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Clark, Natalie, Johnson, Melissa, Kottam, Lucksy et al. (3 more authors) (2025) Implementing evidence into practice for the management of frozen shoulder: Engaging with key stakeholders and evaluating barriers and facilitators using the Consolidated Framework for Implementation Research. Health Research Policy and Systems. 73. ISSN 1478-4505

https://doi.org/10.1186/s12961-025-01335-7

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Implementing evidence into practice for the management of frozen shoulder: engaging with key stakeholders and evaluating barriers and facilitators using the Consolidated Framework for Implementation Research

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Abstract

Background Frozen shoulder (FS) is a painful, stiff and disabling shoulder condition affecting adults of working age. A multi-centre randomised controlled trial (UK FROST) comparing three of the most common treatments provided by the National Health Service (NHS) in secondary care found all three treatments improved patient outcomes, with none being overall clinically superior. Each treatment had its advantages and disadvantages. This paper describes the use of the Consolidated Framework of Implementation Research (CFIR) as an exemplar of knowledge translation for the latest evidence from UK FROST in the management of FS. It describes using stakeholder feedback in the development of a FS pathway, considering the barriers and facilitators to implementation in relation to the UK FROST findings and current clinical practice.

Methods Healthcare professionals, academics, policymakers and patient and public representatives were invited as stakeholders to three meetings held in November 2022 and January 2023. An overview of the United Kingdom Frozen Shoulder Trial (UK FROST) study, current pathways, referral processes and guidelines for FS in the context of the study results and the development of patient resources were discussed at the first meeting in November. Outcomes from this meeting informed the January meetings. The CFIR was used to guide analysis of the discussions from the stakeholder meetings.

Results Overall, 67 stakeholders attended across three meetings. From the meetings, we categorised the FS pathway into four components (1) presentation and assessment; (2) initial management; (3) treatment options – physiotherapy and steroid injection, secondary care referrals; and (4) enhanced recovery and follow-up, with shared decision-making emphasised throughout the pathway. Barriers and facilitators in each of the pathway components were identified using the five domains of the CFIR. A proposed evidence-based FS pathway was developed with stakeholders using an eight-step process.

Conclusions This study has led to the development of an evidence-based FS care pathway, ready to be considered by policymakers for implementation, with considerations of barriers and facilitators. There was consensus that it

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is feasible to embed a modified physiotherapy intervention form UK FROST within current primary and community care settings to optimise service delivery and referral pathways.

Trial Registration The trial registration is ISRCTN48804508.

Keywords Frozen shoulder, Implementation, Stakeholder engagement, Evidence-based practice, Knowledge translation

Background

There is an evident disconnect when implementing research into current clinical practice, despite both having an overall goal to improve policy and practice and to manage patients most effectively [1–3]. Knowledge translation (KT) is an emerging discipline, incorporating implementation science, that can help to integrate research and practice so that evidence-based treatments can be better translated [4, 5]. However, literature is limited on the methods and evaluations to do this effectively. This paper describes the use of the Consolidated Framework of Implementation Research (CFIR) as an exemplar of KT in the context of disseminating and implementing the latest evidence in the management of frozen shoulder (FS).

FS (adhesive capsulitis) [6] is a painful and stiff shoulder condition with symptoms impacting daily functioning and causing sleep disturbances [7, 8]. It mostly occurs in adults of working age [7], with females more likely to be affected than males [7, 8]. Treatment options include oral analgesia, oral corticosteroid, intra-articular corticosteroid injections, physiotherapy, arthroscopic capsular release (ACR), manipulation under anaesthesia (MUA) and hydrodilatation [9, 10].

A systematic review examined the effectiveness of physiotherapy with a steroid injection, MUA, ACR, and hydrodilatation to manage FS across nine randomised controlled trials (RCTs) [10]. The review concluded that while the effectiveness of hydrodilatation was found to be inconclusive on the basis of four RCTs and remains an evidence gap, the findings from a large multi-centre RCT-United Kingdom Frozen Shoulder Trial (UK FROST) [11, 12] provided the strongest evidence for the clinical and cost-effectiveness of three commonly offered National Health Service (NHS) treatment options, ACR, MUA, and early structured physiotherapy (ESP). All three treatments improved the patients' pain and function, with none being overall clinically superior using the Oxford Shoulder Score [12], though each treatment had advantages and disadvantages to consider. The findings were summarised as a YouTube animation [13]. Patients undergoing ACR with MUA were less likely to need further treatment; however, this carried higher risks and costs. MUA with an intra-articular steroid injection was the most cost-effective option to the NHS with a higher cost than ESP but better quality-adjusted life years (QALYs); however, MUA did have a longer NHS waiting time than ESP. Despite a small proportion needing further treatment, ESP with an intra-articular steroid injection could be accessed quickly in the NHS at a lower cost than MUA or ACR with similar benefit to patients in shoulder function and pain; therefore, ESP has the potential for implementation into wider clinical practice, prior to requiring secondary care interventions, and policy [12].

Embedded within the trial was a nested qualitative study exploring the experiences of the participants who had received and healthcare professionals who had delivered the study treatments [14]. Both groups had generally positive experiences of participating in the trial and delivering the treatments, respectively. Within the ESP treatment arm, specifically, the participants recognised that the steroid injection reduced the pain so that they could perform the exercises to improve shoulder function. It was important to participants that these exercises were not time consuming and could be incorporated into their daily routine. The physiotherapists, however, commented that the feasibility of delivering 12 sessions of ESP outside the trial setting would be challenging due to the current NHS climate, outlining the current practical and contextual implications of embedding the research findings into practice. Given it is low cost, less invasive compared with surgical options, and can be delivered across different settings, we should explore the barriers and facilitators to implementing this within different NHS settings.

In this study, we outline our process in engaging with key stakeholders to optimally implement the latest evidence for FS into current practice. We use the CFIR as a mechanism to understand stakeholder feedback and application to the development of a FS pathway and related resources to convey treatment options and optimise shared decision-making between patients and professionals. The CFIR will help to identify key factors, including barriers and facilitators, that influence implementation, tailoring it to specific intervention designs and contexts [15, 16]. A systematic review of studies utilising CFIR concluded that more implementation studies need to include use of the CFIR in pre-implementation work [17]. Through doing so, studies can identify

potential barriers and facilitators to implementation, refining their implementation strategy and improving KT [18].

