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Stratified models of care

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A B S T R A C T

Stratified care for back pain involves targeting treatment to subgroups of patients based on their key characteristics such as prognostic factors, likely response to treatment and underlying mechanisms. It aims to tailor therapeutic decisions in ways that maximise treatment benefit, reduce harm and increase health-care efficiency by offering the right treatment to the right patient at the right time. From being called the 'Holy Grail' of back pain research over a decade ago, stratified care is becoming the zeitgeist in research and clinical practice. In this chapter, we introduce and evaluate the quality and underpinning evidence for three examples of stratified care for back pain to highlight their general principles, research design issues and clinical practice implications. We include consideration of their merits for implementation in practice. We conclude with a set of remaining, key research questions.

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Introduction

A sobering reflection is that despite a general increase in low back pain research study numbers and quality in recent decades, available treatments tend to produce at best, small-to-moderate mean effects [1], typically in the short term, with none affecting longer-term prognosis [2]. There are several key explanations, explored in detail elsewhere [3,4], but one that has spawned a surge in clinical and research interest in the last decade is that of patient heterogeneity or variability in response to treatment. As randomised trials usually focus on average treatment effects in heterogeneous patient groups, they can fail to reveal the wide range of individual responses to specific treatments, from those who benefit a great deal, to those who benefit little or may even be harmed. Thus, a compelling argument for achieving better treatment results is to match groups of patients with the most appropriate treatment for their profile, referred to as stratified care.

Stratified care involves targeting treatment to patient subgroups based on key characteristics such as their prognostic profile, likely response to specific treatment and suspected underlying causal mechanisms. It 'fast tracks' patients to appropriate treatment by supporting therapeutic decision making in order to maximise treatment-related benefit, reduce harm and increase health-care efficiency [5]. Low back pain is an ideal clinical condition within which to research stratified care as it includes a heterogeneous population with clear variation in prognosis and numerous treatment options, some of which are costly and associated with higher risks [5–7]. In addition, most clinicians believe nonspecific low back pain to include a number of distinct conditions and therefore already use pattern recognition and patient profiling to target their treatment decision making [8]. Stratified care is also particularly suited to low back pain given that the sheer numbers of patients make it unsustainable to offer resource-intensive treatments to all. Subgrouping and targeting care for these patients has been a top international research priority for over 17 years [9,10]. From being called the 'Holy Grail' of back pain research over a decade ago [11], stratified care is becoming the zeitgeist or dominant school of thought in research and clinical practice.

The idea of stratification is more than 50 years old given that, in 1957, Cronbach wrote "we should design treatments not to fit the average person but to fit groups with particular aptitude patterns…on the assumption that aptitude-treatment interactions exist." [12]. The term 'stratified medicine' has been particularly coined in relation to drug targeting in cancer [13], but globally many clinical fields are progressively moving towards stratified care (e.g., diabetes [14] and cardiovascular risk [15]) with the ultimate goal of personalised medicine in the future.

There has been a proliferation of studies testing a wide array of approaches to stratifying low back pain patients for treatment, each with different (but sometimes overlapping) philosophies and methods. There are now almost as many systematic reviews on this topic [1,16–22] as original studies and collectively these highlight the limitations in the evidence base to date. These include the lack of plausible rationales for the patient groups or classifications [20], wide variation in the proportions of patients classified into groups [18], small sample sizes [16,18], concerns about spectrum bias [18] as well as the lack of published protocols, trial registration [18] and long-term follow-up [16]. Overall, the reviews either conclude there is limited evidence to support the clinical application of stratified care [17,20] or they go further to say that available data do not provide evidence of improved patient outcomes [1]. Interestingly, no stratified care approach has yet attempted to subgroup patients across the whole spectrum of available treatments (physical, pharmacological and surgical) [19]. Of particular importance is the fact that most available studies use designs that cannot differentiate between more general predictors of outcome (prognosis regardless of treatment) and predictors of response to specific treatment (treatment effect modifiers) [18,20], as very few use the randomised controlled trial (RCT) design.

Reassuringly, there is a growing body of published guidance focussed on the key stages of research in stratified care, including early stages of development or derivation of the subgrouping method, testing and validating it in both narrow (similar clinical setting and population) and broad validation (broader clinical settings and populations) and assessing its impact on patient outcomes, clinical behaviour, resource use and costs [23–27]. The proliferation of interest in prognostication to guide treatment decisions, in general, and stratified medicine, in particular, has fuelled a recent initiative, the MRC PROGnosis RESearch Strategy (PROGRESS) Partnership (www.progress-partnership.org) and a series of helpful publications (e.g., Refs. [5,7]). In this chapter, we consider stratified care as broadly one