

Advancing practice for back pain through stratified care (STarT Back)

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Abstract

Background: Low Back Pain (LBP) is common, however research comparing the effectiveness of different treatments over the last two decades conclude either no or small differences in the average effects of different treatments. One suggestion to explain this is that patients are not all the same and important subgroups exist that might require different treatment approaches. Stratified care for LBP involves identifying subgroups of patients and then delivering appropriate matched treatments. Research has shown that stratified care for LBP in primary care can improve clinical outcomes, reduce costs and increase the efficiency of health-care delivery in the UK. The challenge now is to replicate and evaluate this approach in

other countries health care systems and to support services to implement it in routine clinical care.

Results: The STarT Back approach to stratified care has been tested in the National Health Service, within the UK, it reduces unnecessary overtreatment in patients who have a good prognosis (those at low risk) yet increases the likelihood of appropriate healthcare and associated improved outcomes for those who are at risk of persistent disabling pain. The approach is cost-effective in the UK healthcare setting and has been recommended in recent guidelines and implemented as part of new LBP clinical pathways of care. This approach has subsequently generated international interest, a replication study is currently underway in Denmark, however, some lessons have already been learnt. There are potential obstacles to implementing stratified care in low-and-middle-income settings and in other high- income settings outside of the UK, however, implementation science literature can inform the development of innovations and efforts to support implementation of stratified care.

Conclusions: The STarT Back approach to stratified care for LBP is a promising method to advance practice that has demonstrated clinical and cost effectiveness in the UK. Over time, further evidence for both the effectiveness and the adaptations needed to test and implement the STarT Back stratified care approach in other countries is needed.

Bullet Points

- The STarT Back stratified care approach involves the use of a prognostic screening tool and matched treatments.
- Two UK studies have demonstrated improved clinical outcomes and cost savings in the National Health Service.
- Studies testing this approach in other countries are needed to adapt the approach to their own healthcare system.
- A number of potential obstacles to implementing stratified care in high- and low-and-middle-income settings are emerging.
- Evidence based innovations and strategies to overcome these obstacles and support successful implementation are discussed.

Keywords: stratified care; back pain; STarT Back; implementation.

Funding sources

The STarT Back trial was funded by the Arthritis Research UK (grant code 17741) and J.C.H. was supported to lead the STarT Back Trial through a post-doc fellowship from Arthritis Research UK (grant code: 17845).

The IMPaCT study was funded by the Health Foundation under its 'Engaging with Quality in Primary Care Programme' (grant code 346/4540) with support from the National Institute of Health Research (NIHR) Primary Care Research Network-North West, the Keele Academic General Practice Partnership, and the Primary Care Musculoskeletal Research Consortium.

N.E.F. was supported in part by a National Coordinating Centre for Research Capacity Development (NCCRC) Primary Care Career Scientist Award and is currently funded by an NIHR Research Professorship (NIHR-RP-011-015).

The development work in Denmark was funded by The Region of Southern Denmark (grant code 14/24247), The University of Southern Denmark, the Danish Rheumatism Association (grant code A3281) and the Association of Danish Physiotherapists (grant code 10/531).

This article/paper/report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Declarations of interest: none

Introduction, rationale and key principles of stratified care

First contact clinical care, or primary care, for most patients with low back pain (LBP) is provided by a range of clinicians such as family doctors/general practitioners (GPs), physiotherapists and chiropractors. The latest LBP clinical guidelines available^{1,2} generally recommend clinicians triage patients into either those with serious spinal pathology (estimated to be no more than 3-6% of LBP patients in primary care)^{3,4}, nerve root problems (estimates include 36% with pain radiating below the knee)⁵ or non-specific LBP (the majority of cases). The last two decades have seen a considerable increase in the volume of research, particularly randomised controlled trials (RCTs) and systematic reviews^{6,7}, comparing the effectiveness of different treatments for non-specific LBP. Many of these RCTs and systematic reviews conclude either no or small differences in the average effects of different treatments, such as exercise, manual therapy and other physiotherapist-led treatments. Whilst there are several potential explanations for these findings, one suggestion is that these are the result of the inclusion of heterogeneous groups of patients with non-specific LBP, that patients are not all the same and that important subgroups exist that might require different treatment approaches.⁸

