Human Immunodeficiency Virus (HIV)

Standards Development
Scoping Report

December 2009
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1 Introduction to NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) is a Special Health Board that advises, supports and assesses NHS boards to help improve the quality of healthcare.

Our vision
An NHS which achieves excellence in the care of every patient, every time.

Our Objectives
Our four corporate objectives are reflected in our work programme, they are:

- **improving quality** – To lead advances in the quality of care in NHSScotland based on a continually refreshed framework for quality improvement
- **making an impact** – To make a demonstrable impact on the quality and safety of patient care and treatment
- **sharing the knowledge** – To contribute to the advancement of knowledge and understanding on quality improvement, and
- **working effectively** – To ensure NHS QIS delivers its functions effectively and efficiently.

What we do
NHS QIS supports NHS boards and their staff to improve the quality of healthcare by:

- providing advice and guidance on effective clinical practice, including setting standards
- driving and supporting implementation of improvements in quality, and
- assessing the performance of the NHS, reporting and publishing our findings.

Within this remit we have central responsibility to support NHS boards to deliver patient safety and clinical governance across NHSScotland.

This is a key strategic priority in the Scottish Government's Better Health, Better Care: Action Plan and NHSScotland’s Quality Strategy

Our values
We aim to be an organisation that is:

- engaged - strongly engaged with NHSScotland, other agencies and with patients, carers and the general public
- efficient - using processes that are fit for purpose, targeted on areas where we can have the greatest impact and as streamlined as they can be without loss of rigour
• enterprising - forward thinking, using innovation to take advantage of new opportunities to promote quality and safety and placing ourselves in the forefront of quality improvement in the UK and internationally

• communicating - maintaining effective two-way communication with all our stakeholders and with other organisations that share and can contribute to achievement of our aims

• coherent - consistent in the approaches we adopt to our work and in the advice and guidance that we provide, and

• conceptual and self-critical - clear about how our activities fit together and about why we are tackling them in the ways that we do, learning and applying the lessons of our own and others’ experience.
2 The HIV Project

2.1 Background to HIV

HIV stands for Human Immunodeficiency Virus and is a virus carried in the blood and other body fluids which damages the body’s immune system leaving it susceptible to illness and infection.

HIV continues to be one of the most important communicable diseases in the UK. It is an infection associated with serious morbidity, high costs of treatment and care, significant mortality and high number of potential years of life lost. Each year, many thousands of individuals are diagnosed with HIV for the first time. The infection is still frequently regarded as stigmatising and has a prolonged ‘silent’ period during which it often remains undiagnosed. There is no cure for HIV but there are drugs that can slow the progress of the condition. If untreated, HIV can progress to an advanced stage known as AIDS (Acquired Immunodeficiency Syndrome).

The number of people living with HIV in Scotland has increased nearly threefold in the last decade, due to a combined increase in new diagnoses and a reduction in the mortality rate from HIV/AIDS consequent on effective therapy now being available\(^1\).\(^2\) The balance of transmission routes in Scotland has changed over the years but there are still groups of people who are at greater risk of HIV infection than others.

The 2001 United Nations General Assembly Special Session (UNGASS) on HIV/AIDS declared that ‘prevention must be the mainstay of our response\(^3\). An important report on HIV prevention in Scotland\(^4\) was published in the same year, but success in this area has been mixed so far. The development of an effective HIV prevention plan for Scotland is central to the recently released HIV Action Plan for Scotland\(^5\).

An important concern for both HIV prevention and HIV treatment and care relates to the ongoing high levels of undiagnosed HIV infection\(^6\). Undiagnosed infection undermines attempts at HIV prevention and is also associated with potentially life-threatening presentations with advanced HIV/AIDS. However, for diagnosed patients, access to HIV treatment in Scotland is generally good, albeit with significant variations in models of care\(^7\) - and probably in the quality of care provided.
2.2 Development of standards for HIV

Building on our previous work on long-term common conditions and, in response to matters raised by patient groups, the Scottish Government and the Audit Scotland Managing Long-term Conditions Report, NHS QIS agreed to undertake development of clinical standards for HIV.

In August 2009, Dr Nick Kennedy, an Infectious Diseases Consultant at Monklands General Hospital in NHS Lanarkshire joined the NHS QIS standards development team as clinical adviser to support this work.

As part of the NHS QIS standard setting process, a scoping exercise was undertaken between August and December 2009. The purpose of this was to define, in detail, the scope of the project specific to the content of the standards, i.e. what could be included and excluded from the HIV standards and how the project will be delivered and managed.

This report is the summary of the scoping process and findings. It has been produced primarily for internal use by NHS QIS and its HIV project group to inform the development of relevant standards and associated project management processes. The report will be fully considered by the project group at its first meeting, where it will comment on the validity of the report’s content, in particular the conclusions drawn and reach a consensus decision on how to use this work in the development of clinical standards for HIV.
3 Scoping process

All standards developed by NHS QIS are evidence-based, with the recognition that levels and types of evidence vary and include evidence relating to patients’ experiences. The collection and processing of evidence during the scoping exercise involved:

- obtaining opinion from patients, healthcare professionals and others on the key issues to be addressed
- identifying areas of importance from HIV literature, and
- assessing the evidence to support our work.

This process aims to ensure the final standards are evidence based, relevant and address existing quality gaps and service issues both locally and nationally in Scotland.

3.1 Professional, patient and/or public opinion

The scoping meeting held in Glasgow on 17 November 2009 was the principal opportunity to obtain opinion from professionals. The delegate list for this meeting is provided in Appendix 3.

Work has also commenced to establish an advocacy group to work alongside the main HIV project group. The scoping meeting for the advocacy group was held on 8 December 2009. The delegate list is provided in Appendix 4.

In addition, specific meetings and/or telephone consultations were held with:

- Sam Allan, Infectious Diseases (ID) Consultant, Ayrshire and Arran
- Martha Baillie, Waverley Care
- Glenn Codere, Health Protection Scotland
- Rosie Hague, Consultant Paediatrician, NHS Greater Glasgow and Clyde (NHS GGC)
- Alan Henderson, Consultant Physician, NHS Highland
- Cathy Johnman, Lecturer in Public Health, University of Glasgow
- Gwyneth Jones, ID Consultant, NHS Dumfries & Galloway
- Roy Kilpatrick, Chief Executive, HIV Scotland
- Alisdair MacConnachie, ID Consultant, NHS GGC
- Rak Nandwani, (GUM) Consultant, NHS GGC
- Felicity Naughton, HIV Programme Manager, Scottish Government,
- Andy Winter, GUM consultant, NHS GGC
3.2 Documented evidence
A huge literature has developed worldwide since the first description of AIDS cases in San Francisco in 1981. A PubMed search of the term ‘HIV’ yields over 200,000 articles along with many thousands of systematic reviews. There are also numerous guidelines, both national and international, along with a wealth or published abstracts from international meetings.

For the purposes of this scoping report only high-level evidence in the form of published systematic reviews and meta-analyses, outputs from international cohort studies, published guidelines, existing standards and material from national and international HIV/AIDS institutions was initially examined. Concentrated searches were also carried out based on the areas of HIV prevention, testing/diagnosis and treatment. A number of important additional papers were then identified from the reference lists in these review papers, along with a limited search of very recent publications and any evidence of particular relevance that was identified by participants at the scoping meeting. Whilst a wide range of material was reviewed, only important documents which are likely to be of relevance to the HIV standards development process have been included in this report (see Section 6: References)
4 Results of the scoping exercise

4.1 National and international strategy documents and guidelines


The British HIV Association (BHIVA) has produced a number of evidence–based guidelines that will be important for the NHS QIS project group to consider. BHIVA guidelines exist for HIV testing and a number of HIV treatment and care issues,\(^3-14\) but there are no specific BHIVA guidelines on HIV prevention. A number of other UK and Scottish organisations have produced guidelines and/or information of relevance to various aspects of HIV care, including:

- the British Association for Sexual Health and HIV (BASSH)\(^10,13,15\)
- National AIDS Trust (NAT)\(^16\)
- Terrence Higgins Trust (THT)\(^17,18\)
- Medical Foundation for AIDS & Sexual Health (MedFASH)\(^19,20\)
- NICE\(^21,22\)
- The Expert Advisory Group on AIDS (EAGA)\(^23-25\)
- The National African HIV Prevention Programme (NAHIP)\(^26,27\)
- Health Scotland\(^28,29\)
- HIV Scotland\(^30\)
- Waverley Care
- Health Protection Scotland (HPS)\(^1,2\), and
- the Health Protection Agency (HPA)\(^6,31,32\).

Both BHIVA\(^33\) and MedFASH\(^19\) have produced standards relating to HIV care. However, their relevance to the Scottish context is often limited - particularly in relation to aspects of service organisation and delivery (with a strong focus on, for example, commissioning).

