntary facilities/social work facilities that we could identify as having some role in helping individuals with alcohol related problems. We did not send out questionnaires to the AA who have already submitted information to the HTBS. Neither did we send questionnaires to private facilities such as Castle Craig or The Priory who were asked to submit comments during the earlier information gathering process.

- 114 questionnaires were sent to various groups and organisations based throughout Scotland. Of these two questionnaires had erroneously been sent to facilities already surveyed. In addition one questionnaire was sent to an NHS service, again by mistake. The number of active questionnaires was therefore 111.

- The organisations, which were sent the questionnaire included all identified Councils on Alcohol (31), although the sub offices of the various Councils were not surveyed. The Council on Alcohol appears to have services in all NHS Boards except Western Isles and Shetland. Other non NHS facilities surveyed included the day services of various voluntary, independent, Church of Scotland and Social Work organisations. Residential rehabilitation facilities and residential homeless facilities, again run by various voluntary, independent, Church of Scotland or Social Work organisations were also surveyed.

- 39 (35%) of the questionnaires were returned (44% of which were from Councils on Alcohol).

- 61% of questionnaires returned were from day services (this was 24 out of 62 (39%) of the day services surveyed).

- 8% of questionnaires returned were from residential rehabilitation services (this was three out of 13 (23%) of the residential rehabilitation services surveyed)

- 31% of questionnaires returned were from residential homeless services (this was 12 out of 37 (32%) of the residential homeless services surveyed).

- The questionnaires returned represent a reasonably broad distribution of the non-NHS services identified for the survey.

- 17 social work facilities were not identified until after the questionnaires had been returned. Information from these services was available from the SACAM survey of alcohol services carried out for the preparation of the Plan for Action on Alcohol Problems.

- Of non-statutory services, 32 Council on Alcohol sub-offices and 10 other facilities identified post-survey from SACAM information were not surveyed.

- The total number of non-statutory facilities (i.e. not including the social work services) identified in Scotland as dealing in some way with people with alcohol-related problems was therefore 139 (of which 97 were surveyed, 36 (37%) of whom returned completed
questionnaires). This figure does not include the very large number of AA meetings, which take place on a daily basis throughout Scotland.
SERVICES SUMMARY IN BRIEF PER NHS BOARD

ARGYLL & CLYDE

(Population: 426 046)

LOMOND & ARGYLL

(Population: 136 046)

NHS STATUTORY SECONDARY CARE

One inpatient and outpatient based secondary care service but no community or day hospital service. (Community Addiction Team, CAT, in Dumbarton area)
14 dedicated inpatient beds, no use of general adult psychiatry beds (total: 14 beds)
Staffing complement includes consultant psychiatrist, other medical staff and RMN trained nursing staff.
Uses acamprosate and disulfiram.
Psychosocial interventions include Motivational Interviewing (MI), Cognitive Behavioural Therapy (CBT), Community Reinforcement Approach (CRA), Social Skills Training (SS), Coping Skills Training (CS), Stress Management (SM), Non-specific Counselling (NSC), Residential Relapse Prevention Programme and Respite Admissions.

NON-NHS SERVICES

In addition to Alcoholics Anonymous (AA), the area has nine of the non-NHS facilities identified, about eight of which are day facilities (seven Council on Alcohol and one social work facility) and one service which is a Church of Scotland residential rehabilitation facility.

REFREWSHIRE & INVERCLYDE

(Population: 290 000)

NHS STATUTORY SECONDARY CARE

Two outpatient and day hospital based services.
11 dedicated inpatient beds and about four other general adult psychiatry beds in use for alcohol problems at any one time (total: 15 beds).
Staffing complement includes consultant psychiatrists, other medical staff, RMN trained nursing staff and clinical psychology staff.
Uses acamprosate, disulfiram and naltrexone (one of services).
Psychosocial interventions include MI, CBT, Brief Intervention (BI), SS, CS, SM, Alcohol Education Groups, Solution Focused Relapse Prevention Groups, Anxiety Management, Anger Management, Relaxation and Exercise Groups, outpatient women’s group ‘self help’.
NON-NHS SERVICES

In addition to AA, the area has 16 of the non-NHS facilities identified, about 12 of which are day facilities (mostly Councils on Alcohol and social work facilities), three of which are residential homeless facilities (Jericho Society) and one facility which is a Salvation Army residential rehabilitation facility.

AYRSHIRE & ARRAN
(Population: 374,545)

NHS STATUTORY SECONDARY CARE

A comprehensive community, outpatient, day hospital and inpatient based service. Six dedicated alcohol beds and 12 beds for residential dual diagnosis service, which at any time are used by approximately 50% alcohol users (total: 12 beds). Staffing complement includes consultant psychiatrist, other medical staff, nursing staff (both RGN and RMN trained) and occupational therapy staff. Uses acamprosate, disulfiram and naltrexone. Psychosocial interventions include MI, CBT, BI, Behavioural Marital/Couples Therapy (BMCT), Couples Therapy, Family Therapy, CRA, SS, CS, SM, NSC, Anger Management, Relapse Management.

NON-NHS SERVICES

In addition to AA the area has eight of the non-NHS facilities identified, all of which are day facilities, spread between the Council on Alcohol, social work, Church of Scotland and an independent voluntary facility.

BORDERS
(Population: 106,389)

NHS STATUTORY SECONDARY CARE

A solely community based service. 1.5 dedicated alcohol beds and 0.8 general psychiatry beds in use for alcohol problems at any one time (total: 2.3 beds) Staffing complement without a consultant psychiatrist or any medical staff, but does have dedicated social work staff as well as nursing staff. Uses acamprosate and disulfiram. No psychosocial interventions offered.

NON-NHS SERVICES

In addition to AA, the area has two of the non-NHS facilities identified, both of which are day facilities (Council on Alcohol and independent voluntary).
DUMFRIES & GALLOWAY
(Population: 147 280)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient based service with no day hospital service.
Four beds dedicated to either alcohol or substance use disorders and two general psychiatry beds in use for alcohol problems (total: six beds).
Staffing complement includes a consultant psychiatrist, other medical staff, RMN and RGN trained nursing staff and occupational therapy staff.
Uses acamprosate and disulfiram.
Psychosocial interventions include MI, CBT, BI, Couples, SS, CS, SM.

NON-NHS SERVICES

In addition to AA the area has two of the non-NHS facilities identified (Councils on Alcohol)

FIFE
(Population: 348 214)

NHS STATUTORY SECONDARY CARE

Two services, a very small outpatient and day hospital based service in West Fife and one solely community based service in Kirkcaldy and related areas.
No dedicated alcohol beds and up to about four general adult psychiatry beds in use at any one time (total: up to four beds).
Staffing complement with no consultant psychiatrist or other medical staff.
Uses acamprosate and disulfiram.
Only one of the two services offers psychosocial interventions, which include MI, CBT, BI, Couples, Family, SS, CS, SM.

NON-NHS SERVICES

In addition to AA the area has four of the non-NHS facilities identified, all of which are day facilities equally spread between Council on Alcohol, social work, Church of Scotland and another independent voluntary facility.
FORTH VALLEY
(Population: 275 806)

NHS STATUTORY SECONDARY CARE

A community and outpatient service with no day hospital or specialist inpatient provision.
No dedicated alcohol beds and two general adult psychiatry beds in use for alcohol problems (total: two beds).
Staffing complement includes consultant psychiatrist and RMN nursing staff.
Uses acamprosate and disulfiram.
Psychosocial interventions include MI, CBT, BI, SS, CS, SM.

NON-NHS SERVICES

In addition to AA the area has four of the non-NHS facilities identified (Councils on Alcohol).

GRAMPIAN
(Population: 532 110)

NHS STATUTORY SECONDARY CARE

A community and outpatient service with no day hospital or specialist inpatient provision.
No acknowledged use of beds for alcohol problems, either dedicated or general adult psychiatry (total: 0 beds).
Staffing complement includes consultant psychiatrist, other medical staff and RMN nursing staff.
Uses acamprosate, disulfiram and naltrexone.
Psychosocial interventions include MI, CBT, BI, Twelve Step Facilitation (TSF), CS, SM.

NON-NHS SERVICES

In addition to AA the area has 14 of the non-NHS facilities identified, nine of which are day facilities (spread across Councils on Alcohol, social work, Salvation Army, Cyrenians etc.), two of which are residential homeless facilities (Cyrenians and independent voluntary) and three residential rehabilitation facilities (one Church of Scotland and two independent voluntary facilities). Albyn House Association Ltd. has 14 hostel beds for respite/rehabilitation and four designated place beds for sobering up of ‘drunk and incapable’ persons arrested by Grampian Police.
GREATER GLASGOW  
(Population: 897 053)

NHS STATUTORY SECONDARY CARE

Four centres, three of which have comprehensive community, outpatient, day hospital and inpatient services, one of which has no day hospital service.  
19 – 21 dedicated alcohol beds and six general adult psychiatry beds in use at any one time (total: 25 – 27 beds). Future planning to reorganize as two 15 bedded units.
Staffing complement includes consultant psychiatrists, other medical staff, nursing staff, consultant clinical psychologists and other clinical psychology staff and occupational therapy staff.
Uses acamprosate, disulfiram and naltrexone (one service).
Psychosocial interventions include MI, CBT, BI, SS, CS, SM, BMCT, Couples, CRA, Anger Management, Relapse Prevention Groups/Programme.

NON-NHS SERVICES

In addition to very large AA presence, the area has 47 of the non-NHS facilities identified, 28 of which are day facilities (nine Councils on Alcohol, 12 social work, others include Church of Scotland, independent voluntary and City Council facilities), 15 of which are residential homeless facilities (six Talbot Association, four City Council, three Simon Community (social work and Health Board funded), and independent voluntary facilities), four of which are residential rehabilitation facilities (one Church of Scotland, one Salvation Army, one Turning Point, one independent voluntary facility).

HIGHLAND  
(Population: 210 418)

NHS STATUTORY SECONDARY CARE

A comprehensive community, outpatient, day hospital and inpatient based service (also employing a prison liaison nurse and providing liaison to general hospital receiving ward and maternity ward) six dedicated alcohol beds and no general adult psychiatry beds used (total: six beds).
Staffing complement includes consultant psychiatrist, other medical staff, nursing staff and social work staff.
Uses acamprosate and disulfiram.
Psychosocial interventions include MI, CBT, BI, BMCT, SS, CS, SM, Solution Focussed Therapy, Assertiveness Training.

NON-NHS SERVICES

In addition to AA the area has 13 of the non-NHS facilities identified, 12 of which are Councils on Alcohol with one Church of Scotland residential rehabilitation facility.
LANARKSHIRE  
(Population: 559 150)

NHS STATUTORY SECONDARY CARE

Three services with base hospitals at Monklands, Hairmyres and Hartwood. All are community, outpatient and inpatient services with no day hospital service. Seven dedicated alcohol beds and eight general adult psychiatry beds in use at any one time (total: 15 beds). Staffing complement includes consultant psychiatrists, RMN trained nursing staff, consultant clinical psychology and other clinical psychology staff and occupational therapy staff. Uses acamprosate and disulfiram. Psychosocial interventions include MI, BI, CS, SS, Couples.

NON-NHS SERVICES

In addition to AA the area has six of the non-NHS facilities identified, five of which are day facilities (three social work, two Councils on Alcohol) with one facility which is a social work residential rehabilitation facility.

LOTHIAN  
(Population: 774 528)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient based service. 12 dedicated alcohol beds and no use of general adult psychiatric beds (total: 12 Beds). Staffing complement includes consultant psychiatrists, other medical staff, nursing staff, occupational therapists and a clinical psychologist. Uses acamprosate, disulfiram and naltrexone. Psychosocial interventions include MI, CBT, BI, TSF, BMCT, SS, CS, SM, Supportive Counselling, Group Therapy (support and relapse prevention groups).

NON-NHS SERVICES

In addition to a large AA presence, the area has 27 of the non-NHS facilities identified, 15 of which are day facilities (nine Councils on Alcohol with one social work and one Church of Scotland facility, the rest being other independent voluntary facilities), nine of which are residential homeless facilities (three Cyrenians, two City Council, one Church of Scotland, one Salvation Army, one independent voluntary) and three of which are residential rehabilitation facilities (one Church of Scotland and two independent voluntary facilities).
ORKNEY
(Population: 19 794)

NHS STATUTORY SECONDARY CARE

A solely community based service.
One bed allocated for use in Balfour NHS Hospital (total: one bed).
Staffing complement with nursing staff only.
Uses acamprosate and disulfiram.
Psychosocial interventions include MI, CBT, BI, SS, CS, SM, Relapse Prevention.

NON-NHS SERVICES

In addition to AA the area has only one of the non-NHS facilities identified (Council on Alcohol).

SHETLAND
(Population: 22 855)

NHS STATUTORY SECONDARY CARE

No specialist service (total: 0 beds).

NON-NHS SERVICES

In addition to AA the area has two of the non-NHS facilities identified (independent voluntary day facilities).

TAYSIDE
(Population: 391 397)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient service with no day hospital service.
12 dedicated alcohol beds as well as general adult psychiatry beds in use (total: 12 beds).
Staffing complement includes consultant psychiatrist, other medical staff and RMN trained nursing staff.
Uses acamprosate and disulfiram.
Psychosocial interventions include MI, CBT, BI, CS, SM, womens’ groups, jointly staffed relapse prevention groups (TAPS and occupational therapy department in Montrose, and NHS and social work department in Angus.)
NON-NHS SERVICES

In addition to AA the area has 13 of the non NHS facilities identified, six of which are day facilities (three social work, two Councils on Alcohol, and one independent voluntary) and seven of which are residential homeless facilities (three Cyrenians, one Jericho Society, three other independent voluntary).

WESTERN ISLES
(Population: 28 476)

NHS STATUTORY SECONDARY CARE

A small but comprehensive community, outpatient, day hospital and inpatient based service. No dedicated alcohol beds and up to 1 – 2 general adult psychiatry beds in use at any one time (total: 1 – 2 beds). Staffing complement includes consultant psychiatrist and nursing staff. Uses acamprosate and disulfiram. Psychosocial interventions include MI, CBT, BI, BMCT, Couples, Family CRA, SS, CS, SM.

NON-NHS SERVICES

In addition to AA the area has two of the non-NHS facilities identified (Church of Scotland day facility and independent voluntary day facility)

Additional notes

1) Residential homeless facilities may not have any specific remit for dealing with alcohol problems. This was the case in about 50% of questionnaires returned.

2) Community Addiction Teams (CATs) may not have been included in all cases due to the newness of the service and the fact that they may not have been picked up as NHS statutory facilities, coming under a social work umbrella instead.
Appendix 8

TABULATED SUMMARY OF RESULTS OF SURVEY OF SERVICES

Psychosocial interventions as used in NHS secondary care alcohol services
<table>
<thead>
<tr>
<th>Intervention</th>
<th>% of those services (n=19) which provide psychosocial interventions</th>
<th>Written protocols</th>
<th>Patient info. leaflets</th>
<th>Individual/group</th>
<th>Residential/non-residential</th>
<th>Proposed duration</th>
<th>Audited % of services stating they use accredited staff</th>
<th>External training</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>100</td>
<td>few</td>
<td>few</td>
<td>mostly individual, some group</td>
<td>mostly non-residential, some residential</td>
<td>up to 6 sessions, rarely longer</td>
<td>few</td>
<td>53</td>
</tr>
<tr>
<td>CBT</td>
<td>84</td>
<td>few</td>
<td>several</td>
<td>mostly individual, some group</td>
<td>mostly non-residential, some residential</td>
<td>variable</td>
<td>very few</td>
<td>63</td>
</tr>
<tr>
<td>BI</td>
<td>89</td>
<td>several</td>
<td>few</td>
<td>mostly individual, some group</td>
<td>mostly non-residential, some residential</td>
<td>variable</td>
<td>very few</td>
<td>53</td>
</tr>
<tr>
<td>TSF</td>
<td>11</td>
<td>none</td>
<td>none</td>
<td>individual</td>
<td>non-residential</td>
<td>6 sessions</td>
<td>no</td>
<td>0</td>
</tr>
<tr>
<td>BMCT</td>
<td>26</td>
<td>none</td>
<td>none</td>
<td>couples</td>
<td>non-residential</td>
<td>1-2 sessions in 1 response</td>
<td>no</td>
<td>20</td>
</tr>
<tr>
<td>CRA</td>
<td>37</td>
<td>few</td>
<td>few</td>
<td>mostly individual, some group</td>
<td>mostly non-residential, some residential</td>
<td>variable</td>
<td>no</td>
<td>43</td>
</tr>
<tr>
<td>SS</td>
<td>79</td>
<td>few</td>
<td>few</td>
<td>both individual and group</td>
<td>mostly non-residential, some residential</td>
<td>variable (up to 10 sessions specified in 1 response)</td>
<td>very few</td>
<td>60</td>
</tr>
<tr>
<td>CS</td>
<td>100</td>
<td>few</td>
<td>few</td>
<td>both individual and group</td>
<td>mostly non-residential, some residential</td>
<td>variable (up to 10 sessions specified in 2 responses)</td>
<td>few</td>
<td>53</td>
</tr>
<tr>
<td>SM</td>
<td>95</td>
<td>very few</td>
<td>several</td>
<td>both individual and group</td>
<td>mostly non-residential, some residential</td>
<td>variable (up to 10 sessions specified in 1 response)</td>
<td>very few</td>
<td>56</td>
</tr>
<tr>
<td>couples</td>
<td>32</td>
<td>none</td>
<td>none</td>
<td>couples</td>
<td>mostly non-residential, some residential</td>
<td>not known</td>
<td>no</td>
<td>0</td>
</tr>
<tr>
<td>RP groups</td>
<td>21</td>
<td>several</td>
<td>none</td>
<td>mostly group</td>
<td>mostly non-residential, some residential</td>
<td>variable (6 sessions specified in 1 service)</td>
<td>few</td>
<td>50</td>
</tr>
</tbody>
</table>

Key to table: MI = motivational interviewing ; CBT = cognitive behavioural therapy ; BI = brief intervention ; TSF = twelve step facilitation ; BMCT = behavioural marital couples therapy ; CRA = community reinforcement approach ; SS = social skills training ; CS = coping skills training ; SM = stress management ; couple = couples therapy ; RP= relapse prevention
Appendix 9
12 STEPS OF ALCOHOLICS ANONYMOUS

TWELVE SUGGESTED STEPS OF ALCOHOLICS ANONYMOUS

1. We admitted we were powerless over alcohol – that our lives had become unmanageable.
2. Came to believe that a Power greater than ourselves could restore us to sanity.
3. Made a decision to turn our will and our lives over to the care of God as we understood Him.
4. Made a searching and fearless moral inventory of ourselves.
5. Admitted to God, to ourselves and to another human being the exact nature of our wrongs.
6. Were entirely ready to have God remove all these defects of character.
7. Humbly asked Him to remove our short-comings.
8. Made a list of all persons we had harmed, and became willing to make amends to them all.
9. Made direct amends to such people wherever possible, except when to do so would injure them or others.
10. Continued to take person inventory and when we were wrong, promptly admitted it.
11. Sought through prayer and meditation to improve our conscious contact with God as we understood Him, praying only for knowledge of His will for us and the power to carry that out.
12. Having had a spiritual awakening as the result of these steps, we tried to carry this message to alcoholics and practice these principles in all our affairs.
Appendix 10

EXAMPLES OF PATIENT INFORMATION IN USE CURRENTLY

Examples of patient information leaflets related to alcohol dependence are reproduced in this appendix. These have been reproduced with kind permission of:

- NHS Orkney (formerly Orkney Health Board)
- Alcohol and Drugs Support South West Scotland
- Alcoholics Anonymous
WHO ARE WE?

