NCCHTA

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RAPID REVIEWS FOR THE HTA PROGRAMME

PROTOCOL: THE EFFECTIVENESS AND COST-EFFECTIVENESS OF DIAGNOSTIC IMAGING TESTS FOR THE ASSESSMENT OF SHOULDER PAIN

A. ***This protocol is provisional and subject to change***

B. Details of review team

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C. Full title of research question

How effective and cost-effective are newer diagnostic imaging tests as an addition to clinical examination and patient history for the diagnosis of soft-tissue shoulder disorders?

D. Clarification of research question and scope

D1. Burden of disease

Shoulder pain is a significant cause of morbidity in the general population. Recent surveys have estimated the prevalence of self-reported shoulder pain at 16%[1] in the UK, rising to 26%[2] in the elderly, and at 21% in the Netherlands.[3] It has been suggested that only 40 to 50% of people with shoulder pain will consult a general practitioner for it,[3] nevertheless it is the third most common cause of musculoskeletal consultation in primary care. Around a quarter of patients presenting with a new episode of shoulder pain report a previous episode of shoulder pain.[4]

D2. The anatomy of the shoulder

The shoulder is made up of several joints that combine with tendons and muscles, allowing a wide range of motion to the arm. Its function involves the thorax and three bones – the humerus, the glenoid scapula and the clavicle – plus nearly 30 muscles. Three articulations – acromioclavicular, sternoclavicular, and glenohumeral – must move normally for the shoulder to function correctly.[5] The stability of the shoulder joint is provided largely by soft tissue structures, and in particular the circle of muscles known as the rotator cuff.

D3. Causes of shoulder pain

The complex anatomy of the shoulder and the wide spectrum of disorders that can lead to shoulder pain symptoms *can* make accurate diagnosis difficult. The lack of consensus on the appropriate

diagnostic criteria and the availability of several diagnostic classifications illustrate the complexity of diagnosis.[6]

Most shoulder problems fall into three major categories: soft tissue disorders; injury or instability; and arthritis. It has been estimated that 90% of lesions causing painful shoulder result from extracapsular soft tissue lesions and these will be the main focus of this report.

D3.1. Soft tissue shoulder disorder: Rotator cuff disorders and impingement syndrome
Soft tissue shoulder disorders result from either the wearing process that takes place over a period of years, or may occur from acute strain or repetitive use, causing friction and irritation. The term 'clinical impingement syndrome' covers a spectrum of shoulder pathologies with distinct clinical symptoms such as pain on attempted use of the shoulder, particularly with overhead activity and/or weakness. The most common of these are shoulder bursitis, rotator cuff tendinitis and rotator cuff tears.

Bursitis occurs where repeated use of the shoulder leads to inflammation and swelling of a bursa (fluid filled sacs located around the joints that lessen the friction caused by movement of the shoulder). Bursitis often occurs in association with rotator cuff tendinitis and tends to be triggered by sports activities, or more commonly physical activity.[5]

Rotator cuff disorders most commonly occur where tendon tissue has weakened or degenerated due to ageing, hypovascularity of the critical zone, repeated microtrauma, or overuse from professional or athletic activity.[7] Rotator cuff tendinitis is more often seen in middle-aged or older patients with chronic shoulder pain than in younger people.

Rotator cuff tear is the end stage on the impingement syndrome spectrum and is more painful than the most severe form of rotator cuff tendinitis. Rotator cuff tears may be either partial or full thickness tears. This splitting and tearing of tendons may result from an injury or degenerative changes in the tendons due to advancing age.

Adhesive capsulitis or "frozen shoulder" can result when inflammation and pain limit the use of the shoulder to the extent that the joint stiffens. It is most commonly seen in older patients whose shoulders are immobilised after an injury and can occur even after minimal trauma.

Unfortunately, a lack of consensus regarding diagnostic criteria and the classification of shoulder disorders make it difficult to estimate the frequency of the underlying causes of shoulder pain. A systematic review of treatment of shoulder pain found that 24 studies had specified 10 distinct diagnoses with 16 definitions to characterise their study population.[8] In one primary study, up to 30% of soft tissue disorders were attributed to rotator cuff tendinitis, 22% to capsular syndrome, 17% to acute bursitis and 13% to chronic bursitis.[9] Another found that around 70% of shoulder disorders primarily involved the rotator cuff.[2] The difficulties of diagnosis are further emphasised by evidence that at the primary care level at least, initial diagnostic categories can change significantly with follow-up visits over time.[9;10]

