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Implementation of musculoskeletal Models of Care in primary care settings: Theory, practice, evaluation and outcomes for musculoskeletal health in high-income economies

Krysia S. Dziedzic, PhD FCSP [a, *],
Simon French, PhD, MPH, BAppSc (Chiro) [b, 1],
Aileen M. Davis, BScPT, MSc, PhD [c, 2],
Elizabeth Geelhoed, DipNucMed RMIT, BEc MPH PhD [d, 3],
Mark Porcheret, MBBS FRCGP PhD [a, 4]

[a] *Institute of Primary Care and Health Sciences, Arthritis Research UK Primary Care Centre, Keele University, Keele, ST5 5BG, UK*
[b] *School of Rehabilitation Therapy, Faculty of Health Sciences, Queen's University, Louise D. Acton Building, 31 George St, Kingston, ON K7L 3N6, Canada*
[c] *Division of Health Care and Outcomes, Krembil Research Institute, University of Toronto, MP11-322, 399 Bathurst Street, Toronto, ON M5T2S8, Canada*
[d] *Health Economics, School of Population Health M431, The University of Western Australia, 35 Stirling Hwy, Crawley, WA 6009, Australia*

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ABSTRACT

Musculoskeletal conditions represent one of the largest causes of years lived with disability in high-income economies. These conditions are predominantly managed in primary care settings, and yet, there is a paucity of evidence on which approaches work well in increasing the uptake of best practice and in closing the evidence-to-practice gap. Increasingly, musculoskeletal models of service delivery (as components of models of care) such as integrated care, stratified care and therapist-led care have been tested in primary health care pathways

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* Corresponding author. Tel.: +44 01782 733907; fax: +44 01782 733911.

E-mail addresses: k.s.dziedzic@keele.ac.uk (K.S. Dziedzic), simon.french@queensu.ca (S. French), adavis@uhnresearch.ca (A.M. Davis), Elizabeth.Geelhoed@uwa.edu.au (E. Geelhoed), m.porcheret@keele.ac.uk (M. Porcheret).

[1] Tel.: +1 613 533 6461; fax: +1 613 533 6776.

[2] Tel.: +1 416 603 5543; fax: +1 416 603 6288.

[3] Tel.: +61 8 6488 7129; fax: +61 8 6488 1188.

[4] Tel.: +44 1782 734861; fax: +44 1782 733911.

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for joint pain in older adults, for low back pain and for arthritis. In this chapter, we discuss why implementation of these models is important for primary care and how models are implemented using three case examples: we review implementation theory, principles and outcomes; we consider the role of health economic evaluation; and we propose key evidence gaps in this field. We propose the following research priorities for this area: investigating the generalisability of models of care across, for example, urban and rural settings, and for different musculoskeletal conditions; increasing support for self-management; understanding the importance of context in choosing a model of care; detailing how implementation has been undertaken; and evaluation of implementation and its impact.

Why implementation of musculoskeletal models of care is important in primary care settings

Primary health care was defined by the World Health Organisation (WHO) as '… the first level of contact of individuals, the family and the community with the national health system ……. and constitutes the first element of a continuing health care process' [1]. Primary care settings are the locations where this type of care is delivered, and for brevity, it will be henceforth referred to as 'primary care'. Although systems of delivery of primary care vary across and within countries, it is the setting in which the vast majority of people first seek help with musculoskeletal conditions and in which many are cared for, and as such, an effective primary care system is central to musculoskeletal health service provision. With its proximity to the community it serves, primary care is directly affected by the high prevalence and impact of musculoskeletal conditions in the community.

The community burden of musculoskeletal conditions in high-income economies is high and rising, placing increasing burden primary care [2]. Most commonly, these conditions include arthritis and low back pain. The prevalence of inflammatory arthritis, while about 2%, incurs huge economic costs to the system and patient, requiring early diagnosis in primary care and management with disease-modifying drugs to maximise outcomes [2]. It is the rising burden of disabling low back pain, osteoarthritis (OA) and falls (especially in those with osteoporosis and skeletal fragility) that will, given that they are highly prevalent and currently managed in primary care, principally affect the primary care workload. This is evidenced for OA and low back pain by data from UK and Swedish general practice records, which indicate that over a 7-year period 11% (Sweden) and 21% (UK) of all registered patients consult for low back pain and of the patients aged 45 years and over, 31% and 35%, respectively, consult for OA [3]. These findings are in line with the Australian data that show low back pain and OA are both in the top 10 of the most common reasons for presenting to a general practitioner (GP) [4]. Projected increases in such a burden as identified by the Global Burden of Disease Study [2] are likely to add significantly to the primary care workload. In addition to future rising demand for primary care, there is a present gap between the recommended practice and day-to-day practice: surveys suggest that current primary care for back pain and OA is suboptimal when judged against quality standards derived from clinical practice guideline recommendations [5–10]. Implementation of models of care may be helpful in bridging this gap and guiding more sustainable and efficient health care.

A model of care has been defined as 'an evidence-informed policy or framework that outlines the optimal manner in which condition-specific care should be made available and delivered to consumers' [11] and addresses system-level delivery and specific service provision in different parts of the system. For clarity in this chapter, the term 'model of service delivery' is used when describing issues related to the provision of care at an operational or service level.

Speerin et al. [12] reviewed models of care for musculoskeletal conditions, giving a range of exemplars from different settings, and a WHO report identified the opportunities to improve musculoskeletal health outcomes afforded by implementation of models of care [13]. Models of care and models of service delivery go beyond clinical practice guidelines in that they not only address what care should be delivered (often derived from guideline recommendations) but also the practical delivery issues of who is to deliver care, when and where care is best delivered and the details of how it is to be delivered and re-evaluated. These are important issues to be addressed in primary care given its multidisciplinary workforce; links with secondary and tertiary care services; and its often complex, and frequently changing, organisational structures [14,15].

Specifically in general practice, there are issues arising from the need to (i) provide a generalist service (primary health practitioners do not just care for people with musculoskeletal conditions and have many demands on their time and professional development), (ii) provide holistic care for people with several long-term conditions (musculoskeletal conditions need to be managed in the context of multiple morbidity) [16] and (iii) meet the ever-rising demand for generalist services from an ageing population. The rationale for the holistic care of people with musculoskeletal conditions is that (i) multimorbidity is increasingly becoming the norm in patients with painful conditions such as low back pain and OA: a primary care database study from Scotland reported that only 13% of patients with a painful condition did not have at least one other long-term condition and 46% had three or more other conditions [17]; (ii) a high proportion of people with a chronic physical ill health report chronic pain: a community survey from Australia reported that 15 out of the 17 chronic conditions studied were significantly associated with pain [16]; (iii) lifestyle treatments, such as increasing physical activity and losing weight, recommended for common musculoskeletal conditions are equally beneficial for many other chronic conditions and so merit being promoted in a holistic manner; (iv) pain, such as joint pain, is often a barrier to increasing physical activity and patients need help in managing this to enable them to gain the benefits of increasing physical activity in other chronic conditions such as diabetes and heart disease [18]; and (v) multimorbidity can result in a considerable treatment burden for patients and a holistic approach can help to reduce this [19].

Whilst primary care offers a generalist approach, and older adults with comorbidities represent a large proportion of the population consulting here, services in secondary care and beyond are often not readily integrated into primary care and coverage of community services can be patchy. It is often left to the patient and their carer to be the coordinator of their care across a range of services, and the 'hard work' of being a patient with comorbidities in the health care system has been recognised [20].

In summary, implementation of musculoskeletal models of care in primary care settings is needed to address current gaps in and future demand for the provision of primary care for people with musculoskeletal conditions.

How to implement: overview and application of theory for implementing musculoskeletal models of care

Implementation has been defined as the process of 'active and planned efforts to mainstream an innovation within an organisation' [21] and use of theory to inform this process has been strongly advocated [22,23]. Many theories, models and frameworks have been developed and used for implementation and the reader is directed to recent narrative reviews for an overview of their range and purpose [24,25]. There are some key implementation principles [26], which the use of theory can help operationalise, and have been summarised as follows:

- Adopt a systematic and stepwise approach to planning and execution
- Have a full understanding of the context for the process of change, including an analysis of current performance in the area in question
- Have a well-defined proposal for change, which can be clearly presented
- Understand the determinants for change: the barriers and facilitators
- Develop and deliver an implementation intervention that addresses relevant determinants for change
- Involve all those in whom change is desired at all stages
- Continuously evaluate and adjust the implementation approach if needed

Despite the range of theories available to plan and develop, understand and describe, and evaluate models of care, there is still an evidence-to-practice gap in primary care [15]. Interventions tested in primary care such as educational outreach, incentives, computer prompts, and clinical champions appear to give only small benefits, and there is no evidence that multimodal approaches are advantageous, but the success of a chosen intervention to implement a model of service delivery is dependent on the context in which it is used [15]. For example, in the context of national recommendations for the care and management of a musculoskeletal condition, implementation of a model of service delivery to increase the uptake of the recommendations for that condition may be given higher priority than if there was no national guidance for that condition.

This section describes the approach employed by the authors in using theory to practically design implementation interventions for GPs to enhance the management of low back pain [27] and OA [28] and is given to illustrate how theory could be used in implementing specific components of musculoskeletal models of care.

The first step was to develop what has been termed the ‘concrete proposal’ for change [26]: a detailed specification of the desired new way of working. In the context of implementing a model of care, this would require the model to be clearly defined in detail. It is recommended that this is undertaken systematically and with the involvement of the ‘target group’ (the people and organisations who will be asked to work according to the model) [26] as stakeholder engagement is a key mechanism for enhancing implementation.

