

## IMAGE-GUIDED HIGH VOLUME INTRA-ARTICULAR INJECTIONS (40MLS+) OF SALINE WITH OR WITHOUT CORTICOSTEROID AND/OR LOCAL ANAESTHETIC FOR THE TREATMENT OF PAINFUL JOINTS

### Questions to be addressed

1. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?
2. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?

### Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, in partnership with Walsall CCG, Wolverhampton CCG and Dudley CCG, requested a rapid evidence review of the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options to inform their decisions on commissioning policy development.

### Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, image-guided HIGH VOLUME intra-articular injections should be offered ONLY to patients who have failed to respond to conventional interventions, including intra-articular corticosteroid injections.
3. The Committee considers that there is sufficient evidence to suggest that image-guided HIGH VOLUME intra-articular injections is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

### Summary

#### Background

- Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous.
- Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. It can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis<sup>a</sup>. Other causes of joint pain include sports injuries, general sprains and strains, adhesive capsulitis, unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

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<sup>a</sup> Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

- Despite the wide range of conditions and symptoms, different types of joint pain may share similar underlying mechanisms, manifestations, and potential treatments.
- Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes oral analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. Image-guided high volume intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are treatment options for adhesive capsulitis (frozen shoulder).

### **Clinical effectiveness**

- We searched for studies that compared image-guided high volume injections to alternative treatment options and the only comparative studies identified were in patients with frozen shoulder. In this rapid evidence review, we report results from two systematic reviews of RCTs and one RCT (published subsequent to the systematic reviews) of the effectiveness of hydrodilatation (also referred to as arthrographic distension) with image-guided high volume injection in patients with adhesive capsulitis (frozen shoulder).
- The systematic review (with meta-analysis) by Saltychev et al (2018) evaluated the evidence on the effectiveness of hydrodilatation (HD) in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The total number of patients included in the review or meta-analysis was not reported.
  - The meta-analysis of seven of the RCTs showed that for hydrodilatation with corticosteroid versus intra-articular corticosteroids injection alone, there were statistically significant improvements in pain ( $p=0.00$ ; numbers needed to treat (NNT)<sup>b</sup> = 12) and range of motion ( $p=0.01$ ; NNT= 12) in favour of hydrodilatation. However, these did not translate to a difference in disability assessment between the two treatment arms ( $p=0.11$ ).
  - The authors concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis. These results need to be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) and only a few outcome measures were reported.
- The systematic review conducted by Catapano et al (2018) to determine whether the combined intervention of hydrodilatation and corticosteroid injection expedites restoration of pain-free range of motion (ROM) compared to a control treatment of corticosteroid injection in patients with adhesive capsulitis included six RCTs involving 410 shoulders.
  - Two studies demonstrated statistically significant improvement in pain measured using the VAS with hydrodilatation and corticosteroid injection when compared to corticosteroid injection alone; one study at 12 weeks ( $p=0.002$ ) and the other at one month ( $p=0.035$ ).
  - Two studies demonstrated statistically significant improvement in favour of hydrodilatation with corticosteroid injection in ROM at 12 weeks (extension ROM  $p=0.03$ ; external rotation ROM  $p=0.010$  and abduction ROM  $p=0.005$ ; internal rotation  $p=0.027$ ) and one at one month (external rotation,  $p=0.005$ ).

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<sup>b</sup> NNT is the number of patients that need to be treated to achieve one patient with an improvement.

- Two studies showed no difference between hydrodilatation with corticosteroid injection and corticosteroid injection alone.
- In contrast to Saltychev et al, and despite considering some of the same studies (reported differently), Catapano et al concluded that combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM. These findings need to be interpreted with caution as the results were not consistent across the studies included and no meta-analysis was carried out.
- Gallacher et al carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)<sup>c</sup> differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)<sup>d</sup> and hydrodilatation (HD). Patients were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2013.
  - At six months after the intervention, both groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort (p= 0.023). The ACR and HD cohorts showed improvements in external rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group (p=0.03 and p=0.023 respectively). Significant improvement in EQ-5D<sup>e</sup> VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant.
  - The authors concluded that ACR is associated with significantly higher OSS at six months than HD however, significant improvement was observed in both groups. These findings need to be interpreted with caution as the study was small (n=50) so may not have been sufficiently powered to show any differences. In addition the fact that this was a patient-reported outcome measure may have introduced some bias especially as they were not blinded to their treatment.

### **Safety**

- Both systematic reviews reported adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.
- Saltychev et al (2018) reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups based on three studies. No absolute numbers or proportions were reported.
- They reported one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid.
- Catapano et al (2018) reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only)

<sup>c</sup> The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

<sup>d</sup> Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

<sup>e</sup> EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

group. They state that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection with no further details.

- The RCT by Gallacher et al (2018) reported that there were no complications with either ACR or hydrodilatation.