Stratified care involves targeting treatment to subgroups of patients with similar characteristics and has been suggested as a method to fast-track patients to

appropriate treatment by supporting clinical decision-making in ways that serve to increase treatment benefit, reduce harm and increase the efficiency of health-care delivery.⁹ LBP is an ideal clinical condition with which to develop and test models of stratified care, given that it includes a heterogeneous population of patients with substantial variability in prognosis,¹⁰ and that numerous treatments are available⁹ with some being costly and associated with high risk (e.g. spinal surgery). Further justification for considering stratified care approaches include the finding that most clinicians believe that non-specific LBP includes a number of distinct patient subgroups¹¹ and that due to the sheer volume of patients attending primary care with LBP it is impractical and unaffordable to refer all for expensive tests and treatments.¹²

There are several broad approaches to stratified care for LBP, those which start with the patient and identify characteristics of patients with which to subgroup them (most commonly using their prognostic profile, key characteristics or an underlying cause or mechanism that is thought to explain their symptoms) or those which start with available treatments and identify patients that appear to benefit more from one treatment over others (most commonly through the development and testing of clinical prediction rules). These different approaches have been considered in more detail elsewhere.¹³ A team at Keele University in the UK have over the last 15 years developed and tested a model of stratified care based on subgrouping and targeting treatment for LBP. Their work has produced a primary care prognostic model in which multiple clinical predictors are used in one simple index of risk (the Keele STarT Back Tool (KSBT)) to identify an individual's risk of persistent disabling LBP and then matches those at low, medium and high risk to appropriate treatments.

The Keele STarT Back Tool

The KSBT is a prognostic tool developed and validated for use in primary care to guide the management of patients with LBP.¹⁴ It has nine items that screen for eight physical and psychological predictors of persistent disabling LBP six months later. These questions are summed into an index score with defined cut-points to identify those at low, medium, or high risk of persistent disabling LBP. The tool has good reliability and validity and has been externally validated in many different settings.¹⁵⁻¹⁸ Clinicians need to interpret the findings of the KSBT in the context of a standard LBP subjective and objective assessment, including a screen for serious pathology (red flags) and a neurological examination. Clinicians can freely download the tool (in a range of languages) from the STarT Back website.¹⁹ This model of stratified care comprises not only the use of the tool but also of matched treatments for each risk subgroup.

The matched treatments

An outline of the three matched treatments is provided below, further information about the development of the STarT Back matched treatments and the associated physiotherapy training and mentoring packages can be found in Sowden et al, 2012, Main et al, 2012,²⁰⁻²¹ and on the STarT Back website.¹⁹

The low risk matched treatments

The matched treatment for patients at low risk of persistent disabling LBP consists of one high quality face to face consultation in which patients are reassured regarding the benign nature of low back pain and its prognosis. Education and advice should focus on positive self-management messages about avoiding bed rest, using appropriate pain medications, keeping active and returning to usual activities, including work or daily routines, as soon as possible. These messages are supplemented and reinforced by evidence based written or online material (e.g. in the UK, the Arthritis Research UK's advice/exercise sheet).²² Patients are discharged after this one-off consultation, thereby avoiding onward referral, unnecessary imaging, sick certification, or strong opioid medication. The data from two UK studies (the STarT Back trial and IMPaCT Back study) suggests that patients at low risk who receive this matched treatment package have pain and function outcomes that are no worse than patients at low risk who go onto receive additional treatments. In fact, for some outcomes, such as time-off-work outcomes were better in those who received stratified care. In addition, the data shows that the healthcare system benefits from greater efficiency and reduced costs from not over-medicalising these low risk patients. This is in keeping with studies in whiplash patients, which suggest that more treatment is not necessarily better²³ and can in fact lead to worse outcomes for some patients.²⁴⁻²⁶ However, clinicians should note that the KSBT aims to assist first-line treatment decision-making and not replace it. Secondary analyses of the STarT Back trial by Beneciuk et al (2017)²⁷ also suggests that low risk patients with low socio-economic status (SES) were more likely to have a poor outcome than patients with high SES.

