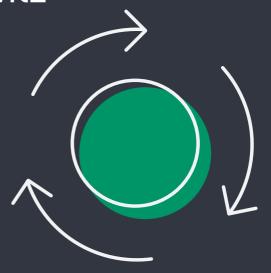


Improving Quality and Safety in Healthcare

Learning Health **Systems**

Thomas Foley and Leora I. Horwitz



Cambridge Elements =

Elements of Improving Quality and Safety in Healthcare edited by

Mary Dixon-Woods,* Katrina Brown,* Sonja Marjanovic,†
Tom Ling,† Ellen Perry,* Graham Martin,* Gemma Petley,*
and Claire Dipple*
*THIS Institute (The Healthcare Improvement Studies Institute)

†RAND Europe

LEARNING HEALTH SYSTEMS

Thomas Foley^{1,2} and Leora I. Horwitz³

¹ Population Health Sciences Institute, Newcastle
University

² School of Medicine, University College Dublin

³ Department of Population Health, NYU Grossman
School of Medicine









Shaftesbury Road, Cambridge CB2 8EA, United Kingdom
One Liberty Plaza, 20th Floor, New York, NY 10006, USA
477 Williamstown Road, Port Melbourne, VIC 3207, Australia

314–321, 3rd Floor, Plot 3, Splendor Forum, Jasola District Centre,

New Delhi – 110025, India

103 Penang Road, #05-06/07, Visioncrest Commercial, Singapore 238467

Cambridge University Press is part of Cambridge University Press & Assessment, a department of the University of Cambridge.

We share the University's mission to contribute to society through the pursuit of education, learning and research at the highest international levels of excellence.

www.cambridge.org
Information on this title: www.cambridge.org/9781009325905

DOI: 10.1017/9781009325912

© THIS Institute 2025

This publication is in copyright. Subject to statutory exception and to the provisions of relevant collective licensing agreements, with the exception of the Creative Commons version the link for which is provided below, no reproduction of any part may take place without the written permission of Cambridge University Press & Assessment.

An online version of this work is published at doi.org/10.1017/9781009325912 under a Creative Commons Open Access license CC-BY-NC-ND 4.0 which permits re-use, distribution and reproduction in any medium for non-commercial purposes providing appropriate credit to the original work is given. You may not distribute derivative works without permission. To view a copy of this license, visit https://creativecommons.org/licenses/by-nc-nd/4.0

When citing this work, please include a reference to the DOI 10.1017/9781009325912

First published 2025

A catalogue record for this publication is available from the British Library

ISBN 978-1-009-32590-5 Paperback ISSN 2754-2912 (online) ISSN 2754-2904 (print)

Cambridge University Press & Assessment has no responsibility for the persistence or accuracy of URLs for external or third-party internet websites referred to in this publication and does not guarantee that any content on such websites is, or will remain, accurate or appropriate.

Every effort has been made in preparing this Element to provide accurate and up-to-date information which is in accord with accepted standards and practice at the time of publication. Although case histories are drawn from actual cases, every effort has been made to disguise the identities of the individuals involved. Nevertheless, the authors, editors and publishers can make no warranties that the information contained herein is totally free from error, not least because clinical standards are constantly changing through research and regulation. The authors, editors and publishers therefore disclaim all liability for direct or consequential damages resulting from the use of material contained in this Element. Readers are strongly advised to pay careful attention to information provided by the manufacturer of any drugs or equipment that they plan to use.

Learning Health Systems

Elements of Improving Quality and Safety in Healthcare

DOI: 10.1017/9781009325912 First published online: March 2025

Thomas Foley^{1,2} and Leora I. Horwitz³

¹ Population Health Sciences Institute, Newcastle University

² School of Medicine, University College Dublin

³ Department of Population Health, NYU Grossman School of Medicine

Author for correspondence: Thomas Foley, thomas.foley@newcastle.ac.uk

Abstract: Despite enormous efforts at healthcare improvement, major challenges remain in achieving optimal outcomes, safety, cost, and value. This Element introduces the concept of learning health systems, which have been proposed as a possible solution. Though many different variants of the concept exist, they share a learning cycle of capturing data from practice, turning it into knowledge, and putting knowledge back into practice. How learning systems are implemented is highly variable. This Element emphasises that they are sociotechnical systems and offers a structured framework to consider their design and operation. It offers a critique of the learning health system approach, recognising that more has been said about the aspiration than perhaps has been delivered. This title is also available as open access on Cambridge Core.

Keywords: learning health system, innovation, knowledge generation, big data, quality

© THIS Institute 2025

ISBNs: 9781009325905 (PB), 9781009325912 (OC) ISSNs: 2754-2912 (online), 2754-2904 (print)

Contents

1	Introduction	1
2	The Data-Knowledge-Practice Learning Cycle	4
3	Understanding and Managing Complexity in Learning Health Systems	g
4	Components of Learning Health Systems	13
5	Critiques of the Learning Health System Approach	19
6	Conclusions	21
7	Further Reading	21
	Contributors	23
	References	25

1 Introduction

A learning organisation can be defined as 'an organization skilled at creating, acquiring, and transferring knowledge, and at modifying its behaviour to reflect new knowledge and insights'. The concept of a learning organisation began to develop during the 1980s and 1990s, as the evidence-based medicine movement aligned with the advent of electronic health data to make large-scale learning both desirable and feasible. It took a leap forward in 2001, when the US Institute of Medicine's (IOM) landmark report *Crossing the Quality Chasm* identified the potential for information technology to underpin improvement. A 2006 IOM roundtable on evidence-based medicine then introduced the idea of a 'learning healthcare system'. Over almost two decades, the concept has evolved and spread, and is now used to describe a wide range of structures and activities.

In this Element, we briefly outline what is meant by a learning health system. We emphasise that while digitisation of healthcare has been crucial to the development of learning health systems, social and cultural factors are critical too. We present a sociotechnical framework, recognising the interaction between people and technology. The framework helps structure thinking about the design and operation of learning health systems. We explore the role of complexity and the components that make up a learning health system. Finally, we offer a critique of the learning health system approach, recognising that more has been said about the aspiration than perhaps has been delivered.

1.1 Learning Health Systems as Sociotechnical Systems

There have been many definitions of a learning health system, but a particularly useful one emerged from the IOM, describing a health system in which:

science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process, patients and families' active participants in all elements, and new knowledge captured as an integral by-product of the delivery experience.

This definition makes it clear that a learning health system is not a data or a technology project, but the evolution of a healthcare system into one that learns from every patient who is treated and is able to apply that learning in real time to shape practice. Learning health systems come in many different shapes and sizes. There is no single typical example. Some learning health systems involve multiple organisations that collectively meet the IOM criteria for a single disease or treatment modality (e.g. ImproveCareNow for paediatric bowel disease); others

are limited to a single healthcare entity but encompass all its care (e.g. Geisinger Health System, Pennsylvania, USA; NYU Langone Health, New York, USA). There are even some efforts to create learning health systems at a national level (e.g. the United States Food and Drug Administration (FDA) Sentinel programme which monitors the safety of medical products). Learning health systems may try to address diverse goals, including:

- · improving patient outcomes and experience
- providing better value healthcare
- · reducing unwarranted variation
- · generating and applying generalisable knowledge
- monitoring evolving trends and epidemiological phenomena
- improving education, training, and performance of the workforce.⁵

Learning health systems can focus on operational improvement, research, or clinical issues. What unites them is the common cycle of capturing data from practice, turning it into knowledge, and putting knowledge back into practice.

A learning health system is not a distinct healthcare improvement method. Rather, a learning health system requires development of systematic organisational capabilities that can enable the routine deployment of multiple improvement methods, including many of those outlined in other Elements in this series. Also fundamental is that a learning health system is an ongoing journey rather than a destination (see Box 1).⁷

Box 1 Geisinger Health System

Geisinger Health System (GHS) is an integrated health services organisation on a learning health system journey. Its aim is to continuously generate knowledge, improve care, and deliver value.⁸

GHS serves more than 2.6 million residents throughout central and northeast Pennsylvania in the USA. It uses advanced patient- and clinician-facing technologies that generate high-quality data assets, with the GHS enterprise warehouse aggregating clinical, financial, and social determinants data from over 100 sources.⁹

As well as data and technology, GHS makes use of patient-populated advisory groups, focus groups, surveys, and other methods to involve patients in policy development, quality improvement, and clinical innovation.⁹

GHS uses data, knowledge, and systems engineering to drive a continuous care improvement cycle in the following ways:¹⁰

Box 1 (cont.)

- process automation to reduce clinical workload for example, by prepopulating clinic notes with existing data
- clinical decision support for example, prepopulating order sets mapped to best practice guidelines
- predictive modelling to identify potentially high-risk or high-cost situations such as clinic 'did not attends'
- collaboration and data sharing with regional neighbours to improve the quality and convenience of care
- national and international collaborations on research and learning health system components
- consultancy support for other organisations.

