NETSCC, HTA

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Management of frozen shoulder:
A systematic review and decision analytic model (HTA No. 09/13)
Research Protocol 1.1

1. Research objectives

The overall aim of the research project is to determine the clinical and cost effectiveness of different methods of managing frozen shoulder, with the following specific objectives:

(1) to evaluate, via a systematic review, the clinical effectiveness (including adverse effects) of strategies currently used in the NHS for the management of frozen shoulder and identify the most appropriate intervention by stage of condition; specifically physical therapies, steroid and other shoulder injections, manipulation under anaesthesia, arthrographic distension, capsular release, watchful waiting and combinations of these interventions;
(2) to evaluate, via a systematic review, the cost-effectiveness of the different interventions in order to inform the development of a decision model;
(3) to develop a decision analytic model to estimate the cost-effectiveness of alternative treatment options for frozen shoulder;
(4) to make recommendations for clinical practice; and
(5) to identify any gaps in the evidence, undertake value of information (VoI) analysis to assess the potential value of future research on interventions for frozen shoulder and to make specific recommendations for further research.

2. Background

Frozen shoulder, also known as adhesive capsulitis is a very painful condition of unknown aetiology, in which movements of the shoulder become severely restricted. The condition is thought to be the result of inflammation and swelling in the lining of the shoulder joint (capsule) and its associated ligaments, with resultant contracture of the shoulder joint capsule. Bunker describes pathology of fibrous contracture of the rotator interval and coracohumeral ligament of the shoulder joint.[1] The lining loses its normal characteristic of flexibilty and elasticity and becomes stiff and painful. The three key characteristics of frozen shoulder are gradual onset of shoulder stiffness, severe pain, especially at night, and near complete loss of passive and active external rotation of the shoulder.[2] Typically there are three overlapping phases of frozen shoulder:[2]
Phase 1 (painful freezing phase) - there is progressive stiffening and loss of motion in the shoulder with increasing pain on movement which may be worse at night (months 2 to 9);
Phase 2 (adhesive phase) - there is a gradual decrease in pain but stiffness remains and there is considerable restriction in the range of movement (months 4 to 12);
Phase 3 (resolution phase) - there is an improvement in range of movement (months 12 to 42).

Although the condition is classically described as having a resolution phase there may not be a complete resolution for all patients. There is variation across case series in the proportion of patients who do not regain full shoulder motion,[2] possibly a reflection of variation in how outcome was assessed. Based on the largest series of patients with a mean follow-up of 4.4 years from onset of symptoms, 59% had normal or near normal shoulders, 35% had mild to moderate symptoms with pain being the most common complaint, and 6% had severe symptoms.[3] Recurrence is unusual though it is estimated that the other shoulder becomes affected in 6-17% of patients within 5 years.[2]

The cumulative incidence of frozen shoulder is estimated at approximately 2.4/1000 per year based on a Dutch general practice sample.[4] It most commonly occurs in people in their mid-

50's and is slightly more common in women than men. In addition to primary or idiopathic frozen shoulder, there is an association between frozen shoulder and a number of other medical conditions, in particular diabetes. The incidence is reported to be 10% to 36% amongst people with diabetes, who tend not to respond as well to treatment.[2]

Diagnosis and management
Diagnosis is based on clinical examination and medical history and a key alerting feature is restriction of shoulder movement in all directions.[5] Blood tests, X-rays and ultrasound are usually normal and not routinely required unless history or physical examination suggest the need to rule out other pathologies.[5]

Frozen shoulder is commonly managed in the primary care setting. There are a number of management options, both surgical and non-surgical, but there is no consensus about management. The aims of treatment, depending on stage of condition are pain relief, increasing arm movement, reducing the duration of symptoms and return to normal activities for the patient. Treatment options include:

- Watchful waiting or 'supervised neglect', which involves explaining the condition to the patient and advising mobilisation within pain limits.
- Oral medications such as non-steroidal anti-inflammatory drugs (NSAIDs) and oral steroids. Although the use of oral steroids is described in the literature they are not a commonly used intervention in the UK.
- Gentle exercise supervised by a physiotherapist or as part of a home exercise program.
- Physical therapies to help regain range of movement and prevent further stiffness. Several different regimes have been described in the literature including supervised exercises, mobilisation, acupuncture, and use of electrotherapeutic interventions such as laser therapy and ultrasound.
- Intra-articular corticosteroid injections to reduce inflammation and provide pain relief. A range of different doses and number of injections are described in the literature. This intervention is usually delivered in the primary care setting but also in the secondary care setting, depending on how services are organized in a particular region.
- Arthrographic distension (also called hydrodilation) which involves controlled dilation of the joint capsule with sterile saline or other solution such as local anaesthetic or steroid guided by radiological imaging (arthrography). This is thought to break the adhesions, which frees up the joint, improving the range of movement. The procedure lasts approximately 15 minutes and is performed under local anaesthetic.
- Manipulation under anaesthesia (MUA) in which the shoulder is freed by rotation while the patient is under short general anaesthesia. This is usually a day procedure and generally lasts a maximum of 15 minutes including anaesthetic time.
- Arthroscopic capsular release, a surgical procedure conducted under general or regional anaesthesia during which the contracted tissue is released. It can be undertaken as keyhole surgery (arthroscopic) or open procedure. This can be undertaken as a day procedure.

These interventions can be used individually or in combination depending on the disease stage. The optimal timing of the interventions is unclear though there is a suggestion that aggressive mobilisation should be avoided in the early, severely painful phase.[5] Surgical intervention is generally, though not exclusively, used where the condition is resistant to the other interventions. There are variations across the country in the order in which treatments are provided, though usually a step-up approach is adopted in terms of degree of invasiveness of the treatment, from primary to secondary care settings. The most commonly used or recommended interventions by G.P.'s physiotherapists and orthopaedic surgeons in

the NHS, based on a recent survey, were conservative treatment (watchful waiting, education, oral pain relief), physical therapy (mainly physiotherapy and mobisilation) and intra-articular injection during the early 'painful' phase and conservative treatment, physical therapy, intra-articular injection and surgery (mainly manipulation under anaesthesia and arthroscopic capsular release) for patients in the 'resolution' phase. [6]

Existing research

We conducted scoping searches of the literature to inform the research proposal which involved searching key sources for clinical guidelines, systematic reviews and cost-effectiveness analyses (Appendix A). We identified only one guideline, from the New Zealand Guidelines Group which was published five years ago and is therefore due for updating,[5] Clinical Evidence, last updated in February 2006, reviewed the evidence on interventions for shoulder pain in general.[7] Although several treatments were classified as likely to be beneficial, these were mainly in relation to other shoulder disorders. MUA plus intra-articular injection was identified as of likely benefit in people with frozen shoulder.

Systematic reviews were identified evaluating oral steroids,[8] corticosteroid injections,[9] physiotherapy,[10, 11] acupuncture[12] and arthrographic distension,[13] but not manipulation under anaesthesia or arthroscopic release (Table 1). Some of these reviews focused on shoulder pain in general, and included a range of conditions. None of the literature searches for the reviews identified are recent. The preliminary scoping searches also indicate that there may be limited evidence on the cost-effectiveness of these treatments for frozen shoulder. Two of the studies we identified were in relation to treatment of people with chronic shoulder complaints[14] and new episodes of unilateral shoulder pain in primary care.[15] One study investigated the effectiveness and cost-effectiveness of physiotherapy following glenohumeral joint distension specifically in relation to patients with frozen shoulder.[16]

It is apparent from previous reviews that there is variation in how frozen shoulder is defined across studies. A review of 21 randomised controlled trials (RCTs) of interventions for frozen shoulder could not derive a consistent description of the condition from the trials investigating this patient group.[17] The included RCTs required that participants had restricted shoulder movement but there was inconsistency across trials in the number of degrees of restriction, the type of restriction (active or passive) and the direction of the restriction (abduction or external rotation).[17] This highlights the difficulty of applying a strict definition for frozen shoulder within the context of a systematic review.

Table 1: Potentially relevant reviews identified during rapid appraisal of the evidence

Author	Intervention	End date for literature search
Buchbinder et al.[8]	Oral steroids	November 2005
Buchbinder et al.[13]	Arthrographic distension	November 2006
Buchbinder et al.[9]	Corticosteroids (for shoulder pain)	June 2002
Cleland & Durall[11]	Physical therapy	December 2000
Green et al.[10]	Physiotherapy (for shoulder pain)	June 2002
Green et al.[12]	Acupuncture (for shoulder pain)	December 2003
Shah & Lewis[18]	Corticosteroid injections	June 2006

3. Research methods

We will undertake a systematic review of the literature on the effectiveness of different methods of managing frozen shoulder, with particular reference to the stage of the condition. The systematic review will inform the development of a decision analytic model. This will be a large and complex project which will involve undertaking a systematic review of six different interventions, one of which (physical therapy) encompasses several different types of therapy, as well as a decision model that reflects the complexity of management of the condition.