### **Cost effectiveness**

- No cost effectiveness studies of hydrodilatation compared to alternative treatment options were found. One systematic review attempted to assess the cost-effectiveness of different interventions used for frozen shoulder, including hydrodilatation (referred to arthrographic distension in the review); however, because of the paucity of evidence, the development of an economic model was not feasible (Maund et al 2012).
- Consequently, the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review.

### **Equity issues**

- It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access or uptake compares to the rest of England.

## 1 Context

### 1.1 Introduction

Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis<sup>f</sup>. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments [1, 2].

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments [1]

Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. High volume injection intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are considered treatment options for adhesive capsulitis (frozen shoulder) [3].

### 1.2 Existing national policies and guidance

There is no relevant published NICE Technology Appraisal Guidance (with statutory requirement for NHS organisations to make funding available), Clinical Guidelines or Quality Standards specifically for image-guided HIGH VOLUME intra-articular injections.

## 2 Epidemiology

Joint pain is one of the leading causes of disability worldwide [4].

A survey carried out by Duncan et al (2011) on the prevalence of arthritis and joint pain in the elderly in Scotland found that 63% of 803 respondents reported joint pain in the previous month. Women reported pain more often than men (68% versus 56%,  $p=0.001$ ). The individuals who experienced pain were most likely to have knee pain (65%), followed by shoulder pain (31%) then lower back pain (28%), hip pain (25%) and hand pain (24%). Pain was more prevalent in women across all joint areas but the gender difference was only statistically significant for foot ( $p=0.002$ ), neck ( $p < 0.0001$ ), ankle ( $p = 0.01$ ) and lower back pain ( $p = 0.001$ ) [5].

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<sup>f</sup> Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

### 3 The interventions

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint usually into the glenohumeral (shoulder) joint. For the purpose of this rapid evidence review we will use the term hydrodilatation (HD). HD is generally carried out with a mixture of contrast medium, long acting anaesthetics, steroids, saline or air. However, because of the inherent compressibility of air, the procedure is more difficult than when saline is used. Dependent upon the contracted state of the joint capsule, HD usually occurs with an injection of between 10ml and 55ml of normal saline [6].

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). HD is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion. The risk of complications is thought to be low and treatment success is known after a couple of weeks [6, 7].

### 4 Findings

We searched Medline, Embase and Cochrane Library on the 19<sup>th</sup> September 2018 using the search strategy detailed in section 7 below. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews.

The search was limited to 2008 onwards and English only and we excluded letters, commentary, case reports and conference papers.

#### 4.1 Evidence of effectiveness

We identified three systematic reviews of RCTs [8, 9, 10] of the effectiveness of hydrodilatation with image-guided high volume injection. All three systematic reviews focused on patients with adhesive capsulitis (frozen shoulder). Of the two SRs published in 2018 [8, 9] only one carried out a meta-analysis [8]. The health technology assessment (HTA) published in 2012, attempted to assess cost-effectiveness but without conducting a meta-analysis of pooled results [10]. We have not reported the clinical effectiveness outcomes reported in the HTA by Maund et al 2012 [10] as they have been superseded by the RCTs in the 2018 systematic reviews. However, the information on costs is reported as it is the only one identified. We also identified one relevant RCT published subsequent to these systematic reviews [3].

Earlier systematic reviews which considered the same RCTs as the recent, included systematic reviews with or without meta-analysis were excluded. Individual studies already included in the systematic reviews have not been reported separately. Non-comparative studies were excluded because they add little when there is RCT evidence.

### 4.1.1 Clinical effectiveness

The systematic review (with meta-analysis) by Saltychev et al (2018) [8] evaluated the evidence on the effectiveness of hydrodilatation with image-guided high volume injection in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The studies included in the meta-analysis compared hydrodilatation with corticosteroid with corticosteroid injection only. The authors stated that the volume of mixture injected for HD to occur varied from 20ml to 90ml in the studies included. The total number of participants was not provided but patient numbers in the studies varied between eight and 60. It was not clear whether the participants had failed other treatment. The authors report that most of the studies were of moderate quality.

The outcomes reported were change in pain severity, disability level and range of movement (ROM). A statistically significant improvement in pain using VAS<sup>g</sup> was reported for hydrodilatation with corticosteroid versus corticosteroids injection (mean difference (MD): 0.37 (95% CI 0.12 to 0.61),  $p=0.001$ ; 5 studies,  $n$ =not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12. There was no information on the details of the VAS used. A statistically significant improvement in range of movement (ROM) based on pooled results from six studies of hydrodilatation with corticosteroid versus corticosteroids [MD: 0.38 (95% CI 0.07 to 0.69),  $p=0.01$ ; 6 studies,  $n$ =not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement was 12. Importantly, the statistically significant difference between the two treatments for pain and for ROM, did not translate to any between group difference in disability assessment measured using SPADI<sup>h</sup> between hydrodilatation with corticosteroid and corticosteroids alone [MD: 0.20 (95% CI 0.-0.04 to 0.44),  $p=0.11$ ; 4 studies,  $n$ =not reported].