The second step was to undertake an analysis of the GPs (as the identified ‘target group’) to understand the barriers to and incentives for adopting the new way of working, and at this step, the theoretical domains framework was utilised [29]. This framework was developed to enable the many psychological theories on ‘determinants of behaviour change’ (factors that determine the extent to which change will occur) to be used in one overarching framework. The behaviour change determinants are grouped into 12 domains, for example, ‘knowledge’, ‘skills’, ‘beliefs about consequences’ and ‘environmental context and resources’, and the domains provide a theory-derived list of factors to be explored in the ‘target group’. When implementing a model of care, this approach would require the model to be presented to the ‘target group’, for example, in focus group workshops, followed by a semi-structured discussion that is recorded and analysed to identify the relevant determinants, for example, a lack of skills in some of those who are to deliver care aligned to the model or a belief in others that the consequence of operationalising the new model would be no better (or worse) than the current practice.

Having identified the relevant determinants in step 2, the third step was to select ‘behaviour change techniques’ to effect change in these determinants, and for this a model that maps behaviour change techniques (BCTs) to the domains of the theoretical domains framework was utilised [30]. The model was developed by identifying and defining a list of ‘behaviour change techniques’ described in the literature and mapping each to one or more of the domains, for example, the use of rehearsal of skills with feedback to target a skills gap. The selected BCTs were incorporated into the implementation intervention: a series of workshops that GPs were invited to attend.

In summary, many theories, models and frameworks have been developed to inform the process of implementation, and we have illustrated, using one example, how theory can be used in a doable and practical manner to develop interventions to support implementation and can be used to implement models of care. The steps outlined earlier have recently been described in a framework to develop, implement and evaluate models of care for musculoskeletal health [31,32]. The framework has been designed by experts from 30 nations of varying wealth and offers a helpful synthesis on how to approach implementation.

Practice points

- Back pain and OA are the most prevalent musculoskeletal conditions managed in primary care
- Efforts to improve primary care of musculoskeletal health should focus on implementation of models of care for these conditions to ensure the right care is delivered at the right time by the right team in the right place
- Implementation theory can help to design and implement models of musculoskeletal care and guide evaluation

Moving from research evidence to implementation of models of care at scale: Using theory to support implementation.

Introduction

In their study of models of care for musculoskeletal health, Speerin et al. [12] identified a range of programmes for the prevention and management of musculoskeletal conditions. In this chapter, we have selected three models of service delivery within primary health care to illustrate how implementation theory can be used in practice. We describe each model of service delivery, as reflected in contemporary models of care, and where indicated, which implementation theory has been used (Table 1).

A model of integrated service delivery for joint pain in older adults: Managing Osteoarthritis in Consultations (MOSAICS)

The first model describes how innovations developed and tested in a research context (the MOSAICS trial) – co-created by GPs, practice nurses, patients and researchers – can be successfully modified and piloted to implement at scale an enhanced care pathway for OA in primary care (Joint Implementation of Guidelines for Osteoarthritis in the West Midlands (JIGSAW)). MOSAICS was tested in a cluster trial to determine the uptake of the core recommendations from OA guidelines; the clinical effectiveness of the model on any changes in health status; and the consequences and cost utility of the new approach. The benefit of the cluster trial design was that it allowed testing of the whole system approach within a defined protocol. The implementation that followed was in response to a strong pull from stakeholders and allowed further testing, adaptation and scale-up in real-world practice. Flow Chart 1 describes some of the lessons learnt during the process of moving *from* a funded research proposal, with oversight of a clinical trials unit, delivered by a multidisciplinary research team to a defined group of general practices, *to* implementation of innovations developed by the research, with oversight of clinical commissioning groups (CCGs), delivered by a multidisciplinary implementation team to an expanding number of general practices.

The model of service delivery

The model of integrated care of joint pain in older adults (MOSAICS) [33] was developed to operationalise, in general practice in United Kingdom (UK), the UK 2008 National Institute of Health and Care Excellence (NICE) OA Guidelines [34], and it describes how initial GP care can be integrated with follow-up practice nurse care and the provision of written patient information. The model focussed on six NICE OA Guideline recommendations: (i) obtaining verbal and written information, (ii) advice to exercise and increase physical activity and (iii) interventions to achieve weight loss should be core treatments for all people with OA; i(v) paracetamol and (v) topical nonsteroidal anti-inflammatory drugs (NSAIDs) should be first-line treatments for analgesia and (vi) a holistic approach to assessment and treatment should be adopted to help people take better self-care of their joint pain and OA.

The three elements of the Whole Systems Informing Self-management Engagement (WISE) approach [35] underpinned the development of the MOSAICS model: relevant and accessible patient information, professionals responsive to the needs of patients and good access to care services (Fig. 1).

The MOSAICS model describes the care that should be offered to adults aged 45 years and over who present to their GP with peripheral joint pain in the hands, knees, hips and feet (a focus of the NICE guidance). It consists of three components: (i) an initial consultation with a GP, followed by (ii) up to four consultations with a practice nurse in an OA clinic, with (iii) the Keele OA Guidebook to support care (Fig. 2).

The delivery of the model is supported by an e-template (Fig. 3) embedded in the GP clinical computer system, and both prompt for key aspects of care and enable delivery of care to be coded in the electronic patient record [36].

Implementation of the model of service delivery

The model has been implemented as a trial intervention in a cluster randomised control trial (the MOSAICS trial) to investigate the acceptability, feasibility and effectiveness of implementing the 2008

Table 1
Programmes of musculoskeletal care in primary care settings.

Model of care	Which programme?	Where implemented?	What constitutes the model of care?	Who delivers the model of care?	How is the model of care implemented?	Outcomes
Integrated care	Managing osteoarthritis in consultations (MOSAICS) [33] JIGSAW Joint Implementation of osteoarthritis guidelines in the West Midlands, UK (Based on MOSAICS study)	UK general practice	Use of an electronic OA template to record key Quality Indicators of OA care. PLUS A model OA consultation with a GP: offers of referral to practice nurse.	General practitioner and practice nurse linked consultation	Adults 45 years and over presenting to their General Practitioner with joint pain (hip, knee, hand, foot), clinical diagnosis; exclusion of red flags. OA e-template fires. GP makes, gives, explains the OA diagnosis, gives OA guidebook; analgesia; offers referral to practice nurse. Practice nurse up to 4 sessions supporting self-management: OA guidebook; exercise/physical activity advice using Arthritis Research UK booklets; weight management; analgesia.	Uptake of Quality Indicators of OA for the core non-pharma and pharma recommendations from the National Institute of Health and Care Excellence
Stratified care	STarT Back: Subgroups for Targeted Treatment (STarT) Low Back pain [39–41] http://www.keele.ac.uk/sbst/	Initially UK, subsequently overseas including Australia, Denmark, Scandinavia, Canada, USA	Patient information; training for psychologically informed physiotherapy; 9-item STarT Back screening tool embedded in general practice electronic medical record systems; e-templates for general practice fire on Read codes.	General practitioners and physiotherapists	Patient consulting with low back pain in general practice, GP enters a Read code for low back pain which fires an e-template prompt to screen for red flags and complete the 9-item STarT Back screening tool, completes tool in real time consultations, tool auto-calculates score	**Improved clinical outcome for patients at 4 and 12 months** Improved patient satisfaction Credible and acceptable to patients Reduced time off work Stratified care was cheaper: Saving an average £34 per individual (health costs) Saving an average £675 per individual (societal costs)

					and identifies level of risk of persistent disabling low back pain (low, medium, high risk). Low risk = support for self-management of back pain by GP; medium risk referral for physiotherapy; high risk = referral for psychologically informed physiotherapy	**Key cost savings** [41] GP consultations Visits to NHS consultants Investigations MRI; x-rays Epidural injections Other private healthcare Medication **Changes in physiotherapy pathway** Low risk = Reduced referral Medium risk = More referrals early High risk patients = More referrals early
Primary therapist model	Arthritis Rehabilitation and Education Program http://arthritis.ca/manage-arthritis/living-well-with-arthritis/living-well-in-your-province/living-well-in-ontario/therapy-services	Services are offered in all of the Provincial health regions, delivering education and care at select Arthritis Society offices, Ontario, Canada, in primary health care clinics, in specialised rheumatology clinics, at home, through a variety of groups, and through telemedicine.	Assessment, diagnosis, triage and independent management of selected musculoskeletal and arthritic disorders	Arthritis Society employs Physiotherapists (PT), Occupational Therapists (OT) and Social Workers	Clients with a confirmed physician diagnosis of arthritis are able to self-refer; referrals also are accepted from other health professionals. The therapist functions as a case manager and multi-skilled rehabilitation professional	

External Context
e.g. governmental, economic, legislation, policy

- Form a core, trusted, multidisciplinary, implementation team
- Identify key stakeholders and co-opt as (virtual) members
- Use patient and public involvement and engagement early
- Design a range of innovations with stakeholders that are flexible and provide solutions to their problems
- Detail the evidence base for the innovations
- Align with policy e.g. international guidelines
- Identify champions in key positions of influence
- Use theory to plan an engagement strategy

Organisational
e.g. primary health care, systems, processes, culture

- Align implementation priorities with the external and internal context
- Understand the overall mission of the organisation
- Second members of the organisation and clinical champions to the core implementation team
- Provide project management
- Secure any additional funding and resources needed
- Consider a Community of Practice to bring stakeholders together
- Aim for whole system buy in
- Use theory to understand uptake
- Provide a range of innovations (e.g. clinical pathway redesign, IT solutions, training, patient information, audit and feedback tools, quality indicators of care, patient satisfaction)
- Design the innovation(s) as the solution to their problem(s)
- Demonstrate how the innovation can help save time (short, medium or long term)
- Demonstrate how the innovation can help optimise resources
- Demonstrate how the innovation can help reduce clinical variation and drive up quality care
- Start with pilots
- Work with the early adopters
- Prepare training that can be delivered at scale
- Use patient and public involvement and engagement
- Learn new skills e.g. writing business cases
- Tailor the innovation to local needs