Methods

Design

We used the CFIR to capture stakeholder feedback from a series of meetings and subsequently to create a revised service delivery pathway for FS, incorporating the latest evidence from UK FROST. This KT method will help to bridge the gap between UK FROST findings and the current practical needs of the stakeholders who would be either responsible for implementing the changes to service delivery or in receipt of these services.

Recruitment

An online stakeholder expression of interest survey was developed using the Research Electronic Data Capture (REDCap) software which, following consent, collected basic demographic information from interested stakeholders (e.g. region, professional role). The survey was distributed in April 2022 via British Elbow & Shoulder Society (BESS) roadshows, social media, relevant professional societies and established patient and public involvement (PPI) groups at South Tees Hospitals NHS Foundation Trust. Stakeholders who had initially expressed an interest were invited to participate in the first meeting via email. Purposive sampling was used to ensure we had an appropriate representation of stakeholders involved in the management of FS as well as those with lived experiences. For this reason, additional stakeholders were sought for subsequent meetings.

To maximise engagement, travel expenses for in-person meetings were reimbursed, and the option for online attendance was available. Patient representatives were provided a monetary incentive of £30 pounds sterling, and professionals were offered this in honorarium following the event.

Stakeholder meetings

Three stakeholder meetings were conducted – the first one in November 2022, followed by two in January 2023. The initial meeting was hybrid, held in person at a central location in England with an option for attendance via Zoom. The aim of the first stakeholder meeting was to provide a brief overview of the UK FROST findings and discussion of pre-identified practical and contextual implications of translating the research findings into practice. The second and third meetings consisted of 3-h Zoom calls, offering stakeholders the flexibility to attend either one of the two days to improve attendance. These meetings summarised the prominent findings from the first meeting relating to early diagnosis and management

plan, treatment, and resources and guidelines. With consent, all meetings were recorded to aid analysis of the feedback.

The first stakeholder meeting began the process of developing a draft service delivery pathway for FS, incorporating the findings from UK FROST and consideration of current contextual factors. Following a presentation of the UK FROST findings, the stakeholders were split into smaller groups to discuss the three pre-prepared topic guides, focusing on: (1) the current pathways and referral processes for FS; (2) the current evidence-based decisionmaking and the use of existing guidelines to diagnose and manage FS; and (3) the current use of resources and scoping the need to develop additional resources and training materials. When smaller group discussions were completed, all stakeholders reconvened to summarise the discussions from the smaller groups and the next steps of the project. Following the initial meeting, the recording from the day was transcribed, supported by additional note-taking from individual group discussions. The material from the discussions was considered in terms of the CFIR domains and used to identify commonly occurring barriers and facilitators. Through this process, a draft FS pathway with supporting resources was produced. This formed the basis of developing the presentation and agenda for the subsequent meetings.

The second round of stakeholder meetings aimed to discuss three main themes: (1) early diagnosis and management plan; (2) treatment; and (3) resources and guidelines. Barriers and facilitators were considered within each theme. Subsequently, the proposed FS pathway was presented for feedback. Both meetings were transcribed to aid further refinement of the draft FS pathway and supporting resources.

Feedback from the stakeholder meetings was sorted according to the following CFIR domains: (1) Intervention Characteristics (e.g. characteristics and core components of the pathway); (2) Inner Setting (e.g. compatibility with the current environment); (3) Outer Setting (e.g. current guidelines and policies); (4) Characteristics of Individuals (e.g. knowledge and attitudes of those involved); and (5) Implementation Process (e.g. engagement with influential stakeholders) [15, 16, 19]. Through this process we were able to determine the potential barriers and facilitators to any changes in service delivery, which were incorporated into the production of a FS pathway.

We documented the iterative process of engaging with key stakeholders to embed evidence into practice, which was condensed into eight steps (Fig. 1). This was driven through continual engagement with key stakeholders, reviewing and analysing their feedback to reach an agreement that has informed our recommendations for a FS

VS Before starting the trial After the trial has ended 1. Devising a plan for implementation, before the trial 1. Devising a plan for implementation, after the study During study design, plans for dissemination and Following the end of the trial, alongside publication of the implementation of the findings, including a strategy for findings, develop an implementation plan by engaging with policymakers and relevant stakeholders. engagement of policymakers and stakeholders should be considered. 2. Establish a stakeholder group Members of the stakeholder group may vary depending on the trial. Ensure there is appropriate representation of professions and commissioners across settings and regions, as well as involvement from patients and public. 3. Preparation for stakeholder engagement 3. Preparation for stakeholder engagement Prior to stakeholder engagement, identify areas from current Prior to stakeholder engagement, identify areas from the trial evidence, practice, and those arising during the trial, taking that need additional clarity, including the trial findings, taking into consideration any practical and contextual implications, into consideration pre-identified practical and contextual barriers, and facilitators. implications from available evidence. 4. Engage with stakeholders 4. Engage with stakeholders Within the initial stakeholder engagement meeting, outline Aim to engage with stakeholders throughout the course of the trial findings and discuss the areas pre-identified as the trial, at predetermined timepoints. Within the initial requiring clarity. Allow for smaller group discussions as well as stakeholder engagement meeting, outline the progress of the trial, preliminary findings and discuss the areas preidentified as requiring clarity. Allow for smaller group discussions as well as wider. 5. Analyse stakeholder findings Following the first stakeholder meeting, review the meeting transcripts, analyse, and code common themes. Establish areas of consensus, barriers and facilitators alongside readiness for change in preparation for the next meeting. 6. Explore feasibility of implementation Re-engage with stakeholders, including the relevant policymakers, to outline the consensus on feasibility of implementation, aiming to discuss facilitators and strategies to overcome the barriers to adoption, including guidelines, care pathways, and resources (existing or to be developed). 7. Make recommendations for implementation Repeat Steps 4 to 7 as necessary, depending on the number of stakeholder meetings planned. Following the final stakeholder meeting analysis, finalise consensus findings with barriers and facilitators, and make recommendations for successful implementation. 8. Implementation and adoption next steps Begin to action the end goal (e.g., development of intervention or pathway) and re-engage with healthcare commissioners and policymakers for adoption and implementation.