We are an independent, voluntary organisation. We help people who are suffering from the effects of alcohol misuse, either through their own excessive drinking or because someone they are close to (spouse, family member, friend) is drinking too much.

We also encourage those who do drink, to do so responsibly, within a safe limit and without causing harm to themselves or others.

Our aim is to limit the effects of alcohol misuse on individuals, families and the community, by providing a range of services and activities.

WHO DO WE HELP?

Anyone, who is in need of information, advice, support or counselling for themselves, a family member, relative or friend. It does not matter how old you are, whether you are still at school or retired, what occupation or lifestyle you have, whether you are male or female, married or not.

The service is open to everyone, is free, and confidential.

WHAT DO WE OFFER?

i) Information
ii) Advice
iii) Counselling
iv) Support

WHAT IS COUNSELLING?

One definition of counselling is "a purposeful relationship in which one person helps another to help himself or herself." Because people are individuals, they have different capabilities for dealing with difficulties. Counselling is geared to meet those different individual needs.

The counsellor is a professional trained to help people address alcohol-related problems. He or she will be sympathetic and understanding, but will take an objective view of the situation.

HOW DO WE OPERATE?

We operate from discreet, but easily accessible premises in Junction Road. The atmosphere is informal, friendly and informal. Counselling is conducted on a one-to-one basis and is confidential. There are only two people in the room you and the counsellor. There is no one else present unless you choose to bring someone else along with you.

You may contact us by phone, make an appointment, speak to a counsellor, or just drop in. In exceptional circumstances, a counsellor may visit you at home. Outside of office hours, there is an answer phone service - you may wish to leave a phone number or an address at which you can be contacted. Appointments can be arranged for evenings and weekends. Remember the service is free and confidential.

SOME BASIC FACTS ABOUT ALCOHOL

Alcohol is the most widely used behaviour-altering drug in our society. 10% of adults in Scotland drink and most people enjoy it without coming to any harm. It is hardly surprising that people often ask, "What's wrong with having a drink?" The answer is nothing; if it is taken sensibly and appropriately.

Alcohol is a drug and must be treated with respect. Alcohol misuse can lead to wide-ranging problems and considerable difficulties in various areas of our lives: relationships with family and friends, employment, finances, health (both physical and psychological) and involvement with the law, amongst others. Even small amounts of alcohol affect our behaviour to some extent.
RELAPSE PREVENTION

It can be helpful to consider the reasons for changing your behaviour. In this case the behaviour we are talking about is drinking alcohol.

The remainder of this page is divided into two columns. On one side I would like you to write the things that alcohol does for you that you consider beneficial. On the other side I would like you to write down the problems that alcohol is causing you.

<table>
<thead>
<tr>
<th>GOOD THINGS</th>
<th>BAD THINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. Helps me sleep</td>
<td>e.g. Causes rows</td>
</tr>
<tr>
<td>e.g. Makes me sociable</td>
<td>e.g. Forgot what I've said</td>
</tr>
</tbody>
</table>
Now that you have considered your reasons for trying to change your behaviour, I would like you to think of ways in which you might achieve the good things listed in other ways.

E.g. sleep - develop a bedtime routine

In your list of good things you will find clues as to what situations might make it difficult for you in the future to maintain your sobriety.

However, there are some situations that are generally recognized as being likely to contribute to a lapse. These are called high-risk situations. They are divided broadly into four categories: Loss, Highs, Fears, and Peer pressure.

Loss are feelings such as anger, frustration, anxiety, sadness, and depression. Highs and feelings such as happiness, excitement, and celebration. Fears are situations where you find you are in conflict with your friends, partner, family, or family. Finally, peer pressure is when you feel that you are the odd one out and need to join in or where people try to persuade you to do what they are doing.

Write down ways that you will deal with these situations should they arise in the next month. Here are some suggestions that others have found useful in dealing with the aforementioned high-risk situations:

1. Identify reasons for feeling low and try to talk about them with a friend or counsellor.
2. Reward yourself in ways that are other than drinking, for things that you have achieved because you are not drinking.
3. If you are aware of a difficult situation avoid it if possible.
4. Reward yourself of what you have gained through not drinking.
5. Plan ahead and ask for help from someone you trust.

Use this space to write down how you might go about achieving these.

CRavings

Most people experience cravings and many find them difficult to cope with. Cravings vary in intensity and frequency. They may emerge as a fleeting feeling to pacing around for hours dominated by thoughts and feelings about alcohol. Some people dream so vividly about alcohol that they wake up unsure as to whether they have had a drink or not. Craving alcohol is quite common in the early stages of withdrawal but it becomes less intense and less frequent as time goes on.

There are several ways of dealing with cravings. One way is to identify triggers to dealing a drink. This can be done by keeping a diary for one week and writing down each time you feel like having a drink and what happened immediately prior to this feeling arising. Hopefully, the diary will then reveal a pattern that you can use to identify triggers.

Ways that people have found of dealing with craving include distractions, relaxation, exercising, talking to a friend about it, getting involved in a hobby, recognizing the feeling and learning how to deal with it in the third person e.g. “You are not going to get a drink today, so you can stop pestering me.”

Make a list of things that you can do when you feel a craving for alcohol.

DRUGS THAT HELP WITH CRavings

There are two drugs, which are used to help deal with cravings, Campral and Antabuse. Both of these can be prescribed by your GP.

Campral is a drug, which some people have found to be effective in relieving craving for alcohol. It is taken in tablet form each day and does not contain alcohol. If you would like more information about this drug, then ask your GP or the Alcohol Specialist Nurse (telephone 885466).
Another drug which has been useful in enabling people to deal with craving, is Antabuse. This is a drug which is taken each day in tablet form and has an effect in any alcohol is taken. It reacts with the alcohol and makes you very sick and eventually collapse if you continue to drink. Once a tablet is taken you cannot have a drink for seven days.

**STRESS**

Stress is an important factor to consider when trying to overcome an alcohol problem. Stress comes in many different forms. It can be because of a major change in your life, e.g. a death or loss of a job. It can also be because of positive events e.g. marriage or birth of a child. There are major stresses in life. However the more frequent day to day happenings seem to be important in how stressed one feels. These are usually described as "hurries" e.g. taking kids to school or "wastiffs" e.g. winning some money on the horses.

It is important to identify sources of stress. Make a list of any you can think of:

- A list of things you should do and the other, write down the things you feel you would really love to do or want to do.

<table>
<thead>
<tr>
<th>SHOULD DO</th>
<th>WANT TO DO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

These two columns should be equal. If they are misleading you will start to feel very stressed. It is important that you correct the balance. Feeling stressed can lead to a lapse.

Think of ways that you have coped with stress in the past and see if you can use them again. Here are some ideas that others have found useful in helping them to deal with stress.

- Prioritise
- Make a list and strike off things you have achieved
- Relaxation: Listen to relaxing music or buy a relaxation tape
- Religious beliefs
- Attend Alcoholic Anonymous meetings. They take place in Orkney in the Orkney Street Hall on Saturday and Thursday evenings. Contact Mike of 892 316 for more details.
- Attend counselling at Orkney Counselling and Advisory Centre Tel: 871 738.
- Attend Citizens Advice Centre to resolve debt matters. Tel 875 216.

These are just a few ideas that might help to get you started.

We all have to cope with the day to day demands on us. Sometimes an imbalance occurs and we start to feel unable to deal with day to day activities.
REMEMBER

- Counseling is free at Alcohol and Drugs Support South West Scotland.

- Whether you drive or walk to a counseling session try to manage your time so that you are free of stress before the session begins.

- A cup of tea or a short walk afterwards is often very useful.

- Please inform Alcohol and Drugs Support South West Scotland staff if you cannot keep your appointment.

Alcohol and Drugs Support South West Scotland

82 King Street, Castle Douglas
DG7 1AD

Tel: 01556 503500

Counselling?

Been offered counselling and you are not sure?


There is nothing magical or mysterious about counselling. Quite often it is just an invitation to look at things in a different way perhaps to see if there other options for you.

“T’ve been told I can see a counsellor. I’m not sure... I don’t know much about it.”
What is counselling?

Counselling is a personal, one-to-one relationship in which you can explore your thoughts and feelings with someone who has the skill to help you. It is not an advice-service.

Advice-givers, whether friends or professionals, seldom know the real you, but they will tell you what they think is best for you or what has worked for themselves or other people. But as we are all individuals, the advice-giving approach does not always suit everyone.

Counsellors try to find out how you usually approach problems and what you have tried before. What worked, or didn’t? What do you think might be useful? What is “just not on” for you? As you actually know more about yourself than anyone else does, the counsellor will ask you about you.

Who will find out what I say?

Confidentiality usually exists within the agency. There is an essential and legal need to protect clients and counsellors. Should there ever be a need to discuss what is being said, you would be advised beforehand. There is a legal duty to protect clients and counsellors should there be a need to break confidentiality.

Goodbye, Counsellor

Not everyone works out of a counselling relationship quickly; however, some may have several different sessions to share at the same time and will need more time than others.

How long and where?

It is practical to meet at a regular time and day each week in a room that you will be familiar with. A receptionist will be nearby, but you will not be able to hear the conversation. As soon as each person is as relaxed as possible, you can discuss what you have for you at our next meeting.

Making your way of life is not a part of the deal and although you may be asked to examine your old habits and consider change, only you can decide when the time is right for you to do so.

With support you will begin to accept how much you already know about yourself and will learn to trust your own experiences and feelings. That is counselling, beginning to work. The eventual goal is to help you, the client, manage your life with the guidance of any counsellor.

Your life, your choices, your success.

A good feeling!

What if we cannot work together?

One skill in counselling is to recognise when it is not working and to respect your right to exit or perhaps seek a counsellor who might suit you better. Usually, however, clients and counsellors work together at their difficulties by facing up to them, just like most problems in life have to be faced.

What problems can I bring?

Whatever you want to bring—the time is yours—but counselling is not easy change. Helping working sessions may be difficult for clients and counsellors alike but are often the most helpful. Facing the problem often brings it down in size.

Will the counsellor have experience of my problem?

Some have personal experience of similar problems, but your experience is much more important. Counselling is not about how a counsellor found answers. It’s more about believing in yourself—the real expert.

Depression, alcohol, drugs and family relationships are typical counselling matters. But no matter how ordinary or unusual you think your problem is, the counsellor will listen to you and treat you with respect.
OUR APPROACH TO COUNSELLING

We treat our clients as individuals. We don't seek to persuade people to accept a particular view of alcohol or drugs problems. Instead, we listen to each person to help them understand the cause of their problems, and to find appropriate solutions.

We also offer support and encouragement. We respect each persons' choice, although if we consider the goal to be unrealistic we'll say so.

OUR STANDARDS

We work hard to offer a good standard of service to all of our clients. To do this we ensure that our counsellors:

- receive appropriate training
- receive case supervision
- meet ethical standards
- maintain client confidentiality outside the agency
- respect our clients as individuals

If you need information about alcohol or drugs......

If you would like advice, assistance or counselling about your own or someone else's alcohol or drugs problem......

Please do not hesitate to contact us:

- telephone to arrange an individual appointment with a counsellor
- ask your GP, employer, social worker, solicitor, family member or friend to make an appointment:

HOW TO CONTACT US

Our office opening hours are:

Monday to Friday
8.00 am to 1.00 pm
2.00 pm to 5.00 pm

Our address is:
Alcohol and Drugs Support South West Scotland
62 King Street
Castle Douglas
DG7 1AD

Tel: 01556 505550
Services across Dumfries and Galloway

ARE YOU WORRIED ABOUT ALCOHOL OR DRUGS?

If you need help - We're only a phone call away!

Alcohol and Drugs Support
South West Scotland
62 King Street, Castle Douglas
DG7 1AD
Tel: 01556 505550
Previously known as The Dumfries and Galloway Council on Alcohol, we are a Registered Charity, offering advice, information and counselling to anyone within Dumfries and Galloway on any alcohol or drug-related matter.

We are affiliated to Alcohol Focus Scotland, the country’s National Alcohol Charity. If your life is affected in any way by alcohol or drugs, whether it is your own or someone else’s problem, we may be able to help.

WHAT CAN WE OFFER YOU?

... We offer a safe and private space away from home for you to concentrate on your concerns.

... We provide a trained counsellor to help you identify the problems you feel you have.

... We can provide information and advice about alcohol and drugs and about the services available to you in the community.

... We have good links with other agencies locally and nationally and can put people in touch with them if it’s appropriate.

Alcohol and Drugs Support South West Scotland does not attach ‘blame’ to people with alcohol or drug problems. We work with anyone who feels they might be in difficulty because of alcohol or drug problems, their own or someone else’s.

Someone in difficulty with alcohol or drugs might:

- Suffer from health or fitness problems
- Find themselves in trouble with employers or the police
- Experience difficulties with money
- Feel unable to cope without a drink or drugs
- Have rows with family and friends
- Drink or take drugs to forget difficult problems
- Be irritable or unable without a drink or drugs
- Face severe medical, legal, marital or employment problems

HOW DO WE DEFINE AN ALCOHOL OR DRUGS PROBLEM?

WHO USES OUR SERVICE?

We can help anyone who is looking for advice and information about alcohol or drugs, or who is worried about their own or someone else’s alcohol or drugs problem. The people who use our service come from all walks of life and contact us for many reasons.

WHAT CAN YOU EXPECT FROM US?

- You can expect honesty without being judged
- You can expect confidentiality within the agency
- You can expect advice, information and one-to-one counselling, independent of any other agency
- You can expect one-to-one communication with a trained counsellor
- You can expect an initial interview followed by a series of appointments if you decide it will help
A variety of leaflets exist to inform people of the services of Alcoholics Anonymous:
ACAMPROSATE SHARED CARE PROTOCOL

The Area Drug and Therapeutics Committee has approved the use of Acamprosate in the treatment of Alcohol Dependence Syndrome on a shared care basis with Primary Care.

**Acamprosate**

Acamprosate is indicated for maintenance of abstinence in patients with Alcohol Dependence.

The mechanism of action is believed to be by stimulating GAB ergic inhibitory transmission and by antagonising excitatory amino acids, particularly glutamic acid. It may surpress cravings for alcohol triggered by conditioned response.

A meta analysis of randomised controlled trials demonstrated that six months to one year treatment with Acamprosate doubles abstinence rates in alcoholics.

An evaluation of treatment with Acamprosate over a one year period in Glasgow showed that two thirds of patients assessed suitable for treatment were compliant after one month and they achieved 83% of potential Cumulative Abstinent Days.

Acamprosate does not interact with alcohol or Benzodiazepines. Acamprosate does not impair an individuals ability to drive or operate machinery.

The main side effects are gastrointestinal as well purites and fluctuation in libido.

**Inclusion Criteria**

Moderate to severe Alcohol Dependence with abstinence goal in conjunction with psychosocial treatments and counselling.

Tendency to anxiety symptoms in post withdrawal phase, not amounting to Generalised Anxiety Disorder or Panic Disorder.

Reported cravings for alcohol, prompting relapse.

**Exclusion Criteria**

Patients with a history of repeated self harm, Anti-Social Personality Disorder or minimal brain damage.

Patients with significant social problems and lack of support.

**Dosage**

Acamprosate should be initiated soon after detoxification.
Acamprosate 333 mg tablets.

For adults over 60 kilograms 2 tablets in the morning, one at noon and one at night with meals.
For adults below 60 kilograms 2 tablets in the morning, one at noon and one at night with meals.

**Shared Care**
Acamprosate will be initiated by Specialist Alcohol Services, as part of therapeutic plan including counselling, relapse prevention or psycho-social support.

Patients would be monitored at least monthly by Specialist Alcohol Services for a three month period. Acamprosate will be dispensed by Hospital Pharmacy during this period.

Specialist Alcohol Services would liaise with general practitioners regarding continued prescribing, for a further nine months (total treatment one year).

Continued monitoring by specialist services, while Acamprosate is prescribed by general practitioner.

**Treatment Discontinuation and Outcome**
Acamprosate should be discontinued following repeated or protracted relapse (relapse is defined as more than five drinks for a five day period) or non compliance.

Outcome will be evaluated by measuring Cumulative Abstinence Days (CADs).

**Contact**
For further information please contact your local specialist service:-

___________________________ Tel No: ____________________________

Dr P Jauhar
Clinical Director
December 2001
Appendix 12

LOTHIAN PROTOCOL FOR USE ON NALTREXONE

Alcohol Problems Service, Lothian Primary Care NHS Trust

PROTOCOL FOR THE USE OF ORAL NALTREXONE

Naltrexone given to detoxified patients, or non-dependent patients who commence taking Naltrexone when sober, reduces the frequency and severity of relapses into “heavy drinking” (over 8 units a day) (references attached). There is one study where Naltrexone was started in patients of mild severity of dependence who continued to drink; overall drinking in the coming year reduced.

Contraindications

Established liver disease (bilirubin currently about 25 mmols/l, history of varices or ascites); current use of opiates or any opiate-like analgesic.

Indications

Either Has achieved abstinence but has repeatedly relapsed to problem drinking despite previous attempts with Disulfiram, Acamprosate, individual or group therapy or, refusal to consider these therapies.

Or Repeated failure to succeed with an abstinence goal and patient and therapist feel that goal of limited drinking is clinically appropriate.

And History of impaired control within sessions of drinking.

Relative Indications

Theoretically, Naltrexone is most likely to help those for whom drinking has positive rewards e.g. euphoria, rather than for reduction of negative feelings e.g. to reduce anxiety or depression.

Procedure

1. Baseline liver function is checked, and a biological marker, sensitive in that patient (GGT, MCV and/or CDT) is chosen so that outcome can be objectively monitored in the coming months.

2. Patient signs Consent Form having read the information Sheet.

3. Initial prescription for one week at a time.

4. Initial prescription 25 mg (half tablet) for first 2 days, to continue at half a tablet until nausea (if present ) diminished, when full tablet 50 mg is taken (with breakfast).
5. Our prescription should be via REH Pharmacy (only if patient unable to attend Pharmacy is the GP asked to prescribe, when he is given full background).

6. Renewed prescriptions only if evidence of reduction of problematic/heavy session drinking e.g. improving blood tests. The patient is breathalysed at each appointment.

7. After 3 months the prescription is changed to “targeted” use only on days when risk of drinking is anticipated and one day before e.g. only taken on Thursday, Friday and Saturday.
ANTABUSE (DISULFIRAM): THE PARTNERSHIP APPROACH

1. A partner is a person who is asked by the patient to observe them taking the Antabuse tablets.

2. So that other tablets cannot be substituted, the genuine Antabuse tablets are marked DUMEX 110 L (Dumex is the manufacturer).

3. To ensure they are not placed under the tongue and removed later, Antabuse tablets should be dissolved in half a glass of water (the tablets break up and disperse and the mixture is tasteless).

4. It does not matter what time of the day the tablet is given. If it is more convenient, it can be given on 3 days per week – instead of one tablet daily it can be taken: 2 on a Monday, 2 on a Wednesday and 3 on a Friday.

5. If it is suspected that the patient has decided to vomit after taking the tablet, the partner can stay with the patient for up to 30 minutes after the tablets are taken (this is rarely necessary).