D3.2. Other causes of shoulder pain
<u>Injury or instability</u>
Dislocation can occur when the bones of the shoulder are knocked out of place without breaking either though injury or instability. Once the joint is relocated, the patient usually recovers in a couple of weeks.[5] Instability can result in a tendency to repeated dislocation of one of the shoulder joints. Recurrent instability is closely correlated with age: patients less than 25 years old at the time of the initial episode have a recurrence rate of 60-90% compared to only 15% in those aged over 45.[5] Although the dislocations should be easy to manipulate back into position, the shoulder joint may be left permanently weakened. This weakness is partly caused by stretching and tearing of the surrounding ligaments, tendons and capsule of the joint. There may also be damage to the cartilage and bone lining the rim of the socket.

Arthritis
Shoulder pain can also result from osteoarthritis or degenerative arthritis. Osteoarthritis (degenerative arthritis) involves wear and tear changes with inflammation of the joint, causing swelling, pain and stiffness. Degenerative arthritis may be related to sports or work injuries or can occur as part of the gradual ageing process. Rheumatoid arthritis is associated with a severe inflammation of the joint lining (the synovium) which then leads to breakdown of the joint surface cartilage and bone.

Referred pain
Shoulder pain can also be caused by referred pain from internal organs, neurological or vascular disorders, neoplasms and disorders of the cervical spine.[9]

D4. Diagnosis of soft tissue shoulder disorders
In the absence of trauma or arthritis, most shoulder pain is caused by periarticular soft tissue injury as described above. Aetiological differentiation of the underlying disorders can be difficult and most important for the assessment of different imaging modalities is their ability to detect combined pathologies of the shoulder joint.[11] Determining the source of the problem in the shoulder is important to be able to recommend the right treatment. The vast majority of patients presenting with shoulder pain will be diagnosed and treated within general practice: only around 10% of patients seen in general practice are referred for a specialist opinion.[9]

There appear to be no clear guidelines for the diagnosis of shoulder pain. Available tests include: clinical assessment, plain X-ray, arthroscopy, ultrasonography, computed tomographic arthrography (CTA), magnetic resonance imaging (MRI) and magnetic resonance arthrography (MRA).

D4.1. Clinical assessment and patient history
Physical examination and history taking are the cornerstones of the diagnosis of shoulder disorders. Patient history provides the first clues to the source of the problem, can distinguish whether the problem is acute or chronic, and should identify cases of referred pain from other sites such as the cervical spine.[12]

Clinical examination includes inspection and palpation, assessment of range of motion and strength, and provocative shoulder testing for possible impingement syndrome and glenohumeral instability.[12] A variety of tests can be used during the examination (Table 1). It is thought that positive findings from these tests may be suggestive of different underlying shoulder disorders, however the individual contribution of each of these tests to shoulder pain diagnosis and the most accurate combination or sequencing of tests is unclear. The different diagnostic classification systems in use and the variation in classification of complaints between clinicians complicate the assessment of these tests.[6]

Table 1. Examples of tests used in clinical examination of the shoulder (adapted from Woodward, 2000[12])

Test	Manoeuvre	Suggested diagnosis on positive finding
Apley scratch test	Patient touches superior and inferior aspects of opposite scapula	Loss of range of motion: rotator cuff problem
Neer's sign[13]	Arm in full flexion	Subacromial impingement
Hawkins' test[14]	Forward flexion of the shoulder to 90° and internal rotation	Supraspinatus tendon impingement
Drop-arm test	Arm lowered slowly to waist	Rotator cuff tear
Cross-arm test	Forward elevation to 90° and active adduction	Acromioclavicular joint arthritis
Spurling's test	Spine extended with head rotated to affected shoulder while axially loaded	Cervical nerve root disorder
Apprehension test	Anterior pressure on the humerus with external rotation	Anterior glenohumeral instability
Relocation test	Posterior force on humerus while externally rotating the arm	Anterior glenohumeral instability

Sulcus sign	Pulling downward on elbow or wrist	Inferior glenohumeral instability
Yergason test[15]	Elbow flexed to 90° with forearm pronated	Biceps tendon instability or tendonitis
Speed's manoeuvre	Elbow flexed 20 to 30° and forearm supinated	Biceps tendon instability or tendonitis
"Clunk" sign	Rotation of loaded shoulder from extension to forward flexion	Labral disorder

D4.2. Plain X-ray
Standard radiography of the shoulder joint tends to be the first study in any patient suffering from a shoulder trauma, chronic shoulder pain or shoulder joint instability. Conventional X-rays will show gross osseous trauma, dystrophic calcifications or spurs, predisposing to impingement. However, their value for soft tissue lesions is limited because in most cases plain X-ray is normal.[11] A lot of films are read in orthopaedic and rheumatology clinics, and diagnosis made there. They will usually be read later by a radiologist.