GHS is increasingly recording patient reported outcomes and patient experience data from inside and outside the clinic. It has created a behavioural insights team that addresses behaviour change challenges across the clinical departments and measures the effectiveness of interventions using rapid A/B testing (a rapid randomised experiment involving two variants).

Patients are encouraged to become active partners with clinicians in their own care through an online portal. They are encouraged to contribute to research, improvement, and innovation through patient and family advisory councils. Patients are also involved in the design process through use of the five-step Stanford design thinking model: empathise, define, ideate, prototype, and test.⁹

At its core, a learning health system is one in which is there is a constant cycle of practice to data to knowledge and then back to practice (Section 2). Such systems are extremely complex (Section 3). Supporting the learning cycle, at whatever level (team, small provider, regional group of organisations, national or even international system), requires the foundations of a learning community and technological infrastructure. Alongside these are several other components, which we refer to in this Element as the foundations and building blocks of a learning health system (Section 4). 8,11-16 Despite the diversity of learning health systems, this framework (shown in Figure 2) seeks to address issues that are common to all the examples which meet the definition given at the beginning of this section.

2 The Data-Knowledge-Practice Learning Cycle

At the core of the learning health system is the learning cycle: collecting data from routine practice, analysing that data to generate new knowledge, and translating that knowledge back into improved practice (Figure 1).¹⁷

2.1 Practice to Data

A learning health system needs to be able to collect and assemble relevant data from practice to support its activities. One key source of data for many learning health systems is the electronic health record, which can generate both highly structured data that can be used for quantitative analysis and free text that can be mined using techniques such as natural language processing or tools such as large language models. ^{18,19,20}

Using data collected during routine care for learning system purposes is not straightforward. Because the data is generated as a by-product of care provision, it is not always high quality. If collected data is inaccurate, incomplete, or out of date, then the knowledge generated may have the same problems, which could result in poor decisions and possibly harm to patients. Improving data quality requires a multi-level, sociotechnical effort from patients and staff, clinical coders, system designers, and analysts, ideally supported by some higher-level oversight. For example, in the NHS, the automated Data Quality Maturity Index (DQMI)²² is used to assess the quality of data submitted by providers. DQMI results are published and fed back to data providers to drive improvements. However, the DQMI cannot detect some important aspects of data quality, such as inaccurate data flowing from a provider. Catching such errors currently depends on analyst's contextual knowledge of the dataset, the



Figure 1 The data-knowledge-practice learning cycle

providers, historical data, and the clinical environment where the data are generated.

Large-scale collection of data across one or more organisations requires standards for their definition and exchange to be interoperable.²³ Standards for the terminologies and classifications^{24,25,26} used to describe healthcare, and how data are structured,^{27,28} transported,^{29,30} and secured,³¹ have been slow to develop, but are now gaining more widespread adoption. For example, the Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT) contains an enormous number of standardised clinical terms, including procedures, symptoms, measurements, diagnoses, and medications.²⁴ This allows data in different electronic health record systems to be stored accurately and consistently.

The level of data quality required will depend on what use the data will be put to in each case. Sometimes, depending on the goals of a particular effort, quality challenges may be impossible to overcome, and data may need to be gathered prospectively for a specific purpose rather than being generated from routine care records.

Data must also be protected from inappropriate access and use. Information governance is how organisations ensure that individuals can trust them to use their data fairly, responsibly, and ethically. In the UK, information governance is underpinned by the General Data Protection Regulation (GDPR), which is implemented in law by the *Data Protection Act 2018*. ^{32,33} In the United States, data use and sharing are governed largely by the *Health Information Portability and Accountability Act of 1996*. ³⁴ But whatever the legislation, a learning health system must co-design an information governance framework to the satisfaction of its patients and learning community as well as addressing legal and ethical requirements.

2.2 Data to Knowledge

Once data are available in a standardised, comprehensive, exchangeable, and analysable form, the next challenge is to derive knowledge from the data. Numerous designs and analytic methods can be used, with a selection outlined in Table 1.

Regardless of the method applied, converting data to knowledge requires more than access to the data and the technical ability to design processes with evaluation in mind. To consistently generate knowledge from the data, those technical skills need to be supported by the foundations and building blocks shown in Figure 2.

One example of how this has been achieved is the NYU Langone Health system in New York, USA. Using a learning system approach, it established

Table 1 Special considerations in design and analytical methods for learning health systems

Method	Special considerations for learning health systems
Experimental designs th	at can be used to generate reproducible knowledge
Randomisation ³⁵	Systems-level or operational activities can be randomised, just like clinical therapeutics. Randomised tests can rapidly generate evidence about the value of different ways of organising workflows, processes, and communications.
Pseudo-randomisation ³⁶	Embedding pure randomisation into routine care is not always practical. But alternatives – such as alternating approaches between week on and week off, or between odd and even medical record numbers – are often close to random and more feasible.
Quasi-experimental ana knowledge	lyses that can be used to generate reproducible
Difference-in-	This is particularly useful for studying unit-, hospital-
differences analysis	or population-level event rates, for which there are often naturally existing control groups.
Interrupted time series (ITS) ³⁷	An advantage of ITS over difference-in-differences design is its ability to account for pre-intervention trends. ITS can also be done without a control group, ³⁸ so it's useful in situations where there is no naturally existing comparison (e.g. to generate data from an entire hospital or ambulatory practice).
Regression discontinuity ^{39,40}	This method is useful when there is a specific threshold at which an intervention is applied (e.g. a target laboratory result, a qualifying income, a population percentage).
Artificial control groups ^{41,42}	These methods allow analysis of patient-level data where there is concern about selection bias – for example, generating knowledge from care coordination programmes in which entrance into the programme is likely confounded by self-efficacy and interest.
Statistical process control ⁴³	This is a useful technique from manufacturing that can help identify whether outcomes are stable over time or varying in a random or non-random fashion. See the Element on statistical process control. ⁴⁴

Table 1 (cont.)

Method	Special considerations for learning health systems			
Non-experimental analyses that can be used to generate reproducible knowledge				
Artificial intelligence (AI)	AI methods can help to discover undiagnosed disease, 45 identify new subtypes of disease, 46 predict future events, 47,48 optimise treatment selection, 49 and manage complex medications. 50			
Learning from local experience	Descriptive statistics alone can generate useful insight. For example, Stanford University developed a service that rapidly interrogates the electronic health records of similar patients when a question arises about a patient's optimal treatment or ultimate prognosis. ⁵¹ The service then delivers a descriptive summary of what happened to the other patients.			
Data visualisation	Creating simple visual or qualitative representations of data can often generate important insights. See the Elements on lean and associated techniques for process improvement, ⁵² and measurement for improvement. ⁵³			
Collaborative learning	Knowledge generation in a learning health system cannot always be automated. Humans are uniquely well suited to understanding the complexity of such systems. Deliberative approaches involving all members of the learning community can generate rich knowledge for improvement. 54			

a rapid randomised quality improvement project unit and randomised over a dozen interventions in its first year. The health system was able rapidly to determine the effectiveness of a variety of interventions, including community health worker facilitation, post-discharge telephone calls, letters, and electronic clinical decision support. ^{35,55,56} However, the programme succeeded not simply because NYU Langone Health had statisticians who could randomise interventions, but because:

 The improvement unit was embedded in a system whose leadership deeply valued achieving best outcomes and cared about proving the value of activities performed by staff.

- Frontline clinical staff had a culture of flexibility, adaptability, and crucially trust, such that they were willing to experiment with different approaches confident that they wouldn't lose their positions if an activity they performed was shown not to be effective.
- The IT system was strategically designed to support evaluation and improvement, not just to allow for billing.
- The interventions tested were co-designed with frontline staff who understood the complexity of the system in which they were working.
- Both intervention and evaluation were designed to account for unintended consequences and downstream effects.

2.3 Knowledge to Practice

A system that purely generates knowledge is not a learning health system. A learning health system must complete the cycle by translating the knowledge gained from the system back into practice to continuously improve health and care. Importantly, learning health systems generate knowledge about operations and management, not only about clinical care. These learnings, too, must be translated into practice.

Knowledge can influence practice through publication in journal articles, books, or guidelines; it can be passed on through formal and informal education, training, or other interactions; and it can be used to redesign care environments and health interventions.

Decision-makers often have preferences based on local knowledge, relationships, power structures, or the experience of neighbours. ⁵⁷ And some aspects of clinical practice, such as general problem-solving, procedural skills, healthy attitudes, and professional behaviours are unlikely to be readily replaced by computable knowledge. Tacit knowledge can be communicated through dialogue. Direct interaction and relationships, as well as cross-boundary dialogue, are critical as drivers of learning. ⁵⁸ This can be fostered through a learning community approach, in alignment with the foundations and building blocks of learning health systems (see Section 4).