Professional
e.g. role, attitudes to change

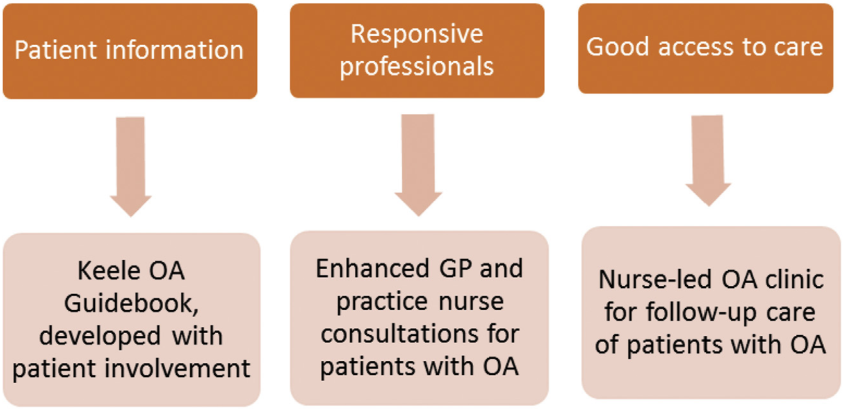
- Consider a Community of Practice to bring stakeholders together
- Provide the ongoing link between professional groups and organisations
- Identify and recruit local clinical champions
- Recognise the barriers to implementation for all professional groups involved
- Identify the facilitators to implementation for all professional groups involved
- Use local patient and public involvement
- Use patient stories
- Use peer to peer support and mentoring
- Recognise health care professionals' confidence and expertise
- Seek rewards, awards and recognition for local participation
- Refine IT solutions for usual care
- Plan feasible training for delivery at scale
- Train the trainers
- Articulate time, tools, resources and expertise needed
- Maximise outreach visits and local educational events
- Share variations in usual practice
- Determine outcomes of quality care
- Use theory to evaluate
- Report findings
- Use a website for external communication

Flow Chart 1. Recommendations for implementing evidence based innovations mapped to the key domains of External Context, Organisational and Professional as described in Lau et al. [15].

NICE OA Guideline in general practice [33] and subsequently in day-to day practice in UK general practices through the Joint Implementation of Osteoarthritis Guidelines in the West Midlands (JIG-SAW) Programme (see Chapter 8). The sections later describe aspects of implementation of the model in the two settings.

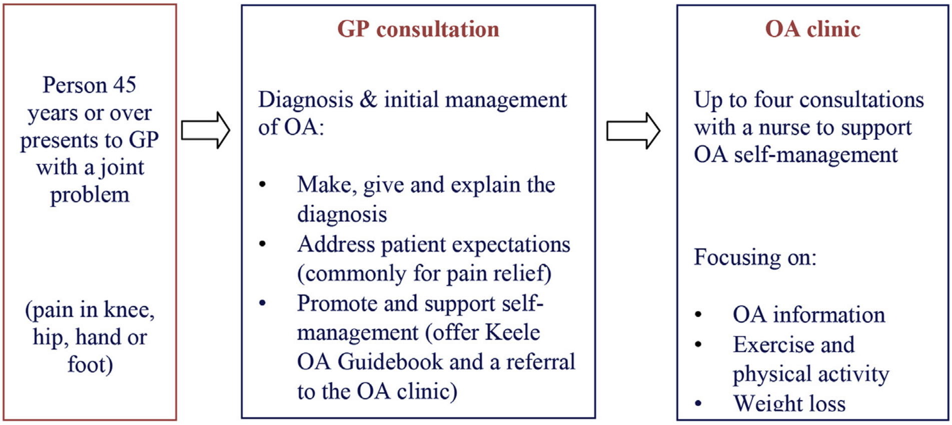
Implementation as a research trial intervention

Four of the eight practices recruited were randomly assigned to the intervention, while the remaining four continued with the e-template alone. To deliver the GP component of the MOSAICS model of care, an intervention was designed using the implementation theory to effect change in GP clinical practice necessary for GPs, in the four intervention arm practices of the MOSAICS trial, to deliver their component of the MOSAICS model of care (the GP consultation – see Fig. 2). Its development utilised the approach described earlier and has been described in detail elsewhere [28]. In summary, (i) a concrete proposal for change was developed through consensus [37] and focus group work; (ii) determinants of change were identified through further focus group work and classified using the theoretical domains framework; and



GP = general practitioner, OA = osteoarthritis

Fig. 1. Operationalisation of the three elements of the Whole Systems Informing Self-management Engagement (WISE) approach in the MOSAICS model [33].



Diagnosis & initial management of OA:

- Make, give and explain the diagnosis
- Address patient expectations (commonly for pain relief)
- Promote and support self-management (offer Keele OA Guidebook and a referral to the OA clinic)

Up to four consultations with a nurse to support OA self-management

Focusing on:

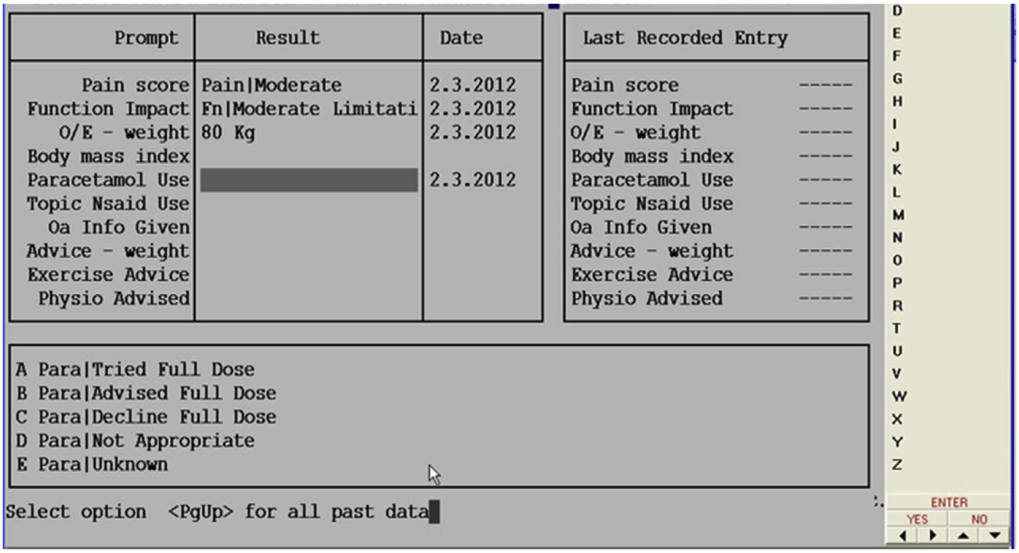
- OA information
- Exercise and physical activity
- Weight loss

GP = general practitioner, OA = osteoarthritis

Fig. 2. MOSAICS model of service delivery for managing OA in general practice.

iii) a programme for a series of workshops to deliver the implementation intervention was developed in four stages: content defined, BCTs selected, mode of delivery agreed and local practicalities addressed. The workshop programme is detailed in Table 2. In brief, workshop 1 was delivered to the Primary Health Care Team (2 h), which covered how OA is managed, OA knowledge update, NICE guidance, case histories and the OA consultation. Workshop 2 was for GPs (2 h) and covered discussion and reflection (video-recorded simulated consultations) and skills training. Workshop 3 for GPs included knowledge updates, discussion and reflection, agenda for skills training and the aide-memoire. The final workshop for GPs included action planning and review of audit data.

GPs in the four intervention arm practices attended these workshops, and change in clinical practice was evaluated through the use of video-recorded consultations with simulated patients and an audit of delivery of the GP consultation during the trial.



Prompt	Result	Date
Pain score	Pain|Moderate	2.3.2012
Function Impact	Fn|Moderate Limitati	2.3.2012
O/E - weight	80 Kg	2.3.2012
Body mass index		
Paracetamol Use		2.3.2012
Topic Nsaid Use		
Oa Info Given		
Advice - weight		
Exercise Advice		
Physio Advised		

Last Recorded Entry	
Pain score	-----
Function Impact	-----
O/E - weight	-----
Body mass index	-----
Paracetamol Use	-----
Topic Nsaid Use	-----
Oa Info Given	-----
Advice - weight	-----
Exercise Advice	-----
Physio Advised	-----

A Para|Tried Full Dose
B Para|Advised Full Dose
C Para|Decline Full Dose
D Para|Not Appropriate
E Para|Unknown

Select option <PgUp> for all past data

Fig. 3. Screenshot mock-up of the OA e-template as displayed in a patient's electronic health record in the MOSAICS study [33].

Practice nurses were invited to a 4-day training programme at Keele University to implement the 'OA clinic' [33]; see Fig. 4, which describes the content of the nurse training programme delivered by the study team.

On further testing, adaptation and scale-up in real-world practice, at a half-way point in the trial, a stakeholder conference was held and clinical case studies were shared by colleagues involved in the programme. For example, a practice nurse described an 80-year-old lady she had seen in the 'OA clinic' whose husband *'wouldn't let her do anything'* because she had osteoarthritis. The practice nurse described how delighted the patient was in being told that keeping moving was key to self-management. *'She was over the moon. It was like a new lease of life. She'd got her guidebook – she used it quite a lot. At her final consultation, she virtually skipped into the room. It was just brilliant to see her because she'd done so well'* (Nurse Practitioner, MOSAICS Stakeholder Conference 2013).

The stakeholder conference proved to be a key factor in the transition from research into implementation. The MOSAICS study generated grass roots interest and support, with GPs and practice nurses reporting greater confidence in managing OA and patients feeling that their joint problems were taken seriously. In addition, the health professionals realised that the core management principles for OA were the same as those for other long-term conditions (LTCs) and that the knowledge and skills they developed were transferable across a range of LTCs.

Following the stakeholder conference, a GP champion and practice nurse asked the trial team for support in rolling the model consultation out into local practices in a pilot. The aim of the pilot was to develop an enhanced care pathway for OA based on the trial intervention. The setting was a cluster of local general practices in South Shropshire, West Midlands, UK.

