

Title: Adaptation and implementation of the STarT Back risk stratification strategy in a US health care organization: A process evaluation

Running title: Implementation of STarT Back risk stratification

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Abstract

Objective: To support implementation of effective treatments for back pain that can be delivered to a range of people, we summarize learnings from our process evaluation of the MATCH trial's implementation of an adaptation of the STarT Back risk-stratified care model.

Design: Our logic model-driven evaluation focused primarily on qualitative data sources.

Setting: This study took place in a US-based health care delivery system that had adapted and implemented the STarT Back stratified care approach. This was the first formal test of the strategy in a US setting.

Methods: Data collection included observation of implementation activities, staff/provider interviews and post-training evaluation questionnaires. Data were analyzed using thematic analysis of qualitative data and descriptive statistics for questionnaire data.

Results: We found that both primary care teams and physical therapists at intervention clinics gave the training high scores on evaluation questionnaires and reported in the interviews that they found the training engaging and useful. However, there was significant variation in the extent to which the risk stratification strategy was incorporated into care. Some primary care providers reported that the intervention changed their conversations with patients and increased their confidence working with

patients with back pain. Providers using the STarT Back tool did not change referral rates for recommended matched treatments.

Conclusions: These insights provide guidance for future efforts to adapt and implement the STarT Back strategy and other complex practice change interventions. They emphasize the need for primary care-based interventions to minimize complexity and the need for ongoing monitoring and feedback.

Trial registration: National Clinical Trial Number NCT02286141, November 5, 2014

Table of Contents Summary: This paper evaluates implementation of an adapted STarT Back risk-stratified care model for back pain in a US healthcare system. The findings provide guidance for future efforts to adapt and implement the STarT Back strategy and other risk-stratification strategies into practice. They also emphasize the need for primary care-based interventions to minimize complexity of the implementation strategy and the need for ongoing monitoring and feedback to create and sustain change.

Key words: back pain, stratified care, STarT Back, process evaluation, quality improvement, primary care.

BACKGROUND

Finding cost-effective treatments for chronic pain remains a major challenge for clinicians, researchers, payers, and patients in industrialized countries. Back pain is the most prevalent and costly type of pain. Annually, more than 50% of US adults are bothered by back pain and up to 80% of adults will have back pain at some time in their lives.^{1,2} Back pain is the second leading symptomatic reason for physician visits.³

A new model of care based on prognostic stratification was developed and tested through a randomized trial and impact analysis study in the United Kingdom (UK).⁴⁻⁶ The stratified care model involved first using the STarT Back risk-stratification tool of 9 questions (Table 1) to group patients into one of three prognostic risk groups in order to match them to recommended group-specific treatments. In the UK trial, the matched treatments included education, advice, and support for self-management for the lowest-risk group; referral to physiotherapists for a course of evidence-based treatment for the moderate-risk group; or referral to physiotherapists with additional training who provided a course of psychologically informed physiotherapy for the highest-risk stratum. The STarT Back trial and IMPaCT Back study found that this stratified primary care model improved patients' function and other outcomes, and was cost-effective for the UK's National Health Service.^{5,6} It is not known whether this model of stratified care might be of benefit in other health care systems.

Our Matching Appropriate Treatments to Consumers' Healthcare needs (MATCH) trial aimed to adapt, implement and compare this stratified primary care model to usual primary care in a US health care delivery system. The setting was Kaiser Permanente Washington (formerly Group Health), an integrated health care system (protocol described in Cherkin et al 2016).⁷ Before MATCH, no published studies explored if and how the STarT Back evidence-based intervention could be amended and implemented in a US health care delivery system.

This paper describes the implementation strategies and uptake of an intervention that incorporated the STarT Back stratified care model into several primary care clinics as part of the MATCH trial. Our evaluation provides insights into how a robust implementation process that achieved positive responses from clinic providers and staff and changed clinic workflow nonetheless did not lead to the hoped for reductions in specific non-evidence-based diagnostic tests, treatments, and referrals. Our findings provide guidance for future efforts to adapt and implement the STarT Back strategy and other complex practice-change interventions.

Intervention Description

The MATCH intervention was multifaceted and involved a variety of implementation strategies. The three major implementation components were: 1) embedding the STarT Back risk-screening tool, matched treatment recommendations, and related tools into a health system's electronic health record (EHR); 2) training and support for primary care

teams; and 3) training and support for physical therapists (PTs).⁷ Within these three components, the specific implementation strategies, per Powell's compiled list of implementation strategies, included but were not limited to providing centralized technical assistance, changing records systems, developing and distributing educational materials, conducting educational meetings and outreach, and mandating workflow changes.⁸ Goals of the intervention included having primary care team members use the STarT Back tool with patients, improving team members' comfort with engaging patients in conversations about biopsychosocial and physiologic aspects of their back pain, and changing diagnostic and treatment recommendations based on patients' STarT Back score and associated risk group.

Three primary care clinics (with onsite PT departments) in the Kaiser Permanente Washington region were randomized to receive training on the stratified care model; three demographically similar clinics were randomized as controls. The goal was to increase staff knowledge of the rationale and evidence for stratified care for low back pain, to support the use of the STarT Back tool and matched evidence-based treatments, and ultimately, to improve quality of care for back pain by encouraging clinicians to use evidence-based treatments for back pain.

Guidelines, electronic health record tools and treatment protocols. This early work involved a system-wide update to Kaiser Permanente Washington clinical guidelines regarding effective care for low back pain and embedding the STarT Back tool into the EHR. All members of the primary care team—primary care providers (PCPs, including medical doctors, osteopathic doctors, nurse practitioners and physician assistants);

registered nurses (RNs); licensed practical nurses (LPNs); and medical assistants (MAs)—were trained to input patient responses to the STarT Back tool’s questions into the EHR, which was programmed to calculate a score and categorize patients into three risk/complexity groups--low, medium or high risk/complexity--which corresponded to their risk of persistent disabling pain. (In the UK trials, "risk" was used to describe the three strata. Instead of "risk," the MATCH implementation used “complexity” with staff and patients, as a potentially more positive term. Study participants used both terms.) The EHR provided brief treatment recommendations, matched to the patient’s risk/complexity group on the same screen as the STarT Back tool questions, responses and overall score. Consistent with the delivery system in this US health care organization, the medium and high groups had a broader range of matched treatment options than the original UK studies. In addition to referring to PTs, PCPs were encouraged to refer patients for acupuncture, chiropractic care, and massage based on current evidence of their treatment efficacy and national and organizational guidelines for treating back pain.⁹⁻¹² A number of other tools were developed to complement the stratified care model including EHR templates that helped staff to document their encounters, a free DVD on chronic back pain, and educational materials and exercise instructions.