6. If the patient decides to stop taking the tablets, the patient or the partner should telephone the treating Doctor or a member of nursing staff so that the reason for this may be discussed.
Appendix 14
EXAMPLE OF CARE PATHWAY

This is the pathway used by Renfrewshire & Inverclyde and is also similar to the one adopted by Lothian PCT.

**Assessment**
Date……………………..
Risk assess.………………
Discharge proforma……..
GP Letter………………..

**Other services**
Physiotherapy
Social work
Occupational therapy
Dietician

Controlled drinking

Refer to Council on Alcohol

Dependent drinker

Inpatient detox

Waiting List
Date……………………..

Admitted
Date……………………..

Discharged
Date……………………..

**Supervised Antabuse**
Acamprosate if appropriate

Programme complete
Discharge proforma…………..
Letter GP……………………..

GP follow up

Medical outpatient

Abstinence support group

Nursing outpatient

Relapse prevention group

1……………2……………3……………
4……………5……………6……………

**Individal motivational sessions**
Session 1…………Session 2…………
Session 3…………Session 4…………

**Education group**
1……………2……………3……………
4……………5……………6……………

**Detox commenced**
Date……………Bloods……………
Physical……..SUCES……………
Front sheet……..DVLA leaflet…
Care plan……..Info leaflets….  
Orientation to unit………………
Abstinence policy explained……

**Orientation to unit**
Abstinence policy explained……

**Individal motivational sessions**
Session 1…………Session 2…………
Session 3…………Session 4…………

**Education group**
1……………2……………3……………
4……………5……………6……………

**Relapse prevention group**
1……………2……………3……………
4……………5……………6……………

GP follow up

Medical outpatient

Abstinence support group

Nursing outpatient

Council on Alcohol
Appendix 15

DATABASES SEARCHED FOR CLINICAL EFFECTIVENESS STUDIES

High Level Literature Search - Sources
An initial search was undertaken in August 2001 to identify HTA reports, systematic reviews and other evidence reports, using the following sources:

- Health Technology Assessment Database
  Via the Cochrane Library (CD-ROM, 2001 Issue 2)
- NICE (National Institute for Clinical Effectiveness)
  http://www.nice.org.uk/
- NCCHTA (National Coordinating Centre for Health Technology Assessment)
  http://www.ncchta.org/
- NHS Centre for Reviews and Dissemination, University of York
  http://www.york.ac.uk/inst/crd/
- Birmingham Technology Assessment Group, Department of Public Health and Epidemiology, University of Birmingham
  http://www.publichealth.bham.ac.uk/wmhtag/
- ScHARR, University of Sheffield
  http://www.shef.ac.uk/~scharr/publications.htm
- South and West R&D Directorate, DEC reports
  http://www.doh.gov.uk/research/swro/rd/publicat/dec/
- British Columbia Office of Health Technology Assessment (BCOHTA)
  http://www.chspr.ubc.ca/bcohta/
- Health Services Utilization and Research Commission (HSURC Saskatchewan)
  http://www.hsurc.sk.ca/
- Institute for Clinical and Evaluative Sciences (ICES)
  http://www.ices.on.ca/
- Manitoba Centre for Health Policy (MCHP)
  http://www.umnanitoba.ca/centres/mchp/
- ISTAHC (International Society of Technology Assessment in Health Care)
  http://www.istahc.org/
- ECRI
  http://www.ecri.org/
- HSTAT
  http://text.nlm.nih.gov/
- Cochrane Database of Systematic Reviews (CDSR)
  Cochrane Library (CD-ROM, 2001 Issue 2)
- Database of Abstracts of Reviews of Effectiveness (DARE)
  Cochrane Library (CD-ROM, 2001 Issue 2)
- Ongoing Reviews database
  http://www.update-software.com/National/
- SIGN (Scottish Intercollegiate Guidelines Network)
  http://www.sign.ac.uk/
- ARIF (Aggressive Research Intelligence Facility)
  http://www.bham.ac.uk/arif/
• Health Evidence Bulletins Wales
  http://hebw.uwcm.ac.uk/
• Centre for Clinical Effectiveness, Monash Institute of Public Health
• TRiP
  http://www.tripdatabase.com/
• Bandolier
  http://www.jr2.ox.ac.uk/bandolier/

Randomised Controlled Trials – Sources
The following sources were searched during December 2001 to identify randomised controlled trials
• Medline (Ovid)
• Premedline (Ovid)
• Embase (Ovid)
• Cochrane Controlled Trials Register (Ovid)
• Psychinfo (Ovid)
• EtOH
  http://etoh.niaaa.nih.gov/
• MRC Funded Research
  http://fundedresearch.cos.com/MRC/
• Current Controlled Trials
  http://www.controlled-trials.com/
• Clinical trials.gov
  http://clinicaltrials.gov/
• NRR
  http://www.update-software.com/National/
• CRISP (Computer Retrieval of Information on Scientific Projects)
  https://www-commons.cit.nih.gov/crisp/
Appendix 16

SEARCH STRATEGY FOR CLINICAL EFFECTIVENESS STUDIES

Search Strategy for clinical effectiveness randomised controlled trials in Medline
Database: MEDLINE
Coverage: <1966 to October Week 5 2001>
Host: Ovid
Date searched: 1/12/01

--------------------------------------------------------------------------------
1 alcoholism/
2 alcohol drinking/
3 alcoholic?.tw.
4 alcoholism.tw.
5 (harmful$ adj1 drinking).tw.
6 dipsomania$.tw.
7 (alcohol adj2 (dependen$ or addict$ or abus$ or misus$)).tw.
8 or/1-7
9 intervention studies/
10 intervention$.tw.
11 (relaps$ adj1 prevent$).tw.
12 or/9-11
13 alcohol deterrents/
14 behavior addictive/dt
15 (alcohol adj2 deter$).tw.
16 (alcohol adj1 sensiti$).tw.
17 (alcohol adj2 aversi$).tw.
19 (pharmacolog$ adj1 (intervention$ or treatment$)).tw.
20 taurine/
21 disulfiram/
22 naltrexone/
23 acamprosate.tw.
24 campral.tw.
25 disulfiram.tw.
26 antabuse.tw.
27 naltrexone.tw.
28 trexan.tw.
29 or/13-28
30 psychotherapy/
31 exp behavior therapy/
32 exp psychoanalytic therapy/
33 exp socioenvironmental therapy/
34 exp self concept/
35 psychotherapy brief/
alcoholics anonymous/
social support/
behavior addictive/px
psychotherap$.tw.
(psychosocial adj2 (care or therap$ or intervention$ or technique$ or treatment$)).tw.
(behavior$ adj2 (therap$ or treatment$ or modification or contracting)).tw.
(assertive$ adj2 (skill$ or training or technique$)).tw.
(aversive$ adj2 (therap$ or treatment$)).tw.
(cognitive adj2 (therap$ or treatment$)).tw.
cbt.tw.
(relaxation adj2 (skill$ or training or technique$)).tw.
sociotherapy.tw.
psychoanaly$.tw.
(socioenvironmental adj2 (therap$ or treatment$)).tw.
therapeutic community.tw.
((group or marital or couple$ or fami$) adj2 (therap$ or intervention$ or technique$ or treatment$)).tw.
(community adj2 reinforc$).tw.
(motivational adj (interview$ or enhancement)).tw.
supportive expressive therap$.tw.
counsel?ing.tw.
counsel?or?.tw.
(cue$ adj1 (therap$ or exposure)).tw.
covert sensitization.tw.
(self adj1 concept).tw.
(self adj (efficacy or esteem or control or care)).tw.
(social$ adj1 support).tw.
(((coping or life) adj1 skills)).tw.
social skill$.tw.
((stress or anger) adj2 manag$).tw.
supportive treatment$.tw.
((brief or short or minimal) adj2 intervention$).tw.
coping behavior$?.tw.
stepped care.tw.
alcoholics anonymous.tw.
aa.tw.
twelve step.tw.
"12 step".tw.
or/30-72
temperance/
temperance.tw.
sobriety.tw.
(alcohol adj2 (consum$ or intake) adj2 (reduc$ or control$ or moderat$ or attenuat$ or restrict$ or restrain$)).tw.
(abstinence or abstain$).tw.
((control$ or moderat$ or attenuat$ or reduc$ or restrain$ or restrict$) adj2 drinking).tw.
This search strategy was reviewed by Gill Ritchie, Information Officer, at CRD, University of York.
Flow chart of literature selection process for meta-analysis

All references identified by literature search n=3065

Search strategy

Reading title and abstract (with selection criteria)

Not relevant n=2737

Potentially relevant for HTA n=328 (exc. duplicates)

Order literature

Available
Systematic search n=316
Submissions m=68

Not available n=12

Evaluation of full manuscript (with selection and quality criteria)

Submissions

Excluded or used as subsidiary evidence n=290

Considered for meta-analysis n=A*

Non quantative synthesis, exploration of heterogeneity

Suitable for meta-analysis n=B*

Non-suitable for meta-analysis n=C*

*P.T.O
Numbers of studies for each meta-analysis (see preceding figure)

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acamprosate</td>
<td>19</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>21</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Disulfiram</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Motivational enhancement</td>
<td>8</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Relapse Prevention</td>
<td>11</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Behavioural self-control training</td>
<td>7</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Coping Skills</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Marital/Relationship therapy</td>
<td>22</td>
<td>12</td>
<td>10</td>
</tr>
</tbody>
</table>
Appendix 17
META-ANALYSES OF TREATMENT EFFECTIVENESS FOR ECONOMIC MODEL

In this appendix, the data extracted from individual studies concerning the numbers of patients in each treatment arm who were considered to have achieved a controlled drinking state at the end of the study follow-up period is presented.

These data are combined using meta-analytic methods in order to give estimates of effectiveness, which can be used as inputs to the cost-effectiveness model.

Trials of pharmacological interventions

The clinical trials of acamprosate and naltrexone generally compare the active drug with a placebo allocated in a random fashion and both the patients and the clinical investigators are unaware of the nature of the intervention received. These are aspects of study design, which are considered important in reducing the likelihood of biased results and, in these respects, these trials are of good quality. The major difficulty with these, and indeed almost all, trials of treatments for alcohol-dependent subjects is the high incidence of patients being lost to follow up before the designated end of the trial. Good practice in analysis requires consideration of the influence which such drop-out might have on inferences drawn from the trial and one method of doing this is to analyse all randomised patients using various strategies to estimate what outcomes might have been observed in drop-outs (an intention-to-treat analysis). In the HTBS analysis, this has been attempted wherever possible using the assumption that drop-outs have relapsed. This is the strategy used in most of the original analyses of acamprosate but not so frequently in analyses of naltrexone where ‘last observation carried forward’ seems to have been preferred. This means that the state of the patient at the end of the study is assumed to be the same as that at the last actual observation.

A successful outcome may either involve complete abstinence on the part of the patient or drinking at a moderate level, which does not cause acute crises, have a deleterious effect on their lifestyle, or unacceptably increase risk of longer-term clinical harm. Either abstinence or controlled drinking may be nominated as the treatment goal and different treatments may be aimed more to one than the other. For instance, acamprosate is licenced for the promotion of abstinence. Trials aimed at abstinence have been combined with those aimed at controlled drinking but outcomes for each trial have been identified in the tables.

A further difficulty in making valid comparisons between acamprosate and naltrexone is that the trials tended to report outcomes at very different times. Many acamprosate studies reported after a year of follow-up whilst naltrexone studies often had only three months. The time at which the results of the HTBS analysis are extracted is shown in the table. Differences are also present in the time duration over which the outcome was assessed. For instance a 12-month outcome might only consider abstinence or control over the previous six months.

There are fewer trials of disulfiram and they are generally of lower quality. Some of this deficiency is unavoidable, for instance the only intended clinical effect of disulfiram is the
unpleasant reaction when alcohol is drunk. Hence an important part of the true effect of disulfiram is the fear of what might happen after drinking. A blinded placebo controlled trial would not measure this effect since the placebo should cause similar fear. Hence simple blinded trials are inappropriate – possibly also unethical since the knowledge that they might be receiving a placebo could encourage the patient to take an unnecessary risk and try drinking.

It has been suggested that the use of disulfiram is only likely to have an effect when it is coupled with some method of increasing compliance. This could involve either a contract with a family member or directly observed administration by clinic staff. Whilst this suggestion appears very reasonable, the evidence to support it is limited. Only one study (Chick et al., 1992) appears to have examined supervised disulfiram in a randomised controlled trial against an inactive comparator without any additional confounding treatment. This study found a statistically significant increase in the number of abstinent days and a reduction in the number of units consumed over six months as assessed by a blinded assessor. The results are not given in terms of abstinence or controlled drinking by patient and hence cannot be used in the economic model. The meta-analysis includes the only other methodologically sound studies of disulfiram but these did not include supervision by a second person and hence did not test disulfiram used according to accepted best practice.

**Trials of psychosocial interventions**

The evaluations of psychosocial interventions are based on a fairly heterogeneous selection of trials. Most of these included a treatment arm in which the intervention was thought likely to have little or no effect and this is used as the comparator arm when available. However, other trials included interventions thought likely to be less effective but not necessarily ineffective. These have also been included and thus it may be that psychosocial intervention effects will be somewhat underestimated. One trial including direct comparison of two of the active treatments has been included in the analysis, this is Project MATCH (Project MATCH Research Group, 1993) which randomised patients to both motivational enhancement therapy and CBT (classed here as skills training).

Psychosocial interventions are poorly standardised in content and duration and cannot be blinded which allows the possibility of many other sources of heterogeneity and bias. The difficulties with respect to length of follow up, high numbers of dropouts and variety of outcome measures which have already been discussed for trials of pharmacological agents are present in the trials of psychosocial treatments. The question of what outcome measure – controlled drinking or abstinence – is appropriate is also more difficult. One of these measures may be specified as the goal for all patients or a decision may be made on a patient-by-patient basis. Often this decision is not clearly reported. Some study reports give both outcomes and do not distinguish the outcome from the prespecified goal. Thus the philosophy of this analysis has been to report and examine the outcome rather than achievement of the goal. In other words, controlled drinking has been considered to be a success even if the declared goal was abstinence. Whilst this seems pragmatic, it should be borne in mind that setting the correct goal may be a very important part of the treatment process and the outcome measures reported in the meta-analysis may not correspond to the goal set in order to achieve the reported outcome. Hence guidance on goal setting should be taken from protocols for delivery of the treatment, not inferred from the outcome tables.
Method of analysis

The method used to combine the results of the various studies is logistic regression allowing for the possibility that individual studies may have systematic differences which will affect the treatment effect. Although systematic within each study these effects are treated as coming from a population of effects which is modeled as a random variation in effects across studies. The program used to fit this model is the GLIMMIX macro in SAS.

Heterogeneity in treatment effects for acamprosate and naltrexone

There are clinically and statistically significant differences between studies in the estimated treatment effects for both acamprosate and naltrexone. The random effects model described above allows the additional uncertainty arising from the variations to be reflected in wider confidence intervals for the estimates of treatment effect derived from the combined results of all the studies. However, the underlying assumption that each trial reflects the true effect in the clinical centres in which it was measured clearly requires investigation.

In order to do this, an explanation of some of the variation between studies in the effect of treatment (TRT) in terms of features of the studies is offered. In particular the size of study (SIZE), the year of the study (YEAR), the nature of the outcome variable (abstinence or controlled drinking) (MEAS) and the time at which the outcome was measured (FU) has been examined. This was done within a fixed effects logistic model.

The results of this analysis for acamprosate are shown below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DF</th>
<th>Estimate</th>
<th>Error</th>
<th>Chi-Square</th>
<th>Pr &gt; Chi Sq</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR*TRT 0</td>
<td>1</td>
<td>0.0280</td>
<td>0.0142</td>
<td>3.9021</td>
<td>0.0482</td>
</tr>
<tr>
<td>SIZE*TRT 0</td>
<td>1</td>
<td>0.000603</td>
<td>0.000298</td>
<td>4.0894</td>
<td>0.0432</td>
</tr>
<tr>
<td>FU*TRT    0</td>
<td>1</td>
<td>-0.0312</td>
<td>0.0127</td>
<td>6.0599</td>
<td>0.0138</td>
</tr>
<tr>
<td>MEAS*TRT 0</td>
<td>1</td>
<td>-0.0813</td>
<td>0.1008</td>
<td>0.6504</td>
<td>0.4200</td>
</tr>
</tbody>
</table>

The statistically significant interaction effects of YEAR and SIZE with TRT (treatment) suggest that the treatment effects decreased in later trials and larger trials. The significant FU effect suggests that the treatment effect odds ratios increase with length of study. Some effect with length of FU is not unexpected and this term is included to eliminate a possible source of confounding in investigation of study size and year.

The results for naltrexone are:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DF</th>
<th>Estimate</th>
<th>Error</th>
<th>Chi-Square</th>
<th>Pr &gt; Chi Sq</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR*TRT 0</td>
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<td>0.0276</td>
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<tr>
<td>SIZE*TRT 0</td>
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<tr>
<td>FU*TRT    0</td>
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<tr>
<td>MEAS*TRT 0</td>
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<td>0.1067</td>
<td>0.1235</td>
<td>0.7459</td>
<td>0.3878</td>
</tr>
</tbody>
</table>

There are no statistically significant effects for naltrexone.

The results for acamprosate are quite difficult to explain. They suggest that some of the variation observed in results may be associated with size of trial or with some factor changing with time.
This rather undermines the use of a random effects model which assumes stability of treatment effects with time and that differences in treatment effect reflect true differences within study locations rather than features of the study design – in this case, trial size. They consequently make generalisation of results difficult.