D4.3. Arthroscopy
Arthroscopy is an invasive procedure whereby a thin fibre-optic endoscope is introduced into the shoulder joint to allow direct visualisation of the internal structures. Arthroscopy also allows a biopsy to be taken and/or operations to be carried out. It tends to be performed in an operating room setting, with sterile conditions, with the patient under general anaesthesia. Complications may occur including septic arthritis and haemarthrosis.

D4.4. Ultrasonography
Ultrasonography uses a pulse echo device to record reflected waves of a sound beam in two dimensions. It is simple, rapid, non-invasive, frequently available and relatively inexpensive. Unlike plain X-ray, it may reveal soft tissue changes. However, reported sensitivity and specificity for the detection of rotator cuff lesions vary between 57-91% and 76-100% respectively.[11;16] It may be most useful for the detection of full-thickness rotator cuff tears.

D4.5. Arthrography
Arthrography is an X-ray procedure involving the intra-articular injection of radiopaque dye into the shoulder to demonstrate the anatomy of the joint by X-ray. Double-contrast arthrography includes the injection of 10-15 ml room air in addition to the contrast agent. This provides detailed images of structures in the axial plane, accurately identifying the glenoid labrum and the extent of the synovial membrane.

The single-contrast technique has been used to evaluate shoulder disorders such as rotator cuff tear and adhesive capsulitis since 1938.[17] The development of double-contrast arthrography in the 1970s increased the ability of the technique to document suspected tears, as well as allowing more accurate evaluation of the size of the defect and quality of the torn tendon edges. The overall accuracy of single or double-contrast arthrography for the diagnosis of complete rotator cuff tears has been put at nearly 100% by some authors,[11] and is considered to be the gold standard. The sensitivity of arthrography for diagnosing partial cuff tears can be improved by exercise before plain film radiographs are taken.

Disadvantages include complications such as infective arthritis, incomplete evaluation of the rotator cuff, and inadequate assessment of the size and quality of the tears.[11]

Computed tomography arthrogropahy (CT arthrography) may also be performed and is said to be potentially useful for the detection of rotator cuff tears.[11] Others however, claim that though CT may highlight bony glenoid or humeral head lesions it is ineffective in evaluating the labrum or the capsulo-ligamentous structures.[18]

D4.6. Magnetic resonance imaging (MRI)

MRI is a non-invasive method of imaging, where the body is placed in a magnetic field which causes certain atomic nuclei to align in the direction of the field. Pulses of radio frequent radiation are then applied. Interpretation of the frequencies absorbed and re-emitted allows an image in any body plane to be built up. MRI is unique in that it allows multiplanar imaging and may be of particular benefit in the assessment of soft tissue structures. As a result, MRI has been intensely investigated for the assessment of shoulder diseases including rotator cuff disease and shoulder joint instability, and appears to provide high sensitivity and specificity in the diagnosis of many causes of shoulder pain.

D4.7. Magnetic resonance arthrography (MRA)
MRA was introduced to overcome the limitations of standard MRI in diagnosing rotator cuff disease and shoulder instability.[11] It can be done with different fluids including pure saline and ringer lactate, or with a mixture of saline and gadolinium contrast medium. MRA is thought to extend the capabilities of conventional MRI because the contrast material delineates intrarticular structures and outlines abnormalities.[19] It has been claimed to improve the differentiation and detection of partial rotator cuff tears and labral tears in comparison to standard MRI.[11]

The relative benefits of these technologies for the diagnosis of shoulder pain in terms of accuracy and cost-effectiveness are currently unknown.