These approaches are often slow. In a learning health system, the process of applying knowledge to practice can sometimes be sped up. First, learning health systems can be designed to rapidly generalise learning. At NYU Langone Health, for example, an iterative, rapid, randomised set of projects ultimately resulted in an optimal script for engaging patients in preventive care such as cancer screening and diabetes-related screening. The key elements of the script (brevity, starting immediately with the 'ask', including direct links to online appointment scheduling where available, tailoring contact times to those most

suited for patient workflow, incorporating reminders) were immediately generalised to other patient outreach scenarios beyond the ones initially tested because the project involved the frontline staff responsible for all outreach and was designed from the start to be relevant to other situations.

Second, clinical decision support systems can be effectively leveraged for rapid deployment of knowledge across a learning health system by bringing knowledge and guidance to the point of care at the specific moment it is needed (see the Geisinger example (Box 1)).

Traditional decision support requires an underlying logical algorithm (e.g. for a patient meeting a, b, and c characteristics but not d, e, or f, suggest x, y, z interventions) that is manually built based on evidence-based rules and is therefore resource-intensive, slow to implement, and vulnerable to becoming obsolete when new knowledge is generated. One way implementation and update of decision support could be sped up would be to represent new knowledge not just as human-readable guidelines, but as machine-readable code, and then to make such code centrally and openly available to any learning health system. Decision support systems could be designed to reach externally for those rules rather than relying on local code, enabling prompt updates and widespread adoption of knowledge into practice. At present, such programmes are more ambition than reality, though several early efforts exist. 59–62

Any decision support system, whether local or centrally built, has limitations. Patients may not fit the guideline criteria if they have multiple conditions or are taking conflicting medications. The decision support system might not incorporate unstated common-sense rules (e.g. suggesting a pregnancy test in male patients). Perhaps unsurprisingly, machine-readable knowledge that is intended to be applied at the point of care therefore has the potential to cause harm. In England, compliance with clinical safety standards DCB0129 (for manufacturers) and DCB0160⁶⁵ (for deploying organisations) is mandatory under the *Health and Social Care Act 2012*. Under the Medical Devices Regulation published by the European Commission in 2017, software such as a clinical decision support system would be considered a medical device and need to be registered with the Medicines and Healthcare products Regulatory Agency in the UK and audited by a notified body. Agency in the UK and audited by a notified body.

3 Understanding and Managing Complexity in Learning Health Systems

The promise of learning health systems has been that they will revolutionise healthcare by capturing and analysing clinical data to continuously inform and improve decision-making and practice, as described in the previous section.^{68,69} But this is to take too simplistic or optimistic a view of what is ultimately a complex intervention in a complex health system. Such complexity helps to explain why, nearly two decades after the IOM first popularised the concept of a learning health system, no nation, region, or single healthcare provider has fully realised that promise.⁵ Indeed, uncontrolled complexity has been cited as the reason for the failure of many health IT programmes and learning health systems to scale successfully.^{16,70}

Healthcare is a complex adaptive system.⁷¹ It has a vast number of interacting elements with non-linear interactions (meaning that small changes can have disproportionate and often unanticipated consequences), the whole is greater than the sum of its parts, and the system evolves in unpredictable ways.⁷² This complexity is exemplified by the NHS in England, with over one million staff and hundreds of provider organisations grouped into regional structures, all overseen by an ever-changing central administrative structure that is influenced by politicians, the media, and professional bodies. It is the largest part of a broader ecosystem of organisations that together represent one tenth of the country's economic output. The learning health system examples outlined in this Element are themselves complex interventions.

In this section, we will explore complexity by applying Greenhalgh et al.'s non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework for health and care technologies to learning health systems (Section 3.1) and looking at Greenhalgh et al.'s principles for how to manage complexity in a learning health system (Section 3.2).

3.1 Understanding Complexity

Greenhalgh et al.'s NASSS framework for health and care technologies¹⁶ (see the Element on approaches to spread, scale-up, and sustainability⁷³) has been operationalised with a series of complexity assessment tools (CATs) called NASSS-CAT.⁷⁴ NASSS guides an understanding of complexity across seven domains, outlined in Box 2.¹⁶

3.2 Managing a Learning Health System as a Complex System

Greenhalgh et al. have adapted existing principles for managing complexity so that they are relevant to the development of a learning health system. They suggest the following:⁷⁴

Box 2 Domains of complexity within the NASSS framework 16

The condition or illness: According to NASSS, the clinical scenario with which a learning health system is concerned is critical to its likelihood of success. Earlier studies have found that potential patients were often deemed unsuitable for a given intervention because of the complexity of their condition, comorbidities, or sociocultural situation.¹⁶

The technology: Problems with usability and dependability have often been cited as reasons for the failure of technology interventions. ⁷⁵ Another danger is that data produced by technologies may be misinterpreted by patients or clinicians, particularly if the data do not measure the underlying illness directly. Skills and training may also be needed to enable scale-up and spread. Systems that are 'plug and play' or 'off the shelf' can more easily be replaced by other equivalent systems and so avoid the risk of lock-in or provider failure.

The value proposition: Is a learning health system worth developing, and for whom will it generate value? If there is no clear business case, then the innovating organisation will be unable to scale and spread. And if there is no value to the organisation (e.g. a hospital or General Practice), then it will be equally likely to fail. Value can include benefit to patients or improved efficiency, and it can rely on reimbursement and payment mechanisms.

The adopter system: The staff, patients, and carers (the 'adopters') who have to adopt the system (and continue using it) are critical to its success. Staff sometimes abandon technology because of usability problems, but more often they do so because of threats to their scope of practice, fear of job losses, or concerns about patients' safety or welfare. ¹⁶ Patients may be unable to realise the benefits because of the amount of work or capability required of them. ¹⁶ The same is likely to be true of learning health systems. Weak social networks or a lack of skills among carers can result in reduced access. ⁷⁶

The organisation: The organisation's capacity and readiness for change will influence the development and scale-up of a learning health system internally. This process can be made easier where there is organisational slack, but a learning health system that requires significant disruption to existing routines can create resistance. The decision on whether to fund and support a learning health system will be influenced by business modelling, yet it is often impossible to predict costs and benefits in

Box 2 (cont.)

advance. The work involved in implementation is commonly extensive and underestimated at the planning stage. In some cases, innovation can be achieved by working with another more innovative organisation.

The wider context: The wider institutional, policy, and sociotechnical context has often been identified as a key factor in organisations' failure to move from demonstration project to a fully mainstreamed service (scale-up) that is widely transferable (spread) and sustainable (i.e. persists over time). This context can include policy, political, information governance, interoperability, legal, market, intellectual property, and regulatory considerations

Adapting over time: All the other domains will change over time, so to be successful a learning health system must be able to adapt to such change. Likewise, the organisation must have the resilience to respond to critical events.

- Acknowledge unpredictability designers of interventions should contemplate multiple plausible futures; implementation teams should tailor designs to local context and view surprises as opportunities.
- Recognise self-organisation designers should expect their designs to be modified, perhaps extensively, as they are taken up in different settings; implementation teams should actively capture data and feed the data into the adaptation process.
- Facilitate interdependencies designers should develop methods to assess
 the nature and strength of interdependencies; implementation teams should
 attend to these relationships, reinforcing existing ones where appropriate and
 facilitating new ones.
- Encourage sense-making designers should build focused experimentation into their designs; implementation teams should encourage participants to ask questions, admit ignorance, explore paradoxes, exchange different viewpoints, and reflect collectively.
- Develop adaptive capability in staff individuals should be trained not merely
 to complete tasks as directed but to tinker with technologies and processes and
 make judgements when faced with incomplete or ambiguous data.
- Attend to human relationships embedding innovation requires people to work together to solve emergent problems using give and take and muddling through.

• Harness conflict productively – there is rarely a single right way of tackling a complex problem, so conflicting perspectives should be viewed as the raw ingredients for multifaceted solutions.

These principles inform the components that need to be considered when developing a learning health system. These are discussed in the following section.

4 Components of Learning Health Systems

To enable the practice-data-knowledge-practice improvement cycle (Section 2) within the complex environment described in Section 3, it is helpful to have a set of building blocks in place. These building blocks align with the foundations of learning health systems, which are learning communities and technology infrastructure. These two foundations and the building blocks are illustrated in Figure 2 and explained in the subsections that follow. The section concludes with an overview of a maturity assessment tool, used to understand the degree to which the components of a learning health system are achieving a specific objective.

4.1 Learning Communities

A learning community, ^{77,78} whose role is to determine what to improve and to direct activity, is foundational to the learning health system. The learning community guides each of the three key stages of learning described in Section 2.