Internationally, the World Health Organisation (WHO)\(^34-36\) and the joint United Nations programme on HIV/AIDS (UNAIDS)\(^37-40\) have produced a number of documents of both strategic and practical relevance – particularly for HIV
prevention standards development, where we currently lack definitive United Kingdom (UK)/Scottish guidance. The publications of the European AIDS Clinical Society (EACS),41-43 the Centers for Disease Control and Prevention (CDC) in the United States (US)44-46 and other US resources such as the AIDSInfo guidelines (available at http://aidsinfo.nih.gov) are also of relevance.

4.2 The epidemiology of HIV - who is at risk?

As many patients living with HIV in the UK have acquired their infection abroad, or through sexual contact with someone from a HIV country of prevalence, an understanding of both the international epidemiology of HIV as well as the Scottish/UK situation is required for HIV prevention and testing strategies.

4.2.1 International situation

HIV (predominantly HIV-1) has now spread to all parts of the world. In 2008, some 33.4 million people were estimated to be living with HIV/AIDS worldwide, with 2.7 million new infections in 2008 and 2 million deaths.40 Although a global pandemic, patterns of spread of HIV vary widely in different regions of the world. The WHO and UNAIDS define several different types of HIV epidemics35,39:

- low-level epidemics – HIV has never spread at substantial levels in any sub-population.
- concentrated epidemics – HIV has spread rapidly in a defined sub-population(s), but is not well established in the general population. HIV prevalence is >5% in at least one sub-population but <1% in pregnant women.
- generalised epidemics – HIV is firmly established in the general population.

In areas with generalised epidemics and the highest infection rates, such as Sub-Saharan Africa (which accounts for 67% of HIV infections worldwide), HIV is spread predominantly through unprotected heterosexual intercourse40.

For concentrated epidemics, the ‘most-at-risk’ populations for HIV, based on a concentration for risk behaviours that lend themselves to efficient HIV transmission, are typically37:

- female sex workers (FSWs)
- clients of FSWs
- injecting drug users (IDUs), and
- men who have sex with men (MSM).

In many parts of the world, including Eastern Europe and Central Asia, HIV infection among injecting drug users (IDUs) remains a huge problem.40,47 HIV sero-prevalence levels may be as high as 35-60% in IDUs in parts of the Ukraine40,47. Furthermore, in Eastern Europe and Central Asia, epidemics that were once
characterised primarily by transmission among IDUs are now increasingly characterised by significant sexual transmission, with transmission amongst heterosexual couples also on the increase in parts of Asia \(^{40}\).

### 4.2.2 The United Kingdom

An estimated 83,000 people were living with HIV in the UK in 2008, of whom one quarter (27\%) were unaware of infection. The HIV prevalence has been rising steadily over the last decade, although the number of new cases has fallen slightly over the last three years from a peak of around 8000 per year in 2005 to 7300 in 2008\(^{6}\).

The HIV epidemic in the UK would be described as a concentrated scenario using the UNAIDS/WHO terminology, with MSM (where seroprevalence levels may exceed 5\%) and Africans at particular risk \(^{40}\). However, the steady rise in new diagnoses among those who have acquired their infection heterosexually within the UK (from 740 in 2004 to 1130 in 2008) should be noted\(^{6}\).

### 4.2.3 Scotland

Figure 1 shows the current epidemiology of HIV in Scotland, indicating the relevant risk groups for transmission\(^1\).

**Figure 1. HIV diagnoses in Scotland by transmission category, 1999-2008.**
*(from Scotland’s Sexual Health Information 2009\(^1\), with permission)*
At the start of the Scottish HIV epidemic in the 1980s, IDUs were a major risk group for HIV. The provision of safe injecting equipment and opiate substitute prescribing has helped to prevent the spread of HIV in IDUs in Scotland, with only a small number of attributable cases on an annual basis\textsuperscript{1, 2}. By international standards, Scotland has done remarkably well in terms of containing HIV infection within the FSW and IDU populations.

Men who have sex with men (MSM) have constituted a major risk group since the start of the HIV epidemic, and this continues to be the case with significant levels of ongoing transmission in the MSM community\textsuperscript{1, 2}. Levels of high-risk sex such as unprotected anal intercourse (UAI) are high\textsuperscript{49-51} and the proportion of MSM reporting UAI with a casual partner increased from 11\% in 1996 to 19\% in 2002, remaining at this level in 2005\textsuperscript{50, 51}. Although knowledge of HIV status may lead to a reduction in HIV risk-taking, studies in HIV positive (+ve) MSM in the UK, and internationally, show roughly 40\% of HIV+ve men continue to engage in UAI, representing a risk for continued HIV transmission\textsuperscript{52, 53}. Drug use may be a factor leading to high-risk sexual behaviours in some cases\textsuperscript{54}.

Over the last few years, heterosexual transmission has been the largest single risk category in Scotland. However, the majority of heterosexually acquired HIV in Scotland at present relates to individuals who have either migrated from an area of high prevalence or who likely have had sexual contact with someone from such an area (often Africa)\textsuperscript{1, 2}.

### 4.3 HIV prevention

HIV recognition and diagnosis has a very important role to play in HIV prevention, but there are also many other facets to HIV prevention. A vast literature relating to HIV prevention activities exists, including many reviews, systematic reviews and meta-analyses. The Cochrane Review Group on HIV and AIDS is a useful resource. Reviews that synthesise the findings from systematic reviews are also available, such as Setswe’s useful overview\textsuperscript{55}. The recent Lancet series on HIV prevention also provides a good overview of the existing literature\textsuperscript{56-62}.

The evidence base for HIV prevention remains quite controversial – particularly as several studies have produced contradictory findings. Many/most interventions also involve aspects of sexual behaviour (e.g. condom education and provision) which can also be controversial, although sexual risk reduction interventions do not appear to increase the overall frequency of sexual activity\textsuperscript{63}. From a Scottish perspective, the fact that much of the published literature relates to American settings or a developing country situation can limit the relevance of published studies. High quality evidence relating directly to the evaluation of HIV prevention activities in Scotland is fairly scant.

Although a recent study did, for the first time, demonstrate that a trial vaccine had some limited protective efficacy\textsuperscript{64}, it is nevertheless clear that a licensed vaccine
for HIV prevention is still many years away. HIV prevention will therefore need to be based on more conventional approaches for the foreseeable future.

4.3.1 HIV prevention policy framework

**UNAIDS and WHO policy**

In 2005 UNAIDS published clear guidance on the essential principles, policy actions and programmatic actions that should underpin HIV all prevention strategies. This policy position was supported in 2007 by the publication of UNAIDS practical guidelines for intensifying HIV prevention, and more recently by WHO guidance. Whilst generic, the UNAIDS and WHO guidelines do have relevance in many areas to the UK/Scottish situation, focusing on ‘most-at-risk populations’ as well as the general population, and should be considered by the NHS QIS project group.

Globally, there is growing evidence of HIV prevention successes in diverse settings. The estimated annual number of new HIV infections worldwide has declined and HIV prevalence among young people has fallen in many countries in recent years.

**United States**

In the US, the Centre for Disease Control and Prevention (CDC) has put a lot of resource into HIV prevention in recent years and has developed a comprehensive list of CDC-evaluated and approved evidence-based interventions. An 89% decline in HIV transmission since the mid-1980s is claimed through the use of effective prevention strategies. However, the relevance of the CDC-approved list to the UK/Scotland is often debatable (in relation to generalisability issues).

**UK and Scotland**

The UNAIDS and WHO approach of ‘know your epidemic, know your response’ implies that for Scotland there is a need for focused HIV prevention work with MSM and black African heterosexuals, in particular. This requirement is reflected in the HIV Action Plan for Scotland. However, as epidemics mature, the extent of heterosexual HIV transmission often increases, so prevention efforts aimed at preventing a concentrated epidemic from becoming a generalised epidemic in the UK are also warranted.

The need to develop new Scottish HIV prevention guidance for MSM and persons originating from countries of high prevalence (particularly Africa), tailored to our local/national circumstances, is described in the HIV Action Plan (Actions 9 and 10). NHS Health Scotland will lead on this piece of work, with the first phase complete by December 2010. In England currently, NICE are also preparing evidence-based prevention guidance.
4.3.2 Classification and description of HIV prevention approaches

Various classifications are in use, which can be confusing. A simple classification commonly used is to separate HIV prevention interventions broadly into three categories\(^57,58,61\):

- biomedical interventions
- behavioural interventions, and
- structural approaches.