D5. Treatment of shoulder pain
Most patients who present with shoulder pain in general practice will undergo conservative treatment based on patient history and clinical examination. A Dutch study of 335 patients with a new episode of soft-tissue shoulder disorder found that in the subsequent year:

- 24% underwent a 'wait and see' policy or received NSAIDs;
- 29% were referred for physiotherapy;
- 23% received a local injection of anaesthetic or steroid;
- 19% were recommended physiotherapy and injections; and
- only 1% underwent surgery.[9]

In spite of treatment, only around 20% of patients report a complete recovery at one month[4;9] and 40-50% report that their symptoms have persisted or recurred one year after the initial consultation.[4;9;10]

In fact, evidence for the effectiveness of conservative treatments is limited. A recent systematic review[8] concluded that non-steroidal anti-inflammatory drugs (NSAIDs) and subacromial glucocorticosteroid injections *may be* superior to placebo in improving the range of abduction in rotator cuff tendinitis but no conclusions could be drawn regarding treatment of adhesive capsulitis. Further systematic reviews have found inconclusive evidence for the efficacy of physiotherapy[20] or steroid injections[21] in the treatment of soft tissue shoulder disorders. No randomised controlled trials of surgical interventions have been identified.[8]

It is likely that the benefits of treatment (conservative or surgical) may vary for different underlying causes of shoulder pain,[6] lending further support to the need for accurate diagnosis at the earliest possible stage.

E. **Report Methods**

E1. Objectives
The aim of this report is to conduct a systematic review of the effectiveness of newer diagnostic imaging tests for the investigation of soft-tissue shoulder disorders in order to identify the most effective diagnostic strategies. Additional economic modelling will be used to determine cost-effectiveness.

The main objectives will be as follows:

1. to establish the effectiveness of clinical examination and patient history at differentiating the underlying causes of shoulder pain

2. to evaluate the benefit gained from use of diagnostic imaging for the identification of soft-tissue shoulder disorders
3. to assess how the individual tests would most effectively and cost-effectively be combined with clinical examination in diagnostic strategies or algorithms
4. to provide some estimate of the current extent of and likely rate of diffusion of the evaluated imaging tests

Tests will be evaluated in terms of accuracy, quality of life and cost. Data on other outcomes including patient outcomes will be examined if available.

E2. Search strategy

Literature will be identified from several sources including electronic databases and other sources including:

i) General health and biomedical databases: MEDLINE; PubMED (current year); EMBASE; Science Citation Index; BIOSIS; AMED
ii) Specialist electronic databases: DARE; MEDION (a database of diagnostic test reviews set up by Dutch and Belgian researchers); EconLit
iii) Research in Progress*:* National Research Register (NRR); Current Controlled Trials; Clinical Trials.gov
iv) Manufacturers of imaging devices will be identified and invited to submit data on efficacy (published or unpublished)
v) Checking of reference lists

A comprehensive database of relevant articles will be constructed. All databases will be searched from 1985 to the current date. Due to time and resource constraints searches will be restricted to English language only. A preliminary search of MEDLINE (from 1990-present) has identified approximately 4000 potentially relevant citations for screening.

Initial searches of MEDLINE, the Database of Abstracts of Review of Effectiveness (DARE) and the NHS Economic Evaluations Database (NHS Eed) have been conducted to identify any existing systematic reviews of diagnostic tests for the investigation of shoulder pain. One systematic review of the effect of MRI of the shoulder on patient outcomes[22] and one cost-effectiveness analysis of arthrography versus MRI[23] were identified. In addition, several systematic reviews demonstrating the effectiveness of treatment of shoulder pain were found.[8;20;21;24;25]

<u>E3. Inclusion criteria</u>

The criteria for study inclusion in the systematic review will be as follows.

E3.1. Population

The majority of patients with shoulder pain are almost exclusively managed in general practice and it is important to focus on the concept of 'shoulder pain' rather than shoulder pathology. For the evaluation of clinical examination therefore (objective 1), all causes of shoulder pain will be included.

The majority of the claimed benefits of the newer imaging techniques are related to the diagnosis of soft-tissue disorders. Imaging modalities such as CTA, MRI and MRA are said to be of particular benefit in the assessment of soft-tissue structures. For the assessment of imaging techniques therefore (objectives 2 and 3), studies of adults with suspected soft tissue disorders of the shoulder including, rotator cuff tendinitis or rotator cuff tears, shoulder bursitis and adhesive capsulitis (or frozen shoulder) will be included.

Studies that include only patients with shoulder pain resulting from 'other' causes such as shoulder instability, arthritis, or referred pain will be excluded. Studies of mixed patient populations will be included where results can be extracted separately for the subgroup of patients with soft-tissue disorders. Studies conducted in children and studies of cadavers will also be excluded.

E3.2. Setting
Studies conducted in any setting will be included in the review, including general practice, accident and emergency, and hospital clinics.

E3.3. Interventions
Objective 1. Clinical examination and patient history
Any study that has compared clinical examination and patient history in comparison to an acceptable gold standard for the evaluation of patients with shoulder pain will be included.

