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HTA Programme: HTA Systematic Review 1

Service delivery organisation for acute low back pain

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CONTENTS

1 EXECUTIVE SUMMARY 1
2 BACKGROUND ON NHS QUALITY IMPROVEMENT SCOTLAND 3
3 SETTING THE SCENE 4
3.1 Low back pain 4
3.2 Impact of back pain 5
3.3 Organisation of back pain services in Scotland 6
3.4 Description of technology 6
3.5 Primary objective and scope of the HTA 7
4 CLINICAL EFFECTIVENESS 8
4.1 Methodology 8
4.1.1 Evidence sources 8
4.1.1.1 Literature searches 8
4.1.1.2 Other evidence sources 8
4.1.2 Study selection 9
4.2 Results 9
4.2.1 Review of evidence on triage of low back pain referrals by a specialist gatekeeper 9
4.2.1.1 Study selection 9
4.2.1.2 Assessment of the evidence 9
4.2.2 Review of evidence on prompt referral, GP referral and patient self-referral to physiotherapy for acute low back pain 22
4.2.2.1 Conclusions 30
4.2.3 Review of evidence on whether feedback on inappropriate referrals affects referral patterns 30
4.2.3.1 Study selection 31
4.2.3.2 Assessment of the evidence 31
4.2.3.3 Conclusions 38
4.2.4 Review of evidence on referral authority of physiotherapists 38
4.2.4.1 Study selection 38
4.2.4.2 Assessment of the evidence 38
4.2.4.3 Conclusions 38
4.2.5 Evidence on GP and physiotherapist direct referral for MRI 38
4.2.5.1 Study selection 39
4.2.5.2 Assessment of the evidence 39
4.2.5.3 Conclusions 41
4.2.6 Review of evidence on physiotherapist treatment modalities 41
4.2.6.1 Study selection 41
4.2.6.2 Assessment of the evidence 41
4.2.6.3 Conclusions 44
4.2.7 Review of evidence on multidisciplinary or multifaceted approaches to rehabilitation 44
4.2.7.1 Study selection 44
4.2.7.2 Assessment of evidence 45
4.2.7.3 Discussion of the evidence 58
4.2.7.4 Conclusion 59
4.3 Discussion and conclusions 59
5 PATIENT ISSUES 60
5.1 Methodology 60
5.1.1 Evidence sources 60
5.1.1.1 Literature search 60
5.1.1.2 Other sources of evidence 61
5.2 Results 61
5.2.1 Use of analgesia by patients with low back pain 61
5.2.1.1 Study selection 61
5.2.1.2 Other evidence 61
5.2.2 Information needs 61
5.2.2.1 Study selection 62
5.2.2.2 Assessment of the evidence 62
LIST OF TABLES

| Table 4-1 | Evidence on triage of low back pain referrals | 10 |
| Table 4-2 | Evidence on the clinical effectiveness of prompt referral, GP referral and patient self-referral to physiotherapy | 23 |
| Table 4-3 | Evidence for feedback on inappropriate referrals for low back pain changing referral patterns | 32 |
| Table 4-4 | Evidence for the clinical effectiveness of GP and physiotherapist direct referral for MRI | 40 |
| Table 4-5 | Evidence on physiotherapist treatment modalities | 42 |
| Table 4-6 | Components of multidisciplinary/multifaceted interventions | 46 |
| Table 4-7 | Evidence for multidisciplinary approaches to the rehabilitation of patients with acute low back pain | 47 |
| Table 4-8 | Supporting data for multidisciplinary approaches to the rehabilitation of patients with acute low back pain | 52 |
| Table 5-1 | Studies of information needs | 63 |
| Table 5-2 | Studies of work-focused interventions | 65 |
| Table 5-3 | Studies of strategies proposed to improve communications between GPs and patients with low back pain | 67 |
| Table 5-4 | Studies of barriers to implementation of guidelines | 71 |
| Table 6-1 | Acute low back pain service delivery models in NHSScotland | 75 |
| Table 7-1 | Evidence on the cost effectiveness of using specialist gatekeepers in primary care and patient self-referral to physiotherapy | 89 |
| Table 7-2 | Average NHS-related costs (2004) by referral type (data from Holdsworth [2006]) | 93 |
| Table 7-3 | Evidence on the cost effectiveness of using specialist gatekeepers in the acute care setting | 95 |
| Table 7-4 | Evidence on the cost effectiveness of using multidisciplinary teams to provide pain management services | 97 |

LIST OF APPENDICES

| Appendix 1 | Experts involved in the HTA | 115 |
| Appendix 2 | Description of redesigned referral and treatment strategies participating in the Outpatient Programme initiative | 116 |
| Appendix 3 | Clinical and cost effectiveness search strategies | 117 |
| Appendix 4 | Review of evidence on triage of low back pain referrals by a specialist gatekeeper | 119 |
| Appendix 5 | Review of the evidence on prompt referral, GP referral and patient self-referral to physiotherapy for acute low back pain | 121 |
| Appendix 6 | Review of the evidence on physiotherapist treatment modalities | 123 |
| Appendix 7 | Review of evidence on whether feedback on inappropriate referrals affect GP referral patterns | 124 |
| Appendix 8 | Review of the evidence on referral authority of physiotherapists | 126 |
| Appendix 9 | Review of evidence on GP and physiotherapist direct referral for MRI | 128 |
| Appendix 10 | Multidisciplinary/multifaceted approaches to rehabilitation | 129 |
| Appendix 11 | Review of the evidence on barriers to GP implementation of acute lower back pain guidelines in primary care and the effectiveness of interventions to overcome these barriers | 131 |
| Appendix 12 | Review of the evidence on strategies proposed to improve communication between GPs and patients with low back pain and assessing their effectiveness in improving patient outcomes and patient and doctor satisfaction | 133 |
| Appendix 13 | Review of the evidence on the role of educational pain management interventions for primary care professionals in improving outcomes among patients with low back pain managed in the community | 135 |
| Appendix 14 | Review of evidence on analgesia use by patients with low back pain | 137 |
| Appendix 15 | Review of the evidence on meeting the information needs of low back pain patients in primary and secondary care and in the community | 139 |
| Appendix 16 | Review of the evidence on the beneficial effects of work-focused interventions delivered by healthcare providers in collaboration with employment services for patients unable to work because of back pain, and association with reduced NHS use for back pain | 141 |
1 EXECUTIVE SUMMARY

Back pain is one of the most common health problems affecting society, with up to 70% of the population experiencing pain at some point in their lifetime. It is associated with significant healthcare use and societal cost in terms of work loss and disability, and has been addressed using a variety of management approaches.

Where possible, this Health Technology Assessment (HTA) Systematic Review focused on evidence relating to non-specific acute low back pain. Non-specific low back pain has no specific pathology, commonly has a mechanical cause and varies with posture and over time. Acute low back pain is often associated with tissue damage, with symptoms usually resolving spontaneously within 6 weeks. However, a small proportion (2–7%) of people with an acute episode develop a chronic condition and the prognosis for individuals once the pain becomes chronic is poorer. In patients with acute low back pain, yellow flag psychosocial indicators (e.g., stress, anxiety, depression, inappropriate attitudes and beliefs about back pain, pain behaviour, poor work satisfaction) are used to identify those at risk of developing a chronic condition or disability.

Early intervention is considered critical to the management of low back pain to ensure that treatment occurs during the acute phase, before the condition deteriorates and becomes chronic. An acute low back pain service delivery model represents a time-efficient approach to help patients with back pain control their symptoms, while remaining active and avoiding loss of usual daily functioning. Various different service models are in use, or have been proposed, to ensure prompt and appropriate diagnosis, management and treatment of acute low back pain. These models vary in their provision of referral management systems, referral authority, use of Extended Scope Practitioners (ESPs) and the availability of prompt access and treatment modalities.

Objectives of the Health Technology Assessment

The objectives of this HTA were:

- to consider the clinical and cost effectiveness of service delivery models for the management of acute low back pain which utilise different triaging referral models
- to assess the impact of various parameters on a service delivery model to optimise its clinical efficacy and cost effectiveness.

This HTA focused on non-specific acute low back pain, where it was possible to distinguish this condition in the supporting literature.

Methods

The scientific literature was systematically searched to identify evidence of the clinical and cost effectiveness of service delivery models for the management of acute low back pain. Experts, professional groups and other interested parties were also invited to submit evidence. All evidence was critically appraised. A survey was undertaken to ascertain current service provision for low back pain services in Scotland.

Results and conclusions

The systematic review of scientific literature found a paucity of high quality evidence to inform the organisation of low back pain services in Scotland. Much of the published research on organisation of low back pain services makes no distinction between acute and chronic back pain, or indeed between back pain and musculoskeletal conditions. A further issue with research in this area is the lack of standardised patient-focused outcome measures and comparators.

Consequently, this HTA cannot recommend a ‘model’ low back pain service to NHS Scotland which brings together the four HTA dimensions of clinical effectiveness, cost effectiveness, patient issues and organisational issues. However, there are a number of conclusions from the systematic review of the evidence which may be of benefit to NHS boards when developing services and determining which treatments to use.

Recommendations

1. NHS boards should take account of existing evidence-based guidelines and advice for the management of low back pain. The Prodigy and European guidelines include recommendations for:
   - giving adequate information and reassurance to the patient, and avoiding negative messages
   - advising the patient to stay active and continue normal daily activities, including work, if possible
   - referral for spinal manipulation for patients who fail to return to normal activities
   - multidisciplinary treatment programmes in occupational settings for workers on sick leave for more than 4–8 weeks.

The Prodigy and European guidelines also identify treatments for which there is either insufficient evidence of effectiveness, evidence of ineffectiveness or inconclusive evidence, including: traction, transcutaneous electrical nerve stimulation (TENS), bed rest, specific exercises, epidural steroid injections, back schools, massage therapy, behavioural therapy, electrotherapy, ultrasound, interferential therapy, laser treatments and acupuncture.

2. NHS boards should consider the following conclusions from the systematic review of service delivery models for acute back pain:
   - The balance of evidence suggests that triage by a specialist gatekeeper, whether a physiotherapist, nurse or other clinician, results in shorter orthopaedic surgeon waiting times and higher conversion to surgery rates. Estimates for the proportion of patients managed entirely by physiotherapy, advice and/or exercise typically
exceed 80%. If orthopaedic surgeons have their referrals triaged, their time will be freed up for patients requiring surgery, who will get faster access to the surgeon. Patients not needing surgery will be managed more appropriately and quickly.

- There is some evidence that self-referral to a physiotherapist can reduce the waiting time for patients when compared with referral by a GP.
- There is weak evidence that using specialist physiotherapists, rather than junior surgeons, as gatekeepers within the acute care setting is clinically and cost effective.

3. Any redesign of services for low back pain in Scotland should include an evaluation element, incorporating consideration of both clinical and cost effectiveness and should use validated clinical outcome measures.

4. NHS boards should take account of the key issues identified by the Patient Issues Sub Group, including reluctance of patients to use medication for pain relief, inadequate information provision for patients and work-related concerns, when developing or redesigning services for low back pain.
2 BACKGROUND ON NHS QUALITY IMPROVEMENT SCOTLAND

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland. NHS QIS sets standards, monitors performance and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements.

Health Technology Assessment

NHS QIS uses the internationally recognised definition of HTA (International Network of Agencies for Health Technology Assessment (INAHTA), 2000) to advise NHSScotland about a specific health intervention, eg medicine, equipment or diagnostic test. HTA evaluates the clinical and cost effectiveness of the various ways in which a particular intervention can be used, comparing alternatives where appropriate. Patient and organisational issues are also considered.

Evidence is identified by systematic literature searching and by assimilating expert evidence, and the views of patient interest groups and manufacturers. The evidence is then critically appraised and robust analyses are undertaken by expert staff. Surveys may also be undertaken to ascertain current clinical practice and patient preferences.

This assessment was conducted by NHS QIS staff from a variety of disciplines, with input from health professionals expert in the particular area of interest (see Appendix 1). Peer review and wide public consultation ensures that all views are considered.
3 SETTING THE SCENE

3.1 Low back pain

Low back pain is defined as pain located in the back, between the bottom of the ribs and the top of the legs (Waddell, 2004). Diagnostic procedures aim to identify those patients with and without specific pathologies and manage their conditions accordingly.

Specific low back pain can be attributed to a definite spinal pathology such as infection, tumour, osteoporosis, rheumatoid arthritis, fracture or inflammation (van Tulder et al., 2002); these are assessed through red flag indicators. Examples of red flag indicators include early (age less than 20 years) or late (age over 55 years) onset, recent history of violent trauma, constant progressive non-mechanical back pain showing no relief with bed rest, thoracic pain, past history of a malignant tumour and prolonged corticosteroid use. The presence of any of these symptoms indicates a higher risk of a serious underlying disorder and requires prompt investigation.

Non-specific low back pain usually has a mechanical cause and varies with posture, with activity, over time and in response to treatment (Waddell, 2004). Most patients experience acute non-specific low back pain as a mild, benign, self-limiting condition and recover rapidly with minimal medical intervention (van Tulder & Koes, 2002; Manchikanti, 2000).

Low back pain is further classified as:

- acute, if it has lasted less than 6 weeks from onset
- subacute, if it has lasted 6–12 weeks
- chronic, if it has lasted for longer than 12 weeks (Quebec Task Force on spinal disorders, 1987).

Acute back pain is often caused by tissue damage, which may be difficult to identify, and accompanied by pain. Management of the condition involves relieving pain symptoms, returning patients to their normal activity levels and reducing the likelihood of chronic pain or disability developing (Waddell, 2004). Though the symptoms of non-specific acute low back pain usually resolve spontaneously within 6 weeks, they may persist, fluctuate or recur (Croft et al., 1998).

In chronic low back pain, there may be little evidence of tissue damage or ongoing stimulation of sensory receptors, rather the pain or disability become self-sustaining (Waddell, 2004). Management of chronic pain becomes more problematical as the condition is often dissociated from the original physical dysfunction (van Tulder et al., 2005; Waddell, 2004). It is associated with repeated rounds of failed treatment, leading to a decline in prognosis (Krause & Ragland, 1994). The resulting emotional and psychological changes can mean that chronic pain is strongly associated with the development of depressive symptoms (Ohayon & Schatzberg, 2003) such as sleep and appetite disturbances, irritability, chronic fatigue and withdrawal from social interactions (Hagen et al., 2006; Marin et al., 2006). As chronic back pain develops it becomes a disability, whereby the capacity for work is compromised and further difficulties are associated with both the rehabilitation process and the patient's social situation (Krause & Ragland, 1994).

The classification of low back pain into acute, subacute and chronic is useful in clinical practice, but represents a potentially misleading simplification. There is no absolute cut-off time at which acute pain becomes chronic and, as the characteristics of low back pain fluctuate over time, distinguishing between a new acute event and an exacerbation of a chronic problem may not be possible (Waddell, 2004; Hestbaek et al., 2003a; Philips & Grant, 1991).

Prognosis of low back pain

For most patients with acute low back pain, pain and disability usually decrease rapidly over the first month, and thereafter continue to decrease at a slower rate. By the end of the first month, approximately 30% of patients are pain free, a further third continue to have moderate back pain and 20–25% experience substantial activity limitation (Van Korff & Saunders, 1996).

Of those patients initially unable to work, 68–86% were able to return to work within 1 month and 91–96% within 3–6 months, although many individuals returning within 12 months had low levels of pain and disability (Pengel et al., 2003). There is a 20–75% risk of back pain recurrence within 12 months (Hestbaek et al., 2003b; Pengel et al., 2003; Andersson, 1999; Von Korff & Saunders, 1996) and a 33% risk of repeated work absence (Hestbaek et al., 2003b).

A small proportion (2–7%) of people with an acute episode develop a chronic condition (Koes et al., 2006). The prognosis for individuals once the pain becomes chronic is poorer (Waddell, 2004; Frank et al., 1998; Frank et al., 1996). The proportion of chronic back pain sufferers returning to work decreases ever more slowly with time (Krause et al., 1999). The probability of returning to work after a 2-year period of disability due to low back pain is virtually zero (van Tulder et al., 2002). In patients with acute low back pain, yellow flag psychosocial indicators (eg stress, anxiety, depression, inappropriate attitudes and beliefs about back pain, pain behaviour, poor work satisfaction) are used to identify those at risk of developing a chronic condition or disability (Jones et al., 2006; van Tulder et al., 2005; Thomas et al., 1999).

The biopsychosocial model of low back pain

The response of the individual to their pain and various psychosocial factors is recognised as having a profound influence on treatment efficacy and the clinical progress of both the pain and associated disability (Burton & Erg, 1997; Papageorgiou et al., 1997). More recent disease models attribute the condition to a mechanical problem, but the pain is understood to be a complex sensory experience. This greater understanding has led to the development of the biopsychosocial model of low back pain, which has five key clinical elements (Waddell, 2004):
• physical dysfunction
• beliefs about back pain
• distress
• illness behaviour
• social interactions.

Pain is both a sensory and an emotional experience and can be modified by both neurophysiological and psychological processes (Waddell, 2004). It is, therefore, accepted that back pain is best managed and understood using the biopsychosocial approach (Waddell, 2002; Turk et al., 1988), which considers physical, psychological and social components of the condition. This model aims to:

• assess the impact of all components on a patient's back pain
• manage the pain
• encourage the patient to accept a role in managing their condition
• prevent the development of chronic disease.

Modern back pain management focuses on the benefits associated with giving patients suitable advice and encouraging them to stay active. Although there is support for a biopsychosocial approach to treat low back pain (Abenhaim et al., 2008; Waddell et al., 1997), its use is still not universally accepted or applied (Jellema et al., 2005a; Rainville et al., 2000).

Diagnosis and management of non-specific acute low back pain

Several guidelines have been published in recent years that make evidence-based recommendations on appropriate methods for the diagnosis and treatment of non-specific acute low back pain (van Tulder et al., 2005; Carter & Birrell, 2000; Royal College of General Practitioners, 1999). The most recent is presented in the updated Prodigy Guidance (Prodigy, 2005), which complements the previous European guideline document (van Tulder et al., 2005). Guidelines were recently published by the Chartered Society of Physiotherapy (2006a; 2006b). These concern persistent rather than acute low back pain, but given the overlap between both practice and research in these areas, they are of interest. Key management recommendations include:

• educational advice
• symptom control using analgesia and a muscle relaxant if spasm is present
• returning to usual activities (including work)
• ensuring as much mobility as possible where symptoms require a few days rest
• referral to musculoskeletal physiotherapists, osteopaths or chiropractors who use a psychosocial approach for physical treatment
• addressing psychosocial risk factors
• assessment of treatment response after 4 weeks.

The Prodigy guidelines promote the use of a multidisciplinary, biopsychosocial approach to the management of non-specific acute low back pain and, as a result, there has been a shift in low back pain treatment practice since the early 1990s (Hagen et al., 2004; Waddell, 2004; Mason, 1994). A 2002 survey showed that 31% of patients are advised to remain active and 64% are prescribed analgesia. Bed rest is recommended for only 3%, and 5% receive a sickness certificate. However, there has been little change in the use of X-rays or the pattern of referral to specialist practitioners since the early 1990s (Waddell, 2004).

3.2 Impact of back pain

Back pain is a common health problem. It is estimated to affect most people at some point in their lifetime (lifetime prevalence of 70%) (van Tulder et al., 2005), with a third of individuals experiencing an episode over the course of a year (Andersson, 1999).

The estimated UK prevalence of back pain was 16.5 million in 2002 (Waddell, 2004), with most episodes being managed and resolved without medical consultation. The Working Backs Scotland 2001 survey estimated a one-year low back pain prevalence of 39% (Waddell, 2004). Non-specific acute low back pain is most common, occurring in approximately 90% of patients. Fewer than 5% of low back pain cases are associated with nerve root pain, less than 1% with serious spinal pathology and less than 1% with inflammatory disease (eg ankylosing spondylitis) (Waddell, 2004).

Back pain is the fifth most common condition requiring primary care consultation in Scotland, with about 6% of the population estimated to visit a GP in any one year (ISD incidence contacts 2004–2005, personal communication). Many of these patients will be treated exclusively in primary care, but about 1.6 million patients with back pain attend an NHS specialist in the UK each year, comprising 5–15% of new outpatient visits (Waddell, 2004; Silman et al., 2000).

Physiotherapists and complementary medical practitioners are often consulted by patients suffering from back pain. Nine percent of patients with back pain will visit a physiotherapist, 5% will be treated by an osteopath, 2% seek help from a chiropractor and 1% visit other specialists (eg acupuncturists, occupational therapists). With the exception of physiotherapy (77% of visits are NHS funded), visits to these practitioners are funded privately, at an estimated cost of £453 million in 1998 (Maniadakis & Gray, 2000).

Various reports indicate that approximately 10% of adults have experienced back pain that led to some degree of disability (Walker et al., 2004; Waxman et al., 2000). UK population surveys have estimated that activity restriction due to back pain translates to an annual prevalence of work loss of 2.4–6.4% (Hillman et al., 1996; Mason, 1994). The Working Backs Scotland survey reported a lower prevalence of 0.8% (Waddell, 2004). Recurrent and chronic low back pain has been estimated to account for 75–85% of total absenteeism (van Tulder et al., 2005), with employment-related costs estimated at £5 billion (Maniadakis & Gray, 2000).

The estimated UK preva
The total NHS costs for back pain in the UK in 1998 were estimated at £845 million, with private healthcare costs of £301 million and societal cost taking the final figure up to £6 billion to £8.2 billion (Waddell, 2004). It is estimated that patients with chronic pain and disability account for about 80% of these costs.

3.3 Organisation of back pain services in Scotland

In Scotland, patients presenting with back pain have traditionally been assessed by their GP and, if appropriate, referred to specialist services. Alternatively some patients self-refer to physiotherapists. The referral system is usually paper based, but urgent cases may be arranged by telephone. On receipt of the referral request by the specialist department, it is vetted and an appointment allocated, based on factors such as the clinical urgency and current waiting times. This system has evolved around the traditional boundaries that exist between departments and between primary and secondary care services.

This system is highly dependent on the GP and the diagnostic pathway chosen, which may be influenced by clinical factors, experience with similar cases, clinical preferences and the local availability of services. The GP is also responsible for overseeing the complex referral and treatment processes for each patient.

From the patient’s perspective, prompt and effective treatment may be compromised by organisational inefficiencies and the need to see a number of healthcare professionals at multiple clinic visits. The resulting extended waiting times may be sufficient for the patient’s low back pain to progress from acute to chronic status.

There is some anecdotal, but no published evidence, that GPs refer patients simultaneously to the same healthcare professional in different hospitals (eg orthopaedics) or different healthcare professionals in the same hospital (eg physiotherapy and orthopaedics) in order to expedite an appointment. This can result in artificially inflated waiting lists and delays if the additional appointments are not cancelled.

To improve the quality of back pain care, a more controlled co-ordinated treatment approach would facilitate timely diagnosis and prompt, effective treatment. In recent years, a number of initiatives have been introduced in areas across Scotland to rationalise the back pain referral and treatment process, in order to overcome organisational inefficiencies and improve prognosis for the patient.

The Centre for Change and Innovation (CCI), now the Improvement and Support Team, launched their outpatient programme in 2003, to develop service redesign programmes in clinical specialties where there is a history of long patient waiting times. The outpatient programme targeted both referral management services and orthopaedic outpatient departments as areas requiring change. This initiative required the development of a formalised low back pain referral and treatment pathway and resulted in a number of Scotland-wide projects to implement and test referral management, musculoskeletal pathways and the role of extended scope practitioners (Parroy, 2005b). NHS board areas involved in this initiative included:

- NHS Greater Glasgow
- the former NHS Argyll and Clyde
- NHS Forth Valley.

Descriptions of service redesign for each area are provided in Appendix 2. These models vary in their provision of referral management systems, the existence of a dedicated back pain service, the use of Extended Scope Practitioners (ESPs), discharge outcomes available to professionals and the self-referral options available to patients.

3.4 Description of technology

An acute low back pain service delivery model represents an organised diagnostic and treatment algorithm, designed to optimise management of the condition and integrate the individual aspects of care into a unified scheme. Assessment at an early stage in an acute back pain episode should facilitate identification of patients at risk of developing chronic disease, allowing them to receive more rigorous specialist management and preventing deterioration of their condition.

A number of low back pain service delivery models have been piloted in recent years, in both primary and secondary care settings (see Appendix 2). These models trial interventions that modify specific aspects of the overall back pain management process. Factors that may differentiate the effectiveness of service delivery are:

- referral management - This involves triage of orthopaedic referrals by an ESP, junior doctor or orthopaedic consultant, in accordance with departmental or consultant guidelines, and subsequent redirection of the referral to the most appropriate healthcare professional.
- the involvement of a clinical physiotherapy specialist, with an extended scope of practice involving working beyond the usual remits, for example: - requesting investigations such as blood tests, scans and nerve conduction studies - using the results of investigations to assist clinical diagnosis and appropriate patient management - referral for surgery and to other medical and paramedical professionals.

ESPs can be involved in referral management and review orthopaedic patients in a similar manner to an orthopaedic surgeon. ESPs can be positioned in either primary or secondary care.
Early intervention ensures that the patient receives prompt assessment and treatment to optimise management of their condition whilst in its acute phase and prevent deterioration into chronic back pain.

Appropriate referral authority has been proposed to allow ESPs to directly refer a patient to another physiotherapist working in an ESP role, to a consultant or for specialist diagnostic procedures. The patient would no longer need to be referred back to their GP before the specialist consultation could be arranged.

3.5 Primary objective and scope of the HTA

The objectives of this HTA are:

- to consider the clinical and cost effectiveness of service delivery models for the management of acute low back pain which utilise different triaging referral models
- to assess the impact of various parameters on a service delivery model to optimise its clinical efficacy and cost effectiveness.

This HTA focuses on non-specific acute low back pain, where it is possible to distinguish this condition in the supporting literature.
4 CLINICAL EFFECTIVENESS

There are a number of service delivery models for the management of low back pain within NHS Scotland. They differ in the use of referral management systems, referral authority, the role of physiotherapists, availability of prompt access, treatment modalities and treatment paradigms. This chapter reviews the evidence relating the following questions:

- Is it clinically effective for a specialist gatekeeper (in primary or secondary care) to triage referrals to orthopaedics? (Section 4.2.1)
- What is the clinical effectiveness of prompt referral, GP referral and patient self-referral to physiotherapy? (Section 4.2.2)
- Is it clinically effective for physiotherapists to have referral authority to consultant services and/or ESPs, compared with restricted referral authority to the GP only? (Section 4.2.3)
- Is it clinically effective for GPs and physiotherapists to have direct referral authority for magnetic resonance imaging (MRI) scans? (Section 4.2.4)
- Does feedback to GPs about inappropriate referrals change their referral pattern? (Section 4.2.5)

During consultation on the questions to be answered by the planned HTA, the treatment offered within service delivery models and in particular the paradigmatic approach to treatment adopted was highlighted as an area of concern by those working in the service. The appropriateness of the evidence base for some of the treatment modalities currently in use was queried and in relation to a biopsychosocial approach, interest was highlighted in the adoption of a multidisciplinary approach in which an integrated programme of physical, psychological and/or social/vocational interventions are delivered by health professionals from different backgrounds. Given this, it was decided to review briefly the clinical effectiveness evidence on two further questions:

- What is the clinical effectiveness of the different physiotherapy treatment modalities? (Section 4.2.6)
- Are multidisciplinary and multi-faceted approaches to the rehabilitation of patients with acute low back pain clinically effective? (Section 4.2.7)

4.1 Methodology

To ascertain low back pain service provision within NHS Scotland and the concerns of service providers, NHS QIS met with the topic proposers in October 2005. Further to these meetings, a protocol was drafted and an HTA Topic Group (Appendix 1) established including patients and healthcare professionals involved in the management of acute low back pain.

4.1.1 Evidence sources

Evidence to support this chapter of the HTA was obtained from a wide variety of sources. This included published literature, grey literature and information submitted from interested parties and topic group members.

4.1.1.1 Literature searches

An initial scoping search to identify high-level evidence such as review articles, previous HTA reports and guidelines was undertaken in November 2005.

The systematic literature search for primary and secondary evidence was undertaken between March and June 2006, and established that the published literature on low back pain was extensive. To refine the search, strategies were designed to combine the concepts of ‘low back pain’ and, eg ‘direct access’ or ‘physiotherapy’ as appropriate to each clinical effectiveness question.

The following sources were used:

- MEDLINE
- MEDLINE In-Process and other non-indexed citations
- EMBASE
- CINAHL
- AMED
- HMIC
- Cochrane Central Register of Controlled Trials
- Web of Science
- PEDRO
- Cochrane Effective Practice, Organisation of Care Group.

Language restrictions were applied, limiting the results to English, Dutch, French, German, Italian, Spanish, Portuguese and those of Scandinavian origin. Only articles published from 1995 onwards were retrieved.

The searches were re-run in June 2007 to retrieve evidence published in the period after the original searches were undertaken.

A list of the sources searched and a copy of the search strategies are provided in Appendix 3. All included strategies were used to search MEDLINE and were adapted to search other databases. A complete list of all strategies can be obtained by contacting NHS QIS.

4.1.1.2 Other evidence sources

To identify ‘patient pathways’, visits were made to various health professionals in different NHS board areas, to include the Greater Glasgow Back Pain Service (GGBPS), Astley Ainslie Hospital (NHS Lothian), Raigmore Hospital (NHS Highland), Crosshouse Hospital (NHS Ayrshire & Arran), Borders General Hospital (NHS Borders) and Hairmyres Hospital (NHS Lanarkshire), between October 2005 and March 2006. Senior physiotherapists at NHS Grampian and NHS Forth Valley were also contacted. Discussions were held with staff at Information Services Division (ISD), the CCI, Pain Association Scotland, BackCare, the Hope Project, and individuals involved in the care of patients with back pain within NHS Scotland and private or voluntary sectors.

Interested parties were invited to submit unpublished research, audit reports and other service-related documents. Other sources of evidence included
submissions from members of the HTA Topic Group, and ongoing monitoring of websites. Due to the complex nature of the search strategies and likely volume of ‘hits’, ‘Zetoc’ alerts (to capture new published papers) were not established. Instead, the original searches were re-run during the consultation period.

The reference lists of included papers were checked for additional relevant studies. Citations searches were also performed when requested by a reviewer. These are used to identify if a paper was referenced in other reports. This usually occurs when a search finds few relevant publications.

4.1.2 Study selection

Titles and abstracts of potential relevance were downloaded into a Reference Manager database. These were independently appraised by two reviewers, based on pre-defined inclusion/exclusion criteria, framed for each clinical effectiveness question using the PICO model (population, intervention, comparator and outcome) (Richardson et al., 1995). Disagreements were discussed until consensus was reached on which papers to include. Cohen’s kappa coefficient was calculated, to measure the level of agreement between reviewers. Full reports were ordered for all the selected articles, which were then evaluated independently by two reviewers against the same (or refined) criteria. Again, disagreements were discussed until consensus was reached. A third person was available to consult in the event of non-consensus at either selection stage, but was not required.

For each clinical effectiveness question, flow charts illustrating the number of papers included and excluded at each stage of the selection process are presented in the appendices (Appendices 4 to 17).

As a result of the service visits, data were obtained from GGBPS, Hairmyres Hospital and a national study of self-referral to physiotherapy (Holdsworth et al., 2006a). Data were also obtained from ISD, the Royal Alexandra Hospital, NHS 24 and the Allied Health Profession (AHP) census.

4.2 Results

Findings are summarised in narrative form and, where possible, grouped according to the type of intervention being considered.

4.2.1 Review of evidence on triage of low back pain referrals by a specialist gatekeeper

Referral management, referral pathways and the use of ESPs to perform patient triaging, in particular within orthopaedics, were new ideas considered as part of the redesign of orthopaedic outpatient services. This section seeks to assess the evidence for triaging of patients with acute low back pain by specialist ‘gatekeepers’ and to examine the relative merits of positioning the gatekeeper in primary or secondary care.

4.2.1.1 Study selection

A search of the bibliographic databases identified 4,433 titles and abstracts of potential relevance. Studies were selected if they reported on the use of a specialist gatekeeper (physiotherapist, ESP, specialist nurse, clinical specialist) to triage low back pain patients. Twenty-four full reports were ordered (kappa =0.52), of which 22 were available. A flow chart representing the selection of literature from title and abstract identification to inclusion of the full report is presented in Appendix 4.1.

Eight reports met the inclusion criteria, with the remaining 14 excluded for the reasons outlined in Appendix 4.2. Four additional relevant papers were identified through the reference lists of the selected publications and other sources.

4.2.1.2 Assessment of the evidence

The 12 selected papers comprised: nine audits of service redesign (one redesign had two reports) aimed at reducing waiting times for patients referred to an orthopaedic surgeon or improving service delivery (Rymaszewski et al., 2005; Curley et al., 2004; Maddison et al., 2004; Mofidi et al., 2003; Bartley, 2002; Harrington et al., 2001; Jones, 2001; Hattam & Smeatham, 1999; Murray, 1997; Hourigan & Weatherley, 1995); one randomised controlled trial (RCT) comparing physiotherapist triage of orthopaedic outpatients with triage by orthopaedic surgeons (Daker-White, 1999); and one non-randomised retrospective study examining the clinical effectiveness of ESP referrals.