Fig. 1 Eight-step stakeholder engagement process to implement evidence into practice

pathway. By the eighth step, trial teams and stakeholders should have agreed upon an outcome to be progressed to the next stage of evidence-based implementation, i.e. engagement with policymakers.

Results

Based on the findings from the stakeholder meetings, the FS pathway can be categorised into four overarching components, (1) presentation and assessment; (2) initial management; (3) treatment options; and (4) enhanced recovery and follow-up (Table 1). A full list of potential barriers and facilitators of the four pathway components was identified using the CFIR across the five domains (Table 2). A table of individual examples of barriers and actionable findings across the pathway components and CFIR domains is also included (Table 3).

Stakeholder characteristics

Overall, 67 stakeholders attended across the three meetings, including an Implementation Scientist, the National Clinical Director for Musculoskeletal (MSK) services for NHS England, and 8 PPI representatives. In total, 10 of the 67 attended both stakeholder meetings. Professional stakeholders mostly resided or worked in the North-East of England, with an equal representation from both primary and secondary care settings and with over 10 years of experience (Table 4).

Presentation and assessment

FS can resolve naturally over time; however, the recovery can be long, with the impact being both physically and mentally disabling, causing anxiety and frustration, as described by our stakeholders and the qualitative study within UK FROST. This is why establishing an early diagnosis is imperative. Participants in UK FROST were those with suspected FS referred to secondary care with an average duration of symptoms of 11 months. We therefore discussed how patients could be triaged to the most appropriate professional in primary care to facilitate an early diagnosis. The stakeholders identified first contact practitioners (FCPs) [20] to be most appropriate, a role within the United Kingdom, being the first contact to review patients presenting with MSK complaints in primary care to reduce the GP burden by providing faster access to the right care. FCPs are specialist physiotherapists by background who can improve the pathway for MSK-related complaints by providing faster assessment, diagnosis, advice and treatment - increasing capacity for GPs, referring fewer to secondary care and improving patient outcomes and experiences.

Following triage, stakeholders recommended that patients should be assessed face-to-face, particularly to check for passive external rotation of both arms to confirm a contracture with movement restriction. Remote assessments were discouraged owing to the inability to check for passive external rotation. It was noted that if a patient presents with any urgent red flags, (e.g. acutely painful and stiff shoulder after trauma or known epilepsy, suspected infection, mass or swelling, previous history of radiotherapy to shoulder or breast) they should not

 Table 1
 Pathway components

Pathway component	Definition
1. Presentation and assessment	The first pathway component considers the patient's first presentation to primary care and subsequent assessment to help facilitate an early diagnosis of FS. This includes being triaged to the most appropriate professional with assessment at a face-to-face appointment, taking into consideration patient history, risk factors and ruling out other stiff shoulder conditions.
2. Initial management	Following presentation and assessment, it is recommended that patients should undergo 6–8 weeks of initial management, including advice, analgesia, activity modification, rest and exercises. If after 6–8 weeks there is no improvement, pain persists or stiffness develops, the patient should re-present and be sent for an X-ray. This will also facilitate diagnosis of FS and rule out any other possible sinister pathologies. However, if a patient presents with any urgent red flags (e.g. acutely painful and stiff shoulder) they should not be made to wait 6–8 weeks and should be referred immediately.
3. Treatment options	Professionals should utilise the shared decision-making tool as produced by UK FROST to decide on treatment options whilst also taking into consideration patient preference and risk factors. All patients are recommended to trial a glenohumeral steroid injection alongside early structured physiotherapy, supported with the UK FROST patient education and exercise booklet, for a maximum of six sessions. The setting in which this is first delivered may vary. The second treatment option if referred for orthopaedic assessment should be MUA with glenohumeral steroid injection. The third option should be ACR.
4. Enhanced recovery and follow-up	This last pathway component is specific to the small number of patients anticipated to be referred for surgical management. Patients should be optimised for surgery and provided the UK FROST pre-operative and rehabilitation booklets.

Table 2 Facilitators and barriers to implementation across the four pathway components using the CFIR framework

			1. Presentation and assessment	2. Initial management	3. Treatment options	4. Enhanced recovery and follow-up
Intervention character-istics						
	Facilita- tors					
	tors	Triaging the patient to the most appropriate primary care professional (e.g. First contact practitioner (FCPs) – a new role that reviews patients presenting with MSK complaints to reduce the burden on general practitioners (GPs))	✓	✓		
		Review of patients at face-to-face appointments or remote assessment (e.g. video call)	✓	✓		
		Assess for external rotation of both arms	✓	✓		
		Provide initial exercises to complete for the first 6–8 weeks	✓	✓	✓	
		Reassess after 6–8 weeks or ask patients to re-present if the pain persists, considering if there has been a change in symptoms or clinical pictures	*	*		
		Request an X-ray if patient presents with an acutely painful and stiff shoulder (do not make them wait 6–8 weeks), there is a change in symptoms, pain persists, or stiffness develops. This will also help rule out other conditions, e.g. osteoarthritis, tumour or posterior dislocations		✓	✓	
		Patients should first trial a glenohumeral steroid injection with early structured physiotherapy as per UK FROST (provide UK FROST patient booklet)		✓	✓	✓
		Prioritise physiotherapy referrals following a glenohumeral steroid injection (maximum 2-week wait), ensuring clear documentation on referrals		✓	✓	✓
		Maximum capacity of six follow-up sessions		✓	✓	✓
		First surgical option should be MUA. If this is not successful, second option should be ACR (provide UK FROST rehabilitation booklet)			✓	✓
		Shared decision-making about treatment between patient and professional, considering patient history and preference			✓	✓
	Barriers					
		Not every primary care setting will have an FCP	×	×		
		Inconsistencies of the FCP role and skill set nationally (e.g. skills to inject or request X-rays)	×	×		
		Some professionals can only request magnetic resonance imaging (MRI) scans and ultrasounds, leading to an unnecessary number of requests. This is attributed to lack of training as well as local policies		*		
		Inconsistency of the number and quality of X-rays being requested		×		
		Concerns around physiotherapy waiting times, capacity, resources, erosion of services and clinic space		×	×	*
		Patients with comorbidities (e.g. diabetes) might need additional support	×	×	×	×
Inner setting						
	Facilita- tors					
		FCPs are a new role that involves reviewing patients present- ing with MSK complaints in primary care settings, reducing the burden on GPs	✓			
		Professionals should be supported through the training process to be able to request X-rays	✓	✓	✓	

