1 Introduction

Establishing the effectiveness of an intervention does not guarantee its adoption into routine practice. Although long recognised, the challenges of getting evidence into practice have become increasingly prominent in recent years as attention has focused on the performance of health systems and the need to ensure that patients benefit from new evidence. Addressing the research–practice gap has spawned a new field that has come to be known as implementation science. Grounded in several disciplines, implementation science is the study of strategies to promote uptake of evidence-based interventions into healthcare practice and policy. The field includes (but is not limited to) the study of professional, patient, and organisational behaviour change. It has championed increased use of empirical research and of theoretical approaches to understand, guide, and evaluate implementation.

In this Element, we describe many of the ideas, theories, and strategies that have emerged from the field over the last decade or so, highlighting how they are or could be applied in practice. We then critically reflect on the overall contribution of the field, outlining a range of challenges in relation to the role and use of theory, the need for mechanism-based explanations of change, and how best to rigorously evaluate change in complex systems.

2 What Is Implementation Science?

Implementation science is commonly defined as the scientific study of methods to promote the systematic uptake of evidence-based clinical treatments and practices and organisational and management interventions into routine practice.[1] It includes the study of implementation processes, intervention adaptation and fidelity, and the influences on patient, professional, and organisational behaviour. Rather than clinical effectiveness, the endpoints of interest for implementation studies are the effects of deliberate and purposive actions to implement evidence-based interventions. Acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability are all of interest.[2] The field also encompasses research focused on the de-implementation of interventions demonstrated to be of low or no clinical benefit.[3,4] With de-implementation, a major focus is on the type of action necessary for de-implementation to occur and the time frame in which it should or can be achieved.[4]

One important question, of course, is whether implementation science is a science. Not really. The term itself is largely derived from the journal of the same name, so in reality it is a publishing construct. A search for the term 'implementation science' in PubMed reveals no use before the journal's

inception in 2006. But, although it is sometimes portrayed as such, this does not make the journal's launch year zero for the field; interest in the uptake of evidence-based interventions and their sustainment in practice has a long lineage, as we describe later in this Element (see Section 3). However, having implementation science as an umbrella term has been useful, in particular in giving some coherence to what is an inherently interdisciplinary, applied research field that draws on theoretical and methodological insights across multiple well-established social science disciplines, including psychology, sociology, economics, and organisation studies. Accordingly, the study of implementation is not (or at least should not be) constrained by any particular research method.

There are of course boundaries. The focus of the field remains resolutely on the uptake of evidence-based interventions. It is, however, engaged in constant reciprocal dialogue with other fields – for example, mainstream health services research has benefited from theoretical and methodological developments in implementation science (something particularly evident in the evaluation of the effectiveness of complex interventions[5,6]). Similarly, biomedical and discovery science are increasingly interested in the role that implementation science methods could play, for example, in accelerating the translation and integration of discoveries into healthcare and ultimately health outcomes.[7]

De-implementation – efforts to remove, reduce, replace, or restrict the use of interventions that have been shown to be of no or low clinical benefit, or that are not cost-effective when compared with alternatives – is an increasing area of interest and investigation for implementation science.[3,4] Although initial theoretical work suggests that behavioural theories may not distinguish between implementation and de-implementation,[8] the factors that shape the processes of implementation and de-implementation are likely to be different and may work in different ways.[9] Frameworks for conceptualising de-implementation are now available[10,11] and, as evidence and practice experience accumulate, so will understanding of the behaviours and processes at play.

3 A Brief History of Implementation Science

Although implementation science is a contemporary term, concerns about unwarranted variation in healthcare and interest in how ideas spread in social systems have a long lineage. These issues, along with the ability to systematically codify evidence-based knowledge to enhance professional practice, have been key drivers in the development of the field.