The research trial had developed four key innovations that formed the practice intervention to deliver the enhanced OA model:

1. An OA guidebook written by patients and health professionals for patients
2. A model OA consultation for primary care to deliver NICE recommendations
3. Training for GPs and practice nurses to deliver the model consultation
4. The development and capture of quality indicators (QIs) of care (through an OA e-template and self-reported questionnaire)

Table 2
Programme for workshops to deliver the GP implementation intervention for the MOSAICS model of care as a trial intervention.

Time (minutes)	Activity
Workshop 1 – attendees: primary healthcare team from a single practice (GPs, practice nurses, practice manager*, receptionists[1]) Duration: 2 h [28,33].	
1* – for first hour only	
5	Introductions – facilitators and practice attendees
20	How is OA managed in your practice? Mapping practice, and local community and secondary care, resources for OA (interactive session with discussion recorded on flipchart)
25	OA knowledge update on pathophysiology, definition and diagnosis, prevalence, prognosis and patient experience of OA (didactic session with discussion)
10	Information on the NICE OA Guideline, support for self-management, the OA Guidebook, the model OA consultation (didactic session with discussion)
5	Break and non-clinical staff leave
20	Presentation and discussion of case histories (GPs previously requested to bring). Difficulties in managing OA – what do GPs and nurses want from the sessions and what would aid them in managing OA (interactive session with issues recorded on flipchart and to be addressed in workshop 3)
25	Details of the model OA consultation – how to deliver it in day-to-day practice – GP and practice nurse roles. Aide-memoire introduced (didactic session with discussion)
10	Conclusion and outline of workshops 2 and 3. GPs given the DVD of simulated patient consultation[2] and asked to view in preparation for workshop 2
	2 – all GPs were invited to undertake a video-recorded consultation with a simulated OA patient prior to workshop 1
Workshop 2 – attendees: GPs from two practices.[3] Duration: 2 h	
3 – GPs from two practices came together for workshops 2 and 3	
10	Introductions – facilitators and GPs. Reflection on, and unanswered questions from, workshop 1.
20	Discussion and reflection on video-recorded simulated patient OA consultations. Comparison between current practice and model OA consultation. Agenda for skills training agreed (interactive session with 'agenda' recorded on flipchart)
10	Introduction to skills training: description of purpose and methods – the GPs were asked to work as a team, trying out in turn bite-sized parts of the consultation with discussion and feedback from colleagues and facilitators (didactic session with discussion)
10	Break
60	Skills training: working through the agenda set earlier. Particular emphasis on communication, use of language for giving and explaining the diagnosis and patient-centred approach (led by an experienced GP educator)
10	Reflection and conclusion. Aide-memoire discussed. Preparation for second video-recorded simulated patient consultation.[4] Outline of workshop 3
	4 – All GPs were invited to undertake a second video-recorded consultation between workshops 2 and 3
Workshop 3 – attendees: GPs from two practices. Duration: 2 h	
40	Knowledge update: addressing needs identified in workshop 1 and questions from GPs and covering: diagnosing OA clinically and 'top tips' for managing OA (interactive session led by academic rheumatologist)
10	Discussion and reflection on second video-recorded consultation. Agenda for skills training agreed (interactive session with 'agenda' recorded on flipchart)
10	Break
50	Skills training: as for workshop 2
10	Conclusion and general reflection. Aide-memoire discussed. GPs invited to complete satisfaction questionnaires. Outline of workshop 4
Workshop 4 – attendees: GPs and practice nurses from a single practice. Duration: 1 h	
40	Action planning on delivery of the model OA consultation in the practice. Final version of the aide-memoire agreed.
10	Presentation of baseline data on OA consultations in the practice (an OA data collection template had been installed in the practices for the 6 months prior to the training)
10	Conclusion and thanks. Attendance certificates issued.

The model of care was evaluated using OA QIs embedded in the general practice OA e-template [36] (Fig. 3) and through a patient-reported OA-QI UK questionnaire [38].

The practice nurse training was reviewed and reduced to 2 days following evaluation, and GPs worked in partnership with an implementation team at Keele University to identify funding to roll out the four key innovations described earlier. The Joint Implementation of Osteoarthritis Guidelines in the West Midlands (JIGSAW) Programme was piloted to test out the practicalities of implementing the enhanced OA pathway.

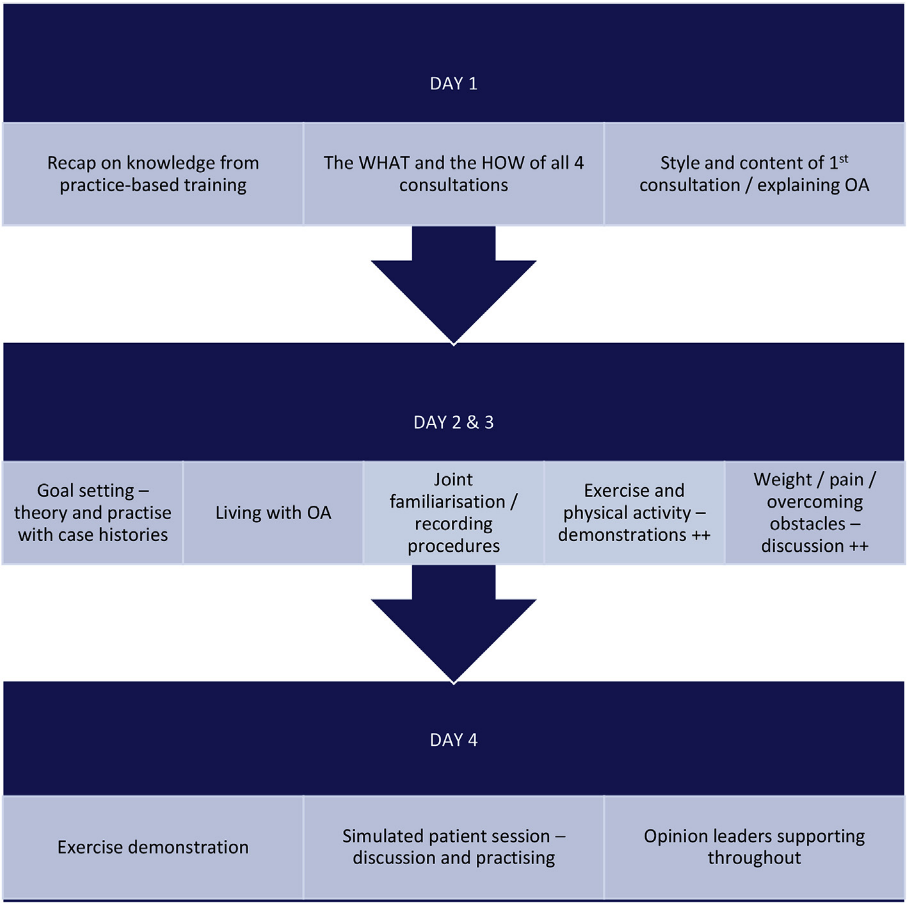


Fig. 4. Content of the 4-day training programme for general practice nurses in the MOSAICS study [33].

JIGSAW identified 15 general practices in the local CCG to be pilot sites. A meeting of stakeholders from each of these practices was convened by the lead GP champion to introduce the proposal and the Keele team. Across these sites, more GP champions (four) and practice nurses (two) were recruited to support colleagues in clusters of up to four practices. Workshops based on the research training for the MOSAICS trial (Table 2) were delivered to the clinical champions at two practice-based meetings to introduce them to the role.

A 2-h evening meeting was then convened to launch JIGSAW in all practices and practice staff. Practice staff met their nominated clinical champion and participated in round table discussions. Topics such as the quality of the evidence, clinical pathways, funding and barriers to uptake were debated. A patient story was used by the GP champion to illustrate the potential benefits of using NICE recommendations in routine care. Practitioners agreed to adopt the OA e-template (used to capture QIs of care) to audit current practice and evaluate successful implementation. A dedicated health informatics specialist from the trial team supported local practices to install the template. A training Digital Video Disc (DVD) was available to guide its use. On the basis of the pilot study, further funding was secured (JIGSAW is further described in Chapter 8).

In summary, JIGSAW has shown that innovations developed and tested in a research context (the MOSAICS trial) – co-created by GPs, practice nurses, patients and researchers – can be successfully modified and piloted to implement at large scale an enhanced care pathway for OA in primary care.

A model of stratified care: Subgroups for Targeted Treatment

The second model describes a research study investigating screening and targeting of matched treatments for back pain (STarT Back) [39–41] and its subsequent uptake informed by a parallel research study of implementation potential (IMPaCT Back) [42]. The STarT Back approach has been adopted widely with examples of where it has been refined to fit with local needs (http://www.keele.ac.uk/sbst/).

In 2011, Hill et al. [39] published the STarTBack trial. STarT Back is an example of a stratified care approach for low back pain and matches patients to treatments based on prognosis or risk of poor clinical outcome (Table 3).

The model of primary care is a collaborative GP–physiotherapist-integrated model of service delivery with patient-centred support for self-management and use of a stratification tool that allows for matching of treatment to the level of risk of persistent, disabling, low back pain (low, medium or high risk). Those at low risk are supported with a self-management plan and those at medium and high risk are referred for physiotherapy, with those at high risk being offered enhanced physiotherapy with a psychologically informed intervention [40].

The STarT Back approach uses a simple nine-item tool to match patients to treatment packages appropriate for them. This has been shown to significantly decrease disability due to back pain, reduce time off work and save money by making better use of health resources as this new model results in greater health benefits, achieved at a lower average health-care cost, with an average saving to health services of £34.39 per patient and societal savings of £675 per patient [41]. The STarT Back website shares the knowledge, resources and experiences of the STarT Back approach for use by clinicians, providers, researchers and patients (http://www.keele.ac.uk/sbst/).