Behavioural interventions can take place at multiple levels including individual, couple, family, peer group/network, institution (e.g. school, workplace, prisons) or community levels\(^57\). Behavioural approaches also use a variety of theoretical and methodological approaches, ranging from intensive one-to-one education, skills building and cognitive behavioural therapy to mass media campaigns and social marketing. Some authors, therefore, separate out psychological and social approaches from other behavioural interventions\(^55,67\).

Structural approaches seek to change the root causes that influence an individual’s vulnerability to HIV – e.g. social, economic and environmental factors\(^58\). These issues are clearly of great importance, but are out with the scope of the work of NHS QIS.

4.3.3 An overview of HIV prevention interventions and the underlying evidence

**Overview of interventions and the evidence base**

I have attempted to provide an overview of some of the more important examples of biomedical and behavioural prevention interventions, with a brief commentary and references to the supporting evidence, in Appendix 1. Professor Flowers also provided an excellent overview of prevention interventions as part of the NHS QIS scoping meeting in Glasgow on 17 November 2009\(^67\).

**Is there a ‘best’ approach to HIV prevention?**

The ‘best’ approach to HIV prevention is not known – and will probably vary depending on local epidemiology. One study found that the most effective interventions were those that contained attitudinal arguments, educational information, behavioural skills arguments, and behavioural skills training, whereas the least effective ones were those that attempted to induce fear of HIV\(^68\). More generally, a combined approach exploiting synergies between a mix of interventions is considered desirable\(^56,62\).
**HIV prevention in Scotland**

There are a number of examples of good practice in Scotland. The success of the Scottish approach to tackling potential HIV infection in FSW and IDUs has already been described. Reference to the previous work undertaken in Scotland by the MSM NSHAC sub-group\(^{51}\) will be useful for NHS QIS standards development. Good, targeted work has been done in several areas with African communities and MSM, such as the social marketing campaigns targeting MSM in Lothian and Glasgow\(^{69,70}\) - and more recently Lanarkshire and Ayrshire. HIV Scotland has also recently co-ordinated an excellent HIV prevention Needs Assessment in NHS Forth Valley\(^{30}\).

4.3.4 Monitoring and Evaluating HIV Prevention Activities

The geographic coverage of targeted HIV prevention activities should be assessed, so as to ensure that programmes are being delivered to the populations in need of services. It is recommended this be re-assessed on, at least, an annual basis. Data on clients reached by the prevention services should be collected at the time of routine monitoring\(^{37}\). Outcome evaluation, although challenging, should also be undertaken. UNGASS indicators relevant to HIV prevention in ‘most-at-risk’ populations (as well as the general population) have been developed\(^{37,71}\). Whilst not comprehensive, and probably of greatest direct relevance to the overall Scottish HIV Action Plan rather than to NHS QIS standards, these indicators should be taken into consideration during NHS QIS standards development.

4.3.5 Output from scoping meeting on 17 November 2009: Key issues, suggestions and comments relating to HIV prevention standards.

**Top 3**
- Condom availability
- Behavioural Interventions with at risk people, and
- Start with the known HIV patients; make sure sexual histories taken etc. Also, ensure access to behavioural interventions.

**Other**
- Treatment is important aspect of prevention
- Ensure there is access to full range of behavioural and psychological services eg. cognitive behavioural therapy, motivational work, other intense support services. Need to be dedicated/ HIV aware.
- Recognition of at risk groups
- Awareness of other national work i.e. evaluation
- Promotion and distribution/availability of condoms (measurable) – aim for 100%. Free condoms/lube
- HIV information
• Appropriately trained staff working in prevention of HIV
• Standardised information/ recommendations across regions based on national standards
• Ensure availability of HIV testing
• Protocols required
• Health board needs assessment for local population
• Staff training for HIV awareness
• Access to specialist health advisor
• Partnership working with voluntary sector, local authorities, social etc
• Difficult to develop standard that is implementable re social/culture aspects
• Risk Assessment and normalizing (for testing)
• Expand testing
• Needle exchanges
• Needs assessment driver to commissioning prevention service across regions - depending on prevalence.
• Post exposure prophylaxis for HIV following sexual exposure (PEPSE) packs and education is of key importance. PEPSE must be available.
• Education on risks of HIV for known HIV positive patients.
• Behavioural interventions after (negative) testing - but don’t make testing more difficult
• Work with sero-discordant couples
• Look at the alcohol brief intervention- can there be something similar to this?
• Widespread testing works in early prevention, maybe a standard about 90% testing and 6 monthly regular testing
  o Targets: MSM, heterosexuals, African communities.
  o Could there be a standard around context specific targeting.
• Information, training and workforce development to be built in to services.
• 100% testing in GUM settings, and
• Health boards to demonstrate use of evidence based promotion in their work.

4.3.6 Other important scoping considerations on HIV prevention
• A variety of biomedical and behavioural interventions are in scope, whilst structural interventions are out of scope for the purposes of the Standards.
• Education and behaviour change is not the same thing – important for MSM prevention interventions in particular.
• Although biomedical interventions will need to be strongly represented in standards, behavioural interventions must not be overlooked
• Standards on HIV prevention will need to be very carefully chosen, based on the strength of evidence for the (potential) impact of an intervention, the ability
of NHS boards to actually deliver the intervention and whether or not the impact of the intervention can be measured.

- The previous work undertaken in Scotland by the MSM NSHAC sub-group will be useful for NHS QIS standards development.
- It will be important for the NHS QIS project group to stay close to the formal evidence reviews being undertaken by NHS Health Scotland and NICE and any emerging new guidance.

4.4 Recognition and diagnosis of HIV infection

Early recognition and diagnosis is a critical issue for both HIV prevention and HIV treatment and care, with a failure to diagnose HIV at an early stage potentially leading to both increased HIV transmission in the community as well as to late clinical presentations with advanced HIV/AIDS.

4.4.1 Types of HIV test

HIV testing will usually consist of a test performed in the laboratory (serology) on a blood sample obtained by venepuncture. However, rapid point of care tests (POCT) which use either a finger prick blood sample or an oral mouth swab are available.

**Laboratory serological testing**

The BHIVA guidelines on HIV testing recommend using a fourth generation assay, which tests for both HIV antibody and p24 antigen simultaneously, as the first-line laboratory test. The HPA has produced a standard algorithm for confirmatory testing.

**Point of care tests**

Point of care tests can be useful in situations where obtaining a blood sample by venepuncture is not possible, or where a rapid result is desirable, but suffer from reduced sensitivity and specificity. Positive POCT test results must be confirmed by serological tests. The use of POCT is recommended in specific contexts only, including:

- clinical settings where a rapid turnaround of results is desirable
- community testing sites
- urgent source testing in cases of exposure incidents
- circumstances in which venepuncture is refused.
4.4.2 Strategies for HIV testing

Traditional approaches to HIV testing

During the 1980s and much of the 1990s, the emphasis in HIV testing guidelines in the UK and other Western countries was on the need for extensive pre- and post-test counselling and the requirement for extremely high levels of patient confidentiality - typically including anonymous rather than named patient testing. However, this approach of ‘HIV exceptionalism’ was increasingly questioned,

as it became apparent it was an important deterrent to the widespread uptake of HIV testing. This gained increasing importance when effective HIV therapy became available in the mid ‘90s.

Professor Kevin De Cock, an Infectious Diseases specialist who is the current director of the WHO Department of HIV/AIDS and a former Director of the CDC Division of HIV/AIDS Prevention and Epidemiology, co-authored an important paper published in the British Medical Journal in 1998. In this paper the need for the ‘normalisation’ of HIV/AIDS was strongly argued. The imperative of seeking an early HIV diagnosis (whilst respecting the requirements for informed consent and clinical confidentiality) by promoting HIV testing in a variety of settings was emphasised, so that appropriate therapeutic and preventive measures could be introduced. This should include universal offering of HIV testing in some situations, such as pregnancy. These arguments have now been generally accepted worldwide, and are endorsed by the current UK guidelines.

Risk-factor based HIV testing strategies

Another ‘traditional’ aspect of HIV testing has been a heavy emphasis on the identification of underlying HIV risk factors, with HIV testing being recommended in a targeted manner only to those who have certain identified risks. A risk factor may relate to an individual's lifestyle (e.g. MSM or history of injecting drug use) or to the clinical setting where a patient has presented (e.g. GUM clinic). The current BHIVA guidelines recommend that HIV testing should be offered routinely to the following risk groups (see full guideline for detailed recommendations).

1) Specific settings
   a. GUM or sexual health clinics
   b. antenatal services
   c. termination of pregnancy services
   d. drug dependency programmes
   e. healthcare services to those diagnosed with tuberculosis, hepatitis B, hepatitis C and lymphoma

2) Identified HIV risk factors in the history
   a. MSM
   b. history of injecting drug use
c. female sexual contacts of MSM
d. sexual partners of men and women who are HIV-positive
e. patients diagnosed with a sexually transmitted infection (STI)
f. men and women from a country of high HIV prevalence (>1%)
g. men and women who report sexual contact abroad or in the UK with individuals from countries of high HIV prevalence.