Saltychev et al (2018) concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis [8]. These results should be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) with only a few outcome measures reported. In addition, the participants were not blinded to their treatment and the assessors were not blinded to the treatment in two of the seven studies included in the meta-analysis.

Catapano et al (2018) [9] conducted a systematic review (no meta-analysis) to determine whether the combined intervention of hydrodilatation and corticosteroid injection(HD) expedites restoration of pain-free ROM compared to a control treatment of intra-articular corticosteroid injection(IAI) in patients with adhesive capsulitis. They included six RCTs (involving 410 shoulders), one of which only used 10ml of injection. The mean age of participants ranged from 51 to 61 years. In most of the studies participants were

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<sup>g</sup> VAS: visual analogue score – the details of the score used was not reported.

<sup>h</sup> The Shoulder Pain and Disability Index (SPADI) was developed to measure current shoulder pain and disability in an outpatient setting. The SPADI contains 13 items that assess two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability.

symptomatic for at least three months. These studies were included in the review by Saltychev et al (2018) [8]. The authors report that the studies were of moderate quality.

Two RCTs (n = 100 shoulders and 90 shoulders respectively) demonstrated statistically significant improvement in pain in favour of treatment with HD compared to IAI: pain (VAS) at 12 weeks (HD 3.29 (SD 0.95) versus IAI 3.57 (SD 1.1), p=0.002), and the other at one month (HD 3.6 (SD 1.3) versus IAI 4.6(SD 1.1), p=0.035).

Three RCTs showed statistically and clinically significant improvement in ROM in favour of treatment with HD compared to IAI:

- at 12 weeks: abduction: (HD 114.4 (SD 30.1) versus IAI 82.7(SD 22.6), p=0.005); internal rotation (HD 55.4<sup>0</sup> (SD 18.2<sup>0</sup>) versus IAI 48.4<sup>0</sup> (SD 10.8<sup>0</sup>), p=0.027; n= 100 shoulders;
- at 12 weeks: (extension ROM p=0.03; external rotation ROM p=0.010; n= not reported - no detailed results were provided;
- at one month; external rotation (HD 36<sup>0</sup> (SD 9<sup>0</sup>) versus IAI 28<sup>0</sup>(SD 8<sup>0</sup>), p=0.005 n= 90 shoulders;

In contrast, two studies demonstrated no benefit in any outcome measures with HD when compared to IAI alone.

The authors concluded that *“combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM”*. The greatest benefit appears to be within the first 3 months of intervention in the RCTs that showed improvement however, long term outcomes were not reported. These findings need to be interpreted with caution as studies were small, and they varied significantly regarding the volume of injection used. In addition, pain scores were reported by patients who were not blinded to their treatment.

Gallacher et al [3] carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)<sup>i</sup> differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)<sup>j</sup> and hydrodilatation (HD).

Patients presenting with severe idiopathic frozen shoulder deemed suitable for surgical intervention by a consultant shoulder surgeon at a UK centre were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2016. Patients had had at least three months' duration of symptoms, and had failed a course of physiotherapy. The average age of the HD and ACR cohorts was 55.2 and 52.6 years, respectively. The primary outcome measure was OSS at six months, with secondary outcomes measures of the EuroQoL-5D<sup>k</sup> visual analogue scale, external rotation, complications, and crossover rate also recorded.

<sup>i</sup> The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

<sup>j</sup> Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

<sup>k</sup> EuroQoL-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The

Six months after the intervention, 20 patients were available for follow-up in the HD cohort and 19 in the ACR cohort. Both groups demonstrated significant improvements in OSS from baseline, but the OSS was statistically and clinically significantly higher in the ACR cohort than the HD cohort (43.8 (95% CI, 42.2 to 45.2) versus 38.5 (95% CI, 34.6 to 42.4),  $p=0.023$ ). The ACR and HD cohorts both showed improvements in external rotation ( $47^\circ$  versus  $34^\circ$ ) and forward elevation ( $83^\circ$  versus  $71^\circ$ ), with the improvement in both outcomes being statistically and clinically significantly greater in the ACR group ( $p=0.03$  and  $p=0.023$  respectively). Significant improvement in EQ-5D VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant (10 versus 19.6 for ACR and HD, respectively,  $p=0.053$ ). Before the 6-month follow-up, four patients crossed over from HD to ACR; in contrast, one patient in the ACR cohort crossed over to HD. For the patients that crossed over from the HD group to the ACR group, the authors observed a mean 11.0 point improvement in the OSS at 6 weeks after HD compared with a 20.6 point improvement in the HD group that did not cross over. After ACR, the crossover patients then demonstrated a 28.0 point improvement in OSS from the baseline at 6 months.

Although significant improvement in OSS was observed in both groups, the results suggest that HD is inferior to ACR as it is associated with significantly lower OSS and change in ROM at six months follow-up. There was no difference in health-related quality of life between the two groups. These findings need to be interpreted with caution because the study was small ( $n=50$ ) and therefore may not have been sufficiently powered to show any differences. It is unclear what criteria would be used to offer patients ACR in every day clinical practice. In addition the pain scores were reported by the patients who were not blinded to their treatment in fact four patients from the HD group crossed over to ACR before treatment was started. It is unclear whether the ROM assessors were blinded to the treatments.