In parallel to the randomised controlled trial to evaluate effectiveness [39], Foster and colleagues studied the potential for implementation of this risk stratification and matched treatment approach for back pain in primary care (the IMplementation to improve Patient Care through Targeted treatment (IMPaCT) Back study) [42]. The implementation study showed that this approach can be successfully embedded into routine primary care [42]. The IMPaCT Back study used the normalisation process theory (NPT) [43] to understand and evaluate the potential for uptake of this stratified care approach prior to the completion of the STarT Back trial. The four key 'how' stages of NPT include (i) 'sense-making' of the approach (e.g. distinguishing it from usual practice), (ii) participation in the new strategy (from the health care professional perspective), iii) taking action to embed the new approach into routines and iv) monitoring the sustainability of any change. Sanders et al. [44] found that GPs in IMPaCT Back perceived back pain as a low clinical priority and highlighted the importance of practical and integrated decision tools to assist in adoption and engagement with STarT Back. Without knowledge of the STarT Back trial results at the time, low back pain was generally perceived by GPs as an 'uninteresting' and a clinically unchallenging health problem [44]. Physiotherapists in contrast were keen to adopt the STarT Back approach, and they perceived that it enhanced their role in the management of Low Back Pain (LBP) [45].

GPs who manage a whole range of conditions have been supported to use the STarT Back approach with the help of implementation strategies outlined by Lau et al. [15], e.g. knowledge mobilisation fellows, clinical champions, electronic templates embedded in routine consultations that prompt screening for red flags, the nine-item STarTBack tool [46] that auto-calculates the score in real time consultations illustrating level of risk, automated access to evidence based patient information and direct electronic referral to physiotherapy for those in medium- and high-risk categories (http://www.keele.ac.uk/sbst/).

The STarT Back approach has also been adopted widely in the UK and overseas and has been refined by local general practice, physiotherapy champions and knowledge mobilisation fellows to fit with local needs (http://www.keele.ac.uk/sbst/).

A dedicated implementation team, led by a knowledge mobilisation fellow (Stevenson) who was funded by the National Institute of Health Research, UK, worked closely with the research team to enhance the uptake of STarT Back. Using the findings from IMPaCT Back, the team worked with local GPs, patients, commissioners and providers and developed, tested and evaluated the uptake of the electronic STarT Back e-template. They installed the e-template initially in 17 general practices and

Table 3
Outcome measure methods for measuring the effects of models of care.

Level of outcome measure	Description	Back pain and OA examples	Data collection options
Patient level	Impact on patients of the model of care	Pain and function, quality of life	Self-reported questionnaires, interviewer-administered questionnaires
Provider level	Impact on health care provider of the model of care	OA: Increased rate of referral for exercise prescription LBP: Decreased rate of X-ray referrals	Administrative/clinical database Quality indicators Questionnaires, interviews with providers
System/society level	Impact on the health system of the model of care	Healthcare costs, waiting times for knee replacement	Administrative database Questionnaires

audited with 866 patients who consulted about low back pain during that time. Locally, 190 physiotherapists have been trained to deliver the matched treatments used in the stratified care approach.

Case studies can help to illustrate the basis of decision-making for GPs on how to integrate the STarTBack Tool in consultations for back pain (e.g. http://www.gmc-uk.org/3_20_MSK_May_2014.pdf_56885470.pdf (accessed 25/02/16)). (See also Supplementary material S2.1 Case Study.)

The STarTBack tool has been translated into 12 languages. Services overseas who are adopting a stratified care approach for back pain include Australia, Denmark, Scandinavia, Canada and the United States. InterMountain Healthcare (based in Salt Lake City) have implemented this for use in Utah and Idaho (across 22 hospitals and 185 clinics); Fair View Healthcare have integrated STarT Back into their electronic patient record (EPIC) and across their services in Minnesota and are collaborating with group health cooperatives, who have implemented the STarT Back approach in Seattle. The Ontario government and the Centre for Effective Clinical Practice have adopted the STarTBack approach into their guidelines, and in Denmark, the government has approved the training of 1000 physiotherapists using translated versions of the training materials (http://www.keele.ac.uk/sbst/commissioners/impact/).

The STarT Back approach now features as a recommendation in the draft 2016 NICE Low Back Pain Guideline.

From discipline-specific to the primary therapist model of service delivery

The Arthritis Society, Ontario Division, Canada, has a long history of providing community-based physiotherapy, occupational therapy and social work services in the home, clinic and through groups as well as individual clients of all ages with arthritis. These services have been and continue to be provided at no cost to the client under the Arthritis Rehabilitation and Education Programme (http://arthritis.ca/manage-arthritis/living-well-with-arthritis/living-well-in-your-province/living-well-in-ontario/therapy-services), which is funded by the Ontario Ministry of Health and Long-term Care (http://www.health.gov.on.ca/en/). Until April 1994, care was provided as discipline-specific services with each service requiring a separate referral, assessment and treatment planning and implementation. It was recognised that there was duplication of services resulting in lost efficiencies (increased travel time, increased charting time) and often lack of continuity of care and a sense of intrusion given the multiple providers by clients [47]. These challenges led the Society to propose and, with funder approval, institute a primary therapist model of care in 1994, which continues today.

In the primary therapist model, clients with a confirmed physician diagnosis of arthritis can self-refer to the programme; referrals are also accepted from other health professionals. The therapist functions as a case manager and multi-skilled rehabilitation professional [47,48]. The first available physiotherapist or occupational therapist assesses the client to initiate education and treatment; other health disciplines serve a consultative role as needed. Transition to a primary therapist model was enabled as, although the disciplines had functioned independently, some aspects of the model were already in place. Specifically, all therapists received the same specialised training in the assessment of polyarthritis [49], and the core assessment components and charting requirements were the same for each discipline. In moving to the primary therapist model, skills of each discipline were enhanced through targeted education to enable therapists to utilise each other in a consultative role rather than having to transfer care to another discipline [47]. For example, the physiotherapist would consult the occupational therapist in recommending off-the-shelf splints to a client rather than transferring the client's care to the occupational therapist.

The Society employs physiotherapists, occupational therapists and social workers, all of whom receive specialised training in arthritis management (Assessment of Inflammatory Polyarthritis Training Programme, now being offered as the Clinical Practice Skills in Inflammatory Arthritis Programme) [49,50]. Additionally, some of the Society therapists have been trained through the Advanced Clinician Practitioner in Arthritis Care Programme and are able to assess, diagnose, triage and independently manage select musculoskeletal and arthritic disorders [51]. Working in an advanced practice role, these healthcare providers perform complete joint examinations, review laboratory and radiology results (in many cases, they are also able to order additional tests) and coordinate care with other providers. All primary therapists consult with the client's primary care physician or rheumatologist if a change in the patient's status requires additional review and consideration of change in management.

Primary therapist services currently are offered in all of the health regions in Ontario, Canada, delivering education and care at select Arthritis Society offices, in primary health care clinics, in specialised rheumatology clinics, at home, through a variety of groups and through telemedicine. This primary therapist model and work within advanced practice roles has facilitated and been integrated into models of care in partnership with other healthcare providers in many jurisdictions to target care gaps and needs (e.g. triage for early access to a rheumatologist for patients with inflammatory arthritis requiring Disease Modifying Anti-Rheumatic Drugs (DMARDS), triage of surgical candidates for hip or knee replacement and ongoing follow-up for stable patients).

Positive health outcomes, including symptom management and improved function and quality of life, were demonstrated for people with rheumatoid arthritis in the initial programme evaluation [47], and these results were supported in a subsequent randomised trial comparing the primary therapist model with traditional outpatient rehabilitation services by physiotherapists or occupational therapists [52]. An analysis of cost-effectiveness from a societal perspective suggested that mean quality-adjusted life years (QALYs) increased for the primary therapist model compared with the traditional physiotherapists (PT) or occupational therapists (OT) delivered in an outpatient setting; however, this difference between the treatment groups was not statistically significant [53]. Given the high variability in the incremental cost-effective ratios in the sensitivity analyses, the authors suggested that strategies to reduce costs need to be considered before the primary therapist model could be recommended for widespread implementation in other jurisdictions. No evaluation data have been published in relation to OA or other types of arthritis.

The primary therapist model development and implementation provides a contrast to the primary care OA and stratified care for back pain models. In the former, recognising the initial primary therapist model was developed and implemented more than 30 years ago, the model has evolved as evidence has accumulated related to best practice care and effective delivery models, including changing health professional roles and processes of care delivery. Province-wide implementation occurred through a single oversight entity, The Arthritis Society, building partnerships with local communities and healthcare providers to contextualise service delivery to the community needs. This contextualisation is evident in the range of services and the variety in the programming and location of delivery (e.g. group, individual, home, clinic). Evaluation of the model in a ‘pure’ research paradigm is limited with the Society responsible for meeting criteria determined with the funder. In contrast, the primary care OA and back pain models evolved through a more traditional evidence-pipeline, with evidence first generated in the context of a randomised controlled trial. The two newer primary care models have the advantage of being developed within a growing culture of implementation research and knowledge mobilisation practice and therefore have implementation frameworks such as those of Nilsen [24] and Briggs et al. [32] to plan, develop, understand and evaluate the model of service delivery. Research on implementation of such models can therefore facilitate implementation activity much earlier in a research cycle.

Summary

Three models of primary care have been described in detail: an integrated model of care, stratified care model and a primary therapist model of musculoskeletal care. Models have developed different approaches to tackle best care for patients with peripheral OA, low back pain and arthritis. Whilst such models differ, they all implement frontline recommendations in primary health care. Within the spectrum of musculoskeletal conditions managed in primary care, models have been successfully tailored to different conditions: integrated care for a LTC such as OA, stratified care for non-specific LBP and multidisciplinary care for arthritis.

We have proposed a number of recommendations for implementing evidence-based innovations mapped to the context within which any implementation is proposed, e.g. governmental, policy; organisational barriers and facilitators, e.g. primary care systems and processes; and professional considerations such as roles and attitudes to change and innovation. Successful pilots can lead to wider uptake and adoption and spread at a pace and scale in high-income countries.