A large system might have multiple learning communities, perhaps involving collaborations with researchers and funders⁷⁹ or organised into specialised

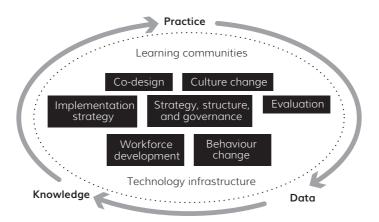


Figure 2 Learning health system framework

institutes.⁹ Learning communities have also been successfully developed for specific diseases, such as ImproveCareNow for paediatric inflammatory bowel disease.^{80,81} Crucially, learning communities should involve patients, not just staff. This is because healthcare is not produced solely by healthcare organisations but co-produced by patients interacting with the healthcare system. Therefore, collaborative learning must involve co-planning, co-design, co-delivery, and co-assessment with patients.⁸²

Detailed resources are available to guide the development of a learning community, ⁷⁷ but in brief, it typically comprises a group of stakeholders who reflect on experience, share judgements, consider uncertainties, and make sense of evidence with the purpose of collective improvement. ⁷⁷ As well as generating knowledge, a learning community can also build trust, capacity, skills, confidence, and agency for change. It should both challenge its members and provide reassurance. ⁷⁷

The learning community has an important role at each stage of the learning cycle: practice to data, data to knowledge, and knowledge to practice.

4.2 Technology Infrastructure

A learning health system will require access to technology infrastructure, perhaps in the form of its electronic health record system or a data warehouse, to support its activities. Technological infrastructure can support every stage of the learning cycle (practice to data, data to knowledge, and knowledge to practice). Recent years have seen the emergence of platforms offering readymade solutions for data management, governance, user interfaces, application programming interfaces, decision support, and workforce solutions. This has made it increasingly affordable for even small organisations to build learning health systems without the need to reinvent each part locally.

Other technological platforms found in a learning health system might include patient portals, decision support systems, regional health information exchanges, business intelligence, and analytics systems.

Platform providers include large IT companies (such as cloud providers), start-ups, electronic record system vendors, academic groups, and even health-care providers. NHS England has developed a national Federated Data Platform that can harness data across multiple providers, enabling more effective transitions of care and operational coordination. In addition, a Secure Data Environment structure for research access allows researchers to access data within the environment while maintaining safety and security. In the environment while maintaining safety and security.

In the United States, the Mayo Clinic Platform links deidentified data from eight health systems in six countries in a federated manner to support health and

health system research as well as to provide data for better health system decision making. Similarly, the electronic health record vendor Epic has aggregated data from across its clients to create a deidentified dataset with data from 259 million patients receiving care at more than 35,400 clinics and more than 1,500 hospitals that is available to member institutions for analytics and research. 86,87

4.3 Building Blocks

As shown in Figure 2, several building blocks need to be considered within a learning health system. These are each discussed next.

4.3.1 Strategy, Structure, and Governance

Strategy generally involves setting goals and priorities, determining actions to achieve those goals, and mobilising resources to execute the actions.⁸⁸ Ultimately, strategy is a set of interrelated choices about how a team or organisation(s) will deliver value.⁸⁹

To be successful, a learning health system requires strategic thinking and must be part of the wider organisation's strategy. And like every other element of a learning health system, strategy must be co-designed by the stakeholders. Many guides and tools are available to help organisations with this. 88–91 Geisinger's learning health system (see Box 1) strategy is, for example, aligned with its organisational strategy. However, Geisinger does not claim to have fully realised its goal of becoming a learning health system, seeing it as 'a moving target'. It recognises a continuing need for better alignment of its midhigh-level leadership with the learning health system concept, including cultural change and strategic alignment in different departments. In common with most organisations, entrenched cultures have been difficult to change. These are expected to be long-term challenges.

Once a strategy has been developed, people and resources must be organised to deliver it effectively – a process sometimes known or represented as a target operating model (TOM) or an organisational architecture. ^{92,93} Britto et al. propose an 'actor-oriented learning network organisational form' with three components: ⁹⁴

- aligning participants around a common goal
- standards, processes, policies, and infrastructure to enable multi-actor collaboration
- a 'commons' (a shared repository) where information, knowledge, resources, and know-how to achieve the goal are created and shared.

4.3.2 Culture Change

A learning health system requires a culture of learning, innovation, sharing, implementation, and research. ⁹⁵ Three interrelated layers of group or organisational culture can be identified: ⁹⁶

- Visible manifestations of a healthcare culture include the distribution of services and roles (e.g. the divide between primary and secondary care, or between health and social care), the physical layout of facilities, pathways of care, workforce practices, reporting arrangements, dress codes, incentive systems, and established quality improvement and clinical governance models.
- Shared ways of thinking include the values and beliefs that justify the
 visible manifestations and the rationales given for doing things differently,
 such as prevailing views on autonomy, dignity, evidence, and service
 improvement.
- **Deeper shared assumptions** are the often-unconscious underpinnings of day-to-day practice, such as assumptions about the roles of patients, carers, and different professionals.

These layers are learned, shaped, and reinforced through training and experience. Culture can be conceptualised as a force that structures and shapes interactions and therefore forms part of the infrastructure of a learning health system. Any given system may include subgroups (e.g. clinicians and managers) with different cultures. The multidisciplinary (often multiagency) nature of a learning health system increases the risk of culture clashes.

Assessing and changing culture are crucial to a learning health system succeeding.⁶ Many tools are available to guide that process, ^{98,99} but no one tool is right for every situation. ¹⁰⁰ Changing a culture is one of the most difficult, but crucial, challenges. See the Element on making culture change happen for further discussion. ¹⁰¹

4.3.3 Workforce Development

A learning health system will contain the broad range of patients and clinical and non-clinical disciplines that would be expected in any health system. It may also include designers, researchers, analysts, data scientists, and knowledge management staff, among others. The workforce may also be distributed across multiple organisations, creating leadership challenges in developing a learning culture and delivering a coherent strategy. 102

As the boxed examples in this Element show, the workforce involved in a learning health system will continue to need the mix of skills required by traditional healthcare organisations. These include leadership, communication, and teamworking skills, service improvement and clinical effectiveness skills, and equality and diversity awareness. ¹⁰³ The workforce may also require new skills around data capture, ¹⁰⁴ data interpretation, ^{18,105,106} research, ¹⁸ and managing continual change. ¹⁰⁵ These requirements are represented in recent UK competency frameworks, ¹⁰⁷ and their systematic development within the workforce will require long-term planning. ⁵

4.3.4 Co-design

Stakeholders should be involved in the development of every element of a learning health system. They are critical to understanding the true complexity of what, superficially, may look like a technical undertaking. Design is a creative process to solve complex problems, ⁸⁶ and user-centred design brings stakeholders into the process. ISO 9241-210 is the international standard in human-centred design for interactive systems. ¹⁰⁸ NHS England has created a set of NHS design principles based on this standard. ¹⁰⁹ Those principles can usefully be applied when developing each element of a learning health system.

The process of meaningfully involving stakeholders has been called many things – co-design, co-production, co-creation, patient-centred, patient engagement, and more. Each of these terms has important definitional differences, but the central objective is to create learning health system interventions that work in the real world. Many guides to co-design are available, along with several online, open-source databases of design tools that can be applied to learning health system development. However, evidence on how to select the most appropriate tools is limited, so that decision will fall to the learning community and will be influenced by the task, the stakeholders, and the outputs required.

Multiple tools may be used to provide different perspectives on the complex system.⁵ It is important to recognise that a learning health system is a service, rather than a product to be manufactured. Therefore, to a greater or lesser extent, it is naturally co-produced by the patient and the clinician through their interactions.⁸² For further discussion of these issues, see the Element on co-producing and co-designing.¹¹⁸

4.3.5 Implementation Strategy

Learning health systems are often large, complex organisations with multiple interventions, so their development is likely to benefit from an implementation strategy. This is an integrated package of discrete approaches, ideally selected to address specific identified barriers to implementation success. ¹¹⁹ Approaches

might cover behaviour change, training, feedback, incentives, learning communities, and stakeholder engagement. The implementation strategy should focus on the successful integration and use of the range of learning health system interventions. See the Element on implementation science for further detail. 120

4.3.6 Behaviour Change

In many cases, a learning health system requires patients, clinicians, and others to change their behaviour to realise an improvement in practice. Many theories and models can be deployed to understand and aid this process.

The behaviour change wheel is one example of a systematic approach to designing, implementing, and evaluating behaviour change interventions in any setting. ¹²¹ It is based on a collection of existing theoretical frameworks and has been applied to learning health systems. The behaviour change wheel begins by understanding the behaviour that is to be changed in terms of three drivers: capability, opportunity, and motivation. An important point to remember, however, is that the people in a learning health system are constrained by the system itself; changing behaviour often requires changing the system. ¹²²

Some organisations (such as Geisinger – see Box 1) have developed behavioural insight teams. For more on behaviour change approaches, see the Element on audit, feedback, and behaviour change. 123

4.3.7 Evaluation

Learning health systems are expensive and can impact the health of large populations, so it is important to understand how effective and cost-effective they are.