Primary care training and follow-up. At intervention clinics, most primary care team members (excluding front desk, laboratory and pharmacy personnel) participated in a series of training sessions over 6 months. PCPs were asked to attend all 6 sessions and other team members were invited to 3 of the 6 sessions. Training sessions lasted

one hour. The research team held trainings in staggered waves and offered sessions at multiple times, typically at the start of the day or at noon with refreshments, to maximize participation. Two lead trainers—a practicing PCP with experience training clinicians (KE) and a practicing psychologist with clinical and research experience treating chronic pain patients (BB)—developed most training materials and facilitated most sessions (Table 2). These trainings included a mix of didactic and interactive content.

In addition, all team members were offered a “chairside” training, which involved one of the trainers working with two staff members to introduce and practice using the STarT Back EHR tools. Of 120 team members, only 5 did not complete a chairside: 1 MA, 2 RNs, and 2 PCPs (one of whom was retiring).

During the 6-month training period, trainers provided support and team members were encouraged to seek help if they had questions or concerns. However, no additional follow-up or additional support (such as reminder emails and data feedback on use of the tools) was provided after trainings were completed.

Physical therapist training and follow-up. In the previous UK studies, physiotherapists (similar to US PTs but with a broader scope of practice) specializing in musculoskeletal pain including low back pain were key to the delivery of matched treatments and participated in a training program to support their use of the STarT Back strategy.^{5,6} MATCH PTs participated in a similar 5-day training program that was designed and delivered by the trainer from the UK studies. The training program

focused on using the STarT Back tool, the biopsychosocial model, cognitive behavioral therapy (CBT)-enhanced physical therapy, and the evidence base supporting current PT treatments (Table 3). PTs were invited to attend 2 of the 6 primary care team training sessions, one of which focused on creating a dialogue and shared understanding of treatment approaches with PCPs.

PTs attended case conferences led by the research team's psychologist (BB) for 6 months after the 5-day training (bi-weekly for 3 months and monthly for 3 months). Case conferences focused on supporting PTs administering STarT Back questions, utilizing the results (as well as the results obtained in primary care) to shape their treatment choices, counseling patients with chronic back pain, making appropriate referrals to a behavioral health provider when psychosocial issues seemed to warrant additional support, and reviewing specific cases. PTs also integrated discussions of the training into weekly team meetings. Finally, PTs were offered one-on-one consultations with the research team psychologist (BB) on topics including using the STarT Back tool, implementing a CBT-enhanced physical therapy approach, and counseling skills for working with patients with back pain.

METHODS

We used a logic model approach to our process evaluation,¹³⁻¹⁵ focusing on both the implementation strategies and the ways that participants responded to and translated the implementation into the intended intervention practice changes (Figure 1). The logic

model approach emphasizes documenting if and how planned activities are implemented as well as focusing on short-term and intermediate-term outcomes that logically should lead to the primary, longer-term outcomes. Methods used included observing implementation activities, administering post-training evaluation questionnaires and conducting interviews with primary care and PT team members.

Ethnographic observations of trainings, chairsides, and trainer case

conference/consultation sessions. Three research team members (SE, CH and the project manager) observed 36 of 50 training sessions (including repetitions of each session at each clinic). We also observed most of the PT training program. Drawing on ethnographic observation techniques^{16,17} and our logic model approach, we used an observation guide (Appendix A) to structure documentation, including prompts to record the number of participants, types of team members present, key content and messages, key behaviors of participants, and the gestalt of the presenter-audience interaction. Observers were experienced using qualitative methods and documenting events using field notes. To increase consistency between observers, two research team members (CH and SE) observed the first session and compared notes to clarify the goals of the observation guide and develop notetaking conventions. All field notes from clinic staff training sessions were reviewed by one observer (SE) and synthesized into a master table with observation overviews; key quotes, messages, challenges and questions from participants; and engagement levels of participants.

Post-training evaluation questionnaires. After each training session, participants were asked fill out an evaluation questionnaire that included four closed-ended questions and three open-ended questions (Appendix B). We collected more than 400 completed evaluation questionnaires across the sessions we observed (Table 4).

Interviews with trainers. Quarterly interviews were conducted with the two research physicians and the psychologist who were responsible for designing and implementing the primary care team training, starting before implementation and ending just after training sessions concluded. Interviews were designed using the logic model approach, which focused on documenting changes in the implementation strategies, challenges encountered and how they were met, and implementation successes.

One-on-one interviews with primary care team members and PTs. About 8 months after the last training session, a sample of intervention clinic care team staff (PCPs, RNs, LPNs and MAs) and PTs were invited to 30-minute semi-structured one-on-one interviews to understand their perspectives and experiences regarding implementation strategies and experiences using the stratified care model. Interview guides (Appendix C), tailored to participants' clinic roles, focused on rich descriptions of implementation at their clinic, examples of implementing suggested workflow changes, and perceived changes to overall care for their patients with back pain. Interviews were audio recorded and professionally transcribed. To ensure diverse perspectives, staff were purposively selected based on: 1) specific intervention clinic, 2) role in clinic, and 3) trainer ratings of staff members' overall engagement in the trainings. An email invited specific individuals

to participate. If any actively or passively declined, another individual who met the same criteria was invited. A total of 22 staff participated in these interviews. Participating staff and refusal rates are in Table 5; 20 interviews were in person, and 2 were by phone. Quotes from MAs, LPNs and RNs were combined into a single category.