3.1 Systematic review of effectiveness of interventions

Search Strategy

Both published and unpublished literature will be identified from systematic searches of electronic sources, hand searching, consultation with experts in the field, and reference checking.

The following databases will be searched: MEDLINE, MEDLINE In-Process, Cumulative Index to Nursing & Allied Health (CINAHL), EMBASE, Science Citation Index, BIOSIS Previews, PEDro, Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA) database, Cochrane Central Register of Controlled Trials (CENTRAL), PASCAL, Manual, Alternative and Natural Therapy (MANTIS) and Latin American and Caribbean Health Sciences (LILACS). Searches of electronic databases will not be restricted by language or study type.

In addition, information on studies in progress, unpublished research or research reported in the grey literature will be sought by searching a range of relevant databases including Conference Proceedings Citation Index, Science, Health Management Information Consortium (HMIC), ClinicalTrials.gov and NTIS.

Selected musculoskeletal disease websites will also be searched such as those of the National Institute of Arthritis & Musculoskeletal and Skin Diseases (NIAMS), the British Elbow & Shoulder Society (BESS), National Physiotherapy Research Network and Primary Care Rheumatology Society.

The MEDLINE search strategy is provided in Appendix B. This will be converted to run appropriately on other databases.

Where papers are not available from the British Library, extended searches will be undertaken only for papers published after 1965 and where it was in a language where we have identified a translator.

Inclusion criteria

Systematic reviews and primary studies will be included if they meet the following criteria:

Population: patients with idiopathic (primary) frozen shoulder (adhesive capsulitis) will be included. Studies where at least 90% of the participants had primary frozen shoulder will be included. Ideally, only patients with loss of active and passive external rotation of the involved shoulder with a normal x-ray would be included. This would allow for exclusion of patients with arthritis of the shoulder which can present as a similar clinical picture. However, based on a sample of the studies we have examined for the application, x-rays are not generally used to exclude joint arthritis. We will therefore take a pragmatic approach and include studies based on the authors' definition of frozen shoulder to ensure we have identified all the relevant evidence. (The impact of how frozen shoulder is defined will then be explored in the synthesis). Studies of general shoulder conditions will only be included if outcome data are reported separately for participants with frozen shoulder. Frozen shoulder

in people with diabetes is defined as primary in some classifications and in others as secondary frozen shoulder. In this review this group is defined as having primary frozen shoulder and will therefore be included in the review.

Intervention: The following interventions, either alone or in combination will be included

- physical therapies including physiotherapy, acupuncture chiropractic and osteopathy interventions). Physiotherapy encompasses a wide range of techniques including mobilisation, biofeedback, ultrasound and laser therapy and all therapies falling under the physiotherapy umbrella will be eligible for inclusion
- arthrographic distension,
- steroid and other shoulder injections such as sodium hyaluronate,
- manipulation under anesthesia
- capsular release (arthroscopic and open) and combinations of these treatments will be included.
- the approach of 'watchful waiting' will also be included.

There are a number of other treatments that have been researched that are not commonly used on the NHS such as radiotherapy, collagenase injection salmon calcitonin and antibodies to tumour necrosis factor-α. These interventions will not be included in the synthesis, though information will be collated on the number of studies assessing uncommon treatments and their study design.

Studies of acupuncture will be included only where the comparator is one of the other treatments of interest in the review. This excludes studies comparing different forms of acupuncture and studies comparing acupuncture with alternative therapies such as moxibustion.

Comparator: Any of the above treatments studies (including studies comparing different regimens of the same intervention), no treatment or placebo.

Outcomes: pain (at rest, on movement, at night); range of movement (e.g. internal and external rotation, elevation); function and disability; quality of life; time to recovery, return to work and recreation; and adverse events.

Study design: Only randomised controlled trials (RCTs) will be eligible for inclusion where this level of evidence is available on an intervention/management strategy. In the absence of randomised trials, quasi-experimental studies (i.e. with a control group) will be eligible for inclusion. If controlled trials are not available for MUA or capsular release, which is likely to be the case, case series will be included. Only case series of at least 50 participants will be included due to the problems of small case series being unrepresentative the clinical population. Where important adverse effects data may not be captured in RCTs, other study designs will also be considered to inform the economic model.