One possibility is that with time and increasing trial size the trial regimen becomes more lax and that the efficacy of acamprosate is very sensitive to the way in which it is used. Such an explanation is akin to those advanced for the failure of the large USA and European studies. However, the precise nature of the changes which led to the reduced efficacy can only be guessed and this leads to doubts about how we can be sure of an effect in clinical practice. Even more than this it lead to doubts about the effectiveness of acamprosate in settings untested in clinical trials such as GP practice.
# TRIALS OF NALTREXONE

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT(^1)</th>
<th>NC(^2)</th>
<th>XT(^3)</th>
<th>XC(^4)</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome(^5)</th>
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</thead>
<tbody>
<tr>
<td>(Anton et al., 2001)</td>
<td>68</td>
<td>63</td>
<td>38</td>
<td>28</td>
<td>1.5833</td>
<td>(0.80, 3.12)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Chick et al., 2000a)</td>
<td>90</td>
<td>85</td>
<td>32</td>
<td>30</td>
<td>1.0115</td>
<td>(0.55, 1.88)</td>
<td>3</td>
<td>C</td>
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<tr>
<td>Dupont-Merck 393-103(^b)</td>
<td>84</td>
<td>87</td>
<td>52</td>
<td>54</td>
<td>0.9931</td>
<td>(0.54, 1.84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Heinala et al., 2001)</td>
<td>63</td>
<td>58</td>
<td>11</td>
<td>4</td>
<td>2.8558</td>
<td>(0.89, 7.71)</td>
<td></td>
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<tr>
<td>(Heinala et al., 2001)</td>
<td>31</td>
<td>33</td>
<td>16</td>
<td>18</td>
<td>1.1250</td>
<td>(0.42, 2.98)</td>
<td></td>
<td></td>
</tr>
<tr>
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## OMITTED STUDIES

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\(^1\) NT=number in test group  
\(^2\) NC=number in control group  
\(^3\) XT=number in test group who achieved given outcome  
\(^4\) XC=number in control group who achieved given outcome  
\(^5\) Outcomes – C = controlled drinking, A = abstinence  
\(^6\) Data from Streeton & Whelan(2001)  

TREATED TOTAL 1171 CONTROL TOTAL 942  
TREATED EVENTS 594 CONTROL EVENTS 387  
CHISQUARE FOR HETEROGENEITY= 27.4 DEGREES OF FREEDOM= 16  
RANDOM EFFECTS ODDS RATIO= 1.46 95% CONFIDENCE INTERVAL= (1.12, 1.90)
SAS COMMANDS FOR ANALYSIS OF NALTREXONE TRIALS

DATA NALTREXONE;
LENGTH MEAS $4.1.;
INPUT YEAR STUDY TRT Y N FU MEAS;
DATALINES;
1992 1 1 5 25 9 C
1992 1 2 6 29 9 C
1992 2 1 4 27 9 C
1992 2 2 12 23 9 C
1997 3 1 23 49 3 C
1997 3 2 31 48 3 C
2001 4 1 104 209 3 C
2001 4 2 235 418 3 C
2001 5 1 7 56 3 C
2001 5 2 19 55 3 C
1992 6 1 16 35 3 C
1992 6 2 5 27 3 C
2001 7 1 7 18 3 A
2001 7 2 16 35 3 A
2000 8 1 30 85 3 C
2000 8 2 32 90 3 C
1999 9 1 5 32 6 A
1999 9 2 3 31 6 A
1997 10 1 15 23 3 C
1997 10 2 18 21 3 C
1999 11 1 3 15 12 C
1999 11 2 11 15 12 C
2001 12 1 28 63 6 C
2001 12 2 38 68 6 C
2000 13 1 32 63 3 C
2000 13 2 35 61 3 C
2001 14 1 32 64 12 C
2001 14 2 32 64 12 C
1997 15 1 54 87 3 C
1997 15 2 52 84 3 C
1998 16 1 18 33 3 C
1998 16 2 16 31 3 C
2001 17 1 4 58 8 C
2001 17 2 11 63 8 C
%INC 'C:\PROGRAM FILES\SAS INSTITUTE\SAS\V8\GLM800.SAS';
%GLIMMIX(DATA=NALTREXONE,
STMTS=%STR(
CLASS STUDY MEAS TRT;
MODEL Y/N = TRT;
RANDOM STUDY TRT*STUDY;
)
)
RUN;
SAS OUTPUT FROM ANALYSIS OF NALTREXONE TRIALS

The SAS System
The Mixed Procedure
Model Information

Data Set     WORK._DS
Dependent Variable     _z
Weight Variable       _w
Covariance Structure  Variance Components
Estimation Method     REML
Residual Variance Method  Profile
Fixed Effects SE Method  Model-Based
Degrees of Freedom Method  Containment

Class Level Information

Class    Levels    Values
STUDY     17    1 2 3 4 5 6 7 8 9 10 11 12 13
           14 15 16 17
MEAS      2    A C
TRT       2    1 2

Dimensions

Covariance Parameters     3
Columns in X              3
Columns in Z              51
Subjects                  1
Max Obs Per Subject       34
Observations Used         34
Observations Not Used     0
Total Observations        34

Parameter Search

CovP1   CovP2   CovP3   Variance   Res Log Like   -2 Res Log Like
Log Like  0.5697  0  1.7672  1.7672  -36.9894  73.9789

Iteration History

Iteration Evaluations   -2 Res Log Like   Criterion
1           1         73.97889369  0.00000000

Convergence criteria met.
The SAS System
The Mixed Procedure
Covariance Parameter Estimates

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<th>Estimate</th>
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<td>STUDY*TRT</td>
<td>0</td>
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<tr>
<td>Residual</td>
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Fit Statistics

-2 Res Log Likelihood: 74.0
AIC (smaller is better): 78.0
AICC (smaller is better): 78.4
BIC (smaller is better): 79.6

PARMS Model Likelihood Ratio Test

<table>
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<tr>
<th>DF</th>
<th>Chi-Square</th>
<th>Pr &gt; ChiSq</th>
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<td>1</td>
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Solution for Fixed Effects

| Effect | TRT | Estimate | Standard Error | DF | t Value | Pr > |t| |
|--------|-----|----------|----------------|----|---------|------|---|
| Intercept |     | -0.1151  | 0.2071         | 16 | -0.56   | 0.5860 |
| TRT     | 1   | -0.3787  | 0.1233         | 16 | -3.07   | 0.0073 |
| TRT     | 2   | 0        | .              | .  | .       | .     |

Type 3 Tests of Fixed Effects

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GLIMMIX Model Statistics

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TRIALS OF ACAMPROSATE

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<th>XT³</th>
<th>XC⁴</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome³</th>
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OMITTED STUDIES

| (Lhuintre et al., 1990) | 569 PATIENTS. SUCCESS RATES NOT REPORTED |

1 NT=number in test group
2 NC=number in control group
3 XT=number in test group who achieved given outcome
4 XC=number in control group who achieved given outcome
5 Outcomes – C = controlled drinking, A = abstinence
6 Data from Mason(2001)
7 Data from AHCP report (West et al., 2000)

TREATED TOTAL 2347 CONTROL TOTAL 2182
TREATED EVENTS 600 CONTROL EVENTS 381
CHISQUARE FOR HETEROGENEITY= 64.4 DEGREES OF FREEDOM= 16

RANDOM EFFECTS ODDS RATIO= 1.73 95% CONFIDENCE INTERVAL= (1.36, 2.20)

The USA multicentre trial (Mason) has not yet published results and the manufacturers report that it will not do so until 2003, however, it has been used in support of a USA application for a marketing authorisation and the results are available on the Food and Drug Administration website. The results used in this analysis are calculated from proportions rounded to whole percentages and hence are only approximate. The percentages given by the FDA are consistent with numbers abstinent between 19 and 21 within the acamprosate group and between 27 and 29 in the placebo group.
SAS COMMANDS FOR ANALYSIS OF ACAMPROSATE TRIALS

DATA ACAMPROSATE;
LENGTH MEAS $1.;
INPUT YEAR STUDY TRT Y N FU MEAS SIZE;
DATALINES;
1993 1 1 7 32 6 A 61
1993 1 2 12 29 12 A 61
1995 2 1 20 177 12 A 538
1995 2 2 67 361 12 A 538
1996 3 1 21 64 3 A 127
1996 3 2 18 63 3 A 127
1996 4 1 28 136 11 A 272
1996 4 2 58 136 11 A 272
1996 5 1 16 224 12 A 448
1996 5 2 41 224 12 A 448
1997 6 1 7 134 12 A 262
1997 6 2 14 128 12 A 262
1997 7 1 16 62 3 A 125
1997 7 2 32 63 3 A 125
1997 8 1 37 124 12 A 246
1997 8 2 53 122 12 A 246
1997 9 1 25 70 2 C 142
1997 9 2 27 72 2 C 142
2000 10 1 48 166 9 A 330
2000 10 2 62 164 9 A 330
1998 11 1 3 55 12 A 110
1998 11 2 14 55 12 A 110
2001 12 1 38 147 6 A 288
2001 12 2 49 141 6 A 288
2000 13 1 32 292 6 A 581
2000 13 2 35 289 6 A 581
1985 14 1 14 43 3 A 85
1985 14 2 26 42 3 A 85
1997 15 1 39 152 12 A 302
1997 15 2 59 150 12 A 302
1992 16 1 2 47 12 A 102
1992 16 2 13 55 12 A 102
2001 17 1 28 257 6 A 510
2001 17 2 20 253 6 A 510
RUN;
%INC 'C:\PROGRAM FILES\SAS INSTITUTE\SAS\V8\GLMM800.SAS';
%GLIMMIX(DATA=ACAMPROSATE,
STMTS=%STR(
CLASS STUDY MEAS TRT;
MODEL Y/N = TRT;
RANDOM STUDY TRT*STUDY;
)
)
RUN;
The SAS System
The Mixed Procedure

Model Information

Data Set: WORK._DS
Dependent Variable: _z
Weight Variable: _w
Covariance Structure: Variance Components
Estimation Method: REML
Residual Variance Method: Profile
Fixed Effects SE Method: Model-Based
Degrees of Freedom Method: Containment

Class Level Information

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<td>A C</td>
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Dimensions

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Parameter Search

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Convergence criteria met.
The SAS System
The Mixed Procedure
Covariance Parameter Estimates

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<th>Cov Parm</th>
<th>Estimate</th>
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<td>STUDY*TRT</td>
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<tr>
<td>Residual</td>
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Fit Statistics

-2 Res Log Likelihood: 64.7
AIC (smaller is better): 68.7
AICC (smaller is better): 69.1
BIC (smaller is better): 70.3

PARAM Model Likelihood Ratio Test

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<thead>
<tr>
<th>DF</th>
<th>Chi-Square</th>
<th>Pr &gt; ChiSq</th>
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<tbody>
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<td>1</td>
<td>0.00</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Solution for Fixed Effects

| Effect   | TRT | Estimate | Standard Error | DF | t Value | Pr > |t| |
|----------|-----|----------|----------------|----|---------|-------|
| Intercept|     | -0.9276  | 0.1835         | 16 | -5.05   | 0.0001|
| TRT      | 1   | -0.5491  | 0.1134         | 16 | -4.84   | 0.0002|
| TRT      | 2   | 0        | .              | .  | .       |       |

Type 3 Tests of Fixed Effects

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GLIMMIX Model Statistics

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<td>Pearson Chi-Square</td>
<td>39.7788</td>
</tr>
<tr>
<td>Scaled Pearson Chi-Square</td>
<td>18.0938</td>
</tr>
<tr>
<td>Extra-Dispersion Scale</td>
<td>2.1985</td>
</tr>
</tbody>
</table>
## TRIALS OF UNSUPERVISED DISULFIRAM

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT¹</th>
<th>NC²</th>
<th>XT³</th>
<th>XC⁴</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Fuller &amp; Roth, 1979)</td>
<td>43</td>
<td>42</td>
<td>9</td>
<td>5</td>
<td>1.9588</td>
<td>(0.61, 5.98)</td>
<td>12</td>
<td>A</td>
</tr>
<tr>
<td>(Fuller et al., 1986)</td>
<td>202</td>
<td>199</td>
<td>38</td>
<td>32</td>
<td>1.2092</td>
<td>(0.72, 2.02)</td>
<td>12</td>
<td>A</td>
</tr>
</tbody>
</table>

1 NT=number in test group  
2 NC=number in control group  
3 XT=number in test group who achieved given outcome  
4 XC=number in control group who achieved given outcome  
5 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL  245 CONTROL TOTAL  241  
TREATED EVENTS  47 CONTROL EVENTS  37  
CHISQUARE FOR HETEROGENEITY= 0.532  DEGREES OF FREEDOM= 1

RANDOM EFFECTS ODDS RATIO= 1.31  95% CONFIDENCE INTERVAL= (0.26, 6.70)
SAS COMMANDS FOR ANALYSIS OF UNSUPERVISED DISULFIRAM TRIALS

DATA DISULFIRAM;
LENGTH MEAS $1.;
INPUT YEAR STUDY TRT N Y FU MEAS SIZE;
DATALINES;
1979 1 1 42 5 12 A 85
1979 1 2 43 9 12 A 85
1986 2 1 199 32 12 A 401
1986 2 2 202 38 12 A 401
RUN;
%INC 'C:\PROGRAM FILES\SAS INSTITUTE\SAS\V8\GLMM800.SAS';
%GLIMMIX(DATA=DISULFIRAM,
STMTS=%STR(
CLASS STUDY MEAS TRT;
MODEL Y/N = TRT;
RANDOM STUDY TRT*STUDY;
);
)
RUN;
The SAS System
The Mixed Procedure

Model Information

Data Set WORK._DS
Dependent Variable _z
Weight Variable _w
Covariance Structure Variance Components
Estimation Method REML
Residual Variance Method Profile
Fixed Effects SE Method Model-Based
Degrees of Freedom Method Containment

Class Level Information

Class Levels Values
STUDY 2 1 2
MEAS 1 A
TRT 2 1 2

Dimensions

Covariance Parameters 3
Columns in X 3
Columns in Z 6
Subjects 1
Max Obs Per Subject 4
Observations Used 4
Observations Not Used 0
Total Observations 4

Parameter Search

CovP1 CovP2 CovP3 Variance Res Log Like -2 Res Log Like
Log Like
0 0 0.2840 0.2840 0.0259 0.0518

Iteration History

Iteration Evaluations -2 Res Log Like Criterion
1 1 -0.05182776 0.00000000

Convergence criteria met.
The SAS System
The Mixed Procedure
Covariance Parameter Estimates

<table>
<thead>
<tr>
<th>Cov Parm</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY</td>
<td>0</td>
</tr>
<tr>
<td>STUDY*TRT</td>
<td>0</td>
</tr>
<tr>
<td>Residual</td>
<td>0.2840</td>
</tr>
</tbody>
</table>

Fit Statistics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2 Res Log Likelihood</td>
<td>-0.1</td>
</tr>
<tr>
<td>AIC (smaller is better)</td>
<td>1.9</td>
</tr>
<tr>
<td>AICc (smaller is better)</td>
<td>5.9</td>
</tr>
<tr>
<td>BIC (smaller is better)</td>
<td>0.6</td>
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</tbody>
</table>

PARMS Model Likelihood Ratio Test

<table>
<thead>
<tr>
<th>DF</th>
<th>Chi-Square</th>
<th>Pr &gt; ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.00</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Solution for Fixed Effects

| Effect | TRT | Estimate | Standard Error | DF | t Value | Pr > |t| |
|--------|-----|----------|----------------|----|---------|------|
| Intercept | 0.4381 | 0.08646 | 1   | 16.63 | 0.0382 |
| TRT 1 | -0.2691 | 0.1286 | 1   | -2.09 | 0.2839 |
| TRT 2 | 0     | .       | .   | .     | .      |

Type 3 Tests of Fixed Effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num</th>
<th>Den</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRT</td>
<td>1</td>
<td>1</td>
<td>4.38</td>
<td>0.2839</td>
</tr>
</tbody>
</table>

GLIMMIX Model Statistics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviance</td>
<td>0.5918</td>
</tr>
<tr>
<td>Scaled Deviance</td>
<td>2.0943</td>
</tr>
<tr>
<td>Pearson Chi-Square</td>
<td>0.5679</td>
</tr>
<tr>
<td>Scaled Pearson Chi-Square</td>
<td>2.0000</td>
</tr>
<tr>
<td>Extra-Dispersion Scale</td>
<td>0.2840</td>
</tr>
</tbody>
</table>
# TRIALS OF BEHAVIORAL SELF-CONTROL TRAINING

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT</th>
<th>NC</th>
<th>XT</th>
<th>XC</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Caddy et al., 1978)</td>
<td>35</td>
<td>35</td>
<td>10</td>
<td>5</td>
<td>2.4000</td>
<td>(0.74, 7.17)</td>
<td>36</td>
<td>C</td>
</tr>
<tr>
<td>(Foy et al., 1984)</td>
<td>30</td>
<td>32</td>
<td>8</td>
<td>7</td>
<td>1.2987</td>
<td>(0.41, 4.10)</td>
<td>12</td>
<td>C</td>
</tr>
<tr>
<td>(Pomerleau et al., 1978)</td>
<td>18</td>
<td>14</td>
<td>13</td>
<td>7</td>
<td>2.6000</td>
<td>(0.61, 10.37)</td>
<td>12</td>
<td>C</td>
</tr>
<tr>
<td>(Sobell et al., 1995)</td>
<td>35</td>
<td>35</td>
<td>5</td>
<td>2</td>
<td>2.7500</td>
<td>(0.54, 12.05)</td>
<td>12</td>
<td>C</td>
</tr>
<tr>
<td>(Stimmel et al., 1983)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL PATIENTS=105</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUCCESS RATES NOT REPORTED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Vogler et al., 1975)</td>
<td>23</td>
<td>19</td>
<td>15</td>
<td>11</td>
<td>1.3636</td>
<td>(0.39, 4.66)</td>
<td>12</td>
<td>C</td>
</tr>
</tbody>
</table>

1 NT=number in test group  
2 NC=number in control group  
3 XT=number in test group who achieved given outcome  
4 XC=number in control group who achieved given outcome  
5 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL  141 CONTROL TOTAL  135  
TREATED EVENTS  51 CONTROL EVENTS  32  
CHISQUARE FOR HETEROGENEITY= 0.96 DEGREES OF FREEDOM= 4

RANDOM EFFECTS ODDS RATIO= 1.75 95% CONFIDENCE INTERVAL= (1.02, 3.02)

All trials other than Foy et al. (1984) used a control arm with a dissimilar and possibly ineffective treatment. Foy used the same Broad Spectrum Behavioral approach in both groups which differed only in the addition of blood alcohol discrimination, responsible drinking skills training and social drinking practice to the BSCT treatment.