Objectives 2 and 3. Evaluation of newer imaging tests
The following diagnostic imaging techniques in comparison to an acceptable reference standard or in comparison with each other will be included in this review:

- ultrasound
- CT arthrography
- magnetic resonance imaging
- magnetic resonance arthrography

Acceptable reference tests for this review are arthroscopy or arthrography. Subsequent surgery will also be considered acceptable as long as those patients who test 'negative' also undergo some form of reference test. The inclusion of MRI as a reference standard will also be explored, in consultation with our expert panel. Arthroscopy and arthrography are the usual gold standards for diagnosing the underlying causes of shoulder pain, however their ability to diagnose soft-tissue lesions may be limited, providing us with the problem of an imperfect gold standard.

Evaluations of plain X-ray will be excluded from the review, as X-ray is recognised to have limited value in the diagnosis of soft-tissue lesions.

E3.4. Outcome measures
There are several levels at which a diagnostic test can be evaluated, ranging from the technical aspects and diagnostic accuracy of the test, to examining efficacy from a societal level to evaluate whether a diagnostic test is an efficient use of societal resources to provide medical benefits to society. In between these extremes lie the establishment of the impact of the test result on the diagnostic thinking of the clinician who ordered it, and the effect on therapeutic efficacy, and subsequently on patient outcomes.[26]

In practice, the evaluation of diagnostic tests has largely focused on the establishment of test accuracy, and this will be the main focus of this review. However, any studies which have examined the effect of diagnosis on diagnostic thinking, patient management or subsequent patient outcomes will also be included. Studies focusing on the establishment of technical efficacy alone will be excluded.

At a minimum, accuracy studies must report summary accuracy statistics or present sufficient raw data to allow these statistics to be calculated. Where relevant data cannot be extracted from published articles, the corresponding author will be contacted to obtain additional information.

Quality of life can be considered in two ways: a) the patient's experience of and preference for the different tests, and b) the effect of a false-positive or false-negative diagnosis. Inaccurate diagnoses will lead to use of inappropriate or delayed treatment and result in delayed recovery. Literature on patient preferences for the different tests will be included and reviewed narratively, as will any studies that have attempted to estimate the utility value associated with a false-positive or false-negative diagnosis. The use of utility values to reflect the impact of accurate versus inaccurate diagnoses will be explored in the economic analysis.

E3.5. Study design
For inclusion in this review, studies must compare a new test or strategy with an established reference test in patients *suspected of having* the target disorder. Studies, particularly case-control studies, which have selected healthy control subjects will be excluded. Retrospective studies will be included only where the original test interpretation was used.

In order to avoid work-up bias, only studies where *all* patients who undergo the index test *also* undergo the reference test will be included. If this policy results in the inclusion of few studies and the exclusion of a large number of studies, all studies will be included in a sensitivity analysis.

For studies evaluating the impact of tests on patient management or patient outcomes, only prospective, controlled trials will be included.

E3. Quality assessment strategy
The methodological quality of all included studies will be appraised using a formal quality assessment tool. There is an ongoing debate over what constitutes the best quality assessment tool for diagnostic test studies, and there is no generally accepted 'best' tool. Several tools have been used to assessed the quality of imaging studies,[27;28] these will be examined and adapted for use in this review. Items relating to the selection of the study cohort, performance of the reference standard, and masked assessment of test results will be included. Table 2 provides a list of possible quality assessment criteria.

Table 2. Possible quality assessment criteria

	Criterion	**Response**
1.	Technical quality of the index test	Description adequate/inadequate
2.	Technical quality of the reference test	Description adequate/inadequate
3.	Use of appropriate reference test	Appropriate/inadequate
4.	Definition of normal/abnormal	Clearly defined; not clear
5.	Independence of test interpretation	Independent, blinded
6.	Cohort assembly	Prospective; retrospective Random sample; consecutive; non-consecutive
7.	Description of the study population	Description adequate/inadequate
8.	Spectrum of participants	Adequate/inadequate
9.	Verification	Complete; partial; differential

Studies of the impact of tests on patient management or patient outcomes will be assessed using a tool for the evaluation of controlled trials such as that developed by Thomas and colleagues.[29]

Study quality will be assessed independently by two reviewers. Any disagreements will be resolved by consensus or if necessary by arbitration by a third reviewer.