Data analysis. A thematic analysis approach was used by project team members who conducted observations and interviews (SE and CH).¹⁸⁻²⁰ We developed a code list based on themes that surfaced during reviews of the transcripts and *a priori* concepts of interest such as training assessments, experience using EHR tools, and impressions of their impact on patients. Both coders coded one transcript using the draft code list and compared their work. Codes were added and revised and definitions clarified. The process was repeated 5 times, after which the coders felt the list was comprehensive, with substantial agreement on code definitions and application. Remaining transcripts were coded by one team member (SE) who reviewed previously coded transcripts to ensure consistent application of the final coding list across all transcripts. After coding, the first author (CH) synthesized the coded data and documented all themes and supporting data in a coding memo that was discussed with the wider research team. Atlas.ti was used to manage coded data.^{21,22}

Responses from post-training questionnaires were entered into SPSS (IBM v22) to calculate percent agreement with statements about the value of the presentations, the clarity of the material, extent to which information would help staff members provide better care, and confidence in helping patients with back pain.

Ethical Review Board Approval:

All study procedures were reviewed and approved by the Kaiser Permanente Washington Health Research Institute Human Subjects Internal Review Board. Written informed consent was obtained from all the individuals quoted in this publication. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

RESULTS

We found little variation among intervention clinics in their overall reactions to implementation of the intervention or in their responses regarding changes in practice; therefore, we present the findings in aggregate. Overall, we found excellent receptivity to the intervention format, content and mandated changes to clinic workflow to accommodate the use of the STarT Back tool (Table 4 and representative quotes below). STarT Back tool use was sustained for about 40% of all appropriate patients after the 6-month training period. However, despite these changes in clinic processes, the outcomes of more appropriate treatments for each risk group and reduced utilization of imaging, steroid injections, and surgery were not achieved.²³ Our evaluation of the MATCH trial helps elucidate where some key translational breakdowns occurred between the implementation strategies and the intervention execution. These breakdowns resulted in the inability to achieve the desired outcomes of more appropriate care based on risk/complexity group, as reported in our main outcomes paper.²³

IMPLEMENTATION STRATEGIES

Staff Engagement Training Reactions: Primary Care Team

Overall participation. Attendance at primary care clinic training sessions was high, varying between 82% and 98% of those invited to the session (Table 6). Observers recorded high staff engagement with many asking questions and engaging in dialogue with trainers. Table 2 synthesizes the discussion topics for each of the training sessions. Emphasis was on how to talk with patients about their pain, with limited discussion of the matched treatment options. The session on complementary and alternative medicine (CAM) treatments focused on understanding the treatment modalities and the evidence behind them but not how these treatments were connected to the STarT Back risk/complexity group. Overall, Table 2 documents the complexity of both the implementation and the intervention, with participants asking many questions about how to translate what they were learning into everyday practice.

Positive overall response to training sessions. Primary care team members who were interviewed were pleased with the training sessions. This finding was reinforced by the post-session evaluation questionnaire results, which found high levels of agreement with statements about the value, clarity and utility of the training sessions (Table 4). Primary care team members appreciated the pragmatic content and the introduction of new concepts and tools that they felt they could effectively implement with their back pain patients. Non-PCP team members (e.g., RNs, LPNs and MAs) appreciated being included, even when the content seemed more appropriate for PCPs.

I thought the trainings were excellent. I thought they were really pragmatic, hands-on information. There was a lot of really great information in terms of statistics and really what worked, what didn't work. (Clinic 2, PCP)

[The trainer] was great. He was amazing, his information was just outstanding. He just showed the psychological aspects of the back issues that people might be having. It doesn't all have to do with just neuromusculoskeletal, it has to do a lot with your mind as well. So even though it wasn't really directed for the medical assistants, it was more for the MDs and the higher scopes of practice, but it just enlightened me. (Clinic 3, MA/LPN/RN)

Many respondents remembered and appreciated the chairside sessions.

Just that first kind of general overview with the one-on-one with the physician was quite helpful; getting to know the tool and the Epic [EHR] tools as well. (Clinic 1, PCP)

A number of PCPs felt that the training gave them new techniques for working with back pain patients.

What was really useful to me was the discussions with the [trainer]...that really changed my focus when talking with patients about back pain, really letting them know that no harm will come to them from being active and how to prepare them appropriately for what physical therapy could offer...(Clinic 1, PCP)

Despite the fact that stratified care was new to the intervention clinics, several PCPs thought that the training did not provide new information but confirmed what they already knew.

I don't think there was anything that really changed a lot in my practice, but just knowing that it's the best practice, what I was already doing, I think that was helpful. (Clinic 3, PCP)

Staff Engagement and Training Reactions: PTs

Overall participation. All 18 PTs at the three intervention clinics attended the 5-day training. Observers noted mixed levels of engagement. Some PTs actively voiced concerns about the content and/or way the content was presented, which was mostly lecture style for the first day and a half. PTs also participated in two of the primary care team training sessions and in monthly PT team consultations with one trainer.

Reaction to training. PTs who were interviewed expressed a range of responses. Some voiced enthusiastic support for the training.

And the course I thought was fantastic...I think implementing it soon after was great, and very easy to do. (Clinic 2, PT)

A few PTs had critical assessments of the training, for example concern that the training required a major shift in thinking with limited ongoing support.

So there was the instruction in the class, which was somewhat stressful because it was a sort of a paradigm shift in some ways...and it seemed like there was good support to follow-up and then it kind of petered out. (Clinic 2, PT)

Several recalled that the monthly team consultations were particularly helpful.

I would say [the sessions with the trainer] were very beneficial because we talked through and we problem-solved some things. And again, my skill isn't necessarily the cognitive behavioral techniques or really approaching from that biopsychosocial mindset and so he definitely helped fill in the gaps, gave me a different perspective...(Clinic 3, PT)

A number of PTs expressed appreciation for the training session that included PTs and PCPs, which was designed to increase dialogue and shared understanding between these providers. PCPs did not single out this session for praise in the same way that PTs did.

It was really nice to meet with the physicians—I think maybe a month later or something—just to hear what they learned and see what they were saying, and that they could learn what we were saying, and I think on both sides we were kind of

surprised about what each other had been doing and will be doing. (Clinic 1, PT)

INTERVENTION

Uptake of the Stratified Care Model and Related Resources

Response to conceptual aspects of stratified care model: primary care teams.