### **Trials in progress**

A search of [clinicaltrials.gov](http://clinicaltrials.gov) did not identify any relevant ongoing trials.

#### **4.1.2 Cost-effectiveness**

We identified one HTA which attempted to assess the cost-effectiveness of the different interventions for frozen shoulder.

However, Maund et al [10] were not able to report the cost-effectiveness of the different interventions for frozen shoulder including arthrographic distension due to a lack of reliable clinical effectiveness outcomes to populate a plausible, economic model.

As an alternative, the authors estimated average costs for the interventions from the perspective of the UK NHS, based on NHS reference costs (2008-9) and resource-use estimates obtained from clinical experts.

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second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

Critically none of the resource utilisation costs listed below take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

The authors estimated that the cost of arthrographic distension derived from NHS reference costs (high volume image-guided injection) was approximately £114.84 (£79.84 to £134.84), depending on the choice of steroid injection. They also reported the costs of other treatments used for frozen shoulder as follows;

- The costs for standard unguided steroid injection varied from £36.16 to £138.51 depending on the practitioner delivering the injection, the type of steroid used and where the practitioner is based (i.e. the setting). These costs suggest that a physiotherapist delivering treatment in a community setting is the cheapest option and a rheumatologist delivering treatment in a hospital setting is the most expensive.
- The estimated costs of standard guided steroid injection ranged from £299.68 to £475.56. These costs were mainly influenced by who delivered the injection; whether it's an orthopaedic surgeon, a rheumatologist or a radiologist.
- Physiotherapy treatment was estimated to cost between £98.75 and £126.75 dependent on setting. The addition of a steroid injection to physiotherapy presented a plethora of scenarios dependent on practitioner, steroid choice and setting; these costs range between £121.43 and £607.31.
- Manipulation under anaesthesia (MUA) was estimated to cost £1446 (£1,213 to £1,522) and capsular release £2,204 (£1,809 to £2,511), both of which included rehabilitation physiotherapy.

**Table 1: Summary of systematic reviews of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options**

Study	Patients	Intervention	Comparator	Outcomes
<p>Saltychev et al 2018 [8] Finland</p> <p>Systematic review and meta-analysis of RCTs</p> <p>12 RCTs in the SR</p> <p>7 RCTs in the meta-analysis</p> <p>RCTs from different countries No UK studies included</p> <p>Search date – September 2017</p>	<p>Adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active &amp; passive glenohumeral joint movements)</p> <p>Total number of patients not reported</p>	<p>Hydrodilataion</p> <p>Volume = 20 to 90ml</p> <p>Mixture = triamcinolone or methylprednisolone + contrast + normal saline ± local anaesthetic</p>	<p>Placebo, sham, other interventions, or no treatment as reported by individual study.</p>	<p><b>PRIMARY OUTCOMES</b></p> <p><b>Pain</b> <b>hydrodilataion + corticosteroid vs corticosteroids (pooled results for 5 studies) –</b> Mean difference in <b>VAS</b> = 0.37 [95% CI 0.12 to 0.61 (p=0.00)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12.</p> <p><b>Disability assessment</b> <b>hydrodilataion + corticosteroid vs corticosteroids (Pooled results for 4 studies)</b> Mean difference in <b>SPADI</b> = 0.20 [95% CI 0.-0.04 to 0.44 (p=0.11)]</p> <p><b>SECONDARY OUTCOMES</b></p> <p><b>ROM</b> <b>hydrodilataion + corticosteroid vs corticosteroids (pooled results for 6 studies)</b> Mean difference in <b>ROM</b> = 0.38 [95% CI 0.07 to 0.69 (p=0.01)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement scores was 12.</p> <p><b>ADVERSE EVENTS (3 studies)</b> Transient flushing or heat regulation disturbances, loss of sensation + motor control in injection arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope observed in both arms. One case of GH joint infection with HD + corticosteroid. <b>No further details provided.</b></p>
<p>Catapano et al 2018 [9] Canada</p> <p>Systematic review without meta-analysis of RCTs from different countries</p> <p>6 RCTs – 5 of the RCTs were also included in the meta-analysis by Saltychev et al 2018 One RCT used a total of 10ml therefore not high volume</p>	<p>Adults with adhesive capsulitis</p> <p>410 shoulders Mean age 51 to 61 years</p> <p>In most of the studies participants have had symptoms for at least three months</p>	<p>Hydrodilataion with or without corticosteroid</p>	<p>Any</p>	<p><b>PAIN - VAS (information on VAS score range for the different studies not reported)</b> Two of the relevant 5 studies reported statistically significant improvement in pain in favour of hydrodilataion (HD) relative to intra-articular injection (IAI); Three showed no difference</p> <p>At 12 weeks: IAI 3.57 (1.1) vs HD 3.29 (0.95) (p=0.002) Reza et al 2013 (100 shoulders) At 1 month: IAI 4.6(1.1) vs HD 3.6 (1.3) (p=0.035) Yoon et al 2016 (90 shoulders)</p> <p><b>ROM</b> Three of the relevant 5 studies reported statistically significant improvement in ROM pain in favour of HD; Two showed no difference</p> <p>At 12 weeks 1) Extension ROM p=0.03; external rotation ROM p=0.01 (no details were provided Gam et al 1998 2) Abduction: IAI 82.7<sup>o</sup>(22.6<sup>o</sup>) vs HD 114.4<sup>o</sup> (30.1<sup>o</sup>) p=0.005; Internal rotation: IAI 48.4<sup>o</sup> (10.8<sup>o</sup>) vs HD 55.4<sup>o</sup> (18.2<sup>o</sup>) p=0.027 Reza et al 2013 (100 shoulders)</p>