The matched treatment for patients at medium risk involves a course of evidence based physiotherapy. In addition to the low risk intervention package, patients at medium risk should receive physiotherapy aimed at reducing pain and disability and promoting self-management of the current episode of LBP, as well as future episodes. The course of physiotherapy includes advice, explanation, reassurance, education, exercise (specific and/or general) and if appropriate, manual therapy. Bed rest, traction, massage and electrotherapy are not generally recommended and were not part of the protocol for patients at medium risk in the UK studies of stratified care. Where indicated, a small proportion of patients can be referred for investigations or specialist interventions.²⁸

The high risk matched treatments

The treatment for patients at high risk involves similar evidence based assessment and management (e.g., advice regarding medication and exercises and manual therapy, as indicated) to that given to medium risk patients. However, these physical

approaches are integrated with psychological approaches to treatment. The phrase 'psychologically informed practice' (PIP) was coined to reflect this biopsychosocial, cognitive behavioural physiotherapy treatment approach.²¹ The physiotherapists treating patients at high risk in the STarT Back trial and IMPaCT Back study received six days training in PIP. The training focussed on the use of enhanced communication skills to build rapport and trust with patients and to establish expectations and agree objectives for treatment. The physiotherapists were trained to validate and normalise patient's experiences and to adopt motivational interviewing techniques to maximise treatment effectiveness. They conducted a comprehensive biopsychosocial assessment to identify the helpful and unhelpful ways in which patients were responding to their pain and the impact of pain on current functioning (physical, psychological and social). They were expected to use clinical reasoning to make sense of complex assessment findings, identify the key issues for individuals, differentiate (where possible) between pain-related and non-pain-related distress and to determine what was or was not modifiable. The patient's values based goals were used to guide treatment. Where patients had persistent pain despite trying sensible treatments, then therapists were expected to shift the agenda away from providing further treatment aimed at pain reduction and towards efforts focussed on improving quality of life and functioning, with pain. The physiotherapists were also trained to utilise cognitive (e.g. reassurance; education; providing a neurophysiological/central sensitisation pain explanation) and behavioural techniques (e.g. behavioural analysis; exposure; behavioural experiments). In determining when and which of these techniques to adopt they were encouraged to consider the purpose of treatment and likely effectiveness for the individual. In addition, the physiotherapist identified and addressed obstacles to remaining or returning to work (e.g. developing and implementing a return to work plan) and provided simple evidence based advice and information aimed at improving sleep pattern, quality and quantity.

Testing the stratified care approach UK: STarT Back Trial and IMPaCT Back study

The programme of stratified primary care research for LBP commenced with the publication of the KSBT in 2008,¹⁴ the STarT Back trial in 2011,^{5,28} and the IMPaCT Back UK implementation study in 2014.^{29,30}

The STarT Back trial involved 851 adults with LBP from 10 general practices in England, with patients randomly assigned in a 2:1 ratio to stratified care (intervention group; n=568) or current best care (control group; n=283). LBP-specific disability measured using the Roland and Morris Disability Questionnaire (RMDQ),³¹ was the primary outcome measure. Cost effectiveness was evaluated by comparing the quality adjusted life years (QALYS) and health-care costs of the intervention and control group. The trial results showed that at both 4 months and 12 months, patients

in the intervention group (who had matched treatments based on their KSBT risk subgroup) had significantly greater improvements in disability scores compared with those in the control group.⁵ In addition, the intervention group were more likely to report reduced fear of movement, less depression, better general health, were more satisfied with their treatment and had taken fewer days off work because of LBP. Patients at low risk received fewer investigations, imaging, and referrals to secondary care, and patients in the medium and high risk subgroups were offered evidence based physiotherapy (medium risk) or psychologically informed physiotherapy (high risk). This stratified care approach also resulted in a greater health benefit that was achieved at a lower average health-care cost, with an average saving of £34.39 per patient.²⁸ The STarT Back trial provided high quality evidence that a stratified care approach significantly improves patient outcomes and is associated with substantial economic benefits compared with current best practice. The approach seemed to be working by changing which patients were referred for physiotherapy treatment in a manner that was more in line with patient prognosis, ensuring patients at low risk were not over-treated unnecessarily and that patients at high risk were provided with a combined physical and psychological intervention in a timely manner. In addition, Mansell et al (2016)³² used a mediation analysis to investigate whether pain and psychological distress were mediators of the effect of the matched treatment for patients at high risk in the STarT Back trial. They demonstrated not only the strong correlation between changes in pain and distress and changes in LBP disability but importantly demonstrated that the training provided to upskill the physiotherapists to deliver a combined physical and psychological programme significantly improved the therapists' abilities to achieve changes in pain and distress with patients at high risk.