Goals of the training sessions for the primary care team included consistent use of the STarT Back tool and matching treatment recommendations to patient's risk/complexity group (low, medium or high risk of persistent disabling pain), increased awareness of the complex nature of chronic pain, a stronger biopsychosocial approach to pain, and increased use of the EHR-based tools and resources (documentation templates, patient-education materials, DVD ordering, etc.). These practice changes were expected to increase use of PT and other evidence-based treatments (acupuncture, chiropractic care and massage) and decrease use of opioids, imaging, steroid injections and surgery.

Overall, members of primary care teams had positive feedback about the stratified care model, particularly the benefits of the overarching framework to guide interactions with patients.

Overall the most helpful thing is it's really kind of given a framework to approach patients with...low back pain. Whereas in the past it's...not an easy clinic visit to lead. Oftentimes it feels like it is only patient-directed, as far as where the conversation would

go, but now we have a bit of a framework to work in and that's pretty nice, actually.

(Clinic 1, PCP)

A few participants voiced reservations about working in this new way. Some were concerned about the complexity of the intervention and the extra time and work required.

It's beneficial, but is it used a lot? I don't know...this is a lot of information and the doctors want ABC. You know what I mean? They don't have time to go through all that, so making it I guess easier or more friendly? (Clinic 1, MA/LPN/RN)

PCPs also noted that providing patients with a description of exercises and decision-aid DVDs on chronic and acute back pain was useful. These tools were available to all clinics, not only the intervention clinics.

Response to conceptual aspects of stratified care: PTs. This new model of care for back pain appeared to create a more dramatic shift in work for PTs than for PCPs. As a result, their responses were more nuanced, although still positive overall.

In general it's been really good and I like the stratifying because then I can see that it's low risk, medium risk, or high risk, and then I really think of the low risk, that we really need to not treat so much, and the high risk, I've got to do a little bit more of the listening piece of it, all their stories...I've been surprised sometimes to hear how afraid the

patients are. (Clinic 1, PT)

PTs also appreciated that the new tools (questionnaire, treatment recommendations, documentation templates, etc.) were shared between primary care and PT and felt they increased consistency in approach.

I ask them often if they got the video from the doctor or the DVD, and often they ordered it or had it already, or they talk about they received the DVD and watched it already. Sometimes they have questions about it and sometimes they don't, but I have a feeling the ones who have already been sorted by the doctor already come in with a different attitude. (Clinic 2, PT)

Workflow Integration: Primary Care Team

A key aspect of implementing the stratified care model was integrating the STarT Back tool and related resources into daily workflow, the goal of which was to increase routine use of the STarT Back tool to support conversations about the biopsychosocial aspects of pain and to match treatment options to the patient's risk/complexity group. Primary care team respondents often reported setting up new workflow that involved MAs giving a paper copy of the STarT Back tool to patients in exam rooms prior to their visit with the PCP. In most cases this strategy seemed to work well for completing the STarT Back tool.

It's just another form to get used to, it's very familiar, because it's basically the same format as the PHQ9. (Clinic 2, MA/LPN/RN)

Yeah for the most part it was pretty fluid in that, especially if the chief complaint, or the reason they were there was for back pain then they definitely got the tool. (Clinic 1, PCP)

In at least two of the three intervention clinics, some MAs entered the STarT Back tool results into the EHR.

I'll take it and put in their MA inbox and they'll enter it...And I know where to do that, but I'm not doing it. I'm scoring it, I'm talking to them. (Clinic 3, PCP)

A few respondents reported challenges remembering to administer the STarT Back tool.

So for a while the medical assistants were giving out the paperwork to everybody and then it would kind of slack off. And then you'd see a bunch of people that never got the questionnaire and we had to remind them again...So that's the hardest part is to keep that going. (Clinic 1, PCP)

Respondents identified a number of other challenges that interfered with consistent use of the STarT Back tool such as patients with multiple health problems to discuss or time constraints. A few respondents reported that the STarT Back tool did not provide them

with information they were not already getting during their physical exam.

I'm not using the tool at all...The tool wasn't really showing me something I didn't already know from my interview and exam. (Clinic 3, PCP)

PCPs reported that they were often selective about who they used the tool with and frequently adapted how they used the questions, sometimes focusing on just one or two of the nine questions.

I'm not sure the distinction between medium and high complexity was terribly useful for me, but I thought the distinction between low complexity and the others was quite helpful. Really focusing in on whatever those supplementary questions...really helped to kind of point where we should go with our visits. (Clinic 1, PCP)

When it's only low back pain I probably do it a lot, especially if I don't know the patient and I want to understand better this low complexity versus high complexity and how that changes your approach on some level. So I do it almost all the time when that's the only complaint, but if it's an add-on complaint I might not end up doing it. (Clinic 2, PCP)

Despite repeated questions regarding how they changed their care as a result of using the new tool, primary care team respondents did not specifically describe using patients' complexity/risk group to guide treatment recommendations.

Workflow Integration: PTs

PTs had fewer team members to help them integrate stratified care into their regular workflow. Therefore, their use of the STarT Back tool and matched treatments appeared to rely more on PTs remembering and/or deciding to use the tool with a patient rather than a more standardized change to PT workflow.

I think we are using the STarT Back tool probably not as much...as we should. We do forget about it still. (Clinic 2, PT)

Like PCPs, PTs adapted how they used the STarT Back tool. Many used the concept but not the actual tool or were selective about the questions they used.

I think we're using what we learned and we're using it instinctively, just because from our subjective evaluation, if the patient tells me that they're still doing all their hobbies and they're participating in their sports and they come in happy, laughing, smiling, then I know they're not a high-risk patient. So you get that without the STarT Back tool... (Clinic 2, PT)

With regard to matching treatments to risk, a few PTs actively resisted the matched recommendations, while others interpreted matching as acknowledging patients' biopsychosocial issues in their interactions with patients.

Clinic Staff Perspectives on Impact on Care: Primary Care Teams

Most primary care team respondents reported that the implementation strategies used (trainings, tools, etc.) did not change the tests and treatments they offered patients.

I don't necessarily think that it affected the treatments that I offered. Maybe it affected how soon I offered those treatments, or how I would talk differently about PT; the tool helped me identify if they were somebody who needed more hands-on stuff right away than later on. (Clinic 1, PCP)

Some participants reported positive changes in: 1) the types of conversations that they were having with patients, 2) their confidence working with patients with back pain, and 3) team communication.