Of the 11 distinct studies, five reported on the triage of back pain referrals (Curley et al., 2004; Mofidi et al., 2003; Bartley, 2002; Harrington et al., 2001; Murray, 1997; Hourigan & Weatherley, 1995) and six related, more broadly, to musculoskeletal conditions or orthopaedic referrals (Rymaszewski et al., 2005; Hattam, 2004; Maddison et al., 2004; Jones, 2001; Daker-White, 1999; Hattam & Smeatham, 1999). Nine studies were based in the UK, one in Ireland (Curley et al., 2004; Mofidi et al., 2003) and one in the US (Harrington et al., 2001). Three studies were set in primary care (Hattam, 2004; Jones, 2001; Hattam & Smeatham, 1999) and the remainder were in secondary care. Triage was performed by ESPs in seven studies (Curley et al., 2004; Harrington et al., 2004; Maddison et al., 2003; Bartley, 2002; Jones, 2001; Daker-White, 1999; Hattam & Smeatham, 1999; Hourigan & Weatherley, 1995), specially trained nurses in two (Murray, 1997; Rymaszewski et al., 2005) and a physician manager (a medically qualified manager) in one (Harrington et al., 2001). In one paper, it was not clear who performed triage (Maddison et al., 2004). A summary of the data extracted from each of these papers is presented in Table 4-1.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Patient characteristic</th>
<th>ESP training</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
<th>Additional comments</th>
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<tr>
<td>(Hourigan &amp; Weatherley, 1995)</td>
<td>Audit in Spinal Unit, Princess Elizabeth Orthopaedic Hospital, Exeter, England (dates not stated). 18-month follow-up</td>
<td>252 patients with spine-related back or leg symptoms. Age (years) mean 47; range 15–79. 54% male; 46% female. Duration of symptoms not stated. Referred by GP with diagnoses suggestive of prolapsed intervertebral disc or chronic degenerative disease. The surgeon saw all referrals from other consultants, children, failed back surgery or suspected tumour and infection.</td>
<td>Chartered physiotherapist with extensive musculoskeletal experience, who attended radiology seminars and international meetings for spinal surgeons. Trained, by the surgeon, in assessment and to refer only cases requiring the surgeon’s opinion.</td>
<td>Triage by physiotherapist acting as orthopaedic assistant in secondary care. Assessment following guidelines set by surgeon, including history taking, examination and lumbar spine X-ray, followed by discussion with surgeon.</td>
<td>Patients seen by spinal surgeon.</td>
<td>61% of patients were managed by physiotherapist. 30% of patients were seen by orthopaedic surgeon. Rate of conversion to surgery increased from 14% to 48%. 9% of patients were referred to rheumatology/neurosurgery/pain clinic. Do not attends (DNA) 9%. Waiting time for initial assessment not stated. Waiting time for orthopaedic surgeon not stated. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed at reducing waiting times and costs.</td>
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<td>Citation</td>
<td>Study type</td>
<td>Patient characteristic</td>
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<td>(Murray, 1997)</td>
<td>Audit in spinal assessment clinic, Middlesbrough, England, 1992–1996. 4-year follow-up</td>
<td>Nearly 4,000 patients with back pain referred by the GP. Age, sex and duration of symptoms not stated.</td>
<td>‘Careful and thorough training’ in the 3 months before the first patient appointment.</td>
<td>Triage by nurse practitioner in secondary care.</td>
<td>Patients seen by spinal surgeon.</td>
<td>Waiting time for initial assessment 6 weeks. 80% of patients given education and follow-up. 20% of patients reviewed by the orthopaedic surgeon. Waiting time for the orthopaedic surgeon reduced from 62 to 30 weeks. Rate of conversion to surgery not stated. Proportion of patients receiving physiotherapy not stated. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed at reducing waiting times.</td>
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<td>Citation</td>
<td>Study type</td>
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<td>(Daker-White, 1999)</td>
<td>RCT in an orthopaedic outpatient department in Frenchay and Southmead hospitals, Bristol, England, 1996–1997. Mean follow-up 5.6 months post-randomisation</td>
<td>383 new GP referrals to orthopaedic outpatients, 47% with back pain. Age over 18 years. Duration of symptoms not stated. Southmead excluded patients likely to require surgery; Frenchay did not. Both excluded those requiring urgent treatment.</td>
<td>Provided on a one-to-one basis by the consultant orthopaedic surgeon to: take history, examine, order investigations, provisionally diagnose, arrange and manage treatment. Additional training in radiographic analysis and radiological protection.</td>
<td>Triage by physiotherapist working in an extended role in secondary care.</td>
<td>Triage by a post-fellowship, junior orthopaedic surgeon (sub-consultant surgical staff including clinical assistants).</td>
<td>Proportion of patients (all conditions) given: physiotherapy 24% intervention; 24% control. Advice/reassurance 59% intervention; 32% control. Referred to orthopaedic surgeon 7% intervention; 17% control. Mean difference [intervention-control (95% CI)]: VAS pain scores Overall 3.3 (-2.5, 8.9); resting 4.4 (-1.5, 10.3); moving 4.3 (-1.6, 10.4). Oswestry Disability Index -2.7 (-7.2, 1.7). DRP perceived handicap scores Functional activities 0.2 (-0.6, 1.1); social activities 0.1 (-0.8, 1.0); socio-economic status 0.5 (-0.4, 1.4); relationships -1.0 (-2.2, 0.3); emotions 0.4 (-0.6, 1.3); body image -1.0 (-2.3, 0.2). SF-36 health scores Physical functioning 0.0 (-3.7, 4.5); physical role -1.4 (-9.7, 7.1); bodily pain -1.8 (-6.5, 2.8); general health -3.0 (-6.6, 0.4); vitality 1.5 (-2.6, 5.5); social functioning 0.1 (-6.0, 6.1); emotional role -2.3 (-12.2, 7.5); mental health 0.6 (-3.0, 4.1). HADS depression scores -0.1 (-0.8, 0.5). EQ-5D quality of life scores health state 0.0 (-0.1, 0.1); thermometer -2.3 (-6.7, 2.2). Mean number of: hospital visits 2.9 intervention; 2.3 control. GP visits 1.28 intervention; 1.02 control. Private/alternative practitioner visits 3.44 intervention; 2.59 control. DNA: 5%. Mean resource utilisation per patient (some hospital costs only): intervention £256; control £498. Waiting time for initial assessment and orthopaedic surgeon and rate of conversion to surgery not stated.</td>
<td>Trial to evaluate effectiveness and cost effectiveness of physiotherapist assessment and management of defined referrals to orthopaedics.</td>
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<td>Citation</td>
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<td>(Hattam &amp; Smeatham, 1999)</td>
<td>Audit of fund-holding GP practices, Sheffield, England, 1996–1997. 1-year follow-up</td>
<td>76 of 84 orthopaedic patients (11 patients [14.5%] LBP) referred to orthopaedic screening service. Age (years) mean 48, range &lt;20–90. 41% male; 59% female. Duration of symptoms unrestricted. Referred by GP, who retained freedom to bypass screening service and refer directly to orthopaedic department (102 direct referrals).</td>
<td>Chartered physiotherapist with 10 years musculo-skeletal experience, extensive postgraduate training, fellowship of society of orthopaedic medicine and diploma in injection therapy.</td>
<td>Triage by physiotherapist in primary care, 40 minute appointment for assessment and treatment.</td>
<td>Patients seen by orthopaedic surgeon.</td>
<td>Proportion of patients (all conditions) managed by: advice/exercise 38% physiotherapy 25% referred to orthopaedic surgeon 26% referred to neurology 1%. Waiting time for: initial assessment mean 32 working days (6 weeks), range 4–87 days orthopaedic surgeon originally 11 months; no patients had been seen by the end of follow up. Rate of conversion to surgery not stated. Reconsultations with GP for same problem 5%. DNA 2.6%. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed to reduce orthopaedic waiting times.</td>
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<td>Citation</td>
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<td>(Jones, 2001)</td>
<td>Audit of Doncaster primary care clinics, 1999–2000. 6-month follow-up</td>
<td>541 orthopaedic referrals, proportion with back pain unknown. Age, sex and duration of symptoms not stated. Referred by GP, who retained freedom to bypass screening service and refer directly to orthopaedic department.</td>
<td>Experienced orthopaedic physiotherapy practitioners shadowing orthopaedic consultants.</td>
<td>Triage by physiotherapist in primary care. Patients seen by the orthopaedic surgeon.</td>
<td></td>
<td>Proportion of patients (all conditions) referred to: physiotherapy 57% orthopaedic surgeon 7%. Waiting time for: initial assessment 3–4 weeks orthopaedic surgeon not stated. Rate of conversion to surgery not stated. No measures of pain, disability, functioning, depression or quality of life. Changes in referral rates to orthopaedics between 1998–1999 and 1999–2000 compared in three pilot areas (other waiting list initiatives mentioned but not detailed) Intervention arm decreases of 25%, 19% and 33% in the three areas. Control arm increase of 14%, no change and decrease of 8% in the three areas.</td>
<td>Review of a pilot project aimed to reduce orthopaedic waiting times.</td>
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Review of a pilot project aimed to reduce orthopaedic waiting times.
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<tr>
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<td>(Harrington et al., 2001)</td>
<td>Audit of Physicians Plus Medical Group, Madison, Wisconsin, affiliated with Merriter Hospital, 1996–1998. 6-month follow-up</td>
<td>25,027 system visits; subsample of 581 referred to specialty; separate telephone survey subsample 112 referred. Age and sex not stated. Back pain: 48% acute low, 32% chronic low, 7% acute sciatica, 13% chronic sciatica.</td>
<td>Not stated.</td>
<td>Triage according to protocol by physician manager in secondary care.</td>
<td>Patients seen by orthopaedic surgeon.</td>
<td>Ratio of system visits in: 1996 before implementation of referral management primary 72%; secondary 28% (total 7,988) 1998 after implementation of referral management primary 83%; secondary 17% (total 9,279). After implementation of referral management, proportion of patients (total 581) referred to: spinal surgeon 32% medical rheumatology specialists 42% sent back to primary care with instructions for further care and follow up 13% handled by non-specialty 13%. Waiting times not stated. Of 112 referrals April–June 1998, 76% had improved or resolved pain and function. Conversion to surgery rate increased from 5% to 21%.</td>
<td>Review of pre-appointment referral management aimed to improve delivery of care.</td>
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<td>Citation</td>
<td>(Bartley, 2002)</td>
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<td>ESP training</td>
<td>Not stated.</td>
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<td>Patient characteristic</td>
<td>1,000 patients referred by GP with back pain. Age, sex and duration of symptoms not stated.</td>
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<td>Comparator</td>
<td>Patients seen by orthopaedic surgeon.</td>
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<td>Intervention</td>
<td>Triage by physiotherapist in secondary care immediately after completing a 40 minute questionnaire including Oswestry Disability score.</td>
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<td>Results</td>
<td>Proportion of patients referred to physiotherapy 36% (10% re-referrals. 45% of those triaged had already received physiotherapy in primary care) reviewed by orthopaedic surgeon/physician 27%. Waiting time for initial assessment: beginning of period - 1 week for priority and 4 weeks for routine, third quarter - 4 weeks for priority and 16 weeks for routine. Waiting time for orthopaedic surgeon reduced from 29 to 20 weeks. Rate of conversion to surgery not stated. No measures of pain, disability, functioning, depression or quality of life.</td>
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<td>Additional comments</td>
<td>Review of a service redesign aimed to reduce surgeon’s list and disability.</td>
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<td>(Curley et al., 2004; Mofidi et al., 2003)</td>
<td>Audit of back pain screening clinic, Adelaide and Meath Hospital, Dublin, Ireland, 2001–2003. 2-year follow-up</td>
<td>2,146 patients with back pain: 91% referred by GP, 9% from A&amp;E. Age (years): mean 41.2; range 16–86. 47% male, 53% female. Symptoms 6–12 weeks, then increased to 1 year, then no limit. Excluded: spinal surgery or deformity.</td>
<td>Senior grade physiotherapist specialised in LBP management.</td>
<td>Triage by physiotherapist in secondary care.</td>
<td>Patients seen by orthopaedic surgeon.</td>
<td>Patient management: advice alone 40% referred to physiotherapy 35% managed by exercise class 9% reviewed by orthopaedic surgeon 15%. Waiting time for initial assessment average 1 week; range 2 days to 2 weeks orthopaedic surgeon reduced from 15 months to 6 weeks. Rate of conversion to surgery 29%. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed to reduce waiting times.</td>
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<td>Citation</td>
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<td>(Maddison et al., 2004)</td>
<td>Audit of TEAMS, North West Wales NHS Trust, 2002–2003. 18-month follow-up</td>
<td>Number of patients not stated. All musculoskeletal and referred by GP. Age (area has high elderly population), sex and duration of symptoms not stated.</td>
<td>Not stated.</td>
<td>Central triage in secondary care using information in generic referral letter (unclear by whom – possibly according to automated protocol). ESP leads back pain pathway, providing physiotherapy service in the community.</td>
<td>Separate referrals to orthopaedics, pain management, therapy services and rheumatology.</td>
<td>Total referrals for all musculoskeletal problems increased by 116%; orthopaedic referrals were slightly reduced. Waiting time for initial assessment: before service redesign orthopaedics 52 weeks; pain management 52 weeks; therapy services 52 weeks; rheumatology 36 weeks. after central triage back pain waiting times went from 52 weeks to approximately 2 weeks orthopaedic surgeon reduced from 52 weeks to approximately 24 weeks. Proportion of patients referred on or followed up &lt;10%. Duplicate referrals ‘all but eliminated’ (details not reported). Rate of conversion to surgery before and after service redesign 37%. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed at reducing waiting times, inappropriate and multiple referrals and lack of service.</td>
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<td>Citation</td>
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<td>Patient characteristic</td>
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<td>(Hattam, 2004)</td>
<td>Non-randomised cross-sectional study of primary care practices referring to the Northern General Hospital orthopaedic department Sheffield, England, 2000–2001. 15-month follow-up</td>
<td>1,301 ESP contacts, 192 referred to orthopaedics. Complete data on 170. All musculoskeletal. Age and duration of symptoms not stated. 51% male; 49% female.</td>
<td>Not stated.</td>
<td>Triage by ESP in primary care.</td>
<td>Patients seen by orthopaedic surgeon.</td>
<td>15% of patients (all conditions) referred to orthopaedic surgeon. For lumbar spine patients, 72% of referrals considered appropriate and 28% inappropriate. Rate of conversion to surgery (all conditions) 52%. Waiting times not reported. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Study of clinical effectiveness of ESP referrals.</td>
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<td>(Rymaszewski et al., 2005)</td>
<td>Audit at Stobhill Hospital, Glasgow, Scotland, 1995–1999. 5-year follow-up</td>
<td>4,568 patients in 1998–1999. All musculoskeletal, fitting protocols. Age, sex and duration of symptoms not stated. Referrals from GP, patients and consultants (proportions not stated).</td>
<td>Training in triage of referral letters.</td>
<td>Triage of referral letters by specialist secondary care nurse, according to protocol. Triage unsupervised, but consultant available to help with queries or discuss letters not fitting protocol.</td>
<td>Patients seen by orthopaedic surgeon.</td>
<td>Number of new referrals increased by 97%. Waiting time for initial assessment (all conditions) decreased from 26 weeks (182 days) to 13 weeks (90 days). Waiting time for orthopaedic surgeon not stated. Rate of conversion to surgery increased from 20% to 70% (38% pre-triage total used as the denominator). Proportion of back pain patients managed in different ways not stated. No measures of pain, disability, functioning, depression or quality of life.</td>
<td>Review of a service redesign aimed at reducing waiting times.</td>
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Triage of back pain referrals by physiotherapist in secondary care

An audit of the spinal unit at Exeter, where triage of referrals was performed by a physiotherapist in consultation with the spinal surgeon, reported that 61% of patients were managed by the physiotherapist alone (Hourigan & Weatherley, 1995). Thirty percent of patients were referred to the orthopaedic surgeon and a further 9% were referred on to other specialties. The rate of conversion to surgery for orthopaedic referrals increased from 14% pre-triage to 48% post-triage.

The orthopaedic centre in Oxford also introduced physiotherapist triage as part of service redesign. Their audit reported a waiting time for initial assessment of routine back pain of 4–16 weeks from referral (Bartley, 2002). Thirty-six percent of triaged patients were referred to physiotherapy and 27% to an orthopaedic surgeon or physician. The waiting time to see an orthopaedic surgeon was reduced from 29 weeks at the introduction of physiotherapist triage to 20 weeks a year later. The author commented that 45% of patients triaged had already received physiotherapy in the community and 10% of physiotherapy referrals were re-referrals.

An audit of physiotherapist triage at the Dublin back pain screening clinic (Curley et al., 2004; Mofidi et al., 2003) reported a 1 week waiting time for initial assessment. The proportion of patients managed by advice alone was 40%, a further 35% were referred to physiotherapy and 9% were directed to an exercise class. Of those triaged, 15% were referred to the orthopaedic surgeon whose waiting time reduced from 15 months before service redesign to 6 weeks thereafter, with a 29% conversion to surgery rate.

Triage of back pain referrals by nurse practitioner in secondary care

A nurse practitioner triaged referrals to the spinal assessment clinic in Middlesbrough, with a waiting time of 6 weeks post-redesign (Murray, 1997). Patients with mechanical back pain (80%) were managed entirely within the clinic, by individual educational sessions and two class sessions, emphasising behavioural modification and increasing ability. Twenty percent of patients were reviewed by an orthopaedic surgeon. The waiting time for the orthopaedic surgeon reduced from 62 weeks before implementation of triage to 30 weeks thereafter. There was no physiotherapist on the clinic staff and it was unclear what proportion of triaged patients was referred for physiotherapy.

Triage of back pain referrals by a physician manager in secondary care

Triage of low back pain referrals was performed, according to a defined protocol, by a physician manager (a medically qualified manager) in a US study (Harrington et al., 2001). Patients who would previously have seen an orthopaedic surgeon were diverted to either physicians in the primary setting for acute non-urgent back pain care, or medical specialists for chronic pain. Rehabilitative care was provided by physiotherapists. The spinal surgeon saw 32% of referrals in the year following implementation, which comprised urgent and surgical cases (with surgical defined as: more than 6 months of failed medical management, persistent sciatica despite rehabilitation and steroid injections, or persistently symptomatic spinal stenosis). Conversion to surgery increased from 5% to 21%. Referral management resulted in an increase in system visits in primary care, rising from 72% in the year before to 83% in the year following implementation.

Triage of orthopaedic referrals by physiotherapist in secondary care

An RCT compared physiotherapist triage with triage by a junior surgeon, in two orthopaedic outpatient departments in Bristol (Daker-White, 1999). Physiotherapists were more likely to give advice and reassurance than junior surgeons (59% versus 32%), whereas junior surgeons were more likely to refer to an orthopaedic consultant (17% versus 7%). Twenty-four percent of patients in each group were referred to physiotherapy. No significant differences were noted in pain, disability, handicap, general health, depression or quality of life. The authors estimated that there were more hospital, GP and alternative practitioner visits for those triaged by a physiotherapist.

When interpreting the findings from this study, a number of limitations were noted:

- The sample size did not achieve that required for statistical power for the main variable of interest (disease repercussion profile) and no information was given on powering for the other outcomes.
- Patient exclusion procedures differed between hospital sites and length of appointment differed between specialties in one hospital. These substantial procedural differences were not controlled for in the analysis and the results were not presented separately by hospital.
- There were protocol violations in both arms of the trial.

Triage of orthopaedic referrals by physiotherapist in primary care

A survey of the clinical effectiveness of orthopaedic referrals by ESPs in primary care to the Northern General Hospital in Sheffield reported a referral rate of 15%, of these 72% of lumbar spine referrals were considered appropriate. A conversion to surgery rate of 52% was noted (Hattam, 2004).

In a previous collaborative audit of the service redesign, the same author reported a waiting time for initial assessment of 32 working days for orthopaedic outpatients, of whom 14% had back pain (Hattam & Smeatham, 1999). In this earlier study, 38% of patients were managed by advice and exercise, 25% were referred to physiotherapy, 26% to orthopaedics and 1% to neurology. The GP reconsultation rate was 5%.
In Doncaster, a pilot primary care project aimed to reduce orthopaedic waiting times by utilising physiotherapist triage (Jones, 2001). The authors reported 3–4 week waiting times for initial assessment, a 57% physiotherapy referral rate, with only 7% of patients being referred to an orthopaedic surgeon. However, it was noted that other local initiatives to tackle waiting times may have confounded the results.

Triage of musculoskeletal referrals in secondary care

In the TEAMS programme in North Wales (Maddison et al., 2004), it is unclear which personnel performed triage, indeed triage may have been automated based on information in a generic referral letter. Patients with mechanical back pain were treated by GPs with a special interest and community ESPs. The waiting time for initial back pain assessment decreased from 52 weeks to 2 weeks. Less than 10% of patients seen on the back pain pathway were referred on or followed up. After service redesign, total referrals increased by 116%, possibly due to a perception of a prior lack of service, and orthopaedic referrals were slightly reduced. Duplicate referrals were ‘all but eliminated’. The waiting time to see an orthopaedic surgeon decreased from 52 to 24 weeks. The rate of conversion to surgery remained relatively high at 37%.

At Stobhill Hospital in Glasgow, 5 years’ data were collected following a redesign of musculoskeletal services, involving triage by a specialist nurse in secondary care (Rymaszewski et al., 2005). The authors noted that the number of new referrals increased by 97%, as GPs from other areas sent patients to the department as it had the shortest waiting time. Despite this, the waiting time for initial assessment decreased from 26 weeks to 13 weeks. The conversion to surgery rate increased from 20% to 38%.

Discussion of the evidence

Limited evidence was identified that specifically considered patients with acute back pain. Most reports did not differentiate between acute, subacute or chronic low back pain. The US study (Harrington et al., 2001) presented system visits separately for duration of low back pain of greater or less than 6 weeks, however referral outcomes were not distinguished in the same way. Another study mentioned an initial restriction on the inclusion of patients based on their duration of back pain symptoms that was later lifted (Murray, 1997).

Some reports did not differentiate between back pain and other musculoskeletal conditions. Only two studies dealing with musculoskeletal conditions gave separate results for back pain (Hattam, 2004; Maddison et al., 2004). In studies where waiting times for initial assessment were of the order of a few weeks, patients would be likely to be seen while their pain was at the acute stage. In other studies, the long waiting period before initial assessment would have meant that no patients were seen at the acute or even subacute stage. Despite triage being an aspect of service redesign that might specifically target patients with acute low back pain, it is not clear from much of the evidence whether the findings are applicable to the acute stage.

Of the studies that described redesigned orthopaedic services and reported post-implementation outcome measures, not all included comparable baseline measures for the period preceding redesign. Even when ‘before’ and ‘after’ triage implementation data were available, it was unclear whether other factors remained comparable over both periods. Any benefits observed may have been due to other waiting list initiatives, changes in catchment area size, the proportion of patients being referred, staffing resources or training, or the treatment approach. All four studies with baseline and post-redesign data on waiting times to see an orthopaedic surgeon reported a substantial reduction for the redesigned service. Of the four studies which reported ‘before’ and ‘after’ conversion to surgery rates, three noted a substantial increase and one (with a relatively high conversion rate at the start) remained unchanged.

The specialist gatekeeper could be placed in either the primary or secondary care setting, within the redesigned orthopaedic service. Location is likely to influence the level of communication between the orthopaedic surgeon and triage personnel, with an opportunity for informal transfer of skills and joint working for ESPs situated within orthopaedic departments. All studies, reporting ‘before’ and ‘after’ data, for triage in secondary care, demonstrated a benefit. It is not possible to draw conclusions concerning the usefulness of locating triage in primary care, as none of these studies reported baseline data.

Various professionals could perform the triage role: most studies described physiotherapists working in an extended scope; two used nurses, one a physician manager and one junior orthopaedic surgeons. In the seven studies including ‘before’ and ‘after’ data (Rymaszewski et al., 2005; Curley et al., 2004; Maddison et al., 2004; Mofidi et al., 2003; Bartley, 2002; Harrington et al., 2001; Murray, 1997; Hourigan & Weatherley, 1995) benefits for triage were reported in: all four studies using a physiotherapist, the two studies using a nurse and the study using a physician manager. The key outcome measures were highly variable among studies and gave no indication of one type of gatekeeper being superior, with respect to waiting time to see an orthopaedic surgeon or conversion to surgery rate. The only study with comparative data on patient outcomes of pain, function, depression and quality of life did not find any difference between patients triaged by an ESP or by a junior orthopaedic surgeon. However, the trial may not have had sufficient power to detect significant differences in these outcome measures (Daker-White, 1999). Costs were lower in the physiotherapist arm of this trial.

The one study directly considering inappropriate referrals, although without baseline data, estimated that 28% of lumbar spine referrals were inappropriate (Hattam, 2004). However if specialist triaging does reduce the incidence of inappropriate referral, high conversion to surgery rates and shorter orthopaedic surgeon waiting times might be expected. A high degree of variability in both of these parameters is reported by the different studies, which may be due to differences in the ratios of patients: physiotherapists: orthopaedic surgeons. Most reports give
minimal information on staff to patient ratios: Hattam & Smeatham (1999) described twice-monthly clinics providing five 40 minute physiotherapy appointments for new patients, in a practice population of 9,363; Rymaszewski et al. described 3.5 full-time equivalent (FTE) orthopaedic and one rheumatology consultant running eight clinics and four ESP sessions (of unknown length or appointment time) per week for a catchment population of 170,000 (Rymaszewski et al., 2005). Protocol differences, or a more or less cautious approach to triage, could result in variations in outcome measures.

Unpublished data

The GGBPS has nine FTE specialist physiotherapists to triage patients with acute low back pain, with 750 patients being referred per month. Eighty-two percent of patients are seen within the target waiting time of 2 weeks, with a ‘did not attend’ rate of 10%. After initial assessment, most patients have one or two physiotherapy follow-up sessions and are then discharged, only 1% of patients are referred to an orthopaedic surgeon. Data on 2,962 patients, comparing initial pain assessments with outcome at discharge, showed improvement in: Quebec task force classification (4% reporting no pain at initial consultation to 34% reporting no pain at discharge), visual analogue scale (VAS) pain score (modal category 5 to 0), proportion off work with back pain (21% to 6%) and function (68% better or much better) (MMcMenemy, Lead Clinician, GGBPS. Personal communication).

The Royal Alexandra Hospital in Paisley, sees patients with acute low back pain, both through referrals to orthopaedics and through a dedicated acute low back pain clinic staffed by 1.2 FTE ESPs. Non-cancer patients with back pain, who have not undergone prior back surgery, are triaged by an ESP following referral to an orthopaedic speciallist. Of 169 new contacts from July 2005 to June 2006, referral rates were: 5% to orthopaedics, 27% to physiotherapy, 1% to other specialties, and 35% of patients were discharged after the first appointment. Seventeen percent of patients failed to keep their appointment. Over the same period, 282 new patients were referred to the acute low back pain clinic, where the referral rate for an orthopaedic specialist was 2% and for a neurological specialist was <1%, and 9% of patients failed to keep their appointment. Twenty percent of patients off work at the start of treatment returned to work (J Manson, Acting Head Superintendent Physiotherapist, RAH. Personal communication).

Conclusions

The balance of evidence suggests that triage by a specialist gatekeeper, whether a physiotherapist, nurse or other clinician, results in shorter orthopaedic surgeon waiting times and higher conversion to surgery rates. Estimates for the proportion of patients managed entirely by physiotherapy, advice and/or exercise typically exceed 80%. If orthopaedic surgeons have their referrals triaged, their time will be freed up for patients requiring surgery, who will get faster access to the surgeon. Patients not needing surgery will be managed more appropriately and quickly.

4.2.2 Review of evidence on prompt referral, GP referral and patient self-referral to physiotherapy for acute low back pain

This section considers the evidence for the effectiveness of service delivery models that target prompt physiotherapy access to patients with acute low back pain, and examines waiting times for patients self-referring to physiotherapy compared with GP referrals.

Direct access to physiotherapy within the NHS setting assumes various definitions. For the purpose of this section, a GP patient referral to physiotherapy is defined as ‘GP referral’ and differs from a ‘GP indirect referral’, where the GP refers to an orthopaedic surgeon who in turn recommends the patient for physiotherapy. Patient direct access to physiotherapy is cited as ‘self-referral’.

Study selection

A search of the bibliographic databases identified 305 titles and abstracts, from which 22 items were selected and full reports ordered (kappa=0.59). A re-run of the search in June 2007 identified one new paper. Studies reporting on the effectiveness of prompt access, GP referral and patient self-referral to physiotherapy were selected. Studies focusing on specific diseases or aetologies, such as cancer, osteoporosis, pregnancy or sports injuries, were excluded, as were those comparing direct and indirect GP referrals. A flow chart representing the selection of literature from title and abstract identification to the inclusion of full report is presented in Appendix 5.1.

All 22 full reports were available; eight met the selection criteria with the remaining 15 being excluded for the reasons outlined in Appendix 5.2.

Assessment of the evidence

The eight selected reports included:

- two observational cohort studies comparing self-referral to physiotherapy with GP referral, for any condition (Holdsworth et al., 2006a; Holdsworth et al., 2006b; Holdsworth & Webster, 2004a)
- one observational study assessing prompt access to physiotherapy via GP referral for a new episode of low back pain (within 72 hours) to a practice-based physiotherapy back pain clinic within primary care (Pinnington et al., 2004; Stanley et al., 2001)
- two RCTs of early physiotherapy intervention for patients with acute low back pain (<6 weeks) (Wand et al., 2004) and low back pain of duration 3–12 weeks (Nordeman et al., 2006), respectively
- one retrospective study assessing the effectiveness of early physical therapy in the treatment of acute low back pain for workers with lumbarsprain of moderate severity, based on a subjective pain scale (Zigenfus et al., 2000).

A summary of the data extracted from each of these papers is presented in Table 4-2.
Table 4-2 Evidence on the clinical effectiveness of prompt referral, GP referral and patient self-referral to physiotherapy

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Results</th>
<th>Additional comments</th>
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<tbody>
<tr>
<td>(Holdsworth &amp; Webster, 2004a)</td>
<td>Observational pilot study in semi-urban primary care, Scotland, 1999–2000. Population 34,000 5-month pilot, followed by 1-year data collection period</td>
<td>340 GP referrals. 92% of conditions musculoskeletal in origin.</td>
<td>GP and self-referrals. Advertised in practice over a 3-month period. Initial appointment allocated on receipt of written GP referral or in response to direct approach by patient.</td>
<td>All GP referrals (339) to physiotherapy in the year prior to introduction of self-referral (1998–1999).</td>
<td>All conditions: Self-referrals - 76 (22.4%) GP referrals - 264 (77.6%) Referral rate - 10 per 1,000 Low back pain: Self-referrals - 35 (46%) GP referrals - 86 (33%) Waiting times: Self-referrals - median 5 days, range 1–21 GP referrals - median 9 days, range 1–31</td>
<td>Waiting time: date of referral to first physiotherapist contact. No advantage in terms of waiting time was afforded to either group. Authors suggest difference in waiting times due to administration differences.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom duration</th>
<th>Self-referral</th>
<th>GP referral</th>
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<tbody>
<tr>
<td>&lt;10 days</td>
<td>12%</td>
<td>1%</td>
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<tr>
<td>11–28 days</td>
<td>20%</td>
<td>2%</td>
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<tr>
<td>1–3 days</td>
<td>34%</td>
<td>6%</td>
</tr>
<tr>
<td>&gt;3 months</td>
<td>34%</td>
<td>91%</td>
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<tr>
<td>Work absence</td>
<td>43 (7%)</td>
<td>107 (42%)</td>
</tr>
</tbody>
</table>

(57% employed) (41% employed)
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<tr>
<th>Citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Results</th>
<th>Additional comments</th>
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</thead>
<tbody>
<tr>
<td>(Holdsworth et al., 2006a)</td>
<td>Observational study</td>
<td>3010 patients &gt;16 years, referred to 100 physiotherapists. Practices defined as: 46% urban, 35% semi-rural and 20% rural. Data for 26 practices included in the analyses.</td>
<td>Self-referral to physiotherapy.</td>
<td>GP written referral. GP suggested referral, i.e. indicated that patient should refer themselves.</td>
<td>GP referrals: 61% Self-referrals: 22% GP suggested referrals: 18% Waiting times (approximately 10% missing data)</td>
<td>Appointment allocation determined locally, but did not advantage self-referrals over GP referrals. No information provided on condition.</td>
</tr>
<tr>
<td>(Holdsworth et al., 2006b)</td>
<td>Observational study of 29 general practices, across a range of geographic and socioeconomic settings in Scotland. Population 163,608. 2–3 month run in, followed by 1-year data collection period</td>
<td>Population 163,608</td>
<td>Self-referral</td>
<td>GP referred</td>
<td>GP suggested</td>
<td>Self-referral</td>
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<td></td>
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<td>Self-referral</td>
<td>GP referred</td>
<td>GP suggested</td>
<td>&lt;2 weeks</td>
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<td>2–4 weeks</td>
<td>15%</td>
<td>22%</td>
<td>16%</td>
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<td>4–12 weeks</td>
<td>37%</td>
<td>38%</td>
<td>46%</td>
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<td></td>
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<td></td>
<td>&gt;12 weeks</td>
<td>5%</td>
<td>6%</td>
<td>4%</td>
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<td></td>
<td></td>
<td>Median (days)</td>
<td>19</td>
<td>23</td>
<td>32</td>
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<td></td>
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<td></td>
<td>Range</td>
<td>0–146</td>
<td>0–235</td>
<td>0–153</td>
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<tr>
<td></td>
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<td>Different referrals rates according to setting (p&lt;0.001)</td>
<td>Urban 41% (1,237) 23% (286) 51% (625) 26% (321)</td>
<td>Semi-rural 45% (1,332) 19% (248) 75% (985) 7% (83)</td>
<td>Rural 15% (441) 26% (114) 43% (185) 32% (138)</td>
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<td></td>
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<td>Different referral rates according to DEPCAT socio-economic group (p&lt;0.001).</td>
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<td>Citation</td>
<td>Study type</td>
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<tr>
<td>(Pinnington et al., 2004)</td>
<td>Observational cohort study of 5</td>
<td>614 patients (18–65 years) with a new episode of LBP presenting to GP (first recorded</td>
<td>Visit to GP, issuing information pack (including The Back Book), referral to</td>
<td>No control.</td>
<td>614 (3.2% of population) referred to PBBPC 522 (85%) attended, 92 (15%) failed to attend.</td>
<td>Functional impairment and pain, no CI or SD presented.</td>
</tr>
<tr>
<td>(Stanley et al., 2001)</td>
<td>practice-based GP/physiotherapy</td>
<td>practice-based back pain clinic (PBBPC)</td>
<td>PBBPC and appointment within 72 hours of GP referral.</td>
<td></td>
<td>Time from referral to appointment: mean 4 days, median 3 days.</td>
<td>&lt;50% thought to be presenting to their GP with LBP were</td>
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<tr>
<td>clinics</td>
<td>Catchment population 19,200</td>
<td>Mean age 42 years (SD=12); 49% female; 72% employed. Patients with red flag signs or</td>
<td>Physiotherapy intervention: assessment; biopsychosocial approach based on</td>
<td></td>
<td>62% (322) seen within 72 hours. 85% within 4 days.</td>
<td>referred to the PBBPC.</td>
</tr>
<tr>
<td>17 GPs, five research assistants and five research physiotherapists</td>
<td>1-year recruitment period. Follow up</td>
<td>symptoms excluded.</td>
<td>McKenzie principles; explanation; conforming to Clinical Standards Advisory</td>
<td></td>
<td>Number of visits: 72% of patients one visit; 16% two visits; 7% three visits; 4% four visits; 1%</td>
<td>No information about administrative resources available.</td>
</tr>
<tr>
<td>12 weeks after discharge from practice based back pain clinic (PBBPC)</td>
<td>12 weeks after discharge from</td>
<td>1-year recruitment period. Follow up 12 weeks after discharge from practice based back</td>
<td>group (CSAG) treatment; advice to encourage activity.</td>
<td></td>
<td>five visits; &lt;1% six visits. Physiotherapist time per patient episode 47 mins (SD 13 minutes).</td>
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<td></td>
<td>practice based back pain clinic</td>
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<td>Mean reduction 3 months from presentation in:</td>
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<td></td>
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<td>RMDQ functional impairment 7 (p=0.0001)</td>
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<td>Interval pain scale (no details provided) 2.5 point reduction (p=0.0001)</td>
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<td>SF36 improvement at follow up (p&lt;0.05) in bodily pain, physical role and social</td>
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<td>SF36 improvement at follow up (p&lt;0.05) in bodily pain, physical role and social and physical</td>
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<td>and physical functioning.</td>
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<td>functioning.</td>
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<td>Time off work for 378 working patients: 199 (53%) no time off work 179 patients</td>
<td></td>
<td>Time off work for 378 working patients: 199 (53%) no time off work 109 (62%) off &lt;1 week; 35 (19%)</td>
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<td>taking time off work; 109 (62%) off &lt;1 week; 35 (19%) off 1–2 weeks; 31</td>
<td></td>
<td>off 1–2 weeks; 31 (17%) off 2–4 weeks; 4 (2%) off &gt;1 month.</td>
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<td>(9%) CI: 7.1–9.9%) had GP visit with new episode in the year prior to the study.</td>
<td></td>
<td>8.5% (95%CI: 7.1–9.9%) had GP visit with new episode in the year prior to the study.</td>
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<tr>
<td>Citation</td>
<td>Study type</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
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<tr>
<td>(Wand et al., 2004)</td>
<td>RCT (single blind) study of patients attending a hospital physiotherapy outpatient department London, UK</td>
<td>Follow-up at 6 weeks, 3 and 6 months</td>
<td>Assess/advise/treat (AAT), 50 patients. Advise: advice to stay active and copy of The Back Book. Treat: physiotherapy commenced at baseline using biopsychosocial approach. Follow-up (number of patients): short-term 35 long-term 30.</td>
<td>Assess/advise/wait (AAW), 52 patients. Advise: advice to stay active and copy of The Back Book. Wait: physiotherapy commenced at 6 weeks using biopsychosocial approach. Follow-up (number of patients): short-term 30 long-term 33.</td>
<td>Primary outcome variable: RMDQ sample size of 49 per group required to detect four point difference between groups, (SD of six points). At 6 weeks: Significant difference between groups favouring AAT (p&lt;0.05) on: STAI, RMDQ, MZSRDS, EuroQol Total Score, EuroQol Health Thermometer, and SF-36 vitality, social functioning and mental health scores. AAT group reported significantly lower disability, fewer depression and anxiety symptoms and better quality of life, vitality, social functioning and mental health. Long-term follow-up: Significant difference between groups favouring AAT (p&lt;0.05) on: STAI, MZSRDS, EuroQol Health Thermometer, and SF-36 emotional role, mental health and health transition scores. AAT group reported fewer depression, somatic distress and anxiety symptoms, better quality of life and mental health and reported less interference of emotional problems with everyday activities. 41% of baseline patients assessed as at risk for depression or distressed-depressive. 31% demonstrated risk of long-term work loss by acute LBP screening questionnaire.</td>
<td>74% of referred patients fell outside the criteria for simple acute LBP. The treatment population might not be comparable to that from which the evidence base is derived. Concludes further research is needed to fully clarify the role of early intervention.</td>
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<tr>
<td>Citation</td>
<td>Study type</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Results</td>
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<td>(Nordeman et al., 2006)</td>
<td>Prospective RCT, Sweden, 2002–2003.</td>
<td>58 physiotherapy patients from Alingsas County (mixed urban and rural), with low back pain of 3–12 weeks duration. Age 18–65 (mean 39). 26 male; 34 female.</td>
<td>Physiotherapy within 2 days of referral.</td>
<td>Physiotherapy 4 weeks after referral.</td>
<td>No statistically significant differences in pain intensity or disability at discharge. Change in Borg pain intensity at 6 months (p=0.06), mean (SD): early access -3.0 (1.7); control -2.0 (2.2). Change in OMPSQ risk of long-term disability at 6 months (p=0.41), mean (SD): early access -26.5 (31.1); control -20.2 (23.4). Change in RMDQ at 6 months (p=0.48), mean (SD): early access -6.3 (5.3); control -5.3 (5.6). Change in sick leave at 6 months (p=0.13), mean (SD): early access 0.7 (1.8); control 0.0 (2.2). There were no significant differences in treatments used or number of sessions.</td>
<td>Study only powered to detect differences in Borg categorical scale of perceived pain; not RMDQ, nor Orebro musculoskeletal pain screening questionnaire for assessing the risk of long-term pain and disability. Baseline differences in duration of symptoms, with control group greater. This was analysed as a covariate.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study type</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
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<td>(Zigenlus et al., 2000)</td>
<td>Retrospective case controlled study, cohorts from an occupational healthcare provider, Concentra Managed Care Inc, USA</td>
<td>Total of 3,867 workers with new acute LBP (&lt; 3 weeks) in primary care. Moderate severity lumbar sprain cases, rating based on a subjective pain scale. Group 1: 1,379, Group 2: 2,005, Group 3: 483.</td>
<td>Group 1: physiotherapy 0–1 day after injury. Physiotherapy defined as non-specific.</td>
<td>Group 2: physiotherapy 2–7 days after injury. Group 3: physiotherapy 8–197 days after injury. Physiotherapy defined as non-specific.</td>
<td>Physician visits (p&lt;0.01): Group 1 = 3.1±1.4; Group 2 = 3.4±1.5; Group 3 = 3.9±1.7. Case duration (days) (p&lt;0.01): Group 1 = 9.8±8.6; Group 2 = 12.3±11.9; Group 3 = 16.5±14.5. Duration (days) of restricted work (p&lt;0.01): Group 1 = 8.1±7.2; Group 2 = 9.9±8.3; Group 3 = 13.4±12.7. Days away from work (p&lt;0.05): Group 1 = 4.5±3.8; Group 2 = 5.2±4.5; Group 3 = 7.0±6.1.</td>
<td>Group 1 had more male patients (p&lt;0.001), a higher proportion of patients under 30 and a low proportion over 40 (p&lt;0.05).</td>
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</tbody>
</table>
Clinical effectiveness of service delivery models which deliver prompt access to physiotherapy

Four reports assessed the implication of prompt patient access to physiotherapy. Pinnington et al. (2004) evaluated access to physiotherapy within 72 hours in a primary care back pain clinic, for new episodes of low back pain seen by a GP. Back pain clinics were held in a group of demographically representative GP practices and staffed by a physiotherapist. The booking of physiotherapy appointments for GP referrals was streamlined and patients left the practice knowing their physiotherapy appointment. A median waiting time of 3 days was reported. The authors reported a statistically significant improvement between the first appointment and 3 months post-discharge in: functional impairment, pain scores, and in SF-36 bodily pain, physical role, social and physical functioning dimensions. The main limitation of the study was the absence of a comparator arm to assess the outcomes for patients who did not receive a physiotherapy referral within 72 hours.