Guidelines from the US and WHO also tend to emphasise female sex workers (FSWs) and their clients and partners\textsuperscript{39,75}.

If applied consistently, a risk-factor based approach could potentially identify most, but not all, HIV-infected individuals\textsuperscript{75, 76}, particularly if clinical presentation-based HIV testing is also incorporated.

**Clinical presentation-based HIV testing strategies**

Studies in the US have shown that some 10 to 25% of HIV-positive individuals have no particular reported HIV risk factors\textsuperscript{75, 76}. Thus relying entirely on reported risk factors would miss a substantial proportion of HIV-positive individuals.

Patients with HIV infection may present to various settings in the health service (i.e. not just GUM or other ‘high risk’ settings) with clinical indicator diseases that point to potential underlying HIV infection. These include symptoms and signs that may occur soon after the time of infection (primary HIV infection or ‘seroconversion’ symptoms, CDC Category A), symptoms consistent with symptomatic HIV infection (CDC Category B conditions) as well as AIDS defining conditions (CDC category C conditions). In addition to risk-factor based testing, BHIVA therefore also recommends HIV testing for patients presenting with a condition where HIV enters the differential diagnosis – irrespective of identified ‘risk’ in the history – and provides a detailed list of such conditions\textsuperscript{10}.

Clinical recognition of possible HIV infection is thus vital. In Scotland, the Chief Medical Officer (CMO) and Chief Nursing Officer (CNO) wrote to all doctors and nurses in Scotland in 2007, requesting:

‘Please be alert to the circumstances in which it is appropriate to offer and recommend an HIV test. This is especially important when the patient may have an unacknowledged but identifiable risk, or have symptoms or signs of HIV infection. As well as non-specific symptoms such as malaise and weight loss, patients with HIV may present across a range of clinical areas, such as:

- thoracic medicine (for example, tuberculosis, pneumonia)
- gastroenterology (for example, oral candidiasis, severe gastroenteritis)
- oncology (for example, lymphoma)
- dermatology (for example, shingles, severe fungal dermatoses)
• haematology (for example, Idiopathic Thrombocytopenic Purpura)
• emergency medicine (for example, coma, meningitis)

Unfortunately, a recent survey of Scottish GPs found that awareness of the letter was poor and overall the CMO/CNO letter appeared to have had little impact on HIV testing amongst the GPs surveyed.

The identification of primary HIV infection deserves specific mention. US studies show that although many patients with symptomatic primary HIV infection seek care they are often not offered HIV testing owing to the non-specific nature of their symptoms. As primary HIV infection is associated with high viral load levels and may, therefore, be associated with a high risk of onward transmission, increased efforts to improve early HIV detection are required.

Universal HIV testing strategies

A risk factor based approach to HIV testing, even with the inclusion of a clinical presentation-based approach as well, will always suffer from significant limitations. In addition to the 10 to 25% of HIV-infected individuals who do not appear to have obvious risk factors, patients are frequently not offered a test even where HIV risk factors are identified. A retrospective case-note study in the Veterans Affairs (VA) healthcare systems in the US study found that one-half to two-thirds of patients who had documented risks for HIV had not been tested. In London, research found that HIV+ve Africans often had contact with both primary and secondary care in the year prior to their eventual diagnosis - often with advanced disease - representing missed opportunities for testing.

An alternative approach is to aim for universal (opt-out) HIV testing, where all individuals/patients attending a specified setting are offered a test, but an individual still has the option to refuse a test. This approach has been highly successful in the context of antenatal HIV testing and testing in GUM/sexual health settings in recent years. In the US, the revised (2006) CDC guidelines recommended universal HIV testing in all health-care settings for patients aged 13 to 64, unless the prevalence of undiagnosed HIV infection in the population has been documented to be < 0.1%. Routine screening was also recently endorsed by the American College of Physicians and HIV Medicine Association.

In the UK, the 2008 BHIVA guidelines recommend that universal testing for all men and women registering in general practice and all general medical admissions should be ‘considered’ where the diagnosed HIV prevalence in the local population exceeds 0.2%

Several cost effectiveness analyses have been undertaken, which demonstrate that universal testing is cost-effective if the population prevalence exceeds 0.05%
- 0.2% (study results depend on whether or not the benefit from transmission reduction as well as clinical benefits are included)\textsuperscript{76}.

### 4.4.3 Testing in Scotland

Some 60,000 HIV tests on approximately 50,000 people are performed per year in Scotland (excluding ‘routine’ testing in areas such as blood transfusion, renal unit and antenatal clinics), with about 1% of the test results being positive (Glenn Codere, personal communication). At present, no ‘universal’ testing is being done other than in pregnant women and the other situations described above. In parts of Edinburgh, the population prevalence of HIV is sufficiently high that, arguably, a pilot of universal testing could be justified. Detail of HIV testing in Scotland, with a regional breakdown, can be found in quarterly updates in the HPS weekly report and the Annual STIEAG reports.\textsuperscript{1,2}

### 4.4.4 Output from scoping meeting on 17 November 2009:

**Key issues, suggestions and comments relating to HIV recognition and diagnosis standards.**

**Top 3**

- Training health care professionals to recognise and test
- Geographical range of testing settings (primary care, secondary care etc)
- % of MSM who have had a test in the last year: it is up to NHS boards to decide how to measure this.

**Other**

- Normalising testing (existing guidelines)
- Identification of undiagnosed
- Specific conditions that dictate testing - easily measurable and could use hospital coding
- Educating of clinicians (non specialist) re acute HIV infection (A&E, GP) measurable?
- Reduction in undiagnosed HIV
- Partner notification essential to be done
- Child testing re partners & parents of HIV (referral road)
- Time to notify results to referring clinics – measurable
- Test results availability (electronically) to clinic staff
- Up-to-date real-time data
- Point-of-care testing
- Core staff education
- Number of tests when key indicators are presented
- Education and training of those delivering tests and general awareness within service as a whole
• Testing kits properly quality controlled
• Standardisation of how people receive results
• New diagnosis should be followed up with 2\textsuperscript{nd} test
• Anyone with positive result receives referral/offer to HIV specialist
• Repeat testing within high risk group/6months
• Where evidence is available to demonstrate prevention - demonstrate how this improves testing
• Named paediatrician for follow up
• Marketing advantages of testing
• Media campaign for public awareness
• Raising awareness for testing among those with asylum status
• System for healthcare profs to recognise people with HIV indicator conditions (in BHIVA Standards)
• System to raise awareness of HIV indicator conditions throughout public
• Surveys to be carried out in health board areas where there are gay bars etc
• People from high prevalence countries to be targeted for testing, is there any data from primary care available? Can data be collected on this?
• Consider those in the prison service also
• Can there be a measure of the time between infection and new diagnosis?

4.4.5 Other important scoping considerations on HIV recognition and diagnosis

• Education for GPs and others in primary and secondary care will be vital. The limitations of relying entirely on risk factors and the need for clinical vigilance needs to be emphasized.
• It will be important to link closely with HPS on monitoring test numbers, % positive, etc.
• HPS already monitor CD4 count and CDC Stage at first diagnosis – this could be incorporated within Standards
• The extent of non-targeted (i.e. general public or ‘routine’ patients) versus targeted work on HIV testing is likely to be a controversial area.
• Equally, should we be doing pilots of universal testing?
• There are significant resource implications of enhanced testing.

4.5 HIV Treatment and Care

During the initial phase of the HIV epidemic, individuals infected by the virus suffered an illness which progressed steadily from asymptomatic infection through symptomatic disease, AIDS and then finally to death. HIV/AIDS became
the leading cause of death in young adults in many parts of the world. Palliative care constituted a significant aspect of HIV-related work. Zidovudine (AZT) became available in the late 1980s, but AZT monotherapy had little durable impact on HIV suppression or disease progression\(^82\).

The breakthrough in HIV therapy came in 1996, with the advent of the combination antiretroviral therapy (cART) – also referred to as highly active antiretroviral therapy (HAART)\(^82\). AIDS registrations and mortality in Scotland\(^1\) (Figure 2) and other industrialised countries\(^82\) fell rapidly after cART was introduced. The estimated median survival for a young person diagnosed with HIV infection is now over 35 years based on Danish cohort study data\(^83\).

Although cART has revolutionised HIV care, treatment is still associated with many potential problems. These include the need for lifelong treatment, numerous potential drug side-effects (short and long-term), food interactions, drug-drug interactions, viral resistance and cost. At a national/health board level, the projected ongoing rise in the size of the HIV population in Scotland that is receiving care\(^7\) – with a corresponding increase in costs – is also a major planning issue.