E4. Data extraction strategy
The extraction of study findings will be conducted in duplicate using a pre-designed and piloted data extraction form to avoid any errors. Given the extent of insufficient reporting in the medical literature, we propose to obtain missing information from investigators whenever possible. It is otherwise impossible to distinguish between what was done but not reported and what was not done. Any disagreements between reviewers will be resolved by consensus or if necessary by arbitration by a third reviewer.

E5. Methods of analysis
Until the data has been obtained, it will not be possible to assess whether quantitative synthesis of results can be undertaken. Synthesis will only be considered if there are several high quality studies of the test of the same design without other clinically important differences. The methods used will depend on the nature of the studies located in the search and included in the review.

For studies comparing patient outcomes, and diagnostic and therapeutic impact comparisons between using and not using each test (or between groups using different tests) standard methods of meta-analysis will be used.

For studies evaluating test accuracy, the sensitivity, specificity and exact 95% confidence intervals will be calculated for each test against the reference standard for each study. Individual studies may have used varying explicit and implicit definitions for an abnormal result. This may be particularly true of imaging studies where interpretation of the same image can vary significantly between interpreters. Explicit variations will be dealt with by extracting data to a standardised cut-off value or by calculating sensitivity and specificity for a variety of cut-offs points. Implicit variations in cut-off manifest themselves in a trade-off between sensitivity and specificity, and will be identified by testing for a correlation between true-positive and false-positive rates.[30;31]

Where no such correlation is revealed, and studies are otherwise sufficiently homogenous, pooled estimates of sensitivity and specificity will be calculated. Summary estimates will be produced with 95% confidence intervals. Random effects methods for meta-analysis will be used where possible, as heterogeneity between test statistics is routinely encountered in diagnostic meta-analyses. Where heterogeneity does exist due to threshold variations meta-analysis using summary ROC curves will be used.

Heterogeneity will be assessed using standard tests, and, time- and data-permitting, pre-specified sources of heterogeneity will be investigated using SROC and other meta-regression analyses.

Sensitivity analyses
Potential sources of heterogeneity that will be investigated will include features of the population (spectrum), test, outcomes and study quality. Regression analysis may be used to identify which, if any, of these factors influence accuracy and relevant subgroup analyses will be undertaken. Likely sources include:

- study setting: general practice vs. hospital clinics
- patient age
- use of blinding
- differential verification
- etc.

<u>E6. Methods for estimating qualify of life, costs and cost-effectiveness and/or cost/QALY</u>
The cost-effectiveness of alternative diagnostic strategies for the identification of shoulder disorders will be evaluated using a decision tree model. It is likely that the model will be based on the use of different imaging modalities in the hospital setting, as this is where the majority of imaging techniques will be used.

A model will be constructed to describe each of the ways in which individual tests can be used either alone or in sequence, in order to achieve an ultimate diagnosis. The ultimate goal of a diagnostic test is to improve patient management and ultimately patient outcomes. These outcomes will be incorporated into the model by considering the:

- unnecessary or inappropriate treatment of those with false-positive diagnoses
- non treatment of those with false-negative diagnoses

Model parameters
It is anticipated that the decision analysis model will require the following data:

1. Incidence and prevalence of soft-tissue shoulder disorders
   This will likely be estimated from survey data and/or data from the ONS General Practice Research Database.

2. Efficacy (accuracy) of alternative diagnostic strategies
   The results of literature review will be used to identify the accuracy of individual tests and diagnostic strategies.

3. Efficacy and side-effects of treatment for shoulder disorders
   Existing systematic reviews of treatment and consultation with experts will be used to estimate the accuracy of different treatments according to the underlying shoulder disorder.

4. Costs (tests and treatment)
   Individual cost components will be identified from the literature review and from consultation with experts. Incremental costs are likely to relate mainly to the cost of the tests and staff costs. Cost data will be obtained from the literature and from local hospital Finance departments.

The relative cost-effectiveness of diagnostic algorithms with different combinations of tests will be examined to determine the incremental cost per additional case identified.

F. Handling the company submission(s)
As this is not a NICE review, no company submissions will be received.

G. **Research in progress**
Research in progress will be identified using the literature search strategy outlined in section E.

H. **Project Management**

a. **Timetable/milestones** - submission of:

Draft protocol: 5/10/01

Finalised protocol: 30/10/01

Progress report: 12/4/02

Draft final report: 28/6/02

b. **Competing Interests**
None

c. **External reviewers**
At least three or four UK clinicians with expertise in the investigation of shoulder disorders will be consulted for advice on the review. These will include representation from radiology, rheumatology, orthopaedics and general practice.

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