				<p>At 1 month External rotation: IAI 28°(8°) vs HD 36° (9°) (p=0.005 Yoon et al 2016 (90 shoulders))</p> <p>It is not clear whether assessors were blinded to treatment</p> <p><b>ADVERSE EVENTS – number of studies or patients not reported</b> Approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection.</p>
<p>Maund et al 2012 [10] UK</p> <p>Systematic review and <b>cost-effectiveness study</b></p> <p><b>No UK based studies included</b></p> <p>3 RCTs of arthrographic distension – all the RCTs were included in SR by Saltychev et al 2018</p>	<p>Adults with adhesive capsulitis</p>	<p>Arthrographic distension (with image-guided high volume injection) with or without corticosteroid and/or saline</p>	<p>Any</p>	<p><b>Included studies have been considered in the reviews by Saltychev et al 2018 and Catapano et al 2018</b></p> <p><b>AVERAGE COST ESTIMATES FOR ARTHROGRAPHIC DISTENSION VERSUS ALTERNATIVE OPTIONS BASED ON NHS REFERENCE COSTS AND RESOURCE USE PROVIDED BY CLINICAL EXPERTS IN THE NHS</b></p> <p><b>£79.84 to £134.84</b> (Arthrographic distension with image-guided high volume injection) Vs standard unguided steroid injection £36.18 to £138.51 vs image-guided steroid injection £299.68 to £475.56 vs physiotherapy treatment alongside steroid injection £121.43 to £607.31 vs physiotherapy treatment only £98.75 to £126.75 vs Acupuncture £117.75 to £126.75 vs MUA £1,213 to £1,522 vs capsular release £1,809 to £2,511</p> <p>The figures represent the range which depends on the setting, the professional delivering treatment or the choice of treatment e.g. steroid injection</p>

Abbreviations: ACR – arthroscopic capsular release; EuroQol-5D VAS- EuroQOL-5D visual analogue scale<sup>12</sup>; HD – hydrodilatation; IAI – intra-articular injection; OSS<sup>13</sup> – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

<sup>12</sup> EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient’s health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems (“no”, “some”, “extreme”) on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from “worst possible” to “best possible” health.

<sup>13</sup> The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

**Table 2: Summary of RCTs of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options**

Study	Patients	Intervention	Comparator	Outcomes
Gallacher et al 2018 [3] UK  RCT  Single centre	Patients with severe idiopathic frozen shoulder for 3 months and had a failed course of physiotherapy  n=50 (39 analysed)  Recruited between June 2013 and December 2016 by consultant shoulder surgeon	Hydrodilatation into GH joint (1ml triamcinolone 80mg, 4ml 2% lidocaine, 40ml normal saline)  n=25 (20 analysed) Mean age = 55.2 years  Patients were unblinded to treatment	Arthroscopic capsular release  n=25 (19 analysed) Mean age = 52.6 years  Patients were unblinded to treatment	<p><b>Oxford shoulder score (OSS) at 6 months</b> Improvement from baseline with HD : 22.3 (95% CI, 16.6 to 27.5; p &lt;0.01)</p> <p>Improvement from baseline with ACR: 26.5 (95% CI, 23.1 to 29.9; p &lt; 0.01)</p> <p><b>OSS at 6 months;</b> <b>ACR vs HD:</b> 43.8 [95% CI 42.2 to 45.2] vs 38.5 [95% CI 34.6 to 42.4], p=0.023</p> <p><b>Difference in improvement in EuroQOL-5D VAS at 6 months</b> (10 vs 19.6 for ACR and HD, respectively, p=0.053)</p> <p><b>Improvement in external rotation at 6 months - ACR vs HD</b> (47° vs 34°) p=0.03</p> <p><b>Improvement in forward elevation at 6 months - ACR vs HD</b> (83° vs 71°) p=0.023</p> <p><b>Crossover</b> &lt; 6-month follow-up, four patients from HD to ACR; one patient from ACR to HD. HD to the ACR group - mean 11.0-point improvement in the OSS at 6 weeks after HD vs 20.6-point improvement in the HD group that did not cross over. In crossover patients a 28.0-point improvement in OSS from the baseline at 6 months after ACR.</p> <p><b>The authors found no complications to report</b></p>