The research team at Keele also conducted a large implementation study called the IMPaCT Back study²⁹ to investigate whether the STarT Back stratified care approach could be implemented into busy, routine primary care and to study the effects of doing so on patients' outcomes, costs and healthcare process outcomes. The study used a sequential comparison before and after study design among 64 general practitioners (GPs) and linked physiotherapy services and 922 patients. GP consultations were enhanced by the use of the KSBT in the consultation. GPs were also encouraged to manage patients at low risk themselves and only refer patients at medium and high risk to physiotherapists, where they then received the appropriate matched treatment (as in the STarT Back trial). The primary outcome was again LBP-specific disability (RMDQ) and in addition, the study captured changes in clinician behaviours and particularly in treatment decision making such as referrals to physiotherapy, imaging, medication prescriptions, and sickness certifications. A cost-utility analysis again estimated incremental quality-adjusted life years and back-related healthcare costs. Results of the IMPaCT Back study showed small but significant improvements in LBP disability scores and large and important reductions in time-off-work (reduced by 50% overall from a mean of 8 to 4 days), without increasing healthcare costs. The study demonstrated that stratified care changed clinician treatment decisions for the better, with greater proportions of patients at

medium and high risk of persistent disabling LBP being referred to physiotherapy.

Following publication of the STarT Back and IMPaCT Back results there has been a great deal of international interest in the STarT Back approach to stratified care for LBP. As a consequence, a number of international research teams have sought to replicate the UK results, with one study to date having reported positive results in Ireland³³ and a further six studies in progress. Over 1000 studies that have cited the KSBT or trial papers, and many studies have tested the predictive abilities of the tool in a range of clinical settings (e.g. chiropractic, secondary care and the emergency department),^{34,18} with different types of patients (acute, chronic) and in many different countries.³⁴⁻⁴⁰ The learning from these studies include a realisation that unsurprisingly the KSBT predicts some outcomes (e.g. LBP disability for which it was developed to predict) better than others (e.g. patient satisfaction), that its prediction has a 'sweet spot' in terms of timing, being less predictive in patients with less than two weeks LBP duration, and less predictive among patients with chronic LBP (more than 3 months), and that the tool predicts observed mean outcome and not change in outcome.

The stratified care research team at Keele University are currently delivering a new programme of research to test whether a similar prognostic model of stratified care might be effective for patients with the five most common musculoskeletal pain presentations in primary care (back, neck, shoulder, knee and multi-site pain). The new Keele STarT MSK Tool⁴¹ is in external validation stages and is expected to be published in 2018. A clinical trial to test the new STarT MSK stratified care approach in UK primary care is in progress. The team are also delivering the SCOPiC clinical trial,⁴² which is testing the clinical and cost-effectiveness of stratified care (combining prognostic risk stratification with clinical indicators of severity) for patients with sciatica.

Testing the stratified care approach in Denmark

In 2010, the KSBT was translated into Danish and validated in a Danish population⁴³⁻⁴⁵ and then in 2015, funding was obtained to conduct a broad replication of the STarT Back trial in Denmark. The trial is currently underway. The key steps in this journey, the progress made to date and key lessons are outlined below.

Translation and Validation of the Keele STarT Back Tool

The process of translating the KSBT followed international standards.^{46,47} The Danish version was then piloted among patients with LBP. In addition, the discriminative ability of the translated Danish version was tested. Seven of the nine items, where reference standards were available, were compared to the original English version. The translated version was found to be linguistically accurate, acceptable to patients and had sufficient discriminative validity to recommend it's use in Denmark.⁴⁵

Predictive ability

In 2012, two studies tested the predictive ability of the Danish STarT Back tool in both primary and secondary care settings, within the Danish Healthcare System. The Danish version was able to predict a similar relative risk for poor outcome on activity limitation in the Danish primary care cohort in the low and medium risk subgroups, but was a little less predictive in the high risk subgroup. Although still significant, the Danish STarT Back Tool had less predictive ability in a Danish secondary care cohort.^{43,44}

Replication of the stratified care approach in a Danish primary care setting

In 2015, the Danish research team commenced testing the stratified care approach used in the STarT Back trial⁵ in the regions of Southern and Central Denmark. They engaged Danish GPs and physiotherapists to participate in the study and considered the practicalities of conducting the trial within the existing Danish healthcare services. The stratified care approach needed to be integrated within the existing Danish clinical pathway and needed to be consistent with the Danish regional guidelines (e.g., targets for the time taken between referral to physiotherapy and the patient being seen). Attention was also paid to identifying and overcoming potential obstacles to testing stratified care in Denmark, these included inadequate clinician knowledge and skills, limited consultation time and the need to have patient resources in the Danish language. The physiotherapists delivering the intervention arm of the trial received training to deliver the matched treatments from the Keele University trainer. Supervision of these physiotherapists for the duration of the trial was conducted in small groups and was facilitated by physiotherapists who had previously attended the Keele stratified care course, had received training from a psychologist and had experience of putting the approach into practice with patients. Patients in the intervention arm received a booklet in Danish containing similar messages to the booklet used in the STarT Back Trial and a web address to a patient video developed by the Keele team, a private healthcare provider (AXA PPP) and a professional film company, subtitled in Danish.