Evaluation of musculoskeletal models of care: process evaluation, QIs and outcome measures

The purpose of this section is to give an overview of process evaluation, QIs and outcome measures for the evaluation of the implementation of models of care for musculoskeletal conditions in the context of a framework recently developed for models of care [32]. We briefly discuss challenges in selecting these measures.

The primary question when evaluating the effectiveness of a new model of care is: ‘Is this model of care effective?’ However, with further consideration more complex questions arise, including the following:

- How was the model of care developed?
- What are the expected causal mechanisms?
- Was the model of care delivered as planned?
- Which components of the model of care are responsible for the outcomes?
- Has the model of care changed from the original intent?
- Which outcomes have the model of care intervention changed, if any?

Hence, the choice of outcomes is critical depending on the primary purpose of the evaluation. The causal pathway when determining whether a model of care is effective is as follows: (1) identify mediators of change to investigate the proposed pathways of change; (2) measure constructs theorised to be mediators of behaviour change; (3) select appropriate outcome measures; and (4) determine the feasibility of outcomes to be measured.

For example, in the IMPLEMENT (IMPLEmenting a clinical practice guide for acute low back pain evidence-based manageMENT in general practice) study, a new model of care was evaluated that aimed to improve the quality of primary care low back pain management [54]. The intervention aimed to decrease lumbar imaging and increase the prescription of advice to stay active. The research team chose a number of different outcomes to determine both the effect of the intervention and the process of behaviour change, including theory-based practitioner process level outcomes through self-reported questionnaire, practitioner clinical behaviour through administrative data (X-ray referral rates) and patient level outcomes measured through patient questionnaire (pain and low back specific disability).

When evaluating the implementation of models of care for the management of OA or low back pain, it is important to assess not only the ultimate outcomes of the model of care implementation but also the processes of implementation. Choosing just a single outcome may not make the best use of the evaluation plan; a range of outcome and process measures would be needed and unintended consequences of the model's implementation should be determined where possible [55].

Many study designs can be used to evaluate the implementation of models of care [56]. Randomised controlled trials are the gold standard for evaluating the implementation of models of care, but effect sizes alone provide limited information [57,58]. Effect sizes do not provide users of the research with information on how a model of care might be replicated in their specific context or whether trial outcomes would be reproduced.

Process evaluations

Currently, there is no accepted framework/method for deciding on process evaluation [57]. Process evaluations are studies run in parallel to, or following, intervention trials and help to understand the trial processes or underlying mechanisms in relation to context, setting, professionals and patients. Process evaluations also provide explanations for the results of the study and enhance understanding on whether, or how, interventions could move from the research setting to clinical practice. Process evaluations can be used to assess intervention fidelity, explore causal mechanisms and identify contextual factors associated with any variations in outcomes.

Process evaluation can combine a range of study methods and cross-sectional or longitudinal designs. These may include questionnaire surveys of the target group for the intervention, qualitative interviews, direct observation and medical record review [55,57].

One example of process evaluation is the evaluation of implementation fidelity, which is a measure of whether an intervention is delivered as planned [59]. If intervention fidelity is not determined, the implications are significant [60]. If a model of care is found to be effective but the model is not delivered with high fidelity, the effect may be due to unknown factors that were unintentionally added or omitted. On the contrary, if the model of care is found to be ineffective, it will not be known if this was because it was an ineffective model of care or if it was poor implementation of an effective model of care [61].

In the IMPLEMENT study referred to earlier, the intervention was a series of interactive educational workshops led by peer opinion leader facilitators, involving simulated patient interactions. A number of BCTs were planned to be delivered across the workshops, and the fidelity evaluation compared planned and actual, and observed versus self-assessed, delivery of these BCTs [62]. A mixed methods approach was used to evaluate the fidelity. The results demonstrated that 75% of GPs assigned to the intervention group attended the workshop, the overall observed adherence to BCTs was 79% and there was no significant difference in adherence to BCTs between different facilitators. As a result of this fidelity assessment, the investigators were confident that trial results are due to an intervention delivered as planned.

QIs of care

Quality of care for people with musculoskeletal pain in general practice is not routinely collected, but QIs can be used to assess whether quality standards of care (e.g. NICE quality standards) are being met [36,38]. QIs have been defined as ‘specific and measurable elements of practice that can be used to assess the quality of care’ and have been developed to audit standards such as those produced by NICE for OA [5,7,63–65] and also by EUMUSC.net for OA and rheumatoid arthritis [63,64]. QIs typically assess the processes of care given to patients by measuring what the provider can offer patients and examining whether standards of care are being met [5,7,38].

QIs can be used in electronic medical records in general practice as a prompt during the consultation [36] (see Fig. 3), in patient self-reported questionnaires to evaluate care following consultations [38,66] and by health care professionals and across organisations to assess variation [67].

Outcome measures

Outcomes to measure change in clinical practice are complex. First, different stakeholders and knowledge users of the research may prioritise different outcomes, for example, health policy makers may prioritise costs, clinician groups may prioritise improved processes of care and patients may prioritise clinical outcomes. In addition, the ‘levels’ of those outcomes vary, and they can be grouped into three broad categories [68,69]: (i) patient level outcomes, i.e. health measures, health behaviours; (ii) healthcare provider level outcomes, i.e., specific practitioner clinical behaviour; and (iii) system/societal level outcomes, i.e., costs, improved waiting times (Table 3).

It has been determined that less than one-third of studies assessing the effectiveness of implementing new models of care, in the form of guideline-based care, measure outcomes at the patient level [68]. However, it may be unreasonable to expect significant change in patient outcomes when the model of service delivery is directed primarily at improving the system, e.g. referral for core non-pharmacological therapy before referral to surgery for knee OA, or at changing health practitioner clinical behaviour, e.g. reduction in the use of imaging for low back pain.

One of the dilemmas faced by researchers when planning to evaluate the implementation of a model of care is to determine which outcome should be the primary outcome. Patient outcomes are available for OA and low back pain that have strong psychometric properties demonstrating reliability and validity [70–72]. Advantages of measuring patient level outcomes include measuring outcomes important to patients, choice of valid and reliable outcome measures; having the ability to undertake a cost-effectiveness analysis and finally having the ability to examine the full causal pathway. The disadvantages include increased resources and time to undertake the study, and it may be unrealistic to expect the patient level change when the intervention is directed primarily at a different level. If the model of care is not directed specifically at improving patient outcomes, then another level of outcome needs to be chosen. If patient outcomes are not chosen as the primary outcome, then researchers need to decide which outcomes best reflect the effect of the implementation of the model of care.

Evaluating an intervention (as a component of care) can use specific measures that determine change in a defined construct, whereas a broader approach is useful for a model of care that might have a number of interdependent facets and may need a multidimensional, mixed methods evaluation. Here, the value patients place on the outcome is important and can increase the sensitivity to broader changes in the system and in care.

The alternate approach is to choose a process level outcome. However, very few of these types of measures are psychometrically validated [73]. Development of more methods is needed in this area, and this is an active and emerging field of implementation science [74,75].

Practice points

- For evaluation of the implementation of models of care, there is a need to measure at multiple levels across healthcare systems, including system level changes (e.g. improved care processes), clinician changes (e.g. clinical behaviour change) and patient health outcomes
- Outcomes can measure the process of the implementation as well as the clinical outcomes for the patient

In summary, more process evaluations in this area will contribute substantially to the knowledge base in this field. For outcome measures, it is important to choose outcome and process measures that stakeholders and knowledge users of the research want and consider important. Meaningful consultation with these interested groups prior to the commencement of the evaluation is critical. It is important to use valid and reliable measures where possible, but researchers must remain flexible when such measures do not exist to measure the domain of choice. This presents an opportunity to evaluate the psychometric properties in parallel to using the measure with development of more methods, which is needed to produce reliable and valid measures [31]. A recently developed evaluation framework for musculoskeletal models of care should also be considered when selecting outcomes [31,32].

Health economics in implementation research and practice: what and how to evaluate

Musculoskeletal diseases are common, the associated impact is pervasive and the sequelae are increasing as the population ages. Hence, the economic burden is considerable. While mortality does not tend to be high for this group, the significant impact on disability, social functioning and employment has severe economic consequences for the individual and their community [32,76].

The economic burden of a disease is commonly classified within direct, indirect and intangible costs. In terms of direct costs or healthcare utilisation, musculoskeletal conditions represent one of the commonest reasons for seeking medical consultations and hence comprise a significant proportion of primary care visits [77]. Associated referrals, hospital admission and prescription medication costs are correspondingly high, although the cost of treatment can be variable, depending on the need for multidisciplinary care, the selected intervention and the severity of the condition. Indirect costs, represented by the impact on productivity, present an even greater economic burden due to the chronicity of conditions, frequent co- and multi-morbidities and the frequent disability that often influences social function and independence [78]. However, indirect costs are in general difficult to measure because of difficulties in ascribing cost to both paid and unpaid work, because the impact of musculoskeletal conditions affects presenteeism as well as absenteeism and because of the heterogeneity of the population. Further costs associated with psychological status, such as anxiety [79], are defined as intangible costs that are also significant for these conditions.

Given the expected large increase in the burden of musculoskeletal conditions combined with the constraints on healthcare spending (largely due to increasing technologies and increased life expectancy), the importance of recognising the economic implications throughout healthcare intervention is paramount. Within the context of an accepted basis of evidence-based care, efficiency is an important element to ensure that resource allocation is optimised to maximise total benefits for the population. However, as a system-level outcome, there are difficulties in encompassing the scope of outcomes as given above.

Cost-effectiveness provides a means of measuring benefit for a given cost. It measures the cost of the intervention and evaluates whether the health benefit gained is worth the cost. A cheaper intervention does not necessarily determine improved cost-effectiveness. The incremental cost-effectiveness ratio – usually expressed as the incremental cost per quality adjusted life year gained (cost/QALY) – provides information on the value (efficiency) of an intervention relative to alternative choices. The total budgetary cost of introducing a new intervention, which considers the prevalence of disease and the potential impact on infrastructure, is additionally of interest to policy-makers in terms of resource allocation.