An additional study, Harris & Miller (1990), was carried out in problem drinkers rather than dependent drinkers. It is of interest, however, because of some suggestion that the BSCT method can be self administered for a few weeks when specialists are unavailable and may prove a useful interim measure.
<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT</th>
<th>NC</th>
<th>XT</th>
<th>XC</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Bowers &amp; al Redha, 1990)</td>
<td>8</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>3.0000</td>
<td>(0.38, 19.30)</td>
<td>12</td>
<td>C</td>
</tr>
<tr>
<td>(Cadogan, 1973)</td>
<td>20</td>
<td>20</td>
<td>13</td>
<td>7</td>
<td>3.4490</td>
<td>(0.95, 10.96)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Corder et al., 1972)</td>
<td>20</td>
<td>20</td>
<td>11</td>
<td>3</td>
<td>6.9259</td>
<td>(1.54, 20.03)</td>
<td>6</td>
<td>A</td>
</tr>
<tr>
<td>(Fichter &amp; Frick, 1993)</td>
<td>49</td>
<td>51</td>
<td>14</td>
<td>16</td>
<td>0.8750</td>
<td>(0.37, 2.05)</td>
<td>18</td>
<td>A</td>
</tr>
<tr>
<td>(Hedberg &amp; Campbell, 1974)</td>
<td>15</td>
<td>30</td>
<td>11</td>
<td>16</td>
<td>2.4063</td>
<td>(0.65, 7.89)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Hunt &amp; Azrin, 1973)</td>
<td>8</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>49.0000</td>
<td>(2.50, **, **)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Hunt &amp; Azrin, 1973)</td>
<td>26</td>
<td>7</td>
<td>15</td>
<td>4</td>
<td>1.0227</td>
<td>(0.19, 5.39)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(McCready et al., 1991)</td>
<td>31</td>
<td>14</td>
<td>9</td>
<td>4</td>
<td>1.0227</td>
<td>(0.26, 4.05)</td>
<td>18</td>
<td>A</td>
</tr>
<tr>
<td>(O'Farrell et al., 1993)</td>
<td>30</td>
<td>29</td>
<td>14</td>
<td>10</td>
<td>1.6625</td>
<td>(0.59, 4.60)</td>
<td>12</td>
<td>A</td>
</tr>
<tr>
<td>(O'Farrell et al., 1996)</td>
<td>12</td>
<td>12</td>
<td>6</td>
<td>6</td>
<td>1.0000</td>
<td>(0.21, 4.79)</td>
<td>12</td>
<td>A</td>
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<tr>
<td>(Smith et al., 1998)</td>
<td>64</td>
<td>42</td>
<td>28</td>
<td>9</td>
<td>2.8519</td>
<td>(1.17, 5.96)</td>
<td>9</td>
<td>A</td>
</tr>
<tr>
<td>(Zweben et al., 1988)</td>
<td>79</td>
<td>139</td>
<td>8</td>
<td>13</td>
<td>1.0921</td>
<td>(0.43, 2.78)</td>
<td>18</td>
<td>C</td>
</tr>
</tbody>
</table>

1 NT=number in test group
2 NC=number in control group
3 XT=number in test group who achieved given outcome
4 XC=number in control group who achieved given outcome
5 Outcomes – C = controlled drinking, A = abstinence
6 No clear statement about randomisation
7 Systematic allocation
8 J. Substance Abuse
9 Behaviour Therapy

| (Azrin, 1976)                          | TOTAL PATIENTS=20 SUCCESS RATES NOT REPORTED |
| (Azrin et al., 1982)                  | TOTAL PATIENTS=43 SUCCESS RATES NOT REPORTED |
| (Kalman et al., 2000)                 | TOTAL PATIENTS=149 SUCCESS RATES NOT REPORTED |
| (Keane et al., 1984)                  | TOTAL PATIENTS=25 SUCCESS RATES NOT REPORTED |
| (Longabaugh, 1993)                    | TOTAL PATIENTS=229 SUCCESS RATES NOT REPORTED |
| (O'Farrell et al., 1996)              | 59 COUPLES SUCCESS RATES NOT REPORTED         |
| (Shoham et al., 1998)                 | 63 COUPLES SUCCESS RATES NOT REPORTED         |

TREATED TOTAL 362 CONTROL TOTAL 380
TREATED EVENTS 142 CONTROL EVENTS 93
CHISQUARE FOR HETEROGENEITY= 15.8 DEGREES OF FREEDOM= 11

RANDOM EFFECTS ODDS RATIO= 1.94 95% CONFIDENCE INTERVAL= (1.37, 2.73)
# TRIALS OF MOTIVATIONAL ENHANCEMENT

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT¹</th>
<th>NC²</th>
<th>XT³</th>
<th>XC⁴</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Bien et al., 1993)</td>
<td>16</td>
<td>16</td>
<td>9</td>
<td>5</td>
<td>2.8286</td>
<td>(0.68, 10.58)</td>
<td>3</td>
<td>A</td>
</tr>
<tr>
<td>(Sellman et al., 2001)</td>
<td>42</td>
<td>80</td>
<td>24</td>
<td>29</td>
<td>2.3448</td>
<td>(1.10, 4.92)</td>
<td>6</td>
<td>C</td>
</tr>
</tbody>
</table>

1 NT=number in test group
2 NC=number in control group
3 XT=number in test group who achieved given outcome
4 XC=number in control group who achieved given outcome
5 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL  58  CONTROL TOTAL  96  
TREATED EVENTS  33  CONTROL EVENTS  34  
CHISQUARE FOR HETEROGENEITY=  0.05  DEGREES OF FREEDOM=  1

Note that Sellman et al.(2001) is a study of mild to moderate alcohol dependence with severe dependence explicitly excluded.

# PROJECT MATCH COMPARISON OF MOTIVATIONAL ENHANCEMENT WITH COGNITIVE BEHAVIORAL SKILLS TRAINING

<table>
<thead>
<tr>
<th>Group</th>
<th>NM¹</th>
<th>NC²</th>
<th>XM³</th>
<th>XC⁴</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aftercare (Project MATCH Research Group, 1998)</td>
<td>242</td>
<td>250</td>
<td>119</td>
<td>145</td>
<td></td>
<td></td>
<td>9</td>
<td>C</td>
</tr>
<tr>
<td>Outpatient (Project MATCH Research Group, 1998)</td>
<td>296</td>
<td>288</td>
<td>112</td>
<td>110</td>
<td></td>
<td></td>
<td>9</td>
<td>C</td>
</tr>
</tbody>
</table>

1 NM=number in motivational enhancement group
2 NC=number in cognitive behavioral skills training group
3 XM=number in motivational enhancement group who achieved given outcome
4 XC=number in cognitive behavioral skills training group who achieved given outcome
5 Outcomes – C = controlled drinking, A = abstinence

COMBINED RESULT FOR MOTIVATIONAL ENHANCEMENT THERAPY

RANDOM EFFECTS ODDS RATIO=  1.88  95% CONFIDENCE INTERVAL= ( 1.28, 2.77)
## TRIALS OF SKILLS TRAINING

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>NT¹</th>
<th>NC²</th>
<th>XT³</th>
<th>XC⁴</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>Months of follow up</th>
<th>Outcome ⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Burtseidt, 2001)</td>
<td>40</td>
<td>40</td>
<td>21</td>
<td>15</td>
<td>1.8421</td>
<td>(0.76,4.37)</td>
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<td>C</td>
</tr>
<tr>
<td>(Monti et al., 1993)</td>
<td>22</td>
<td>18</td>
<td>11</td>
<td>7</td>
<td>1.5714</td>
<td>(0.45,5.33)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Monti et al., 2001)</td>
<td>77</td>
<td>88</td>
<td>48</td>
<td>32</td>
<td>2.8966</td>
<td>(1.53,5.17)</td>
<td>12</td>
<td>C</td>
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<tr>
<td>(Allsop &amp; Saunders, 1997)</td>
<td>20</td>
<td>40</td>
<td>6</td>
<td>4</td>
<td>3.8571</td>
<td>(0.99,17.19)</td>
<td>12</td>
<td>C</td>
</tr>
<tr>
<td>(McCrady et al., 1999)</td>
<td>31</td>
<td>30</td>
<td>12</td>
<td>11</td>
<td>1.0909</td>
<td>(0.39,3.04)</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>(Heinata et al., 2001)</td>
<td>67</td>
<td>54</td>
<td>10</td>
<td>5</td>
<td>1.7193</td>
<td>(0.57,4.96)</td>
<td>8</td>
<td>C</td>
</tr>
<tr>
<td>(O'Malley et al., 1992)</td>
<td>50</td>
<td>54</td>
<td>16</td>
<td>11</td>
<td>1.8396</td>
<td>(0.76,4.36)</td>
<td>9</td>
<td>C</td>
</tr>
</tbody>
</table>

1 NT=number in test group  
2 NC=number in control group  
3 XT=number in test group who achieved given outcome  
4 XC=number in control group who achieved given outcome  
5 Outcomes – C = controlled drinking, A = abstinence  
6 Systematic allocation  

TREATED TOTAL 307 CONTROL TOTAL 324  
TREATED EVENTS 124 CONTROL EVENTS 85  
CHISQUARE FOR HETEROGENEITY= 3.86 DEGREES OF FREEDOM= 7  

COMBINED RESULT INCLUDING PROJECT MATCH DATA  

RANDOM EFFECTS ODDS RATIO= 2.11 95% CONFIDENCE INTERVAL= (1.53, 2.92)
SAS COMMANDS FOR ANALYSIS OF PSYCHOSOCIAL THERAPY TRIALS

DATA PSYCHO;
LENGTH MEAS PSYCH $1.;
INPUT YEAR STUDY TRT N Y FU MEAS PSYCH;
DATALINES;
1995 1 1 35 2 12 C B
1995 1 2 35 5 12 C B
1975 2 1 19 11 12 C B
1975 2 2 23 15 12 C B
1978 3 1 35 5 36 C B
1978 3 2 35 10 36 C B
1978 4 1 14 7 12 C B
1978 4 2 18 13 12 C B
1984 5 1 32 7 12 C B
1984 5 2 30 8 12 C B
1990 6 1 8 4 12 C F
1990 6 3 8 6 12 C F
1973 7 1 20 7 6 C F
1973 7 3 20 13 6 C F
1972 8 1 20 3 6 A F
1972 8 3 20 11 6 A F
1993 9 1 51 16 18 A F
1993 9 3 49 14 18 A F
1974 10 1 30 16 6 C F
1974 10 3 15 11 6 C F
1973 11 1 8 1 6 C F
1973 11 3 8 7 6 C F
1971 12 1 7 4 6 C F
1971 12 3 26 15 6 C F
1991 13 1 14 4 18 A F
1991 13 3 31 9 18 A F
1993 14 1 29 10 12 A F
1993 14 3 30 14 12 A F
1996 15 1 12 6 12 A F
1996 15 3 12 6 12 A F
1998 16 1 42 9 9 A F
1998 16 3 64 28 9 A F
1988 17 1 139 13 18 C F
1988 17 3 79 8 18 C F
1993 18 1 16 5 3 A M
1993 18 4 16 9 3 A M
2001 19 1 80 29 6 C M
2001 19 4 42 24 6 C M
2001 20 1 40 15 6 C S
2001 20 5 40 21 6 C S
1993 21 1 18 7 6 C S
1993 21 5 22 11 6 C S
2001 22 1 88 32 12 C S
2001 22 5 77 48 12 C S
1997 23 1 40 4 12 C S
1997 23 5 20 6 12 C S
1999 24 1 30 11 6 C S
1999 24 5 31 12 6 C S
2001 25 1 54 5 8 C S
2001 25 5 67 10 8 C S
1992 26 1 54 11 9 C S
1992 26 5 50 16 9 C S
1997 27 4 242 119 9 C A
1997 27 5 250 145 9 C A
1997 28 4 296 112 9 C A
RUN;
%INC 'C:\PROGRAM FILES\SAS INSTITUTE\SAS\V8\GLMPOWER.SAS';
%GLIMMIX(DATA=PSYCHO,
STMTS=%STR(
CLASS STUDY MEAS PSYCH TRT;
MODEL Y/N = TRT;
RANDOM STUDY TRT*STUDY;
ESTIMATE 'BSCT AGAINST CONTROL' TRT 1 -1 0 0 0;
ESTIMATE 'FAMILY AGAINST CONTROL' TRT 1 0 -1 0 0;
ESTIMATE 'MET AGAINST CONTROL' TRT 1 0 0 -1 0;
ESTIMATE 'SKILLS AGAINST CONTROL' TRT 1 0 0 0 -1;
)}
RUN;
SAS OUTPUT FROM ANALYSIS OF PSYCHOSOCIAL THERAPY TRIALS

The SAS System
The Mixed Procedure

Model Information

Data Set WORK._DS
Dependent Variable _z
Weight Variable _w
Covariance Structure Variance Components
Estimation Method REML
Residual Variance Method Profile
Fixed Effects SE Method Model-Based
Degrees of Freedom Method Containment

Class Level Information

Class Levels Values
STUDY 28 1 2 3 4 5 6 7 8 9 10 11 12 13
14 15 16 17 18 19 20 21 22 23
24 25 26 27 28
MEAS 2 A C
PSYCH 5 A B F M S
TRT 5 1 2 3 4 5

Dimensions

Covariance Parameters 3
Columns in X 6
Columns in Z 84
Subjects 1
Max Obs Per Subject 56
Observations Used 56
Observations Not Used 0
Total Observations 56

Parameter Search

CovP1 CovP2 CovP3 Variance Res Log Like -2 Res Log Like
Log Like 0.5276 0.008215 0.9474 0.9474 -58.2954

Iteration History

Iteration Evaluations -2 Res Log Like Criterion
1 1 116.59078923 0.00000000
The SAS System
The Mixed Procedure

Convergence criteria met.

Covariance Parameter Estimates

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<tr>
<td>STUDY*TRT</td>
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<tr>
<td>Residual</td>
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Fit Statistics

-2 Res Log Likelihood: 116.6
AIC (smaller is better): 122.6
AICC (smaller is better): 123.1
BIC (smaller is better): 126.6

PARMS Model Likelihood Ratio Test

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<th>DF</th>
<th>Chi-Square</th>
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<td>2</td>
<td>0.00</td>
<td>1.0000</td>
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Solution for Fixed Effects

| Effect | TRT | Estimate     | Standard Error | DF | t Value | Pr > |t| |
|--------|-----|--------------|----------------|----|---------|------|---|
| Intercept |     | -0.1565     | 0.1940         | 24 | -0.81   | 0.4278 |
| TRT     | 1   | -0.7482     | 0.1568         | 24 | -4.77   | <.0001 |
| TRT     | 2   | -0.1868     | 0.3011         | 24 | -0.62   | 0.5409 |
| TRT     | 3   | -0.08690    | 0.2216         | 24 | -0.39   | 0.6984 |
| TRT     | 4   | -0.1153     | 0.2216         | 24 | -0.82   | 0.4179 |
| TRT     | 5   | 0           | .              | .  | .       | .     |

Type 3 Tests of Fixed Effects

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<th>Den DF</th>
<th>F Value</th>
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</thead>
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<tr>
<td>TRT</td>
<td>4</td>
<td>24</td>
<td>9.76</td>
<td>&lt; 0.001</td>
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</table>
### The SAS System

**The Mixed Procedure**

### Estimates

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<th>Estimate</th>
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<th>DF</th>
<th>t Value</th>
<th>Pr &gt;</th>
<th>t</th>
</tr>
</thead>
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<td>Extra-Dispersion Scale</td>
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Appendix 18

CONCLUSIONS FROM COMPREHENSIVE REVIEWS OF ALCOHOL TREATMENT

This appendix presents:

1. the ordering of all interventions in Table 18-1 derived using the Mesa Grande methodology (Miller & Wilbourne, 2002)
2. some recommendations for a comprehensive UK alcohol problems treatment service from the report by Raistrick and Heather (Raistrick & Heather, 1998)
3. some conclusions from the Swedish health technology agency (SBU) report on management of drug and alcohol problems (Andreasson et al., 2001).

Table 18-1 Mesa Grande Project (Miller & Wilbourne, 2002) – Rankings of interventions derived from controlled trials in patients with alcohol problems of any severity

<table>
<thead>
<tr>
<th>Rank</th>
<th>Treatment modality</th>
<th>N</th>
<th>Rank</th>
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<td>Brief intervention</td>
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<tr>
<td>2</td>
<td>Motivational enhancement</td>
<td>17</td>
<td>46</td>
<td>‘Moral reaconation’ therapy</td>
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<td>3</td>
<td>GABA agonist</td>
<td>5</td>
<td>47</td>
<td>Community reinforcement – buddy</td>
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<tr>
<td>4</td>
<td>Anti-depressant, non-SSRI</td>
<td>6</td>
<td>48</td>
<td>Recreational therapy</td>
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<tr>
<td>5</td>
<td>Opiate antagonist</td>
<td>6</td>
<td>49</td>
<td>Job finding</td>
<td>1</td>
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<tr>
<td>6</td>
<td>Social skills training</td>
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<td>50</td>
<td>Legally sanctioned probation/rehab.</td>
<td>2</td>
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<td>7</td>
<td>Community reinforcement</td>
<td>4</td>
<td>51</td>
<td>Medical monitoring</td>
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<td>8</td>
<td>Behaviour contracting</td>
<td>5</td>
<td>52</td>
<td>BAC surveillance</td>
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</tr>
<tr>
<td>9</td>
<td>Behavioural marital therapy</td>
<td>8</td>
<td>53</td>
<td>Occupational therapy</td>
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</tr>
<tr>
<td>10</td>
<td>Dopamine antagonist</td>
<td>2</td>
<td>54</td>
<td>Tobacco cessation with nicotine gum</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>Sensory deprivation</td>
<td>2</td>
<td>55</td>
<td>Tobacco cessation with exercise</td>
<td>1</td>
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<tr>
<td>12</td>
<td>Biofeedback</td>
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<td>56</td>
<td>Aversion therapy, electric</td>
<td>20</td>
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<tr>
<td>13</td>
<td>Case management</td>
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<td>57</td>
<td>Twelve-Step facilitation</td>
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<tr>
<td>14</td>
<td>Cue exposure</td>
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<td>Antidepressant, SSRI</td>
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<td>Developmental counselling</td>
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<tr>
<td>16</td>
<td>Anti-convulsant medication</td>
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<td>60</td>
<td>Dopamine precursor</td>
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<tr>
<td>17</td>
<td>Detoxification as treatment</td>
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<td>Serotonin precursor</td>
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<tr>
<td>18</td>
<td>Significant other as treatment support</td>
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<td>62</td>
<td>BAC discrimination training</td>
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<tr>
<td>19</td>
<td>Self-monitoring</td>
<td>6</td>
<td>63</td>
<td>Beta blocker</td>
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<tr>
<td>20</td>
<td>Transcendal meditation</td>
<td>1</td>
<td>64</td>
<td>Client choice among options</td>
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<tr>
<td>21</td>
<td>Assessment as intervention</td>
<td>1</td>
<td>65</td>
<td>Psychotherapy, group process</td>
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<tr>
<td>22</td>
<td>Aversion therapy, negative emotion</td>
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<td>66</td>
<td>Lithium</td>
<td>7</td>
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<tr>
<td>23</td>
<td>Feedback</td>
<td>1</td>
<td>67</td>
<td>Marital therapy, other</td>
<td>8</td>
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<td>24</td>
<td>Hypnotic medication</td>
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<td>Electrical stimulation of the head</td>
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<td>Cognitive therapy</td>
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<td>Client-centred counselling</td>
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<td>Anti-psychotic mediation</td>
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<td>27</td>
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<td>71</td>
<td>Hypnosis</td>
<td>4</td>
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<td>28</td>
<td>Unilateral family therapy</td>
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<td>Aversion therapy, apnoeic</td>
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<td>30</td>
<td>Covert sensitization</td>
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<td>74</td>
<td>Calcium carbimide</td>
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<td>‘Affective contra-attribution’ therapy</td>
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<td>75</td>
<td>Serotonin antagonist</td>
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<td>32</td>
<td>Problem solving</td>
<td>2</td>
<td>76</td>
<td>Anti-anxiety medication</td>
<td>14</td>
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</table>

*N denotes the number of studies on which each intervention is ranked. It should be noted that the project authors have concerns about ordering an intervention on the basis of less than three studies and hence split the above list into two sections for those based on three or more studies and those based on two or fewer studies.

**Summary of recommendations by Raistrick and Heather (Raistrick & Heather, 1998)**

1. Inpatient and supported residential units might be shared between several health districts.

2. Arrangements should be in place to deal with mentally ill, violent or aggressive patients and those with acute stress reaction.

3. An argument is put for Motivational Enhancement Therapy as a standard of treatment. It may be a self-contained treatment or a preparation for more intensive treatment (Brown & Miller, 1993).

4. Pharmacotherapies should be integrated into the treatment model.

5. ‘Relapse prevention should not be seen as a treatment in itself but should be a component part of all treatment programmes’.

6. Information on local mutual aid groups should be available through staff.

7. There is a marked diversity of clients and, although Project MATCH did not support the systematic matching of therapies to clients it is clear that different facilities will be necessary: for instance for homeless or very young people.

8. Disulfiram is considered to have some effect as a sensitising agent. The importance of monitoring compliance is noted.

9. Naltrexone and acamprosate are both considered to have a role in treatment of alcohol problems. Four uses are suggested (1) when sensitising agents are contraindicated (2) enhancement of abstinence oriented programmes when clients are in the pre-contemplation or contemplations stages of change (3) an
enhancement to controlled drinking programmes (for some subgroups not yet determined) (4) an aid to containing relapse.

**Conclusions from SBU report (Andreasson et al., 2001)**

Amongst the conclusions are:

1. The effectiveness of certain ‘mini interventions’ that are possibly not used as much as they might be.

2. That certain other psychosocial treatments have beneficial effects, which are similar to each other. These include types of CBT (e.g. 12 steps) and motivational programmes. Structured interactional therapy and structured modern therapy with psychodynamic reference frameworks seem similar in effect to CBT. Partner therapy and family intervention show positive effects.

3. Only weak evidence exists on subgroup effects. Inpatient and outpatient results are similar. Important to address problems of mental illness and lifestyle problems concurrently with abuse.