So the questionnaire helped me sort out the psychological aspects because I wasn't very good at that...People that interpret their pain as oh my God, I'm dying every time—those are the ones that start making me nervous (laughs). Like oh shoot, I'm going to miss something...But then...you can see by the way they answer the questions, it gives you a little way of teasing out the emotional psychological aspect of the pain. (Clinic 1, PCP)

I'm not sure how much I've changed objective things I ordered, but I think the way I talk to patients...low back pain can be one of those ones you see on your appointments and

say "God, no" (laughs) or "Oh, I can deal with this, I'm going to be good at this." And I think these tools help it go into that [second] category better. (Clinic 2, PCP)

Perspectives on Impact on Care: PTs

Unlike PCPs, PTs reported that the stratified care model changed their overall thinking and approach to back pain. A few mentioned changes in how they spent time with patients and the treatments they used. In particular, PTs reported using different approaches with patients depending on their risk/complexity group.

I did realize through the training itself as well as implementing the tool and in my practice that there were probably a lot of people that I was overutilizing therapy...and it really gave me kind of a fresh perspective on how that can actually work against those patients. (Clinic 3, PT)

One PT thought it didn't change their approach to care but helped introduce a conversation about psychosocial issues with patients in a way that was more comfortable.

I wouldn't say it changed my style of talking about those things or my willingness to talk about those things, but it is a nice clean-cut sort of way to open that conversation. (Clinic 2, PT)

DISCUSSION

Our evaluation found that both primary care teams and PTs at intervention clinics generally praised the strategies used to implement the stratified care model and spoke highly of the STarT Back tool as a way to improve care for patients. However, despite the fact that they reported using the tool for many of their back-pain patients, they did not report changes in their clinical practice in terms of treatments offered to patients. This finding was corroborated by our analyses of patient utilization data, which found the implementation strategy had no effect on the tests or treatments patients received. Quantitative data and a discussion about how the results compare to the trials done in the United Kingdom are published in our main outcomes paper.²³

The MATCH study adapted an intervention with positive outcomes in the UK and tested its implementation in a US delivery system. This adaptation required significant changes to the intervention to accommodate differences between the two health care systems including the roles and availability of UK physiotherapists versus US physical therapists, a cultural focus on choice in the US health care system, and dissimilar financial incentives. To frame the factors that contributed to the lack of intervention effect, even among clinicians reporting frequent use of the STarT Back Tool, we drew on Carroll et al's implementation fidelity model. The model posits two main elements of implementation fidelity that are important to evaluate—adherence and moderators. Adherence encompasses the content, coverage frequency, duration, and other factors associated with replicating a particular intervention. Moderators are factors that

influence implementation fidelity such as intervention complexity, delivery quality, and participant responsiveness.²⁴ Adherence to the stratified care model as used in the UK was low. In adapting the stratified care model to a US health care system, the MATCH study differed from the STarT Back trial and IMPaCT Back study both in implementation strategies and the intervention itself. Some key differences included: 1) the training given to primary care teams emphasized general concepts and use of the STarT Back tool, but focused less on matched treatment recommendations. 2) All primary care team members were trained, not just physicians, and therefore responsibility for completing the STarT Back tool with patients was more diffuse, providing many points of possible failure (for example, the STarT Back tool could be administered by an MA and never reviewed with the patient by a physician), 3) MATCH referred patients to physical therapy, behavioral health and/or CAM providers, whereas in the UK studies, all patients at medium and high risk were referred to physiotherapists, and 4) . the MATCH trial did not conduct provider-level audits and feedback due to technical, logistical, and resource constraints.

Moderators to implementation fidelity also played an important role in the implementation process. The complexity of the MATCH version of stratified care was high as evidenced by the themes in the results that highlight how primary care team members and PTs adapted the tool, often dropping questions; also, their lack of understanding of the connection between STarT Back tool risk/complexity groups and the matched treatments may have exacerbated by the number of treatment choices offered. Our findings showed that primary care teams and PTs used the tool with only a

subset of patients and/or focused only on part of the approach. In addition, while the primary implementation strategies were robust and varied, PCPs and PTs had little ongoing support and feedback to reinforce use of the STarT Back strategy. Therefore, after the 6-month training period, PCPs, other primary care team members and PTs expressed concerns about sustaining consistent use of the tool. They also struggled with counseling patients in ways that were consistent with the matched treatment approach. A few primary care team respondents expressed concern about the time associated with stratified care, which might reflect modifying or skipping the strategy when necessary.

Our evaluation focused on documenting the implementation process, and assessing participants' reactions and uptake of the intervention. Our results are consistent with several recent systematic reviews that have found that changing care for back pain is difficult.^{25,26} Mesner found that intervention frequency and duration are associated with greater success with implementation efforts.²⁵ While the MATCH intervention lasted over 6 months, the frequency of patient encounters for back pain in primary care is relatively low. Beyond the educational efforts and the workflow changes, there were not more concerted or sustained efforts to hold primary care teams accountable for using the STarT Back tool or the matched treatments. PTs received more support through leadership audits and ongoing case review; however, PTs could not refer to other treatments. For many, their overall training around the biopsychosocial approach to back pain was limited to what they received during the MATCH training. Additional training was not feasible given time and resource constraints.

Our evaluation surfaced lessons that might help implementation of risk-stratification strategies or other new models of primary care in other settings. For example, our evaluation highlights that for a complex intervention involving multiple implementation strategies, much of the intervention may be well received and people may even change some aspects of their behavior, such as administering a particular tool. Nonetheless, these changes might not result in the desired changes in practice behavior or improvements in patients' outcomes. Understanding where in the implementation process breakdowns occur is important for adapting implementation models for different settings. Second, the complexity of our intervention, especially providing PCPs with multiple matched treatment options, meant that they often adapted the process to fit their existing approaches to back pain rather than following the recommended process, especially for prescribing matched treatments. A key distinction between the MATCH implementation and the previous UK implementations was that in our US trial, providers who identified patients at medium- and high-risk had to choose from multiple treatment and referral options. In contrast, the UK implementations had a single patient-referral option, to trained physiotherapists who performed a wide range of therapies (such as spinal manipulation). Future implementations of the STarT Back strategy should consider more limited treatment options or providing educational communication tools for primary care teams and patients that present treatment options in a way that easier to understand, remember, and implement. Also, one-time presentations of this material may not be sufficient to fully integrate a completely new approach to treatment decision-

making for both primary care teams and patients. Implementation strategies may need to include repeated interaction with clinical staff about the expected changes in care.²⁵

Our evaluation has limitations. First, due to resource constraints, we did not interview all primary care team members and PTs that participated in the MATCH trial and we might not have captured all perspectives or insights. Although we purposively selected participants to represent a range of levels of engagement in the implementation process, some sampling bias might have resulted from staff actively and/or passively refusing to be interviewed. Finally, this study occurred in a large, integrated delivery system and may have limited application for practices that do not have support for training, quality improvement and communication between primary care and clinical services such as PT.