Wand et al. (2004) assessed the effect of timing of physical intervention on the management of acute low back pain. The two patient groups ‘Assess/Advise/Treat’ and ‘Assess/Advise/Wait’ were similar in respect to the ‘Assess/Advise’ component, but differed with respect to timing of treatment, with the latter group receiving treatment 6 weeks after the former. This study examined the impact of the timing of early intervention, once the patient reached the outpatient physiotherapy clinic, but did not consider the potential for early intervention during the time from GP referral to physiotherapy appointment. Of the 804 referred patients, 46% were excluded as they had low back pain for longer than 6 weeks by the time of the physiotherapy appointment. Whether these patients would have been study candidates had access been more rapid is unknown. The study indicated that neither the primary disability outcome (Roland Morris disability Questionnaire [RMDQ]) or pain (Visual Analogue Scale [VAS]) scores were significantly different between the groups at long-term follow-up, concluding that these parameters were unaffected by the choice of treatment model. The limitations of this study were that:

- at 3 and 6 months the number of patients fell short of the sample size required to have sufficient power to detect the predefined, clinically relevant difference in the disability measure.
- long-term follow-up estimates were derived from available data at 3 and 6 months, however, the method used was not specified. This has implications as these repeated observations are not independent.
- the authors concluded that there was no difference in long-term VAS pain scores between groups, however the study was not powered to detect such differences.
- patients referred with back pain of greater than 42 days duration were included in the study. It is unclear whether the potential baseline variability in duration of low back pain, ie 0–42 days, was taken into account with respect to analysis of intervention timing.

A Swedish RCT in patients with low back pain of duration 3–12 weeks compared early access physiotherapy (defined as within 2 days of referral) with a control group that had a waiting time of 4 weeks to referral (Nordeman et al., 2006). Although no difference between groups was noted at discharge, a larger reduction in pain intensity was observed in the early access group at 6 months follow-up. The authors suggested that this effect was due to initiating treatment in the period when patients were highly motivated, receptive to advice on self-care, and less likely to exhibit fear-avoidance behaviour. The study was limited by its small size, and consequent lack of power to detect differences in secondary outcome measures.

A retrospective study (Zigenfus et al., 2000) evaluated the impact of time to physiotherapy intervention (0–1 days, 2–7 days, 8–197 days), due to lumbar sprain injury, for patients with acute low back pain in the occupational health setting. The study showed that initiating physiotherapy early was associated with fewer physician visits, earlier discharge from care, fewer restricted workdays and fewer days away from work. The study also reported that the shorter the delay to physiotherapy: the fewer physician visits, the shorter the case duration and the faster patients returned to work at full capacity. The limitations of this study included:

- the inability to draw definitive conclusions regarding the causal relationship between the timing of physiotherapy and treatment outcomes due to its retrospective nature. The authors acknowledged this and noted that it is conceivable that the relationships observed may be due to other factors.
- the 8–197 day time interval does not facilitate assessment of the impact of early access to physiotherapy for patients with acute (less than 3 months) low back pain.

The studies highlight differences with respect to the definition of baseline when measuring the time to physiotherapy intervention: Pinnington et al. (2004) assumed baseline to be the day of GP referral, Zigenfus et al. (2000) assumed baseline as prior to injury, Nordeman et al. (2006) described a self-referral system taking the date the physiotherapy appointment was made as baseline, and Wand et al. (2004) used the day prior to the date of the physiotherapy outpatient appointment, which could be up to 42 days post-onset of acute low back pain.

As time from onset of episode is not the standard outcome measure, there is an inherent assumption that all patients were still in the acute phase of back pain during these studies. This may not be the case if the period between onset of the episode and the day of GP referral, or physiotherapist visit was greater than 12 weeks. The impact of the variability in the timing between onset of the episode and GP or physiotherapist visit was not considered in this assessment.

In the Pinnington et al. (2004) and Zigenfus et al. (2000) studies, early access to physiotherapy was defined as 0–3 days and in the Nordeman et al. (2006) study 0–2 days; whereas in the Wand et al. (2004) study, all patients had...
experienced low back pain for less than 6 weeks. No information is provided regarding the variability in duration of low back pain or how such variability was handled in the analyses. Patients with an outpatient visit to physiotherapy occurring later than 42 days from onset of low back pain (46% of patients) were excluded from the study. This implies that 46% of patients may have been denied the opportunity to benefit from an early physiotherapy intervention.

Comparison of physiotherapy waiting times for self-referred and GP referred patients

Three reports were included in this assessment. The two observational studies assessed the impact of self-referral to physiotherapy compared with GP referral in the primary care setting, but were not specific to low back pain (Holdsworth et al., 2006b; Holdsworth & Webster, 2004a). A pilot study, involving one general practice, (Holdsworth & Webster, 2004a) reported a median waiting time of 5 days (range 1 – 21 days) for self-referring patients compared with 9 days (range 1 – 31 days) for GP referred patients; suggesting that access to physiotherapy was more rapid for patients who self-refer. The authors defined waiting time as being from the date of referral to the first physiotherapy contact and indicated that no advantage in terms of waiting time to physiotherapy was afforded to either group.

Although patients who selfREFER have a shorter median physiotherapy waiting time, the authors report that this difference could be attributable to the decreased administrative time associated with registering and issuing a self-referral appointment. The self-referred patient either presents in person or telephones the unit, offering the opportunity to arrange a mutually acceptable appointment time. For GP referrals, in all but urgent cases, the GP initiates the request for physiotherapy by completing a written form, which needs to be taken to the individual responsible for appointment allocation. The appointment must then be posted to the patient. The authors note that it may have been more equitable to encourage GP referred patients to arrange their own physiotherapy appointments to bypass the administrative process.

In their follow-up study involving 29 geographically and socioeconomically diverse general practices throughout Scotland, Holdsworth et al. (2006a) report a median waiting time of 19 days (range 0 – 146) for self-referring patients, 23 days (range 0 – 235) for GP referrals and 32 days (range 0 – 153) for the ‘GP suggested’ referral group.

The evidence shows a larger median waiting time for GP referred patients compared with self-referred patients, however, as Holdsworth & Webster (2004a) acknowledged in their pilot study, waiting times differences may be attributable to inequities in the appointment administrative system. In this larger study, the appointment system was not standardised and the impact of that inequity and variability in administrative processes might have on differences in waiting time were not explored (Holdsworth et al., 2006a). The limitations of these studies include:

- an imbalance in baseline patient characteristics in the absence of randomisation, eg in the pilot study 91% of the GP referral group had a symptom duration of more than 3 months compared with 34% in the self-referral group (Holdsworth & Webster, 2004a).
- the studies were not specific to patients presenting with low back pain, raising uncertainty as to whether the results can be extrapolated to this group.
- the absence of information regarding the use of low back pain protocols and the impact these may have on prompt access to physiotherapy.
- the results may not be fully representative of Scottish practices. The pilot study involved only one general practice and observed waiting times could be attributable to an adequate staff: patient ratio.
- no consideration was given to the period between time of onset of acute low back pain and the day of referral, as waiting times were measured relative to either the day of GP referral or day of self-referral. The impact of this period on waiting times is unknown.

4.2.2.1 Conclusions

There is evidence from one study that access to physiotherapy within a GP practice setting can be achieved within 3 – 4 days, from the point of referral for the new episode of acute low back pain. This timeframe is conditional on the appropriate resources being available and an efficient appointment booking system. There is limited weak evidence from the same study that prompt access to physiotherapy within 72 hours improves outcome at 3 months for patients presenting with a new episode of acute low back pain. There is limited evidence, from the occupational health setting, that initiating physiotherapy early (0 – 7 days after injury) is associated with fewer physician visits, earlier discharge from care, fewer restricted workdays and fewer days away from work. There is limited good evidence that the Assess/Advise/Treat approach for patients with acute back pain of onset more than 42 days is more effective than Assess/Advise/Wait, when considering disability and some dimensions of health-related quality of life, but not pain at 6 weeks. The evidence is inconclusive as to whether the benefits of the Assess/Advise/Treat strategy are sustained at 6 months.

Noting the above limitations, the evidence indicates that patients referred to a physiotherapist by a GP in Scotland can have a longer waiting time than self-referring patients.

4.2.3 Review of evidence on whether feedback on inappropriate referrals affects referral patterns

GP adherence to evidence-based guidelines on the management of low back pain should reduce the number of inappropriate referrals to secondary care. Whilst acknowledging that there are various barriers preventing GPs from fully adhering to guidelines (as discussed in Section ), this section investigates the evidence that audit and feedback encourage guideline compliance and hence more appropriate referral of patients with low back pain.
4.2.3.1 Study selection

A search of the bibliographic databases identified 106 titles and abstracts of potential relevance. Four records were selected (kappa = 0.58) and full reports ordered. Studies comparing GP referral practice for patients with acute or chronic low back pain before or after feedback, or between groups of GPs receiving or not receiving feedback were included. An inappropriate referral was defined as one that was inconsistent with treatment guidelines.

A flow chart representing the selection of literature from title and abstract identification to inclusion of the full reports is presented in Appendix 6.1.

All four full reports were available and two met the inclusion criteria (Kerry et al., 2000b; Schectman et al., 2003). The other two were Cochrane systematic reviews (Jamtvedt et al., 2006; Grimshaw et al., 2005); which did not meet the inclusion criteria for the reasons outlined in Appendix 6.2, but were used to provide supporting information.

Four additional potentially relevant reports (Grimshaw et al., 2004; Eccles et al., 2001; Garala et al., 1999; Freeborn et al., 1997) were identified through the reference lists of the selected reports and from other questions considered in this HTA. Grimshaw et al. (2004) did not meet the inclusion criteria as shown in Appendix 6.2, but was used to provide additional information.

4.2.3.2 Assessment of the evidence

The five included studies comprised three RCTs (Schectman et al., 2003; Eccles et al., 2001; Kerry et al., 2000b), one controlled clinical trial (CCT) (Freeborn et al., 1997) and one observational study (Garala et al., 1999). The Schectman et al. (2003) study was limited to patients with acute low back pain, whereas the others included all back pain patients irrespective of the duration or nature of their symptoms. Three studies were conducted in the UK and two in the USA. Four studies (Eccles et al., 2001; Kerry et al., 2000b; Garala et al., 1999; Freeborn et al., 1997) considered referral for radiological examination only. A summary of the data extracted from these papers is presented in Table 4-3.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study setting</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Kerry et al., 2000b)</td>
<td>RCT in general practice in Diagnostic Radiology, St George's Healthcare Trust, London, UK, 1995. Follow-up 6 months post-guideline implementation</td>
<td>69 practices/175 GPs referring more than 50 patients in a 6-month period in 1993.</td>
<td>Intervention: 33 practices, 84 GPs. RCR guidelines and individual feedback consisting of: comparison of X-rays ordered by practices in the 6-month period February-August 1995, after guideline introduction vs. the same 6-month period in the previous year. Feedback issued in November 1995 with updated guidelines.</td>
<td>Control: 36 practices, 91 GPs. Guidelines issued at the end of the study period. End of study undefined.</td>
<td>Lumbar spine X-rays. Comparison from February 1995–January 1996 vs. February 1994–January 1995. Intervention: 15% reduction in X-ray requests Control: 5% increase in X-ray requests Difference: 20% (95% CI: 3, 37).</td>
<td>Randomisation at practice level; stratified by number of partners, referral rate, fundholding status and having previously received guidelines. Outcome of number of X-rays used, does not necessarily reflect quality of individual decision making. Only absolute number of X-rays ordered was recorded. No consideration given to the ratio of X-rays to the number of patients.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study setting</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Results</td>
<td>Additional comments</td>
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<tr>
<td>(Schectman et al., 2003)</td>
<td>RCT Washington DC, USA</td>
<td>14 practice sites, 106 clinicians, acute back pain patients. Group practice sites affiliated with two not-for-profit group model Health Maintenance Organisations (HMOs). Clinicians comprised: internists, family physicians, nurse practitioners and physician assistants. Baseline year: July 1993–June 1994. Study year: August 1994–July 1995.</td>
<td>Physician guideline implementation: education and feedback* supporting guidelines; patient education materials consistent with guidelines; both forms of feedback. *Feedback as audit report on adherence to guidelines during the baseline period and another 6 months into the study year. No physician education and feedback, or patient education materials.</td>
<td>Utilisation (within the 3-month period after the patient visit). Guideline consistent behaviour increased by 5.4% for intervention group vs. a 2.7% decline in the control group (p&lt;0.046). Not consistent with guideline (% of patients based on episode of care)</td>
<td>Intervention and control groups were demographically similar, however there appeared to be greater resource utilisation in the intervention group at baseline compared with the control group - possibly a more severe case mix. Intervention effect size did not diminish after clinical covariate adjustments. Regression to mean possible explanation for reduced utilisation.</td>
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### Physician education and feedback:

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Study period</th>
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<tbody>
<tr>
<td>X-ray</td>
<td>14.5%</td>
<td>8.1%</td>
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<tr>
<td>Physiotherapist referral</td>
<td>10.0%</td>
<td>9.2%</td>
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<tr>
<td>CT or MRI</td>
<td>5.7%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Speciality referral</td>
<td>9.5%</td>
<td>8.6%</td>
</tr>
<tr>
<td>≥1 of above</td>
<td>29.9%</td>
<td>21.2%</td>
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</table>

### Control group:

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Study period</th>
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<tbody>
<tr>
<td>X-rays</td>
<td>8.2%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Physiotherapist referral</td>
<td>10.9%</td>
<td>12.0%</td>
</tr>
<tr>
<td>CT or MRI</td>
<td>3.5%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Speciality referral</td>
<td>4.0%</td>
<td>5.6%</td>
</tr>
<tr>
<td>≥1 of above</td>
<td>21.5%</td>
<td>24.3%</td>
</tr>
<tr>
<td>Citation</td>
<td>Study setting</td>
<td>Patient characteristics</td>
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<tr>
<td>(Freeborn et al., 1997)</td>
<td>CCT HMO, Kaiser Permanente Northwest Region, USA</td>
<td>Guideline-only phase for 4 months, then first feedback report. Two more feedback reports at 2-monthly intervals and behaviour tracked for 2 months after final feedback</td>
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<tr>
<td>Citation</td>
<td>Study setting</td>
<td>Patient characteristics</td>
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<td>--------------------------</td>
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<tr>
<td></td>
<td>Pre-intervention period: 12 months Post-intervention period: 12 months (2 years total)</td>
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<tr>
<td>Citation</td>
<td>Study setting</td>
<td>Patient characteristics</td>
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<tr>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(Garala et al., 1999)</td>
<td>Retrospective audit followed by prospective audit Coventry, UK 3-month retrospective audit and then 3-month prospective audit following intervention</td>
<td>8 general practices completed retrospective audit, 86 patients analysed. Prospective audit; 7 practices. 5 practices participated in both audits. Number of patients included in both retrospective and prospective audits not specified.</td>
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</table>
In the study by Eccles et al. (2001), 247 GP practices in Scotland and north-east England were issued with a locally adapted version of the Royal College of Radiologists’ (RCR) guidelines and the Royal College of General Practitioners’ back pain guidelines. Practices were then randomised to receive: audit and feedback; educational reminder messages; audit, feedback and educational reminders; or no intervention. Feedback was given on the number of lumbar spine X-rays for the practice compared with requests made by all GPs in the study. The educational reminder stated that ‘in either acute (less than 6 weeks) or chronic pain, without adverse features, radiograph is not routinely indicated’ and was attached to the report of every lumbar spine radiograph. The relative risk reductions for audit and feedback and educational reminder messages were approximately 0% and 20%, respectively, when compared with the control. No significant differences in concordance with the guidelines were observed between those receiving audit and feedback or educational reminder messages.

Kerry et al. (2000b) considered the number of X-rays requested in patients referred to St George’s Healthcare Trust, London, in the year preceding and the year following the introduction of a locally produced version of the RCR radiological referral guidelines. Thirty-three GP practices received the guidelines and individual feedback on their referral rates for the six months post-guideline receipt, and were compared with a control group of 36 practices receiving no guidelines or feedback. A 15% reduction in lumbar spine X-rays was seen over a one-year period in the group receiving guidelines and feedback compared with an increase of 5% in the control group. This resulted in a statistically significant 20% difference between groups (95% CI: 3, 37). These findings should be viewed with caution, as the study did not consider potential differences in the number of patients presenting to their GP with a lumbar spine condition in each group over the two calendar periods used for analysis.

Freeborn et al. (1997) examined whether dissemination of a locally produced clinical practice guideline alone or together with clinical practice feedback, reduced variability in request rates for lumbar spine X-rays, computed tomography (CT) and MRI scans among primary care physicians (comprising general internal medicine physicians and family practice physicians). Forty-two primary care physicians in one Health Maintenance Organisation (HMO) administrative area were sent the guidelines. After 4 months, they received a feedback report which displayed their procedure rates and the corresponding usage rates for other physicians in the study. A further two sets of feedback were given at 2-monthly intervals. A control group of 33 physicians in a second HMO administrative area were not issued with the guidelines until the end of the intervention period. No significant differences in pre- to post-intervention change were found between the two groups when considering the number of tests per 1,000 visits in patients aged ≥18 years. These results must, however, be interpreted in the light of confounding effects between the intervention and administrative areas. All physicians in one area received the intervention whereas those in the other, administratively distinct area, did not. As the guidelines used by the intervention group were developed by specialists in that group, it is possible that the process of guideline development may have influenced practices during the pre-intervention period in those testing the guidelines.

The observational study by Garala et al. (1999) comprised a retrospective audit of the number of lumbar X-rays requested in the 3-month period prior to the issue of RCR summary guidelines to GPs in Coventry, followed by a prospective audit of the impact of the guidelines in conjunction with feedback of the previous audit findings over a period of 3 months. Results for both audits were obtained for five GP practices. A 61% reduction in the total number of X-rays ordered was observed between the first and second audits. In addition, there was a 14% increase in the number of patients experiencing a change in their clinical management. As with the Kerry et al. (2000b) study, only the absolute number of X-rays ordered was reported, and consideration was not given to potential differences in practice size or in the number of patients presenting to the practice with a lumbar spine condition during the two audit periods.

The Schectman et al. study (2003) differed in that it examined audit and feedback in combination with physician education, and included referral for specialist care (neurosurgery, orthopaedic, rheumatology, spine centre), physical therapy and radiological assessment. A total of 116 clinicians (14 practices) in Washington DC were stratified by practice affiliation (academic or non-academic) and randomised to receive: physician education and feedback supporting the guidelines, patient educational materials consistent with the guidelines, both interventions, or neither intervention.

A 5.4% increase in guideline-consistent behaviour was observed in physicians receiving education and feedback, compared with a 2.7% decline in the no intervention group (p=0.046). The authors concluded that using clinician education and feedback produced a modest improvement in referral behaviour. They noted, however, that these effects may be partly accounted for by regression to the mean during the study year and resource utilisation baseline differences between intervention and control groups.

Assessing the appropriateness of referrals provides better information than simply citing the change in numbers, as it indicates the quality of the physicians’ decision making. Schectman et al. (2003) and Eccles et al. (2001) considered whether referrals were consistent with guidelines issued to physicians. The other three studies (Kerry et al., 2000b; Garala et al., 1999; Freeborn et al., 1997) reported only changes in the number of radiological referrals.

Two systematic reviews and one HTA identified by literature searches did not meet the inclusion criteria, as they did not specifically consider back pain patients. However, their findings were assessed to determine how back pain data compare with the wider literature. In a review of RCTs, Jamtvedt et al. (2006) found that audit and feedback can effect improvements in patient care practices, however, the magnitude of these changes is
usually small. The largest effects were seen when baseline compliance with best practice was low and when intensive feedback was provided. The review by Grimshaw et al. (2005) investigated interventions designed to improve referral from primary to secondary care. The study included only one controlled trial considering feedback and found no significant improvement in the resulting referral rates. The HTA by Grimshaw et al. (2004) examined different guideline dissemination and implementation strategies, and identified 12 studies evaluating the effects of audit and feedback. The authors concluded that feedback may have a small effect on guideline implementation.

4.2.3.3 Conclusions

All the studies providing evidence concerning feedback to GPs about inappropriate referrals for low back pain focused on radiological referrals, with only one (Schectman et al., 2003) also considering specialist referral. Given that this study was conducted in the USA under a very different health system, the results are of limited relevance to NHS Scotland.

Regarding feedback on radiological referrals, of the two UK RCTs, one (Kerry et al., 2000b) showed a reduction in the number of lumbar X-ray requests after audit and feedback whereas the other (Eccles et al., 2001) showed no effect. The findings of the latter study can be viewed with greater confidence as the results were presented in terms of the number of radiograph requests per 1,000 patients rather than the absolute number. The audit by Garala et al. (1999) reported a reduction in number of referrals after feedback, but also suffered from the limitation of only reporting absolute numbers of radiograph requests. The Eccles et al. study (2001) did identify significant benefit associated with the use of educational reminder messages attached to X-ray reports.

The findings from the two studies conducted in the US are of limited relevance to NHS Scotland. Freeborn et al. (1997) found no effect for feedback on referral rates, however, these findings must be interpreted in the light of confounding effects apparent in this study. While the Schechtman et al. study (2003) provides more robust evidence, it is not possible to determine how much of the modest improvement in guideline consistent referral rates was specifically due to audit and feedback.

Given the limited quantity and quality of the evidence, providing feedback appears to make little difference to the number of X-rays requested by their appropriateness, although educational reminders may have more impact. This assertion is consistent with the evidence from a wider systematic review, which shows a limited effect of audit and feedback on referral practice.

4.2.4 Review of evidence on referral authority of physiotherapists

There is variation in the level of authority attributed to physiotherapists, in terms of referring to an ESP physiotherapist or to a consultant. The lack of referral authority may: increase patient waiting times for an ESP or consultant referral, affect patient outcome, and undermine the physiotherapist’s judgement. This section examines the clinical effectiveness of physiotherapists having referral authority to consultant services and/or ESPs, compared with restricted referral authority to the GP only.

4.2.4.1 Study selection

A flow chart representing the selection of literature from title and abstract identification to the inclusion of full reports is presented in Appendix 7.1.

From the 4,433 titles and abstracts, five papers of potential relevance were selected (kappa =0.47) and the full reports ordered. All five reports were available, but none met the inclusion criteria; the reasons for exclusion are outlined in Appendix 7.2.

4.2.4.2 Assessment of the evidence

Given the lack of published literature, data were sought from within the service to allow this question to be addressed. Physiotherapists within GGBPS can refer patients directly to spine surgeons. An audit was undertaken in 2005 (Baxter) to review the appropriateness of referrals made by GGBPS physiotherapists, with results being available for 53 of the 72 patients referred in 2003. Of these, six patients did not attend or cancelled their appointment, three were still awaiting consultation, two were added directly to surgical waiting lists based on imaging results and for one patient data were missing. Of the remaining 41 patients, 27 were diagnosed as having a prolapsed disc or major condition that required scanning and surgery. The audit report stated that while the other 14 patients were unsuitable for surgery, they presented with extensive symptoms and pain that warranted further investigation. It must be noted that only patients referred to spinal surgeons were included in the audit and no information is provided on the vast majority of GGBPS patients not referred for surgery.

4.2.4.3 Conclusions

The lack of literature addressing this issue might be partly because referral by physiotherapists to ESPs or consultants forms only one aspect of back pain management, and most studies in this area assess the impact of overall management on patient outcome (Daker-White, 1999). Larger studies, preferably longitudinal RCTs, are required to record final management decisions for all patients managed by the physiotherapist and not only those referred to secondary care.

4.2.5 Evidence on GP and physiotherapist direct referral for MRI

Allowing GPs direct access to MRI scanning should be a consideration in the design and delivery of secondary care low back pain services. However, there is some concern that inappropriate referrals for MRI scans might occur. The evidence for GP and physiotherapist direct referrals for MRI scans is investigated in this section.
4.2.5.1 Study selection

A search of the bibliographic databases identified 256 papers of potential relevance. Studies considering adults with low back pain (acute, chronic, mixed and undefined) and excluding specific disease or aetiology populations such as cancer, osteoporosis, pregnancy, sports injuries or trauma were included. The intervention of interest was GP or physiotherapist referral for MRI scan, in a primary or secondary care setting, within the UK or other publicly funded health service. A flow chart representing the selection of literature from title and abstract identification to inclusion of the full reports is presented in Appendix 8.1.

An initial review of the titles and abstracts identified only one relevant article and this full report formed the sole evidence source for this section. A difference in interpretation of the inclusion criteria gave rise to a low inter-rater reliability (kappa=0.16) as one reviewer considered non-UK studies whereas the other did not. No unpublished data were obtained for this research question.

4.2.5.2 Assessment of the evidence

The selected paper reported on an audit of GP direct referral for MRI in Wales (Chawda et al., 1997). A summary of the data extracted from this paper is presented in evidence Table 4-4. The authors noted a similar pattern for GP and hospital outpatient doctor referrals for MRI. No information was provided regarding the stage of training or seniority of the hospital outpatient doctor. The number of referrals for MRI scan was similar between the two groups. There was a statistically significant difference in the number of MRI scans resulting in a spondylolisthesis/degeneration diagnosis, which formed a greater proportion of the GP referred MRIs. No significant differences were observed in the diagnostic rates for disc herniation (with or without symptoms), spinal stenosis, ‘normal’ and ‘other abnormalities’ (including cancer, spondylolisthesis, Scheuerman’s disease and scoliosis).

The mean waiting time for an MRI appointment was 6 days longer for patients referred by their GP, although the total wait of 19 days was still relatively short when compared with the many months wait to see an outpatient clinician. As almost 50% of patients referred for MRI by their GP were conservatively managed in primary care, the authors concluded that GP direct access to MRI shortens investigation time, potentially reduces waiting lists and allows GPs to make more informed management decisions.

This audit was undertaken from 1993–1994, prior to the advent of low back pain guidelines recommending that X-rays and MRI scans are not used for patients with simple low back pain, and the results may, therefore, not be generalisable to the current treatment setting. It is of note that 50% of patients for whom the GP ordered an MRI scan did not require secondary care follow-up, which may indicate over-utilisation of direct access MRI. Details of this study are tabulated in Table 4-4.
Table 4-4 Evidence for the clinical effectiveness of GP and physiotherapist direct referral for MRI

<table>
<thead>
<tr>
<th>Citation</th>
<th>Setting</th>
<th>Study aim</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Chawda et al., 1997)</td>
<td>Audit in Cardiff Royal Infirmary, Wales, 1993–1994.</td>
<td>Comparison of MRI referrals from GPs and hospital outpatient doctors and assessment of GP management after scan.</td>
<td>892 total referrals, 397 GP referrals with history of sciatica or suspected spinal claudication, with follow-up data (follow-up response rate 87%). Referred for MRI scan of the lumbar spine. Excluded: patients with previous surgery, chemonucleolysis or trauma and paediatric patients.</td>
<td>GP direct referral for MRI.</td>
<td>Hospital outpatient doctor referral for MRI.</td>
<td>Total referrals 457 435 MRI result Disc herniation corresponding to symptoms 39.8% 37.9% (NS) Disc herniation not corresponding to symptoms 10.1% 12.6% (NS) Spinal stenosis 4.4% 4.6% (NS) Spondylosis/degeneration 24.9% 17.7% (p&lt;0.01) Normal 12.5% 15.6% (NS) Other abnormalities 8.3% 11.5% (NS) Mean waiting time 19 days 13 days Of 397 GP referrals with follow-up data, management following scan was 50% hospital referral and 50% conservative.</td>
</tr>
</tbody>
</table>
4.2.5.3 Conclusions

The one paper (Chawda et al., 1997) providing evidence for this question concluded that it was clinically effective for GPs to have direct access to MRI of the lumbar spine, if appropriate protocols were in place. However, the findings pre-date guidelines advising against the use of MRI scans for simple low back pain and may not be relevant to current practice.

No evidence was found on the subject of physiotherapists having direct access to MRI.

4.2.6 Review of evidence on physiotherapist treatment modalities

Within Scotland, there is variability in the choice of treatment modalities used by physiotherapists for managing acute low back pain. This section examines the evidence base for the individual treatment modalities.

4.2.6.1 Study selection

A search of the bibliographic databases identified 609 papers of potential relevance. An initial review of titles and abstracts relating to secondary evidence identified two guidelines, the European guidelines for the management of acute non-specific low back pain (van Tulder et al., 2005) and the Prodigy guidelines (Prodigy, 2005), and a systematic review of conservative interventions for low back pain (Pengel et al., 2002). As these assessed the evidence for treatment modalities, no further consideration was given to the primary literature.

A flow chart representing the selection of literature from title and abstract identification to inclusion of the full reports is presented in Appendix 9.1.

4.2.6.2 Assessment of the evidence

A summary of the data extracted from these papers is presented in Table 4-5. The European guidelines for the management of acute (duration of episode less than 6 weeks) non-specific low back pain in primary care (van Tulder et al., 2005) were based on a systematic review of individual treatment modalities. Recommended treatments included giving adequate information and reassurance, with advice to stay active and keep working. If the patient was not returning to normal activities, spinal manipulation or a multidisciplinary treatment programme in an occupational setting was to be considered. The evidence was found to be insufficient or contradictory for certain treatments namely: specific exercises, back schools, behavioural therapy, massage and TENS. Bed rest and traction were advised against.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Results</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Pengel et al., 2002)</td>
<td>Systematic review of RCTs</td>
<td>Subacute LBP. Duration of symptoms broadened to include 1 week–6 months.</td>
<td>Conservative treatment.</td>
<td>Authors concluded that little research has been directed at the identification of effective treatments for subacute LBP. Studies lack a uniform definition of subacute LBP. No evidence of high internal validity was seen for the strict definition of subacute back pain (6–12 weeks). Broadening the definition of duration 1 week–6 months indicated high quality evidence of effectiveness: • Manipulation improved pain and disability compared with TENS Difference in change in VAS pain score 0.5 (0.1, 1.0) and RMDQ score 1.3 (0.5, 2.0). • Manipulation improved disability compared with massage Difference in change in RMDQ score 1.5 (0.8, 2.2). • Exercise program improved disability compared with usual care Difference in change in RMDQ score 0.2 (0.1, 0.5) at 6 months; 0.3 (0.1, 0.5) at 12 months. • Wearing a corset improved disability compared with massage Difference in change in RMDQ score 0.9 (0.1, 1.6). • Co-ordination of healthcare for injured workers improved disability compared with usual care Difference in change in Oswestry score 0.4 (0.1, 0.9). • Rehabilitation with TENS improved return to work compared with rehabilitation alone Relative risk 2.0 (0.7, 5.9).</td>
<td>Quality systematic review.</td>
</tr>
<tr>
<td>(van Tulder et al., 2005)</td>
<td>European guidelines systematic review</td>
<td>Non-specific, acute LBP.</td>
<td>Treatments for acute back pain.</td>
<td>Review not restricted to RCTs and considered non-systematic reviews. Authors note that treatment recommendations are only included if there is evidence from systematic review or high quality RCTs. • <strong>Recommended initial treatments</strong> Provision of adequate information and reassurance; advised to stay active and continue normal daily activities including work if possible. • <strong>Recommended further treatments if not returning to normal activities</strong> Spinal manipulation; multidisciplinary occupational treatment programme for workers on sick leave for over 4–8 weeks. • <strong>Treatments not recommended</strong> Traction; TENS; bed rest; specific exercises; epidural steroid injections; back schools; massage therapy; behavioural therapy. • <strong>Treatments not included in guidelines</strong> acupuncture, herbal medicine, inferential therapy and heatwrap therapy.</td>
<td></td>
</tr>
<tr>
<td>Citation</td>
<td>Study type</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Results</td>
<td>Additional comments</td>
</tr>
<tr>
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</tr>
<tr>
<td>(Prodigy, 2005)</td>
<td>Prodigy guidelines</td>
<td>Simple, acute LBP</td>
<td>Treatments for acute back pain</td>
<td>No systematic review was undertaken for these modalities: &lt;br&gt;&lt;br&gt; <strong>Recommended initial treatments</strong> Educational advice including absence of serious pathology, good prognosis, no need for X-ray, remaining active; rapid return to usual activities including work.  &lt;br&gt;&lt;br&gt; <strong>Recommended</strong>¹ further treatments if adequate pain control is not achieved with analgesia when given with a psychosocial approach, available locally and of interest to patient Multidisciplinary biopsychosocial assessment; short course spinal manipulation or mobilisation; exercise therapy; back school.  &lt;br&gt;&lt;br&gt; <strong>Treatments not recommended</strong> Traction; TENS; bed rest; electrotherapy; ultrasound; interferential therapy; laser therapy; acupuncture.</td>
<td>Evidence base unclear</td>
</tr>
</tbody>
</table>
The Prodigy guidelines for the management of simple acute (less than 6 weeks) low back pain (Prodigy, 2005) was based on the European guidelines (van Tulder et al., 2005), ‘The back pain revolution’ (Waddell, 2004), and some later material (Airaksinen et al., 2005; Friedrich et al., 2005; Hay et al., 2005; Hayden et al., 2005b; Hayden et al., 2005a; Manheimer et al., 2005; Frost et al., 2004; UK BEAM Trial Team, 2004). Since the European guidelines were the principal source of evidence for the Prodigy guidelines, the two concur on the clinical effectiveness of education and reassurance, and advice to stay active and keep working. Where back pain has not resolved within 4–6 weeks, both guidelines recommend spinal manipulation or a multidisciplinary treatment programme (the latter limited in the European guidelines to the occupational setting for workers with sick leave in excess of 4–8 weeks). A biopsychosocial approach was emphasised by both guidelines. Exercise therapy was suggested in the Prodigy guidelines, without elaborating on the type of exercise, whereas the European guidelines advised against specific exercises while supporting the general principal of keeping active. The advice on back schools also differed between guidelines, with Prodigy recommending them and the European guidelines advising against (noting that they may be appropriate for the treatment of subacute or secondary prevention of chronic low back pain). The two guidelines also differed in their non-recommended treatments with overlap only for traction, TENS and bed rest. Acupuncture was not assessed in the European guidelines.