4. Acamprosate, naltrexone and disulfiram are noted to have confirmed effect. Disulfiram only when given under supervision.

Certain areas for research are noted. Of particular interest for the current assessment are:

- Integration of psychosocial and pharmacological interventions
- Optimal intensity and duration of different treatment interventions
- The cost effectiveness of different treatment methods

Conclusions from the SBU economic review are:

A search of several literature databases found 1200 articles of which 24 studies were economic analyses and eight were based on RCTs. These included alcohol and drug studies. About half the studies were of poor quality and the remainder covered diverse areas. It was concluded that evidence was weak and contradictory. No conclusions on cost effectiveness could be drawn.
Appendix 19

PROTOCOL FOR PATIENT PREFERENCE STUDY

Project title
A study of the relapse prevention treatment preferences of individuals\(^\text{1}\) who have experienced alcohol dependence.

Names and contact details of investigator
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Glasgow G4 0BA
Tel 0141 331 3457; Fax 0141 331 8312
Email h.e.watson@gcal.ac.uk

Brief summary of project
The project aims to describe the experiences and preferences of individuals for pharmaceutical or psychosocial interventions, or a combination of both, for the treatment for alcohol dependence. A qualitative approach will be adopted whereby data will be collected using in-depth, one-to-one interviews with a purposive sample of people who have relevant personal experience. The focus of the study will be to explore patients’ treatment preferences and also to elicit factors which prevent relapse to drinking.

1. Background to project

The International Classification of Diseases (ICD), describes alcohol dependence syndrome as a cluster of symptoms which include a subjective compulsion to drink, physiological dependence (tolerance and withdrawal) and rapid reinstatement of symptoms after a period of abstinence. There may be a loss of control over drinking, an increased urgency to drink, and increased priority of alcohol over the person’s previous interests and activities. The individual persists with drinking despite evidence of its harmful effects (ICD-10, WHO 1992).

The goals of treatment are to reduce alcohol-related harm. This may be achieved at differing levels, and by a variety of means (Heather 2001). Such goals may range from achievement of controlled drinking at a negotiated level to the achievement and indefinite maintenance of total abstinence. Decisions concerning goals may depend on therapists’ philosophies, and patients’ preferences are likely to impinge on the treatment approach adopted.

---

\(^{1}\) This term is used to denote a person who has experienced treatment for alcohol dependence syndrome. It encompasses the terms ‘patient’ and ‘client’. Where either of these latter terms is used, the intention is to refer to such an individual.
Relapse prevention aims to reduce the impact of cues which precipitate relapse to alcohol (Brown 2001). Because the goals of treatment are so variable, the concept of relapse can be interpreted in a range of ways. For the purposes of the Health Technology Board for Scotland’s (HTBS) Health Technology Assessment (HTA) of alcohol dependence relapse prevention strategies, the following definition was agreed: “Failure to achieve a pre-determined goal (e.g. complete abstinence, < 5 drinks on one occasion, total number of drinks over a certain time period, or cumulative number of days of complete abstinence)” see Minutes of Topic Specific Group meeting, 31 May 2001).

People’s preferences are closely bound to motivation and, in terms of treatment for an alcohol problem, with adherence with treatment (Donovan 1998). Given that more than two-thirds of clients of alcohol treatment programmes may relapse within six months of treatment (Marlatt and Gordon 1985), it is important to consider the preferences of such clients in order to find ways of improving patient outcomes through corresponding improvements in compliance rates.

In order to develop services, which meet the needs of local populations it is crucial that the views of users are sought (WHO 1996, Coulter 1999). As highlighted in the Plan for Action for the NHS (Scottish Executive 2000), this is particularly true for individuals and groups who are marginalised and whose voices may not be heard for a range of reasons. Those who misuse alcohol constitute just such a group.

A literature search has revealed some case study work on potential causes of relapse but no comparable wide-ranging study exists which attempts to identify and explore patient attitudes to relapse. It is therefore timely that such a study be conducted. This study aims to explore and describe the relapse prevention treatment options from the perspective of individuals who have themselves experienced alcohol dependence.

2. Aim

The project aims to describe the experiences and preferences of individuals with regards pharmaceutical and/or psychosocial interventions for the treatment for alcohol dependence. Furthermore, the study will attempt to elicit factors that prevent relapse to drinking.

3. Methods

A phenomenological approach is the methodology of choice as this can facilitate an understanding of the social world from the standpoint of the individuals (Wilkes 1991). As a qualitative research method it provides a rigorous, critical and systematic means of investigating complex phenomena which are enmeshed in the life experience of people (Streubert and Carpenter 1995).

Sample
The sample will comprise individuals who have used the alcohol treatment services of three geographically distinct areas in Scotland within the past year. Individuals who have experienced treatment for alcohol dependence from one of three NHS Primary Care Trust, two of which provide services within rural and semi-urban areas, and one whose catchment area is urban, will be invited to participate in the study.
The sample will be recruited in two ways. Firstly, posters will be displayed in prominent positions within treatment facilities and information about the study was made available to anyone who expressed interest in participating. In addition, the nurse managers will write to a random sample of patients who have attended for treatment during the past year, seeking volunteers for the study and suggesting that those interested should contact the researcher. In this way the anonymity of patients will be protected until they agree to volunteer. Moreover, since the study involves an element of service evaluation, the random process of sample recruitment via the nurse managers will ensure that bias in the selection is minimised.

There will be no exclusions with regard to gender, age, social class or employment status.

In keeping with the tenets of qualitative research, data collection will continue until saturation is reached, (i.e. until no new themes emerge). It is therefore not possible to determine the exact sample size necessary to achieve this at the outset of the study (Polit and Hungler 1997). However, it is anticipated that it will be necessary to undertake approximately forty interviews.

**Procedures**

One-to-one in-depth interviews will be conducted during which the participants will be asked to recount their experiences of treatment and their preferences of pharmacological and psychosocial interventions (e.g. disulfiram, acamprosate, motivational enhancement therapy, cognitive-behavioural therapy, supportive psychotherapy, group work, counselling, the 12-steps approach). They will be invited to discuss the factors which they perceived as contributing to the experience being either positive or negative, and to reflect on the reasons for their preferences. An interview guide will be used to ensure that all relevant topics are addressed (Appendix 1). Prompts will be used for clarification if necessary, and to encourage further disclosure. Interviews will be conducted at the location of the participants’ choice and, with permission, audio-tape recorded. It is anticipated that each interview will last for approximately 1 hour.

**Analysis**

All tape-recorded interviews will be transcribed verbatim. Burnard’s framework for thematic analysis of qualitative data will be used to search for themes and patterns in the data (Burnard 1991). As a means of ensuring rigour in the process, a sample of the transcriptions will be independently analysed by a colleague of the researcher with experience of phenomenology. Points of divergence will be discussed and agreement reached for the final analysis. The participants will be invited to comment on a summary of the findings as part of the validation process for qualitative research (Sandalowski 1993, Whittemore et al 2001).
Relapse prevention treatment preference of people who have experienced alcohol dependence

Coding Scheme

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<th>Group Work</th>
<th>One-to-One sessions</th>
<th>Residential</th>
<th>Day Care</th>
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Coding Scheme (continued)

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<th>Acamprosate</th>
<th>Community reinforcement</th>
<th>Relapse</th>
<th>Default/ non-adherence</th>
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<td>-ves</td>
<td>+ves</td>
<td>-ves</td>
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</table>

12-88
Plans for ethical approval and access negotiation

Approval of each of the Local Research Ethics Committees of the participating Trusts has been granted. Verbal permission for access has been agreed from the consultant psychiatrists with responsibility for all participating patients.

Full informed consent will be sought in writing from all individuals who are invited to participate. Permission to tape-record the interviews will be sought, and participants will be assured that they may request that recordings cease at any point. All participants will be informed that they can withdraw without penalty at any stage in the project. Those who agree to participate will be guaranteed confidentiality. However, since their identity will need to be known if they are to be contacted to provide verification of the findings full anonymity cannot be assured. If they do not wish to be contacted again their full anonymity can and indeed will be afforded.

The conditions of the Data Protection Act (1998) will be observed.

Existing facilities

The study will be based in the Caledonian Nursing and Midwifery Research Centre. This is located within the Department of Nursing and Community Health and has all the advantages of the modern facilities of the new Faculty of Health building. The researcher has access to a wide range of support systems, such as library and computing advice. Equipment for tape-recording and transcribing the interviews are available, as are computing hardware and the necessary software.

Justification of requirements

Given the sensitivity of the interviews it is important that the data are collected by an individual who has experience both of the research methods and of working with people with problems of alcohol dependence. Since the participants’ views of their treatment are being explored, it is preferable that the researcher is not be regarded by the participants as being part of the NHS culture. It is therefore proposed that the data be collected by a member of the academic fraternity whose Curriculum Vitae is appended (Appendix 2). A secretary will be employed on a part-time basis to transcribe the tape-recorded interviews.

4. Dissemination plans

The following strategies will be adopted to disseminate the study findings:

1. Copies of the research report will be sent to the Health Technology Board for Scotland from which it will be available to all interested parties.
2. The report will be lodged in the libraries of the participating voluntary organisations and NHS Trusts, and Glasgow Caledonian University.
3. Results will be presented at relevant medical, social science and nursing conferences.
4. Manuscripts will be submitted for publication in appropriate specialist and generic professional journals, such as Addiction, Addiction Research, the Health Bulletin.
5. **Research expertise/practice experience**

The applicant has research experience in the management of problem drinkers and has investigated aspects of the nurse’s role in relation to working with problem drinkers in acute care settings, having undertaken a PhD and published widely in this area.

**Key references**


ADDENDUM

A study of the relapse prevention treatment preferences of individuals who have experienced alcohol dependence.

Interview guide

1. Introduction, reiteration of the purpose of the study, and explanation of the processes for data collection, including the use of the tape recorder.

2. Discuss drinking history and treatment history.

3. Explore the form(s) of treatment the patient has experienced, and his/her views of its effectiveness and acceptability. (using layman’s terms, cover disulfiram, acamprosate, psychosocial interventions including individual, group and 12-step).

4. If relevant, depending on the answer to item 3, explore patient’s preferences for treatments, and reasons for answers.

5. Explore whether some treatments may be more appropriate at different times in one’s life/drinking history, and what these might be.

6. If appropriate, ask how important it is that the person’s wife/husband/partner is involved in the treatment to help him/her to continue.

7. Ascertain whether the person has relapsed. If so, explore the circumstances; duration of period of abstinence/controlled drinking; the extent of the relapse, and the pattern of relapses.

8. Ask what might have prevented the relapse(s).

9. What aspects of the service does the person perceive to be good, and what is felt to be less good/bad (if not already discussed).

10. To what extent was the person involved in decision-making about the choice of treatment? Does s/he see this as this relevant to relapse prevention?

11. If the patient has defaulted from an appointment, what action did s/he take?

12. How proactive should the service provider be in trying to re-establish contact?

Ask if the patient feels I should know anything else; thank the patient for his/her time; end recording.
Appendix 20

SUMMARY OF RESPONSES TO CONSULTATION QUESTIONS (PATIENT ISSUES)

1. From your experience of services for alcohol problems, what do you think is working well and what could be improved on?

Residential treatment was generally thought to be essential amongst service users who responded to consultation. It was felt that the length of wait for admission to residential facilities should be improved upon. While some service users found the AA approach to be of great value, a few did not like the excessive emphasis on what they perceived as ‘religion’. An issue raised was that the needs of women with dependents need to be taken account of so that they can attend residential care.

The key components of services that work well were generally thought to be contact with people, one-to-ones, support, discipline and companionship in adversity. Being given the knowledge and skills to prevent relapse seems to be considered crucial, as does addressing the underlying problems.

Amongst the people who expressed an opinion, abstinence worked well whereas controlled drinking was not seen to be as effective. There was some criticism that these two conflicting approaches lead to confusion.

A common suggestion was that NHS and non-statutory services are currently too separate and should be networked to capitalise on the individual resources.

It was emphasised that treatment had to be followed up with aftercare to be effective and suggested that aftercare programmes should be improved.

GPs were widely thought to regard alcoholism as a personal weakness and not as a disease. The opinion was expressed that local/rural doctors know little about addiction and the treatment available. It was felt that the general public and health professionals should be educated to improve understanding.

It was highlighted that people have to want help for treatment of any nature to be effective.

2. If you have ever used the medicines, are there any issues about their use that you think should be considered?

Opinions varied, from those who thought that medicines were ineffective to those who thought that acamprosate and disulfiram were necessary in the acute stages as a short-term solution.

Among the people who disagreed with the use of medication, a common point was that chemicals should not be used to replace alcohol. Encouraging the body to rely on another substance was seen to be counter productive. Additionally, whilst such drugs may help prevent drinking, they do not address the real problems. As such, there was a view that medications just delay the inevitable relapse and the counselling is more effective. It was considered to be easy to cheat whilst using Antabuse and very much
felt that individuals still had to be motivated for drugs to work. Antabuse, taken with excessive alcohol, was sometimes seen as a method of suicide and it should be considered that this could be a temptation for some people. Conversely, the danger of taking alcohol at the same time as Antabuse cannot be underemphasised.

Those who felt that medication had some treatment value emphasised that greater support from health professionals might increase the effectiveness.

It was recognised the medication offered the families of people with alcohol dependency a degree of comfort and confidence.

3. Do you have views about the information provided to raise awareness of services for people with alcohol problems, and their families/friends? Did you receive enough information about the different ways alcohol problems can be treated?

Again, there were conflicting views. Some people felt that information was good although one person felt that the tone of information is ‘preaching’ and not appropriate. Others did not consider that it was easy to obtain information. In particular, GPs were not thought to offer enough information because they do not view alcohol dependence as a disease. This appeared to create a lack of trust between service users and GPs. It was suggested that each surgery should have one GP who specialises in alcohol problems. Information leaflets for employers were also suggested. It was felt that the availability of information may vary according to location. While it was recognised that information on recognising the symptoms was available, there was not thought to be any information on how to accept the problem.

The issue was raised that people who are dependent on alcohol are not very likely to seek out information or ask for help. Often it is friends or relatives who do this, but even they are reluctant due to shame or embarrassment, and often do not know where to go for help. It was pointed out that advice for carers should be more widely available. The need for a national helpline was raised.

Alcohol dependence was thought by some to be a social stigma and people felt that to avoid this, information should be available to educate the general public.

From the responses, even in cases where people felt that information was available, it seemed as though there was insufficient discussion and information to allow the service user to make an informed choice about their treatment. It is important that people know that if one avenue of treatment does not work, there are other areas that can be explored.

4. Is it useful to be able to offer residential treatment for people with alcohol problems or can it all be done while staying at home?

In general, people who had experience of residential treatment considered it to be an essential part of treatment. It was felt that the home life and social circle of a person who is dependent on alcohol is intrinsically linked with drinking habits and that the only way of preventing relapse is to be removed from the home environment. Regular nutritious meals and companionship with others experiencing the same problems were considered to be amongst the benefits of residential treatment that are not possible to
achieve with home treatment. It was also recognised that family members get space to recover when a person with alcohol dependency is admitted to a residential facility.

Some people believed that while residential treatment can be beneficial it is not the only answer. It was thought that home treatment could be effective for some people, although this would depend on the will power of the individual, the home environment, social circle and support of families and friends. It was suggested that home treatment could be effective for the less chronic stages of alcohol dependency. One person intimated that day centres in poorer areas may facilitate home recovery.

5. Do you feel it is sensible to help people with alcohol problems and people with drug problems within the same service/clinic?

Views on this differed considerably. The reasons that people gave for and against are summarised in the following table:

<table>
<thead>
<tr>
<th>Sensible to treat together because:</th>
<th>Not sensible to treat together because:</th>
</tr>
</thead>
<tbody>
<tr>
<td>should not be naïve to other types of addicts, emphasises more than one type of addiction</td>
<td>can cause opposing cliques and thereby have a negative effect on the treatment regimes</td>
</tr>
<tr>
<td>dissuades people with alcohol dependency from turning to drugs (prevention rather than cure)</td>
<td>people receiving treatment for alcohol dependency felt threatened by the difference in cultures</td>
</tr>
<tr>
<td>both are drugs</td>
<td>tends to be a generation gap: people with alcohol dependency older than people with drug dependency</td>
</tr>
<tr>
<td>process of recovery is the same</td>
<td>Temptation to substitute one drug for another</td>
</tr>
<tr>
<td>shouldn’t categorise people in terms of the substance that they abuse: all are people with an addiction</td>
<td></td>
</tr>
<tr>
<td>highlights cross-addiction</td>
<td></td>
</tr>
<tr>
<td>leads to a more tolerant attitude and all round understanding of addiction</td>
<td></td>
</tr>
</tbody>
</table>

Other people felt that the clinical approach to treating dependency means that there are times when the programmes should overlap, but that group therapy should be separate.

6. Is the fact that alcohol services are usually part of the local mental health service a source concern or a discouragement to seeking help?