CONCLUSIONS

We found that the implementation strategies of providing tools, education, support for workflow changes, and 6 months of ongoing support (for PTs only) were well received. However, the implementation was only partially successful in creating the desired practice change intended by the intervention. Primary care teams and PTs administered the STarT Back tool with about half of the patients with low back pain seen at the intervention clinics but in ways that varied greatly between individuals and we saw no evidence that treatment recommendations and decision-making changed. Our findings highlight how breakdowns can occur in areas that span implementation and

intervention. Our insights can inform future efforts to adapt and implement complex intervention in new contexts.

LIST OF ABBREVIATIONS

Physical therapist=PT

Matching Appropriate Treatments to Consumers Healthcare needs trial=MATCH trial

electronic health record=EHR

Primary care providers=PCPs

cognitive behavioral therapy=CBT

DECLARATIONS

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The authors declare that the data supporting the findings of this study are available within the article. However, additional data are available upon request from the corresponding author [CH]. The data are not publicly available since they contain information that could compromise research respondents' confidentiality as promised in the consent process.

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Authors' contributions:

CH: Designed and collected qualitative data. Analyzed data and drafted the manuscript.

SE: Designed and collected qualitative data. Reviewed initial data analysis document (coding memo), helped draft sections of the manuscript pertaining to methods and reviewed multiple drafts of the manuscript.

BB: Co-led the design of the implementation strategies. Facilitated trainings. Helped design data collection materials. Helped draft sections of the manuscript pertaining to descriptions of the intervention and reviewed multiple drafts of the manuscript.

KJS: Designed and delivered one of the primary care training sessions. Helped design data collection materials. Reviewed and gave substantive input into multiple drafts of the manuscript.

NF: Helped design the implementation strategies and reviewed training content. Reviewed and gave substantive input to the manuscript.

KE: Co-led the design of the implementation strategies. Facilitated trainings. Reviewed and gave feedback on manuscript.

ML: Provided oversight for the design of the implementation strategies. Facilitated trainings. Reviewed and gave feedback on manuscript.

DC: As the principal investigator, was responsible for the overall design, collection and interpretation of the data. Reviewed and gave substantive input into multiple drafts of the manuscript.

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TABLES

Table 1: STarT Back Tool

	Questions: Thinking about the last 2 weeks tick your response to the following questions:	Response Option (score)
1	My back pain has spread down my leg(s) at some time in the last 2 weeks	Disagree (0)/Agree (1)
2	I have had pain in the shoulder or neck at some time in the last 2 weeks	Disagree (0)/Agree (1)
3	I have only walked short distances because of my back pain	Disagree (0)/Agree (1)
4	In the last 2 weeks, I have dressed more slowly than usual because of back pain	Disagree (0)/Agree (1)
5	It's not really safe for a person with a condition like mine to be physically active	Disagree (0)/Agree (1)
6	Worrying thoughts have been going through my mind a lot of the time	Disagree (0)/Agree (1)
7	I feel that my back pain is terrible and it's never going to get any better	Disagree (0)/Agree (1)
8	In general I have not enjoyed all the things I used to enjoy	Disagree (0)/Agree (1)
9	Overall, how bothersome has your back pain been in the last 2 weeks	Not at all (0)/ Slightly (0)/ Moderately (0)/ Very much(1)/ Extremely(1)

Table 2: Summary of Primary Care Training Sessions

	Overview	Staff roles present	Key issues or questions raised by participants	Most valuable aspects (from participants)	Success factors for an engaged session
Session 1 (5 sessions observed)	<p>Introduced the researchers, the aims of the study, and set the tone for what the study would involve over the next 6 months.</p> <p>Introduced the general concepts behind the STarT Back tool and matched treatments. An important focus was getting clinics on board to support the work and get them excited about the opportunity to improve back pain care in their clinics.</p>	PCPs, RNs, LPNs, MAs, and PTs	<p>Seeking strategies to communicate with patients about chronic back pain and treatment options.</p> <p>Questioned coverage for the treatments to be recommended as part of study (ie, massage, chiropractor, yoga).</p> <p>Interest in differences between the U.K. and U.S. patient populations and treatment for back pain.</p>	<p>Knowing about the study, the plan, and the process.</p> <p>Realizing different treatments are available for back pain care.</p> <p>The whole clinic in attendance, staff engagement and buy-in of the process.</p>	<p>A clinical champion present.</p> <p>Urging to hear thoughts and opinions; lots of open-ended questions directed at audience.</p> <p>Uniting clinic in one group training seemed to ignite enthusiasm.</p> <p>Good food.</p>
Session 2 (8 sessions observed)	<p>Focused on getting PCPs and staff comfortable with administering the STarT Back tool (includes: use in EHR, scoring of tool, understanding treatment recommendations for each complexity level). Included discussions of how the tool could be integrated into each clinics' unique flow, use of secure messages, ordering DVDs, and flow sheets.</p> <p>Strong messaging about the biopsychosocial nature of back pain, how to describe the tool to patients and a review of recommended treatment options.</p> <p>Reviewed performing a</p>	PCPs, RNs, LPNs, MAs, and PTs	<p>Questioned the language in the tool, suggesting "catastrophizing." There was a strong need for messaging around the importance of maintaining the language of the tool to open up conversations about underlying psychosocial influences on back pain.</p> <p>Providers continued to be concerned about whether their patients would have access to the services recommended to them, and which specific CAM providers to refer the</p>	<p>Explaining the purpose and how to use the tool.</p> <p>How to guide therapy decisions.</p> <p>Interactive time (ie, questions, discussion).</p>	<p>Role play worked well with use of STarT Back tool and practicing the questions on one another; photos in the slides were interesting and engaging [laughter].</p> <p>Asking questions of the crowd about their personal practice with chronic low back pain patients.</p>