Systematic reviews will be included if (1) they fulfill all the relevant criteria, (2) have no significant sources of error and bias and (3) are reported in detail and the raw data are available from the report or authors to allow an update of the synthesis (if searches are more than 12 months out of date). If they do not meet all the criteria, systematic reviews will be used as sources of potentially relevant studies. It is anticipated that most of the systematic reviews available will be sources of relevant primary studies.

Screening and study selection

Two researchers will independently screen all titles and abstracts obtained through the searches for potentially relevant studies. Full manuscripts of potentially relevant studies will be ordered and two researchers will independently assess the relevance of each study using

the criteria above. Discrepancies will be resolved by consensus or recourse to a third researcher if necessary.

Data extraction

A data extraction form will be developed, piloted on a small selection of studies and adjusted as necessary. Data extracted will include details of the study methods, setting, patient characteristics (including stage of condition), intervention, comparators, outcome measures and results. Data will be extracted into EPPI-Reviewer (a software package for managing systematic review production).

For continuous outcomes the post-intervention mean (and standard deviation) for each group will be extracted, where available. Otherwise the mean change from baseline for each group will be extracted.

Authors will be contacted where clarification of data is required for any of the primary outcomes (see synthesis below). Standard data imputation methods will be used, where necessary.[19]

Data extraction will be undertaken by one researcher and checked by another, with discrepancies resolved by consensus or recourse to a third researcher if necessary.

Quality assessment

Quality assessment will also be undertaken by one researcher and checked by a second with discrepancies resolved by consensus or recourse to a third researcher if necessary. Studies will be quality assessed using the checklist in Appendix C. The criteria for assessing randomized and nonrandomised trials are based on recent CRD guidance;[20] the criteria for case series are based on those used in recent systematic review including case series. [21]

Data synthesis

The synthesis will focus on comparing the main treatment options (for example whether mobilization is more effective with or without steroid injection during the adhesive phase of the disease), rather than the effect of small variations in approach within the treatment classes. However, in reality there may be considerable variability within the different treatment options which will influence the type of analyses that are possible.

The primary outcomes will be patient-assessed pain intensity, quality of life (including disability measures such as the Oxford Shoulder Score and generic quality of life such as SF-36) and range of movement. Given that the symptoms of frozen shoulder change over time (with pain being the strongest characteristic of the early stages but not later) it is not appropriate to use a single primary outcome. Other outcomes such as time to return to work will be considered, evidence permitting. In addition to the proposed primary outcomes being the most clinically useful and patient-focused, it will also be more feasible to map these onto a utility measure for the decision model than the secondary physiological outcomes. Adverse effects of treatment will also be considered.

A narrative and tabular summary of key study characteristics, results and quality assessment will be provided. Where appropriate (based on clinical and statistical heterogeneity and the necessary data being available) individual study results will be combined in a series of pair-wise meta-analyses based on type of intervention and comparator, using a random effects model. As it is anticipated that the measures used to assess continuous outcome (for example pain) will vary between studies, standardized mean differences will be calculated, where appropriate and combined using the generic inverse variance method. Heterogeneity will be assessed using x^2 tests[20] and inconsistency will be quantified using the I^2 statistic.[22]

Given the range of interventions being considered, a mixed treatment comparison or network analysis could permit ranking of the benefits and harms of the different treatments options.[23] However, the appropriateness of such an approach depends on the principle of exchangeability i.e. that there are no systematic differences between the trials that test particular types of intervention. From the information we have gathered so far, and our clinical experience of the condition, we anticipate that the exchangeability assumption is unlikely to be met by the studies available. The treatment that patients currently receive is at least partly determined by the severity of symptoms, stage of the condition and progress with a given treatment modality. If this is reflected in the trials then it is unlikely, for example, that the populations included in trials of arthroscopic capsular release are similar to those where the intervention being investigated is home exercise. However, the feasibility and appropriateness of a MTC will be explored and conducted if appropriate.[24] Current guidance on good practice will be followed.[25]

Sub-group analyses will be restricted to a small number of potentially important characteristics that may reasonably be expected to modify the effect of the intervention. This will include sub-grouping studies based on how frozen shoulder was defined, stage of condition and/or severity (if such information is available), and whether study participants had diabetes.