Conservative interventions for subacute low back pain (of duration 6 weeks–3 months) were examined in a systematic review of RCTs (Pengel et al., 2002). Having identified few high quality studies meeting their criteria, the authors used an alternative definition of subacute as low back pain of duration 1 week–6 months. The definition included patients with low back pain of less than 6 weeks duration and was, therefore, of interest to this HTA. The review provided evidence that: exercise programs, co-ordinated care and wearing a corset reduced disability; manipulation reduced pain and disability; and TENS in combination with rehabilitation increased return to work rate.

4.2.6.3 Conclusions

The Prodigy and European guidelines recommend the following treatment modalities for acute low back pain:

- giving adequate information and reassurance to the patient, and avoiding negative messages
- advising the patient to stay active and continue normal daily activities, including work, if possible
- referral for spinal manipulation for patients who fail to return to normal activities
- multidisciplinary treatment programmes in occupational settings for workers on sick leave for more than 4–8 weeks.

Treatments that the guidelines do not recommend for acute low back pain (either because of insufficient evidence of effectiveness, evidence of ineffectiveness or inconclusive evidence) include: traction, TENS, bed rest, specific exercises, epidural steroid injections, back schools, massage therapy, behavioural therapy, electrotherapy, ultrasound, interferential therapy, laser treatments and acupuncture.

4.2.7 Review of evidence on multidisciplinary or multifaceted approaches to rehabilitation

Multidisciplinary approaches are most commonly considered for chronic back pain patients. However, there could also be a role for multidisciplinary rehabilitation in the acute and subacute context. More particularly, given the shorter timescales involved, there is a potential to use multifaceted rehabilitation (although not necessarily multidisciplinary). A multifaceted approach which addresses psychological, social, vocational and physical problems could be used for patients not responding to first-line GP management or presenting with obvious yellow flag indicators. Given the involvement of psychosocial factors in the progression of acute to chronic low back pain (Linton, 2002), it would seem plausible that adopting a multifaceted approach to managing low back pain could limit the transition from acute to chronic pain in susceptible patients. This section, therefore, examined the evidence for multidisciplinary and multifaceted approaches to the rehabilitation of patients with acute low back pain.

4.2.7.1 Study selection

This HTA sought to assess the evidence on multidisciplinary approaches to pain management for patients with chronic low back pain. However, after an initial review of the literature followed by discussion with staff in NHSScotland, it became apparent that it would be more useful to examine the effects of multidisciplinary approaches in terms of overall patient rehabilitation rather than just pain management and to consider an acute/subacute rather than chronic population. The results and selected literature were revisited based on this revision. A Cochrane review covering the multidisciplinary literature on acute low back pain to November 2002 had already been identified (Karjalainen et al., 2003), so only literature published after this time was considered. The inclusion criteria for the later literature were widened from that of the Cochrane review to identify multifaceted and multidisciplinary interventions. A further search covered terms related to multifaceted intervention from 2002. Literature was sought on patients suffering from the current back pain episode for less than 12 weeks and receiving either a truly multidisciplinary intervention or an intervention that comprised a physical activity component together with a psychosocial component aimed at modifying behaviour. Each component was to constitute a significant aspect of the rehabilitation, and studies of interventions that were primarily physically based, but adopted cognitive principles were not included. As with the Cochrane review, only RCTs or controlled clinical trials were included. Comparators could be usual care or an intervention not adopting a multidisciplinary or multifaceted approach.

The original literature search identified 1,914 bibliographic records of potential relevance to the clinical efficacy
question on chronic pain. On revisiting the search results for literature published after November 2002 and relating to acute low back pain, a subset of 129 records were identified. Six of these records were selected (kappa=0.76) and the full text ordered. On reading the full text, three studies reported in four papers (Schiltenwolf et al., 2006; Damush et al., 2003a; Damush et al., 2003b; Gatchel et al., 2005) were considered to meet the inclusion criteria. The further literature search identified 237 papers, of which eight were selected (kappa=0.77) and the full text ordered. One study (Hay et al., 2005) was not retrieved in the original search, but met the inclusion criteria. In addition, an update of all the clinical effectiveness literature searches was undertaken in June 2007 and identified a further three studies (Anema et al., 2007; Gohner & Schlicht, 2006; Karjalainen et al., 2004) relevant to this question.

A flow chart representing the selection of literature from title and abstract identification to inclusion of the full reports is presented in Appendix 10.1 and excluded studies are detailed in Appendix 10.2.

4.2.7.2 Assessment of evidence

Secondary literature

Scoping searches had identified a relevant well-conducted Cochrane systematic review (Karjalainen et al., 2003). This review included RCTs or controlled clinical trials of multidisciplinary rehabilitation in employed, working-age adults with back pain of 4 weeks–3 months duration, excluding that of neurological origin or due to trauma. The multidisciplinary programme was to include physician consultation plus a psychological, social or vocational intervention, or a combination of these. Despite the postulated importance of early intervention in back pain only two relevant RCTs (Loisel et al., 1997; Lindstrom et al., 1992), neither of high quality, were identified by the authors. The Lindstrom et al paper pre-dates the 1995 cut-off point of this project, but given the small quantity of relevant literature was included. The results must be viewed with caution, however, as the comparator practice used is not typical of current practice. Both RCTs involved occupational interventions combined with clinical treatment. Variations in interventions and outcome measures used in the studies meant that pooling of the results was not possible. Using a ‘best evidence’ synthesis approach the authors were able to conclude that there was moderate evidence that multidisciplinary rehabilitation involving occupational intervention can enable patients to return to work more quickly, have fewer episodes of sick leave and reduce subjective disability compared with standard care. Based on this evidence, the European guidelines (van Tulder et al., 2005) recommend that occupational multidisciplinary treatment programmes should be considered for workers with sick leave of more than 4–8 weeks.

Primary literature – randomised controlled trials

In addition to the primary literature assessed in the Cochrane review, seven subsequent trials meeting the inclusion criteria were identified. One multi-faceted intervention was conducted within a primary care setting in the UK (Hay et al., 2005), another was also conducted within primary care, but within a very specific US setting (Damush et al., 2003a; Damush et al., 2003b). Of the other studies considering multidisciplinary interventions: one was conducted in a primary care setting in Finland (Karjalainen et al., 2004); two were conducted in Germany, one in an inpatient setting (Schiltenwolf et al., 2006), and the other within private physiotherapy practice (Gohner & Schlicht, 2006); one study (Anema et al., 2007) was based upon the Dutch Loisel et al. (1997) trial; and one amongst USA outpatients (Gatchel, 2005). The interventions varied considerably between studies. Three of the primary studies (Anema et al., 2007; Gatchel, 2005; Karjalainen et al., 2004) included an occupational element, as did the studies considered in the Cochrane review. Details of the interventions are presented in Table 4-6, Table 4-7 and Table 4-8.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Biomedical</th>
<th>Physiotherapy exercise</th>
<th>Education</th>
<th>Psychological</th>
<th>Social/occupation/vocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Lindstrom et al., 1992)</td>
<td></td>
<td>Measurements of functional capacity Exercise programme with operant-conditioning</td>
<td>Back school education</td>
<td></td>
<td>Work place visit</td>
</tr>
<tr>
<td>(Loisel et al., 1997)</td>
<td>Visit to back specialist</td>
<td>Functional rehabilitation therapy</td>
<td>Back school education</td>
<td></td>
<td>Visit to occupational physician; work place visit</td>
</tr>
<tr>
<td>(Schiltenwolf et al., 2006)</td>
<td></td>
<td>Functional restoration with individual and group physiotherapy; exercise workout;</td>
<td>Back school education</td>
<td>Psychotherapy Relaxation therapy</td>
<td></td>
</tr>
<tr>
<td>(Hay et al., 2005)</td>
<td></td>
<td>General fitness and exercise</td>
<td>Explanations about pain</td>
<td>Encouraging positive coping strategies,</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>mechanisms and distress</td>
<td>overcome fear of hurt=harm; graded</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>return to usual activities</td>
<td></td>
</tr>
<tr>
<td>(Gatchel et al., 2005)</td>
<td>Physician evaluation</td>
<td>Physical therapy evaluation; physical therapy sessions; exercise classes</td>
<td>Group didactic sessions</td>
<td>Biofeedback/pain management session</td>
<td>Case management and occupational therapy sessions</td>
</tr>
<tr>
<td>(Damush et al., 2003a;</td>
<td>Physician letters of support, telephone follow-up, analgesics</td>
<td>Handouts showing exercises</td>
<td>Group education classes</td>
<td>Classes covering goal setting, problem</td>
<td></td>
</tr>
<tr>
<td>Damush et al., 2003b)</td>
<td></td>
<td></td>
<td></td>
<td>solving, social support</td>
<td></td>
</tr>
<tr>
<td>(Anema et al., 2007)</td>
<td>Consultation with occupational physician</td>
<td>Graded activity programme</td>
<td>Education about good prognosis</td>
<td></td>
<td>Work place visit</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>and the importance of keeping</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>active</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Gohnner &amp; Schlicht, 2006)</td>
<td></td>
<td>Standardised exercise programme</td>
<td></td>
<td>Three cognitive behavioural sessions</td>
<td></td>
</tr>
<tr>
<td>(Karjalainen et al., 2004)</td>
<td>Physician examination</td>
<td>Consultation with physiotherapist to discuss daily activities and provide a tailored</td>
<td></td>
<td></td>
<td>Work place visit</td>
</tr>
</tbody>
</table>
Table 4-7 Evidence for multidisciplinary approaches to the rehabilitation of patients with acute low back pain

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Karjalainen et al., 2003) Includes (Lindstrom et al., 1992; Loisel et al., 1997)</td>
<td>Systematic review to determine the effectiveness of multidisciplinary rehabilitation for subacute LBP</td>
<td>Working age adults (18 - 65); LBP for 4 weeks–3 months Study 1; N=103 Study 2: N=130</td>
<td>Physician consultation + either a psychological, social or vocational intervention, or a combination of these</td>
<td>Not specified</td>
<td>1–2 years</td>
<td>Pain intensity Global status Disorder specific functional status Generic functional status or quality of life Ability to work Healthcare consumption and costs Treatment satisfaction</td>
</tr>
<tr>
<td>(Lindstrom et al., 1992);</td>
<td>RCT to determine whether graded activity restored occupational function</td>
<td>19–64 year old blue-collar workers at the Volvo factory in Gothenberg, Sweden. N=103 Sick listed for 6 weeks. 69% male</td>
<td>Graded four-part activity programme (measurement of functional capacity, workplace visit, back school education and a gradually intensifying program with operant-conditioning behaviour approach)</td>
<td>Traditional care (general rest, analgesics, unspecified physical treatment modalities)</td>
<td>2 years</td>
<td>Pain intensity (Borg) Subjective disability (Waddell and Main) Return to work Pain behaviour Physical examination (mobility, strength, fitness)</td>
</tr>
<tr>
<td>Citation</td>
<td>Study</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Length of follow-up</td>
<td>Outcome measure</td>
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<tr>
<td>(Loisel et al., 1997)</td>
<td>RCT to develop and test a model of subacute back pain management, to prevent prolonged disability</td>
<td>Patients in Quebec, Canada, with thoracic or lumbar back pain absent from work cumulatively for 4 weeks–3 months over past year. Recruited from workplaces with &gt;175 employees N=130 60% male</td>
<td>Occupational intervention (consultation with occupational physician after 6 weeks absence and work place visit) and clinical intervention (after 8 weeks absence consultation with back specialist and back care education; after 12 weeks absence multidisciplinary work rehabilitation including functional rehabilitation therapy)</td>
<td>Occupational intervention Clinical intervention Usual care (received treatment from attending physician, at liberty to prescribe any test, treatment, or specialist referral)</td>
<td>1 year</td>
<td>Pain intensity (McGill), Disorder specific functional status (Oswestry), Generic functional status (SIP), Ability to work (median days off)</td>
</tr>
<tr>
<td>(Schiltenwolf et al., 2006)</td>
<td>RCT to compare multidisciplinary biopsychosocial treatment (BT) with biomedical treatment (MT) for subacute LBP patients</td>
<td>Age 18–50 First period of sick leave with back pain lasting 3–12 weeks. Have received outpatient treatment. Co-interventions avoided during treatment. No restriction in follow-up period</td>
<td>6 hours of inpatient treatment, for 15 days in 3 week period. Treatment comprised biomedical intervention plus psychotherapy three times a week and psychotherapist relaxation therapy four times week. N=33</td>
<td>Biomedical interventions, functional restoration program of: individual physiotherapy, group water therapy, workout, back school, passive physiotherapy. Treatment duration and intensity as per intervention. N=31</td>
<td>Post-treatment: 3 weeks 6 months 2 years</td>
<td>Primary outcome – pain intensity; Secondary outcomes – spinal mobility, torque of flexor and abdominal muscles, functional capacity of back (Hannover Functional Status Questionnaire-Back), depressive dysfunction (CES-D) and sick leave</td>
</tr>
<tr>
<td>Citation</td>
<td>Study</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Length of follow-up</td>
<td>Outcome measure</td>
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<td>-----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>(Hay et al., 2005)</td>
<td>RCT to compare the clinical effectiveness of a brief pain management programme (BPMP) vs. a physiotherapy programme in primary care</td>
<td>18-64 years visiting one of 28 general practices in North Staffordshire for first or second time with an episode of non-specific LBP (&lt;12 weeks) N=201 per arm 48% male</td>
<td>Brief pain management programme including assessment, development of a management plan including general fitness and exercise, explanation about pain mechanisms and distress, encouraging positive coping strategies, overcoming fear of hurt=harm, graded return to usual activities Delivered by three musculoskeletal physiotherapists trained in the biopsychosocial care model</td>
<td>Hands-on manual physiotherapy consistent with UK current best practice Delivered by three physiotherapists with postgraduate training in manual therapy</td>
<td>3 months and 12 months after randomisation (interventions started within 10 days of randomisation)</td>
<td>Primary outcome: change in RMDQ score at 12 months Secondary outcomes: participants overall assessment of change; pain location, rating of pain severity, nature of pain (short form McGill pain questionnaire), depression and somatic distress (DRAM score of psychological distress); fear of movement (Tampa scale of kinesiophobia), coping strategies; satisfaction with treatment, days off work and cointerventions</td>
</tr>
<tr>
<td>(Gatchel, 2005)</td>
<td>RCT to evaluate the clinical effectiveness of employing an early intervention program in patients at high risk of chronic disability</td>
<td>Fully employed, patients attending orthopaedic practices, Dallas, Texas, aged 18–65 with acute LBP of less than 2 months duration No history of chronic episodic back pain</td>
<td>Functional restoration Consisted of maximum of the following: three physician evaluations; one 1 hour physical therapy evaluation, nine 15 minute physical therapy sessions consisting of individual exercise classes; nine 30 minute physical therapy sessions consisting of group exercise classes; nine biofeedback/pain management sessions; nine 45-minute didactic group sessions; nine 30-minute case management / occupational therapy sessions; three interdisciplinary team conferences N=22</td>
<td>High risk, no intervention N=48 Low risk, no intervention N=54</td>
<td>Follow-up by phone interview at 3, 6, 9 and 12 months</td>
<td>Self-reported pain (Characteristic Pain Inventory), return to work status; average number of healthcare visits, average number of disability days due to LBP, injury recurrence and medication use</td>
</tr>
<tr>
<td><strong>Study</strong></td>
<td><strong>Citation</strong></td>
<td><strong>Patient characteristics</strong></td>
<td><strong>Intervention</strong></td>
<td><strong>Comparison</strong></td>
<td><strong>Length of follow-up</strong></td>
<td><strong>Outcome measure</strong></td>
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</tr>
<tr>
<td>Damush et al., 2003a; Damush et al., 2003b</td>
<td></td>
<td>Aged 18-82; non-painful, back pain of less than 3 months duration; patients from inner city area of America, predominantly African/American, and socio-economically vulnerable</td>
<td>Three weekly classes, 3 weeks, class covering educational material, goal setting, problem solving, and social support. Classes supplemented with handouts showing exercises, physicians support letters and telephone follow-up</td>
<td>Usual care including analgesics, back exercises, physiotherapy, occupational or physical therapy, and social support</td>
<td>4 and 12 months post baseline</td>
<td>Primary outcomes: functional status and patient satisfaction. Functional status measured using components from the Arthritis Impact Measurement Scales (AIMS2) and Roland Disability questionnaire; patient satisfaction measured by scale validated for low back patients. Secondary outcomes: self efficacy, self management, social support, and fear of movement</td>
</tr>
<tr>
<td>Damush et al., 2007</td>
<td>Working age adults in the Netherlands; sick leave due to LBP for 2-6 weeks</td>
<td>Workplace intervention and graded activity in addition to usual care according to Dutch guidelines followed by usual care</td>
<td>Workplace intervention and graded activity in addition to usual care according to Dutch guidelines</td>
<td>Usual care according to Dutch guidelines</td>
<td>1 year from first day of sick leave</td>
<td>Primary outcome: Duration of sick leave in calendar days from first day of sick leave to full return to work in own or equal work for at least 4 weeks. Total duration of sick leave during the entire 12-month follow up period. Secondary outcome: Functional status (RMDQ) Pain intensity (VAS)</td>
</tr>
</tbody>
</table>

The Table above summarizes the characteristics, intervention, comparison, length of follow-up, and outcome measures of the studies. The studies included a randomized controlled trial (RCT) to evaluate a self-management programme on primary care acute LBP patients. The primary outcomes were functional status and patient satisfaction. Secondary outcomes included self-efficacy, self-management, social support, and fear of movement. The comparison group received usual care, including analgesics, back exercises, physiotherapy, occupational or physical therapy, and social support. The length of follow-up was 4 and 12 months post baseline. The primary outcome was the duration of sick leave in calendar days from the first day of sick leave to full return to work in own or equal work for at least 4 weeks. The total duration of sick leave during the entire 12-month follow-up period was also measured. The secondary outcome was functional status (RMDQ) and pain intensity (VAS).
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Gohner &amp; Schlicht, 2006)</td>
<td>RCT to determine whether cognitive behavioural therapy (CBT) enhanced patient’s self efficacy, severity perception and reduced perception of barriers to treatment compared with physiotherapy</td>
<td>Adults ≥18 years old with LBP of 7 days–7 weeks duration, who were patients of private physiotherapy practices in two cities in Southern Germany</td>
<td>Three 50-minute psychologist CBT sessions and six standardised physiotherapy exercise sessions N=25</td>
<td>Standardised physiotherapy exercises alone N=22</td>
<td>Questionnaires before the first physiotherapy session; after the last session; and 3 and 6 months later</td>
<td>Self-efficacy (4-point Likert scale) Barriers (4-point Likert scale) Severity (4-point scale) Intention (4-point scale) Behaviour (4-point scale) Pain intensity (10-point scale)</td>
</tr>
<tr>
<td>(Karjalainen et al., 2004)</td>
<td>RCT to investigate the long-term effectiveness, cost and effect modifiers of usual care with additional incremental effect of worksite visit for subacute disabling LBP</td>
<td>25–60 year old employees in the Helsinki area with current daily LBP. This had made working difficult for 4 weeks–3 months</td>
<td>Mini-intervention: consultation with senior physician specialising in physical medicine (physiatrist) and a physiotherapist with aim of reducing patients’ concerns about back pain by providing accurate information and encouraging physical activity N=56 Mini-intervention and 75-minute worksite visit with the patient, patient’s supervisor, company nurse, physiotherapist and occupational physician N=51</td>
<td>Usual care. GP treatment in primary healthcare with specialist consultation when necessary N=57</td>
<td>Questionnaires at 3, 6, 12 and 24 months after randomisation</td>
<td>Self-rated intensity of LBP (scale 0–10) Frequency and bothersomeness of pain Interference of the pain with daily life Perceived disability (Oswestry) Health-related quality of life (HRQoL [15D]) Overall satisfaction with care (scale 0–10) Healthcare consumption and costs Back pain-related sick leave</td>
</tr>
</tbody>
</table>
### Table 4.8 Supporting data for multidisciplinary approaches to the rehabilitation of patients with acute low back pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Baseline</th>
<th>Graded 4-part activity programme</th>
<th>Traditional care</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Karjalainen et al., 2003) Lindstrom 1992 study</td>
<td>Baseline</td>
<td>3.3</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>Graded 4-part activity programme</td>
<td>2.4</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>Traditional care</td>
<td>2.1</td>
<td>19.6</td>
</tr>
</tbody>
</table>

**Comment**
- Pain intensity
- Subjective disability
- Return to work (weeks to return) at 2 years' follow-up
- *p<0.05

<table>
<thead>
<tr>
<th>Study</th>
<th>Baseline</th>
<th>Occupational and clinical intervention</th>
<th>Clinical intervention</th>
<th>Usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loisel 1997 study</td>
<td>Baseline</td>
<td>7.0</td>
<td>-10.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Occupational effect (I and C1 vs. C2 and C3)</td>
<td>-1.06</td>
<td>-4.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical effect (I and C2 vs. C1 and C3)</td>
<td>4.4</td>
<td>-7.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disorder specific functional status (I vs. C3)</td>
<td>-1.4</td>
<td>-10.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Occupational effect (I and C1 vs. C2 and C3)</td>
<td>-1.6</td>
<td>-5.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical effect (I and C2 vs. C1 and C3)</td>
<td>1.7</td>
<td>-4.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic functional status (I vs. C3)</td>
<td>-1.2</td>
<td>-4.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Occupational effect (I and C1 vs. C2 and C3)</td>
<td>-1.3</td>
<td>-3.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical effect (I and C2 vs. C1 and C3)</td>
<td>0.0</td>
<td>-2.3</td>
<td></td>
</tr>
</tbody>
</table>

**Ability to work (median days off):**
- I = 60; C1 = 67; C2 = 131; C3 = 120.5; p<0.05

Reviewer’s overall outcome conclusions positive.
<table>
<thead>
<tr>
<th>Study</th>
<th>Effect size</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Schiltenwolf et al., 2006)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>T0 - 3 weeks post-treatment</strong></td>
<td><strong>T1 - 6 months post-treatment</strong></td>
<td><strong>T2 - 2 years post-treatment</strong></td>
</tr>
<tr>
<td>Changes mean (SD)</td>
<td>MT</td>
<td>BT</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1 vs. T0</td>
<td>1.46 (2.7)</td>
<td>1.70 (2.1)</td>
</tr>
<tr>
<td>T2 vs. T0</td>
<td>-0.52 (3.2)</td>
<td>2.96 (2.5)</td>
</tr>
<tr>
<td><strong>Functional capacity (FFbH-R)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1 vs. T0</td>
<td>6.41 (14.9)</td>
<td>10.0 (17.0)</td>
</tr>
<tr>
<td>T2 vs. T0</td>
<td>1.19 (31.4)</td>
<td>25.75 (22.4)</td>
</tr>
<tr>
<td><strong>Depression (CES-D)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1 vs. T0</td>
<td>3.74 (4.5)</td>
<td>2.4 (4.6)</td>
</tr>
<tr>
<td>T2 vs. T0</td>
<td>-0.86 (7.8)</td>
<td>6.62 (7.5)</td>
</tr>
<tr>
<td>Sick leave periods per patient (2 year follow up)</td>
<td>11.4</td>
<td>3.86</td>
</tr>
<tr>
<td>Sick leave days per patient (2 year follow-up)</td>
<td>111.40</td>
<td>41.45</td>
</tr>
<tr>
<td>Study</td>
<td>Effect size</td>
<td>Comment</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
<td>---------</td>
</tr>
</tbody>
</table>
| (Hay et al., 2005) | BPMP - brief pain management programme  
MP - manual physiotherapy | **Study**  
**Effect size**  
**Comment** |
| RMDQ scores: Mean (SD) | Baseline  
Change from baseline at 3 months  
Change from baseline at 12 months | Median number of physiotherapy visits was significantly lower in the BPMP group for both intention-to-treat and per protocol analysis |
| BPMP | 13.8 (4.8) | 7.8 (6.6) | 8.8 (6.4) |
| MP | 13.3 (4.9) | 8.1 (6.0) | 8.8 (6.1) |
| Mean difference | -0.2 (-1.6 to 1.2) | 0 (-1.3 to 1.4) | p=0.755 | p=0.994 |
| Secondary care consultations over 12 months number (%) | | |
| BPMP | 2 (1) |
| MP | 11 (7) |
| Difference | -5.7% (-10.1% to -1.2%) |
| (Gatchel, 2005) | HR-I high risk intervention  
HR-NI high risk, no intervention  
LR low risk | **Study**  
**Effect size**  
**Comment** |
| Average of self-rated most intense pain at 12-month follow-up (0-100 scale) | 46.4 | 67.3 | 44.8 |
| ANOVA p value=0.001 | |
| Average of self-rated pain over last 3 months (0-100 scale) | 26.8 | 43.1 | 25.7 |
| ANOVA p value=0.001 | |
| Return to work at follow-up | 91% | 69% | 87% |
| Chi square p value=0.027 | |
| HR-NI group received:  
Medical office visits | 52% |
<p>| Physical therapy | 21% |
| Chiropractic care | 19% |
| Diagnostics | 23% |
| Injection procedures | 10% |
| Passive treatments | 29% |
| Electrical stimulation | |
| Additional treatments received by HR-I and LR groups were not recorded |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Effect size</th>
<th>Comment</th>
</tr>
</thead>
</table>
| (Damush et al., 2003a; Damush et al., 2003b) | 4-month outcomes compared with baseline  
Usual care n=87  
Intervention n=76  
12-month outcomes compared with baseline  
Usual care n=76  
Intervention n= 63 | **Average treatment effect**  
4 months  
12 months  
**Functional status (AIMS2)**  
Symptoms  
Physical function  
Emotional function  
LBP specific scale  
**Functional status (RDQ)**  
**Patient satisfaction**  
| AIMS2 Scale used validated for arthritis, also questions regarding the appropriateness of using only part of the scale.  
Patients who dropped out reported significantly worse physical function and lower self efficacy at managing symptoms than those who completed the trial. |

| (Gohnen & Schlicht, 2006) | **t2 - after last physiotherapy session**  
t3 - 3 months later  
t4 - 6 months later | **Difference (p)**  
Differences between CBT + standardised physiotherapy exercises group vs. standardised exercises  
t2  
t3  
t4  
Self-efficacy  
Barriers  
Severity  
Intention  
Mean differences over time for CBT + standardised physiotherapy exercises group  
t1-t2  
t1-t3  
t1-t4  
Self-efficacy  
Barriers  
Severity  
Intention  
Behaviour  
| 54 patients were enrolled in the study, but analysis was based only upon the 47 completing the intervention.  
Based upon private healthcare |
<table>
<thead>
<tr>
<th>Study</th>
<th>Effect size</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Karjalainen et al., 2004)</td>
<td></td>
<td>Statistical power based on Intensity of pain outcome Also assessed modifiers of treatment effect</td>
</tr>
<tr>
<td>A - mini-intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B - mini-intervention + workplace visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C - usual care</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Groups A vs. C</td>
<td>Groups B vs. C</td>
</tr>
<tr>
<td>Intensity of pain (mean difference, 95% CI)</td>
<td>-0.07 (-0.79, 0.65) p=0.857</td>
<td>-0.1 (-0.84, 0.64) p=0.781</td>
</tr>
<tr>
<td>Daily symptoms (odds ratio, 95% CI)</td>
<td>0.39 (0.19, 0.79) p=0.009</td>
<td>0.52 (0.26, 1.02) p=0.059</td>
</tr>
<tr>
<td>Very or extremely bothersome pain during the past week (odds ratio, 95% CI)</td>
<td>0.55 (0.3, 0.99) p=0.048</td>
<td>0.71 (0.38, 1.32) p=0.284</td>
</tr>
<tr>
<td>Oswestry disability index (mean difference, range)</td>
<td>-2.02 (-6.51, 2.47) p=0.376</td>
<td>-0.42 (-5.02, 4.18) p=0.857</td>
</tr>
<tr>
<td>Days on sick leave</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.03</td>
<td>p=0.133</td>
</tr>
</tbody>
</table>
Hay et al. (2005) undertook a study in North Staffordshire to compare the clinical effectiveness of a primary care brief pain management programme delivered by physiotherapists with that of physiotherapy alone. The pain management programme involved the development of a management plan, including education on pain mechanisms and beliefs, encouraging positive coping strategies, and gradual return to activity and exercise. The physiotherapy programme was based on manual therapy techniques consistent with current UK best practice. After randomisation, participants started treatment within 10 days. Interventions targeted patients with subacute low back pain, as at this stage psychological factors can be key in influencing progression to chronic pain. Each programme commenced with a 40-minute assessment and treatment session, followed by up to six subsequent 20-minute sessions. Outcome assessment at 12 months was considered important as recurrence is common during this time. There was no clinically or statistically significant difference between treatment groups in the change from baseline in RMDQ scores or other secondary outcome measures. However, patients receiving brief pain management had 5.7% (CI 1.2 to 10.1) fewer secondary care consultations compared with those undergoing physiotherapy, although the confidence interval was wide as the number of consultations was small. Pre-planned subgroup analysis of the mean reduction in RMDQ scores at 12 months among patients categorised as distressed/depressed was 9.2 in participants receiving the brief pain management programme compared with 6.8 in those assigned to physiotherapy, although the numbers in subgroup analysis were too small for conclusions to be drawn.

This large NHS study involved interventions that would be practical to implement and is very relevant to the delivery of back pain services in NHS Scotland. However, the study did not include a control group. There was little evidence of differences in clinical outcomes between interventions, and the authors suggested that either could be employed. Brief pain management potentially requires fewer sessions and secondary referrals. Some commentators have suggested that the time interval until the first assessment was too long at 3 months, and that greater benefit might be seen if the intervention was implemented earlier (Shekelle & Delitto, 2005).

The study by Damush et al. (2003a; 2003b) was based on a primary care intervention, among disadvantaged US inner city dwellers. The authors examined the effectiveness of a programme aimed at improving self-management of acute low back pain, comprising weekly small group classes covering educational material, goal setting, problem solving and social support. Classes were supplemented with handouts showing exercises, physician support letters and telephone follow-up. These interventions were in addition to usual care which could include analgesics, back exercise sheets, and physiotherapy, occupational or neurological centre referral. The intervention group displayed significantly improved emotional functioning, using the Arthritis Impact Measurement Scale, at both 4 (p<0.0001) and 12 months (p=0.009), but no difference in symptoms.

Physical function showed significant improvement at 12 months (p=0.02). There was evidence of improved functional status, as shown by the low back pain specific RMDQ, at 4 months, with the improvement achieving statistical significance by 12 months (p=0.009). Significant improvements were noted at 4 and 12 months on the secondary outcome measures of self-efficacy and fear avoidance. There was insufficient evidence of a difference between intervention and control groups in secondary outcomes relating to self-management, apart from the total time spent on physical activities at 4 months. These study findings should, however, be interpreted with caution. A fairly large subset of the population was lost to follow-up (23% at 4 months and a further 11% at 12 months) and there were notable differences in the severity of back pain in these patients. One of the primary assessment tools is validated for use in patients with arthritis rather than back pain. However, the results do suggest that using a multifaceted intervention, in a primary care setting, can modify the beliefs of socioeconomically disadvantaged patients and this may enable them to cope better with their back pain.

A more resource intensive approach was assessed in a German trial of inpatients experiencing subacute (3–12 weeks) low back pain related sick leave (Schillenwolf et al., 2006), comparing the effectiveness of combined psychotherapy, with relaxation and standard biomedical therapy versus standard biomedical therapy alone. Each patient received 6 hours of psychotherapy with relaxation treatment a day, 5 days a week. In both groups over the 3 week programme, the improvements were only sustained in the group receiving the additional interventions. By the 6 months follow-up the differences between the two groups were statistically significant for these outcomes. Patients receiving combination therapy also experienced significantly less sick leave. However, the number of subjects allocated to each treatment arm was small, limiting the weight that can be attached to this evidence. The authors suggested that the better efficacy experienced by patients receiving biopsychosocial therapy could be due to the treatment itself or to the patients being better able to identify and utilise beneficial post-treatment therapies. Whichever the explanation, the clinical significance of the results needs to be considered in terms of economic costs and benefits.

Gohner and Schlicht (2006), considered the benefit of cognitive behaviour therapy (CBT) in terms of prolonging adherence to exercise programmes. The effectiveness of combining a short CBT programme, delivered by a psychologist, with standardised physiotherapy exercises versus standardised exercises alone was assessed. The authors noted significant improvements in self-efficacy scores, barriers to following treatment, perception of condition severity, intention to follow treatment and adherence to treatment in the group receiving CBT. Improvements in pain severity were noted in both treatment groups, with the scores for the group receiving CBT tending to be lower 6 months after treatment, although the differences were not statistically significant.
The findings of this study should be considered exploratory due to: the short follow-up period, the small number of patients, the possibility that more motivated patients and physiotherapists were likely to participate, and analysis being based on the per protocol population. The results do, however, indicate a role for psychological therapy as an adjunctive treatment.

While the aim of the Gatchel study (2005) was to assess the benefit of early intervention in a subgroup of patients at high risk of developing chronic disease, it is also of interest as the intervention used was multidisciplinary. The intervention comprised a maximum of the following: three physician evaluations; one physical therapy evaluation; nine individual exercise sessions; nine group exercise sessions; nine didactic sessions, nine case management/occupational therapy sessions; and three interdisciplinary team conferences, all being delivered by trained professionals. The no intervention group pursued a variety of treatments, including physician consultations, physical therapy modalities, chiropractic care, diagnostic tests and injection treatments. At 12 months follow-up, 91% of the intervention group had returned to work compared with 69% of the control group (p=0.027). The intervention group also displayed statistically significant lower ratings on pain measurement scales. However, the number of patients randomised to each study arm was small and further research is required before firm conclusions can be drawn.

Workplace interventions were considered in two primary studies (Anema et al., 2007; Karjalainen et al., 2004). The study by Anema et al. (2007) aimed to compare the effects of components of a workplace multidisciplinary intervention with graded activity versus usual care. While the workplace intervention alone significantly reduced the time to return to work, there was no evidence of a difference in time to return to work, functional status, or pain intensity for the combination of workplace intervention with graded activity. In the Karjalainen et al. (2004) study a mini-intervention, delivered by a specialist physician and physiotherapist in primary care, focused on patient education and physical activity, but lacked sufficient psychosocial elements to meet the definition of multi faceted adopted by this review. However, the study was of interest as it considered the incremental effect of a worksite visit in combination with the mini-intervention. While the group receiving the mini-intervention had significantly fewer days sick leave and fewer daily symptoms than those receiving usual care, the differences observed between those receiving the worksite visit plus the mini-intervention and the usual care group were not statistically significant. The results from Anema et al. (2007) and Karjalainen et al. (2004) regarding workplace interventions appear contradictory, but the studies were not comparable given the nature of the interventions combined with the worksite visits and that the professionals delivering the interventions differed. More details on aspects of the working environment are also required to fully interpret the results.