**Figure 2.** HIV diagnoses, AIDS registrations and deaths, and individuals undergoing CD4 monitoring by year of report/death, Scotland, 1992-2008. (from Scotland’s Sexual Health Information 2009\(^7\), with permission)

4.5.1 Clinical assessment and investigation at initial and follow-up visits
The recently updated European AIDS Clinical Society (EACS) 2009 Clinical Management and Treatment Guidelines give clear guidance on this topic\(^43\).

4.5.2 Opportunistic Infection (OI) prophylaxis and vaccination
Individuals with significant HIV related immunosuppression may develop an opportunistic infection (OI). Some infections, such as *Pneumocystis jiroveci* pneumonia (PCP), are AIDS defining conditions and can be life-threatening. Appropriate use of prophylactic antimicrobial therapy, pending immune recovery from cART, is important. There are no current UK guidelines on OI prophylaxis, but comprehensive US guidelines are available\textsuperscript{84,85} that have been endorsed by the British Infectious Diseases Society (BIS) Guidelines Development Group.

Vaccination can protect against certain infections that HIV patients are prone to, due to immunosuppression (e.g. pneumococcal disease) or lifestyle (e.g. hepatitis B). BHIVA guidelines exist that cover these areas\textsuperscript{9}.

### 4.5.3 Antiretroviral therapy

**When to start cART**

There is increasing evidence that starting treatment too late is associated with adverse health outcomes\textsuperscript{86,87}. The BHIVA and EACS guidelines suggest starting when the CD4 count falls below 350, with certain subgroups of patients being advised to start earlier\textsuperscript{14,43}. A summary of the current (2008) BHIVA guidance is shown below. The 2009 EACS recommendations are very similar\textsuperscript{43} as are the recently updated WHO guidelines\textsuperscript{36}.

**Summary of BHIVA (2008) guidelines for starting cART\textsuperscript{14}**

<table>
<thead>
<tr>
<th>PRESENTATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Primary HIV infection</td>
<td>No treatment indicated, unless neurological involvement, any AIDS-defining illness or CD4 count &lt; 200 for 3/12 or more</td>
</tr>
<tr>
<td>2. Established HIV infection</td>
<td></td>
</tr>
<tr>
<td>CD4 count &lt; 200</td>
<td>Treat</td>
</tr>
<tr>
<td>CD4 count 201 – 350</td>
<td>Treat as soon as possible when patient ready</td>
</tr>
<tr>
<td>CD4 count 350 - 500</td>
<td>Treat in specific situations with higher risk of clinical events (see BHIVA guidelines for detail)</td>
</tr>
<tr>
<td>3. AIDS defining illness present</td>
<td>Treat (except for Tuberculosis (TB) when CD4 count &gt; 350)</td>
</tr>
</tbody>
</table>

Patients should be fully involved in the decision on whether or not to start treatment, which should take into account a wide range of patient-related factors,
in addition to the immunological, virological and clinical issues. The 2009 EACS guidelines provide useful guidance in this area\textsuperscript{43}.

**Initial antiretroviral cART regimen**

Many HIV drugs and combination preparations are now licensed (Appendix 2). Screening for HIV drug resistance should be performed prior to starting therapy. Whilst there is a vast and rapidly expanding literature on HIV therapy, there is no need to review this literature in detail here as it is incorporated within the BHIVA\textsuperscript{14}, EACS\textsuperscript{43} and US\textsuperscript{88} evidence-based adult treatment guidelines. Guidelines are also available for prescribing in pregnancy\textsuperscript{89} and to children\textsuperscript{90}. These guidelines are reviewed and updated regularly. The BHIVA guidelines are the principal adult guidelines used in the UK, including Scotland. Whilst not specifying preferred drug regimens, NHS QIS standards could set performance targets for adherence to key aspects of the BHIVA guidelines.

**Treatment adherence**

Very high levels of treatment adherence are required for sustained virological response during HIV therapy. Low adherence is associated with treatment failure, progression to AIDS and death\textsuperscript{14}. Patients should be screened for decision-making and adherence barriers before starting cART\textsuperscript{43} and all HIV treatment services should have strategies in place to support treatment adherence. There is now good evidence that strategic treatment interruptions should be avoided.

**Treatment failure and second-line HIV drug regimens**

Complete virological suppression to a viral load (VL) of < 50 copies/ml is usually achieved within 4 to 6 months after starting combination ART and a failure to fully suppress to <50 copies/ml indicates treatment failure. Transient ‘blips’ in VL to just above detectable levels are not infrequent on treatment, but a sustained rise after initial full suppression also indicates virological failure. Sub-optimal drug exposure (most commonly due to poor treatment adherence but sometimes due to other factors such as drug-drug interactions) and HIV mutations resulting in drug resistance are the commonest causes for treatment failure\textsuperscript{14, 43}.

A careful assessment should be performed before potentially switching therapy including an evaluation of adherence, tolerability, drug-drug interactions, drug-food interactions and psychosocial issues. Drug resistance testing should be performed where possible (if adequate HIV VL for a reliable result) and historical resistance test results reviewed for archived mutations\textsuperscript{14, 43} Wherever possible, the advice of a specialist HIV virologist should be sought to help the construction of complex regimens (e.g. third regimen and above).
**Drug toxicity**

This is an important issue for many patients. Drug toxicity may impact adversely on treatment adherence as well as on long-term morbidity and indeed mortality. The screening for and management of drug toxicity will, therefore, be an important issue for the NHS QIS HIV standards project group to address, although detailed discussion is not required here (see also 4.5.6 ‘Non-infectious complications of HIV’).

**4.5.4 Infectious complications of HIV/AIDS (other than STIs)**

Although AIDS notifications are falling, around 1/3 of HIV-infected patients still present late, not infrequently with an AIDS defining condition such as PCP. As described under ‘recognition and diagnosis’, recognition of these late presenters by non-specialists in primary and secondary care is vital to prevent unnecessary morbidity and mortality. Equally, clinical management, particularly for unwell patients requiring inpatient therapy, should be provided by clinicians with appropriate training and experience in HIV/AIDS medicine including OI diagnosis and therapy. In the Scottish context, this generally means that inpatients should be managed within an Infectious Diseases unit, unless there are particular reasons why the patient should be managed in another area (e.g. critical care). BIS endorsed US guidelines are available to inform OI therapy as well as prophylaxis, with specific BHIVA guidelines for TB therapy and hepatitis B or C available.

**4.5.5 Sexual and reproductive health of HIV-infected individuals**

This is an important area, both for the HIV-infected individual as well as for their partner(s) and the wider community. Considerable prominence has been given to this issue in recent years. Comprehensive BHIVA/BASSH guidelines are available, and the sexual health of HIV-infected individuals was also included within the recent NHS QIS Sexual Health Standards. All HIV treatment services in Scotland should ensure they have mechanisms in place whereby they can ensure the requirements of the NHS QIS Sexual Health Standards are met.

**4.5.6 Non-infectious complications of HIV infection**

This is another very important area that is gaining increasing prominence as patients survive longer on the virologically successful therapy. Increasingly, deaths in HIV-infected individuals are due to non-infectious complications including heart disease, liver disease and malignancy, rather than the traditional AIDS-defining illnesses of the pre-cART era. Indeed, a chronic disease management framework, similar to that adopted with diabetes, is applicable to many aspects of HIV care now. This will, therefore, form an important area for NHS QIS during standard development.
Non-infectious complications may be due to HIV infection itself, to treatment, or to a combination of both. Examples that fit into these 3 groups would, respectively, include certain malignancies, lipodystrophy, and liver disease due to chronic hepatitis (the latter can progress more rapidly in immunosuppressed HIV-infected individuals, with liver disease also potentially being exacerbated by drug-induced hepatotoxicity).

A detailed discussion of this topic is not necessary for this report. However, the following should be flagged up as being important areas to address during the process of standards development:

- cardiovascular disease
- renal disease
- hepatic disease
- metabolic complications (including lipodystrophy and hyperlipidaemia)
- neoplastic complications
- bone pathologies
- depression and neuro-cognitive problems

EACS and BHIVA have provided useful guidance in these areas\textsuperscript{11, 42}.

4.5.7 Pregnancy
An ‘opt-out’ approach to HIV testing in pregnancy was formally adopted in Scotland in 2002\textsuperscript{96}. The combined use of maternal ART, appropriate management of labour, avoidance of breastfeeding and zidovudine (or cART) PEP for 4 weeks for the infant can reduce the risk of HIV transmission to <2\%. However, the mother’s stage in pregnancy, virological and immunological status needs to be considered. Detailed BHIVA guidelines are available\textsuperscript{12}.