3.1 Origins of Efforts to Understand Uptake and Reduce Unwarranted Variation

Concerns about the uptake of research findings and reducing unwarranted variation in practice and outcomes are not new. Spiegelhalter eloquently detailed the long history of enquiry into unwarranted variation in surgical outcomes initiated first in the nineteenth century by Florence Nightingale and then later championed by others, including Ernest Codman.[12] Codman advocated systematic follow-up of all patients to understand treatment outcomes, including whether errors were due to lack of 'technical knowledge or skill'.

> *To effect improvement, the first step is to admit and record the lack of perfection. The next step is to analyze the causes of failure and to determine whether these causes are controllable. We can then rationally set about effecting improvement by enforcing the control of those causes which we admit are controllable, and by directing study to methods of controlling those causes over which we now admit we have but little power.*[13]

In the 1930s, emphasis started to shift towards consideration of variation in the face of what was known to represent effective practice. Glover famously highlighted wide variation in tonsillectomy rates across England and Wales and argued that the only plausible explanation was that 'it is too often performed without adequate cause, or sufficient regard to the possibility of enlargement being temporary, physiological, or immunological'.[14]

This interest was accompanied by the development of methods to improve the quality and efficiency of healthcare, culminating in Donabedian's paradigm-shifting work on structure, process, and outcome,[15] which remains core to much of measurement in health services research. Alongside this work, Lembcke pioneered the use of audit and feedback.[16] He demonstrated that by using predetermined criteria, it was possible to collect, compare, and share data on variation in performance with clinicians in ways that could enhance the quality of care delivered. Interest in audit and feedback was rekindled in the 1980s through concerns that simply identifying suboptimal performance was in itself not sufficient to change clinicians' behaviour.[17,18] The effects of audit and feedback are among the most researched aspects of implementation science[19] (for further details, see the Element on audit, feedback, and behaviour change[20]).

3.2 Diffusion of Innovations

Alongside long-standing concerns about the need to reduce unwarranted variation, the roots of implementation science are deeply embedded within the social sciences, particularly in the literature relating to diffusion of innovations.

The history of diffusion research is well described elsewhere,[21,22] but essentially it offers a theory of how, why, and at what rate new ideas or innovations spread through defined populations and social systems. The influence of the early work of Everett Rogers in rural agriculture is well known, but it is perhaps the work of medical sociologist James Coleman that highlighted the potential of the theory, particularly to those concerned with the production and dissemination of evidence-based clinical guidelines in the late 1980s and early 1990s.

Working in the 1950s, Coleman et al.[23] investigated the adoption of the then-new antibiotic tetracycline by clinicians in Illinois. They interviewed clinicians about their use of tetracycline 15 months after the drug was introduced, and found that the social networks of participants were strongly associated with uptake.

> *. . . these comparisons suggest that the process of introduction for those doctors who were deeply embedded in their professional community was in fact different from the process for those who were relatively isolated from it. The highly integrated doctors seem to have learned from one another, while the less integrated ones, it seems, had each to learn afresh from the journals, the detail man (drug salesman), and other media of information.*[23]

Rogers reported that later analysis suggested more influence from advertising and pharmaceutical representatives.[21] Nevertheless, Coleman's work surfaced the potential for strategies – opinion leaders, educational outreach, and persuasive communications – that could be used to promote the uptake of research findings or, more pressingly, for codified knowledge in the form of evidence-based clinical guidelines. This became an increasing concern on both sides of the Atlantic.

3.3 Growing Interest in Getting Research Evidence into Practice

The early period of evidence-based medicine focused on producing and synthesising research evidence, on making it more accessible, and on promoting its use in the development of clinical guidelines. This required the creation of methods and supporting evidence infrastructures. In the late 1980s, the RAND Corporation were pioneers of systematic and standardised processes to assess health technologies.[24] Also in the USA, the Agency for Health Care Policy and Research was established in 1989 to enhance the quality, appropriateness, and effectiveness of healthcare services.[25] These early iterations of what has become known as health technology assessment is now a mainstay of health systems globally and one of the key building blocks of evidence-based clinical guidelines.