Design

The Danish trial of stratified primary care for LBP (article submitted) consisted of a randomised controlled trial in primary care involving ten cities. Patients were recruited by GPs, when they consulted with an episode of non-specific LBP. The GPs assessed and electronically referred patients to private physiotherapy clinics. All patients referred to physiotherapy completed the Danish STarT Back tool online before their first physiotherapy appointment. In each city, a matched pair of physiotherapy clinics was randomised. The physiotherapists in one clinic delivered the intervention arm. They were informed of the patient's Danish STarT Back Tool score and risk subgroup and were to deliver the matched treatments. The physiotherapists in the control arm did not have access to the patient's STarT Back

tool results, did not receive any matched treatment training and were expected to deliver current practice.

Outcome measures

The primary outcomes in the trial are time off work, LBP-related disability measured by the RMDQ³¹ and patient reported global change. Secondary outcomes are pain intensity, patient satisfaction, data on patient health care resource utilization and health care costs. Referrals to secondary care are also being monitored.

Lessons learnt to date

This Danish trial has just completed patient recruitment (n=333), patient follow up is ongoing, however the research team have already learnt a number of things. In Denmark GPs and physiotherapists are privately funded, therefore, although their participation in the trial is funded, it is very difficult for them to engage in research over a longer period, due to workload and competing interests. Recruitment of patients to the study was slow, this might have had an adverse impact on treatment fidelity as each clinician may need to see a number of patients throughout the trial in order to develop and maintain their skills and confidence in delivering the treatment approach. Shorter recruitment and treatment periods, a greater throughput of referrals and more regular contact with the research team might enhance fidelity to the treatment approach. Most physiotherapists delivering the intervention arm stated that the approach was useful for other musculoskeletal patients as well as ones with low back pain. In the trial, the researchers chose to match two clinics in the same city and randomize patients to either intervention or usual care. As a result, there is a possibility of contamination, particularly as the physiotherapy profession in Denmark is quite small and the study has received some publicity.

If this replication trial produces promising results it is hoped that stratified care for LBP will form part of the national Danish implementation strategy for evidence-based LBP care in primary care. If so, it is advisable to use existing frameworks for implementation and evaluation of studies, given the complexities of research and clinical practice.

Implementation of stratified care (STarT Back)

It is widely acknowledged that adoption rates for complex interventions are low and that there is often a knowledge-to-practice gap. Poor or ineffective implementation appears at least partly, to explain this.⁴⁸ Unfortunately, healthcare which does not integrate evidence not only runs the risk of harm but also misses the opportunity to benefit patients.⁴⁹ An Impact Acceleration Unit (IAU) has been established within the Research Institute for Primary Care & Health Sciences at Keele University in the UK,

tasked with supporting the implementation of key musculoskeletal research findings into policy and practice. To date, this has primarily involved supporting healthcare systems, services and clinicians to implement stratified care within the UK NHS. Throughout this process, the IAU has worked in conjunction with healthcare purchasers and providers to understand potential barriers and design solutions to enhance implementation, taking account of their specific context.

Whilst, no single strategy is likely to work and innovations and strategies may need to be adapted to suit different groups or contexts (e.g. because of different patient population needs, health care services or resources)⁴⁸ the IAU has drawn on the implementation and knowledge mobilisation science literature when developing innovations and supporting services to implement them. Unfortunately, there isn't a one-size-fits-all, step-by-step instruction manual for implementation, as implementation is difficult and takes place in a complex environment,⁴⁹ however the below evidence based implementation innovations and strategies, if adapted and adopted flexibly, may well support successful implementation of stratified care, in different health care contexts. Further information about these and other innovations and resources, most of which are freely available, can be found on the STarT Back website.¹⁹

Identify the evidence to practice gap

If stratified care for LBP is going to be implemented into policy and/or practice, it is important to have a good understanding of the STarT Back and IMPaCT Back study's research design, interventions delivered and results. Next it is important to determine to what extent the KSBT is currently being used in the local LBP population, what proportion of patients are classified as at low, medium or high risk and how they are currently being managed. It should then be possible to identify any gap, in other words, to determine in what ways current clinical practice is similar or different to what was done in the research study. Whilst stratified care is more likely to be successfully implemented if it is adapted to suit the local context, population needs, financial and other resource constraints, it is important to stay as close to what was done in the research studies as possible, otherwise there is a risk that whilst something is being implemented, it is not necessarily being implemented with fidelity or in keeping with the evidence.