Where meta-analysis is not appropriate a narrative synthesis will be undertaken. Where possible, results will be shown graphically. Studies will be grouped by type of intervention and comparator in the first instance and also the sub-groups identified above. Results will be interpreted in the context of the quality of the individual studies.

3.2 Systematic review of previous economic evaluations

A systematic review of economic evaluations will be undertaken to identify any models used previously and to inform the estimation of parameters for the decision model. Searches for economic evaluations of management strategies for frozen shoulder will be undertaken in the databases listed above (3.1). The search strategy will be adapted to focus on economic evaluations using search terms derived from the strategies used to identify studies for inclusion on the NHS Economic Evaluation Database (NHS EED). (see link for details http://www.crd.york.ac.uk/crdweb/html/helpdoc.htm#item17). In addition, searches of NHS EED and the Health Economic Evaluation Database (HEED) will be undertaken.

All full economic evaluations which meet the population and intervention inclusion criteria above will be eligible for inclusion.

A full economic evaluation will be defined as any study in which a comparison of two or more relevant alternatives was undertaken and with costs and outcomes examined separately for each alternative. This will include cost-effectiveness analysis (including cost-consequence analysis) where health outcomes are expressed in natural units; cost-utility analysis where benefits are measured in utility units or utility weighted life-years; and cost-benefit analyses, where benefits are measured in monetary form using approaches such as ‘willingness to pay’ or ‘human capital approach’. Based on our preliminary scoping of the evidence available, we believe that only a small number of economic evaluations of management strategies for frozen shoulder are likely to be available. The quality of economic evaluations will be assessed based on a modified version of the Drummond checklist[26] and relevant data will be extracted.

3.3 Systematic review of service-users’ views of interventions for frozen shoulder

Time permitting, a systematic review of the research literature on patients’ views about interventions for frozen shoulder will also be undertaken.

Searches of MEDLINE, CINAHL and PsycINFO (from 1980 onwards) will be carried out. The search strategy used will be based upon the one used to identify studies for the effectiveness review (Appenbdix B) but will be adapted to include a qualitative design filter.[27]

Studies investigating patients views about the treatments included in the main review will be eligible for inclusion. Only English language qualitative studies assessing patients' views and experiences in relation to treatments for frozen shoulder will be eligible; expert opinion, letters containing no data on patient views, editorials and discussion papers will be excluded.

The processes for study selection, data extraction and quality assessment will follow those of the main review. Information extracted will include study aim, participant characteristics, methods of collecting data on patient views and experiences, method of analysis, results in the form of a summary of key themes arising from the analysis and authors' conclusions. Study quality will be assessed using a tool developed by Hawker et al. [28] A narrative synthesis of the data will be undertaken.

3.4 Development of a decision model

A decision analytic model will be developed to estimate the cost-effectiveness of the different treatments for frozen shoulder. The specific objectives of the cost-effectiveness analysis will be to (1) assess the cost-effectiveness of the named interventions for frozen shoulder to inform clinical practice and (2) to identify the key uncertainties relating to the cost-effectiveness analysis and to use these to inform future research priorities.

In developing the model, NICE guidance on methods for technology appraisal will be followed.[25] The approach will be as follows:

- A clinically relevant and appropriate decision model will be structured to map patients' care pathways for the alternatives therapies, in a way that is clinically appropriate and accounts for the phase of condition when treatment is received. The effect of treatment on short and longer-term costs and health related quality of life will be considered. The clinical experts on the team (from general practice, physiotherapy and orthopaedic surgery) will review the structure of the model to ensure it has good clinical face validity and only those pathways considered clinically meaningful will be modelled. In addition, the results of a current survey of a large sample of healthcare professionals will be used to inform the model.

- Treatment order will be an important aspect to incorporate into the model. In the clinical setting there are variations in practice but, in general, a step up approach tends to be used in terms of treatment invasiveness, from primary to secondary care settings. The methods used to identify the optimum ordering of treatments will build on previous work undertaken by the CRD/CHE technology assessment group. [29]

- An appropriate time horizon will be chosen for the decision model that is long enough to capture the relevant costs and benefits. It is anticipated this will be at least 5 years duration.