Evaluating learning health systems can be challenging. A recent scoping review of current evidence found no published rigorous evaluation of a learning health system. Some effects of a learning system may be unintended, they may manifest only over the very long term, and they may occur in related fields beyond health, such as social care, education, justice, and employment. Traditional randomised controlled trials are often not feasible because the intervention changes rapidly. This also makes it difficult to generalise findings. Qualitative evaluation methods can add an additional dimension and can help to understand how the intervention works. Size

Failure is itself an important source of learning. For example, it can help others to decide whether and how to join a learning health system. But organisations are generally less enthusiastic about publicising failures than successes, ¹²⁵ and finding published examples of learning health systems that have failed is difficult.

4.4 Maturity

It is important to understand the degree to which the components of a learning health system are able to achieve a specific objective in a predictable way. 126 Tools to assess the maturity of health IT systems 127 have been around for a long time, but Lannon et al. 126 have recently developed a process maturity assessment tool specifically for learning health systems. The tool is a capability maturity grid that covers six domains:

- Systems of leadership a set of methods to encourage a network to perform as a system. Activities focus on defining the system's purpose, understanding the system, measuring the system, and planning for improvement.
- Governance and management how policies, processes, controls, oversight, norms, and actions are set up, sustained, and regulated.
- Quality improvement systematic and continuous actions towards measurable improvements in outcomes.
- Community building and engagement the structures and processes that enable all stakeholders to become involved.
- Data and analytics collecting, validating, organising, and standardising data relevant to the system's purpose.
- Research generating knowledge through a range of research methods.

These domains represent characteristics that are likely to ensure high performance. ¹²⁶ The domains also broadly map onto the building blocks outlined above.

5 Critiques of the Learning Health System Approach

There are numerous examples of learning health systems generating important new knowledge. The For example, the Health Maintenance Organisation (HMO) Research Network has for decades generated high-quality research on topics related to organisation, delivery, and quality of care. The REDUCE MRSA collaborative demonstrated in a randomised trial embedded into routine practice that universal decolonisation was more effective than decolonisation of MRSA-positive individuals in reducing bloodstream infections. This was a study that would have required 64 years to do at a typical single hospital, but instead took 18 months and cost less than \$3 million. The system of the

Despite examples like this, there is a dearth of evidence on the likely return on investment associated with learning health systems. ¹²⁹ By emphasising that learning health systems are embedded in healthcare delivery, the literature sometimes suggests that they are always low cost or free. In reality, they require upfront and ongoing investment in technological infrastructure, data collection, and training.

An interdisciplinary science is developing around learning health systems, ⁷⁰ as seen by funding calls, ^{129,130} global communities of practice, ⁶¹ the formation of new university departments, ¹³¹ conferences, ¹³² and an academic journal, ¹³³ all helping to move the field forward. In this context, a common critique of the learning health system concept is that because the definition is so broad, it risks being all things to all people – and therefore nothing about it is distinctive. The learning health system literature has been criticised for being detached from existing theory around organisational and social learning ⁵⁸ and for being insufficiently focused on practical implementation. Conversely, putative learning health systems have been criticised for focusing only on one component of the learning health system (such as making use of big data) or implementing learning health system-type activities only in one area or population. Ideally, a true learning health system would be implemented across the whole system in question and characterised by constant iteration, adaptation, and learning, not static systems.

The gap between ambition and feasibility underlies many of these issues. The framework we have set out in this Element attempts to provide more focus on the challenges around implementation, but the practicalities will be different in each learning health system.

A second challenge for learning health systems relates to data. Data are indisputably at the heart of any learning health system. But they are also its biggest vulnerability. Clinical and operational data are inevitably incomplete, biased, delayed, or otherwise imperfect, since, by definition, learning health systems attempt to learn from data generated during everyday activity, rather than data specifically collected in a high-quality fashion for a particular intervention. A learning health system dependent on faulty data runs a real risk of producing adverse events and suboptimal outcomes. Explicit tests for bias and for data integrity are therefore essential to avoid inadvertently worsening outcomes.

Perhaps the most fundamental critique is that learning health systems may have limited capacity for generating new knowledge or radical systems improvements if they rely on learning from what is being done, rather than promoting innovative, creative tests of what *could* be done. A high-performing learning health system should therefore strive explicitly to incorporate innovation, creativity, and out-of-the-box thinking through culture change and infrastructure to support rapid testing and learning.

Although experimentation and learning are central to learning health systems, a paradox is that the system-wide, complex, multifaceted nature of learning systems make them in themselves not particularly amenable to rigorous, randomised evaluation. More mixed methods research is required to design methods that can determine whether different types of learning health systems work and, if so, under which circumstances.

6 Conclusions

A learning health system is not another healthcare improvement method. Instead, it is the development of systematic organisational capabilities that enable the routine deployment of multiple improvement methods. As described in this Element, a learning health system depends on:

- developing a learning community who can champion the work and foster mutual learning
- explicitly recognising the influence of multiple sociotechnical domains and the crucial role played by institutional culture
- harnessing data effectively but cautiously, with attention to data quality and gaps
- embedding a variety of healthcare improvement and research techniques into routine care
- avoiding oversimplification while valuing complexity.

The complexity of healthcare organisations means that no two learning health systems will be the same. A system cannot be lifted and shifted from one organisation to another, and there is no 'how to' guide for building them. The framework presented here includes the common sociotechnical components of learning at an organisational level. A toolkit has been developed, based on this framework, to curate tools related to each of these challenges. ¹³⁴

As more health systems begin to implement learning health system components, the research community will need to shift from evaluation of individual improvement efforts towards evaluation of how and why learning health systems succeed or fail at scale.

This Element also makes links to other Elements within the series that can help to deliver a learning health system. Ultimately, the development of a learning health system is a journey that will, by definition, never be complete.

7 Further Reading

- Institute of Medicine⁴ the first report of the US Institute of Medicine's roundtable on evidence-based medicine was also the first to put forward a definition of the learning health system.
- McGinnis et al.⁶ this book is the culmination of several years of meetings of the US Institute of Medicine's roundtable on value and science-driven healthcare, which evolved from the roundtable on evidence-based medicine and continued its work on learning health systems for the next six years.

- Learning Health Systems¹³³ an open-access, peer-reviewed, international journal whose goal is to advance the interdisciplinary area of learning health systems.
- Foley et al.⁵ this report describes the framework for understanding learning health systems that was used to structure this Element.
- Hardie et al.¹³⁰ the final output of Health Data Research UK's Better Care
 Catalyst programme's policy and insights workstream, which researched the
 barriers and enablers for implementing learning health systems approaches in
 the UK.
- Zurynski et al. 7 a recent scoping review of current learning health system evidence, published by the Australian Institute of Health Innovation.

Contributors

Both authors have been involved with planning, drafting, reviewing, and approving this Element. Both authors have approved the final version.

Conflicts of Interest

Leora Horwitz is a member of the Geisinger Health System Scientific Advisory Board.

Acknowledgements

We thank the peer reviewers for their insightful comments and recommendations to improve the Element. A list of peer reviewers is published at www.cambridge.org/IQ-peer-reviewers.

Funding

This Element was funded by THIS Institute (The Healthcare Improvement Studies Institute, www.thisinstitute.cam.ac.uk). THIS Institute is strengthening the evidence base for improving the quality and safety of healthcare. THIS Institute is supported by a grant to the University of Cambridge from the Health Foundation – an independent charity committed to bringing about better health and healthcare for people in the UK.

About the Authors

Dr Thomas Foley is principal investigator on the Learning Healthcare Project at Newcastle University, adjunct associate professor at University College Dublin Medical School, clinical lead on the Health Service Executive Ireland Community EHR Programme, and a practicing child and adolescent psychiatrist.

Dr Leora Horwitz is director of the Center for Healthcare Innovation and Delivery Science at NYU Langone Health, director of the Division of Healthcare Delivery Science in the Department of Population Health at NYU Grossman School of Medicine, tenured professor of population health and medicine, and a practicing internist.

Creative Commons License

The online version of this work is published under a Creative Commons licence called CC-BY-NC-ND 4.0 (https://creativecommons.org/licenses/by-nc-nd/4.0). It means that you're free to reuse this work. In fact, we encourage it. We just ask that you acknowledge THIS Institute as the creator, you don't distribute a modified version without our permission, and you don't sell it or use it for any activity that generates revenue without our permission. Ultimately, we want our work to have impact. So if you've got a use in mind but you're not sure it's allowed, just ask us at enquiries@thisinstitute.cam.ac.uk.

The printed version is subject to statutory exceptions and to the provisions of relevant licensing agreements, so you will need written permission from Cambridge University Press to reproduce any part of it.

All versions of this work may contain content reproduced under licence from third parties. You must obtain permission to reproduce this content from these third parties directly.