4.2.7.3 Discussion of the evidence

Whilst all studies met the inclusion criteria, the Cochrane review and the seven additional primary studies are very different in their approaches, settings and the outcomes measured. This makes it difficult to draw overall conclusions. The Hay et al. study (2005) is most relevant to NHSScotland and the most robust in terms of design. The findings suggest that a brief pain management programme, delivered by an appropriately trained clinician, could offer a less resource intensive alternative to physiotherapy with manual therapy, but raises questions in relation to the targeting of interventions. The other primary studies and the Cochrane review showed benefits in terms of pain, function, psychosocial measures and return to work following a multidisciplinary/multi faceted intervention. The Cochrane review considered two methodologically low quality RCTs and, at best, constitutes moderate evidence. In addition, the studies only considered patients in employment. The study sizes were small for three reports (Gohner & Schlicht, 2006; Schiltenwolf et al., 2006; Karjalainen et al., 2004), involved a resource intensive programme in Schiltenwolf et al. (2006), and concerned a very restricted socioeconomic population in the study by Damush et al. (2003a; 2003b).

There is further uncertainty over the duration, intensity and optimal composition of multidisciplinary/multifaceted interventions. The overall approach to rehabilitation is considered, by some, to be more important than the individual interventions (Hay et al., 2005). Employing a multidisciplinary or multifaceted approach, by its nature, tends to ensure the use of a broad based psychosocial strategy.

A number of issues emerged that warrant further investigation:

- The analysis by Hay et al. (2005) suggests that patient subgroups may benefit from particular interventions, and that using a ‘one-size-fits-all’ treatment approach may not be optimal (Macfarlane et al., 2006). Modifiers of treatment effect are examined in the analysis undertaken by Karjalainen et al. (2004) and these authors also suggest that different interventions may be appropriate for different individuals. High-risk patients offered early intervention by Gatchel (2005) exhibited favourable return to work outcomes, but these effects could be attributed to intervention timing rather than a specific patient subgroup. Screening tools such as fear avoidance questionnaires and clinical prediction rules could be used to identify subgroups most likely to benefit from specific interventions. In all the studies described, the improvement in outcomes is modest and potential benefit or harm in specific patient subgroups may be masked.

- There are uncertainties surrounding intervention delivery. It is questionable whether a brief training programme is sufficient to equip a healthcare professional to deliver a psychosocial intervention (Macfarlane et al., 2006). Inadequate delivery may
impact on the success of a psychosocial programme. Gohner & Schlict (2006) suggest that physiotherapists be trained to offer CBT, whereas others argue that trained psychologists are needed (Morgan, 2005). Delivery format is also of interest. In the Damush et al. study (2003a; 2003b), a large proportion of patients were not able to attend classes, but received material by post. If it could be established that interventions could be delivered using less resource intensive methods, there is potential for significant cost savings.

- Some studies such as that by Gohner and Schlict (2006) considered whether an intervention impacts on the patient’s actions, perceptions and attitudes. It is important to understand whether the psychosocial component of the intervention is making a difference. However, there does not seem to be consensus on the time points at which these parameters should be measured. Improvements in some measures are seen in the short-term and others in the long-term. In terms of preventing the acute pain episode of becoming chronic, it would be important to detect short-term improvements. However, to reduce the occurrence of future episodes, consideration of long-term benefits is required.

Due to time constraints, this review did not consider literature on multifaceted interventions published prior to the Cochrane review (Karjalainen et al., 2003). It is possible, therefore, that a number of publications relevant to this question have not been considered. Eleven studies excluded by Karjalainen et al. (2003) might have been considered if assessed under the broader definition of multifaceted interventions.

4.2.7.4 Conclusion

There is moderate evidence that multidisciplinary and multifaceted interventions are beneficial for patients with acute or subacute back pain, but these require further research. It is important to understand why multifaceted/multidisciplinary interventions have shown only limited success in improving outcomes for acute or subacute back pain. It may be that expectations of improvements have been unrealistic for low back pain, which is a complex multifactorial condition, and delivery may need to be targeted according to individual patient characteristics. It also needs to be considered whether the intervention being delivered matches that intended (Macfarlane et al., 2006).

4.3 Discussion and conclusions

The search for evidence related to acute non-specific low back pain has revealed a dearth of primary research for key aspects of service delivery. In particular, no published literature was found on physiotherapists having direct referral authority to consultant or MRI services. The only evidence for GP direct referral for MRI scan was outdated.

Much of the clinical effectiveness evidence related to musculoskeletal conditions, and was not specific to acute or subacute low back pain. Even where low back pain was the focus of a study, it was rarely possible to establish the symptom duration and whether treatment occurred during the acute phase.

The quality of studies was such that the findings should be interpreted with caution. Few studies were randomised and baseline data and comparator arms were often lacking. Many studies were compromised by confounding factors and a lack of power to detect differences.

A lack of consistency in outcome measures precludes pooled statistical analysis. Much of the literature on the impact of triage comprised audits, where the focus was on service redesign to reduce orthopaedic waiting times, and did not include data on patient outcomes. Triage of referrals by a physiotherapist, nurse or other clinician appeared to reduce orthopaedic waiting times and increase conversion to surgery rates.

Assessment of the evidence on whether prompt physiotherapy access improved patient outcomes was hampered by a lack of comparator data and it could not be determined whether improvements would have occurred had access been slower. There was evidence that self-referral to physiotherapy reduced waiting times; possibly by bypassing the GP referral administrative system.

In terms of first-line physiotherapy treatment modalities, the European and Prodigy guidelines recommend information and reassurance with advice to stay active and keep working. If a patient fails to return to normal activity, the guidelines suggest considering spinal manipulation or multidisciplinary treatment in an occupational setting. Traction, TENS, bed rest, specific exercises, epidural steroid injections, back schools, massage therapy, behavioural therapy, electrotherapy, ultrasound, interferential therapy, laser treatments and acupuncture are not recommended.

Evidence on whether feedback to GPs about inappropriate referrals changed referral patterns was minimal and of poor quality. Most of the evidence concerned X-ray requests, on which educational reminder messages may have some impact, but feedback on referral rates does not.

There was some evidence of effectiveness of multidisciplinary treatment modalities, although limited literature relevant to NHSScotland was available. This issue required further investigation particularly in increasing understanding of the mechanisms by which the interventions operate.

More quality primary research is required to address the evidence gaps highlighted in this HTA. Only then can strong recommendations be made to NHSScotland regarding service delivery for low back pain.
5 PATIENT ISSUES

This section describes issues of importance to people with low back pain attending medical services and the methods used to ascertain these issues.

To understand the patient issues associated with low back pain service provision within NHSScotland, a subgroup of the HTA Topic Group was convened, including patients attending the GGBPS.

The group identified key issues. This was supplemented by transcripts from patients contributing to the Database of Individual Patient Experience (DIPEx) (www.dipex.org).

Issues for patients

It was noted by participants in the HTA Topic Specific Group, the Patient Issues Sub Group, patients attending the GGBPS and patient transcripts from DIPEx that many patients with low back pain are reluctant to use medication prescribed for pain relief regularly, even for short periods of time.

Another issue highlighted was the perceived failure of the service to provide adequate information to people with low back pain. There were concerns regarding the information on low back pain as a condition and the services available to patients.

Work-related concerns were common to the Patient Issues Sub Group, patients attending the GGBPS and transcripts from patients contributing to DIPEx. Working patients with back pain fear losing their jobs, because of absence or not being able to perform tasks, or use coping strategies in their work environment. In addition, returning to employment can be daunting for patients with chronic pain who have not worked for some time.

Other issues identified

Participants in the HTA Topic Group and the Patient Issues Sub Group believed that the current primary care service culture is a barrier to good pain management. In particular, non-adherence to guidelines on the management of acute low back pain is a problem in primary care, resulting in patients not receiving timely, appropriate management. They voiced concerns regarding the effectiveness of communication between patients with low back pain and their GP and recognised that patients with low back pain generally expect a diagnosis with unambiguous explanations.

Based on the groups’ discussions and on meetings held with professionals working with people who have back pain, six research questions were defined to inform aspects of the patient issues section of the HTA.

Research questions

1. What evidence is there concerning how patients with low back pain use drugs prescribed for analgesia, i.e., are they used as prescribed with regard to effectiveness, adverse effects and patient acceptability?

2. How can service providers in primary and secondary care and in the community best meet the information needs of patients with low back pain?

3. Is there evidence of a beneficial effect on health outcomes from work-focused interventions, delivered by healthcare providers in collaboration with employment services, for patients unable to work because of back pain? Is this associated with benefit to the NHS in terms of reduced health service use for back pain?

4. What strategies have been proposed to improve communication between GPs and patients with low back pain, and how effective are they in improving patient outcomes and patient and doctor satisfaction?

5. Is there evidence that educational interventions on pain management, for primary care professionals, improve outcomes among patients with low back pain who are managed in the community?

6. What barriers exist to the implementation by GPs of guidelines for the management of acute low back pain in primary care, and is there evidence for the effectiveness of interventions to overcome these barriers?

5.1 Methodology

5.1.1 Evidence sources

5.1.1.1 Literature search

The following databases were searched for secondary literature in July 2006:

- Cochrane Database of Systematic Reviews (CDSR)
- Database of Abstracts of Reviews of Effects (DARE)
- HTA Database.

To identify primary literature, the following sources were searched:

- Medline
- Embase
- HMIC
- Cochrane Central Register of Controlled Trials
- CINAHL
- Web of Science.

The searches covered the period from 1995 and were restricted to common European languages. Copies of the search strategies can be obtained by contacting NHS QIS. Additional literature was identified by scanning the reference lists of retrieved studies and by citation searching on key papers.
The title and abstracts obtained from the searches were assessed against pre-defined inclusion and exclusion criteria. For those appearing to meet the criteria, the full text was ordered, which was then assessed in detail against the criteria. Data were extracted from the papers selected to produce evidence tables and a narrative synthesis of the evidence for each question (see Appendices 4–16).

### 5.1.1.2 Other sources of evidence

Other sources of evidence included submissions from members of the HTA Topic Group, the Patient Issues Sub Group and other service members, and ongoing monitoring of websites such as DIPEx.

### 5.2 Results

#### 5.2.1 Use of analgesia by patients with low back pain

Anecdotal evidence suggests that even when advised to take analgesic drugs at regular intervals, many patients reserve taking medication until their pain is intolerable. Patients voiced concerns about dependency, fearing that drugs taken too often would become less effective and be disinclined to be on medication. Adverse drug effects were of more concern to patients with chronic low back pain on long-term medication using several agents. Another reason for not using analgesia resulted from patients’ belief that not being able to feel pain could lead them to damage their back through over exertion (Schers et al., 2001).

**5.2.1.1 Study selection**

Studies were selected if they:

- elicited information from adults with simple, acute or chronic low back pain; and
- identified investigations eliciting information on whether patients prescribed analgesics used them as prescribed, or the patient perspective on the use of analgesia for low back pain; or
- assessed how patients use prescribed drugs with regard to: deviation from directed use, acceptability of the prescribed drug regimen, patients’ reasons for not using drugs as prescribed, the effect of actual analgesic use patterns on clinical effectiveness and adverse effects.

Studies were excluded if they solely assessed the clinical effectiveness/adverse effects of analgesic agents or solely quantified drug use for analgesia.

The literature search identified 573 titles and abstracts, which were screened to identify potentially relevant articles. A flow chart representing the selection of literature from the title and abstract identification stage to inclusion of the full report in evidence synthesis is presented in Appendix 11.1. Full reports were obtained for four studies, none of which met the inclusion criteria. The excluded studies are summarised in Appendix 11.2.

#### 5.2.1.2 Other evidence

Anecdotal evidence indicates that patients with back pain adjust their prescribed medication regimens to fit their needs. As a result, many prescriptions are not obtained or medications are obtained, but not administered. A survey of chronic non-cancer pain management in primary care in the UK assessed 504 responding GPs, for whom an average of 40% of patients had low back pain. Most GPs believed the management of chronic pain to be suboptimal (Stannard & Johnson, 2003), with patient non-compliance with medication regimens, side-effects and lack of efficacy being cited as significant contributors to under-treatment. The authors concluded that patient education and dissemination of specialist pain service information to colleagues in primary care could increase the proportion of patients receiving optimum pain control (Stannard & Johnson, 2003).

The impact and management of chronic pain in primary care in Scotland was considered by a PhD thesis (Selbie, 2006), which reported a dislike of taking medication among the majority of patients surveyed. The reasons given were in accord with those discussed above and highlighted patients’ concerns regarding the lack of a permanent solution offered by medication. The author suggested that this originates from the patient perception of there being a ‘cure’ for back pain, and reiterated the need for good communication and patient education as advocated by other studies.

#### 5.2.2 Information needs

This area overlapped with other patient issues, particularly those regarding communication. Patients with low back pain who felt they had not been given the right information about their condition early enough, felt that this explained why they had subsequently gone round and round the healthcare system.

GPs advised that it was useful to have information about low back pain to give to patients, but that The Back Book (2002) was not routinely given out because it needs to be purchased by GP practices. Service users identified areas for improvement as being the low visibility of patient information in GP practices and the reliance on GPs disseminating the information. Transcripts from patients contributing to DIPEx cited the internet as a source of information on back pain, its management and what specialist services are available. One GP noted that DIPEx was a resource that could be used to promote further discussion with patients, but awareness of the database is generally poor.

Both service users and providers questioned whether GPs had sufficient information on the services available locally and nationally. Patients whose GP gave out contact details for a direct access back pain service considered that their information needs were met in that setting.

In Scotland, a radio advertisement to convey messages from the Working Backs Scotland campaign was run from October–November 2000 and repeated in spring 2001.
The advertisement resulted in a 22% improvement in awareness in the general population of how to manage low back pain (http://www.sehd.scot.nhs.uk/publications/fm29/fm29-01.htm).

5.2.2.1 Study selection

Studies were selected if they:

- elicited information from patients with simple acute or chronic low back pain; and
- considered patient information in terms of patient information needs and content, or delivery strategies aimed at meeting identified information needs; and
- assessed patient outcome in terms of satisfaction, knowledge, beliefs, enablement and health. These studies were to incorporate a control group that did not receive the intervention, or that compared outcomes before and after intervention.

The literature search identified 27 titles and abstracts, which were screened to identify potentially relevant articles (Appendix 12.1). Full reports were obtained for eight of nine selected studies, of which seven met the inclusion criteria. A qualitative study (Coulter et al., 1998) of patient and specialist views on selected patient information materials (Appendix 12.2) was excluded as several patients had severe, chronic back problems associated with congenital defects or accidents.

5.2.2.2 Assessment of the evidence

The assessed studies included one systematic review (Henrotin et al., 2006), two RCTs (Little et al., 2001; Burton et al., 1999), three qualitative studies (Glenton et al., 2006; McIntosh & Shaw, 2003; Glenton, 2002) and a website survey (Butler & Foster, 2003). One RCT (Burton et al., 1999) was included in the systematic review and was, therefore, not assessed separately for this HTA. Three primary studies were conducted in England (Butler & Foster, 2003; McIntosh & Shaw, 2003; Little et al., 2001) and two in Norway (Glenton et al., 2006; Glenton, 2002). The studies assessed are summarised in Table 5-1.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study aim</th>
<th>Study setting</th>
<th>Method</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Henrotin et al., 2006)</td>
<td>Determine if LBP patient information is effective and which type is most effective</td>
<td>Systematic review of 11 RCTs (7 'high' quality), one non-randomised controlled study, one population-based before and after study</td>
<td>MEDLINE, EMBASE, PsycInfo searched to April 2004 with reference and citation searching; independent/consensus selection; quality assessment score; positive/negative vote counting; evidence hierarchy</td>
<td>Adequate search, selection and quality criteria; quality scores not a reliable measure of validity</td>
</tr>
<tr>
<td>(Glenton et al., 2006)</td>
<td>Evaluate how users respond to the BackInfo website</td>
<td>Qualitative study in Norway; recruitment through website advertising; Back Pain Association and flyers; focus groups; thematic framework analysis</td>
<td>18 patients with chronic back pain</td>
<td></td>
</tr>
<tr>
<td>(Butler &amp; Foster, 2003)</td>
<td>Evaluate the quality of patient accessible internet information on LBP</td>
<td>Survey of English websites</td>
<td>60 back pain websites accessed in January 2000</td>
<td></td>
</tr>
<tr>
<td>(McIntosh &amp; Shaw, 2003)</td>
<td>Ascertain GP and patient experiences and expectations of LBP information</td>
<td>Qualitative English study; purposive/convenience sampling; semi-structured GP interviews; patient focus groups; framework analysis</td>
<td>15 GPs; 37 patients with LBP</td>
<td>Study also included in Table 5-2</td>
</tr>
<tr>
<td>(Glenton, 2002)</td>
<td>Identify information needs of back pain sufferers and barriers to accessing this information</td>
<td>Qualitative Norwegian study; sampling method unclear; in-depth interviews; content/thematic analysis Data from a website discussion list and a literature search were also used</td>
<td>15 patients with back pain (mostly chronic) and four close family members</td>
<td></td>
</tr>
<tr>
<td>(Little et al., 2001)</td>
<td>Assess the effectiveness of a self-management booklet for patients with back pain</td>
<td>English RCT of a patient information booklet ('Back Home') with and without GP advice to exercise vs. GP advice to exercise alone vs. neither intervention</td>
<td>239 patients consulting a GP for a new episode of back pain (acute or chronic)</td>
<td>Generation of random sequence not reported; allocation concealment adequate; 23% of 311 patients randomised lost to follow-up, similar between groups; primary outcome pain/function score validated</td>
</tr>
</tbody>
</table>
The literature was consistent in reporting patients' need for accurate and up-to-date information regarding their condition and the services available to them. Almost all of the 37 participating patients in focus groups conducted in England said they had received little or no information from their GP, but were eager to know how to self-manage their condition and were frustrated by their lack of knowledge (McIntosh & Shaw, 2003).

GPs' views on the value of patient information materials varied from being supportive to being reluctant to give them out, because their benefits were unproven or because patients were unlikely to read them. Many GPs who were supportive of patient information cited cost as one obstacle to their providing such materials. These findings suggest that patients are likely to continue to experience inequity in the information materials that they receive from their GP (McIntosh & Shaw, 2003).

A Norwegian qualitative study found that other barriers to accessing information included: health professionals' attitudes and lack of communication skills, GPs lack of time and knowledge about low back pain, timeliness of information, mismatch of explanatory models between patients and providers, and patient attitudes (Glenton, 2002).

Several studies sought to establish the effectiveness of patient information materials, with varying results. Little et al. compared the effect of a self-management booklet and/or GP advice to take exercise on parameters of pain/function, satisfaction and knowledge in patients with a new episode of low back pain. There was a moderate improvement in pain/function in the first week in patients who received the booklet or advice to take exercise compared with the control group. By the third week, there was no significant difference between intervention groups and the control. Both interventions increased some elements of patient satisfaction and the booklet increased knowledge. Little difference in outcomes was detected when comparing patients who received both interventions with those in the control group, and the authors believed that the negative interaction of the combined interventions was not a chance finding (Little et al., 2001).

The systematic review of the effectiveness of patient information materials for low back pain assessed 13 studies, of which 11 were RCTs (Henrotin et al., 2006). This reasonably well-conducted review concluded that patient information booklets improve knowledge and beliefs, but found no evidence of an effect on absenteeism and showed conflicting evidence regarding their effect on health outcomes and healthcare use. There was evidence from one RCT that a psychosocial booklet, The Back Book (2002) was more effective than a biomedical booklet at challenging beliefs on activity, but this was not associated with differences in outcomes of pain or disability (Burton et al., 1999). McIntosh & Shaw (2003) asked patients and GPs to review The Back Book (2002) and most feedback was positive, although one GP said it 'medicalised' simple back pain and some patients criticised the tone and language. Some patients with chronic low back pain believed they might have been better able to self-manage their condition if they had received The Back Book (2002) earlier.

The format of information given to patients is widely believed to influence its effectiveness. Little et al. (2001) postulated that it may not be helpful to give information in more than one format, particularly if they differ in the amount or detail of information provided. Glenton et al. (2006) found that patients were enthusiastic about personal stories describing the experiences of others.

Studies also suggest that the source of information influences its effectiveness. McIntosh & Shaw (2003) report that patients who accessed various sources often found conflicting information and found it difficult to know what was reliable. Participants in a qualitative study in Norway questioned the applicability of research findings to themselves as individuals (Glenton et al., 2006).

The BackInfo project aimed to develop an internet-based information service for back pain patients, a medium the authors believed to be suited to a patient-centred holistic approach to information provision (Glenton, 2002). English researchers evaluated the quality of low back pain information accessible on the internet (Butler & Foster, 2003). Their survey of 60 websites, accessed in January 2000, found that the majority were of poor quality on the basis of composite scores for general and low back pain content. The authors concluded that individuals using the internet for information on back pain will find much advice that is not based on the best available evidence. They recommended that health professionals should not suggest that patients use the internet as a source of information and advice on low back pain, unless experts have evaluated the sites to ensure that the content is evidence based.

5.2.3 Work-focused interventions

The Department for Work and Pensions (DWP) leads an initiative, in partnership with the Department of Health and the Scottish Government, to help people claiming incapacity benefit return to the labour market. One element of this is the Condition Management Programme (CMP), run jointly by Jobcentre Plus and local NHS providers (CMP practitioners) including nurses, occupational therapists and physiotherapists. CMP practitioners provide CBT to enable patients to self-manage their condition. While return to work is the main outcome of interest to Jobcentre Plus, other outcomes are more applicable to patients and the NHS.

5.2.3.1 Study selection

CMP is being piloted in four sites in Scotland, therefore, search terms related to that intervention only. The literature search used the key terms ‘condition management programme’, ‘pathways to work’ and ‘Jobcentre plus’. Studies were selected if they:

- elicited information from patients unable to work because of back pain; and
- considered the use of a CMP; and
• assessed patient health outcomes related to low back pain or health service resource use during treatment of low back pain. These studies were to incorporate a control group that did not receive the intervention, or to compare outcomes before and after intervention.

Studies were excluded if they only reported on employment-related outcomes.

The literature search identified 30 titles and abstracts, which were screened to identify potentially relevant articles. A flow chart representing the selection of literature from the title and abstract identification stage to inclusion of the full report in evidence synthesis is presented in Appendix 13.1. A full report was obtained for one study, which met the inclusion criteria.

5.2.3.2 Assessment of the evidence

A qualitative study published by the DWP was assessed that included information from in-depth interviews with CMP practitioners and focused on challenges to implementation, but not client outcomes. The study is summarised in Table 5-2. The report stated that the outcomes considered important by CMP practitioners were not well represented by the standard outcome form returned to Jobcentre Plus. As a result, some CMP practitioners had their own outcome forms. CMP practitioners were interested in factors such as reduced medication need, increased functioning and quality of life (Barnes & Hudson, 2006). It was not clear if such data were collected as part of the study. Citations in the report referred to qualitative studies on the views and experiences of clients, but did not consider the effects of CMP on health outcomes or NHS resource use.

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study aim</th>
<th>Method</th>
<th>Participants</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Barnes &amp; Hudson, 2006)</td>
<td>Identify challenges to implementation of CMP</td>
<td>Qualitative in-depth interviews; thematic analysis</td>
<td>37 CMP practitioners, co-ordinators and managers</td>
<td></td>
</tr>
</tbody>
</table>
5.2.4 Improving communication

Some of the terminology used and explanations provided by the GP can act as an obstacle to recovery. Inappropriate diagnosis and labelling of the condition can encourage cure seeking, strain the relationship between the patient and their GP and promote fear avoidance behaviour. These concerns were also noted in patients attending the GGBP and recorded in transcripts from those contributing to DIPEx. Although GPs considered it useful to have patient information to give out, patients consulting with low back pain in Scotland are not usually offered The Back Book (2002). Patients and providers both mentioned the constraints placed on communication by the short consultation time routinely available in general practice.

5.2.4.1 Study selection

Studies were selected if they considered:

- investigations eliciting information on the nature (quality, problems, barriers etc) of communication between patients with simple, acute or chronic low back pain and GPs during the general practice consultation; or
- strategies aimed at improving communication between the patient and GP during the general practice consultation; and
- patient outcomes related to: back pain, patient understanding, patient/GP satisfaction and/or any measure of communication between the patient and GP. These studies were to incorporate a control group that did not receive the intervention, or to compare outcomes before and after intervention.

The literature search identified 560 titles and abstracts, which were screened to identify potentially relevant articles (Appendix 14.1). Full reports were obtained for eight studies, of which seven met the inclusion criteria; the remaining study was excluded for the reasons outlined in Appendix 14.2.

5.2.4.2 Assessment of the evidence

All studies which met the inclusion criteria used qualitative methods to explore GP and patient views on various aspects of low back pain management in primary care. The study populations are small and may not have reached ‘theme’ saturation. Conclusions drawn from qualitative studies are context and locality specific and might not be valid in other settings because, for example, deprivation is likely to be a confounder. Five of the studies were conducted in England; the remaining two were not UK-based. The assessed studies are summarised in Table 5-3.
Table 5-3 Studies of strategies proposed to improve communications between GPs and patients with low back pain

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study aim</th>
<th>Study setting</th>
<th>Method</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>(McIntosh &amp; Shaw, 2003)</td>
<td>Ascertain GP and patient experiences and expectations of information on LBP</td>
<td>Qualitative study, England</td>
<td>Purposive/convenience sampling; semi-structured interviews of GPs; patient focus groups; framework analysis</td>
<td>15 GPs; 37 patients with LBP</td>
</tr>
<tr>
<td>(Miller &amp; Pinnington, 2003)</td>
<td>Explore GPs behaviour and perceptions in relation to patients with LBP</td>
<td>Qualitative study, England</td>
<td>Semi-structured interviews, thematic analysis</td>
<td>17 GPs</td>
</tr>
<tr>
<td>(Rogers, 2002)</td>
<td>Explore GPs attitudes towards respect for patient autonomy in the management of LBP</td>
<td>Qualitative study, Australia</td>
<td>Purposive sampling; semi-structured interviews; thematic analysis</td>
<td>21 GPs</td>
</tr>
<tr>
<td>(Layzell, 2001)</td>
<td>Assess patient beliefs about back pain and satisfaction with services</td>
<td>Qualitative study, England</td>
<td>Focus group, thematic analysis; questionnaire survey</td>
<td>Eight volunteers with a back problem; questionnaires from 120 patients recently treated for back pain</td>
</tr>
<tr>
<td>(Schers et al., 2001)</td>
<td>Explore how GPs manage patients with LBP and factors that determine non-adherence to guidelines</td>
<td>Qualitative study, The Netherlands</td>
<td>Purposive sampling of GPs; each GP invited the first patient presenting with non-specific LBP to participate; semi-structured interviews; qualitative analysis</td>
<td>20 GPs and 20 of their patients (one per GP)</td>
</tr>
<tr>
<td>(Chew-Graham &amp; May, 1999)</td>
<td>Explore GPs understanding, approach to consultation and conceptualisation of the management of chronic LBP</td>
<td>Qualitative study, England</td>
<td>Purposive sampling; semi-structured interviews; thematic analysis</td>
<td>20 GPs</td>
</tr>
<tr>
<td>(Skelton et al., 1996)</td>
<td>Elicit patient views on LBP and its management in general practice</td>
<td>Qualitative study, England</td>
<td>Patients recruited by one invited GP in each of 12 practices; semi-structured interviews; thematic analysis</td>
<td>52 patients with recurrent LBP</td>
</tr>
</tbody>
</table>
A recent study of 17 GPs in England found that GPs perceived low back pain according to a biomedical model of illness, which did not take account of the psychosocial impact of low back pain on patients (Miller & Pinnington, 2003). A consequence of this was a negative attitude towards patients who did not recover. An earlier study of 20 GPs in England found that when GPs did consider chronic low back pain in the psychosocial context, this was at odds with the medical model adopted by patients to account for their pain. GPs did not challenge the patients’ views in order to avoid upsetting the patient-doctor relationship. This led to frustration and pessimism on both sides and ultimately undermined the patient-doctor relationship. According to the authors, the management of chronic low back pain must be seen in the context of the patient-doctor interaction, where negotiation has an impact on patient outcome (Chew-Gráham & May, 1999).

A recurring theme was the patients’ need for a clear diagnosis. Focus group participants in one English study believed that this validated their illness (Layzell, 2001) and patients in another study, also in England, reported discontent when their GP did not give them an explicit diagnosis (McIntosh & Shaw, 2003). Most patients interviewed in a Dutch study stated that they expected a specific diagnosis from their GP (Schers et al., 2001). Patients had their own ideas on the cause and prognosis of their condition and a diagnosis of non-specific back pain was not considered satisfactory.

McIntosh & Shaw (2003) reported that none of the 37 participants understood the diagnostic uncertainty associated with low back pain. Only a small number of patients believed that the uncertainty they felt regarding their condition reflected genuine professional uncertainty (Skelton et al., 1996). Patients misinterpreted diagnostic uncertainty as the GP being unable to help or believing them to be malingering. If the back pain subsequently became chronic, patients appeared to then blame it on their GP. The problems that diagnostic uncertainty causes for patients appeared not to be acknowledged or addressed adequately by most GPs (McIntosh & Shaw, 2003). The authors concluded that improved communication between doctor and patient on the nature of low back pain is warranted, requiring clinicians to communicate more effectively and have a better understanding of patients’ beliefs, experiences and behaviours. Schers et al. concur, suggesting that GP training in communication, negotiation and knowledge transfer skills could lead to more effective low back pain management (Schers et al., 2001).

Patients’ satisfaction regarding the management of their back pain was repeatedly linked with the quality of the explanation given to them by their GP. Layzell (2001) reported that 43% of respondents considered that their GP had given a clear explanation of their back problem. Only 29% considered that their GP gave clear instructions on which activities they could carry on doing. Another reason for dissatisfaction was insufficient consultation time preventing a full discussion of the condition (Layzell, 2001). Similarly, in the study by Skelton et al., patients felt satisfied if they felt that they had been listened to and had been given the opportunity to discuss their condition. Dissatisfaction was not always blamed on the GP, but when it was, it was associated with a perceived lack of interest and poor communication. Again, the authors concluded that patients’ views are complex and must be taken in to consideration to achieve good low back pain management (Skelton et al., 1996).

A study, in which 21 Australian GPs were interviewed on the management of low back pain, showed that attitudes towards the patient’s right to exercise freedom of choice varied (Rogers, 2002). GPs tended to be controlling and to promote medical interventions, with patient autonomy being most respected in decisions on the use of alternative therapies. Some GPs justified their attitudes based on ethical considerations or factors such as expediency. The author acknowledged that consultation time, the presence of co-morbidities and the doctor-patient relationship may influence attitudes, and concluded that there is a need for better GP understanding and respect for patient autonomy (Rogers, 2002).

5.2.4.3 Other studies

Studies considering the terminology used in relation to low back pain and its effect on patients’ perception of their condition were not identified by this search. However, several studies were identified during the course of this HTA as summarised below.

Abenhaim et al. (1995) noted that the patient’s initial diagnosis was strongly associated with the risk of chronicity. Hafner (2002) reported the use of language implying that low back pain arises from damage to the spine, thereby suggesting a requirement for rest, protection and surgery. Patient explanations included phrases such as: “deterioration in the spine with the discs narrowing”, “degenerative discs”, “the base of … the spine was worn out”, “discs had crumbled” and “wear and tear”. One patient commented that they had an image of their spine as crumbling and breaking down…and that “the more it hurt the more it was wearing away”. Another thought that “the bones were rubbing together and that it was a fairly hopeless situation”.

Given such statements, rest may appear to be the only option, with a decline in the condition being inevitable. Cedraschi (1998) showed the impact of presenting pathological findings as part of the clinical diagnosis, as making one patient fearful of participating in an educational programme having been told that his X-ray showed a herniated disc. For the patient, the concept of a torn disc was incompatible with a functional recovery and precluded exercise, which might be associated with risk of further tearing. The link between what patients are told and their interpretation is not straightforward, and depends on psychosocial factors including a need to gain legitimacy for their pain. Waddell argued that a common language would be advantageous for communication, to ensure that patients with non-specific back pain believe the prognosis is good and do not perceive their condition as serious or disabling (Waddell, 2004).
5.2.5 Education on pain management

The issue of pain education for primary care professionals was raised by members of the Patient Issues Sub Group and other contacts. With appropriate training, primary care professionals can facilitate self-management of pain for some patients, without the need for the involvement of specialist services (Jones, 2003). It has been reported that knowledge of pain among community-based professionals in Scotland is lacking, and that education is needed if they are to provide appropriate early intervention and long-term support (Jones, 2003). A number of educational institutions in Scotland and elsewhere in the UK offer interdisciplinary courses on pain for community-based professionals and the importance of assessing the impact of pain education has been highlighted (Jones, unpublished).

5.2.5.1 Study selection

The literature search was broadened to include all non-cancer pain due to the dearth of literature specifically related to low back pain. Studies were selected if they:

- elicited information from healthcare professionals working in primary care; and
- identified interventions aimed at providing pain management education to primary care professionals; and
- assessed outcomes related to low back pain and/or patient/provider satisfaction with low back pain management in primary care. These studies were to incorporate a control group that did not receive the intervention, or to compare outcomes before and after intervention.

The literature search identified 800 titles and abstracts, which were screened to identify potentially relevant articles. A flow chart representing the selection of literature from the title and abstract identification stage to inclusion of the full report in evidence synthesis is presented in Appendix 15.1. Full reports were obtained for five studies, none of which met the inclusion criteria. The excluded studies are summarised in Appendix 15.2.

Of these excluded studies, the most relevant was an RCT comparing an evidence-based training programme on the management of low back pain for community-based physiotherapists in an area of England compared with standard in service training (Stevenson et al., 2006). Outcomes measured were in terms of the use and importance placed by physiotherapists on treatments for low back pain. The study found that while there was some indication that psychosocial management of patients with low back pain was being used there was little change in what physiotherapists perceived to be important to patient recovery and actual clinical practice. There was, however, no measurement of patient outcomes.

5.2.5.2 Other evidence

The findings of primary research conducted in Scotland were obtained through personal contact with the investigator (Jones et al., 2001a). This postal survey (response rate 42%) indicated that community-based professionals (GPs, practice nurses, district nurses, physiotherapists, occupational therapists and social workers) in one Scottish local authority held attitudes and beliefs about chronic pain that would not enable them to provide effective early intervention. In addition, the conflicting beliefs among different professional groups could result in patients receiving mixed messages, eg with regard to activity. The researchers assessed pain education needs and preferences, and the perceptions of competence and performance in a multidisciplinary group of community-based professionals who attended a course on chronic non-cancer pain management (Jones & Martin, 2002; Jones et al., 2001b). Course participants reported increased knowledge, skills and attitudes, and changes in performance that could contribute to better pain management. Some participants reported organisational barriers to implementing their new knowledge, leading the authors to conclude that this required further investigation. The impact of education on patient health outcomes has yet to be evaluated (Jones & Martin, 2002).

Providers of interdisciplinary courses have noted that finding time to attend training may be a particular problem for GPs (Jones, 2003).

5.2.6 Barriers to implementation of guidelines

Several reasons for non-adherence were suggested including: the large number of guidelines available, GPs' attitudes and beliefs about low back pain, patients' expectations, aspects of primary care service organisation, and GPs not knowing what services are available.

GPs believed that guidelines are more likely to be used if they:

- are produced by a reputable source
- are a manageable size
- have content that is accessible without specialist knowledge
- are presented in a style that facilitates sharing with patients.

5.2.6.1 Study selection

Studies were selected if they:

- elicited information from GPs concerning why guidelines on the management of acute low back pain are not followed; or
- identified interventions aimed at overcoming barriers to acute low back pain guideline implementation in the general practice setting; and
- assessed outcomes of guideline compliance, patient outcomes related to back pain and/or patient/GP satisfaction. These studies were to incorporate a control group that did not receive the intervention, or to compare outcomes before and after intervention.

Studies were excluded if they solely quantified compliance with guidelines or assessed guideline dissemination or
implementation strategies not specifically targeted at an
identified implementation barrier(s). The systematic review
by Grimshaw (2004) concludes that feedback may have a
small effect on guideline implementation, however, this is
not discussed further in this section.