- The model will be populated using the most appropriate data identified systematically from the literature and routine sources. The parameter point estimates and distributions for the effectiveness of the different interventions will be taken directly from the results of the systematic review. For those parameters where estimates are not available directly from the systematic review, the health economists, information specialist and the researchers undertaking the systematic review will work closely to identify the best quality evidence available for that parameter. The information

specialist will work in close liaison with the health economist to identify the model questions. Information to answer these questions will be provided by focused searching of appropriate databases, statistical sources and other relevant sources of information. The quality of all data used in the model will be explicitly discussed. The specific details of the data to be used to populate the model will await the development of the model structure and systematic review.

- Health benefits will be expressed in terms of quality adjusted life years (QALYs).

- The primary analysis will calculate the incremental cost-effectiveness of the different strategies based on an assessment of long-term NHS and Personal Social Service costs and quality adjusted utility.

- The uncertainty in the data used to populate the model will be captured through the use of probabilistic modelling which requires that each input in the model is entered as a distribution rather than a fixed parameter. Using Monte Carlo simulation, this parameter uncertainty will be translated into uncertainty in the overall results. The results of this analysis will be presented graphically using cost-effectiveness acceptability curves which show the probability that each intervention is cost-effective conditional on a range of possible threshold values attached to an additional QALY.

- To inform future research priorities, the model will be used to undertake a value of information (VoI) analysis. Decisions based on existing information will inherently be uncertain. We propose to conduct an expected value of information analysis to help estimate the cost of this uncertainty and identify whether it is of value to conduct further research in this area. If the expected value of perfect information for the population of interest exceeds the expect costs of such additional research, then potentially, it will be cost-effective for further research to be funded to better inform this decision in the future.

3.5 Dissemination

It will be important to ensure that those who need to know about the results of this review are informed and make sense of the findings. A detailed dissemination strategy will be produced to ensure that key groups are informed about the findings. Health professionals often differ in the amount of information they want to receive. CRD's research into, and experience of disseminating the results of systematic reviews has repeatedly shown that providing a brief overview of the topic, results and implications is the best way to communicate important messages to time-poor health professionals. We will produce a short non-technical summary giving brief background details, information about the quality of evidence, the results and clinical implications. The summary report will be targeted to appropriate clinical groups throughout the UK, such as orthopedic surgeons, GPs and physiotherapists and via networks such as the National Physiotherapy Research Network, the British Elbow and Shoulder Society and the Primary Care Rheumatology Society. Publication of the findings will be press released and the potential for short articles in the relevant lay media explored.

Other dissemination activities will include the submission of papers for peer-reviewed publication and submission of abstracts to conferences. The results will also be made available on the CRD website. All dissemination activities will involve signposting those interested in further details to the full HTA report.

4. Advisory Group

The project Advisory Group will meet on three occasions and between meetings contact will be made with the group or individuals depending on the query. Three individuals who

currently or previously have had frozen shoulder have also been invited to provide input in relation to: identifying the outcomes that have most significance for people with the condition and whether the care pathways underpinning the economic model reflect their experience. They will also be invited to comment on the non-technical summary of the final report.

5. Project timetable and milestones

The project will take place over a 12 month period (1 March 2010 to 14 March 2011). The key milestones are as follows:

Protocol development and peer review	Month 1-2	April 2010
Literature searches (including economics)	Month 3-4	April 2010
Screening and study selection	Month 4-5	May-June 2010
Develop decision model structure	Month 3-4	May-June 2010
Data extraction and checking	Month 5-6	June-July 2010
Populate decision model with parameters not derived from systematic review	Month 5-6	July-August 2010
Systematic review data analysis and synthesis	Month 7-9	August-October 2010
De-bug decision model, analysis including sensitivity analysis	Month 7-9	September to Nov 2010
Draft final report	Month 9-10	Nov-December 2010
Draft report to advisory panel	Month 11	January 2011
Address peer comments	Middle of month 12	February 2011
Submit final report	End of Month 12	14 March 2011
Draft summary and papers for dissemination		

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Appendix A

Rapid appraisal search to identify systematic reviews, published and in progress, guidelines and ongoing primary research.