Identify and engage your key stakeholders

Stakeholders may include managers and providers of services, users of services and carers, as well as purchasers of services. It is important to identify and actively engage your key stakeholders early in the process of implementation and decision-making by utilising existing relationships and by building relationships where non exist. The mechanisms through which you engage your stakeholders may vary (e.g. opportunistic conversations, formal meetings, being introduced by others) and you may need to 'flex' the message depending on the target audience. Different

audiences may be more receptive to people from a particular professional background or role, so it can also be advantageous to have different professional backgrounds and roles represented within the wider implementation team.

Consider how and where stratified care fits into the Organisation and wider context

It may be necessary to 'sell' the benefits of stratified care and to seek the endorsement of clinical and other organisational stakeholders. An organisation, healthcare economy and or government are more likely to modify or adopt a new system, process or practice if it aligns to contemporary standards, current policy and legislation. Consideration should be given to how implementing stratified care and potentially improving clinical outcomes, improving health care efficiency, reducing health care utilisation, increasing clinician knowledge and skills or increasing patient satisfaction, might address some of the challenges within the local health care system. It may be useful to cite international and national policy and practice documents in which STarT Back has been recommended, for example, in 2016, the updated NICE LBP guidelines² and the National Back Pain Pathway⁵⁰ in the UK recommended use of stratification tools including the Keele STarT Back Tool and a recent Public Health England⁵¹ document outlined the cost effectiveness of implementing stratified care in the UK. Stratified care is now also part of the recently developed low back and radicular pain pathway in Belgium.⁵² It may be helpful to have a suit of 'evidence' as different types of 'evidence' such as research findings, audit data, patient stories or guidelines may influence different types of stakeholders. If developing a business case, (see STarT Back website for a draft business case template), be mindful of the economic/financial climate locally and nationally when detailing the resource required (cost, return on investment, 'opportunity cost'), wherever possible use policy language and make it as easy as possible to implement (highest return for lowest investment).

Agree the care pathway

Implementation of research findings may impact on existing workflows, systems and processes within the organisation. Stratified care is a systems approach, so whilst it can be implemented within a physiotherapy service, it is best implemented at the most appropriate point within the patient clinical pathway. This may require a new pathway or a revision of an existing one, either way, it is helpful to be able to answer the following questions.

- At what point(s) will the KSBT be completed and how will this be done (e.g., phone, post, in person)?
- Who will manage the patients at low risk and how will unnecessary over-treatment be prevented?
- How will PIP be delivered to patients at high risk?

Engage patients and the public

Engaging the patient and public can help ensure that pathways of care are relevant, feasible and acceptable to the people who will be using the clinical services. Service users have a unique view of clinical provision and can give valuable insight into how experiences and services could be improved. One of the innovations that the IAU has supported, is the co-production of a patient information leaflet for patients with back pain. It has been written by patients, illustrated with patient stories and underpinned by the latest research evidence.⁵³

Specify the behaviour change needed and the health care professional group(s) whose behaviour needs changing.

Consider how the new intervention influences or fits with the clinicians role e.g. will clinicians see use of the tool and matched treatments as congruent with their role, style of practice, personal interests and their consultation workflow? Ensure as much as possible that stratified care has good integration with existing systems and workflows, and is adaptable to the local context (e.g., population needs, healthcare setting, expertise and number of clinicians). Consider innovations that might make it easier for busy clinicians to integrate the KSBT into their consultations. For example, the IAU, in collaboration with GPs developed an electronic e-tool (the StarT Back EMIS tool). This is embedded within GP clinical computer systems, facilitates the completion of the SBST within busy GP consultations and guides the GP in providing evidence based stratified care. It also has a simple electronic referral to physiotherapy and a patient information leaflet integrated into it.