Abbreviations: ACR – arthroscopic capsular release; EuroQoL-5D VAS- EuroQOL-5D visual analogue scale<sup>n</sup>; HD – hydrodilatation; IA – intra-articular injection; OSS<sup>o</sup> – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

<sup>n</sup> EuroQoL-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

<sup>o</sup> The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

## 4.2 Safety

Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups from three studies. They stated that one case of glenohumeral joint infection was reported in a patient treated with hydrodilatation and corticosteroid. No further details including the number of patients were provided.

Catapano et al [9] reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only) group. They stated that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection. The authors indicate that these were typically rated as mild and spontaneously resolved completely, lasting only for a short period of time. However, no further details on the number of studies or patients were provided.

In the RCT of 50 patients, no complications were noted in either the ACR or hydrodilatation groups at six months follow-up [3].

## 4.3 Summary of findings

We identified three systematic reviews of RCTs [8, 9, 10] of hydrodilatation with high volume intra-articular injection for adhesive capsulitis, compared to alternative treatment options. The earliest of these also explored cost-effectiveness [10]. We also found one RCT [3] published subsequent to the systematic reviews. However, we have not reported clinical outcomes from the earliest systematic review as the studies have been superseded by those included in the most recent ones. The main outcomes measures reported include changes in pain scores and range of movement. Change in Oxford Shoulder Scores (OSS) and quality of life was reported.

**Pain.** Two systematic reviews (one with meta-analysis) reported significant improvements in pain scores using VAS with hydrodilatation with corticosteroid compared with corticosteroids injections alone. The findings from the systematic review (with meta-analysis) by Saltychev et al (2018) [8] was based on pooled results from five RCTs ( $p=0.00$ ; NNT= 12) while those from Catapano et al (2018) [9] were from two out of five RCTs included in their review; one study at 12 weeks ( $p=0.002$ ) and the other at one month ( $p=0.035$ ).

**Range of Movement.** Significant improvements in range of movement were reported by two systematic reviews and one RCT. The findings reported by Saltychev et al were based on pooled results from six RCTs ( $p=0.01$ ; NNT= 12) while those by Catapano et al were from two of five RCTs; one at 12 weeks (extension ROM  $p=0.03$ ; external rotation ROM  $p=0.010$  and abduction ROM  $p=0.005$ ; internal rotation  $p=0.027$ ) and one at one month (external rotation,  $p=0.005$ ) in favour of the hydrodilatation group. Two RCTs included in Catapano et al showed no difference between hydrodilatation with corticosteroid injection and intra-articular corticosteroid injection alone. The RCT by Gallacher et al reported that the ACR and HD cohorts showed improvements in external

rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group ( $p=0.03$  and  $p=0.023$  respectively).

**Oxford Shoulder Score.** The RCT by Gallacher et al reported that both the HD and ACR groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort ( $p= 0.023$ ).

**Quality of Life.** Significant improvement in EQ-5D<sup>P</sup> VAS was also noted in both the HD and ACR groups in the RCT by Gallacher et al, but the difference in improvement between the groups at any time point was not significant.

These findings need to be interpreted with caution as they are all from small studies which may not have been sufficiently powered to show any meaningful differences. Also many of the outcomes measured were patient-reported; these patients were not blinded to their treatments, so this is likely to have introduced some bias.

**Adverse events.** Two systematic reviews [8, 9] reported on adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.

Based on three studies, Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups. They stated that there was one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid. Catapano et al [9] reported similar adverse effects stating that approximately 15% of patients were affected. Neither of the reviews provided any further details

**Cost Effectiveness.** Maund et al [10] set out to carry out a cost-effectiveness analysis however, were unable to do so due to paucity of evidence. Instead the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review based on NHS reference costs and resource use provided by clinical advisers.

The costs estimated by the authors do not take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

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<sup>P</sup> EuroQoL-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

## 5 Equity issues

It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

## 6 Discussion and conclusions

### *Question 1*

**In adults with a painful joint, is image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?**

It is unclear whether treatment for joint pain with an image-guided HIGH VOLUME intra-articular injection is clinically effective compared to alternative treatment options.

Evidence from two systematic reviews of RCTS comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and ROM (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the ROM assessors were blinded to the treatments.

### *Question 2*

**In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?**

It is unclear whether image-guided HIGH VOLUME intra-articular injection is cost-effective compared to alternative treatment options. One study by Maundy et al (2012)[ref] attempted to establish the relative cost-effectiveness of image guided high volume intra-articular injections in painful joints but was unable to do so due to paucity of evidence data on the interventions.