 Table 2 (continued)

			1. Presentation and assessment	2. Initial management	3. Treatment options	4. Enhanced recovery and follow-up
		Prioritise physiotherapy referrals following a glenohumeral steroid injection (maximum 2-week wait), ensuring clear documentation on referrals		✓	✓	
		Maximum capacity of six follow-up sessions		✓	✓	
		Upskilling patients to complete exercises independently and signpost to appropriate resources		✓	✓	
	Barriers					
		Not every primary care setting will have an FCP	*	×		
		Inconsistencies of the FCP role and skill set nationally (e.g. skills to inject or request X-rays)	×	*		
		Some professionals can only request MRIs and ultrasounds, leading to an unnecessary number of requests. This is attrib- uted to lack of training as well as local policies		*		
		Inconsistency of the number and quality of X-rays being requested		×		
		Concerns around physiotherapy waiting times, capacity, resources, erosion of services and clinic space		×	×	*
		Patients with comorbidities (e.g. diabetes) might need additional support	*	×	×	*
Outer setting						
	Facilita- tors					
		Guidelines will provide the supporting evidence and justify the steps recommended in the pathway	✓	✓	✓	✓
		Improvements to the FCP roadmap (i.e. training requirements)	✓			
		Development of decision-making tools	✓	✓	✓	
		Engagement with NHS England, Getting It Right First Time (GIRFT), National Institute for Health and Care Excellence (NICE)	✓	✓	✓	✓
	Barriers					
		Current NICE guidelines state X-rays are not routinely necessary for FS $$	*	×	×	
		Current Royal College of Radiologist iRefer national guidelines suggest going straight to an ultrasound		×		
Charac- teristics of individuals involved						
	Facilita- tors					
		Patients want an early, clear diagnosis to reduce anxiety and frustration	✓	✓		
	Barriers	Identify patients' level of self-efficacy	✓	✓	✓	✓
	Danners	Professional resistance (e.g. requesting X-rays) owing to a lack of supporting and consistent quidelines	*	×		
		Confirmation bias following UK FROST		×	×	×
		Concerns around physiotherapy waiting times, capacity, resources, erosion of services and clinic space		*	*	×
		Lack of consensus between orthopaedic surgeons about which surgical option (MUA or ACR) to recommend first and lack of training of MUA for trainees			*	*
Implementa- tion process						
p. 000033	Facilita-					
	tors					

Table 2 (continued)

		1. Presentation and assessment	2. Initial management	3. Treatment options	4. Enhanced recovery and follow-up
	Stiff shoulder pathway with FS embedded	✓	✓	✓	✓
	Engagement with NHS England, GIRFT, NICE	✓	✓	✓	✓
Barriers					
	Confirmation bias following UK FROST		*	*	×

progress to the next pathway component and instead be sent to accident and emergency (A&E), or an urgent orthopaedic referral should be made.

It is acknowledged that the inner setting will vary nationally, and not every primary care setting will have an FCP, and that role may be inconsistent. Some FCPs can provide an injection and request X-rays, whereas others must request these procedures via a GP if deemed necessary for the patient, evidencing barriers relating to the characteristics of individuals involved (Table 2). Therefore, it was suggested from an outer setting perspective that the FCP roadmap should be amended to improve the mandatory training for FCP requirements, improving consistency of the role nationally. Considering the variability in inner settings, it is important that the skills and training requirements recommended for FCPs within the pathway are transferable to other healthcare professionals in primary care. This would support the outlined intervention characteristics within this pathway component.

Initial management

Following presentation and assessment, stakeholder discussions focussed on the initial management of a patient with suspected diagnosis of FS within primary/community care, and the below recommendations were made:

- Provide exercises to complete for 6–8 weeks alongside advice, analgesia, activity modification and rest.
- Reassess the patient after 6–8 weeks or ask them to re-present if the pain persists. During or after this timeframe, symptoms or their clinical picture could change.
- If there is a change, pain persists, stiffness develops or the patient is not responding to a prescribed exercises programme after 6–8 weeks, requesting a twoview X-ray would be clinically indicated...

X-rays can aid FS diagnosis as well as rule out similar presenting conditions and common misdiagnoses such as osteoarthritis, tumours and posterior dislocations [21]. However, one FCP discussed being restricted

by local radiology policies in the number of views they can request in primary care compared with their role in secondary care (inner settings). In addition, the current guidelines for requesting imaging for a suspected FS are conflicting (outer setting). National Institute for Health and Care Excellence (NICE) guidelines for shoulder pain diagnosis, last revised in November 2022, state [21], "X-rays are not routinely needed [for FS] unless to exclude arthritis". Experienced clinician stakeholders strongly recommended updating these guidelines to ensure the importance of excluding arthritis for FS diagnosis to ensure alignment with the latest clinical consensus (potentially requiring further work) for clarity and reducing the resistance that some stakeholders described facing when making X-ray requests.

Stakeholders further expressed concern for the excess number of inappropriate referrals from primary care for MRI and ultrasound (US) scans, without performing an X-ray, making an accurate diagnosis of FS difficult, describing this as frustrating. This has been attributed to the existing guidance and abovementioned local restrictions for professionals being unable to refer for an X-ray, particularly physiotherapists and FCPs, from both an inner and outer setting perspective. There is also a training gap and local restrictions that can be addressed partly by encouraging and supporting more professionals through the process to request X-rays. This would address the barriers of individuals involved (Table 2) and ultimately benefit the patient, the professional, the services and overall intervention.