	Overview	Staff roles present	Key issues or questions raised by participants	Most valuable aspects (from participants)	Success factors for an engaged session
	<p>diagnostic exam to rule out serious specific causes of chronic low back pain, Shared real-life examples of high-complexity patients and the role of the tool for those patients.</p> <p>Discussed CAM modalities, emphasizing the importance of recommending a balance of active vs. passive treatments.</p>		<p>patients to.</p> <p>Will we be trained in behavioral health? “Do you really want us to walk through this conversation?”</p> <p>Many questions about when and how to use the STarT Back tool: who (ie, anyone with back pain even if not primary complaint; acute vs. chronic), when (every visit?), how (flow?)</p>		
Session 3 (3 sessions observed)	<p>Checked in on clinic’s use of tool and “refresher” on how to diagnose different back pain presentations (based on location on back- L2-L4, L5, S1). Reviewed cases: differentials, how to diagnose, questions to tease apart patterns, red flags to look for serious conditions.</p> <p>Training included language to use with patients regarding the decision about ordering imaging as well as “hurt vs. harm” in terms of asymptomatic patients (pain free) that on x-ray and MRI have many problems.</p> <p>Problem-solving in these sessions where the trainer learned about obstacles with flow integration.</p> <p>Reiterated that they should be</p>	PCPs	<p>At this point providers had experience using the tools, some did not find it useful: “What’s the point of using the tool? All that matters is that the patient feels better, not whether or not their scores increased/decreased.”</p> <p>More questions about who to use tool with, and appropriateness of recommendations with geriatric population.</p>	<p>Case review</p> <p>Discussion/group interaction</p> <p>Visual cheat sheet handout of “red flags” and differentials.</p>	A handful of people found the review of cases very helpful.

	Overview	Staff roles present	Key issues or questions raised by participants	Most valuable aspects (from participants)	Success factors for an engaged session
	using STarT Back tool with every back pain patient and how to use it. A handout was provided to help identify “red flag” diagnoses (ie, diagnoses that may indicate pathology that needs immediate medical attention) and some information about assessing where issue might be. There tended to be lower engagement in this session—though it was well received in post-evaluation survey as a “great refresher.”				
Session 4 (10 sessions observed)	<p>Used findings from focus groups with chronic low back pain patients and insights from patient advocates to focus on ways to communicate well about chronic pain. The session offered 5 steps for what providers can “do”:</p> <ol style="list-style-type: none"> 1. Give diagnosis that goes beyond chronic pain ie, “mechanical back pain,” 2. Explain anatomical links to pain, 3. Explain what chronic pain is (pain centralization, gate theory, reoccurrence of pain—having continued pain with no injury), 4. Talk about red flags and when to come back to primary care, 5. Focus on function rather than pain reduction. <p>The session also covered how to communicate while using the STarT Back tool: Reflecting what is heard, focus on the items of the</p>	PCPs, RNs, LPNs, MAs, and PTs	<p>Providers did not have clear understanding of “pain centralization” or pain gate theory concepts. Providers expressed their concerns with not being able to manage conversations around chronic pain well—and that visits may end poorly if listen to the patient “complain” was the key focus.</p> <p>“Do you think patients don’t feel heard, because they’re not getting better? Do you think they equate those two?”</p> <p>Concerns related to talking to patient about depression without making patient feel that PCP thinks it “all in their head.”</p>	<p>How to word messages/appropriate language for patients.</p> <p>Understanding need for specific explanation, including diagnosis, and information of back pain conditions. Describing the use of the STarT Back tool as a launching point for discussion about back pain.</p> <p>Understanding the perspective of back pain patient and the consultation.</p> <p>Learning about pain gate theory and how to talk to about chronic pain with patients.</p>	<p>Introductions of everyone done at the beginning.</p> <p>Trainer continually prompts for audience engagement: “I want this to be interactive—I want you to challenge me.”</p>

	Overview	Staff roles present	Key issues or questions raised by participants	Most valuable aspects (from participants)	Success factors for an engaged session
	tool marked yes, how to ask differently if patient confused by the question. Approach tool as conversation starter.			<p>The interface between back pain and behavioral health.</p> <p>The need to ask more questions of the patients to help them feel heard.</p>	
Session 5 (5 sessions observed)	<p>Oriented session towards relationship building and sharing knowledge between PCPs and PTs. Attempt to address the need for better integration of care.</p> <p>PTs informed physicians about the nature of the PT training and discussed what changed about their practice (ie, use of tool, focus on function vs. pain, goal-setting with patients) as well as how they used the tool.</p> <p>Attempted to align PCP's and PT's work with back pain patients by using a unified message around function and need for seeing behavioral health in some circumstances.</p>	PCPs and PTs	Ideas for improving collaboration between primary care and PT were discussed: use “goal-oriented/function-oriented” language, how and when to refer to PT.	<p>Communication, interaction and discussion between PTs and PCPs.</p> <p>Great to learn how PTs work and what they do.</p> <p>Learning to do consistent messaging.</p>	<p>PTs who are comfortable speaking in front of others.</p> <p>Managers/facilitators present to guide flow of conversation.</p>
Session 6 (5 sessions observed)	Aimed session at building an understanding of the role that CAM can play for back pain patients. Emphasis was on very practical information. Evidence was presented, contraindications, dosing, and background for CAM modalities: acupuncture, chiropractor, yoga, and massage.	PCPs	<p>Providers main questions during the session centered around:</p> <ol style="list-style-type: none"> 1. Specific questions about modalities and wanting to parse out best options for patients. 2. Questions about referral—who refers? How many can they have? To 	<p>CAM providers resource.</p> <p>Presentation of data and evidence-base around modalities.</p> <p>The need to combine an active approach with passive</p>	PCPs responded well to the scientific evidence.