References

- 1. Garwin DA. Building a learning organization. *Harvard Business Review* 1993; 71(4): 73–91.
- 2. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: The National Academies Press; 2001.
- 3. Institute of Medicine. *The Learning Healthcare System: Workshop Summary*. Washington, DC: The National Academies Press; 2007.
- National Academy of Medicine. The Learning Health System Series. 2007. https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/ (accessed 27 July 2024).
- 5. Foley TH, Zahran, R. *Realising the Potential of Learning Health Systems*. 2021. https://learninghealthcareproject.org/realising-the-potential-of-learning-health-systems/ (accessed 27 July 2024).
- McGinnis JM, Stuckhardt L, Saunders R, Smith M. Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. Washington, DC: The National Academies Press; 2013.
- Zurynski Y, Smith CL, Vedovi A, et al. Mapping the Learning Health system:
 A Scoping Review of Current Evidence. 2020. www.mq.edu.au/__data/assets/pdf_file/0011/1083809/Mapping-the-Learning-Health-System-A-white-paper-web.pdf (accessed 27 July 2024).
- 8. Psek WA, Stametz RA, Bailey-Davis LD, et al. Operationalizing the learning health care system in an integrated delivery system. *EGEMS* 2015; 3(1): 1122. https://doi.org/10.13063/2327-9214.1122.
- 9. Davis FD, Williams MS, Stametz RA. Geisinger's effort to realize its potential as a learning health system: A progress report. *Learn Health Syst* 2021; 5(2): e10221. https://doi.org/10.1002/lrh2.10221.
- 10. Foley T, Fairmichael F. Geisinger Health System Site Visit. www.learnin ghealthcareproject.org/section/evidence/34/63/site-visit-to-geisinger-health-system (accessed 27 July 2024).
- University of Michigan. Our Approach to Learning Health Sciences. https://medicine.umich.edu/dept/lhs/explore-learning-health-sciences/our-approach (accessed 27 July 2024).
- 12. McLachlan S, Potts HWW, Dube K, et al. The Heimdall framework for supporting characterisation of learning health systems. *J Innov Health Inform* 2018; 25(2): 77–87. https://doi.org/10.14236/jhi.v25i2.996.

- 13. Menear M, Blanchette MA, Demers-Payette O, Roy D. A framework for value-creating learning health systems. *Health Res Policy Syst* 2019; 17(1): 79. https://doi.org/10.1186/s12961-019-0477-3.
- 14. Monash Partners. Initiatives: Learning Health System. https://monashpart ners.org.au/initiatives/learning-health-system/ (accessed 27 July 2024).
- 15. Allen C, Coleman K, Mettert K, et al. A roadmap to operationalize and evaluate impact in a learning health system. *Learn Health Syst* 2021; 5(4): e10258. https://doi.org/10.1002/lrh2.10258.
- 16. Greenhalgh T, Wherton J, Papoutsi C, et al. Beyond adoption: A new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *J Med Internet Res* 2017; 19(11): e367. https://doi.org/10.2196/jmir.8775.
- 17. Flynn AJ, Friedman CP, Boisvert P, Landis-Lewis Z, Lagoze C. The Knowledge Object Reference Ontology (KORO): A formalism to support management and sharing of computable biomedical knowledge for learning health systems. *Learn Health Syst* 2018; 2(2): e10054. https://doi.org/10.1002/lrh2.10054.
- 18. Foley T, Fairmichael F. Dr Paul Wallace Interview. https://learninghealthcareproject.org/dr-paul-wallace-interview/ (accessed 27 July 2024).
- 19. Fink MA, Bischoff A, Fink CA, et al. Potential of ChatGPT and GPT-4 for data mining of free-text CT reports on lung cancer. *Radiology* 2023; 308(3): e231362. https://doi.org/10.1148/radiol.231362.
- 20. Hsueh JY, Nethala D, Singh S, et al. Exploring the feasibility of GPT-4 as a data extraction tool for renal surgery operative notes. *Urol Pract* 2024; 11(5): 782–789. https://doi.org/10.1097/upj.0000000000000599.
- 21. Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 2019; 366(6464): 447–453. https://doi.org/10.1126/science.aax2342.
- 22. NHS Digital. Data quality Current Data Quality Maturity Index (DQMI). https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/data-quality#current-data-quality-maturity-index-dqmi-(accessed 27 July 2024).
- 23. ONC. Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure. 2014. www.healthit .gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf (accessed 27 July 2024).
- 24. SNOMED International. What Is SNOMED CT? www.snomed.org/whatis-snomed-ct (accessed 27 July 2024).

- 25. World Health Organization. International Classification of Diseases and Related Health Problems (ICD). www.who.int/standards/classifications/classification-of-diseases (accessed 27 July 2024).
- 26. LOINC: The International Standard for Identifying Health Measurements, Observations and Documents. https://loinc.org/ (accessed 27 July 2024).
- 27. HL7. Standards-Based Product Grid. www.hl7.org/implement/standards/product_matrix.cfm (accessed 27 July 2024).
- 28. OHDSI. OMOP Common Data Model. www.ohdsi.org/data-standardiza tion/the-common-data-model/ (accessed 27 July 2024).
- 29. HL7. FHIR Overview. www.hl7.org/fhir/overview.html (accessed 27 July 2024).
- 30. DICOM. DICOM Standard. www.dicomstandard.org (accessed 27 July 2024).
- 31. CIO. Introduction to HTTPS. https://https.cio.gov/faq/ (accessed 27 July 2024).
- 32. UK Gov. Data Protection Act. www.legislation.gov.uk/ukpga/1998/29 (accessed 27 July 2024).
- 33. ICO. Lawful Bases for Processing. https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/#what (accessed 27 July 2024).
- 34. Health and Human Services (HHS). Health Information Privacy. www.hhs.gov/hipaa/index.html (accessed 27 July 2024).
- 35. Horwitz LI, Kuznetsova M, Jones SA. Creating a learning health system through rapid-cycle, randomized testing. *N Engl J Med* 2019; 381(12): 1175–1179. https://doi.org/10.1056/NEJMsb1900856.
- 36. Ellenberg SS. The stepped-wedge clinical trial: Evaluation by rolling deployment. *JAMA* 2018; 319(6): 607–608. https://doi.org/10.1001/jama.2017.21993.
- 37. Penfold RB, Zhang F. Use of interrupted time series analysis in evaluating health care quality improvements. Research Support, Non-U.S. Gov't Research Support, U.S. Gov't, P.H.S. Review. *Acad Pediatr* 2013; 13(6 Suppl): S38–S44. https://doi.org/10.1016/j.acap.2013.08.002.
- 38. Devkaran S, O'Farrell PN. The impact of hospital accreditation on quality measures: An interrupted time series analysis. *BMC Health Serv Res* 2015; 15(1): 137. https://doi.org/10.1186/s12913-015-0784-5.
- 39. Maciejewski ML and Basu AA . Regression discontinuity design. *JAMA* 2020; 324(4): 381–382. https://doi.org/10.1001/jama.2020.3822.
- Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. N Engl J Med 2018; 378(6): 539–548. https://doi.org/10.1056/ NEJMsa1706475.

- 41. Rosenbaum PR. Modern algorithms for matching in observational studies. *Annu Rev Stat Appl* 2020; 7: 143–176. https://doi.org/10.1146/annurev-statistics-031219-041058.
- 42. Iacus SM, King G, Porro G. Causal inference without balance checking: Coarsened exact matching. *Political Analysis* 2017; 20(1): 1–24. https://doi.org/10.1093/pan/mpr013.
- 43. Neuburger J, Walker K, Sherlaw-Johnson C, van der Meulen J, Cromwell DA. Comparison of control charts for monitoring clinical performance using binary data. *BMJ Qual Saf* 2017; 26(11): 919–928. https://doi.org/10.1136/bmjqs-2016-005526.
- 44. Mohammed MA. *Statistical process control*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality and Safety in Healthcare. Cambridge: Cambridge University Press; 2024. https://doi.org/10.1017/9781009326834.
- 45. Bejnordi BE, Veta M, Diest PJV, et al. Diagnostic assessment of deep learning algorithms for detection of lymph node metastases in women with breast cancer. *JAMA* 2017; 318(22): 2199–2210. https://doi.org/10.1001/jama.2017.14585
- 46. Seymour CW, Kennedy JN, Wang S, et al. Derivation, validation, and potential treatment implications of novel clinical phenotypes for sepsis. *JAMA* 2019; 321(20): 2003–2017. https://doi.org/10.1001/jama.2019.5791.
- 47. Pavlou M, Ambler G, Guttmann O, et al. How to develop a more accurate risk prediction model when there are few events. *BMJ* 2015; 351): p.h3868.
- 48. Miotto R, Li L, Kidd BA, Dudley JT. Deep patient: An unsupervised representation to predict the future of patients from the electronic health records. *Sci Rep* 2016; 6(1): 26094. https://doi.org/10.1038/srep26094.
- 49. Liang G, Fan W, Luo H, Zhu X. The emerging roles of artificial intelligence in cancer drug development and precision therapy. *Biomed Pharmacother* 2020; 128: 110255. https://doi.org/10.1016/j.biopha.2020.110255.
- 50. Woldaregay AZ, Arsand E, Walderhaug S, et al. Data-driven modeling and prediction of blood glucose dynamics: Machine learning applications in type 1 diabetes. *Artif Intell Med*; 98(98): 109–134. https://doi.org/10.1016/j.artmed.2019.07.007.
- 51. Longhurst CA, Harrington RA, Shah NH. A 'green button' for using aggregate patient data at the point of care. *Health Aff* 2014; 33(7): 1229–1235. https://doi.org/10.1377/hlthaff.2014.0099.
- 52. Radnor Z, Williams S. *Lean and associated techniques for process improvement*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements of Improving Quality and Safety in Healthcare. Cambridge University Press; Forthcoming.