Treatment options

Physiotherapy and steroid injection

UK FROST successfully provided evidence of a bespoke programme of physiotherapy of up to 12 sessions, both as a standalone intervention (ESP) and for rehabilitation after surgery. As the standalone intervention can be accessed quickly and is an effective, safe and cheaper option compared with the surgical interventions, it was important to discuss with stakeholders how this can be implemented in current pathways and services.

 Table 3 Examples of barriers across the CFIR domains by pathway components and facilitators or actionable findings to these

CFIR domain	Pathway component	Barrier	Facilitator or actionable finding
Intervention characteristic	1. Presentation and assessment	It was acknowledged by the stakeholders that patients with FS with comorbidities (e.g. diabetes) might need additional support following their diagnosis, particularly within the management.	Stakeholders suggested that patients should be stratified at the presentation and assessment stage. This would enable patients with significant comorbidities to be categorised and managed differently from others. Professionals could tailor treatment and management of the condition to the patients who would require additional support. Those without comorbidities would be assessed for self-efficacy and suitability of delivering self-management strategies, pursuing a more patient-initiated follow-up pathway and improving the capacity for healthcare professionals to review patients who really need the input.
	2. Initial management		
	3. Treatment options		
	4. Enhanced recovery and follow-up		
Inner setting	1. Presentation and assessment	FCP is still a developing role, and it is recognised that not every primary care setting will have the luxury of this role.	Firstly, for the inner settings that employ FCPs, it is vital that the FCP role (i.e. skills and training) is consistent nationally, as it has been acknowledged that this role is currently variable, understandably, given that this role is new and evolving. Secondly, taking into consideration the variability of inner settings nationally, stakeholders recognised the importance of ensuring the steps within the pathway as well as skills and training specific to FCPs are transferable to other healthcare professionals within primary care.
	2. Initial management		
Outer setting	1. Presentation and assessment	Guidelines for FS are conflicting, for example, the current NICE guidelines state X-rays are not routinely necessary for FS.	As discussed with the stakeholders, an X-ray is justified if the patient has persistent pain or stiffness develops after 6–8 weeks of initial management. This X-ray can help to facilitate an early diagnosis as well as help rule out any other sinister pathologies that have a similar presentation, such as a tumour, posterior dislocation or osteoarthritis.
	2. Initial management		
	3. Treatment options		
Characteristics of individuals involved	2. Initial management	There are concerns, specifically from physiotherapists, around physiotherapy waiting times, capacity, resources, erosion of services and clinic space.	In the UK FROST trial, it was recommended that a patient has up to 12 sessions of physiotherapy. However, the median number of sessions that was delivered in the trial across the groups was between seven and nine sessions. According to current MSK guidelines, there is a maximum capacity of up to six sessions. Stakeholders also suggested stratifying patients with high self-efficacy to self-manage their condition and utilise patient-initiated follow-up to improve the capacity for physiotherapists. Resources such as a website, app and/or booklets can also support those patients who are self-managing their condition.
	3. Treatment options		

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CFIR domain	Pathway component	Barrier	Facilitator or actionable finding
	4. Enhanced recovery and follow-up		
Implementation process	2. Initial management	It was recognised that some professionals might be exhibiting confirmation bias following the UK FROST findings.	Despite the UK FROST findings, it was highlighted that, specifically from a surgical point of view, this will not change some surgeons' preferences of offering ACR first as opposed to MUA. MUA has clear additional benefits over an ACR and is a much less invasive first-line surgical treatment. We have therefore outlined within the pathway recommendations for surgery which needs to then be supported by the additional guidelines published by NICE and GIRFT. An additional option is promoting this recommendation via surgical training.
	3. Treatment options		
	4. Enhanced recovery and follow-up		

Table 4 Professional stakeholder characteristics

	Physiotherapists N = 27	First Contact Practitioners N = 9	Consultant Trauma & Orthopaedic Surgeons N = 7	Radiologists N = 2	General Practition N = 2	er* Total
Care setting						
Primary	8	9	-	-	2	19
Secondary	13	-	6	2	-	21
Intermediate	3	-	-	-	-	3
Other	3	-	1	-	-	4
Length of time in role						
0-10 years	13	7	-	1	-	21
10+ years	11	-	4	-	2	
Not stated	3	2	3	1	-	
Region						
Greater London	2	-	-	-	-	2
North-East	12	7	-	2	2	23
North-West	2	-	2	-	-	4
South-East	2	-	1	-	-	3
South-West & Midlands	1	-	3	-	-	4
East of England	3	-	-	-	-	3
Yorkshire & the Humber	r 5	2	-	-	-	7
Other	-	-	1	-	-	1
*1 GP was also a retired Primary Care Network Clinical Director						

Despite a significant shift in physiotherapy services since UK FROST, including reduced clinical capacity and promotion of self-management and patient-initiated follow-up, stakeholders agreed it was possible for the ESP intervention to be embedded across current NHS settings (primary, community, secondary) and using existing resources, if the resources are reorganised appropriately and barriers considered. Stakeholders agreed that every patient with FS coming through the primary or community care setting should be prescribed ESP with a glenohumeral steroid injection as the first-line treatment (Fig. 2). Following this programme will reduce the variance of physiotherapy being delivered nationally and ensure that everyone is offered a steroid injection into the glenohumeral joint at the earliest opportunity, unless contraindicated.

Similar to the first pathway component, stakeholders discussed barriers from the inner and outer settings, predominantly due to national variability in services and pathways. Firstly, triage for treatment following diagnosis can take several weeks in some areas, with one FCP additionally describing how some referrals are misdiagnosed as rotator cuff shoulder-related pain and subsequently, when it comes to triage, this will not get prioritised over a FS. This relates back to ensuring that the intervention characteristic of the patient being assessed by the right

healthcare professional at the right time is supported. To improve triage within the inner setting, stakeholders stated that once a patient has had an injection, it is essential that their physiotherapy referrals are prioritised, and this requires clear documentation that the patient has had an injection, as sometimes this is not included on the referral form.