RUNNING TITLE: Implementation of StarT Back risk stratification

	Overview	Staff roles present	Key issues or questions raised by participants	Most valuable aspects (from participants)	Success factors for an engaged session
	The primary message was that all options recommended in the guidelines have proven benefit, but benefit is moderate, and being active is important. We don't know which patients will benefit most from a particular CAM modality but it is important that patients feel they have options.		whom? Based on their insurance/Medicare?	modalities. Knowledge about kinds of CAM advice to give patients.	

PCPs, primary care providers; RNs, registered nurses; LPNs, licensed practical nurses; MAs, medical assistants; PTs, physical therapists; CAM, complementary and alternative medicine; MRI, magnetic resonance imaging; EHR, electronic health record

Table 3: Description of Physical Therapy Training

	Planned Topics	Emergent issues/topics
Day 1	<ul style="list-style-type: none"> • Description of STarT Back Trial, IMPaCT study and other related research • Description of stratified care (use of the STarT Back tool and matched treatments) • Myths and facts about patients that have chronic pain 	<ul style="list-style-type: none"> • Need for good care coordination between PTs and other care team members • Concern about getting only difficult patients and/or impact on PTs practice • Need to develop a shared language between care team members

RUNNING TITLE: Implementation of StarT Back risk stratification

	<ul style="list-style-type: none"> Research on pain models, the complexity of pain experiences, with special emphasis on moving away from seeing pain as an indication of tissue damage Research on neurophysiology of pain 	<ul style="list-style-type: none"> regarding how they talk about back pain Questions about opioid use/abuse
Day 2	<ul style="list-style-type: none"> Research on neurophysiology of pain (continued) Review of key factors that contribute to development and maintenance of pain-related disability Communication skills for working with patients with disabling chronic pain 	<ul style="list-style-type: none"> Topics related to pain behaviors: depression, catastrophizing, self-efficacy, operant conditioning View of negative behaviors as “normal,” not problem behaviors Self-efficacy and operant conditioning and how to reinforce the behaviors you want
Day 3	<ul style="list-style-type: none"> Assessment of high-complexity patients Managing/treating high-complexity patients Integrating the psychosocial approach into manual therapy 	<ul style="list-style-type: none"> Using EHR tools and administering the STarT Back tool Working with patients who are angry, depressed or distressed How to respond to suicidal ideation Discussion about the efficacy/effectiveness of manual therapy Cost/benefits of disability
Day 4	<ul style="list-style-type: none"> Explaining pain Managing expectations Facilitating behavioral change/goal setting 	<ul style="list-style-type: none"> Moving from reassurance to behavior change Examples of how to talk with patients about their pain (duration, reasons, etc.) Balancing between not minimizing patient experience while also encouraging movement and behavior change
Day 5	<ul style="list-style-type: none"> Managing disability Vocational rehabilitation Clinical decision making and treatment planning Monitoring and modifying treatment plans 	<ul style="list-style-type: none"> Perceiving and probing on psychosocial barriers

PTs, physical therapists; EHR, electronic health record

Table 4: Primary Care Training: Post-Session Evaluation Questionnaire Results¹

	Session 1 n=79	Session 2 n=84	Session 3 n=40	Session 4 n=81	Session 5 n=37	Session 6 n=81
Today's session was a valuable use of my time.	88%	91%	95%	88%	98%	98%

RUNNING TITLE: Implementation of StarT Back risk stratification

The information was clearly presented.	94%	93%	93%	96%	87%	100%
I learned information that will help me improve my care for patients with back pain.	70%	85%	95%	83%	87%	93%
Because of this session I am more confident that I can help my patients with back pain.	55%	73%	90%	82%	81%	89%

¹Results are percentages of all respondents who endorsed the statement with "agree or strongly agree."

Table 5: Primary Care Team and PT Interview Recruitment Summary

<i>Type of Team Member</i>	Recruitment Target (per clinic)	Clinic 1	Clinic 2	Clinic 3	Total Interviews Completed
<hr/>					

RUNNING TITLE: Implementation of StarT Back risk stratification

<i>PCP</i>	3	Completed Interviews	3	3	2	8
		Recruitment Letters Sent (active/passive refusals)	7 (4)	5 (2)	7 (5)	
<i>MA</i>	1	Completed Interviews	1	1	2	4
		Recruitment Letters Sent (active/passive refusals)	6 (5)	3 (2)	4 (2)	
<i>LPN</i>	1	Completed Interviews	1	1	1	3
		Recruitment Letters Sent (active/passive refusals)	2 (1)	2 (1)	2 (1)	
<i>PT</i>	Clinics 1 & 3: 2 / Clinic 2: 3-4	Completed Interviews	2	3	2	7
		Recruitment Letters Sent (active/passive refusals)	2 (0)	4 (1)	3 (1)	
<i>RN</i>	As needed	Completed Interviews				
		Recruitment Letters Sent (active/passive refusals)	1 (1)	0	2 (2)	
Total			7	8	7	22

PCP, primary care provider; MA, medical assistant; LPN, licensed practical nurse; RN, registered nurse; PT, physical therapist

Table 6: Primary Care Team Training Sessions: Attendance

RUNNING TITLE: Implementation of StarT Back risk stratification

	Session 1 (Intro)	Session 2 (Start Back)	Session 3 (Diagnosis)	Session 4 (Words to Use)	Session 5 (PT update)	Session 6 (CAM, self care)	Chairside Competencies
INVITED							
Clinic 1	39	34	14	34	19	14	34
Clinic 2	64	56	27	56	35	27	56
Clinic 3	29	25	8	29	8	8	25
TOTAL ALL CLINICS	132	115	49	119	62	49	115
Number ATTENDED							
Clinic 1	36	30	13	25	13	11	32
Clinic 2	51	48	27	50	30	24	56
Clinic 3	29	25	8	26	8	8	23
TOTAL ATTENDING ALL CLINICS	116	103	48	101	51	43	111
% ATTENDED							
Clinic 1	92%	88%	93%	74%	68%	79%	94%
Clinic 2	80%	86%	100%	89%	86%	89%	100%
Clinic 3	100%	100%	100%	90%	100%	100%	92%
TOTAL % ATTENDING	88%	90%	98%	85%	82%	88%	97%

FIGURES

Figure 1: Basic Logic Model (relationship between the implementation strategies and key intervention components).