- 53. Toulany A, Shojania K. *Measurement for improvement*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements of Improving Quality and Safety in Healthcare. Cambridge University Press; Forthcoming. www .cambridge.org/core/publications/elements/elements-of-improving-qual ity-and-safety-in-healthcare/listing?aggs[productTypes][filters] = ELEMENT&sort=canonical.date:desc.
- 54. Martin G, Dixon-Woods M. *Collaboration-based approaches*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality and Safety in Healthcare. Cambridge: Cambridge University Press; 2022. https://doi.org/10.1017/9781009236867.
- 55. Horwitz LI, Krelle HA. Using rapid randomized trials to improve health care systems. *Annu Rev Public Health* 2023; 44: 445–457. https://doi.org/10.1146/annurev-publhealth-071521-025758.
- 56. Austrian J, Mendoza F, Szerencsy A, et al. Applying A/B testing to clinical decision support: Rapid randomized controlled trials. *J Med Internet Res* 2021; 23(4): e16651. https://doi.org/10.2196/16651.
- 57. Swan J, Clarke A, Nicolini D, et al. *Evidence in Management Decisions* (EMD): Advancing Knowledge Utilization in Healthcare Management. Final report. 2012. https://warwick.ac.uk/fac/soc/wbs/research/ikon/research/emd/final report fr-08-1808-244.pdf (accessed 27 July 2024).
- 58. Milligan C, Berta W. Reimagining community relationships for organizational learning: A scoping review with implications for a learning health system. *BMC Health Serv Res* 2021; 21(1): 603. https://doi.org/10.1186/s12913-021-06640-9.
- 59. OpenClinical. OpenClinical. www.openclinical.net (accessed 27 July 2024).
- 60. MCBK. Mobilizing Computable Biomedical Knowledge. https://mobilizecbk.med.umich.edu/ (accessed 27 July 2024).
- 61. Ohno-Machado L, Gennari JH, Murphy SN, et al. The guideline interchange format: A model for representing guidelines. *J Am Med Inform Assoc* 1998; 5(4): 357–372. https://doi.org/10.1136/jamia.1998.0050357.
- 62. HL7 & Boston Children's Hospital. Home Page CDS Hooks. https://cds-hooks.org/ (accessed 27 July 2024).
- 63. Walsh K, Wroe C. Mobilising computable biomedical knowledge: Challenges for clinical decision support from a medical knowledge provider. *BMJ Health Care Inform* 2020; 27(2). https://doi.org/10.1136/bmjhci-2019-100121.
- 64. Wong D, Peek N. Does not compute: Challenges and solutions in managing computable biomedical knowledge. *BMJ Health Care Inform* 2020; 27(2): e100121. https://doi.org/10.1136/bmjhci-2019-100123.
- 65. NHS Digital. DCB0160: Clinical Risk Management: Its Application in the Deployment and Use of Health IT Systems. https://digital.nhs.uk/data-and-

- information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems (accessed 27 July 2024).
- 66. Health and Social Care Act 2012. www.legislation.gov.uk/ukpga/2012/7/contents/enacted (accessed 27 July 2024).
- 67. Gov UK. Guidance: Approved Bodies for Medical Devices. www.gov.uk/government/publications/notified-bodies-for-medical-devices/notified-bodies-for-medical-devices (accessed 27 July 2024).
- 68. Bernstein JA, Friedman C, Jacobson P, Rubin JC. Ensuring public health's future in a national-scale learning health system. *Am J Prev Med* 2015; 48(4): 480–487. https://doi.org/10.1016/j.amepre.2014.11.013.
- 69. Friedman C, Rubin J, Brown J, et al. Toward a science of learning systems: A research agenda for the high-functioning Learning Health System. *J Am Med Inform Assoc* 2015; 22(1): 43–50. https://doi.org/10.1136/amiajnl-2014-002977.
- 70. Foley T. Nonadoption, Abandonment, Scale-Up, Spread and Sustainability in LHS Workshop. https://learninghealthcareproject.org/wp-content/uploads/2021/04/NASSS-Workshop-Writeup-201020.pdf (accessed 12 January 2021).
- 71. Braithwaite J. Changing how we think about healthcare improvement. *BMJ* 2018; 361: k2014. https://doi.org/10.1136/bmj.k2014.
- 72. Snowden DJ, Boone ME. A leader's framework for decision making. *Harv Bus Rev* 2007; 85(11): 68–76.
- Papoutsi C, Greenhalgh T, Marjanovic S. Approaches to spread, scale-up, and sustainability. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality and Safety in Healthcare. Cambridge: Cambridge University Press; 2024. https://doi.org/10.1017/ 9781009326049.
- 74. Greenhalgh T, Maylor H, Shaw S, et al. The NASSS-CAT tools for understanding, guiding, monitoring, and researching technology implementation projects in health and social care: Protocol for an evaluation study in real-world settings. *JMIR Res Protoc* 2020; 9(5): e16861. https://doi.org/10.2196/16861.
- 75. Carayon P, Hoonakker P. Human factors and usability for health information technology: Old and new challenges. *Year Med Inform* 2019; 28(1): 71–77. https://doi.org/10.1055/s-0039-1677907.
- 76. Waights V. *Technologies for Care the Imperative for Upskilling Carers*. 2018. The Knowledge Exchange Seminar Series. www.niassembly.gov.uk/globalassets/documents/raise/knowledge_exchange/briefing_papers/series7/waights140318.pdf (accessed 27 July 2024).

- 77. Wilson L, Lowe T. *The Learning Communities Handbook: Collective Improvement in Complex Environments*. 2019. www.humanlearning.systems/uploads/The-Learning-Communities-Handbook.pdf (accessed 27 July 2024).
- 78. Ferguson L, Dibble M, Williams M, Ferraro J. Operationalizing a learning community for a learning health system: A practical guide. 2020. https://deepblue.lib.umich.edu/handle/2027.42/163515 (accessed 27 July 2024).
- 79. NHS Digital. Engagement with the Data-Enabled Research Community. https://digital.nhs.uk/services/research-advisory-group (accessed 27 July 2024).
- Seid M, Dellal G, Peterson LE, et al. Co-designing a collaborative chronic care network (C3N) for inflammatory bowel disease: Development of methods. *JMIR Hum Factors* 2018; 5(1): e8. https://doi.org/10.2196/ humanfactors.8083.
- 81. Hartley DM, Keck C, Havens M, Margolis PA, Seid M. Measuring engagement in a collaborative learning health system: The case of ImproveCareNow. *Learn Health Syst* 2021; 5(2): e10225. https://doi.org/10.1002/lrh2.10225.
- 82. Batalden M, Batalden P, Margolis P, et al. Coproduction of healthcare service. *BMJ Qual Saf* 2016; 25(7): 509–517. https://doi.org/10.1136/bmjqs-2015-004315.
- 83. NHS Digital. NHS Federated Data Platform (FDP). www.england.nhs.uk/digitaltechnology/nhs-federated-data-platform/ (accessed 27 July 2024).
- 84. NHS Digital. Secure Data Environment. https://digital.nhs.uk/services/secure-data-environment-service (accessed 27 July 2024).
- 85. Mayo Clinic. Mayo Clinic Platform_Connect. www.mayoclinicplatform .org/mayo-clinic-platform-connect/ (accessed 27 July 2024).
- 86. Epic. Epic Cosmos. https://cosmos.epic.com/ (accessed 27 July 2024).
- 87. Tarabichi Y, Frees A, Honeywell S, et al. The cosmos collaborative: A vendor-facilitated electronic health record data aggregation platform. *ACI Open* 2021; 5(1): e36–e46. https://doi.org/10.1055/s-0041-1731004.
- 88. Freedman L. Strategy: A History. Oxford: Oxford University Press; 2015.
- 89. Lafley AG, Martin RL. *Playing to Win: How Strategy Really Works*. Boston, MA: Harvard Business Press; 2013.
- 90. Porter ME. What is strategy? Harvard Bus Rev 1996; 74(6): 61-78.
- 91. Rumelt RP. Good strategy/bad strategy: The difference and why it matters. Strateg Dir. 2012; 28(8). https://doi.org/10.1108/sd.2012.05628haa.002.
- 92. Target Operating Model (TOM) at a Glance. www2.deloitte.com/content/dam/Deloitte/lu/Documents/strategy/lu-target-operating-model-glance-122014.pdf (accessed 27 July 2024).