However, calculation and interpretation of the cost-effectiveness ratio can be problematic for interventions related to musculoskeletal conditions in primary care. This group of diseases reflects a broad range of severity, large variation in interventional options including referral patterns and considerable population diversity. Problems include the potential variation in cost-effectiveness across subgroups, the choice of comparator (i.e. baseline) and the perspective taken. In terms of perspective, costs and outcomes reflecting the health system may, for example, exclude important societal outcomes. In the case of more complex interventions, delivered as components of models of care, cost-effectiveness may depend on the characteristics of the relevant healthcare providers (such as the level of expertise in applying screening tools and undertaking treatment plans) and characteristics of individual patient response to treatment protocols. These factors raise difficulties in generalising results across providers. Further, cost-effectiveness ratios do not commonly include indirect costs because of the problems identified above. Given that indirect costs can be overriding in this group of diseases, the measured value of an intervention may be severely underestimated (i.e. the cost savings can be expected to be much higher) if, in addition to improving health, the return to regular social functioning and work occurs sooner.

The cost-effectiveness of a stratified approach to a model of care for back pain provides a salient example of different outcomes according to a targeted approach to chronic back pain (see also the case study described earlier) [41]. Whitehurst et al. [41] compared a stratified intervention for back pain with non-stratified best practice for three groups classified as high, medium or low severity and outcomes were adjusted for quality of life. The medium-severity group demonstrated a cost-saving intervention, while the groups with greater or lesser severity demonstrated cost-effectiveness. A cost-saving result indicates that the intervention will improve the health of the target group and concurrently reduce the resource demand. Most interventions require net resource inputs (i.e. costs) to achieve a health benefit and these are ‘cost-effective’ when they fall below a given threshold. Higher- and lower-severity groups were appropriately deemed cost-effective interventions since ratios fell well below the accepted thresholds.

Important elements of cost-effectiveness include establishing a clear baseline of the status quo to compare the incremental difference in terms of both resource inputs (costs) and health outcomes. Costs and outcomes require evaluation over the same time horizon. Resource inputs require identification, measurement and valuation. That is, each resource input should be measured in terms of the number of units (e.g. hours of physiotherapy time or days of hospital admission), then valued as a cost by ascribing a per unit cost value standardised to an index year. Outcomes may be represented in natural units such as fractures prevented or life years gained, but to provide information for resource allocation, generic outcome units such as QALYs are necessary. Sensitivity analysis is a necessary addition to assess robustness given the potential variation of parameters. A formal cost-effectiveness evaluation may require expert input to ensure appropriate collection of data (e.g. quality of life requires a suitable generic instrument rather than a disease-specific instrument for the calculation of QALYs) and to estimate acceptability curves and confidence ellipses (see for example Whitehurst et al. [41]).

Practice points

- Health economic evaluations are important in the transfer of models of care from evidence to practice
- Cost-effectiveness to assess the value of health outcomes subject to intervention requires consideration rather than simply seeking cost savings
- Economic evaluation for MSK may require more complex methodological techniques such as multi-criteria decision analysis in order to adequately capture the complexity of outcomes

In summary, musculoskeletal conditions present a significant cost to countries throughout the world and the problem is set to increase as the global population ages. Despite the challenges of measurement and interpretation of cost-effectiveness, it will be necessary to develop models of care, including calculation of efficiency, to minimise social and economic consequences.

Future directions and research priorities

Given the heterogeneity of severity, issues of chronicity and co-morbidity, ongoing work to develop and improve risk stratification to personalise evidence-based care for those with musculoskeletal conditions is needed. Stratification, as a component within contemporary models of care, may be one mechanism to ensure people get the right care at the right time by the right provider to improve the use of limited resources. There is a need to consider how the models described in this chapter can be implemented in care settings where geography and long distances pose challenges. Technology for training healthcare professionals such as web-based training and other technologies for delivering models of care, e.g. across Canadian northern communities, Australia, and the US by using telemedicine and Information Technology (IT) applications (Apps) for patient information and self-assessment to support self-management, have the ability to transform the implementation of models of care in the future.

Box 1 describes potential research priorities.

Box 1
Research priorities.

1. Risk stratification development, especially for musculoskeletal pain where benefits for low back pain might be transferable to other musculoskeletal conditions
2. Understanding how context impacts implementation to facilitate upfront planning for spread and implementation in other settings
3. Studying self-management as a focus of models of service delivery – patients want to self-monitor and be able to re-engage with providers at appropriate times for advice or revised interventions.
4. Understanding the barriers and facilitators to self-monitoring, including those of the organisation, e.g. limited linkage of technologies with health data; those of the health professionals, e.g. confidence in remote consultations; and patients, e.g. use of new technologies and considering how this might fit into models of care.
5. Ongoing development of methods for the evaluation of models of care, outcomes and costing approaches to provide data that can be easily interpreted for business cases and service planning in primary care practice.

Summary

Musculoskeletal conditions represent one of the largest causes of years lived with disability in high-income nations. These conditions are predominantly managed in primary care where there are numerous evidence-to-practice gaps; however, there is a paucity of evidence on which approaches work well in increasing the uptake of best practice. Increasingly, musculoskeletal models of care, which include specific service delivery models such as integrated care, stratified care and therapist-led care have been tested in primary healthcare pathways for joint pain in older adults, low back pain and arthritis. In this chapter, we have discussed why implementation of these models is important for primary care using three case examples; we reviewed implementation theory, principles and outcomes; we considered the role of health economic evaluation; and we highlighted key evidence gaps. The recommendations and processes put forward relate specifically to high-income nations, and other approaches to delivering the right care will necessarily vary in low- and middle-income economies.

Research priorities for this area include investigating the generalisability of models of care across, for example, urban and rural settings, and for different musculoskeletal conditions; increasing the support for self-management; understanding the importance of context in choosing an appropriate model of care; and evaluating implementation and its impact in real-world applications.

Conflict of interest statement

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.berh.2016.08.004.

References

[1] World Health Organization. Alma-Ata 1978: primary care report. Report of the International Conference on Primary Care, Alma-Ata, Union of Soviet Socialist Republics, 6–12 September 1978. Geneva: World Health Organization; 1978.

[2] Murray C, Vos T, Lozano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012;380:2197–222.

[3] Jordan KP, Joud A, Bergknut C, et al. International comparisons of the consultation prevalence of musculoskeletal conditions using population-based healthcare data from England and Sweden. Ann Rheum Dis 2014;73(1):212–8.

[4] Britt H, Miller GC, Henderson J, et al. General practice activity in Australia 2014–15. General practice series no. 38. Sydney: Sydney University Press; 2015. Available at, purl.library.usyd.edu.au/sup/9781743324523.

[5] Steel N, Bachmann M, Maisey S, et al. Self reported receipt of care consistent with 32 quality indicators: national population survey of adults aged 50 or more in England. Br Med J 2008;337:a957.

[6] Porcheret M, Jordan K, Jinks C, et al. Primary care treatment of knee pain–a survey in older adults. Rheumatology (Oxford) 2007;46(11):1694–700.

[7] Broadbent J, Maisey S, Holland R, et al. Recorded quality of primary care for osteoarthritis: an observational study. Br J Gen Pract 2008;58(557):839–43.

[8] Williams CM, Maher CG, Hancock MJ, et al. Low back pain and best practice care: a survey of general practice physicians. Arch Intern Med 2010;170(3):271–7.

[9] Runciman WB, Hunt TD, Hannaford NA, et al. CareTrack: assessing the appropriateness of health care delivery in Australia. Med J Aust 2012;197(2):100–5.

[10] Mafi JN, McCarthy EP, Davis RB, et al. Worsening trends in the management and treatment of back pain. JAMA Intern Med 2013;173(17):1573–815.

*[11] Briggs AM, Towler SC, Speerin R, et al. Models of care for musculoskeletal health in Australia: now more than ever to drive evidence into health policy and practice. Aust Health Rev 2014;38:401–5.

*[12] Speerin R, Slater H, Li L, et al. Moving from evidence to practice: models of care for the prevention and management of musculoskeletal conditions. Best Pract Res Clin Rheumatol 2014;28:479–515.

[13] Briggs AM, Cross MJ, Hoy DG, et al. Musculoskeletal health conditions represent a global threat to healthy aging: a report for the 2015 World Health Organisation World Report on Ageing and Health. Gerontologist 2016;56:S234–55.

[14] Kadu MK, Stolee P. Facilitators and barriers of implementing the chronic care model in primary care: a systematic review. BMC Fam Pract 2015;16:12.

[15] Lau L, Stevenson F, Ong BN, et al. Achieving change in primary care—causes of the evidence to practice gap: systematic reviews of reviews. Implement Sci 2016;11:40. http://dx.doi.org/10.1186/s13012-016-0396-4.

[16] Dominick CH, Blyth FM, Nicholas MK. Unpacking the burden: understanding the relationships between chronic pain and comorbidity in the general population. Pain 2012;153(2):293–304.

[17] Barnett K, Mercer SW, Norbury M, et al. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet 2012;380(9836):37–43.

[18] Dhalwani NN, O'Donovan G, Zaccardi F, et al. Long terms trends of multimorbidity and association with physical activity in older English population. Int J Behav Nutr Phys Act 2016;13:8.

[19] Mathers N, Paynton D. Rhetoric and reality in person-centred care: introducing the House of Care framework. Br J Gen Pract 2016 Jan;66(642):12–3.

[20] May C. The hard work of being ill. Chron Illn 2006;2(3):161–2.

[21] Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q 2004;82(4):581–629.

*[22] Eccles M, Grimshaw J, Walker A, et al. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. J Clin Epidemiol 2005:107–12.