## 7 Search Strategy

Search date: 19<sup>th</sup> September 2018

We searched PubMed, Embase and Cochrane Library – limiting to last 10 years and English language. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

### Search terms

#### Medline:

1. ((arthrograph\* or arthroscop\* or capsular or joint\*) adj5 disten?ion).ti,ab.
2. (hydrodilata\* or hydro-dilat\*).ti,ab.
3. hvigi.ti,ab.
4. Injections, Intra-Articular/ or \*Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high\* or large) adj2 volume\*).ti,ab.
9. 7 and 8
10. ((high volume\* or large volume) adj5 (inject\* or saline or steroid\* or corticosteroid\* or glucocorticoid\* or cortiso\* or hydrocortis\* or triamcinolone or methylprednisolone or prednisolone or an?esthe\*)).ti,ab.
11. 8 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi\*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic\* or glenohumer\* or gleno-humeral or shoulder or acetabul\* or hip or tibiofem\* or patellofem\* or knee\* or joint\*) adj2 pain).ti,ab.
20. joint diseases/ or exp bursitis/ or femoracetabular impingement/ or patellofemoral pain syndrome/ or shoulder impingement syndrome/
21. exp Tendinopathy/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit\* or degenerative arthri\*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath\* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")

**Embase:**

1. ((arthrograph\* or arthroscop\* or capsular or joint\*) adj5 disten?ion).ti,ab.
2. (hydrodilata\* or hydro-dilata\*).ti,ab.
3. hvigi.ti,ab.
4. ar.fs. or \*Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high\* or large) adj2 volume\*).ti,ab.
9. 7 and 8
10. ((high volume\* or large volume) adj5 (inject\* or saline or steroid\* or corticosteroid\* or glucocorticoid\* or cortiso\* or hydrocortis\* or triamcinolone or methylprednisolone or prednisolone or an?esthe\*)).ti,ab.
11. 9 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi\*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic\* or glenohumer\* or gleno-humeral or shoulder or acetabul\* or hip or tibiofem\* or patellofem\* or knee\* or joint\*) adj2 pain).ti,ab.
20. exp elbow disease/ or exp shoulder disease/ or exp hip disease/ or exp knee disease/
21. exp Tendinitis/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit\* or degenerative arthri\*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath\* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")
29. conference\*.pt.
30. 28 not 29

**Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic - Inclusion criteria for identification of relevant studies**

Question	Population	Indication	Intervention	Comparator	Outcomes	Studies
In adults with a painful joint, what is the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options?	Adults with a painful joint	Pain management in degenerative joints	High-volume image guided injection (HVIGI) (40mls+) of saline with or without corticosteroid and/or local anaesthetic.	Any including:  Standard volume intra-articular corticosteroid injection (image guided/not image guided)  Conservative treatment with lifestyle modification and/or medication and/or physiotherapy	Clinical effectiveness including Pain Function/mobility QoL AE Cost effectiveness  Subsequent arthroscopy  Subsequent arthroplasty	Standard evidence review in order to be robust enough to influence/change clinical practice.  SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies  Cost effectiveness studies
<p><b><u>Inclusion Criteria</u></b> Peer reviewed publications English language</p> <p><b><u>Exclusion Criteria</u></b> Abstracts Letters Commentaries Conference papers Case reports Papers published more than 10 years ago Papers published online subsequent to the search date</p>						

## 8 References

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## 9 Clinician comments after 3 week consultation of the draft evidence review

Date	Clinician	Comments	SPH Response
04/12/2018	Mr. Samir Massoud Consultant  Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham	In relation to the review of ultrasound guided Hydrodilatation for frozen shoulder, I agree that these are not likely to be more effective than steroid injection alone and are significantly more painful for patients.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
10/12/2018	Paresh Jobanputra (Cons Rheumatologist)	My experience in this area is limited. Given what is believed about the natural history of frozen shoulders, the only condition I consider for hydrodilatation, a pathway of conservative therapy with or without clinical landmark based injection, perhaps repeated if necessary (either using clinical landmarks or US guidance) and only then considering surgical input seems reasonable.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
13/12/2018	Alison Jackson Clinical Team Leader (MSK) Musculoskeletal & Orthotics Good Hope and Solihull Hospitals	<p><b>Dear All</b>  <b>Please see below information which has been compiled by a specialist physiotherapist working in UHB HGS physiotherapy injection service which provides US guided HV injections as well as US guided and blind injections. HGS US guided service has been operational for the delivery of HV shoulder joint injections since 2013: governance evidenced by PGD and relevant inclusion/exclusion criteria.</b></p> <p><b>Comments</b></p> <ul style="list-style-type: none"> <li>• <b>Evidence review</b> – Agree the inclusion of relevant studies and appropriate summaries however additional studies incorporated below with summaries highlighted in yellow.</li> </ul> <p>5.</p> <ul style="list-style-type: none"> <li>• <b>Current clinical practice</b> – HV shoulder joint injections are considered when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets, consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always</li> </ul>	<p>Thank you for your helpful feedback. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.</p> <p>We deal with the additional studies separately below.</p>