4.5.8 HIV in children
A considerable number of children are now born to HIV-infected mothers. These children require supervision of their PEP as well as appropriate clinical follow-up and blood samples to test for HIV infection. This work may be undertaken by general paediatricians/neonatologists. The Paediatric European Network for Treatment of AIDS (PENTA) guidelines have been adopted for use in the UK\textsuperscript{90}.

New HIV infections in children born in Scotland are now fortunately rare. The management of HIV-infected children is a very specialised area which should be performed by a paediatrician with appropriate training and experience, following the Children’s HIV Association (CHIVA) and PENTA advice/ guidelines (see www.chiva.org.uk). In general, this will mean that children are managed in either
Glasgow or Edinburgh, although this does pose access issues for children living elsewhere in the country.

4.5.9 Output from scoping meeting on 17 November 2009: Key issues, suggestions and comments relating to HIV treatment and care standards.

Top 3
- Specialist Units/support/treatment
- GP involvement in care should be the norm, letter sent to GP post consultation
- Access to an agreed set of CORE staff for patients.

Other important issues
- BHIVA standards? Applicable to Scotland?
- Geography- ensure equitable treatment
  - Late presentation
- Proportion of patients on therapy
- Types of therapy being used
- Arrangements for specialist review
- Specialist provision/cover (other AHPs)
- Pharmacy services for HIV services
- Smaller units- access to specialist support
- Issue of sustainability for specialist unit
- Treatment failure patients
- Clinic space and facilities- privacy/dignity
- Access use of the areas- cardiology, diabetes etc also have access to other services specific to HIV
- GP. awareness of diagnosis and access to information, treatment etc
- Transitional care – difficult
- Paediatrics
- CPD in primary care to ensure/enable involvement
- Define core set of services, staff, core set of personnel – delivery of services – or access
- Service user involvement to define core set
- Access to diagnostic procedures
- Access to ART same across Scotland
- Access to sexual health advisor
• Access to condoms throughout Scotland
• Access to PEPSE for known sero-discordant couples
• Children of parents diagnosed with HIV – testing offered and follow up
• Every health board has a clear care plan with equitable access to treatment
• Standards treatment per BHIVA guidelines and treatment and care for complications
• Core team should include health professionals such as specialist pharmacists, psychologists, BBV staff etc.
• This core set of staff could be affiliated with another service? Could it be dependent on the health board area since some areas do not have all of the multidisciplinary team available?
• There should be a set care pathway for patients.
• More service user involvement.
• Inpatient services
• Role of GPs in the core set of staff and primary care. GPs should be notified of patients with HIV.
• Patients must see the same consultant at least once per year?
• There should be something on pregnancy when a patient has HIV.
• Partnership with social services or defined links?

4.5.10 Other important scoping considerations on HIV recognition and diagnosis
• Drug regimens themselves will be out of scope – too complex and fast-moving
• Chronic disease management ought to be a major theme – note new EACS guidelines.
• Can look at adherence to BHIVA/ EACS guidelines
• Can link with HPS for some of the ‘routine’ monitoring/run-chart type data – based on CD4/VL form returns and the HPS database.
• Some data not suitable for continuous measurement/run-charts – a standard might then be e.g. ‘a protocol for X needs to be available and in use’
• Significant resource issues.

4.6 Delivery and co-ordination of care

4.6.1 Principles
An HIV-infected individual accessing clinical services in NHS Scotland has a right to expect certain minimum clinical standards to be provided wherever he/she chooses to attend for their care. There are a number of different models of HIV care in operation in Scotland - the recent HIV Needs Assessment provides a lot
of useful information in this area\textsuperscript{7}. Rather than try to define what 'the best' model of care is, the NHS QIS standards might more usefully examine what the core elements are that ought to be in place for any HIV service – including staffing and physical resources.

4.6.2. Multidisciplinary approach and clinical networks

The MedFASH\textsuperscript{19} and BHIVA Standards\textsuperscript{33} both identified the importance of multidisciplinary care, with clinical networks being developed that are appropriate to meet the needs of HIV-infected patients. This view is also endorsed by the HIV Action Plan for Scotland, which will provide regional HIV facilitation teams for HIV care\textsuperscript{5}. This is a mechanism whereby it should be possible to ensure that, even if a patient is attending a smaller centre, all aspects of HIV care are potentially available to him/her.

One vital issue for both the NHS QIS standards project group as well as for HIV services will be to ensure that patients, carers and the voluntary sector are fully involved in developing standards and services. As described earlier (section 3.1) an advocacy group has already been established that will work alongside the main project group and ensure that the voice of patients and carers is heard. Much of the detail of how this will be achieved has now been discussed and agreed.

4.6.3 Linking HIV prevention with treatment and care

An important part of HIV prevention relates to working with those individuals who are already infected, to ensure that risk behaviours are adequately addressed. There is evidence to support this approach\textsuperscript{97} – and it was also strongly supported at the scoping meeting itself.

4.6.4 Local care where possible

The geography of Scotland makes it sensible to try to keep care (including HIV inpatient care) as local as possible. However, there may be occasion when specialised treatment is required. The development of the regional clinical networks should allow for the coordination of this.

4.6.5 Appropriately trained staff

HIV/AIDS medicine is a complex and fast-moving area. It is vital that all staff who have a responsibility for providing HIV care should be appropriately trained and keep themselves up to speed through regular continuing professional development. The BHIVA Standards\textsuperscript{33} covers this issue to a certain extent. For nursing staff, National HIV Nurses Association has also provided useful guidance on core competencies\textsuperscript{97b}.

\textsuperscript{19}\textsuperscript{33}\textsuperscript{97}\textsuperscript{97b}
5 Conclusion

The epidemiology of HIV infection has been reviewed, along with the evidence for key interventions relating to HIV prevention, diagnosis, treatment and care. This information, along with the excellent information that was captured at the scoping meeting on 17 November 2009, provides a solid basis for teasing out the key issues further and developing these into standards through the work of the project group. At this stage (i.e. prior to the project group meeting) it would be premature to be too prescriptive about the key issues that should be taken forward for standards development. Nevertheless, it can be seen that a number of areas of particular importance have emerged from the scoping exercise that are likely to be incorporated. These include the following:

Prevention

- NHS boards should have a clear plan/strategy for HIV prevention – reviewed annually and adapted as new evidence emerges – that is based on local epidemiology and incorporates an appropriate mix of evidence-based HIV prevention activities
- appropriate HIV education/awareness raising at NHS board level, to include NHS staff, local authorities and the public. This should incorporate both generic education and targeted (e.g. for MSM and Africans) education and social marketing
- promotion/distribution of (free) condoms and lube
- provision of/access to a variety of HIV prevention behavioural interventions
- ensure that education on the prevention of onwards transmission of HIV is undertaken routinely and comprehensively at HIV treatment centres for known HIV positive patients
- access to a specialist health advisor at HIV clinics – and link HIV prevention to a wider STI/sexual health discussion
- access to, and education on, PEPSE for sero-discordant couples
- substitute prescribing and needle exchange schemes for IDUs
- evidence of partnership working with local authorities and voluntary sector
- data on clients reached by prevention services should be collected as part of routine monitoring

Recognition and Diagnosis

- HIV education emphasising the importance of early diagnosis - public, local authority and all NHS staff
- further ‘normalisation’ of HIV testing
- targeted HIV education/social marketing for specific risk groups (especially. MSM and Africans) with promotion of testing
- wider availability and uptake of HIV testing in a variety of settings, including primary care settings – based on BHIVA guidelines
• ensure healthcare workers recognise and test for HIV when certain indicator conditions (e.g. TB) are present irrespective of identified ‘risk’ behaviour – and monitor this

• routine offer of ante-natal HIV testing

• routine offer of HIV testing in certain high-risk settings at least (e.g. GUM clinics) and other settings where estimated HIV prevalence is ≥ 1:1000

• regular repeat testing for certain individuals – esp. sexually active MSM

• partner notification

• robust mechanisms for results handling

• mechanisms at NHS board level for closely monitoring the number of HIV tests being performed and where/why these are being performed

• proportion of late presenters (CD<200) – monitor NHS boards

Treatment and Care

• OI prophylaxis and vaccination

• appropriate use of cART: time of treatment initiation, initial regimen used, proportion of local cohort on treatment, proportion with undetectable VL, use of resistance testing, evidence of clinical virology advice being sought for complex cases, etc.