Identify the obstacles and solutions to implementation

It is important to consider contextual, organisational, professional and intervention factors when considering potential barriers and solutions to implementation as implementation success appears to be influenced by these four factors. For example, potential barriers to implementing stratified care in the UK, included GPs reporting insufficient time in the consultation to use the KSBT, a difficulty integrating it into their usual workflow and challenges around assessing patients for red flags. The IAU has therefore developed a video of a model first contact consultation between a GP and a LBP patient in which the tool is introduced and completed. The IAU also put information about examining LBP patients and identifying red flags on the STarT Back website and a link to a video presentation about red flags and LBP is also available on u-tube.⁵⁴ The IAU are aware that clinicians can find it challenging to deliver the matched treatments so they have developed a number of resources to assist with this. For example, they have outlined the clinician behaviours that are

desirable in delivering stratified care (Desirable Clinician Behaviours) and have developed a method whereby clinicians in the same geographical area might come together and support each other to manage high risk patients. This has been termed 'Peer Practice Based Support' and a number of documents relating to this can be found on the STarT Back website. The IAU continue to deliver training courses for physiotherapists, however, in order to meet the challenge of delivering training at pace and scale, we are considering the development of a 'train the trainers' course. Another barrier identified by the IAU was the cost to clinical services of the patient DVD and leaflets that were used in the STarT Back and IMPaCT Back trials so the IAU and a private health care provider (AXA PPP) commissioned a professional film company to produce a high quality patient DVD called 'The Truth About Back Pain',⁵⁵ which is freely available.

Devise a strategic implementation plan

The next step might be to work with key stakeholders, including a user reference group to collaboratively devise an implementation plan and support its delivery. Ideally, this would include realistic, measurable and co-ordinated goals and milestones, clearly defined roles and responsibilities and clarity about the required resources for all stages (e.g., funding; adequate staff with appropriate skills; training and ongoing support) and details of how to provide these resources.⁴⁹ The resources needed may however vary, depending on the phase and scale of implementation.

Engage the workforce

The success of implementation will in large part be determined by the extent to which key internal and external stakeholders engage in the process. Local clinical champions can influence key professional groups and can find practical solutions to overcome obstacles and help implement them. Evidence suggests '...spread depends on more than good ideas and willing adopters...it is a complex social process'⁵⁶ so it may be advantageous to develop and engage networks and communities of practice. Physiotherapy champions and partnerships have resulted in stratified care being successfully embedded within a number of clinical pathways in the UK (e.g., Stoke on Trent, Birmingham, Salford and Gloucestershire).⁵⁷

Identify how you will measure success

It is desirable to identify measures of success (e.g. pre and post clinical outcomes, process measures, healthcare utilisation and costs, patient, referrer and clinician experience) and establish how these will be assessed. The Keele IAU have developed an audit tool which is free to download and use and they recommend the use of a recently published generic musculoskeletal patient reported outcome measure called the MSK-HQ.⁵⁸ For permission to use this questionnaire, please

contact:<https://innovation.ox.ac.uk/outcome-measures/musculoskeletal-health-questionnaire-msk-hq/>. Lastly, agree a 'go live' date, evaluate the effects of your implementation, share experiences and learning, and celebrate your success.

It is becoming clear that the implementation of this stratified care approach (using both the tool and matched treatments) in some countries is challenging, either because treatments are largely driven by patient choice or the types of matched treatments that best address the needs of patients at medium or high risk of persistent disabling pain are not available. In some countries where a private model of healthcare dominates, there are strong financial incentives for over-treating patients at low risk. A further issue is the lack of high quality training available to upskill physiotherapists to feel confident at offering the psychologically informed physiotherapy intervention for patients at high risk. To help those in other countries who might be considering whether and how to implement stratified primary care for low back pain, in particular those in low-and-middle-income settings, the following section considers the example of Africa.

South African and Regional Perspectives

The burden of LBP is growing considerably in low-and-middle-income regions such as Africa. In sub-Saharan Africa LBP is a leading cause of disability and among the most common reasons for visiting a primary care facility.⁵⁹ Despite this, there are no documented efforts by government departments to improve the efficiency and cost-effectiveness of the management of LBP in Africa. This is arguably because the focus of health targets in regions such as Africa is on saving lives instead of improving quality of life. However, there is increasing acknowledgment of morbidity as the burden of disease is transitioning from communicable disease mortality to communicable and non-communicable disease morbidity. Hopefully, this will trigger more action towards optimising health and cost outcomes for people with conditions such as LBP.