The literature search identified 273 titles and abstracts,
which were screened to identify potentially relevant
articles. A flow chart representing the selection of
literature from title and abstract identification to inclusion
of the full report in evidence synthesis is presented in
Appendix 16.1. Full reports were obtained for 12 studies,
comprising two systematic reviews and 10 primary
studies. Seven primary studies met the inclusion criteria
and the remaining five were excluded for the reasons
outlined in Appendix 16.2.

5.2.6.2 Assessment of the evidence

The literature search mainly identified evidence from
research not undertaken in the UK. Back pain
management is likely to be influenced to a certain extent
by the configuration of health services, which differs
greatly between countries, therefore, data obtained from
non-UK settings should only be extrapolated to the
Scottish setting with caution. A summary of the data
extracted is presented in Table 5-4.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study aim</th>
<th>Study setting</th>
<th>Participants</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Engers et al., 2005)</strong></td>
<td>Study aim: Assess effectiveness of a multifaceted intervention vs. no intervention in primary care</td>
<td>RCT of multifaceted intervention vs. no intervention</td>
<td>41 GPs, 616 consultations with 531 patients with non-specific LBP (331 initial and 85 follow-up consultations)</td>
<td>Adequate generation of random sequence and allocation concealment; primary outcome completed referral to physical, manual or exercise therapy; 35% drop-out rate balanced between groups; poor compliance with some intervention components. Mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
</tr>
<tr>
<td><strong>(Webster et al., 2005)</strong></td>
<td>Study aim: Assess whether primary care GP management of LBP is consistent with guidelines, considering variation in relation to sciatica and physician characteristics</td>
<td>Cross-sectional questionnaire survey based on two acute LBP scenarios, with and without sciatica; test of paired proportions, logistic regression in the US</td>
<td>720 GPs practising in primary care (103 in general practice, 196 in family practice)</td>
<td>13 GPs, 65 GPs, 21 nurses, 2020 physical assistants, 2020 patients in baseline year, 2,240 patients in study year; mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
</tr>
<tr>
<td><strong>(Espeland &amp; Baerheim, 2003)</strong></td>
<td>Study aim: Identify barriers to GP guideline adherence with regard to decision on plain radiography</td>
<td>Qualitative research; purposive sampling, focus groups, phenomenological analysis in Norway</td>
<td>13 GPs, 21 nurses, 2020 physical assistants, 2020 patients in baseline year, 2,240 patients in study year; mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
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</tr>
<tr>
<td><strong>(Schectman et al., 2003)</strong></td>
<td>Study aim: Investigate the impact of GP education and feedback, and patient education on saliva and physician characteristics</td>
<td>RCT of physician education and feedback, patient education, both or neither</td>
<td>85 GPs, 1,036 patients, 1,036 consultations, with and without education; mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
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</tr>
<tr>
<td><strong>(Schers et al., 2001)</strong></td>
<td>Study aim: Determine how GP management of LBP relates to patient and practice characteristics and reasons for non-adherence to guidelines</td>
<td>Qualitative research; purposive sampling; each GP systematically recruited one patient; semi-structured interviews; qualitative analysis</td>
<td>The Netherlands</td>
<td>20 GPs, 20 patients with non-specific LBP; mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
</tr>
<tr>
<td><strong>(Scheres et al., 2000)</strong></td>
<td>Study aim: Determine how GP management of LBP relates to patient and practice characteristics and reasons for non-adherence to guidelines</td>
<td>Computed questionnaire completed by GPs for all LBP consultations, regression analysis</td>
<td>The Netherlands</td>
<td>20 GPs, 20 patients with non-specific LBP; mixed physician population; 25% response rate; order of presentation of scenarios may have influenced responses.</td>
</tr>
<tr>
<td><strong>(Little et al., 1998)</strong></td>
<td>Study aim: Determine medical and psychosocial reasons for requesting back X-rays</td>
<td>Postal questionnaire</td>
<td>England</td>
<td>166 GPs; 70% response rate.</td>
</tr>
</tbody>
</table>
Patient expectations and GPs' perception of these were reported as reasons for non-adherence to guidelines (Schers et al., 2001; Schers et al., 2000). Past experience often shaped patients' views of what to expect from medical services when presenting with back pain and GPs acceded to this to avoid conflict (Schers et al., 2000). A UK study based on questionnaire responses from 166 GPs in England demonstrated that patient satisfaction and reassurance were common reasons for GPs requesting back X-rays, and that many GPs lacked confidence in back pain management (Little et al., 1998). These findings were supported by a qualitative study conducted in Norway, which identified the following non-clinical criteria that could influence a GP's decision to give a patient a radiography referral for back pain (Espeland & Baerheim, 2003): the patient's wishes (sometimes influenced by other healthcare professionals); a desire to maintain control while showing willingness to help; uncertainty (including lack of clinical skills); protection of professional dignity; the anticipated consequences of obtaining an X-ray result; access to alternative services and compliance with pressure from other healthcare providers.

Little et al. suggested that a strategy aimed at improving GPs' confidence and understanding of patients' concerns would encourage them to provide reassurance, by explaining the nature of back pain, the consequences and risks of spinal X-rays and the desire to avoid unnecessary X-rays (Little et al., 1998). Schers et al. (2001) surmised that back pain care could be improved by training GPs in communication methods, however, the views of GPs and patients and the need to maintain a good relationship between the two must be considered for guideline implementation to be successful.

Webster et al. (2005) observed in a US survey that GPs were less compliant with guidelines when managing patients with sciatica than when managing patients with non-specific back pain without sciatica. They concluded that more research on factors underlying the apparent influence of sciatica on non-compliance was needed to inform interventions to change physician behaviour.

An RCT conducted in the Netherlands measured the effect of a multifaceted intervention designed to overcome patient-related barriers to guideline adherence identified in previous studies (Engers et al., 2005). The intervention included GP and patient education and a tool to help GPs concord with physical therapists on the management of non-specific low back pain. No significant differences were seen between intervention and control groups in the overall rate of referral to physical therapy, prescription of pain medication or the adequacy of patient education provided by the GPs. However, there were significantly fewer GP referrals to physical therapy during follow-up consultations, suggesting improved guideline adherence. The authors concluded that the intervention had minimal impact on guideline adherence, but that this was probably because GPs in both intervention and control groups were already highly compliant.

The effect of a patient education intervention combined with a physician education and feedback strategy was assessed in a US RCT (Schectman et al., 2003). Physician education and feedback addressed physicians' views on low back pain which conflicted with guideline recommendations. The patient education component, including a pamphlet and video, was designed to tackle patients' beliefs and expectations which conflicted with the guidelines. The study found physician education and feedback were associated with an increase in guideline-consistent behaviour, but showed no benefit for patient education. The patient education intervention did not alter the common patient belief that low back pain should be treated by a specialist with use of an X-ray. However, less than a third of the physicians in the intervention group reported issuing patients with the pamphlet and fewer used the video. A weakness of the study is that a similar proportion of patients in the control and intervention groups reported receiving patient education material (Schectman et al., 2003).

5.3 Discussion and conclusions

The findings from many of the studies identified by the literature search should only be generalised to the Scottish setting with caution as the research was qualitative or was not conducted in the UK. While the majority of literature searches were restricted to low back pain as this is the focus of the HTA, it is recognised that this, in part, accounts for the retrieval of few or no studies which meet the inclusion criteria.

Anecdotal evidence suggests that low back pain management using analgesic medications is suboptimal. However, further research is needed to determine how patients actually use prescribed drugs. GPs cited patient non-compliance with treatment regimens, side-effects and lack of efficacy as contributors to the under-treatment of pain. Education and good communication may help to alter patient views on the appropriate use of analgesic agents.

The benefits of patient education are not clear. The literature highlights shortcomings in patient information provision, relating to both low back pain and access to services. GPs are uncertain regarding their role in providing information, suffer from inadequate resourcing, and are sometimes limited in their knowledge and ability to provide information. If GPs are unable to provide the information, it is important that they can direct the patient elsewhere for appropriate advice. Patients expressed a desire for reliable, relevant patient-centred information and some favoured the use of personal stories to illustrate research outcomes. Positive reactions to The Back Book were usually noted but, despite its small cost, financial restrictions limit its more widespread use. Internet information is often inaccurate and misleading and, whilst information is needed by patients, consideration must be given to its quality, nature, timing of provision and purpose.

The systematic review noted improved knowledge and beliefs among patients following provision of patient information, but conflicting results regarding health outcomes and healthcare use. Patient-centred information
professionals’ attitudes, beliefs and behaviour towards chronic non-cancer pain such as low back pain. Further research is needed to determine whether pain education improves patient outcomes.

Evidence regarding GP guideline implementation, during the management of acute low back pain in primary care, is largely consistent in finding that the main barriers are associated with: preconceived attitudes, beliefs and expectations and with the way services are organised. Within general practice, it is recognised that issuing guidelines does not alter clinical practice, as GPs can feel overwhelmed by the volume of guidelines issued. Consideration should also be given to other ways of promoting the translation of evidence into practice.

Evidence for the effectiveness of interventions aimed at overcoming known barriers is limited in terms of the small number of trials, poor compliance with interventions within trials, and the applicability of the findings when guideline compliance is poor. However, overall the evidence indicates that interventions designed to enhance guideline implementation are not particularly effective (Jewell, 2003). Research into effective ways of improving the care provided by GPs needs to consider contextual barriers to implementing change.

As a result of the lack of outcome data, no conclusions could be reached concerning the beneficial effects of work-focused interventions for either the patient or NHSScotland.

Literature reports from qualitative research spanning almost 10 years are consistent in the finding that there is a need to improve the way that GPs explain low back pain to their patients. This is likely to require both a change in attitudes and improved communication and negotiation skills. These conclusions imply a need for better understanding of the patient’s perspective of their back pain. However, emphasis on the need for negotiation may be at odds with the brevity of the standard consultation in general practice. Published studies considering the effectiveness of interventions that improve communication are scarce. However, a population-based education strategy was shown to have a positive influence on both patient expectations and GP beliefs, which may have improved GP management of low back pain and patient outcomes.

Published and unpublished studies suggest that pain education can have a positive influence on primary care professionals’ attitudes, beliefs and behaviour towards chronic non-cancer pain such as low back pain. Further research is needed to determine whether pain education improves patient outcomes.

Evidence regarding GP guideline implementation, during the management of acute low back pain in primary care, is largely consistent in finding that the main barriers are associated with: preconceived attitudes, beliefs and expectations and with the way services are organised. Within general practice, it is recognised that issuing guidelines does not alter clinical practice, as GPs can feel overwhelmed by the volume of guidelines issued. Consideration should also be given to other ways of promoting the translation of evidence into practice.

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6 ORGANISATIONAL ISSUES RELEVANT TO CLINICAL AND COST EFFECTIVENESS

6.1 Introduction

This section describes current service provision for low back pain services in Scotland, as evaluated from the questionnaire survey and data from other sources. Organisational issues include the use of: triage back pain services; access to investigations, physiotherapy, orthopaedics and pain management services; referral processes; staff resources; training needs; and use of e-referrals. The implications of these factors are considered in conjunction with the conclusions from the clinical and cost effectiveness evidence, and patient issues sections.

6.2 Acute low back pain service delivery models – A survey of current practice

A survey was undertaken of the acute low back pain service delivery models currently used in each of the NHS boards in Scotland. This augmented information that was already available from work undertaken as part of the CCI orthopaedic redesign projects and a report produced on AHP activities within musculoskeletal services (Parroy, 2005a).

Methodology

Between April and July 2007, lead physiotherapists, or their closest equivalent, in each NHS board were contacted by telephone or email, and questioned about the delivery of services for acute low back pain within the NHS board. It was not possible in the time available to obtain complete coverage for all NHS boards, and the results obtained should be considered as providing an indication of the service delivery models available, rather than a fully comprehensive listing.

Information gathering focused upon the aspects of service delivery models investigated within the clinical effectiveness section of this HTA, namely triage of orthopaedic referrals, prompt referral and referral authority for physiotherapists to consultant services and for MRI scans. The following specific points were covered:

- self-referral to physiotherapy
- electronic referral to physiotherapy
- the role of ESPs
- availability of a dedicated back pain service
- exercise classes and other supporting services.

A summary of the information gathered, which provides an indication of the service delivery models available across NHSScotland is presented in Table 6-1.
Table 6-1 Acute low back pain service delivery models in NHSScotland

<table>
<thead>
<tr>
<th>NHS board</th>
<th>Can patients self-refer to physiotherapy?</th>
<th>Are electronic referral systems used?</th>
<th>Role of extended scope practitioner</th>
<th>Availability of dedicated back pain service</th>
<th>Classes and other support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayrshire &amp; Arran</td>
<td>No</td>
<td>To be introduced in Ayr Hospital on 12 June 2007</td>
<td>Three musculoskeletal ESPs, one based at Ayr Hospital, one at Crosshouse Hospital and one at Ayrshire Central. ESPs hold clinic sessions alongside orthopaedic consultants. Referrals triaged by orthopaedic consultants and passed to ESPs where appropriate. ESPs can refer for MRI and X-rays, and give injection therapy.</td>
<td>No</td>
<td>Functional restoration and educational classes are held in all acute hospitals. Hydrotherapy is available at Crosshouse Hospital and Arroll Park, Ayr.</td>
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<tr>
<td>Borders</td>
<td>Three 6-month pilots taking place. One in Borders Hospital with GPs from Galashiels, and two in community with GPs in Hawick and Coldstream. Physiotherapy at Borders General Hospital has been able to receive electronic referrals for several years. Not all GPs use electronic referral, but all should have option to do so.</td>
<td>One ESP within the orthopaedic service. ESP triages referrals and has the patient list. ESP can request X-rays and MRI scans. An A&amp;E based physiotherapist on weekdays, one based in rheumatology. (Certain senior physiotherapists can request X-rays or refer into the pain service.)</td>
<td>Has had back pain service since 1999. Originally comprising three area-based physiotherapists, but as a result of staff retention difficulties, there is now one central post within Borders General Hospital. Provide specialist opinion and see difficult cases. Potentially cover patients from all areas of the Borders, but most acute back pain.</td>
<td>Back classes are within Borders General Hospital and health centres.</td>
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</tr>
<tr>
<td>Dumfries &amp; Galloway</td>
<td>Three practices currently participating in pilot study of self-referral to secondary care. Self-referral in Annandale and Eskdale/Nithsdale.</td>
<td>No</td>
<td>One ESP triages with podiatry, an occupational therapy and orthopaedic team member weekly. ESP operates own patient lists resulting from triage process. ESP not able to refer for X-ray or MRI, but discussions regarding this were taking place at the time of the survey. ESP can give injection therapy.</td>
<td>No</td>
<td>Spinal fitness exercises. Patients assessed individually for suitability.</td>
</tr>
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<td>NHS board</td>
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<tr>
<td>Fife</td>
<td>Self-referral in place at Rosewell Clinic with discussions as to extending the practice. Patients within Dalgety Bay Health Centre can self-refer. Most referrals within acute hospitals are from other parts of the hospital.</td>
<td>Not at present, although Hospital Information System, a Fife wide scheme was due to be implemented at the time of the survey.</td>
<td>Eight ESPs covering all specialties. ESPs see patients who need further investigation. Can also refer to consultants, and for X-rays and MRI. Orthopaedic surgeon triages referrals, and sends some patients to ESPs, creating two waiting lists. Looking into having one list, with ESPs working alongside orthopaedic surgeons. Due to advertise for a new post of consultant physiotherapist, at time of survey, to work within primary care and CHP. To ensure that patients receive appropriate primary care and do not need to be referred to acute care. Mainstream physiotherapists can refer to ESPs.</td>
<td>No</td>
<td>Back to Fitness classes including pain management run at each acute hospital site. Patients attend twice a week for 8 weeks. End stage programme at Fife Institute for patients who have not progressed sufficiently.</td>
</tr>
<tr>
<td>NHS board</td>
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<tr>
<td>Forth Valley</td>
<td>Self-referral was expected to start within a few months of the survey.</td>
<td>All GPs have capacity to refer electronically, but few do so to Stirling hospital, and none to Falkirk.</td>
<td>Musculoskeletal ESPs for shoulder and neck conditions. Acute back pain tends to be managed by mainstream physiotherapy. One ESP in the back pain service.</td>
<td>Service set up 2.5 years before survey to help manage the orthopaedic waiting list. ESP triages and then sees most orthopaedic patients. ESP can refer to orthopaedics and for MRI. If mainstream physiotherapists need to refer to orthopaedics, for MRI or blood tests, they go via ESP. Long-term plan to get into community to see patients at source, and prevent unnecessary orthopaedic referral, also to have a GP education role. These aims have not been realised due to existing waiting lists.</td>
<td>Pain Association Scotland asked to provide a service for chronic pain patients on waiting lists. This has worked well, and all physiotherapists can refer to this programme. Back in Action programme has been set up and is held in community leisure centre. 3-week programme, with one session a week consisting of 30 minutes exercise and 30 minutes information. Exercise component led by leisure centre assistant, and information by ESP. On completion, patients encouraged to continue with exercise. Physiotherapists encouraged to refer into programme. Links with ‘Well Connected’ in Stirling and JobCentre Plus in Falkirk, to provide support for those with employment issues.</td>
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<tr>
<td>Grampian</td>
<td>Central Aberdeenshire only</td>
<td>No</td>
<td>ESPs work with two spinal surgeons in the Western Infirmary and Glasgow Royal Infirmary.</td>
<td>Grampian wide LBP pathways for those working in acute and primary care sectors. Acute and primary care have back rehabilitation classes within Aberdeen. Back classes in Stonehaven are linked with leisure centres. Provide general rehabilitation, hydrotherapy, Pilates, relaxation and stress management.</td>
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<td>Central Aberdeenshire only</td>
<td>Yes</td>
<td>Yes</td>
<td>GPs can refer electronically to orthopaedics but are encouraged to refer via GGBPS physiotherapy specialists.</td>
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<tr>
<td>Greater Glasgow and Clyde secondary care</td>
<td>Yes</td>
<td>Yes</td>
<td>13 clinical specialists work within normal outpatient physiotherapy departments across community and acute settings.</td>
<td>Greater Glasgow and Clyde secondary care LBP service for acute patients has been running since 1998. Community low back pain service has been running since July 2004.</td>
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<td>No</td>
<td>ESPs can refer electronically to orthopaedics but are encouraged to refer via GGBPS physiotherapy specialists.</td>
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<td>Greater Glasgow and Clyde former area</td>
<td>Yes</td>
<td>Yes</td>
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<td>Greater Glasgow and Clyde remote area</td>
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</table>

*GGBPS* = Greater Glasgow and Clyde physiotherapy service

**Note:** Grampian does not cover parts of Aberdeenshire for LBP service. Some parts of Aberdeenshire for LBP service are covered by the Grampian LBP service. In Aberdeen, only LBP classes are mainstream physiotherapy. Some parts of Aberdeenshire for LBP service are covered by the Grampian LBP service. In Aberdeen, only LBP classes are mainstream physiotherapy.
<table>
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<tr>
<th>NHS board</th>
<th>Availability of dedicated back pain service</th>
<th>Classes and other support</th>
<th>Role of extended scope practitioner</th>
<th>Electronic referral systems used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highlands</td>
<td>No</td>
<td></td>
<td>Raigmore Hospital has three musculoskeletal ESPs, and two senior physiotherapists who are GP partners (one attends GP surgeries). ESPs are triage service. ESPs are responsible for assessing patients and advising whether they a) are not suitable for physiotherapy, b) need orthopaedic referral, and c) need to be seen by an orthopaedic surgeon. They can self-refer to ESPs or refer to other physicians. Caithness, Lochaber, Fort William, East Highlands, Badenoch and Strathspey have musculoskeletal specialists who cannot refer to orthopaedics. ESPs cannot make radiological referrals, though it is hoped to set this up in the future.</td>
<td>Raigmore Hospital has three musculoskeletal ESPs, and two senior physiotherapists who are GP partners (one attends GP surgeries). ESPs are triage service. ESPs are responsible for assessing patients and advising whether they a) are not suitable for physiotherapy, b) need orthopaedic referral, and c) need to be seen by an orthopaedic surgeon. They can self-refer to ESPs or refer to other physicians. Caithness, Lochaber, Fort William, East Highlands, Badenoch and Strathspey have musculoskeletal specialists who cannot refer to orthopaedics. ESPs cannot make radiological referrals, though it is hoped to set this up in the future.</td>
</tr>
<tr>
<td>East Highlands, Badenoch and Strathspey</td>
<td>Not available in Inverness.</td>
<td>6 weeks of supervised exercise sessions available. Physiotherapists can refer patients to local leisure centre.</td>
<td>Raigmore Hospital has three musculoskeletal ESPs, and two senior physiotherapists who are GP partners (one attends GP surgeries). ESPs are triage service. ESPs are responsible for assessing patients and advising whether they a) are not suitable for physiotherapy, b) need orthopaedic referral, and c) need to be seen by an orthopaedic surgeon. They can self-refer to ESPs or refer to other physicians. Caithness, Lochaber, Fort William, East Highlands, Badenoch and Strathspey have musculoskeletal specialists who cannot refer to orthopaedics. ESPs cannot make radiological referrals, though it is hoped to set this up in the future.</td>
<td>To be implemented in Oban and North Argyll.</td>
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*ESP*: Extended scope practitioner.
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</tr>
</thead>
<tbody>
<tr>
<td>Lanarkshire</td>
<td>No</td>
<td>ESP service designed electronic forms for musculoskeletal and LBP referrals, to improve triage information quality.</td>
<td>ESP physiotherapy clinics in place in Hairmyres Hospital and being extended to Wishaw General and Monklands General at the time of survey. ESPs work alongside orthopaedic consultants and carry out primary vetting of all orthopaedic referrals and directs them to ESP, podiatry, spinal and musculoskeletal clinics with the remainder going to consultants. ESPs assess and organise case management, with referral to other services if necessary. Can refer to back classes at venues across Lanarkshire. ESPs do joint and soft tissue injections. ESPs carry out venupuncture and request blood tests. ESPs are currently able to request MRI scans, but not X-rays. Protocols are being developed Lanarkshire wide to facilitate ESP request of X-rays.</td>
<td>ESP physiotherapists see complex back pain cases alongside consultants’ clinics. Have remit in primary care to educate GP and physiotherapists on guideline use. Physiotherapists can access orthopaedic clinics for appropriate back pain patients where ESP agrees clinical need.</td>
<td>Back classes set up in conjunction with South Lanarkshire leisure services across multiple venues and being rolled out across Lanarkshire in 2007.</td>
</tr>
<tr>
<td>NHS board</td>
<td>Can patients self-refer to physiotherapy?</td>
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<tr>
<td>Lothian - Edinburgh secondary care</td>
<td>No</td>
<td>No, since March 2006 all GP referrals to the spinal orthopaedic service are triaged by the spinal physiotherapy practitioner.</td>
<td>One spinal ESP clinic held with consultants. Orthopaedic spinal team also includes a musculoskeletal consultant who will see ESP patients for facet joint injections, epidurals etc. Spinal ESP can refer to other consultants (neurosurgery, rheumatology etc), pain clinic, Western General Hospital (Royal Infirmary, Edinburgh, until recently only saw chronic pain patients with peripheral problems). ESP can request MRI, X-rays, blood tests, dexa scans and put patients on surgical waiting lists. ESP has a role in developing service and a teaching commitment to the community triaging service.</td>
<td>Referral to the Astley Ainsley pain management service (clinical psychologist, medical and physiotherapy service).</td>
<td>TENS service available for all spinal patients. Introducing functional and educational back classes. Referral to Ashley Ainsley back pain association for hydrotherapy sessions. Referral to community leisure centres.</td>
</tr>
<tr>
<td>Lothian - East and Midlothian</td>
<td>No</td>
<td>Across East Lothian and Midlothian, GPs have the capacity to refer electronically via SCI Gateway, though not all practices choose to. Physiotherapy has an SCI Gateway address for receiving e-referrals, located in Roodlands Hospital.</td>
<td>East Lothian has one ESP in the musculoskeletal clinic in Roodlands Hospital. Holds clinic sessions alongside orthopaedic medicine consultants, orthopaedic surgeon and rheumatologist. ESP triages referrals alongside one of the orthopaedic medicine consultants and has own caseload with independent problem solving and decision making, referring onwards as appropriate. Can refer for X-rays, blood tests, ultrasound scans, give injection therapy etc. MRI requires consultant referral. Also has developmental role with physiotherapy service and responsibility for audit and research.</td>
<td>Not at the time of survey. Current LBP service pilot in Dunbar area - multi-agency, multidisciplinary, physiotherapy-led project delivering self-referral for LBP population with phone triage and streaming to appropriate resource. Red flags indicate GP assessment, ‘simple’ back pain referred to local physiotherapy department. Exercise group in local leisure facility bridges to healthy living type physical activity on completion. Chronic pain yellow flag group receive CBT in local leisure setting. Lessons learned to be used across East Lothian.</td>
<td>Work under way in Midlothian to develop exercise groups in leisure setting, to include those with LBP. Chronic pain services under development in Midlothian, to include patients with LBP.</td>
</tr>
<tr>
<td>NHS board</td>
<td>Can patients self-refer to physiotherapy?</td>
<td>Are electronic referral systems used?</td>
<td>Role of extended scope practitioner</td>
<td>Availability of dedicated back pain service</td>
<td>Classes and other support</td>
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</tr>
<tr>
<td>West Lothian</td>
<td>Yes</td>
<td>Electronic referral for domiciliary services only.</td>
<td>ESP covers several clinics (consultant orthopaedic and community) and has a clinical workload.</td>
<td>No</td>
<td>Back fitness classes are run which patients attend twice a week for an hour. Consist of warm up, stretches, aerobic exercises with an emphasis on exercise quality. A tip of the day is given and discussed during the class. Patients can also attend a back and neck education class. A partnership with West Lothian Leisure refers patients directly to a tailored fitness programme, as part of, or following, treatment.</td>
</tr>
<tr>
<td>Orkney</td>
<td>No</td>
<td>Some email referrals from the islands because quicker, but mostly traditional referral methods.</td>
<td>No. Orthopaedic surgeon at capacity, but another orthopaedic surgeon position planned rather than ESP.</td>
<td>No</td>
<td>Because a small NHS board, there are informal arrangements for consultan referrals.</td>
</tr>
<tr>
<td>Shetland</td>
<td>No</td>
<td>No</td>
<td>No. One physiotherapist with extended training including McKenzie method and special interest in backs, who gives advice.</td>
<td>No</td>
<td>Back school classes run in local leisure centre and core stability classes within hospital. These are mainly for chronic pain patients.</td>
</tr>
<tr>
<td>NHS board</td>
<td>Can patients self-refer to physiotherapy?</td>
<td>Are electronic referral systems used?</td>
<td>Role of extended scope practitioner</td>
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<tr>
<td>Tayside</td>
<td>No</td>
<td>Yes, across the trust GPs can email referrals.</td>
<td>Three ESPs in post who triage orthopaedic referrals and clinics in Perth and Angus. Dundee - orthopaedic and neurosurgery referrals. ESPs can refer for X-ray, ultrasound and MRI and are able to see and discharge patients without discussion with consultant.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Western Isles</td>
<td>Not at time of survey, but hopefully by end of 2007.</td>
<td>No (perceived as useful, but insufficient IT support).</td>
<td>One musculoskeletal/orthopaedic ESP who holds clinic sessions alongside the orthopaedic consultant in orthopaedic and fracture clinic. Undertakes orthopaedic triage with orthopaedic consultant. Can give injection therapy, request blood tests, ultrasound, X-rays. MRI requires consultation with orthopaedic consultant as referral to the mainland. Can refer to consultants.</td>
<td>No</td>
<td>GP exercise referral scheme, in conjunction with the local sports centre. All mainstream physiotherapists can refer directly to ESP who can then refer to orthopaedic consultant without going back to GP.</td>
</tr>
</tbody>
</table>
6.3 Results

6.3.1 Self-referral

In Greater Glasgow and Clyde, all patients with acute low back pain can self-refer. In four NHS boards, self-referral is available in some areas, whilst another two NHS boards are currently running pilots in parts of their regions. Of the remaining NHS boards, two indicated that an option for patients to self-refer should become available later in 2007 and five that self-referral was not available.

6.3.2 Electronic referral

This was taken to include both specialist computer systems to allow electronic referral, and the use of email referral. Electronic referral is available in at least part of the region for eight NHS boards. A further two NHS boards hope to introduce this capability in the near future. There is no use of electronic referral in three NHS boards.

6.3.3 Role of extended scope practitioners

Physiotherapists work in extended scope roles within all NHS boards except Orkney and Shetland. In some NHS boards, these practitioners work exclusively with low back pain, whilst in others they see a broader range of musculoskeletal conditions. The extended roles carried out include triaging patients referred to orthopaedic consultants, having an orthopaedic referral caseload, and making direct consultant and radiological referrals. Educational and support functions for other physiotherapists and GPs also come under the remit of some ESPs.

ESP within Borders, Dumfries & Galloway, Forth Valley, Greater Glasgow and Clyde, Highland, Lanarkshire, Lothian, Tayside and the Western Isles triage orthopaedic referrals. This triage primarily occurs within secondary care, but in some NHS boards, such as Highland, it occurs in primary care. Measures to prevent unnecessary referral from primary to secondary care are in place or planned in Fife, Forth Valley, Greater Glasgow and Clyde, Grampian, Lanarkshire and Lothian. However, outreach work is often limited due to lack of funding and long waiting lists.

ESP hold clinics alongside orthopaedic consultants in most NHS boards, namely Ayrshire and Arran, Borders, Dumfries & Galloway, Fife, Forth Valley, Greater Glasgow and Clyde, Highland, Lanarkshire, Lothian, Tayside and Western Isles.

In Fife, Forth Valley, Greater Glasgow and Clyde, Grampian, Highlands, Lanarkshire and the Western Isles, ESPs can refer directly to orthopaedic consultants without referring back to the patient’s GP. Likewise, direct referral for MRI scans is available to ESPs in Ayrshire & Arran, Borders, Fife, Forth Valley, Greater Glasgow and Clyde, Tayside and parts of Lanarkshire and Lothian. In some NHS boards, such as Fife, Forth Valley and the Western Isles, mainstream physiotherapists can refer to ESPs for onward referral to orthopaedics or for MRI, rather than referring back to the patient’s GP.

6.3.4 Back pain service

The Borders, Forth Valley, part of Grampian, Greater Glasgow and Clyde, Lanarkshire and Tayside have a dedicated low back pain service. An ongoing pilot of a low back pain service was taking place in East Lothian at the time of the survey. These services differ greatly in their scope and scale, reflecting the nature and size of the areas they serve. The most developed and extensive service is that available in Greater Glasgow (Greater Glasgow Back Pain Service, 2006).

6.3.5 Classes and other support

A variety of different types of classes for low back pain patients take place around Scotland, involving both exercise and educational components. Some are held in the acute hospital setting, whilst others are provided in health centres and other community venues. In some instances, links are in place with organisations such as Pain Association Scotland and local leisure centres, to provide classes within the community.

6.3.6 Additional information

In addition to the specific information gathered during the questionnaire, a number of common themes emerged during discussion with lead physiotherapists or equivalents. These included the continued inappropriateness of many orthopaedic consultant referrals, the need for closer links between primary and secondary care with support and advice for GPs, the usefulness of protocols and pathways, and the importance of providing support services within the community. It was noted that service redesigns have been undertaken, but encounter difficulties in sustaining momentum and funding.

6.4 Discussion

A variety of service delivery models are in place across Scotland. These different models reflect the diverse nature of the areas served by each NHS board, historical service provision, the enthusiasm and expertise of local staff, and the availability of funding and support. Every NHS board has some of the aspects of service delivery models considered in this HTA in place.

6.5 Implications for NHSScotland

The survey of service delivery models in Scotland demonstrates the variation of approaches in terms of: self-referral by patients, use of electronic referral systems, the role of ESPs and the availability of a dedicated back pain service. While the clinical effectiveness conclusions identify the paucity of evidence to recommend specific delivery models, it is possible to highlight issues that NHSScotland should consider when developing low back pain services. In addition, research is needed to address gaps in the evidence base.

The development of low back pain services should be seen in the context of the five key domains identified for quality in healthcare (Institute of Medicine, 2001):
• effectiveness – healthcare should be based on the best evidence
• access and timeliness – healthcare should be based on the best evidence
• safety
• patient-centredness
• disparities, ie healthcare should be provided on the basis of clinical need, and should aim to reduce differences in health status and outcomes across subgroups.

Leatherman and Sutherland (2005) highlight a sixth domain of ‘capacity’, which they argue is important in the historical context in which the NHS operates.

Clinicians and health service managers developing low back pain services will need to take account of some key publications noted in this HTA. The Prodigy and European guidelines (Prodigy, 2005; van Tulder et al., 2005) on low back pain describe evidence-based recommendations for the diagnosis and treatment of acute non-specific low back pain. The development of low back pain services requires the implementation of these guidelines. The Musculoskeletal Services Framework (2006) identifies issues for promoting services redesign, exploiting the skills and new roles of health professionals to ensure better outcomes for patients with musculoskeletal problems. The framework highlights the need to improve care outside of the hospital setting, eg the role of professionals in developing self-care skills, and at the interface, with secondary care. NHS boards need to develop local evidence-based protocols, if not already available, for local audit of low back pain services.

NHS boards will need to consider the following issues as they develop local protocols:

• referral to the service, eg self or GP referral
• the mode of referral – electronic or paper
• referral information quality (Grimshaw et al., 2005)
• how protocols are disseminated (Grimshaw et al., 2004)
• point of referral receipt, eg orthopaedics or physiotherapy
• management of referrals
• the use of telephone and paper triage
• patient-focused booking
• condition management, ie clinical physiotherapy practice, evidence-based therapy
• exit strategies, eg self-management, leisure services, pain service and exercise classes.

Each NHS board needs to consider how the protocols will configure local services. Some, such as GCBPS, have a separate low back pain service. Others will manage low back pain as part of either orthopaedic or orthopaedic services. It is crucial that services are used appropriately and that patients with simple mechanical back pain are streamed to the physiotherapy service and not onto orthopaedic waiting lists.

The use of primary vetting by ESPs in Lanarkshire has allowed removal of patients with mechanical low back pain from orthopaedic consultant waiting lists, to be preferentially assessed by the physiotherapy service. Patients requiring further investigation were then fast tracked into the orthopaedic service where clinical need was identified. Physiotherapy practitioners were able to request an MRI scan if necessary without conferring with an orthopaedic consultant. Where the scan was consistent with a clinical picture indicating amenability to surgery, referral to a spinal surgeon was made. This practice cut the waiting time from referral to surgery by more than 52 weeks for patients in Lanarkshire. It reduced the time to first appointment and facilitated appropriate assessment and management for simple mechanical low back pain cases.

6.6 Staffing – resources and training

As NHS boards develop back pain services, staff will need appropriate training for new and extended roles. This needs to occur in conjunction with clinical governance arrangements in NHS boards and needs to address medico-legal issues and staff responsibility and accountability. Appropriate, structured, evidence-based training for physiotherapy staff who manage patients with low back pain is paramount in delivering quality services.

Physiotherapists working in orthopaedic triage roles will require a level of training and experience to allow them to fulfill the gatekeeper role. This training can be given ‘on the job’ with input from orthopaedic medical colleagues. These physiotherapists are required to have highly developed examination and assessment skills appropriate to identifying which patients require investigations and/or surgical intervention. Using these skills within the published low back pain guidelines allows effective management.

Training may be in the form of taught external courses, which individual therapists attend, or in-service training where senior staff cascade theoretical and practical knowledge throughout the staff in a service. There is a need for consistency of the knowledge and practical ability among therapists across grades, teams and geographical sites. This will ensure that evidence-based guidelines are applied and effective diagnosis and treatment is given to the benefit of the patient.

A first step could be to evaluate and analyse the training needs of all staff in relation to the services provided. Needs analysis will identify themes to facilitate the development of training packages appropriate to meeting service delivery. For example, it is important for individual therapists to be able to assess the individual patient to determine whether their back pain condition is amenable to physiotherapy or whether a more hands-off management approach is appropriate.

6.7 Information and management of technology

Accurate, accessible and appropriate information allows referrals to be streamed to the most appropriate individual for management. Referrals may be through manual or
electronic referral systems (e-referrals), which some NHS boards have now initiated. Experience with e-referrals suggests that they can make audit of local protocols more effective and efficient.