• ensure a chronic disease management/long-term conditions approach to HIV care is firmly embedded (see EACS guidelines), with evidence of active screening for cardiac, liver, renal, bone, etc. complications/risks

• sexual health of HIV-infected individuals (see existing NHS QIS standards)

• GP involvement in care, particularly in the chronic disease management areas (cardiac risk monitoring/ intervention, smoking, alcohol, etc)

• agreed set of ‘core’ staff available at, or closely affiliated to all HIV clinics

• outpatient facilities at HIV clinics must be fit for purpose and of adequate capacity. Confidentiality essential, as is the requirement to have an adequate number of rooms for true multi-disciplinary care to be delivered at the time that a patient attends for their clinic review appointment

• access to an appropriate, dedicated HIV inpatient service

• formal links between adult HIV, paediatric and obstetric services

• Clearly defined links to other relevant NHS (e.g. neurology, oncology, etc) and non-NHS (e.g. social services) HIV care providers

• Outcomes should be monitored – including mortality rates

Overall Service Organisation

• ensure access to appropriate HIV information, prevention, diagnosis and treatment services, irrespective of NHS board of residence

• ensure a multidisciplinary approach is taken

• clinical networks and service integration – linking larger and smaller units in Scotland (see also HIV Action Plan)
• clear pathways into and through services
• link prevention, diagnosis and treatment services
• staff training/competencies and workforce development - as well as adequate staff numbers
• patient/carer involvement in service planning
• linking NHS, local authority and voluntary sector services
• reliable information systems and evidence of regular audit

Although the discussion in this scoping report has focused on the production of standards, it is important to realise that significant change will be taking place within NHS QIS itself over the coming year. Importantly, there will be a greater emphasis on health improvement and less of an emphasis on undertaking scrutiny visits to NHS boards. These changes in emphasis at NHS QIS will need to be reflected in the work of the project group and the eventual format of the standards that the group produces.
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7. Appendices

Appendix 1: Commentary on selected HIV Prevention Interventions (see also UNAIDS guidance)

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>COMMENT</th>
<th>REFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines</td>
<td>Only one, preliminary study has shown any (minor) efficacy. An effective vaccine is unlikely to be available for many years.</td>
<td>64</td>
</tr>
<tr>
<td>Condoms</td>
<td>Male condoms are very effective if used consistently ($\geq 80%$ effective in sero-discordant heterosexual couples); less information is available on female condoms</td>
<td>61, 65, 98</td>
</tr>
<tr>
<td>Other barrier methods (e.g. female condoms and diaphragm)</td>
<td>Some studies show protective effects, but evidence less clear than for male condoms</td>
<td>61</td>
</tr>
<tr>
<td>Male circumcision</td>
<td>Large studies in heterosexual African men strongly support the effectiveness of this intervention, but the data to date for MSM do not show a clear benefit. The role of circumcision in the UK is therefore controversial</td>
<td>99-101</td>
</tr>
<tr>
<td>Control of STIs (particularly genital ulcer disease).</td>
<td>Genital ulcer disease (e.g. syphilis and HSV-2) are associated with an increased risk of acquiring HIV. However, 2 recent trials of HSV suppression to try to prevent HIV acquisition were unsuccessful.</td>
<td>102</td>
</tr>
<tr>
<td>Topical microbicides</td>
<td>Trials aimed at preventing male-to-female transmission, using products such as nonoxynol-9, and more recently Carraguard and Pro 2000, have been unsuccessful.</td>
<td>103-105</td>
</tr>
<tr>
<td>Antiretroviral therapy (ART) to prevent HIV transmission</td>
<td>The role of post-exposure prophylaxis (PEP) in occupational and non-occupational settings is now well-established – although the evidence base for efficacy is limited. Trials are underway to establish the role of pre-exposure prophylaxis (PrEP) in various settings, including sero-discordant heterosexuals, MSM and IDUs.</td>
<td>15, 23, 46, 61, 106-109</td>
</tr>
<tr>
<td>Methadone treatment and needle exchange schemes for IDUs</td>
<td>The evidence of efficacy is strong. Scotland and the UK have been very proactive in this area and now have very low levels of HIV in IDUs by international standards.</td>
<td>2, 110-112</td>
</tr>
<tr>
<td>Interventions to prevent mother to child transmission</td>
<td>Routine ‘opt-out’ HIV testing in pregnancy was adopted in Scotland in 2002. The combined use of maternal ART, appropriate management of labour, avoidance of breastfeeding and ART (PEP) for the infant dramatically reduces the risk of HIV transmission. BHIVA guidelines are available.</td>
<td>12, 96, 113</td>
</tr>
<tr>
<td>Enhanced HIV diagnosis/ testing</td>
<td>The prevalence of high-risk sexual behaviours typically decrease substantially after individuals become aware that they are HIV positive. However, this is not invariably the case in the MSM group. Uptake of HIV testing in MSM in Scotland is low by international standards. Surveys in gay bars in Scotland found that 41% of HIV+ men were unaware of their infection and over ½ had a previous negative HIV test and perceived themselves as HIV-ve</td>
<td>53,114-116</td>
</tr>
</tbody>
</table>

2. BEHAVIOURAL INTERVENTIONS*

<p>| Sexual Abstinence programs | ‘Abstinence only’ programs are ineffective; interventions that promote abstinence but also encourage condom use and safer sex practices (‘abstinence plus’) have been more successful. | 117, 118 |
| Mass media interventions for promoting HIV testing | A Cochrane review showed that mass media campaigns have an immediate and significant overall effect on testing rates, but no significant long-term effect. | 119 |
| Interventions for injecting drug users | HIV-risk reduction interventions can reduce injecting and non-injecting drug use, increase drug treatment entry, increase condom use and decrease trading of sex for drugs. | 120 |
| Heterosexual adults, including black Africans | Interventions within several high prevalence countries (eg. Uganda) have been effective. The CDC has identified a number of interventions that have been effective in heterosexuals in the US, including US minority groups. There is much less evidence in the Scottish/UK context, although NICE considers the predominantly US-based data on one-to-one interventions to be applicable in the UK context. NICE is currently developing guidance on reducing HIV transmission among African communities in England. | 22, 26, 27, 57, 65, 121 |</p>
<table>
<thead>
<tr>
<th>Interventions for HIV-ve MSM</th>
<th>A variety of behavioural interventions have been efficacious in reducing risky sexual behaviours and/or increasing HIV testing uptake. Individual-level, group-level, and community-level HIV behavioural interventions can be effective. However, changes may be difficult to sustain and reductions in HIV incidence have not been demonstrated</th>
<th>51, 55, 57, 69, 70, 122-125</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions for HIV+ve individuals (including heterosexual, IDUs and MSM)</td>
<td>The size of the HIV-positive population has grown and work to prevent onwards transmission is vital. A variety of behavioural approaches have been shown to be effective. However, high rates of UAI in HIV+ MSM persist</td>
<td>53, 55, 97, 114, 126</td>
</tr>
</tbody>
</table>

*The approaches taken and the actual interventions delivered in ‘behavioural intervention’ studies have been very diverse*
### Appendix 2. Approved antiretroviral drugs in the UK (2009)

#### A. Drugs available

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual adult dose</th>
<th>Food restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Nucleoside/ nucleotide reverse transcriptase inhibitors (NRTIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zidovudine (AZT)</td>
<td>250 mg twice daily</td>
<td>-</td>
</tr>
<tr>
<td>Didanosine (ddI)</td>
<td>250mg once daily (wt&lt;60kg) &lt;br&gt; 400mg once daily (wt&gt;60kg)</td>
<td>1/2 hour before or 2 hours after a meal</td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>150mg twice daily &lt;br&gt; or 300mg once daily</td>
<td>-</td>
</tr>
<tr>
<td>Stavudine (d4T)</td>
<td>30 mg twice daily (wt&lt;60Kg) &lt;br&gt; 40mg twice daily (wt &gt; 60kg)</td>
<td>-</td>
</tr>
<tr>
<td>Abacavir (ABC)</td>
<td>300 mg once daily</td>
<td>-</td>
</tr>
<tr>
<td>Tenofovir disoproxil fumarate (TDF)</td>
<td>245 mg once daily</td>
<td>-</td>
</tr>
<tr>
<td>Emtricitabine (FTC)</td>
<td>200 mg once daily</td>
<td>-</td>
</tr>
<tr>
<td><strong>2. Non-nucleoside reverse transcriptase inhibitors (NNRTIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevirapine (NVP)</td>
<td>200mg once daily for 14 days, then 200mg twice daily</td>
<td>-</td>
</tr>
<tr>
<td>Efavirenz (EFV)</td>
<td>600 mg once daily</td>
<td>Best on an empty stomach, at bedtime.</td>
</tr>
<tr>
<td>Etravirine (ETR)</td>
<td>200 mg twice daily</td>
<td>Take with/after food</td>
</tr>
<tr>
<td><strong>3. Protease inhibitors (PIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saquinavir (SQV)</td>
<td>1000 mg twice daily, with ritonavir (100 mg b.d.) boosting</td>
<td>Take within 2 hours of a meal</td>
</tr>
<tr>
<td>Ritonavir (RIT)</td>
<td>Rarely used, other than as a booster for other drugs</td>
<td>Preferably with food</td>
</tr>
<tr>
<td>Indinavir (IDV)</td>
<td>800mg three times daily (boosted regimes unlicensed)</td>
<td>1 hour before or 2 hours after a meal</td>
</tr>
<tr>
<td>Nelfinavir (NFV)</td>
<td>1250 mg twice daily</td>
<td>Take with food</td>
</tr>
<tr>
<td>Fosamprenavir (FPV)</td>
<td>700 mg twice daily, with ritonavir (100 mg b.d.) boosting</td>
<td>-</td>
</tr>
<tr>
<td>Lopinavir + ritonavir (Kaletra®) (LPV/r)</td>
<td>Two 200/50mg tablets twice daily</td>
<td>-</td>
</tr>
<tr>
<td>Combination</td>
<td>Generic name</td>
<td>Trade name</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>2 NRTIs</td>
<td>Zidovudine + lamivudine</td>
<td>Combivir ®</td>
</tr>
<tr>
<td></td>
<td>Zidovudine + abacavir</td>
<td>Kivexa ®</td>
</tr>
<tr>
<td></td>
<td>Emtricitabine + tenofovir</td>
<td>Truvada ®</td>
</tr>
<tr>
<td>3 NRTIs</td>
<td>Zidovudine + lamivudine + abacavir</td>
<td>Trizivir ®</td>
</tr>
<tr>
<td>PI + low-dose ritonavir (booster)</td>
<td>Lopinavir + ritonavir</td>
<td>Kaletra ®</td>
</tr>
<tr>
<td>2 NRTIs + NNRTI</td>
<td>Tenofovir + emtricitabine efavirenz</td>
<td>Atripla ®</td>
</tr>
</tbody>
</table>