The management of LBP in Africa remain fragmented, non-standardised, not based on evidence and primarily relies on the opinion and clinical judgement of each individual clinician.⁶⁰ In many low-income countries, the basic diploma level of physiotherapy training does not cover the assessment of musculoskeletal conditions such as LBP. There are also extremely limited continuous professional education opportunities for these physiotherapists to upskill themselves as there are no or very few clinical leaders in these countries. High-and-middle-income countries such as South Africa play an important role in steering the education and training of physiotherapists treating LBP in Africa. Goal oriented, collaborative linkages with a focus on education between low-and-middle income countries is an important stimulus to improve the care of LBP and to assess the feasibility of stratified care for LBP in Africa.

The healthcare systems in African countries are complex and constrained by financial and dire workforce shortages. High levels of inequality prevail in many African countries. For instance, in South Africa, there are two systems i.e. the public and private system. The inequality between these two systems is of great concern as 80% of people depend on the public system while there are significantly more financial resources within the private system.⁶¹ Currently, the public and private systems operate as two, separate, parallel systems of healthcare. In the private sector, private medical insurers are eager to apply cost-effective strategies such as stratified care for LBP. Implementation of stratified care for LBP is therefore likely to be feasible within the immediate and short-term within the private system, provided it is supported by the medical insurer and adapted appropriately for the local population. Implementation within the public healthcare system in African countries will be challenging. The first challenge is the ability to advocate for the improved care of musculoskeletal conditions such as LBP. This will require leading researchers, clinicians, and other knowledge brokers to develop collaborations with influential stakeholders who can facilitate healthcare system changes. At primary care level, all patients with LBP are initially seen by a primary care nurse or medical doctor. Since the disease profiles of patients are complex and multi-morbid, LBP is not usually a priority during the less than five minute consultation. The referral rate to a physiotherapist (if available at the primary care facility) is very low.⁶² These barriers to the implementation of stratified care for LBP can potentially be addressed by strategies such as improved communication and patient education to improve referral of LBP patients to physiotherapists. However, there must also be increased pressure on governments in low-and-middle income countries to respond to the call by the World Health Organisation by increasing the number of rehabilitation workers to improve the care of LBP.⁶² In many low-and-middle income countries there is only one rehabilitation worker for one million people. However, due to resource constraints, improvements in human resources may not be realised within the immediate or short-term. Therefore, an alternative consideration is to implement the stratified care approach (or a contextualised version) into the content and training of evidence-based guidelines available for primary care nurses.⁶³

Although there are strategic goals from African departments of health to encourage patient self-management, this remains challenging, given the low levels of education, poor compliance, and cultural context. In addition, there are many social problems such as unemployment, low levels of health literacy, the value placed on traditional healers, crime/war, political instability, poverty, reliance on social grants, less than ideal physical infrastructure for wellness and inadequate inter-sectorial integration. Therefore stratified care for LBP in Africa will likely first need to be adapted to suit local contexts before wider implementation is considered.

High quality research will help identify and quantify the need for improved care models for LBP in Africa, identify the African and local context specific obstacles to implementation and how to overcome them and then test out one or more implementation approaches.

Summary

LBP is common and LBP related disability is increasing, highlighting the need for new models of healthcare that ensure that LBP patients receive less of the wrong sort of care and more of the right sort of care. In this paper, we have introduced and explained a relatively new model of primary care developed in the UK for patients with non-specific LBP, based on patients' risk of persistent disabling pain, called the STarT Back stratified care model. It involves two key components, first use of a short tool, the KSBT, to identify patients as at low, medium or high risk of persistent disabling pain and secondly application of matched treatments for each subgroup. The evidence from two studies (a randomised trial and an implementation study) in the UK is that this new approach to care reduces unnecessary overtreatment in patients who have a good prognosis (those at low risk) yet increases the likelihood of appropriate healthcare and associated improved outcomes for those who are at risk of persistent disabling pain. The approach has been shown to be implementable and cost-effective in the UK healthcare setting, is being recommended in recent guidelines and new LBP clinical pathways of care and had generated international interest. We have therefore, through this paper, also shared experiences from examples of teams in other countries who are currently testing this stratified care approach for LBP or who are, for the first time, considering whether this new model of care might be implementable in their own healthcare setting. We have provided key points of learning from the UK based team and from other countries that represent both high- and low-and-middle-income settings. As further studies (both research trials and implementation studies) are conducted, the evidence for both the effectiveness and the adaptations needed to the STarT Back stratified care approach will become clearer.

Acknowledgements

We thank the members of the Impact Accelerator Unit, in particular, Kay Stevenson (Senior Knowledge Mobilisation Fellow) who commented on part of a late draft of the manuscript.

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