This question surprised some people as they were unaware that alcohol services were part of mental health services. Of the service users who answered this question, there were those who were very much of the opinion that alcohol services should not be part of mental health services as they did not like the stigma associated with this. Others were of the opinion that by the time you are desperate enough to seek treatment you do not care where it comes from. Several service users recognised that many people with a dependency on alcohol have underlying problems such as
depression and therefore felt that it was important that alcohol services do come under the ‘mental health’ umbrella.
Appendix 21

DATABASES SEARCHED FOR COST EFFECTIVENESS STUDIES

Cost Effectiveness Literature Search – sources
The following sources were searched during February 2002 to update the search undertaken by CRD, York during 2000:

- Medline (Ovid)
- Premedline (Ovid)
- Embase (Ovid)
- DARE
  - Cochrane Library (CD-ROM, 2001 Issue 4)
- NHS EED
  - Cochrane Library (CD-ROM, 2001 Issue 4)
- HTA
  - Cochrane Library (CD-ROM, 2001 Issue 4)
- Ongoing Reviews
- National Research Register
- HEED (CD-ROM, Feb, 2002)
- Econlit (OCLC)
- Social Science Citation Index (ISI Web of Science)
- Science Citation Index (ISI Web of Science)
- Cinahl (Ovid)
- British Nursing Index (SilverPlatter)
- Psychinfo (Ovid)
- AMED (Allied and Complementary Medicine Database) (Ovid)
- PAIS (Public Affairs Information Service) (CSA)
- HMIC (SilverPlatter)
- SIGLE (SilverPlatter)
- ASSIA Plus (Applied Social Sciences Index and Abstracts) (CSA)
- EconBase
  - http://www.elsevier.nl/homepage/sae/econworld/menu.htm
- HDA Evidencebase
  - http://213.121.184.60/hda/docs/evidence/eb2000/corehtml/intro.htm

In addition, the following web-sites were searched:

- EtOH
- Health Economics Research Unit, Aberdeen
  - www.abdn.ac.uk/heru
- Centre for Health Economics, York
  - www.york.ac.uk/inst/che/
- Health Economics Research Centre, Oxford
  - www.ihs.ox.ac.uk/herc/
- Health Economics Research Group, Brunel
- Health Economics Group (HEG), Newcastle
www.ncl.ac.uk/dep/healthgroup.html

- SCHARR School of Health and Related Research, Sheffield
  www.shef.ac.uk/uni/academic/R-Z/scharr/

- Health Economics Group, East Anglia
  www.uea.ac.uk/menu/acad_depts/hsw/hpp/hegwelc.htm

- Institute of Health Economics IHE, Alberta, Canada
  www.ihe.ab.ca

- LSE London School of Economics and Political Science
  www.lse.ac.uk/

- Southampton University Economics Department
  www.soton.ac.uk/~econweb/

- Centre for Health Economics Research and Development CHERE, University of Sydney and Central Sydney Area Health Service
  www.chere.usyd.edu.au

- Institute of Health Economics (IHE), Alberta, Canada
  www.ihe.ab.ca/

- International Health Economics Association iHEA
  www.healtheconomics.org/cgi-bin/WebObjects/ihea

- Centre for Health Economics and Policy Analysis (CHEPA), McMaster University
  www.chepa.org/

- Centre for Health Program Evaluation (CHPE), University of Melbourne and Monash University, Australia
  chpe.buseco.monash.edu.au/

- NetEc
  http://netec.mcc.ac.uk/NetEc.html

- IDEAS Internet Documents in Economics Access Service
  http://ideas.uqam.ca/
Appendix 22

SEARCH STRATEGY FOR COST EFFECTIVENESS STUDIES

Search Strategy for cost effectiveness studies in Medline

Database: Medline
Coverage: <January 2000-January 2002 Week 3>
Host: Ovid
Date Searched: 11/02/02

1. alcoholism/
2. alcohol drinking/
3. alcoholic?.tw.
4. alcoholism.tw.
5. (harmful$ adj1 drinking).tw.
6. dipsomania$.tw.
7. (alcohol adj2 (dependen$ or addict$ or abus$ or misus$)).tw.
8. or/1-7
9. intervention studies/
10. intervention$.tw.
12. or/9-11
13. alcohol deterrents/
14. behavior addictive/dt
15. (alcohol adj2 deter$).tw.
17. (alcohol adj2 aversi$).tw.
19. (pharmacolog$ adj1 (intervention$ or treatment$)).tw.
20. taurine/
21. disulfiram/
22. naltrexone/
23. acamprosate.tw.
24. campral.tw.
25. disulfiram.tw.
26. antabuse.tw.
27. naltrexone.tw.
28. trexan.tw.
29. or/13-28
30. psychotherapy/
31. exp behavior therapy/
32. exp psychoanalytic therapy/
33. exp socioenvironmental therapy/
34. exp self concept/
35. psychotherapy brief/
36. alcoholics anonymous/
37. social support/
38. behavior addictive/px
39. psychotherap$.tw.
40. (psychosocial adj2 (care or therap$ or intervention$ or technique$ or treatment$)).tw.
41. (behavior adj2 (therap$ or treatment$ or modification or contracting)).tw.
42. (assertive$ adj2 (skill$ or training or technique$)).tw.
43. (aversi$ adj2 (therap$ or treatment$)).tw.
44. (cognitive adj2 (therap$ or treatment$)).tw.
45. cbt.tw.
46. (relaxation adj2 (skill$ or training or technique$)).tw.
47. sociotherapy.tw.
48. psychoanaly$.tw.
49. (socioenvironmental adj2 (therap$ or treatment$)).tw.
50. therapeutic community.tw.
51. ((group or marital or couple$ or famil$) adj2 (therap$ or intervention$ or technique$ or treatment$)).tw.
52. (community adj2 reinf$.tw.
53. (motivational adj (interview$ or enhancement)).tw.
54. supportive expressive therap$.tw.
55. counseling.tw.
56. counselor?.tw.
57. (cue$ adj1 (therap$ or exposure)).tw.
58. covert sensitization.tw.
59. (self adj1 concept).tw.
60. (self adj (efficacy or esteem or control or care)).tw.
61. (social$ adj1 support).tw.
62. ((coping or life) adj1 skills).tw.
63. social skill$.tw.
64. ((stress or anger) adj2 manag$).tw.
65. supportive treatment$.tw.
66. ((brief or short or minimal) adj2 intervention$).tw.
67. coping behavio?r.tw.
68. stepped care.tw.
69. alcoholics anonymous.tw.
70. aa.tw.
71. twelve step.tw.
73. or/30-72
74. temperance/
75. temperance.tw.
76. sobriety.tw.
77. (alcohol adj2 (consum$ or intake) adj2 (reduc$ or control$ or moderat$ or attenuat$ or restrict$ or restrain$)).tw.
78. (abstinence or abstain$).tw.
79. ((control$ or moderat$ or attenuat$ or reduc$ or restrain$ or restrict$) adj2 drinking).tw.
80. (self adj (change or help)).tw.
81. maturing out.tw.
82. or/74-81
83. exp economics/
84. exp "quality of life"/
85. (economic$ or cost$).tw.
86. "quality of life".tw.
87. qol$.tw.
88. quality adjusted life year$.tw.
89. qaly$.tw.
90. or/83-89
91. 200$.em.
92. 8 and 12 and 90 and 91
93. 8 and 29 and 90 and 91
94. 8 and 73 and 90 and 91
95. 8 and 82 and 90 and 91
96. or/92-95

This search strategy was reviewed by Gill Ritchie, Information Officer, at CRD, University of York.
## Appendix 23

### ECONOMIC DATA EXTRACTION

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Authors</td>
<td>Annemans L., Vanoverbeke N., Tecco J., D’Hooghe D.</td>
</tr>
<tr>
<td>Study Perspective</td>
<td>Health care payers in Belgium</td>
</tr>
<tr>
<td>Clinical Data Sources</td>
<td>Survey of 129 GPs informed frequency of somatic, psychic and other problems related to alcohol use</td>
</tr>
<tr>
<td>Diagnostic Technology</td>
<td>Acamprosate is an anti-craving neuromodulator</td>
</tr>
<tr>
<td>Study Population</td>
<td>RCT (n = 448) for relapse rates; RCT (n=582) unpublished trial for type of relapse in second line management and Belgian registry data</td>
</tr>
<tr>
<td>Data Sources for Resource Use</td>
<td>Resource savings from sample of GP records. Success of detox from RCT (N = 164). Resource costs and resource use, from official statistics from Ministry of Health</td>
</tr>
<tr>
<td>Outcome Measures</td>
<td>Net cost savings per incremental abstinent patient</td>
</tr>
<tr>
<td>Method of Analysis</td>
<td>Monte Carlo Markov model</td>
</tr>
<tr>
<td>Discounting</td>
<td>No discounting applied; study period 2 years</td>
</tr>
</tbody>
</table>
| Assumptions | • % of patients remaining abstinent after 2 years 11.9% for acamprosate and 4.9% for placebo  
• saving from institutional and ambulatory detoxification, acute and long term hospitalisation and liver complications. |
| Results | Average net saving per patient over the two year period of 21,301 BEF (528 Euro) |
| Comments | High lost to follow up and unclear of treatment of this group.  
• Rate of abstinence under acamprosate has greatest impact on net savings  
• The model assumes that the abstinence rate after 48 weeks is continued, with no further relapses. |
<table>
<thead>
<tr>
<th><strong>Study Paper</strong></th>
<th>The Cost Effectiveness of Acamprosate in the Treatment of Alcoholism in Germany (1998)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Authors</strong></td>
<td>Schadlich PK., Brecht JG</td>
</tr>
<tr>
<td><strong>Study Perspective</strong></td>
<td>The German healthcare system</td>
</tr>
</tbody>
</table>
| **Clinical Data Sources** | Retrospective analysis of clinical data on the effects of acute alcohol dependency on the incidence of  
- alcoholic psychosis  
- alcoholic dependency syndrome  
- fatty liver  
- hepatitis and  
- cirrhosis |
| **Drug Technology** | Acamprosate was registered in Germany in 1996 and is an anti-craving neuromodulator |
| **Study Population** | Abstinent clients in 12 German psychiatric outpatient clinics |
| **Data Sources for Resource Use** | Effectiveness data from a RCT; health resources savings from retrospective German registry data; health savings per resource from insurance and administration sources and expert knowledge |
| **Outcome Measures** | Net cost savings per incremental abstinent patient from treatment avoided |
| **Method of Analysis** | Decision tree analysis using Monte Carlo simulation |
| **Discounting** | 5% discount rate |
| **Assumptions** | Key assumptions are:  
- 39.9% of acamprosate treated clients remain abstinent after 48 weeks in comparison to 17.3% of the placebo; and  
- health care savings from avoiding alcoholic psychosis, alcohol depending syndrome, fatty liver, hepatitis and liver cirrhosis |
| **Results** | Net savings in direct medical costs of DEM2600 per additional abstinent alcoholic |
| **Comments** | • The rate of abstinence under acamprosate has the greatest impact on the net savings.  
• The model assumes that the abstinence rate after 48 weeks is continued, with no further relapses. |
| Study Paper | The Long-Term Cost-Effectiveness of Improving Alcohol Abstinence with Adjuvant Acamprosate (2000) |
| Study Authors | Palmer AJ., Neeser K., Weiss C., Brandt A., Comte S., Fox M |
| Study Perspective | German health insurance perspective |
| Clinical Data Sources | Probabilities for clinical events were retrieved from published literature |
| Drug Technology | Acamprosate was registered in Germany in 1996 and is an anti-craving neuromodulator except registered in Germany 1996 |
| Study Population | A typical male cohort aged 41, 80% with fatty liver, 15% with cirrhosis, 22% with pancreatitis and 1% with alcoholic cardiomyopathy |
| Data Sources for Resource Use | - disease incidences and transitional probabilities from literature  
- disease costs from literature and an expert German health economics company |
| Outcome Measures | Incremental savings in mean total lifetime costs with acamprosate compared to standard therapy |
| Method of Analysis | Meta-analysis to inform a series of Markov sub-models |
| Discounting | 5% per annum |
| Assumptions | - key assumption is description of disease in cohort (see above)  
- acamprosate assumed to prevent relapse in 40% of the cohort in comparison to 20% for the placebo |
| Results | Mean expected total lifetime discounted savings per patient of 1662 DEM |
| Comments | All assumptions are from meta-analysis and no validation of the model and its assumptions |
Appendix 24

DISEASE COSTS

Table A24-1 SMR01 day case discharges, Scotland, Year Ending March 1998\(^1,2\)

<table>
<thead>
<tr>
<th>ICD10 Code(s)</th>
<th>Episodes</th>
<th>Patients</th>
<th>CIS(^3)</th>
<th>Average day cases per patient</th>
<th>Cost (£)</th>
<th>Average cost per patient (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C15 Oesophagus</td>
<td>800</td>
<td>488</td>
<td>768</td>
<td>1.64</td>
<td>266 119.30</td>
<td>545.33</td>
</tr>
<tr>
<td>C16 Cardiac</td>
<td>1274</td>
<td>612</td>
<td>1246</td>
<td>2.08</td>
<td>424 399.81</td>
<td>693.46</td>
</tr>
<tr>
<td>C18 Colon</td>
<td>8164</td>
<td>1057</td>
<td>8072</td>
<td>7.72</td>
<td>2 913 380.20</td>
<td>2756.27</td>
</tr>
<tr>
<td>C20 Rectum</td>
<td>1326</td>
<td>411</td>
<td>1308</td>
<td>3.23</td>
<td>467 075.99</td>
<td>1136.44</td>
</tr>
<tr>
<td>C32 Larynx</td>
<td>76</td>
<td>57</td>
<td>73</td>
<td>1.33</td>
<td>28 877.90</td>
<td>506.63</td>
</tr>
<tr>
<td>C34 Bronchus and lung</td>
<td>2640</td>
<td>1625</td>
<td>2626</td>
<td>1.62</td>
<td>802 910.79</td>
<td>494.10</td>
</tr>
<tr>
<td>C50 Breast</td>
<td>11 073</td>
<td>2156</td>
<td>10 965</td>
<td>5.14</td>
<td>3 767 410.08</td>
<td>1747.41</td>
</tr>
<tr>
<td>C61 Prostate</td>
<td>681</td>
<td>625</td>
<td>679</td>
<td>1.09</td>
<td>181 243.31</td>
<td>289.99</td>
</tr>
</tbody>
</table>

Mental Disorders

<table>
<thead>
<tr>
<th>ICD10 Code(s)</th>
<th>Episodes</th>
<th>Patients</th>
<th>CIS(^3)</th>
<th>Average day cases per patient</th>
<th>Cost (£)</th>
<th>Average cost per patient (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F10.2 ADS</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>1.00</td>
<td>930.01</td>
<td>310.00</td>
</tr>
<tr>
<td>F10.3 Withdrawal State</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>1.00</td>
<td>351.24</td>
<td>351.24</td>
</tr>
<tr>
<td>F10.4 Delirium</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>F10.5 Psychotic disorder</td>
<td>0</td>
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<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>F10.6 Amnesic syndrome</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>1.00</td>
<td>765.75</td>
<td>382.87</td>
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<tr>
<td>F10.7 Residual psychotic</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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</table>

Digestive Diseases

<table>
<thead>
<tr>
<th>ICD10 Code(s)</th>
<th>Episodes</th>
<th>Patients</th>
<th>CIS(^3)</th>
<th>Average day cases per patient</th>
<th>Cost (£)</th>
<th>Average cost per patient (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K70.1 Hepatitis</td>
<td>14</td>
<td>12</td>
<td>13</td>
<td>1.17</td>
<td>4360.70</td>
<td>363.39</td>
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<tr>
<td>K70.2 - K70.9 Cirrhosis</td>
<td>291</td>
<td>225</td>
<td>286</td>
<td>1.29</td>
<td>91 778.04</td>
<td>407.90</td>
</tr>
<tr>
<td>K80 Cholelithiasis</td>
<td>885</td>
<td>816</td>
<td>860</td>
<td>1.08</td>
<td>296 305.71</td>
<td>363.12</td>
</tr>
<tr>
<td>K86.0 Pancreatitis</td>
<td>13</td>
<td>11</td>
<td>11</td>
<td>1.18</td>
<td>4569.96</td>
<td>415.45</td>
</tr>
</tbody>
</table>

Others

<table>
<thead>
<tr>
<th>ICD10 Code(s)</th>
<th>Episodes</th>
<th>Patients</th>
<th>CIS(^3)</th>
<th>Average day cases per patient</th>
<th>Cost (£)</th>
<th>Average cost per patient (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G62.1 Polyneuropathy</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>I42.6 Cardiomyopathy</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>1.00</td>
<td>1240.02</td>
<td>310.00</td>
</tr>
<tr>
<td>G40.5 Epileptic syndrome</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
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| Total                 | 34 438   | 13 899   | 34 107    | 35.00                         | 11 176 156 | 11 756                        |

2. Principal diagnosis only.

A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between NHS Boards). CIS’s are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records,
decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.
* - any counts of less than 5 have been blanked out so as to meet patient confidentiality guidelines
## SMR01 day case discharges, Scotland, Year ending March 1999¹ ²

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<tr>
<th>ICD10 Code(s)</th>
<th>Episodes</th>
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<th>Cost (£)</th>
<th>Av cost per patient (£)</th>
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### Mental Disorders

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### Digestive Diseases

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<th>Cost (£)</th>
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### Others

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|                       | 37,171   | 15,006   | 36,659| 35  | 12,068,480 | 11,867               |

2. Principal diagnosis only.
3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS’s are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.

* - any counts of less than 5 have been removed so as to meet patient confidentiality guidelines
## SMR01 day case discharges, Scotland, Year ending March 2000

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<td>945</td>
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<td>1156</td>
<td>8250</td>
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<td>484</td>
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<td>89</td>
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<td>921</td>
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<td>F10.4 Delirium</td>
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<td>Z72.1 Alcohol use</td>
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</table>

| Total         | 9,368     | 7,807   | 41,470      | 36                      | 13,961,148 | 12,631 |

2. Principal diagnosis only.
   (whether or not this involves transfer between hospitals or even between Health Boards). CIS's are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.

* - any counts of less than 5 have been removed so as to meet patient confidentiality guidelines.
SMR01 day case discharges, Scotland, Year ending March 2001¹,²

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<th>Cost (£)</th>
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<tr>
<td>C15 Oesophagus</td>
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Mental Disorders

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Digestive Diseases

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Others

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|               | 43,178   | 16,931   | 42,730 | 34 | 14,382,479 | 11,464 |

2. Principal diagnosis only.
3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS’s are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.

* - any counts of less than 5 have been removed so as to meet patient confidentiality guidelines
## SMR01/ SMR04 inpatient discharges, Scotland, Year ending March 1998

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**Notes**

2. Principal diagnosis only.
3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS's are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.
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53,775 31,854 47,646 570,600 1,196 138,359,196 218,178

2. Principal diagnosis only.

3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS’s are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.

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## Inpatients

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<th>Cost (£)</th>
<th>Av. Cost per patient (£)</th>
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Notes

2. Principal diagnosis only.
3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS’s are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.
4. Length of stay (LOS) is measured in bed days.

* - any counts of less than 5 have been removed so as to meet patient confidentiality guidelines
<table>
<thead>
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55,039 32,234 48,911 514,649 960 129,737,405 182,726

2. Principal diagnosis only.
3. A Continuous Inpatient Stay (CIS) is defined as all the SMR records referring to the same continuous spell of inpatient treatment (whether or not this involves transfer between hospitals or even between Health Boards). CIS's are built up by examining the intervals between successive linked records for a given patient. Thus for each interval a decision is made as to whether the records constitute part of a continuous stay according to defined rules. Apart from the length of interval between two records, decisions hinge on whether the type of discharge of the first record or type of admission of the second record is a transfer.
4. Length of stay (LOS) is measured in bed days.

* - any counts of less than 5 have been removed so as to meet patient confidentiality guidelines
## Appendix 25

### SENSITIVITY ANALYSIS ON ECONOMIC MODEL

This appendix contains the full results of the pair-wise sensitivity analysis referred to in Chapter 7.

### Table A25-1 Acamprosate

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<td>Average treatment cost, average intervention effectiveness, varying disease cost</td>
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<td>Average treatment cost, average intervention effectiveness, varying disease cost</td>
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### Table A25-4 Coping Skills

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<td>Average treatment cost, average intervention effectiveness, varying disease cost</td>
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<td>Average intervention effectiveness, average disease cost, varying treatment cost</td>
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<tr>
<td>Table A25-5 Behavioural Self-Control Training</td>
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<td>High estimate (£)</td>
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<td>---------------------------------------------</td>
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<td>Average treatment cost, average disease cost, varying intervention effectiveness</td>
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<table>
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<td>Average treatment cost, average intervention effectiveness, varying disease cost</td>
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13. GLOSSARY AND ABBREVIATIONS

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<td>A&amp;E</td>
<td>Accident and Emergency</td>
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<tr>
<td>AA</td>
<td>Alcoholics Anonymous: A fellowship whose purpose is to help men and women to overcome alcohol problems.</td>
</tr>
<tr>
<td>AAT</td>
<td>Alcohol Action Team</td>
</tr>
<tr>
<td>Acamprosate</td>
<td>A drug that in combination with counselling may be helpful in maintaining abstinence in alcohol dependent patients.</td>
</tr>
<tr>
<td>Accreditation</td>
<td>A process, based on a system of external peer review using written standards, designed to ensure the quality of an individual, activity, service or organisation.</td>
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<tr>
<td>Adverse effect</td>
<td>An unpleasant and unwanted effect of a treatment or procedure.</td>
</tr>
<tr>
<td>AFS</td>
<td>Alcohol Focus Scotland</td>
</tr>
<tr>
<td>Alcohol Development Officers</td>
<td>Government-funded personnel appointed to support local Alcohol Action Teams in promoting and executing local alcohol misuse strategies.</td>
</tr>
<tr>
<td>Alcoholic dementia</td>
<td>Loss of intellectual and memory functions due to the toxic effects on the brain of chronic alcohol use.</td>
</tr>
<tr>
<td>Alcoholic hepatitis</td>
<td>Inflammation of the liver due to alcohol.</td>
</tr>
<tr>
<td>Alcohol Support Groups</td>
<td>Self help groups offering support and advice to people with alcohol problems and their families.</td>
</tr>
<tr>
<td>Antabuse</td>
<td>Manufacturers’ name for disulfiram.</td>
</tr>
<tr>
<td>Anaemia</td>
<td>A shortage of red blood cells, causing pale skin, breathlessness and tiredness.</td>
</tr>
<tr>
<td>Appraisal (critical)</td>
<td>Evaluation of evidence from scientific studies against objective criteria.</td>
</tr>
<tr>
<td>APTU</td>
<td>Alcohol Problems Treatment Unit</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>A condition in which the heart beats with an irregular or abnormal rhythm.</td>
</tr>
</tbody>
</table>
AUDIT  
Alcohol Use Disorders Identification Test

Audit  
The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.