Secondly, despite acknowledging that the physiotherapy programme (ESP) is feasible to embed, some stakeholders expressed concerns about capacity, resources, erosion of services and concerns for clinic space, stating these factors as contributing to a crisis in physiotherapy. Another barrier included the waiting time to see a physiotherapist, which was reported to range from 2 to 9 months nationally. The implementation process should consider structuring the pathway around the existing resources available within the inner setting, supported by the outer setting, without causing an additional burden on already strained services.

Lastly, the stakeholders were concerned that it would be impossible to deliver up to 12 sessions of physiotherapy within an NHS setting over a period of 12 weeks, as was stipulated in the trial. However, the median number of sessions delivered across the three groups in UK FROST was between seven and nine sessions. The current MSK guidelines [22] allow for a maximum capacity

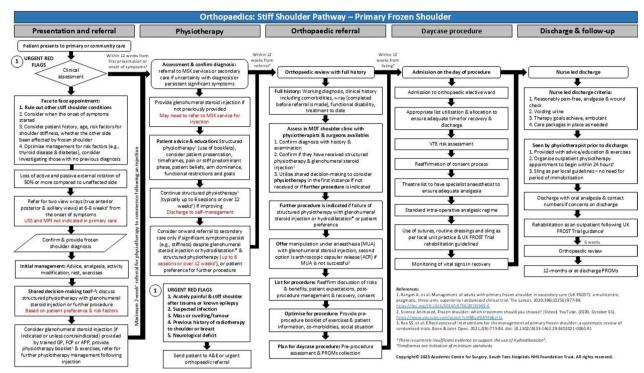


Fig. 2 Orthopaedics Stiff Shoulder Pathway – Primary Frozen Shoulder

of six follow-up sessions. Amongst the stakeholders, it was thought that not everyone would need six in-person sessions and, instead, patients could be stratified on the basis of individual needs, with patient-initiated follow-up. For example, patients with comorbid diabetes are likely to have a longer recovery and therefore need additional support, whilst others who can complete home-based exercises independently should be upskilled and signposted to appropriate resources. It is important, however, to be mindful of the evidence from UK FROST that the six sessions should be encouraged where feasible for physiotherapy to be effective.

Secondary care referrals

Developing an evidence-based pathway with the focus on physiotherapy, as supported by the findings from UK FROST, should help to minimise patients requiring secondary care referrals to specialists, considering this as end of the line or last resort. If physiotherapy with steroid injection is unsuccessful or is unable to be delivered in the primary care setting, this referral should be considered. Patients should ideally be assessed within a multidisciplinary clinic with physiotherapists and orthopaedic surgeons to confirm clinical history and previous treatments. If ESP with steroid injection has not been previously offered, this should be carried out in the first instance.

If surgical treatment is indicated, in line with the UK FROST findings, the first surgical option should be MUA with steroid injection, which was the most cost-effective option to the NHS of the three treatments. However, it was evident amongst the professional stakeholders that there would be some barriers (Table 2: Characteristics of the individuals involved), particularly around consensus for which surgical option should be offered first. Some surgeons do not offer MUA, whereas others regularly teach MUA, believing that this should be the first surgical option offered as it is simple and works. Despite UK FROST findings, it would appear there is confirmation bias with some professionals offering ACR more commonly than MUA, or that professionals would list for an MUA with the possibility of proceeding with an ACR in the same theatre space. This defeats the additional benefits of an MUA which is that it is more time efficient. On the basis of the evidence from UK FROST, the pathway recommends that if a patient is listed for surgery, the first option should be an MUA. If MUA is not successful, then a subsequent second option could be an ACR.

Enhanced recovery and follow-up

The success of this pathway component is dependent on ensuring that the appropriate resources and guidelines are developed or adapted to suit and support the proposed pathway (Table 2: Implementation process), ensuring the patients' enhanced recovery following physiotherapy or surgery. Stakeholders identified several useful resources, including an app, or website, to provide patient education and information on, whilst also considering those who are not digitally aware and the disabled as well. Patient and professional resources, such as booklets, which are accessible online and offline, were drafted as part of stakeholder discussions, which received good feedback and are currently in their final iterations.

Outlining the treatment options, recovery and rehabilitation for FS in an easy-to-understand, accessible format for both patients and professionals could further reduce the number of referrals to secondary care for surgery. Both populations need the data to be presented in the right format, alongside appropriate shared decisionmaking tools, so that the pros and cons of each treatment option are made clear. This would help primary care professionals to present accurate and clear information about the surgical options alongside the non-surgical options, e.g. physiotherapy. The stakeholders provided a few examples of useful resources, whereby something for FS could be developed in a similar format. This included the decision support tools as designed by NHS England, which are currently used in other conditions such as hip and knee osteoarthritis [23], which were praised by stakeholders for discussing the risks and benefits in an easy-to-understand format. Such resources would be well placed to support patients throughout the FS pathway.

Shared decision-making

Equally important when discussing treatment options is that shared decision-making is met throughout the pathway, this will be supported by the necessary resources and guidelines developed as part of the implementation process. For example, when stratifying patients' ability to self-deliver exercises, one stakeholder suggested asking how likely it would be that the patient would do the exercise. A question that was acknowledged to be rarely asked but would help to clarify the patient's level of self-efficacy towards completing the exercises as prescribed [24]. This would help both professionals and patients determine if self-management is suitable for them. In addition, this stratification approach should be considered when determining which patients are appropriate for secondary care referral and intervention, using current evidence where applicable.

Proposed frozen shoulder care pathway

Following the stakeholder discussions, and identification of barriers and facilitators using the CFIR for the four pathway components, a proposed FS pathway that sits within a larger stiff shoulder pathway was drafted using the Getting It Right First Time (GIRFT) format [25]

(Fig. 2). The timeframes and steps included within the proposed pathway are indicative of the minimum standards expected, acknowledging national variability. This has been shared further with stakeholders in primary and secondary care settings for feedback, of which they were largely supportive. Hydrodilatation at the time of UK FROST was not routinely used and still lacks a rigorous evidence base to support its use. However, within the discussions, stakeholders acknowledged that its increasing popularity and consensus were reached to include hydrodilatation within the pathway if hydrodilatation was being delivered as part of a setting's local policy and practice.