4. Fusion and entry inhibitors

<table>
<thead>
<tr>
<th>Fusion inhibitor</th>
<th>Generic name</th>
<th>Trade name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enfuvirtide (T20)</td>
<td>90 mg subcutaneously twice daily</td>
<td>-</td>
</tr>
<tr>
<td>CCR5-inhibitor</td>
<td>Maraviroc (MVC)</td>
<td>300 mg twice daily</td>
</tr>
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</table>

5. Integrase inhibitors

B. Combination Tablets
# Delegate List

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Health Board/Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kirsty Abu-Rajab</td>
<td>GUM Consultant</td>
<td>NHS Forth Valley</td>
</tr>
<tr>
<td>Celia Aitken</td>
<td>Consultant</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Steve Baguley</td>
<td>Secretary BASHH/Consultant Genito-urinary Physician</td>
<td>NHS Grampian</td>
</tr>
<tr>
<td>Martha Baillie</td>
<td>Member HIV Action Plan Group</td>
<td>Waverley Care</td>
</tr>
<tr>
<td>Indranil Banerjee</td>
<td>GUM Consultant</td>
<td>NHS Fife</td>
</tr>
<tr>
<td>Georgina Brown</td>
<td>General Practitioner</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Katherine Brown</td>
<td>Lead Pharmacist HIV/ID Antimicrobials</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Nicky Coia</td>
<td>Health Promotion Officer</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Peter Davies</td>
<td>Social Worker</td>
<td>Western General Hospital</td>
</tr>
<tr>
<td>Phil Eaglesham</td>
<td>Health Improvement Programme Manager</td>
<td>NHS Health Scotland</td>
</tr>
<tr>
<td>Paul Flowers</td>
<td>Prof of sexual health psychology</td>
<td>Glasgow Caledonian University</td>
</tr>
<tr>
<td>Ray Fox</td>
<td>Consultant in infectious diseases</td>
<td>Brownlee Centre</td>
</tr>
<tr>
<td>Tony France</td>
<td>Consultant Physician</td>
<td>NHS Tayside</td>
</tr>
<tr>
<td>Shirley Fraser</td>
<td>Health Improvement Programme Manager</td>
<td>NHS Health Scotland</td>
</tr>
<tr>
<td>Ysobel Gourlay</td>
<td>BBV Pharmacist</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Rosie Hague</td>
<td>Consultant Paediatrician</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Name</td>
<td>Position/Role</td>
<td>Organization</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Catherine Johnman</td>
<td>Senior SpR</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Roy Kilpatrick</td>
<td>Chief Executive</td>
<td>HIV Scotland</td>
</tr>
<tr>
<td>Robert Laing</td>
<td>Consultant ID Physician</td>
<td>NHS Grampian</td>
</tr>
<tr>
<td>Clifford Lean</td>
<td>Professor of Infectious Diseases</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Patricia Lornie</td>
<td>Clinical Nurse Specialist/HIV Team Leader</td>
<td>NHS Tayside</td>
</tr>
<tr>
<td>Laura Mathers</td>
<td>BBV CNS team leader</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Liz McCann</td>
<td>Counselling Services Coordinator</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Gordon McKenna</td>
<td>Branch Chair</td>
<td>British Assoc for sexual health &amp; HIV</td>
</tr>
<tr>
<td>Tina McMichael</td>
<td>Health Promotion Officer</td>
<td>NHS Ayrshire &amp; Arran</td>
</tr>
<tr>
<td>Rhoda Morgan</td>
<td>Pharmacist</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Sheila Morris</td>
<td>Research Co-ordinator</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Catherine Murphy</td>
<td>Policy Officer</td>
<td>Terrence Higgins Trust</td>
</tr>
<tr>
<td>Marie Murray</td>
<td>Nurse Specialist</td>
<td>NHS Dumfries &amp; Galloway</td>
</tr>
<tr>
<td>Rak Nandwani</td>
<td>Member HIV Action Plan Group/GUM Consultant</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Felicity Naughton</td>
<td>Sexual health and HIV Programme Implementation Manager</td>
<td>Scottish Government</td>
</tr>
<tr>
<td>Cheryl Paris</td>
<td>Policy Manager</td>
<td>Scottish Government</td>
</tr>
<tr>
<td>Ian Robertson</td>
<td>Social Work</td>
<td>Fife Council</td>
</tr>
<tr>
<td>Nicola Rowan</td>
<td>Programme Manager (HepC Action Plan)</td>
<td>Health Protection Scotland</td>
</tr>
<tr>
<td>Tracy Russell</td>
<td>Dietician</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Gordon Scott</td>
<td>GUM Consultant</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Isabel Steele</td>
<td>HIV/AIDS, Sexual Health and Young People’s Health Officer</td>
<td>NHS Western Isles</td>
</tr>
<tr>
<td>Lesley Wallace</td>
<td>Senior Epidemiologist</td>
<td>Health Protection Scotland</td>
</tr>
<tr>
<td>David Wilson</td>
<td>Senior Sexual Health Advisor</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Andy Winter</td>
<td>GUM Consultant</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
<tr>
<td>Roger Wong</td>
<td>Clinical Co-ordinator/Psychiatrist</td>
<td>NHS Greater Glasgow &amp; Clyde</td>
</tr>
</tbody>
</table>
Support from NHS Quality Improvement Scotland provided by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clare Echlin</td>
<td>Acting Head of Standards Development</td>
</tr>
<tr>
<td>Nick Kennedy</td>
<td>Clinical Advisor</td>
</tr>
<tr>
<td>Gill Ryan</td>
<td>Programme Manager</td>
</tr>
<tr>
<td>Karen Grant</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Ali McAllister</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Margaret McAlees</td>
<td>Project Administrator</td>
</tr>
</tbody>
</table>
Appendix 4 HIV scoping meeting delegate list

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Health Board/Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martha Baillie</td>
<td>Member HIV Action Plan Group/Senior Manager</td>
<td>Waverley Care</td>
</tr>
<tr>
<td>Ron Christie</td>
<td>Project Manager</td>
<td>Body Positive Tayside</td>
</tr>
<tr>
<td>Roy Kilpatrick</td>
<td>Chief Executive</td>
<td>HIV Scotland</td>
</tr>
<tr>
<td>Dave Liddell</td>
<td>Director</td>
<td>Scottish Drugs Forum</td>
</tr>
<tr>
<td>Catherine Murphy</td>
<td>Policy and Parliamentary Officer</td>
<td>Terence Higgins Trust</td>
</tr>
<tr>
<td>Margaret Totten</td>
<td>Adviser</td>
<td>HIV-AIDS Carers and Families Service Support Provider Scotland</td>
</tr>
</tbody>
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Support from NHS Quality Improvement Scotland provided by:

<table>
<thead>
<tr>
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<td>Programme Manager</td>
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<td>Karen Grant</td>
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<tr>
<td>Alan Bigham</td>
<td>PFPI Officer</td>
</tr>
<tr>
<td>Margaret McAlees</td>
<td>Project Administrator</td>
</tr>
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</table>