An example of this was seen in the Lanarkshire NHS board where an electronic referral screen was developed to guide the GP in giving appropriate information on the site of pain, symptom duration, medication and any possible red flags. Integral to this is the Referral Management Service which receives all orthopaedic referrals including those for low back pain. These are vetted daily on receipt and passed to the most appropriate clinical service and, through triage, referred to the most appropriate clinician. Educational reminders are built into the referral process to guide the GP on red flags and X-ray requests (Eccles et al., 2001). Physiotherapy staff are able to deal with mechanical back pain, to identify patients requiring further investigation. Using compatible information packages, patient demographic information and medical history can be ‘bolted on’ to the referral at source further facilitating triage. The use of e-referral speeds up the process, with GPs able to send the referral directly from the office at the time of consultation with no delays for typing and mailing (Grimshaw et al., 2005).

6.8 Quality assurance

Quality assurance of low back pain services requires audit and monitoring of training, as noted above, and also assessment of a range of indicators including:

- whether GPs refer at the right time and to the right low back pain service, eg physiotherapy or orthopaedic, in accordance with local protocols?
- whether their message is consistent eg giving out appropriate advice and using materials such as The Back Book?
- waiting time to first appointment
- treatment outcomes, eg physiotherapy and orthopaedic interventions
- patient satisfaction with services and outcomes, eg physiotherapy and GP
- patient and public expectations of back pain treatment.

6.9 Discussion and conclusions

Whilst it is disappointing that systematic review of the clinical effectiveness evidence has not provided more precise answers on the issue of organisation of low back pain services, it is important to note that there is evidence on how to treat low back pain. This HTA cannot recommend a ‘model’ low back pain service to NHSScotland which brings together the four HTA dimensions of clinical effectiveness, cost effectiveness, patient issues and organisational issues. However, there is sufficient evidence to outline the principles for low back pain services in the Prodigy and European guidelines (Prodigy, 2005; van Tulder et al., 2005) and other publications. Following these principles will meet the key domains of quality in healthcare.
7 COST EFFECTIVENESS

7.1 Introduction

This section summarises the cost effectiveness evidence available from the published literature on the referral of patients with acute low back pain. The objective of the economic evaluation was to review:

- the evidence for the cost effectiveness of adopting specialist gatekeepers in conjunction with GPs within the primary care setting, through which referrals to secondary care or further primary care are passed, compared with current practice
- the evidence for the cost effectiveness of adopting specialist gatekeepers within a secondary care setting, who assess relevant low back pain referrals to orthopaedics and/or neurosurgery and/or radiology and/or A&E, compared with current practice
- the evidence for the cost effectiveness of patient self-referral to a physiotherapist compared with the standard care option of GP referral
- the evidence for the cost effectiveness of multidisciplinary or multifaceted approaches to the rehabilitation of acute low back pain.

7.2 Methodology

This section evaluates the cost effectiveness of different referral options within primary and secondary care for the management of acute low back pain, using the same comparators and associated patient pathways as described in the clinical effectiveness section.

The interventions assessed comprised:

- the use of specialist gatekeepers within the primary or secondary care setting, to assess patients with low back pain
- direct patient access to physiotherapy by either self-referral or referral on the suggestion of a GP
- improving speed of access to specialists for patients referred by GPs
- the use of multidisciplinary or multifaceted approaches to the rehabilitation of acute low back pain.

The economic outcomes assessed were:

- the health service resource costs to undertake the intervention and any consequential changes in patient management costs
- the initial patient costs and any cost changes that occur as a result of the intervention
- the societal costs and any cost changes that occur as a result of the intervention
- quality of life
- utility usage implications.

7.2.1 Evidence sources

Evidence to support this section of the HTA was obtained from a wide variety of sources. Initial scoping searches were performed to identify economic evaluations relating to the different low back pain referral options within primary and secondary care. The NHS Economic Evaluation Database (NHSEED), the Health Economics Evaluation Database (HEED) and websites of major international health economics research units were searched for relevant economic evaluations. A copy of the strategy used to search the MEDLINE database is presented in Appendix 3, and this strategy was adapted to search other databases. A complete listing of all strategies can be obtained by contacting NHS QIS.

As little additional supporting data were identified by the scoping searches, a separate systematic literature search was not performed. Instead the clinical effectiveness data were examined for relevant economic information. In addition, a small number of studies were identified by scanning the bibliographies of retrieved items and on recommendation from members of the HTA Topic Group and as part of the submission process.

7.2.2 Study selection

Studies were included if their assessment population comprised: adults with acute or chronic low back pain, mixed populations with acute and chronic low back pain, or adults with undefined low back pain. This comprised a wider patient group than that assessed for clinical effectiveness, in order to capture economic evaluations that considered the impact of acute back pain becoming chronic. No limitation was placed with respect to location, the use of a comparator or the study design.

The electronic search yielded 1,174 references. Full text articles were obtained for 83, and the others were excluded as irrelevant on the basis of title and or abstract alone. Of the 83 studies, 14 met the inclusion criteria.

7.3 Results

7.3.1 The cost effectiveness of using specialist gatekeepers within primary care and providing direct patient access to physiotherapy

The traditional referral pathway for patients with acute low back pain presenting to primary care involves them being assessed clinically by a GP. If the GP considers that the patient requires further consultation, a referral is made to secondary care using a standard referral letter or form, or, in urgent cases, by telephone.

Several studies have investigated the cost effectiveness of using specialist gatekeepers, usually appropriately trained physiotherapists, to manage the care of patients referred by GPs for further assessment. Such models aim to free GP time in the primary care sector and consultant time in the secondary care sector. Adopting specialist gatekeepers and introducing direct clinic access have been trialled simultaneously in most studies and so the evidence for these two interventions is considered together.
7.3.1.1 Assessment of the evidence

Six relevant reports were identified, comprising: one literature review (Robert & Stevens, 1997), three observational studies (Holdsworth, 2006; Pinnington et al., 2004; Gatchel et al., 2003), one pilot study of GPs referring patients directly to physiotherapy services (Fordham & Hodkinson, 1998) and one retrospective study of health insurance claims (Mitchell & de Lissovoy, 1997). Three studies were set in Scotland or England and two in the USA. Two studies recruited only patients with low back pain and the other four considered a wider group with musculoskeletal disorders. A summary of the data from each of these papers is presented in Table 7-1.
Table 7-1 Evidence on the cost effectiveness of using specialist gatekeepers in primary care and patient self-referral to physiotherapy

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Setting</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Pinnington et al., 2004)</td>
<td>Observational study using a practice-based prompt access physiotherapy service</td>
<td>Assessment of NHS costs for a new LBP episode at 12 weeks after discharge</td>
<td>614 patients in Cheshire from 17 GPs</td>
<td>About 50% of patients presented with LBP</td>
<td>Prompt access (within 72 hrs where possible) Primary care physiotherapy service for new LBP episodes Back pain clinics with access to back pain rehabilitation service</td>
<td>Conventional management</td>
<td>All patients had at least one GP visit. Average cost per LBP episode Medication £8.34 In patients £4.46 GP visits £20.67 Other community/hospital services £10.35 Physiotherapy £30.24 Total £74.06, compared with management using exercise programme £86.83 and GP management £111.05.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study type</td>
<td>Setting</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
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<tr>
<td>(Robert &amp; Stevens, 1997)</td>
<td>Literature review</td>
<td>8 studies</td>
<td>Patients requiring physical therapy (back, neck, shoulder)</td>
<td>GPs with self-referral to physical therapy (practice-based)</td>
<td>Usual care</td>
<td>Little evidence of reduced physiotherapy attendance. Waiting time reduced. Consultant referrals reduced with open-access. Recovery time better for open-access. No difference in return to work. Self-referral rate higher than for indirect access (consultant referral). Financial costs to patient. Physiotherapist employed by GP £0.74 Open-access £9.55 Referral £47.94 Health service costs: one onsite physiotherapist doubled referral rates vs. open hospital access. Additional cost to physiotherapy department with open-access was £3,300 per annum Open-access patients used less physiotherapy time than consultant-referred. Generated a demand for service that would otherwise be unmet. Self-referred patients were likely to have a higher referral rate and lower medication usage than GP referred. GPs were good at selecting patients for open-access Advantages: reduced waiting time, convenience, reduced patient and health authority costs. Recovery time may be better, but no evidence that patient had reduced treatment duration or time off work.</td>
<td>None compared costs and savings from, eg less medication, fewer repeat GP visits and fewer consultant referrals</td>
</tr>
<tr>
<td>Citation</td>
<td>Study type</td>
<td>Setting</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Results</td>
<td>Additional comments</td>
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<tr>
<td>(Gatchel et al., 2003)</td>
<td>Observational study</td>
<td>USA</td>
<td>Acute LBP &lt;2 months since onset of episode and fully employed at time of study</td>
<td>High-risk patients randomly assigned to functional restoration early intervention</td>
<td>Non-intervention plus low risk and no early intervention</td>
<td>Early intervention cost effective</td>
<td>High-risk early intervention group had fewer chronic pain disabilities and a higher return to work rate than high-risk (91% vs. 69%) and no intervention (87% for low-risk patients)</td>
</tr>
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<td></td>
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<td>Costs $12,721 for high-risk intervention vs. $21,843 for high-risk no intervention patients – cost of programme offset by fewer healthcare visits and less time off work</td>
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</tr>
<tr>
<td>(Holdsworth, 2006)</td>
<td>Multi-centre national, cost minimisation study</td>
<td>3,010 patients in 26 general practices in Scotland</td>
<td>Patients with musculo-skeletal conditions</td>
<td>Self-referral (22%) and GP suggested referral (18%)</td>
<td>GP referral (60%) and GP suggested referral (18%)</td>
<td>No difference in outcomes for the 3 interventions so cost minimisation used</td>
<td>Assumes national mean referral rate of 53.5–66.0 per 1,000 in rural and 44.5 in urban practices</td>
</tr>
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<td></td>
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<td></td>
<td>Average costs:</td>
<td>Good rates of referral to X-ray and secondary care. Number of GP appointments, prescribing rates, costs of drugs, MRI, X-ray referral etc given</td>
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<td></td>
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<td></td>
<td>• Self-referral £66</td>
<td>Assumes all patients comparable at baseline though this was not measured</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>• GP referral £89</td>
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<td>• GP suggested £80</td>
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<td></td>
<td></td>
<td>Extrapolated to Scotland gives £2 million annual savings</td>
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<td></td>
<td>Self-referral did not increase overall referral rate, except where the service was previously underprovided</td>
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<td>Citation</td>
<td>Study type</td>
<td>Setting</td>
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| (Fordham & Hodkinson, 1998)    | Pilot of GP open-access in Calderdale Health Authority, 1985–1986 Hospital and GP workload and associated costs and benefits assessed at 2 months | E&W 2 practices. 390:249 in intervention vs. 141 in control                   | Patients had one of six pains: Acute neck, Acute shoulder, Back, Arthritis, Soft tissue injury, Acute back pain. | Open-access physiotherapy (19%) Consultant referral of patients who could have been referred to open-access had it been available (34%) | Consultant referrals (16.5% vs. 29.8%). Referrals to physiotherapy higher for open access (19% vs. 8%). 76% of the open access group received physiotherapy, but 59% of control group were not referred on | Resources
Open access 6.6 physiotherapy sessions, mean time 187 minutes
Consultant referred 10.1 physiotherapy sessions, mean time 312 minutes
GP practice consultant referral 8.2 sessions, mean time 295 minutes.
Shorter waiting times (22 days vs. 124 vs. 91 days)

Costs
Average physiotherapy costs cost per case
£42 for usual care
£25 for open-access
No change in GP costs or consultations
| Evidence of substitution of open-access to physiotherapist for no further referral
Additional cost to physiotherapy department for service £3,300 (unclear if per patient)
Private treatment data presented |
| (Mitchell & de Lissovoy, 1997) | Retrospective review Visits and reimbursement assessed | USA, direct access patients | Acute musculoskeletal condition needing physical therapy. Health insurance claims used to identify patients | Self-referral (252 patients) | Self-referral reimbursement $324 per claim cheaper for physical therapies Total costs $2,236 for physician referral vs. $1,004 for self-referral. Self-referral associated with fewer visits and lower costs | Patients not matched so reason for differences in treatment costs is unknown |
The literature review (Robert & Stevens, 1997) identified eight studies of models providing physical therapy services and reported that:

- self-referred patients used significantly less physiotherapy time than consultant-referred patients
- the option for self-referral generated a demand for services that would otherwise not have been met.

Cost effectiveness analyses and cost minimisation procedures were not used in any of the component studies; none compared the marginal costs of the service with the savings from fewer repeat GP visits, reduced consultant time or medication usage. One study reported that patient financial costs were lower when GPs employed a physiotherapist compared with self-referral or consultant-referral.

A national study of 3,010 patients (Holdsworth, 2006) from 26 Scottish GP practices compared the costs associated with managing three patient groups: GP referrals, GP suggested referrals and patient self-referrals to a physiotherapy service. As there was no difference in clinical outcome between groups, the author assessed the cost minimisation impact on NHS expenditure. The mean costs of an episode of care were lowest for self-referred patients at £66 and rose to £80 for patients undergoing GP suggested referral and to £89 for GP referred patients.

Further cost data from a subset of 806 of these patients were analysed, as summarised in Table 7-2. In this patient subset, 24% of patients self-referred, 54% were referred by their GP and 22% underwent GP suggested referral.

Patients referring to physiotherapists based on a suggestion from their GP required fewer contacts with both the GP and physiotherapist. However, fewer patients in the self-referral group required additional referrals to secondary care or imaging; prescription of medication (in particular NSAIDs and combination analgesia) was also less likely in self-referring patients.

The mean cost of a care episode was lowest for patients referred following their GP’s suggestion at £83, rising to £91 for self-referred patients and £98 for GP referred patients. The ‘mixed economy’ option, where self-referral to physiotherapy is available alongside GP referral, was associated with lower NHS costs than only GP referral in all geographical settings (urban, semi-rural and rural). The total financial benefit to NHSScotland of using a parallel system of physiotherapy self-referral for low back pain was estimated at £650,000 per year.

Another UK study (Fordham & Hodkinson, 1998) of GP referral to a prompt access, physiotherapist-led back pain clinic reported similar findings, with the mean NHS costs

### Table 7-2 Average NHS-related costs (2004) by referral type (data from Holdsworth [2006])

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Self-referral</th>
<th>GP suggested</th>
<th>GP referral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP appointments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>2.12±1.00</td>
<td>1.90±0.85</td>
<td>2.17±0.99</td>
</tr>
<tr>
<td>Range</td>
<td>1–4</td>
<td>1–4</td>
<td>1–4</td>
</tr>
<tr>
<td>Total sample</td>
<td>188</td>
<td>175</td>
<td>432</td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£38.16</td>
<td>£34.20</td>
<td>£39.06</td>
</tr>
<tr>
<td><strong>Physiotherapy contacts</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>4.56±3.90</td>
<td>3.63±2.67</td>
<td>4.45±3.14</td>
</tr>
<tr>
<td>Range</td>
<td>1–22</td>
<td>1–18</td>
<td>1–21</td>
</tr>
<tr>
<td>Hours*</td>
<td>1.7</td>
<td>1.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Total sample</td>
<td>189</td>
<td>171</td>
<td>428</td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£41.50</td>
<td>£33.03</td>
<td>£40.50</td>
</tr>
<tr>
<td><strong>MRI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£2.44</td>
<td>£2.61</td>
<td>£3.17</td>
</tr>
<tr>
<td><strong>X-ray</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£3.77</td>
<td>£5.61</td>
<td>£7.05</td>
</tr>
<tr>
<td><strong>Prescribed NSAIDs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£2.71</td>
<td>£3.16</td>
<td>£3.43</td>
</tr>
<tr>
<td><strong>Prescribed analgesia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£2.07</td>
<td>£2.89</td>
<td>£3.01</td>
</tr>
<tr>
<td><strong>Referral to secondary care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost per episode</td>
<td>£0.43</td>
<td>£1.40</td>
<td>£2.46</td>
</tr>
<tr>
<td>Total average cost per episode</td>
<td>£91.08</td>
<td>£82.90</td>
<td>£98.68</td>
</tr>
</tbody>
</table>

Based on GP costs of £18 per appointment; physiotherapy costs of £9.10 per contact; MRI £152.35; X-ray £54.5; NSAID £10.39; analgesia £7.50; outpatient referral £82. *Assumed 22.5 minute physiotherapy appointment (0.375 hour).
of managing a patient being approximately £75 compared with over £110 for GP management alone. A pilot study of open-access to physiotherapy services in Yorkshire (Robert & Stevens, 1997) concluded that the additional annual costs of providing open-access to physiotherapy was about £3,300 per GP practice. The number of consultant referrals fell and open-access patients used significantly less physiotherapy time, but this did not reduce GP workload. No formal cost minimisation analysis was undertaken.

A US study Gatchel et al. (2003) concluded that providing patients with access to early intervention services is cost saving, by reducing healthcare and drug costs and facilitating an earlier return to work thereby reducing social costs. Retrospective analysis of insurance claims (Mitchell & de Lissovoy, 1997) in the US reported that self-referral episodes of care were shorter and had lower associated costs ($1,000 compared with $2,240).

7.3.1.2 Implications of the studies to the Scottish setting

These studies suggest that providing direct and early access to physiotherapy services can lower costs. However, as none of the studies randomised patients to their respective assessment arm, patient characteristics could account for some of the cost differences observed. This would have a notable impact if patients with more severe symptoms attend their GP in the first instance, rather than self-referring to a physiotherapist.

7.3.2 The cost effectiveness of using specialist gatekeepers within the acute care setting

Only one report was identified that was considered suitable to inform this question (Daker-White, 1999) and a summary of the data from this paper is presented in Table 7-3.
Table 7-3 Evidence on the cost effectiveness of using specialist gatekeepers in the acute care setting

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Setting</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
</tr>
</thead>
</table>
| (Daker-White, 1999)       | RCT, NHS research and development | Assessed pain measures at 5.6 months | 481 Bristol outpatients                                 | Trained physiotherapist assessment and management of patients referred to outpatients | Junior surgeons    | • Orthopaedic physiotherapy specialists as effective as post-fellowship junior staff and assistant surgeons in initial assessment and management of new referrals. Physiotherapy specialist assessment was associated with lower initial costs.  
• Patient satisfaction was higher with physiotherapist service.  
• No differences in patient outcome.  
• Physiotherapists ordered fewer tests and made fewer referrals to surgeons.  
• No clinical differences.  
• Cost minimisation showed no significant differences in patient costs or NHS primary care costs.  
• Direct hospitals costs were lower for physiotherapists (mean cost £256 vs. £498 for junior doctor).  
• Main savings in fewer radiographic assessments and referral to surgery. |
The study evaluated the use of trained physiotherapists to assess and manage outpatients with musculoskeletal problems. The comparator arm used junior surgeons for patient assessment and management. There were no differences in patient outcomes between groups, but higher patient satisfaction and lower costs were associated with the physiotherapy arm. The lower costs were mainly due to fewer requests for radiographic assessment and fewer referrals for orthopaedic surgery. The study, therefore, suggested that using specialist physiotherapists as gatekeepers within the acute care setting was cost effective compared with using junior surgeons in the same role.

Seven relevant articles were identified by the literature search, two were systematic reviews (van der Roer et al., 2005; Thomsen et al., 2001), one was an economic analysis alongside a randomised trial (Whitehurst et al., 2007), three were randomised trials (Jensen et al., 2005; Skouen et al., 2002; Grahn et al., 2000) and one was an observational study (Cipher et al., 2001). Two studies were conducted in Sweden and one each in Norway, the USA and England. Most patients had long-term musculoskeletal disorders and were off work. The evidence from these studies is summarised in Table 7-4.

7.3.3 The cost effectiveness of multidisciplinary/multifaceted approaches to the rehabilitation of acute low back pain patients
Table 7-4 Evidence on the cost effectiveness of using multidisciplinary teams to provide pain management services

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Setting</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Thomsen et al., 2001)</td>
<td>Systematic review</td>
<td>Danish hospital</td>
<td>Patients with chronic pain, 4 of 9 studies considered back pain</td>
<td>Multidisciplinary pain management</td>
<td>Standard care (14 reports of 9 studies )</td>
<td>Multidisciplinary management was associated with significant cost savings and fewer attendances. Functional restoration programmes were better than less intensive programmes, based on both the patient perspective and cost effectiveness considerations. Addition of cognitive/relaxation therapy added cost with no clinical benefit.</td>
<td>Costings poor; only 4 studies were RCTs, follow-up was short. Due to serious methodological issues with study design and outcome measures no conclusions were possible.</td>
</tr>
<tr>
<td>(Cipher et al., 2001)</td>
<td>Observational study</td>
<td>31 patients in tertiary centre in Texas</td>
<td>Patients with chronic pain (&gt;6 months) referred to multidisciplinary pain clinic</td>
<td>Compared medication alone vs. medication and CBT</td>
<td>No treatment</td>
<td>CBT cost effective vs. no therapy or medication only: costs comparable with no therapy, but better efficacy achieved, medication alone showed no improvement. Mean functional scores were the same for medication and PCT and neuroflextherapy (NT) but were lower for medication alone. Cost highest ($6,281) were for medication alone (medication + CBT $2,695; NT cost $2,328)</td>
<td>Bias introduced as determined by insurance status.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study type</td>
<td>Setting</td>
<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Results</td>
<td>Additional comments</td>
</tr>
<tr>
<td>----------------------</td>
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<td>-----------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>(Jensen et al., 2005)</td>
<td>Randomised study</td>
<td>Absence from work, healthcare utilisation and QoL assessed 36 months post-rehabilitation</td>
<td>Patients with long-term non-specific back pain, sick listed for 1–6 months, between 18–60 years of age and covered by an insurance scheme</td>
<td>Therapies for 4 weeks with 4–8 participants including six psychological sessions and one clinician examination 1. Behaviour orientated physiotherapy 2. CBT 3. CBT plus behaviour management</td>
<td>Standard care</td>
<td>The full time behavioural program was effective at increasing health and decreasing costs for women but not for men. No significant differences in return to work and few statistical differences for healthcare use. Option 3 patients consulted fewer physiotherapists. Cost per patient: 1. €1,000 2. €1,179 3. €1,862 Option 3 had lowest total cost (intervention + sick leave + pension) for women, others not dissimilar to usual care.</td>
<td>Wide confidence intervals and underpowered.</td>
</tr>
<tr>
<td>(Skouen et al., 2002)</td>
<td>RCT</td>
<td>Productivity gains assessed at 26 months</td>
<td>Chronic LBP patients, sick listed for &gt;8 weeks (mean 3 months) or not sick listed but sick for &gt;2 months per year for 2 years</td>
<td>Light multidisciplinary therapy (n=52) - 1 hour physiotherapy, 30 minutes nurse, 1 hour psychologist + three follow-up sessions Extensive multidisciplinary therapy (n=57) for 4 weeks of 6 hour sessions, 5 days a week CBT + education + exercise</td>
<td>Usual care at spine clinic, referral back to GP (n=86)</td>
<td>Offering patients a light multidisciplinary program at a spine clinic was associated with highest time at work (24 months)  • Men - 16.9 months vs. 11.1 usual care vs. 14.1 extensive care  • Women - 13.1 months vs. 11.9 usual care vs. 12.4 extensive care No statistical differences between extensive therapy and usual care. Net societal gain of US $852,000 for 57 patients.</td>
<td></td>
</tr>
</tbody>
</table>
### (Grahn et al., 2000)

**Study type**: Prospective matched controlled study  
**Setting**: Health related QoL and patient costs assessed at 2 years  
**N**: 122  
**Patient characteristics**: Patients with prolonged musculoskeletal disorders and long sick periods  
**Intervention**: 4 weeks full-time multidisciplinary rehabilitation using body awareness therapy, CBT, pain + stress management  
**Comparator**: Usual care drugs + physiotherapy  
**Results**: Intervention group had higher direct costs (median £6,106 vs. £1,959) with no difference in indirect costs (£12,946 vs. £15,390). Tendency for improved QoL in rehabilitation group.  
**Additional comments**: Highly motivated patient have lower mean costs over 2 years.

### (van der Roer et al., 2005)

**Study type**: Systematic review  
**Setting**: Functional measures, satisfaction, disability, pain and costs assessed  
**Patient characteristics**: Patients with LBP  
**Intervention**: 17 studies: five on acute LBP; three subacute; five chronic; four mixed. Variety of interventions, eg exercise, chiropractor, multidisciplinary rehabilitation, ergonomics, bed rest and worksite visit with booklet  
**Comparator**: Mixed  
**Results**: Six studies were cost effective vs. control: Early intervention Neuroflextherapy Exercise program Light mobilisation Light multidisciplinary treatment Interventions superior to self exercise. Other studies showed no differences.  
**Additional comments**: Number of intervention studies limited. Interventions, comparators and patient groups heterogeneous, so no definite conclusions. Methods used to identify costs inconsistent.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Setting</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Results</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Whitehurst et al., 2007)</td>
<td>Economic analysis with a randomised trial</td>
<td>28 GP practices in Staffordshire</td>
<td>402 patients with LBP &lt;12 weeks duration</td>
<td>Biopsychosocial brief pain management programme (BPMP)</td>
<td>Physical therapy (PT) including spinal mobilisation</td>
<td>No statistical difference in clinical outcomes using RMDQ at 3 and 12 months. Similar back pain function, psychosocial, measures and clinical assessments. Mean cost per patient £142 for BPMP vs. £195 for PT. QALYs per patient 0.754 for BPMP vs. 0.774 for PT. ICER £2,360 for PT compared with BPMP. Sensitivity analyses reported only 17% chance that BPMP is cost effective compared to PT.</td>
<td>Non responders account for 36% of costs (n=264) and may cause bias if not matched across treatment arms. Cost included private care, which was used more frequently in PT. Removing private costs increases cost/QALY.</td>
</tr>
</tbody>
</table>
The most recent systematic review (van der Roer et al., 2005) considered 17 studies, with most comparing a variety of interventions for cost effectiveness analysis. The authors were unable to reach any conclusions on the cost effectiveness of any intervention because of the heterogeneity of the component studies. The second review (Thomsen et al., 2001) considered 14 reports from nine studies evaluating the economic consequences of multidisciplinary treatment of chronic pain. One study was from the UK and only four were specific to back pain. Due to serious methodological concerns regarding study design and outcome measures, the authors were unable to draw conclusions on cost effectiveness.

The results of the only economic analysis performed in the UK (Whitehurst et al., 2007) compared a biopsychosocial brief pain management programme with physical therapy including spinal mobilisation. The interventions consisted of one 40-minute assessment/treatment session plus up to six subsequent 20-minute treatment sessions. The study concluded that, when compared with a biopsychosocial management programme, physical therapy:

- had higher healthcare costs, mainly from more inpatient episodes
- showed slightly greater clinical benefit
- was likely to be more cost effective.

The reasons why the physical therapy arm had higher medical and surgical inpatient episodes were not identified.

7.4 Discussion and conclusions

The literature review and synthesis of selected studies for patients with acute low back pain found:

- no robust evidence from randomised studies to show that provision of direct and early access to physiotherapy services can lower NHS costs
- weak evidence that using specialist physiotherapists, rather than junior surgeons, as gatekeepers within the acute care setting is clinically and cost effective
- weak evidence that multidisciplinary/multifaceted approaches may not be cost effective compared with physical therapy.

There are many limitations with the studies, particularly the systematic reviews where studies could not be combined because of heterogeneity of the component studies and variability in outcomes. Other concerns include the non-generalisability of the results from studies in non-UK settings to Scotland.

The paucity of evidence on the clinical effectiveness for these interventions has been discussed in Section 4. Given the lack of robust measures of clinical effectiveness, no economic modelling was judged to be of value.
8 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

8.1 Consideration of the evidence

Back pain is one of the most common health problems affecting society, with up to 70% of the population experiencing pain at some point in their lifetime. It is associated with significant healthcare use and societal cost in terms of work loss and disability, and has had a variety of approaches to management.

Various different service models are in use or have been proposed in Scotland to ensure the prompt delivery of appropriate diagnosis, management and treatment of acute low back pain. A survey conducted as part of the HTA found that services vary in their provision of referral management systems, referral authority, use of extended scope practitioners, the availability of prompt access and treatment modalities. Many NHS boards have already started to redesign services.

To inform future development of services in Scotland, this HTA considered the clinical and cost effectiveness of service delivery models for the management of acute low back pain which utilise different triaging referral models.

The systematic review of scientific literature found a paucity of high quality evidence to inform the organisation of low back pain services in Scotland. Much of the published research on organisation of low back pain services makes no distinction between acute and chronic back pain or indeed between back pain and musculoskeletal conditions. A further issue with research in this area is the lack of standardised patient-focused outcome measures and comparators.

Consequently, this HTA cannot recommend a ‘model’ low back pain service to NHSScotland that brings together the four HTA dimensions of clinical effectiveness, cost effectiveness, patient issues and organisational issues. However, there are a number of conclusions from the systematic review of the evidence which may be of benefit to NHS boards when developing services and determining which treatments to use.

8.2 Recommendations

1. NHS boards should take account of existing evidence-based guidelines and advice for the management of low back pain. The Prodigy and European guidelines include recommendations for:

   • giving adequate information and reassurance to the patient, and avoiding negative messages
   • advising the patient to stay active and continue normal daily activities, including work, if possible
   • referral for spinal manipulation for patients who fail to return to normal activities
   • multidisciplinary treatment programmes in occupational settings for workers on sick leave for more than 4–8 weeks.

   In addition, the Prodigy and European guidelines identify treatments for which there is insufficient evidence of effectiveness, evidence of ineffectiveness or inconclusive evidence, including: traction, TENS, bed rest, specific exercises, epidural steroid injections, back schools, massage therapy, behavioural therapy, electrotherapy, ultrasound interferential therapy, laser treatments and acupuncture.

2. NHS boards should consider the following conclusions from the systematic review of service delivery models for acute back pain:

   • The balance of evidence suggests that triage by a specialist gatekeeper, whether a physiotherapist, nurse or other clinician, results in shorter orthopaedic surgeon waiting times and higher conversion to surgery rates. Estimates typically exceed 80% for the proportion of patients managed entirely by physiotherapy, advice and/or exercise. If orthopaedic surgeons have their referrals triaged, their time will be freed up for patients requiring surgery, who will get faster access to the surgeon. Patients not needing surgery will be managed more appropriately and quickly.

   • There is some evidence that self-referral to a physiotherapist can reduce the waiting time for patients when compared with referral by a GP.

   • There is weak evidence that using specialist physiotherapists, rather than junior surgeons, as gatekeepers within the acute care setting is clinically and cost effective.

3. Any redesign of services for low back pain in Scotland should include an evaluation element, incorporating consideration of both clinical and cost effectiveness and should use validated clinical outcome measures.

4. NHS boards should take account of the key issues identified by the Patient Issues Sub Group, including reluctance of patients to use medication for pain relief, inadequate information provision for patients and work-related concerns, when developing or redesigning service for low back pain.


9 ACKNOWLEDGEMENTS

NHS Quality Improvement Scotland is grateful to all experts (Appendix 1) who gave generously of their precious time to contribute constructively to evidence appraisal and the writing of this report. Thanks to those who provided information on patient pathways: Chris Johnstone, Debbie Kirk, Charles Martin, Stephen Robinson, Alan Yorston, Lynn Scott, Nick Gibson, Janet Braidwood, Rob Forbes, Ian Yellowlees, Helen Robertson, Audrey Watson, Rhona Pennie, Charles Boyce, Graham Blamire, Hilary Gilmore, John McClennan, Margaret Kerr, Nia Taylor, Mrs Forrest, Mitchell Flores, Mandy Ferguson, Lesley Holdsworth, Janet Hall, Jane Green, Vivien Thomson and Nigel Raby. Thanks to those who provided information on economics: Robert McKay, Susan Smith and Gordon Davidson. Finally, we would like to express our appreciation to all respondents to the organisational issues telephone survey. We hope this has also achieved an important goal of sharing knowledge and best practice across Scotland.
10 REFERENCES


Jones D. *Professionals attitudes and beliefs about chronic non-cancer pain*. [Unpublished].


Parroy S. 2005a. AHP activities in Scottish MSK services: A scoping study for NHSScotland.


### Appendix 1  Experts involved in the HTA

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Geraldine Allison</td>
<td>Public Partner</td>
<td>Glasgow</td>
</tr>
<tr>
<td>Professor Rosaline Barbour</td>
<td>Professor of Health &amp; Social Care</td>
<td>University of Dundee</td>
</tr>
<tr>
<td>Ms Karen Baxter</td>
<td>Public Partner</td>
<td>Glasgow</td>
</tr>
<tr>
<td>Ms Mairi Caldwell</td>
<td>Policy Advisor</td>
<td>Scottish Government Health Directorates</td>
</tr>
<tr>
<td>Ms Eve Cruickshank</td>
<td>Acting Head Occupational Therapist</td>
<td>Woodend Hospital, Aberdeen</td>
</tr>
<tr>
<td>Mr David Falconer</td>
<td>Pain Association Scotland</td>
<td>Edinburgh</td>
</tr>
<tr>
<td>Ms Gillian Grant</td>
<td>Clinical Specialist Physiotherapist</td>
<td>Woodend Hospital</td>
</tr>
<tr>
<td>Ms Karen Henderson</td>
<td>Mental Health Project Manager</td>
<td>Merchiston Hospital</td>
</tr>
<tr>
<td>Ms Harriet Hughes</td>
<td>Project Manager</td>
<td>Scottish Government Health Directorates</td>
</tr>
<tr>
<td>Mr Mick McMenemy</td>
<td>Lead Clinician</td>
<td>Greater Glasgow Back Pain Service</td>
</tr>
<tr>
<td>Dr Stewart Mercer</td>
<td>Senior Clinical Research Fellow</td>
<td>University of Glasgow</td>
</tr>
<tr>
<td>Dr Blair Smith</td>
<td>Reader in General Practice &amp;</td>
<td>University of Aberdeen</td>
</tr>
<tr>
<td></td>
<td>Honorary Consultant in Primary Care</td>
<td></td>
</tr>
<tr>
<td>Dr Frank Smith</td>
<td>Consultant Radiologist</td>
<td>Aberdeen Royal Infirmary</td>
</tr>
<tr>
<td>Ms Janie Thomson</td>
<td>Physiotherapist</td>
<td>Hairmyres Hospital</td>
</tr>
<tr>
<td>Ms Norma Turvill</td>
<td>Physiotherapist</td>
<td>Falkirk &amp; District Royal Infirmary</td>
</tr>
<tr>
<td>Professor Gordon Waddell</td>
<td>Orthopaedic Surgeon</td>
<td>Glasgow</td>
</tr>
</tbody>
</table>
Appendix 2  Description of redesigned referral and treatment strategies participating in the Outpatient Programme initiative

The Greater Glasgow Back Pain Service

The GGBPS was launched in September 2002 to provide a better care pathway for patients with low back pain by using a specialist team of physiotherapists and psychologists (http://library.nhsgg.org.uk/mediaAssets/library/greater_glasgow_back_pain_service_annual_report_2004.pdf). The GGBPS clinical team triages patients to assess their need for specialist imaging or orthopaedic referral. The service has integrated within primary and acute care physiotherapy departments to promote prompt treatment access for patients with acute low back pain.

NHS Argyll and Clyde

In the former NHS Argyll and Clyde region, specialist community physiotherapists are available to assess and treat self-referring patients with low back pain, using protocols developed by local GPs, consultants and allied health professionals.

NHS Forth Valley

In the Forth Valley service, redesign has been implemented to streamline the referral of patients with low back pain to ensure prompt and appropriate management. As a result, all patients with low back pain that remains unresolved after 12 weeks are referred to a single assessment point.
Appendix 3  Clinical and cost effectiveness search strategies

Clinical effectiveness searches were conducted for each of the questions within this HTA. The following search strategy was developed for questions covering triage of low back pain and specialist gatekeepers in primary and secondary care.