Discussion

This paper outlines the discussions from three stakeholder meetings regarding how best to implement the latest evidence from UK FROST in the management of FS, informed by the CFIR as an exemplar of KT. Recommendations across four main pathway components (presentation and assessment; initial management; treatment options; and enhanced recovery and follow-up) have been made, acknowledging the potential challenges and barriers in the various settings as well as the facilitators to help overcome and mitigate these. This has led to the development of an evidence-based FS care pathway that can be implemented into practice within the NHS.

NHS England has recently published an MSK improvement framework [22] and guidance for optimising MSK referrals [26], both supporting community MSK services, reducing waiting times and providing high-quality care for patients by ensuring that they are seen by the most appropriate person. The expectation is that by following these guidelines, only a small number of patients will need to be referred to secondary care. Our proposed FS pathway recommendations align with the framework to ensure patients presenting with shoulder pain are triaged to the most appropriate professional in primary care, such as an FCP. In addition, the framework and our recommendations are supportive of the use of self-management resources, including embedding and delivering physiotherapy interventions within these settings. Implementation of the proposed pathway needs to consider the available local or regional infrastructure and resources available to support the pathway.

Physiotherapists have previously stated that assessment of a patient's range of movement is essential to inform their diagnosis of a FS. Most of the physiotherapists emphasised the importance of testing passive external rotation within this assessment, which is simple to perform [27] and can be used to confirm diagnosis. Outlining restricted external rotation as an assessment for FS, ensuring both arms are assessed for comparison, would

aid diagnostic uniformity [27]. Additional recommended assessments to support diagnosis were the use of X-rays in the scenario of any urgent red flags or persistent pain and stiffness following initial management. The value of utilising X-rays is evidently under-recognised [27], whilst the overuse of assessments such as ultrasound and MRI, partly due to restrictions on some healthcare professionals to request an X-ray, were raised by the stakeholders. Additional literature supported our recommendations that X-rays can support the diagnosis of FS if the patient has re-presented owing to lack of improvement and can further rule out other more serious pathologies that can present similarly, even if this is only a small percentage of patients [28].

The ESP with intra-articular steroid injection used within UK FROST standardises the physiotherapy being delivered to patients with FS whilst allowing for a degree of flexibility to account for variations in professional expertise and settings, reducing inconsistencies nationally with physiotherapy management and delivery [9, 29]. UK FROST participants stressed the importance of early diagnosis and access to treatment, of which ESP with steroid injection can be accessed quickly, with additional benefits of being a cheaper, effective and safer treatment option compared with the surgical options. From our discussions with stakeholders, there was consensus that it is feasible to embed a modified ESP intervention within current primary and community care settings, thus optimising service delivery and referral pathways.

Regarding referral to secondary care for discussion of the surgical options, some of our stakeholders reported to offer ACR as the first surgical option over MUA, with additional literature suggesting the preference relates to ACR having less complications [30]. However, the UK FROST findings evidenced MUA to be more cost-effective with less risks. Considering ACR was not clinically significantly superior to MUA and there were no differences in patient-reported outcomes, we recommend that MUA should be the first surgical option offered for the small percentage of patients referred for surgical consideration on the basis of evidence. Stakeholders within our group also discussed hydrodilatation, suggesting it as an additional less invasive treatment option to consider. However, this currently lacks a sufficient evidence base to demonstrate its effectiveness and safety [10, 31, 32]. We acknowledge this within the proposed pathway and suggest it is only used if this is local practice.

There is a lack of good examples of how best to implement research into practice once a trial has concluded [33]. Here, we have provided an efficient method of working with a range of key stakeholders using an iterative process on how to embed UK FROST evidence within current care settings, including essential adaptations. The

CFIR framework has assisted in our understanding of the real-life barriers to implementing the UK FROST findings into practice, as described by the key stakeholders, with additional understanding of the influence of other factors and contexts across the five CFIR domains. We were then able to focus further discussions on the facilitators, considering the current NHS climate and resources available. This has led to contextualisation and consolidation of current evidence and practice to propose a care pathway for FS, which should make it easier for policymakers to consider for implementation. Ideally, this pathway will be best placed within an overarching stiff shoulder pathway, where FS would be one of the conditions.

Limitations

Whilst our purposive approach to the recruitment of stakeholders did result in a good spread of relevant characteristics and, in particular, included the key policymaker for MSK policy in England, there could have been more geographical spread. A suggested strategy to improve an equal representation of stakeholders and assist with engagement activities, while ensuring numbers were manageable, would have been the "Power-Interest Grid" [34]. In addition, there are alternative approaches to stakeholder engagement, such as the Delphi consensus process. This method is better suited to quantify consensus [35] in comparison to the current study which used a more qualitative approach; therefore, consideration of the various approaches and selecting one most suitable to the individual project is imperative. A recommendation for trialists would be to devise an enhanced dissemination and implementation plan at initial study design, whereby the current plan was devised following the end of the study. Our eight-step stakeholder process offers a pathway for devising an implementation and engagement plan before starting a trial, as well as after, to account for those in the same circumstance as UK FROST. A general limitation of the work is the limited ability we have as researchers to influence policymakers to consider and incorporate research findings into practice in a timely fashion, as well as the lack of coordinated mechanisms and guidance to support researchers in this work.

Next steps

Following our recommendations and proposed FS pathway, the next steps involve working with policymakers and commissioners. Currently, the development of this pathway is being discussed with GIRFT, ensuring that the steps within the pathway, with emphasis on the physiotherapy intervention, align with the MSK improvement framework by NHS England [22]. We also recommend NICE to update the guidelines for management of

FS [36]. The current "basis for recommendation" in the guidance should be updated in the context of the results and recommendations from UK FROST. In conducting this programme of work, we are providing a stronger evidence base that supplements the trial findings by discussing with stakeholders the additional individual and contextual factors, barriers and facilitators to guide implementation by healthcare commissioners and policymakers. The resources developed to support shared decision-making between the patient and healthcare professional can be adapted and further developed to support care pathways for the most appropriate management of FS.