BEF  
Belgian Francs

Behaviour Contracting  
A procedure involving the client signing a contract that he/she will attend a specified number of continuing care meetings; this is combined with active follow-up if the client fails to meet the conditions of the contract.

BENELUX  
Belgium, The Netherlands and Luxembourg

BI  
Brief Intervention

Bias  
A systematic error or deviation in results or inferences. Bias can arise from systematic differences in the groups that are compared (selection bias), the care that is provided, or exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into the study (attrition bias) or how outcomes are assessed (detection bias). Bias does not necessarily carry an imputation of prejudice, such as the investigator’s desire for particular results.

Blinding  
Concealment of intervention in a controlled trial to ensure the absence of subjective bias in evaluation of intervention effects.

BMCT  
Behavioural Marital/Couples Therapy

BNF  
British National Formulary

BSCT  
Behavioural Self-Control Training

CAD  
Cumulative Abstinence Duration/Days

Campral  
Trade name for acamprosate.

Capital costs  
The non-recurring cost of investment in items which remain useful beyond the period when costs are incurred.
Cardiomyopathy
A disease of heart muscle.

Carer
A person, paid or unpaid, who regularly helps another person, often a relative or friend with all forms of care as a result of illness or disability. This term incorporates spouses, partners, parents, guardians, paid carers, other relatives, and voluntary carers who are not health professionals.

CBT
Cognitive Behavioural Therapy

CET
Cue Exposure Therapy

Chronic
Present over a long period of time.

CI
Confidence Interval
A confidence interval is an interval likely to contain the true value of an unknown quantity (e.g. the true sensitivity of a test). For a 95% CI, if the experiment were repeated many times, 95% of the intervals would contain the value of the unknown quantity that is being estimated.

Cirrhosis
Liver disease characterised by replacement of normal liver cells by harder tissues and loss of function, which leads to yellowing skin, accumulation of fluid in the legs and abdomen, swelling of veins in the lining of the gullet and stomach, and failure of body chemistry causing disturbances such as a bleeding tendency.

Clinical effectiveness
The evaluation of the balance between benefits and risks in a standard clinical setting using outcomes of importance to the patient.

Clinical Governance
A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.


Clinical service
Health services provided to users who:
- have a particular condition or diagnosis
- present with a range of manifestations
• form a particular group e.g. older people.

**Clinical trial**
Research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease.

**CM**
Case Management

**CMR**
Continuous Morbidity Recording

**Committee on Safety of Medicines (CSM)**
An independent advisory committee established under the Medicines Act (Section 4). The CSM advises the UK Licensing Authority (Government Health Ministers) on the quality, efficacy and safety of medicines.

**Comorbidity**
The presence of coexisting or additional diseases with reference to either an initial diagnosis or the index conditions that is the subject of study. Comorbidity may affect the ability of affected individuals to function and also their survival; it may be used as a prognostic indicator for length of hospital stay, cost factors, and outcome or survival.

**Complementary therapy**
Treatments considered as complementary to traditional medicine, such as acupuncture and hypnosis.

**Contraindication**
Any factors related to the patient’s condition, medical history or other current treatments which generally or absolutely preclude the use of the treatment in question.

**Control**
Standard against which comparison is made in a clinical trial or an experiment.

**Corroborative**
Supported with evidence or authority.

**Cost effectiveness**
Cost effectiveness is used in its broadest form to encompass all forms of economic analysis.

**Cost-effectiveness analysis**
A form of economic analysis which compares two interventions in terms of both their costs and their effect upon patients, to ascertain whether the additional cost of the more expensive intervention gives rise to sufficient additional patient benefits to warrant the additional cost.
Cost-effectiveness ratio

The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions. This gives a cost per effect, such as the additional cost per true positive from a screening test, or a cost per patient outcomes, such as the cost per QALY.

Counselling

The task of counselling is to encourage the client to reach a greater level of understanding, or a greater commitment to take action. The process involves enabling clients to realise that alternatives exist, and helping them to clarify what some of those choices may be.

CPN

Community Psychiatric Nurse

CRA

Community Reinforcement Approach

CRD

Centre for Reviews and Dissemination

CS

Coping Skills

CSA

Common Services Agency

A Special Health Board in NHSScotland.

CSM

Committee on Safety of Medicines

CST

Communication Skills Training

Day facilities

Non-residential facilities. Opening hours and type of intervention may differ.

Decision tree

A diagram that sets out all possible choices, all possible consequences, the probability of these consequences and the resulting costs and benefits.

DEM/DM

Deutchmark

Detoxification

Treatment designed to free an addict from his/her clinical dependence.

Diagnosis

Identification and classification of an illness or disease by means of its signs, symptoms and the results of investigations. This involves ruling out other illnesses and causal factors for the clinical manifestations.
**Discounting**  
A means of converting the value of future events to their value in the present period. Future costs are converted using a financial discount rate similar to the interest rate, while patient benefits are converted using the reported time preference for health benefits. This reflects society’s preference for immediate benefits compared to benefits occurring in the future.

**Distribution**  
A mathematical function describing the variability of a value or set of values.

**DoH**  
Department of Health (England).

**Drinkwise**  
A campaign to promote the reappraisal of personal drinking behaviour.

**DSM**  
American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders

**Economic evaluation**  
The comparative analysis of alternative courses of action, estimating the likely effects (i.e. clinical effectiveness) and corresponding resource implications.

**Economic model**  
This simplifies the patient pathway to a level that describes the essential choices and consequences within treatment options. Linking patient outcomes to resource usage enable different courses of action to be compared from an economic viewpoint. Modelling may also be used to extrapolate from existing data into the longer term.

**Effect sizes**  
A measure of the magnitude of a treatment effect commonly used in meta-analyses.

**EMTREE**  
Embase (literature searching database) Subject Headings.

**Epidemiology**  
The scientific study of the natural history of diseases and factors associated with diseases. It may involve purely observational studies or interventions in populations.

**EU**  
European Union

**Evidence-based**  
The process of systematically finding, appraising, and using contemporary research findings as the basis for clinical decisions.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAST</td>
<td>Family Addiction Screening Tool</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GABA</td>
<td>(\beta)-aminobutyric acid</td>
</tr>
<tr>
<td>GGT</td>
<td>Gamma glutamyltransferase</td>
</tr>
<tr>
<td>Gastritis</td>
<td>Inflammation of the stomach lining.</td>
</tr>
<tr>
<td>GGHB</td>
<td>Greater Glasgow Health Board</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>Grey literature</td>
<td>Although the most likely sources of evidence for assessment are databases of the mainstream journal literature, useful evidence can be found in symposium proceedings, government monographs, industry reports, unpublished studies and other non-traditional sources.</td>
</tr>
<tr>
<td>Health education</td>
<td>Educational strategy designed to improve health knowledge and promote informed decisions conducive to health.</td>
</tr>
<tr>
<td>Health care professional</td>
<td>A person qualified in a health discipline.</td>
</tr>
<tr>
<td>HEBS</td>
<td>Health Education Board for Scotland</td>
</tr>
<tr>
<td>HEED</td>
<td>Health Economics Evaluation Database</td>
</tr>
<tr>
<td>HQ</td>
<td>Headquarters</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment is a multidisciplinary field of policy analysis which studies the medical, social, ethical and economic implications of development, diffusion and use of health technology.</td>
</tr>
<tr>
<td>HTBS</td>
<td>Health Technology Board for Scotland</td>
</tr>
<tr>
<td>Hypertension</td>
<td>High blood pressure (beyond that which is recognised as normal for an individual).</td>
</tr>
<tr>
<td>ICD</td>
<td>International Coding Dictionary</td>
</tr>
<tr>
<td><strong>ICER</strong></td>
<td>Incremental Cost Effectiveness Ratio</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td>The additional cost of the more expensive intervention divided by the difference in effect or patient outcome between the interventions. This gives a cost per effect, such as the additional cost per true positive from a screening test, or costs per patient outcomes, such as the cost per QALY.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>INAHTA</strong></th>
<th>International Network of Agencies for Health Technology Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incidence</strong></td>
<td>The number of new cases of a disease among a certain group of people during a specific period of time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Indication (therapeutic)</strong></th>
<th>The diseases or conditions for which a health technology may be suitable.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention (health)</strong></td>
<td>An item or service delivered or undertaken primarily to prevent, diagnose or treat a medical condition or to maintain or restore functional ability.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ISD</strong></th>
<th>Information and Statistics Division</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ISPOR</strong></td>
<td>International Society for Pharmacoeconomics and Outcomes Research</td>
</tr>
<tr>
<td><strong>IT</strong></td>
<td>Information Technology</td>
</tr>
<tr>
<td><strong>ITT</strong></td>
<td>Intention to treat</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Korsakoff’s syndrome</strong></th>
<th>Found in people with chronic alcohol problems, characterised by very poor short-term memory, which results in disorientation and concoction of stories to make up for the gaps in memory.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LFT</strong></td>
<td>Liver Function Test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>LHCC</strong></th>
<th>Local Health Care Cooperatives are voluntary groupings of GPs and other local health care professionals within Primary Care Trusts in Scotland, who plan and coordinate local health care.</th>
</tr>
</thead>
</table>

| **Life tables** | Tabulated mathematical models presenting, for example, the number of individuals who have experienced a certain event by a specified time. |
LSD  Lysergic acid diethylamide

Managed Clinical Networks  A formally organised network of clinicians. The main functions are to facilitate access and to audit performance on the basis of standards and guidelines, with the aim of improving health care across a wide geographic area or for specific conditions.

Markov modelling  Markov models are analytical structures that represent patient flows through key health states of a disease and are commonly used for economic evaluations. Within a Markov model, numerical values are assigned to the costs and outcomes of each health state. Over time, patients progress through the different health states based on transitional probabilities. Such models enable the synthesis of data on epidemiology, costs and outcomes of alternative clinical strategies to be compared.

MATCH  Matching Alcoholism Treatments to Client Heterogeneity

MCV  Mean Cell Volume

Median  The middle observation of a series arranged in ascending order.

Medication  Drugs prescribed to treat a condition.

MeSH  Medical Subject Headings

MET  Motivational Enhancement Therapy

Meta-analysis  Statistical method to combine the outcomes of more than one randomised clinical trial.

MI  Motivational Interviewing

Morbidity  The frequency (incidence and/or prevalence) of a particular disease or group of diseases.

Mortality rate  The number of deaths in a given population during a specified period of time.

Multidisciplinary  A multidisciplinary team is a group of people from different disciplines (both health care and non-health care) who work together to provide care for patients with a particular condition. The composition of multi-
Disciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided and geographical/socio-economic factors in the local area.

<table>
<thead>
<tr>
<th>NA</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAIP</td>
<td>National Alcohol Indicators Project</td>
</tr>
<tr>
<td>NAIR</td>
<td>National Alcohol Information Resource</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>An opioid antagonist, blocks the action of opioids and precipitates withdrawal symptoms in opioid-dependent subjects.</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
</tbody>
</table>

**NHS Boards**
The role of the NHS Boards is to ensure the efficient, effective and accountable governance of the local NHS system. There 15 NHS Boards in Scotland.

**NHS EED**
NHS Economic Evaluation Database

**NHSScotland**
National Health Service in Scotland

**NICE**
National Institute for Clinical Excellence

**NMDA**
N-methyl-D-aspartate

**NS**
Not Significant

**Odds**
The odds of a random event (E) occurring is the probability that it will occur divided by the probability that it will not occur.

**Odds ratio**
The association between a random event (E) and some condition (A), expressed as the odds that E occurs when A is true divided by the odds that E occurs when A is not true.

**Opportunity cost**
The opportunity cost of selecting a particular health technology is the amount of alternative health technologies that could have been obtained had that selection not been made.
OR  Odds Ratio

Oropharyngeal cancer  Cancer of the oropharynx, ie the part of the throat lying behind the mouth.

Outcome  The end result of care and treatment. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care and treatment. Also referred to as patient impact or patient benefit.

p.a  Per annum

Pancreatitis  Inflammation of the pancreas.

Patient  A person who is receiving medical treatment (especially in a hospital). Also, a person who is registered with a doctor, dentist, etc and is treated by him/her when necessary.

Sometimes referred to as a user.

Patient information leaflet  A document targeted at a patient audience that clearly describes key facts about a treatment or procedure. It should include diagrams, if appropriate, and clear explanations of complicated terms.

Patient pathway  The pathway taken through the health care system by the patient.

PCT  Primary Care Trust

Peripheral neuropathy  Damage due to alcohol in the nerves in the limbs causing weakness and numbness.

Pharmacological  The properties of drugs and their effects on the body.

Placebo  Dummy treatment which is given to some of the volunteers participating in a clinical trial. Patients can experience effects even when the treatment they are given is a ‘sugar pill’ or placebo.

Plan for Action  Refers to the SACAM document ‘The Plan for Action on Alcohol Problems’ (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002).

PP  Per protocol
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRAMA</td>
<td>Prevention of Relapse with Acamprosate in the Management of Alcoholism</td>
</tr>
<tr>
<td>Prevalence</td>
<td>The number of existing cases of a disease among a certain group of people, usually at a specified point in time.</td>
</tr>
<tr>
<td>Prognosis</td>
<td>An assessment of the expected future course and outcome of a person’s disease.</td>
</tr>
<tr>
<td>Prospective</td>
<td>A study in which subjects are enrolled before the intervention under test has taken place and followed at least until the intervention has occurred.</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>A therapeutic intervention that uses cognitive, behavioural and supportive interventions.</td>
</tr>
<tr>
<td>Psychotherapy</td>
<td>This term is frequently used to refer to talking treatment based upon psychodynamic or psychoanalytic principles. In practice the term is also used to refer to a wide range of psychological interventions.</td>
</tr>
<tr>
<td>p-value</td>
<td>The chance that the observed data or some data less probable would be observed under the model being investigated. Values range between zero and one and low values suggest the model is incorrect.</td>
</tr>
<tr>
<td>PYLL</td>
<td>Person Years of Life Lost</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td></td>
<td>Improving performance and preventing problems through planned and systematic activities including documentation, training and review.</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Year</td>
</tr>
<tr>
<td></td>
<td>A means of adjusting the benefits accruing to patients that takes into account the quality of life of each year.</td>
</tr>
<tr>
<td>QUADS</td>
<td>Quality in Alcohol and Drugs Services</td>
</tr>
<tr>
<td>r</td>
<td>Pearson’s r</td>
</tr>
<tr>
<td></td>
<td>An estimate of the association between two variables.</td>
</tr>
<tr>
<td>Randomised</td>
<td>Randomly allocated to one or more than one different choice of health intervention. Randomisation is used to</td>
</tr>
</tbody>
</table>
ensure that bias is minimised in clinical trials.

RCT
Randomised controlled trial

Referral
The process whereby a patient is referred from one professional to another, usually for specialist advice or treatment.

Risk factor
A clearly defined occurrence or characteristic that increases the possibility that a person will develop a disease or die from a disease he or she already has.

RP
Relapse Prevention

RR
Risk ratio

RSI
Rough Sleepers Initiative

SACAM
Scottish Advisory Committee on Alcohol Misuse

SBU
Swedish Council on Technology Assessment in Health Care

Scottish Executive
The Scottish Executive is the devolved government for Scotland. It is responsible for most of the issues of day-to-day concern to the people of Scotland, including health, education, justice, rural affairs and transport.

SD
Standard deviation

SE
Standard error

SEHD
Scottish Executive Health Department

Sensitivity
The probability that a test result is positive given the subject has the disease.

Sensitivity analysis
An exploration of the impact upon results of changing parameter values within a model.

SF-36
Short Form 36 Health Questionnaire

Shared care
Care of a service user shared between primary and secondary care services

Side effect
A side effect is an unpleasant and unwanted effect of treatment.
Single Shared Assessment

Uses a lead professional, with appropriate specialist inputs, to assess a service user only once. That information is used by different agencies, subject to protocols for sharing information and protecting confidentiality, to provide a faster gateway to services.

Sobriety

A state of being alcohol free (Awaiting confirmation from AA)

SIGN

Scottish Intercollegiate Guideline Network

SPC

Summary of Product Characteristics

SPS

Scottish Prison Service

SSRI

Selective Serotonin Reuptake Inhibitor

STRADA

Scottish Training on Drugs and Alcohol

Supportive-Expressive Psychotherapy

Is a time limited, focused psychotherapy. (This approach has been adapted for heroin and cocaine use.)

The therapy has two main components:

- Supportive techniques to help patients feel comfortable in discussing their personal experiences.

- Expressive techniques to help patients feel comfortable in discussing their personal experiences.

Special Attention is paid to the role of drugs in relation to problem feelings and behaviours and how problems may be solved without recourse to drugs.

Tachycardia

An abnormally rapid heart rate.

Task Centred Counselling

A method of cognitive behavioural therapy.

Trust

There are two types of trust in Scotland: Acute Hospital Trusts and Primary Care Trusts. Acute Hospital Trusts are responsible for a defined set of acute hospital services. Primary Care Trusts have the responsibility for the provision of the full range of primary care, community and mental health services. Both types of trust operate within the geographical boundaries of an
<table>
<thead>
<tr>
<th><strong>Individual NHS Board.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TSF</strong> Twelve-Step Facilitation</td>
</tr>
<tr>
<td>Please see definition of Twelve-Step Model.</td>
</tr>
<tr>
<td><strong>TSG</strong> Topic Specific Group.</td>
</tr>
<tr>
<td><strong>12-step approach</strong> A progression of states intended to achieve a goal of complete sobriety. It is a treatment programme most closely associated with Alcoholics Anonymous but also used in some specialist treatment centres for alcohol dependence. It is based on the model of alcohol dependence as an illness.</td>
</tr>
<tr>
<td><strong>UK</strong> United Kingdom</td>
</tr>
<tr>
<td><strong>USA</strong> United States of America</td>
</tr>
<tr>
<td><strong>Utility</strong> The desirability of a given state of health expressed as a fraction of the desirability of perfect health, derived from the individual’s preference under conditions of uncertainty.</td>
</tr>
<tr>
<td><strong>Vocational Training</strong> Focuses on developing skills to enhance employment prospects, often through re-training, further education or government employment initiatives.</td>
</tr>
<tr>
<td><strong>Wernicke syndrome</strong> A syndrome found in people with chronic alcohol problems due to a thiamine deficiency and characterised by disturbances in eye movements and control, unsteadiness and disorientation; and may co-exist with Korsakoff’s syndrome.</td>
</tr>
<tr>
<td><strong>WHO</strong> World Health Organisation</td>
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</table>