Databases: MEDLINE, MEDLINE IN PROCESS, EMBASE, CINAHL, AMED, HMIC

Platform: OVID multifile

Coverage:
• MEDLINE: Up to March Week 2 2006
• MEDLINE IN PROCESS: Up to March Week 2 2006
• EMBASE: Up to 2006 Week 11
• CINAHL: Up to March Week 2 2006
• AMED: Up to March 2006
• HMIC: Up to March 2006

Search run: 22 March 2006 (the strategy was adapted for AMED and HMIC and run on 4 April 2006). All database searches repeated on 11 June 2007.

Search terms were:
1. exp back pain/ use mesz
2. exp polyradiculopathy/ use mesz
3. exp sciatic neuropathy/ use mesz
4. intervertebral disk displacement/ use mesz
5. exp back ache/ use emez
6. radiculopathy/ use emez
7. radicular pain/ use emez
8. radiculitis/ use emez
9. polyradiculitis/ use emez
10. sciatic neuropathy/ use emez
11. ischialgia/ use emez
12. exp intervertebral disk disease/ use emez
13. spinal pain/ use emez
14. exp back pain/ use nursing
15. radiculopathy/ use nursing
16. exp sciatica/ use nursing
17. intervertebral disk displacement/ use nursing
18. (back adj2 pain$).tw.
19. backpain$.tw.
20. (lbp or albp).tw.
22. backache$.tw.
23. lumbago.tw.
24. (spin$ adj3 pain$).tw.
27. dorsalgia.tw.
28. ((prolapse$ or hernia$ or slip$ or ruptur$ or perforat$ or protrus$ or displac$ or lesion$ or degenerat$) adj3 (disk? or disc?)).tw.
29. (dis$tis and pain$).tw.
30. (nerve adj3 root? adj3 (pain? or avulsion? or compress$ or inflammat$)).tw.
32. (radicul$ and pain$).tw.
33. (cauda equina and (syndrome or pain$)).tw.
34. (polyradicul$ and pain$).tw.
35. or/1-34
36. patient care management/ use mesz
37. case management/ use mesz
38. critical pathways/ use mesz
39. patient-centered care/ use mesz
40. nurse practitioners/ use mesz
41. models organizational/ use mesz
42. “referral and consultation”/ use mesz
43. gatekeeping/ use mesz
44. triage/ use mesz
45. continuity of patient care/ use mesz
46. delivery of health care/ use mesz
47. disease management/ use mesz
48. family physician/ use mesz
49. physician’s practice patterns/ use mesz
50. primary health care/ use mesz
51. program evaluation/ use mesz
52. “physical therapy (specialty)”/ use mesz
53. patient care/ use emez
54. clinical pathway/ use emez
55. good clinical practice/ use emez
56. nurse practitioner/ use emez
57. patient referral/ use emez
58. health care delivery/ use emez
59. general practitioner/ use emez
60. exp primary health care/ use emez
61. health care quality/ use emez
62. physiotherapist/ use emez
63. disease management/ use emez
64. general practice/ use emez
65. clinical practice/ use emez
66. case management/ use nursing
67. critical path/ use nursing
68. patient-centered care/ use nursing
69. nurse practitioners/ use nursing
70. “referral and consultation”/ use nursing
71. gatekeeping/ use nursing
72. triage/ use nursing
73. continuity of patient care/ use nursing
74. health care delivery/ use nursing
75. disease management/ use nursing
76. family physician/ use nursing
77. primary health care/ use nursing
78. program evaluation/ use nursing
79. physical therapists/ use nursing
80. ((clinical or critical or patient) adj2 (path? or pathway?).).tw.
81. (extended adj2 (scope or role?).).tw.
82. ((orthop?edic or specialist) adj practitioner?).tw.
83. ((refer or referred or referral?) adj3 (manag$ or screen$ or filter$ or assess$ or multiple or inaccurate$ or appropriate$ or unnecessary$ or direct$ or rapid$ or fast or self or secondary or hospital)).tw.
84. gate keep$.tw.
85. gatekeep$.tw.
86. triag$.tw.
87. ((continuity or continuum or integrat$) adj2 care).tw.
88. ((deliver$ or organi?ed or organi?e or organi?ation or provide? or provision?) adj2 (health or healthcare or service?.)).tw.
89. physiotherapist?.tw.
Further details concerning the search and a copy of all search strategies can be obtained by contacting NHS QIS.

**Sources:**

**Secondary literature and policy documents**

- NCCHTA (National Coordinating Centre for Health Technology Assessment), www.ncchta.org/
- NICE (National Institute for Health and Clinical Excellence), www.nice.org.uk/
- Health Technology Assessment database, via the Cochrane Library
- NHS Centre for Reviews and Dissemination, University of York, www.york.ac.uk/inst/crd/
- West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham, www.pcpoh.bham.ac.uk/publichealth/wmhtac/
- SchARR (School of Health and Related Research), University of Sheffield, www.shef.ac.uk/scharr/research/publications
- Southampton Health Technology Assessment Centre, University of Southampton, www.wihrd.soton.ac.uk/shtac.htm
- ECRI, www.ecri.org
- Cochrane Database of Systematic Reviews (CDSR), via the Cochrane Library
- Database of Abstracts of Reviews of Effectiveness (DARE), via the Cochrane Library
- SIGN (Scottish Intercollegiate Guidelines Network), www.sign.ac.uk/
- Health Evidence Network, www.euro.who.int/HEN

- National Horizon Scanning Centre, Department of Public Health and Epidemiology, University of Birmingham, www.pcpoh.bham.ac.uk/publichealth/horizon/
- ARIF (Aggressive Research Intelligence facility), University of Birmingham, www.arif.bham.ac.uk/
- Clinical Evidence, http://clinicalevidence.bmj.com/ceweb/conditions/conditions.jsp
- Prodigy, www.prodigy.nhs.uk
- Bandolier, www.jr2.ox.ac.uk/bandolier/
- NeLH (National electronic Library for Health), www.nelh.nhs.uk/
- EPOC (Effective Practice and Organisation of Care Group), via Cochrane Group
- Scottish Executive, www.scotland.gov.uk/Home
- SHOW, http://www.show.scot.nhs.uk/
- DIPEx, www.dipex.org/
- NHS Economic Evaluation Database (NHS EED), via the Cochrane Library
- Health Economic Evaluation Database (HEED)

**Primary literature including ongoing research**

- MEDLINE, via OVID
- MEDLINE In-Process and Other Non-Indexed Citations, via OVID
- EMBASE, via OVID
- CINAHL, via OVID
- AMED, via OVID
- HMIC, via OVID
- WEB OF SCIENCE, via ISI
- CCRCT (Cochrane Central Register of Controlled Trials), via the Cochrane Library
- NRR (National Research Register), www.nrr.nhs.uk/
Appendix 4  Review of evidence on triage of low back pain referrals by a specialist gatekeeper

Appendix 4.1 Literature selection flow chart

- Potentially relevant papers identified, by literature search, n=4433
  - Papers identified through submission, n=0
  - Papers requested for detailed assessment, n=24
  - Papers received and assessed, n=22
  - Papers excluded, n=4409
  - Studies unobtainable, n=2
  - Papers excluded, n=14
  - Papers potentially suitable for inclusion in the review of clinical effectiveness, n=8
    - Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=4
    - Papers excluded from the evidence synthesis, n=0
  - Papers included in the evidence synthesis, n=12
### Appendix 4.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Anon., 1997)</td>
<td>Journalism [Reports on Mr Andy Leech appointed to North Staffordshire HA in ‘experimental post’ of back pain co-ordinator. Stevenson et al. report audit of this service (Stevenson &amp; Hay, 2004).]</td>
</tr>
<tr>
<td>(Heyes-Moore, 1998)</td>
<td>No data.</td>
</tr>
<tr>
<td>(Horwitz et al., 1998)</td>
<td>Not considering ESP as gatekeeper (chiropractor in American setting).</td>
</tr>
<tr>
<td>(Rae et al., 1998)</td>
<td>Not considering triage.</td>
</tr>
<tr>
<td>(Anon., 2003)</td>
<td>No data.</td>
</tr>
<tr>
<td>(Breen et al., 2004)</td>
<td>Not considering triage.</td>
</tr>
<tr>
<td>(Laird, 2004)</td>
<td>Journalism [Reports on Teignbridge primary care trust triage, Fiona Jenkins, South Devon].</td>
</tr>
<tr>
<td>(Knott, 2004)</td>
<td>No data.</td>
</tr>
<tr>
<td>(Stevenson &amp; Hay, 2004)</td>
<td>No data.</td>
</tr>
<tr>
<td>(Dennis-Jones, 2005)</td>
<td>Journalism.</td>
</tr>
</tbody>
</table>
Appendix 5 Review of the evidence on prompt referral, GP referral and patient self-referral to physiotherapy for acute low back pain

Appendix 5.1 Literature selection flow chart

Potentially relevant studies identified, by literature search, n=302

Studies identified through submission, n=4

Studies requested for detailed assessment, n=23

Studies excluded, n=283

Studies unobtainable, n=0

Studies received and assessed, n=23

Studies potentially suitable for inclusion in the review of clinical effectiveness, n=8

Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=0

Papers excluded from the evidence synthesis, n=0

Studies included in the evidence synthesis, n=8
(includes multiple reporting of same study, n=2)
### Appendix 5.2  Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Cremin &amp; Finn, 2002)</td>
<td>No relevant clinical effectiveness data.</td>
</tr>
<tr>
<td>(Fischbacher, 2002)</td>
<td>No relevant clinical effectiveness data.</td>
</tr>
<tr>
<td>(Forrest et al., 2001)</td>
<td>No relevant clinical effectiveness data. Patient satisfaction outcome.</td>
</tr>
<tr>
<td>(Holdsworth &amp; Webster, 2004b)</td>
<td>Another report was included describing more detailed results from this pilot study.</td>
</tr>
<tr>
<td>(Holdsworth, 2006)</td>
<td>Cost study. The clinical outcomes part of this study was reported in another publication, which has been included.</td>
</tr>
<tr>
<td>(Layzell, 2001)</td>
<td>No relevant clinical effectiveness data. Patient preference outcome</td>
</tr>
<tr>
<td>(Lewis et al., 2000)</td>
<td>No relevant clinical effectiveness data. Patient preference outcome</td>
</tr>
<tr>
<td>(Limb, 2004)</td>
<td>No relevant clinical effectiveness data but makes reference to Wand et al., (Wand et al., 2004), which has been included.</td>
</tr>
<tr>
<td>(Martell, 2005)</td>
<td>No relevant clinical effectiveness data. Press article.</td>
</tr>
<tr>
<td>(Mielenz et al., 1997)</td>
<td>No data on clinical effectiveness of direct access.</td>
</tr>
<tr>
<td>(NHS Scotland, 2002)</td>
<td>Refers to a study performed in Westgate Health Centre, Dundee, Scotland (Holdsworth &amp; Webster, 2004b), which is included.</td>
</tr>
<tr>
<td>(Taylor et al., 2002)</td>
<td>No clinical effectiveness data. Patient satisfaction outcome.</td>
</tr>
<tr>
<td>(Robert &amp; Stevens, 1997)</td>
<td>Focuses on the evidence for GP referral compared with consultant referral to physiotherapy, rather than patient self-referral.</td>
</tr>
<tr>
<td>(Ferguson et al., 1999)</td>
<td>Study does not assess prompt access or allow comparison of time to appointment for self-referral vs. GP referral, there being no control arm.</td>
</tr>
</tbody>
</table>
Appendix 6  Review of the evidence on physiotherapist treatment modalities

Appendix 6.1 Literature selection flow chart

Potentially relevant papers identified, by literature search, n=609
Papers identified through submission, n=2

Papers requested for detailed assessment, n=3

Papers excluded, n=608
Papers unobtainable, n=0

Papers received and assessed, n=3

Papers excluded, n=0

Papers potentially suitable for inclusion in the review of clinical effectiveness, n=3

Additional papers identified from scanning bibliographies and additional search on acupuncture, n=0

Papers excluded from the evidence synthesis, n=0

Papers included in the evidence synthesis, n=3
Appendix 7  Review of evidence on whether feedback on inappropriate referrals affect GP referral patterns

Appendix 7.1  Literature selection flow chart

- Potentially relevant studies identified, by literature search, n=106
  - Studies identified through submission, n=0
    - Studies requested for detailed assessment, n=4
      - Studies excluded, n=102
      - Studies unobtainable, n=0
        - Studies received and assessed, n=4
          - Studies excluded, n=2
            - Studies potentially suitable for inclusion in the review of clinical effectiveness, n=2
              - Additional studies identified and used from zetoc alerts, scanning bibliographies and interested parties, n=4
                - Studies excluded from the evidence synthesis, n=1
                  - Studies included in the evidence synthesis, n=5
### Appendix 7.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Jamtvedt <em>et al.</em>, 2006)</td>
<td>Studies were not restricted to feedback between primary and secondary care on the management of patients with low back pain.</td>
</tr>
<tr>
<td>(Grimshaw <em>et al.</em>, 2005)</td>
<td>Studies were not restricted to feedback between primary and secondary care on the management of patients with low back pain.</td>
</tr>
<tr>
<td>(Grimshaw <em>et al.</em>, 2004)</td>
<td>Studies were not restricted to feedback between primary and secondary care on the management of patients with low back pain.</td>
</tr>
</tbody>
</table>
Appendix 8  Review of the evidence on referral authority of physiotherapists

Appendix 8.1  Literature selection flow chart

Potentially relevant studies identified, by literature search, n=4433

Studies requested for detailed assessment, n=5

Studies excluded, n=4428

Studies received and assessed, n=5

Studies unobtainable, n=0

Studies potentially suitable for inclusion in the review of clinical effectiveness, n=0

Additional studies identified by scanning bibliographies or submitted from interested parties, n=0

Studies excluded from the evidence synthesis, n=0

Studies included in the evidence synthesis, n=0
## Appendix 8.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Tippey, 2005)</td>
<td>News article on GGBPS, for which data already assessed. Insufficient detail provided.</td>
</tr>
<tr>
<td>(Dennis-Jones, 2005)</td>
<td>News article. No reference to physiotherapists having referral authority.</td>
</tr>
<tr>
<td>(Saunders &amp; O’Flanagan, 1999)</td>
<td>No reference to physiotherapists having referral authority.</td>
</tr>
<tr>
<td>(Knott, 2004)</td>
<td>Descriptive article. No data provided.</td>
</tr>
</tbody>
</table>
Appendix 9 Review of evidence on GP and physiotherapist direct referral for MRI

Appendix 9.1 Literature selection flow chart

Potentially relevant papers identified, by literature search, n=256

Papers identified through submission, n=0

Papers requested for detailed assessment, n=1

Papers excluded, n=255

Papers unobtainable, n=0

Papers received and assessed, n=1

Papers potentially suitable for inclusion in the review of clinical effectiveness, n=1

Additional papers identified and used from zetoc alerts, scanning bibliographies, interested parties, n=0

Papers excluded from the evidence synthesis, n=0

Studies included in the evidence synthesis, n=1
Appendix 10  Multidisciplinary/multifaceted approaches to rehabilitation

Appendix 10.1 Literature selection flow chart

Potentially relevant studies identified, by literature search, 1914

Studies requested for detailed assessment, n=14

Studies excluded, n=1900

Studies received and assessed, n=14

Studies unobtainable, n=0

Studies potentially suitable for inclusion in the review of clinical effectiveness, n=5

Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=1

Studies excluded from the evidence synthesis, n=0

Studies included in the evidence synthesis, n=6
### Appendix 10.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(George et al., 2003)</td>
<td>Physiotherapy based on cognitive principles – no separate psychosocial component.</td>
</tr>
<tr>
<td>(Jellema et al., 2005b)</td>
<td>No physiotherapy component.</td>
</tr>
<tr>
<td>(Linton et al., 2005)</td>
<td>Patients with chronic back pain (whereas refocused question was on acute/subacute patients).</td>
</tr>
<tr>
<td>(Macfarlane et al., 2006)</td>
<td>Not a trial.</td>
</tr>
<tr>
<td>(Petrides, 2002)</td>
<td>Not a trial.</td>
</tr>
<tr>
<td>(Schonstein et al., 2003)</td>
<td>Cochrane review in which none of the included studies meet the criteria for this review.</td>
</tr>
<tr>
<td>(Steenstra et al., 2003)</td>
<td>Trial protocol.</td>
</tr>
<tr>
<td>(Storheim et al., 2003)</td>
<td>Does not combine physical therapy with psychosocial approach.</td>
</tr>
<tr>
<td>(Wand et al., 2004)</td>
<td>Comparing timing of physiotherapy component of intervention.</td>
</tr>
</tbody>
</table>
Appendix 11  Review of the evidence on barriers to GP implementation of acute lower back pain guidelines in primary care and the effectiveness of interventions to overcome these barriers

Appendix 11.1 Literature selection flow chart

[Diagram]

- Potentially relevant studies identified by literature search, n=273. Studies identified through submission, n=0
  - Studies excluded, n=261
  - Studies requested for detailed assessment, n=12
    - Studies unobtainable, n=0
    - Studies received and assessed, n=12
      - Studies excluded, n=5
        - Studies potentially suitable for inclusion in the review, n=7
          - Additional studies identified and used from zetoc alerts, scanning bibliographies, interested parties, n=0
            - Studies excluded from the evidence synthesis, n=0
              - Studies included in the evidence synthesis, n=7
### Appendix 11.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Bishop &amp; Wing, 2006)</td>
<td>RCT of guideline implementation strategy not specifically targeted at identified barsiers.</td>
</tr>
<tr>
<td>(Dey et al., 2004)</td>
<td>RCT of guideline implementation strategy not specifically targeted at identified barriers.</td>
</tr>
<tr>
<td>(Jamtvedt et al., 2006)</td>
<td>Systematic review of effects of audit and feedback on compliance with recommended practice. Includes one study in primary care relevant to back pain, which identified a barrier to guideline implementation (Kerry et al., 2000a).</td>
</tr>
<tr>
<td>(Shiffman et al., 1999)</td>
<td>Not general practice: systematic review of computer based guideline implementation systems; contains one low back pain study of an emergency department computer charting system.</td>
</tr>
<tr>
<td>(Underwood et al., 2002)</td>
<td>Study of the acceptability of a training strategy to support guideline implementation.</td>
</tr>
</tbody>
</table>
Appendix 12 Review of the evidence on strategies proposed to improve communication between GPs and patients with low back pain and assessing their effectiveness in improving patient outcomes and patient and doctor satisfaction

Appendix 12.1 Literature selection flow chart

Diagram:

- **Potentially relevant studies identified by literature search, n=560. Studies identified through submission, n=0**

  - Studies requested for detailed assessment, n=8
    - Studies excluded, n=552
    - Studies unobtainable, n=0
    - Studies received and assessed, n=8
      - Studies potentially suitable for inclusion in the review, n=7
        - Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=3
          - Studies excluded from the evidence synthesis: 3 Did not meet inclusion criteria but are discussed alongside the evidence synthesis
          - Studies included in the evidence synthesis, n=7

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HTA Systematic Review 1
### Appendix 12.2  Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Howie et al., 1999)</td>
<td>No information on communication, no data for low back pain.</td>
</tr>
</tbody>
</table>
Appendix 13 Review of the evidence on the role of educational pain management interventions for primary care professionals in improving outcomes among patients with low back pain managed in the community

Appendix 13.1 Literature selection flow chart

Potentially relevant studies identified by literature search, n=800. Studies identified through submission, n=0

Studies requested for detailed assessment, n=5

Studies excluded, n=795

Studies unobtainable, n=0

Studies received and assessed, n=5

Studies excluded, n=5

Studies potentially suitable for inclusion in the review, n=0

Additional studies identified and used from zetoc alerts, scanning bibliographies, interested parties, n=3

Studies included in the evidence synthesis, n=0

Studies excluded from the evidence synthesis: 3 Did not meet inclusion criteria but are discussed
### Appendix 13.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Latimer et al., 2004)</td>
<td>Measured the effect of a teaching module on chronic low back pain on attitudes and beliefs among physiotherapy students in Australia; no patient outcomes.</td>
</tr>
<tr>
<td>(Roberts et al., 2002)</td>
<td>English GPs identified learning needs and preferred style of education around improving musculoskeletal services in primary care; no mention of pain management; no outcomes.</td>
</tr>
<tr>
<td>(Stannard &amp; Johnson, 2003)</td>
<td>Measured English GPs’ interest in receiving training or education on the treatment of chronic non-cancer pain; no outcomes.</td>
</tr>
<tr>
<td>(Steen et al., 1997)</td>
<td>Reports on a Norwegian training programme for occupational health personnel focusing on counselling methods to enable self-management of chronic musculoskeletal pain; no patient/client outcomes.</td>
</tr>
<tr>
<td>(Liard et al., 2002)</td>
<td>Internet survey in France of GP educational needs; no patient outcomes.</td>
</tr>
</tbody>
</table>
Appendix 14  Review of evidence on analgesia use by patients with low back pain

Appendix 14.1 Literature selection flow chart

Potentially relevant studies identified by literature search, n=573. Studies identified through submission, n=0

Studies requested for detailed assessment, n=4

Studies excluded, n=569

Studies unobtainable, n=0

Studies received and assessed, n=4

Studies excluded, n=4

Studies potentially suitable for inclusion in the review, n=0

Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=2

Studies excluded from the evidence synthesis: 2 Did not meet inclusion criteria but are discussed

Studies included in the evidence synthesis, n=0
### Appendix 14.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Saunders et al., 1999)</td>
<td>Number of prescriptions used as a measure of healthcare utilisation in US, but no information on actual use.</td>
</tr>
<tr>
<td>(Nentwig et al., 2001)</td>
<td>Postal survey of German physicians and patients, comprising specific questions to quantify the use and adverse effects of opioids.</td>
</tr>
<tr>
<td>(Zelman et al., 2004)</td>
<td>Pain medications not specified by prescription; includes low back pain and other persistent pain conditions but results not fully distinguished by condition. US study.</td>
</tr>
<tr>
<td>(Zwart et al., 2003)</td>
<td>Does not specify analgesics as prescribed, or relate actual use to use as prescribed. Norwegian study.</td>
</tr>
</tbody>
</table>
Appendix 15: Review of the evidence on meeting the information needs of low back pain patients in primary and secondary care and in the community

Appendix 15.1 Literature selection flow chart

- Potentially relevant studies identified by literature search, n=27. Studies identified through submission, n=0
- Studies requested for detailed assessment, n=9
- Studies excluded, n=18
- Studies unobtainable, n=1
- Studies received and assessed, n=8
- Studies excluded, n=1
- Studies potentially suitable for inclusion in the review, n=7
  Additional studies identified and used from zetoc alerts, scanning bibliographies, interested parties, n=0
- Studies excluded from the evidence synthesis, n=0
- Studies included in the evidence synthesis, n=7
### Appendix 15.2 Excluded studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Coulter et al., 1998)</td>
<td>Several patients involved in the back pain focus group, of whom nine had severe, chronic back problems stemming from congenital defects or accidents.</td>
</tr>
</tbody>
</table>
Appendix 16 Review of the evidence on the beneficial effects of work-focused interventions delivered by healthcare providers in collaboration with employment services for patients unable to work because of back pain, and association with reduced NHS use for back pain

Appendix 16.1 Literature selection flow chart

- Potentially relevant studies identified by literature search, n=30. Studies identified through submission, n=0
  - Studies excluded, n=29
    - Studies requested for detailed assessment, n=1
      - Studies unobtainable, n=0
        - Studies received and assessed, n=1
          - Studies potentially suitable for inclusion in the review, n=1
            - Additional studies identified and used from, zetoc alerts, scanning bibliographies, interested parties, n=0
              - Studies excluded from the evidence synthesis, n=0
                - Studies included in the evidence synthesis, n=1
12 GLOSSARY

AAT
Assess/advise/treat

AAW
Assess/advise/wait

accreditation
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.

acupuncture
The insertion of needles into pressure points on the body to relieve symptoms. It is a treatment generally considered as complementary to traditional medicine.

acute low back pain
Pain located in the back, between the bottom of the ribs and the top of the legs, that has lasted less then 6 weeks.

aetiology
The cause or origin of a disease.

AHPs
Allied health professions
These are physiotherapy, occupational therapy, chiropody, radiography, dietetics, orthoptics, art, music and drama therapies.

algorithm
A flow diagram or similar schematic outline which summarises information and desired directions using an illustrative method. Treatment algorithms are not meant to be rigid formulas for patient management; they are meant to guide clinicians to attend to patient care in a uniform manner.

analgesia
Pain relief.

anecdotal
Evidence based on reports of specific individual cases rather than controlled, clinical studies.

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.

back pain service
A service dedicated to the management of back pain which offers prompt access to specialist physiotherapists.

back school
A program of education, usually in a group setting, designed to inform patients about low back problems.

baseline
Before treatment.

biomedical therapy
Treatment using only conventional medical disciplines such as physical therapy. This type of treatment does not consider psychological and social factors that may contribute to back pain.

biopsychosocial model
An approach taken to the management of back pain which assumes that biological, psychological and social factors all contribute to the condition.

benign
Non-cancerous. Refers to tumours which grow slowly in one place and which, once removed by surgery, tend not to recur. However, some benign tumours may go on to become malignant.

BPMP
Brief Pain Management Programme

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
A collection of therapeutic approaches carried out with the aim of changing behaviour and altering thought patterns. The therapist helps the person to identify their own untrue or destructive beliefs in order to reduce distress and develop coping strategies.

CCI
Centre for Change and Innovation

CCT
Controlled clinical trial. A clinical study that includes a comparison (control) group. The comparison group receives placebo, another treatment or no treatment at all.

chiropracter
Practitioner who diagnoses and treats back disorders through manual manipulation of the spine.

chronic
Continuing over a long period of time; in this report defined as >12 weeks.

CI
Confidence interval
An interval likely to contain the true value of an unknown quantity. 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.
clinical effectiveness
The evaluation of the balance between benefits and risks in a standard clinical setting, using outcomes of importance to the patient.

CMP
Condition Management Programme

cohort study
A study in which a group of people exposed and a group of people not exposed to a suspected risk factor are followed up in time and the incidence of the outcome in one group is compared with the incidence in the other.

compliance
Willingness to follow or adhere to certain accepted standards.

confounding
A relationship between the effects of two or more causal factors observed in a set of data, such that it is not logically possible to separate the contribution of any single causal factor to the observed effects (on-line medical dictionary http://cancerwer.ncl.ac.uk/omd/index.html).

cost effectiveness
A form of economic analysis which compares two interventions in terms of both their costs and their effect on patients, to ascertain whether the additional cost of the more expensive intervention gives rise to sufficient additional benefits to warrant the additional cost.

CSAG
Clinical Standards Advisory Group

CT
Computerised tomography

DARE
Database of Abstracts of Reviews of Effects

DEPCAT
Carstairs and Morris Deprivation Score

diagnostic pathway
Steps taken to make a diagnosis.

didactic
Medical teaching by lectures or textbooks.

DIPEx
Database of Individual Patient Experience

direct access
A hospital service to which GPs are able to refer patients directly. Examples of departments which provide direct access services are X-ray and physiotherapy.

disc herniation
A condition affecting the spine, in which a tear in the outside of the discs between the bones of the spine allows the soft, central portion to protrude. Often misleadingly called a ‘slipped disc’.

DNA
Do not attends

DWP
Department for Work and Pensions

early intervention
Prompt patient assessment and treatment, to optimise the management of back pain while in its acute phase.

efficacy
Strength or effectiveness of a treatment. Its ability to control or cure an illness.

electrotherapy
The use of electricity to treat pain.

epidural
Administration of local anaesthetic by injection into the space surrounding the spinal cord to suppress sensation, usually in the lower part of the body.

ESP
Extended scope practitioner

A clinical physiotherapy specialist in any recognised specialty, with an extended scope of practice. Extended scope of practice implies working beyond the recognised scope of practice, for example: requesting investigations, eg blood tests, scans, nerve conduction studies; using the results of investigations to assist clinical diagnosis and appropriate management of patients; listing for surgery and referring to other medical and paramedical professionals.

FTE
Full-time equivalent

GGBPSP
Greater Glasgow Back Pain Service

GP
General practitioner

guidelines
Systematically developed statements which assist in decision making about appropriate actions.

HADS
Hospital Anxiety and Depression Scale

healthcare professional
A person qualified in a health discipline.

health intervention
An item or service delivered or undertaken primarily to prevent, diagnose or treat a medical condition or to maintain or restore functional ability.

HEED
Health Economic Evaluation Database
HMO
Health Maintenance Organisation

HTA
Health Technology Assessment

A multidisciplinary field of policy analysis which studies the medical, social, ethical and economic implications of development, diffusion and use of health technology.

inferential therapy
A form of electrical stimulation to help relieve back pain.

ISD
Information Services Division

Part of NHS National Services Scotland. Health service activity, staffing and finance data are collected, validated, interpreted and distributed by ISD. These data are received from NHS boards and general practices. Website address: www.isdscotland.org

LBP
Low back pain

lumbar
Refers to the part of the back from just below the ribs to the pelvis.

marginal costs
The change in total cost that arises when the quantity produced changes by one unit.

mechanical back pain
Non-specific back pain. There is often no identifiable pathology and no structural abnormality of the back.

median
The middle observation in a series of numbers arranged in ascending order.

modality
One form of therapy as opposed to another, such as the modality of physiotherapy that contrasted with that of radiotherapy.

MRI
Magnetic resonance imaging

multidisciplinary
An approach combining the knowledge, skills and expertise of a range of organisations and professionals.

multifaceted
Having many aspects.

multifactorial
Involving several factors or causes.

musculoskeletal
Refers to the muscles and skeleton of the body.

MZSRDS
Modified Zung Self Rated Depression Score

neurophysiological
Refers to the relationship between brain function and behaviour.

NHS QIS
NHS Quality Improvement Scotland

NHS QIS is a statutory body, established as a special health board in January 2003. Its role is to focus on improving the quality of patient care and the health of patients. It has a particular emphasis on the quality of care and the patient journey for vulnerable groups. Website: www.nhshealthquality.org

NHSScotland
National Health Service in Scotland

nociceptor
Pain receptors that function in times of injury and inflammation; a type of sensory neuron that reports irritation of soft tissue and bone to the brain.

non-specific low back pain
Low back pain that cannot be attributed to a specific pathology.

observational study
Documentation of results of different treatments by observing which action or medication appears to give best improvements.

occupational therapist
A health professional who finds ways to help people live at home and be independent, despite their illness.

OR
Odds ratio

orthopaedic
Pertaining to the science of correcting deformities caused by disease of or damage to the bones and joints of the skeleton.

osteopath
A specialist with knowledge of the muscular and skeletal systems.

osteoporosis
Disease involving a loss of bone material. The bones become less dense and more likely to break or fracture.

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.

outpatient
A patient reviewed in a hospital, but who does not need to be admitted to the hospital.
paradigm
A typical example or pattern of something.

paramedical
Refers to professions allied to medicine, such as physiotherapy.

pathology
The study of disease processes with the aim of understanding their nature and causes. This is achieved by observing samples of blood, urine, faeces, and diseased tissue obtained from the living patient or at autopsy, by the use of X-rays, microscopy and by many other techniques.

patient pathway
The pathway through the health services taken by the person who is receiving treatment, and as viewed by that person.

PBBPC
Practice Based Back Pain Clinic

physiotherapist
A health practitioner who uses exercise and physical movement to condition muscles and improve a person’s level of activity. For the purpose of this a specialist physiotherapist is a physiotherapist working in a back pain service who has received extra training in the management of back pain.

pilot
A practical advance testing of the suitability of a process, standard, or object for the job it is intended to do. Depending on the outcome, refinements may be made.

prevalence
The number of existing cases of disease amongst a certain group of people, usually at a specified point in time.

prognosis
An assessment of the expected future course and outcome of a person’s disease.

primary care
The conventional first point of contact between a patient and the NHS. This is the component of care delivered to patients outside hospitals and is typically, though by no means exclusively, delivered through general practices. Primary care services are the most frequently used of all services provided by the NHS. Primary care encompasses a range of family health services provided by GPs, dentists, pharmacists, optometrists and ophthalmic medical practitioners.

primary evidence
Generally the first published record on the results of new or original research. In scientific disciplines, it is most often published as an article in a scholarly journal. Examples include journal articles, conference proceedings, and PhD and Masters theses.

protocol
A policy or strategy which defines appropriate action. Also covers the adoption, by all staff, of national or local guidelines to meet local requirements in a specified way.

psychological
Relating to human behaviour.

psychosocial
Relating social conditions to mental health.

QoL
Quality of life

radiography
The technique of examining the body by directing X-rays through it to produce images on photographic films or fluorescent screens.

RAH
Royal Alexandra Hospital, Paisley

RCR
Royal College of Radiologists
The professional and advisory body overseeing education and qualifications of radiologists. Website: www.rcr.ac.uk

RCT
Randomised controlled trial

referral
The process whereby a patient is referred from one professional to another, usually for specialist advice or treatment.

referral management
A referral management system for the purposes of this HTA is a system which intercepts referrals to orthopaedic specialist services, with the aim of directing the patient to the most appropriate place for treatment.

rehabilitation
Intended to aid return of physical or mental function after illness or injury, often with the assistance of specialised medical professionals.

retrospective study
A study in which subjects are enrolled after the intervention of interest has occurred; their situation before the intervention is ascertained from case notes or interviews.

rheumatoid arthritis
Long-term disease of the joints involving pain, swelling, redness and heat.

risk factor
A clearly defined occurrence or characteristic that has been associated with the increased rate of a subsequently occurring disease or health problem. Risk factors include aspects of personal behaviour, lifestyle, environmental exposure, or inborn or inherited characteristics, which are known to be associated with the disease.
RMDQ
Roland Morris disability questionnaire

dsampling size
The number of people studied in a trial.

Scheuermann's disease
A condition which usually develops in young people while the bones are still growing, in which the back of the vertebrae in the upper part of the spine grows more quickly than the front. This makes each vertebrae grow into a wedge shape, causing the spine to curve.

sciatica
Symptoms of pain and numbness affecting the back, hip and outer side of the leg, resulting from abnormal pressure on the largest nerve in the body (the sciatic nerve).

scoliosis
Abnormal curvature of the spine to one side which may cause back pain due to structural strain.

screening
Examination of people with no symptoms to detect unsuspected disease.

SD
Standard deviation

secondary care
Hospital-based health services which are provided on an inpatient or outpatient basis.

secondary evidence
Results from literature written to analyse, describe and synthesise the primary or original source. Although not original research, it can provide an excellent source of background information on a topic. Examples include review papers, bibliographies, and abstracts/indexes.

SEHD
Scottish Executive Health Department (now Scottish Government Health Directorates)

self-referral
The option for patients to directly request a physiotherapy appointment, without the need for GP referral.

sensory
Refers to physical sensations.

service delivery model
An organised diagnostic and treatment algorithm designed to optimise back pain management and integrate the individual aspects of care into a unified scheme.

socioeconomic
Refers to the interaction of social and economic factors.

specialist gatekeeper
A health professional who regulates whether and when specialty consultation and treatment are available.

specific low back pain
Low back pain that can be attributed to a definite spinal pathology.

spinal
Refers to the spine.

spondylosis
A condition that causes neck pain and stiffness.

spondylolisthesis
Forward slippage of one of the bones of the back onto the one below it due to degeneration or deficient development.

STAIS
Spielberger State-trait Anxiety Inventory

statistical power
The probability that a statistical test will not fail to observe a difference when there is one.

statistically significant
Unlikely to have occurred by chance.

stenosis
The abnormal narrowing of a passage or opening.

subacute
Lasting 6–12 weeks.

symptomatic
Exhibiting features of a disease.

systematic literature search
The process of explicit and reproducible searching of the literature utilising the most appropriate information resources based upon their scope and content.

TENS
Transcutaneous electrical nerve stimulation

The Back Book
A booklet, aimed at people with back pain, which offers evidence-based advice on overcoming the condition.

traction
Keeping a fractured bone in position or correcting a deformity by applying a sustained pull on the limb.

triage
A system whereby a group of casualties or patients is sorted according to the seriousness of their injuries or illnesses so that treatment priorities can be allocated between them.

UK
United Kingdom

ultrasound
A widely used medical imaging technique. High frequency sound waves are directed into the body and an image is formed from those waves by reflection from internal structures.
**US**  
United States

**USA**  
United States of America

**VAS**  
Visual analogue scale

**vertebral**  
Refers to the bones that make up the spine.

**X-ray**  
An imaging technique that uses energy beams of penetrating electromagnetic energy.