Conclusions

This programme of work has successfully led to the development of a draft FS care pathway that may be progressed further by policymakers for implementation within the United Kingdom. In addition, we have outlined an eight-step process for initial engagement with stakeholders that has been useful in identifying barriers and facilitators for implementation. A similar approach may be considered by future trialists and funders to support implementation of research evidence into practice.

Abbreviations

ACR	Arthroscopic capsular release
BESS	British Elbow and Shoulder Society

CFIR Consolidated Framework for Implementation Research

ESP Early structured physiotherapy FCP First contact practitioner FS Frozen shoulder

GIRFT Getting It Right First Time
GP General practitioner
KT Knowledge translation
MRI Magnetic resonance imaging
MSK Musculoskeletal

MUA Manipulation under anaesthesia
NHS National Health Service

NICE National Institute for Health and Care Excellence
NIHR National Institute for Health and Care Research

PPI Patient and public involvement
QALY Quality-adjusted life years
RCT Randomised controlled trial
REDCap Research electronic data capture
UK FROST United Kingdom Frozen Shoulder Trial

US Ultrasound

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12961-025-01335-7.

Additional File 1

Acknowledgements

We would like to reiterate our thanks to the UK FROST Stakeholder Group, including the patient and public representatives, and healthcare professionals who did not wish to be named in the group, for their invaluable contributions to the meetings. We would also like to express thanks to the healthcare professionals who attended further conferences and meetings where we

presented our work and provided additional feedback on the work produced. UK FROST Stakeholder Group: Mr Simon Aldous (Airedale NHS Foundation Trust), Miss Alison Armstrong (University Hospitals of Leicester NHS Trust), Miss Annabelle Armitage (Humber Teaching NHS Foundation Trust), Miss Cheryl Baldwick (Royal Devon University Healthcare NHS Foundation Trust), Mrs Jenna Bardsley (Liverpool University Hospitals NHS Foundation Trust), Mr Andrew Bennett (GIRFT Community MSK Services; Epsom and St Helier University Hospitals NHS Trust), Dr Brian Blacklidge (South Tees Hospitals NHS Foundation Trust), Mrs Rowena Broughton (Gateshead Health NHS Foundation Trust). Mrs Fran Cabry (Harrogate and District NHS Foundation Trust). Miss Aimee Carr (Durham Dales Health Federation), Professor Charalambos P Charalambous (School of Medicine, University of Central Lancashire; Blackpool Teaching Hospitals NHS Foundation Trust), Mrs Caroline Christmas (Patient and public representative), Mr Peter E J Clark (Patient and public representative), Mrs Eleanor S Cramb (Weardale Physiotherapy), Mrs Linda Furness (South Tees Hospitals NHS Foundation Trust), Mrs Ann-Marie Ginnever (Gateshead Health NHS Foundation Trust), Mrs Kate Graham (Gateshead Health NHS Foundation Trust), Mr Paul William Green (Holgate Primary Care Network), Mrs Jillian Hughes (County Durham and Darlington NHS Foundation Trust), Dr Maya Jafari (South Tees Hospitals NHS Foundation Trust), Ms Anju Jaggi (Royal National Orthopaedic Hospital NHS Trust), Mr Falama Kadafa (Solent NHS Trust), Mr Cormac Kelly (The Robert Jones and Agnes Hunt Orthopaedic Hospital), Miss Su Leeming (Harrogate and District NHS Foundation Trust), Mrs Jeehan Lynch (Solent NHS Trust), Mrs Clare Mitchell (Weardale Physiotherapy), Mrs Sibongile Mtopo (North Tees and Hartlepool Foundation NHS Trust), Mrs Lynn Nelson (Patient and public representative), Mr Simon Nicole (St George's University Hospitals NHS Foundation Trust), Mrs Jayanti Rai (Kent Community Health NHS Foundation Trust), Dr Adnan Saithna (AZBCS Orthopaedics, Scottsdale, Arizona, USA), Mrs Gemma Shearer (St George's University Hospitals NHS Foundation Trust), Mrs Claire Southey (Filey and Scarborough Healthier Communities Network), Mrs Kate Stevenson (George Eliot Hospital NHS Trust), Mrs Helen Thompson (East Lancashire Teaching Hospitals NHS Trust), Miss Suzanne Timney (Patient and public representative), Dr David Tomson (Retired PCN director North Shields and Executive partner Collingwood Health Group), Miss Aisha Warsama (North Tees and Hartlepool Foundation NHS Trust), Ms Helen Watson (Newcastle Hospitals NHS Foundation Trust), Mr Mark Robert Webb (Countess of Chester NHS Foundation Trust), Mr Gareth Whelan (York and Scarborough Teaching Hospitals NHS Foundation Trust), and Mr Chris Wright (South Tees Hospitals NHS Foundation Trust)

Author contributions

NC, MJ and LK contributed to data collection. NC and MJ contributed to data analysis and the drafting and revising of the manuscript. NC, MJ, LK, SB, JA and AR contributed to the design of the stakeholder meetings, attended the meetings, and commented on and approved the final manuscript.

Funding

This project was funded by the National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) programme (project 13/26/01). The views expressed are those of the authors and do not necessarily reflect those of the NIHR or the Department of Health and Social Care.

Availability of data and materials

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

An online stakeholder survey via REDCap was disseminated to stakeholders, who confirmed their consent to be contacted for stakeholder meetings. Ethical approval was not applicable for this programme of work.

Consent for publication

The stakeholder group were contacted for consent for their name to be included within the collaboration author group.

Competing interests

The authors (NC, MJ, LK, SB and JA) declare that they have no competing interests. AR declares grants from NIHR, AO UK&I and H2020 for other projects;

is a member of the NIHR i4i funding committee; and received research and educational grants for the department from DePuy J&J Ltd.

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Received: 30 January 2025 Accepted: 24 April 2025 Published online: 30 May 2025

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