[23] ICEBeRG. Designing theoretically-informed implementation interventions. Implement Sci 2006;1:4.

[24] Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015;10:53. http://dx.doi.org/10.1186/s13012-015-0242-0.

[25] Hudon A, Gervais MJ, Hunt M. The contribution of conceptual frameworks to knowledge translation interventions in physical therapy. Phys Ther 2015;95(4):630–9.

[26] Grol R, Wensing M, Eccles M. Improving patient care: the implementation of change in clinical practice. Edinburgh: Elsevier; 2005.

[27] French SD, Green SE, O'Connor DA, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. Implement Sci 2012;7:38.

*[28] Porcheret M, Main C, Croft P, et al. Development of a behaviour change intervention: a case study on the practical application of theory. Implement Sci 2014;9:42.

[29] Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: a consensus approach. Qual Saf Health Care 2005;14(1):26–33.

*[30] Michie S, Johnston M, Francis J, et al. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. Appl Psychol Int Rev 2008:660–80.

*[31] Briggs AM, Jordan JE, Jennings M, et al. A framework to evaluate musculoskeletal models of care. Cornwall: Global Alliance for Musculoskeletal Health of the Bone and Joint Decade; 2016. http://bjdonline.org/a-framework-to-evaluate-musculoskeletal-models-of-care/.

[32] Briggs AM, Jordan JE, Jennings M, et al. Supporting evaluation and implementation of musculoskeletal Models of Care: development of a globally-informed framework for judging 'readiness' and 'success'. Arthritis Care Res 2016; Jun 6. http://dx.doi.org/10.1002/acr.22948 [Epub ahead of print] PubMed PMID: 27273891.

*[33] Dziedzic K, Healey E, Porcheret M, et al. Implementing the NICE osteoarthritis guidelines: a mixed methods study and cluster randomised trial of a model osteoarthritis consultation in primary care - the Management of OsteoArthritis In Consultations (MOSAICS) study protocol. Implement Sci 2014;9:95.

[34] Conaghan PG, Dickson J, Grant RL, et al. Care and management of osteoarthritis in adults: summary of NICE guidance. Br Med J 2008:502–3.

[35] Kennedy A, Rogers A, Bower P. Support for self care for patients with chronic disease. Br Med J 2007;335(7627):968–70.

[36] Edwards J, Jordan K, Peat G, et al. Quality of care for OA: the effect of a point-of-care consultation recording template. Rheumatology 2015;54:844–53.

[37] Porcheret M, Grime J, Main C, et al. Developing a model osteoarthritis consultation: a Delphi consensus exercise. BMC Musculoskelet Disord 2013;14:25.

[38] Blackburn S, Higginbottom A, Taylor R, et al. Patient-reported quality indicators for osteoarthritis: a patient and public generated self-report measure for primary care. Res Involv Engagem 2016;2:5. http://dx.doi.org/10.1186/s40900-016-0019-x.

*[39] Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011:1560–71.

[40] Main CJ, Sowden G, Hill JC, et al. Integrating physical and psychological approaches to treatment in low back pain: the development and content of the STarT Back trial's 'high-risk' intervention (StarT Back; ISRCTN 37113406). Physiotherapy 2012;98(2):110–6.

[41] Whitehurst DG, Bryan S, Lewis M, et al. Exploring the cost-utility of stratified primary care management for low back pain compared with current best practice within risk-defined subgroups. Ann Rheum Dis 2012;71(11):1796–802.

[42] Foster NE, Mullis R, Hill JC, et al. Effect of stratified care for low back pain in family practice (IMPaCT Back): a prospective population-based sequential comparison. Ann Fam Med 2014;12(2):102–11.

[43] May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: Normalization Process Theory. Implement Sci 2009;4:29.

[44] Sanders T, Foster NE, Ong BN. Perceptions of general practitioners towards the use of a new system for treating back pain: a qualitative interview study. BMC Med 2011;9:49.
[45] Sanders T, Ong BN, Sowden G, et al. Implementing change in physiotherapy: professions, contexts and interventions. J Health Organ Manag 2014;28(1):96–114.
[46] Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum 2008;59(5):632–41.
*[47] Lineker SC, Wood H, Badley EM, et al. Evaluation of the primary therapist model of service delivery as implemented by The Arthritis Society, consultation and rehabilitation service. Phase 1: therapist survey. Working Paper 98-5. Toronto, Ontario, Canada: Arthritis Community Research & Evaluation Unit; 1998.
[48] Hurst K. Multi-skilled health carers: nature, purpose and implications. Health Manpow Manag 1997;23:197–211.
[49] Helewa A, Smythe HA, Goldsmith CH, et al. The total assessment of rheumatoid polyarthritis—evaluation of a training program for physiotherapists and occupational therapists. J Rheumatol 1987;14(1):87.
[50] Stokes BA, Helewa A, Lineker SC. Total assessment of rheumatoid polyarthritis–a postgraduate training program for physical and occupational therapists: a 20 year success story. J Rheumatol 1997:1634–8.
[51] Lundon K, Shupak R, Schneider R, et al. Development and early evaluation of an inter-professional post-licensure education programme for extended practice roles in arthritis care. Physiother Can 2011;63(1):94–103.
[52] Li LC, Davis AM, Lineker SC, et al. Effectiveness of the primary therapist model for rheumatoid arthritis rehabilitation: a randomized controlled trial. Arthritis Rheum 2006;15;55(1):42–52.
[53] Li LC, Maetzel A, Davis AM, et al. Primary therapist model for patients referred for rheumatoid arthritis rehabilitation: a cost-effectiveness analysis. Arthritis Rheum 2006;55(3):402–10.
[54] McKenzie JE, French SD, O'Connor DA, et al. IMPLEmenting a clinical practice guideline for acute low back pain evidence-based manageMENT in general practice (IMPLEMENT): cluster randomised controlled trial study protocol. Implement Sci 2008;3:11.
[55] Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655.
[56] Portela MC, Pronovost PJ, Woodcock T, et al. How to study improvement interventions: a brief overview of possible study types. BMJ Qual Saf 2015;24(5):325–36.
[57] Grant A, Treweek S, Dreischulte T, et al. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. Trials 2013;14:15.
[58] Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015;350:h1258.
[59] Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol 2005;73(5):852–60.
[60] Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J Public Health Dent 2011;71(Suppl. 1):S52–63.
[61] Briggs AM, Jordan JE, Speerin R, et al. Models of care for musculoskeletal health: a cross-sectional qualitative study of Australian stakeholders' perspectives on relevance and standardised evaluation. BMC Health Serv Res 2015;15:509.
*[62] French SD, Green SE, Francis JJ, et al. Evaluation of the fidelity of an interactive face-to-face educational intervention to improve general practitioner management of back pain. BMJ Open 2015;5(7).
[63] Stoffer MA, Smolen JS, Woolf A, et al. Development of patient-centred standards of care for osteoarthritis in Europe: the eumusc.net-project. Ann Rheum Dis 2015 Jun;74(6):1145–9.
[64] Petersson IF, Strömbeck B, Andersen L, et al. Development of healthcare quality indicators for rheumatoid arthritis in Europe: the eumusc.net project. Ann Rheum Dis 2014;73(5):906–8.
[65] National Institute for Health and Care Excellence. Quality standard for osteoarthritis (QS87). https://www.nice.org.uk/guidance/qs87. [accessed 01.06.16].
[66] Østerås N, Garratt A, Grotle M, et al. Patient-reported quality of care for osteoarthritis: development and testing of the osteoarthritis quality indicator questionnaire. Arthritis Care Res 2013;65:1043–51.
[67] Østerås N, Jordan KP, Clausen B, et al. Self-reported quality care for knee osteoarthritis: comparisons across Denmark, Norway, Portugal and the UK. RMD Open 2015;20;1(1):e000136.
[68] Hakkennes S, Green S. Measures for assessing practice change in medical practitioners. Implement Sci 2006;1:29.
[69] Straus SE, Tetroe J, Bhattacharyya O, et al. Monitoring knowledge use and evaluating outcomes. In: Straus S, et al., editors. Knowledge translation in health care: moving from evidence to practice. 2nd ed. 2013. Chichester, West Sussex; Hoboken, NJ: Wiley/BMJ Books.
[70] Ostelo RW, de Vet HC. Clinically important outcomes in low back pain. Best Pract Res Clin Rheumatol 2005;19(4):593–607.
[71] Chiarotto A, Deyo RA, Terwee CB, et al. Core outcome domains for clinical trials in non-specific low back pain. Eur Spine J 2015:1127–42.
[72] Pham T, van der Heijde D, Altman RD, et al. OMERACT-OARSI initiative: Osteoarthritis Research Society International set of responder criteria for osteoarthritis clinical trials revisited. Osteoarthr Cartil 2004;12(5):389–99.
[73] Rabin BA, Lewis CC, Norton WE, et al. Measurement resources for dissemination and implementation research in health. Implement Sci 2016;11:42.
[74] Lewis CC, Fischer S, Weiner BJ, et al. Outcomes for implementation science: an enhanced systematic review of instruments using evidence-based rating criteria. Implement Sci 2015;10:155.
[75] Martinez RG, Lewis CC, Weiner BJ. Instrumentation issues in implementation science. Implement Sci 2014;9:118.
[76] Hunter DJ, Schofield D, Callander E. The individual and socioeconomic impact of osteoarthritis. Nat Rev Rheumatol 2014;10:437–44.
[77] http://www.who.int/bulletin/volumes/81/9/Woolf.pdf.
[78] Arthritis and Osteoporosis Victoria. A problem worth solving. The rising cost of musculoskeletal conditions in Australia. Melbourne: Arthritis and Osteoporosis Victoria; 2013. http://www.move.org.au/Research/Funded-Research/Completed/A-Problem-Worth-Solving.
*[79] Lubeck DP. The costs of musculoskeletal disease: health needs assessment and health economics. Best Pract Res Clin Rheumatol 2003;17(3):529–39.