Completed and ongoing reviews	
Cochrane Database of Systematic Reviews http://www.thecochranelibrary.com	17 (11)
DARE http://www.thecochranelibrary.com	18 (14)
HTA Database http://www.thecochranelibrary.com	6 (5)
SIGN Guidelines http://www.sign.ac.uk	0
NICE (published appraisals) http://www.nice.org.uk/guidance/TA/published	0
National Guideline Clearinghouse http://www.guidelines.gov	6 (3)
HSTAT http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat	0
National Coordinating Centre for Health Technology Assessment http://www.hta.nhsweb.nhs.uk/	0
TRIP http://www.tripdatabase.com	423 (4)
Economic evaluations	
NHS EED http://www.thecochranelibrary.com	8 (7)
Indexes to and summaries of clinical effectiveness sources including reviews, appraisals of reviews, and evidence based guidelines	
Clinical Evidence http://clinicalevidence.bmj.com/ceweb/index.jsp	1 (1)
Health Evidence Bulletins Wales http://hebw.uwcm.ac.uk/	0
Supplementary MEDLINE search	
MEDLINE http://ovidsp.ovid.com/	2969

Appendix B Search Strategy

Database: Ovid MEDLINE(R)
Search Strategy:

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1 (frozen adj6 shoulder$).ti.
2 (stiff$ adj3 shoulder$).ti.
3 (adhesive adj (capsulitis or capsulitides)).ti.
4 ((bursitis or bursitides) adj6 shoulder$).ti.
5 ((capsulitis or capsulitides) adj6 shoulder$).ti.
6 1 or 2 or 3 or 4 or 5
7 (frozen adj6 shoulder$).ab.
8 (stiff$ adj3 shoulder$).ab.
9 exp bursitis/
10 (adhesive adj (capsulitis or capsulitides)).ab.
11 ((bursitis or bursitides) adj6 shoulder$).ab.
12 ((capsulitis or capsulitides) adj6 shoulder$).ab.
13 ((periarthritis or peri-arthritis or periarthritides or peri-arthritides or peri-capsulitis or pericapsulitis) adj6 shoulder$).ti,ab.
14 shoulder pain/
15 (shoulder$ adj3 (pain or pains or painful or complain$)).ti,ab.
16 Shoulder Impingement Syndrome/
17 (shoulder$ adj6 impinge$).ti,ab.
18 subacromial impingement syndrome.ti,ab.
19 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 Arthrography/
21 (arthrograph$ adj6 (distension$ or distention$)).ti,ab.
22 (arthrogram$ adj6 (distension$ or distention$)).ti,ab.
23 (glenohumeral adj6 (distension$ or distention$)).ti,ab.
24 Dilatation/
25 (dilatation or hydrodilat$).ti,ab.
26 or/20-25
27 19 and 26
28 Arthroscopy/
29 (arthroscop$ adj6 (releas$ or decompress$ or capsulotom$)).ti,ab.
30 ((capsular adj2 releas$) or interventional microadhesiolysis or capsulotomy).ti,ab.
31 or/28-30
32 19 and 31

33 Injections, Intra-Articular/
34 33 and 19
35 injections/
36 35 and 19
37 ((bursa$ or intrabursa$ or intra bursa$ or periartic$ or peri artic$ or intraartic$ or intra artic$) adj3 inject$).ti,ab.
38 37 and 19
39 ((subacromial or acromioclavicular or glenohumeral) adj3 inject$).ti,ab.
40 ((extra articular or extraarticular or shoulder$) adj3 inject$).ti,ab.
41 34 or 36 or 38 or 39 or 40
42 exp Physical Therapy Modalities/
43 (physiotherapy or physiotherapies or physical therap$ or manual therap$).ti,ab.
44 (passive adj (motion or movement)).ti,ab.
45 CPM.ti,ab.
46 muscle stretching exercises/
47 (stretching or stretches).ti,ab.
48 (mobilisation or mobilization).ti,ab.
49 (exercise$ adj2 (program$ or strength$ or intervention$ or training or prescription$ or prescrib$)).ti,ab.
50 (exercise$ adj2 (therap$ or therapeutic)).ti,ab.
51 ((home or supervis$) adj2 exercis$).ti,ab.
52 ((pendular or pendulum) adj exercis$).ti,ab.
53 ((isokinetic or resist$) adj2 exercise$).ti,ab.
54 or/42-53
55 19 and 54
56 exp Musculoskeletal Manipulations/
57 chiropractic$.ti,ab.
58 osteopath$.ti,ab.
59 (manipulat$ adj3 (anesthesia or anaesthesia or anesthetic$ or anaesthetic$)).ti,ab.
60 MUA.ti,ab.
61 56 or 57 or 58 or 59 or 60
62 19 and 61
63 (TENS or ALTENS).ti,ab.
64 ((electric$ adj2 stimulat$) or (transcutaneous adj2 stimulat$) or (transdermal adj2 electrostimulat$) or (cutaneous adj2 electrostimulat$) or electroanalgesia or electro analgesia).ti,ab.
65 (muscle adj2 stimulat$).ti,ab.
66 (neuromodulation or neuro modulation or neurostimulation or neuro stimulation).ti,ab.
67 interferential.ti,ab.
68 or/63-67
69 19 and 68
70 biofeedback.ti,ab.
71 Biofeedback, Psychology/
72 or/70-71
73 19 and 72
74 cryotherapy/
75 ice/
76 diathermy/