Alongside the systematic codification of knowledge, there was renewed and increasing interest in getting the presented evidence to be adopted and used in practice. In Canada, Lomas et al. were recognising that guidelines alone were unlikely to effect change in actual practice.[26,27] In the USA, Soumerai et al. were investigating strategies to improve the prescribing practices of primary care clinicians.[28] And in Europe, Grol[29] and Grimshaw and Russell[30] were exploring how best to implement clinical guidelines in primary care.

In 1994, the Agency for Health Care Policy and Research convened a conference of experts, including Everett Rogers, to discuss and provide guidance on effective methods of guideline dissemination.[31] At the same time, in the UK these ideas were also being shared with mass audiences in the National Health Service (NHS) via the groundbreaking *Effective Health Care* series of bulletins – first through *Implementing clinical practice guidelines*[32] in 1994 and then later through *Getting evidence into practice*.[33] The *Effective Health Care* bulletins, which were produced by the University of York and began in 1992, predated the creation in 1999 of a national guideline infrastructure in the form of the National Institute for Clinical Excellence (NICE). The bulletins were charged with synthesising and disseminating the best available evidence on selected topics to inform NHS policy and practice.

The 1999 *Getting evidence into practice* bulletin was one of the first publications to advocate, albeit somewhat naïvely, for theoretically informed implementation.[33] More rigorous and systematic approaches to theory development and application were to follow, most notably led by Michie and Johnston.[34] Underpinning these approaches was the principle that because evidence-based practice depends on human behaviour, change efforts could be improved by drawing on theories of behaviour change.[34] Advocacy for and use of theoretical approaches to understand, guide, and evaluate implementation processes was one of the key pre-existing principles from which a new general field of implementation science would emerge. With the launch of the journal *Implementation Science* in 2006,[1] the field finally had a focal point for its outputs.

3.4 Evolution and Investment in Implementation Studies As a Research Field

Globally, significant investment in research funding and training now supports the field of implementation. The past decade has seen an increase in dedicated, standalone training courses and, most recently, more formal doctoral-level courses. These often adapt and apply methods that are drawn from spheres such as clinical epidemiology, health services research, sociology, and

psychology to implementation science questions.[35,36] This growth in bespoke training has led in turn to the emergence of researchers who now define themselves as implementation scientists rather than as working within a particular discipline.

The other significant investment has been in research infrastructure. As the potential of implementation science methods has become increasingly recognised, the need to harness the expertise and resources of the field in continuous efforts to improve healthcare systems has also been acknowledged. This recognition has led to the development of new models of research and practice partnerships. In the USA, the Veterans Health Administration has long been at the forefront of efforts to enhance partnered research through its Health Services Research and Development Service and the Quality Enhancement Research Initiative (QUERI).[37] Since 1998, QUERI collaborations have identified service gaps and developed evidence-based best practices, embedding them into routine practice across the Veterans Health Administration system.[38] The key feature of QUERI has been a strong focus on rigorous comparative effectiveness research and the evaluation of implementation strategies to support uptake and spread. This approach has been mirrored in other geographical settings, most notably in the UK through Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), which were launched in 2008 and funded by the National Institute for Health Research.

CLAHRCs were collaborative partnerships between universities and surrounding health service organisations and were focused on improving patient outcomes through the conduct and application of applied health research. Although CLAHRCs generated a large body of knowledge and learning, the relative lack of national impact on healthcare provision or outcomes has been noted.[39] The policy shift from CLARHCs to Applied Research Collaborations (ARCs) in 2019 suggests efforts to address this. With a clearer focus on high-quality applied health and care research, ARCs may be closer to the QUERI initiative in both form and function.

4 Implementation Science in Action

Traditionally, implementation science has three areas of focus. First, it encompasses theory and research focused on exploring the contexts, behaviours, and practices that can act as influences on successful implementation, specifically exploring barriers and enablers. Second, there is a focus on the design and evaluation of strategies to address those factors identified as helping or hindering the implementation of evidence-based interventions in a given context. Finally, the field features an increasing focus on understanding the process of