		<p>followed up to review as part of this procedure.</p> <p><b>6.</b></p> <ul style="list-style-type: none"> <li><b>Clinical opinion</b> - Our clinical experience suggests that patients tolerate a guided shoulder distension procedure well and refer to an intense pressure feeling rather than pain. There have been no complications within our physiotherapy service and all have improved. I believe it works well particularly for patients with recalcitrant frozen shoulders, particularly females, in mid 50s and diabetic patients.</li> </ul> <p>Pain relief appears to be the most significant feature with variable movement improvement. This then allows tolerance of appropriate rehabilitation/stretching. I believe there are few risk factors, particularly when patients are appropriately screened pre procedure. It is easily performed as an outpatient procedure and patients often continue with their normal day with no restrictions.</p> <p>Cost effectiveness – (page 9 of the BSOL &amp; Black Country HVIGI for joint pain Consultation Draft Nov 18 attachment) – no reference is made to the cost of physio led USG HV intra articular shoulder injection – only to palpation guided and we would encourage you to review this.</p> <p>I believe that physios are best placed to offer this safe, cost effective service as we assess and treat all aspects of the patients presenting problem from assessment to diagnosis, procedure and then rehab afterwards – a seamless service as suggested by Dr Jeremy Lewis's presentation at the 5<sup>th</sup> biennial Emirates physiotherapy conference in May 2016 "Don't want to be left out in the cold": Non-surgical management of Frozen Shoulder. The patient presents to the right person at the right time in their pathway therefore receiving the most appropriate management located in community or acute care settings.</p>	<p>We did not identify any cost-effectiveness studies on physiotherapy led USG high volume intra articular shoulder injection that met the PICO inclusion criteria.</p>
<p>11/12/2018</p>	<p>Physiotherapists  BHH</p>	<p>I agree with the options for the commissioners on page 1 as we only use this for the shoulder joint when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets , consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always followed up to review as part of this procedure.</p>	<p>Thank you very much for these helpful comments and the one below. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.</p>

		<p>With regard to clinical effectiveness, safety and cost implications – the following references</p> <ol style="list-style-type: none"> <li>1. The effectiveness of ultrasound guided hydrodistension and physiotherapy in the treatment of frozen shoulder/adhesive capsulitis in primary care: a single centre service evaluation. Michael Bryant, Andrew Gough, James Selfe .First Published May 17, 2017 <a href="https://doi.org/10.1177/1758573217701063">https://doi.org/10.1177/1758573217701063</a></li> </ol> <p>Conclusions This service evaluation demonstrates that management of frozen shoulder stage II to III, as conducted by physiotherapists in a primary care setting utilizing hydrodistension and a guided exercise programme, represents an effective non-operative treatment strategy. Also details cost effectiveness when comparing with surgery or secondary care guided injection.</p> <ol style="list-style-type: none"> <li>2. Analysis of hydrodilatation as part of a combined service for stiff shoulder. Shoulder Elbow 2017 Jul;9 (3): 169-177</li> <li>7. Rajendranath Sinha,<sup>1</sup> Priyesh Patel,<sup>1</sup> Nicky Rose,<sup>1</sup> John Tuckett,<sup>2</sup> Anurag N Banerjee,<sup>3</sup> John Williams,<sup>1</sup> Stephen Aldridge,<sup>1</sup> and Paul Stuart<sup>2</sup></li> <li>8. Conclusions Hydrodilatation results in a significant improvement of symptoms in patients with adhesive capsulitis. An MDT approach has improved the management of the stiff and painful shoulder and markedly reduced the need for surgery – with table of figures over 4 years.</li> </ol> <ol style="list-style-type: none"> <li>3. Effectiveness of Glenohumeral Joint Dilatation for Treatment of Frozen Shoulder: A Systematic Review and Meta-analysis of Randomized Controlled Trials Wei-Ting Wu, Ke-Vin Chang, Der-Sheng Han, Chung-Hsun Chang, Fu-Sui Yang &amp; Chih-Peng Lin</li> <li>9. Scientific Reports volume 7, Article number: 10507 (2017)   Download Citation</li> <li>10.</li> <li>4. Frozen Shoulder: long term outcome following arthrographic distension. R Clement; A Ray; C Davidson; et al Acta Orthop. Belg 2013,79,368-374. Conclusions Arthrographic distension is safe and effective - including for diabetic patients. They reported long term improvement (12/12s+). The low number of patients requiring a second procedure makes it preferable to MUA.</li> </ol>	<p>This service evaluation (not a clinical trial) was not included in the rapid evidence review because it did not meet the PICO inclusion criteria.</p> <p>This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.)</p> <p>This systematic review and meta-analysis (Wu et al) was excluded from the rapid evidence review because it has been superseded by a later one (Saltychev et al 2018) which assessed all the trials included in Wu et al and more.</p> <p>This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.)</p>
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**Competing Interest**

All SPH authors have completed the ICMJE uniform disclosure form ([www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf)) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

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