77 hyperthermia, induced/
78 hot temperature/
79 ((cold or ice or heat or hot) adj (pack$ or therap$ or treat$)).ti,ab.
80 (thermograph$ or thermotherap$ or thermo therap$ or hypertherm$ or hyper therm$ or diatherm$ or cryotherap$ or cryo therap$).ti,ab.
81 or/74-80
82 19 and 81
83 exp Laser Therapy/
84 ultrasonic therapy/
85 ultrasound.ti,ab.
86 Ultrasonography, Interventional/
87 (electrotherapeutic adj (intervention$ or treat$)).ti,ab.
88 or/83-87
89 19 and 88
90 magnetic field therapy/
91 pulsed electromagnetic field therapy.ti,ab.
92 ((electromagnetic$ or magnetic$) adj3 field$).ti,ab.
93 (biomagnetic$ or bio magnetic$ or pulsed signal).ti,ab.
94 PEMF.ti,ab.
95 or/90-94
96 19 and 95
97 nerve block/
98 neuromuscular blockade/
99 (nerve adj2 block$).ti,ab.
100 or/97-99
101 19 and 100
102 exp Acupuncture Therapy/
103 acupuncture$.ti,ab.
104 (electroacupuncture$ or electro acupuncture$).ti,ab.
105 (osteopuncture$ or osteo puncture$).ti,ab.
106 (perioste$ adj3 (stimulat$ or therap$ or needling)).ti,ab.
107 or/102-106
108 19 and 107
109 massage/
110 (massag$ or acupressure or shiatsu or shiatzu or zhi ya or chih ya).ti,ab.
111 109 or 110
112 19 and 111
113 (rehabilitat$ adj2 (program$ or protocol$)).ti,ab.
114 19 and 113
115 ((watch$ adj2 wait$) or (conservative adj2 treat$)).ti,ab.
116 19 and 115
117 (management adj2 (decision$ or option$ or choice$)).ti,ab.
118 19 and 117
119 114 or 116 or 118
120 6 or 27 or 32 or 41 or 55 or 62 or 69 or 73 or 82 or 89 or 96 or 101 or 108 or 112 or 119
121 limit 120 to yr="1966 -Current"

Appendix C Quality Assessment

	Criteria	Score ('Yes', 'No', 'Unclear', 'Not applicable (NA)')
1	Was the number of participants randomised stated?	
2	Was the method of randomisation adequate (e.g. use of random number table, computer random number generator, coin tossing, shuffling of cards or envelopes, throwing of dice)?	
3	Was allocation concealment adequate (e.g. central allocation, sequentially numbered opaque sealed envelopes)?	
4	Were the treatment groups comparable at baseline for important prognostic factors?	
5	If the above answer was no, was a suitable statistical method used to adjust for possible baseline imbalance?	
6	Was the study reported as being at least double blind?	
7	Were patients blinded?	
8	Were outcome assessors blinded?	
9	Were care givers blinded?	
10	Was intention-to treat analysis used (i.e. were all participants included in the analysis in the group to which they were allocated)?	
11	Were there any unexpected imbalances in drop outs between groups? If so, were they explained or adjusted for?	
12	Was selection/eligibility criteria adequately reported?	
13	Was the selected population representative of that seen in normal practice?	
14	Was an appropriate measure of variability reported?	
15	Was loss to follow-up reported or explained?	
16	Were at least 90% of those included at baseline followed up?	
17	Were patients recruited prospectively?	
18	Were patient recruited consecutively?	
19	Did the study report relevant prognostic factors?	

Case series quality rating

Good: the answer is 'yes' to criteria 12-19

Satisfactory: the answer is 'yes' to criteria 13 and 15-18

Poor: the answer is not 'yes' to one or more of the criteria listed for satisfactory