- 93. How to Design a Target Operating Model (TOM) [Updated 2019]. https://strategiccoffee.chriscfox.com/2012/12/how-to-design-target-operating-model-tom.html (accessed 27 July 2024).
- 94. Britto MT, Fuller SC, Kaplan HC, et al. Using a network organisational architecture to support the development of Learning Healthcare Systems. *BMJ Qual Saf* 2018; 27(11): 937–946. https://doi.org/10.1136/bmjqs-2017-007219.
- 95. Scobie S, Castle-Clarke S. What Can the NHS Learn from Learning Health Systems? www.nuffieldtrust.org.uk/files/2019–05/learning-health-systems-v3.pdf (accessed 27 July 2024).
- 96. Mannion R, Davies H. Understanding organisational culture for healthcare quality improvement. *BMJ* 2018; 363: k4907. https://doi.org/10.1136/bmj.k4907.
- 97. Vinson AH. Culture as infrastructure in learning health systems. *Learn Health Syst* 2021; 5(3): e10267. https://doi.org/10.1002/lrh2.10267.
- 98. The King's Fund. Improving NHS Culture. www.kingsfund.org.uk/pro jects/culture (accessed 27 July 2024).
- 99. Shirai B. Dave Snowden How Leaders Change Culture though Small Actions. https://medium.com/@brixen/dave-snowden-how-leaders-change-culture-though-small-actions-766cd2bf5128 (accessed 27 July 2024).
- 100. Jung T, Scott T, Davies HTO, et al. Instruments for exploring organizational culture: A review of the literature. *Public Adm Rev* 2009; 69(6): 1087–1096. https://doi.org/10.1111/j.1540-6210.2009.02066.x.
- 101. Mannion R. Making culture change happen. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality and Safety in Healthcare. Cambridge: Cambridge University Press; 2022. https://doi.org/ 10.1017/9781009236935.
- 102. Wachter RM, Adler-Milstein J, Brailer D, et al. Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England: Report of the National Advisory Group on Health Information Technology in England. Vol. 2021. https://assets.publishing.service.gov .uk/government/uploads/system/uploads/attachment_data/file/550866/ Wachter_Review_Accessible.pdf.
- 103. Foley T, Woollard J. *The Digital Future of Mental Healthcare and Its Workforce*. 2019. https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-Mental-health-paper.pdf (accessed 27 July 2024).
- 104. Foley T, Fairmichael F. Workforce and Training Focus Group. https://learninghealthcareproject.org/workforce-and-training-focus-group/(accessed 27 July 2024).

- 105. Foley T, Fairmichael F. Professor Charles Friedman Interview. https://learninghealthcareproject.org/professor-charles-friedman-interview/(accessed 27 July 2024).
- 106. Foley T, Fairmichael F. Dr Jeff Brown Interview. www.learninghealthcarepro ject.org/publication/5/60/dr-jeff-brown-interview (accessed 27 July 2024).
- 107. The Chartered Institute for IT. Core Competency Framework for Clinical Informaticians. www.bcs.org/membership-and-registrations/become-amember/skills-framework/ (accessed 27 July 2024).
- 108. Human-Centred Design for Interactive Systems. www.iso.org/standard/77520.html (accessed 27 July 2024).
- 109. Design Principles. https://service-manual.nhs.uk/assets/nhs-design-principles.pdf (accessed 27 July 2024).
- 110. Reponen S. Co-design Framework. http://results.learning-layers.eu/methods/co-design/ (accessed 27 July 2024).
- 111. Sanders EB-N, Eva Brandt TB. A Framework for Organizing the Tools and Techniques of Participatory Design *ACM International Conference Proceeding Series*. 2010: 195–198. https://10.1145/1900441.1900476.
- 112. EBCD: Experience-Based Co-design Toolkit. www.pointofcarefoundation .org.uk/resource/experience-based-co-design-ebcd-toolkit/ (accessed 27 July 2024).
- 113. Digital Health. Co-design in Health. https://digital-health-lab.org/code sign-in-health (accessed 27 July 2024).
- 114. Design Kit. Design Kit. www.designkit.org/ (accessed 27 July 2024).
- 115. Service Design Tools. Service Design Tools. https://servicedesigntools.org/ (accessed 27 July 2024).
- 116. The Right Question. The Right Question. https://rightquestion.org/ (accessed 27 July 2024).
- 117. Vandekerckhove P, de Mul M, Bramer WM, de Bont AA. Generative participatory design methodology to develop electronic health interventions: Systematic literature review. *J Med Internet Res* 2020; 22(4): e13780. https://doi.org/10.2196/13780.
- 118. Robert G, Locock L, Williams O, et al. Co-producing and co-designing. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality and Safety in Healthcare. Cambridge: Cambridge University Press; 2022. https://doi.org/10.1017/9781009237024.
- 119. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. *BMC Psychol* 2015; 3(1): 32. https://doi.org/10.1186/s40359-015-0089-9.
- 120. Wilson P, Kislov R. *Implementation science*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements in Improving Quality

- and Safety in Healthcare. Cambridge: Cambridge University Press; 2022. https://doi.org/10.1017/9781009237055.
- 121. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci* 2011; 6: 42. https://doi.org/10.1186/1748-5908-6-42.
- 122. Seid M, Hartley DM, Margolis PA. A science of collaborative learning health systems. *Learn Health Syst* 2021; 5(3): e10278. https://doi.org/10.1002/lrh2.10278.
- 123. Ivers N, Foy R. *Audit, feedback, and behaviour change*. In Dixon-Woods M, Brown K, Marjanovic S, et al., editors. Elements of Improving Quality and Safety in Healthcare. Cambridge University Press; Forthcoming.
- 124. Foley T. Evaluation in LHS Workshop. https://learninghealthcareproject.org/evaluation-in-lhs-workshop/ (accessed 27 July 2024).
- 125. Leviss J. HIT or Miss, 3rd Edition Lessons Learned from Health Information Technology Projects. Oxford: Taylor & Francis; 2019.
- 126. Lannon C, Schuler CL, Seid M, et al. A maturity grid assessment tool for learning networks. *Learn Health Syst* 2021; 5(2): e10232. https://doi.org/10.1002/lrh2.10232.
- 127. Steiner JF, Paolino AR, Thompson EE, Larson EB. Sustaining research networks: The twenty-year experience of the HMO research network. EGEMS (Wash DC) 2014; 2(2): 1067. http://dx.doi.org/10.13063/2327-9214.1067.
- 128. Huang SS, Septimus E, Kleinman K, et al. Targeted versus universal decolonization to prevent ICU infection. *N Engl J Med* 2013; 368(24): 2255–2265. https://doi.org/10.1056/NEJMoa1207290.
- 129. Bindman AB. Learning healthcare systems: A perspective from the US. *Public Health Res Pract* 2019; 29(3): 2931920. https://doi.org/10.17061/phrp2931920.
- 130. Hardie T, Horton T, Thornton N, Home J, Pereira P. *Developing Learning Health Systems in the UK: Priorities for Action*. 2022. www.health.org.uk/publications/reports/developing-learning-health-systems-in-the-uk-priorities-for-action (accessed 27 July 2024).
- 131. University of Michigan. Department of Learning Health Sciences. https://medicine.umich.edu/dept/learning-health-sciences (accessed 27 July 2024).
- 132. MCBK. 2024 MCBK Global Meeting. https://mobilizecbk.med.umich .edu/news-events/mcbk-meetings/2024-meeting (accessed 27 July 2024).
- 133. Friedman C. Learning Health Systems. https://onlinelibrary.wiley.com/journal/23796146 (accessed 27 July 2024).
- 134. INACT-LHS. Learning Health System Toolkit. https://lhstoolkit.learninghealthcareproject.co.uk/ (accessed 27 July 2024).

Cambridge Elements =

Improving Quality and Safety in Healthcare

Editors-in-Chief

Mary Dixon-Woods

THIS Institute (The Healthcare Improvement Studies Institute)

Mary is Director of THIS Institute and is the Health Foundation Professor of Healthcare Improvement Studies in the Department of Public Health and Primary Care at the University of Cambridge. Mary leads a programme of research focused on healthcare improvement, healthcare ethics, and methodological innovation in studying healthcare.

Graham Martin

THIS Institute (The Healthcare Improvement Studies Institute)

Graham is Director of Research at THIS Institute, leading applied research programmes and contributing to the institute's strategy and development. His research interests are in the organisation and delivery of healthcare, and particularly the role of professionals, managers, and patients and the public in efforts at organisational change.

Executive Editor

Katrina Brown

THIS Institute (The Healthcare Improvement Studies Institute)

Katrina was Communications Manager at THIS Institute, providing editorial expertise to maximise the impact of THIS Institute's research findings. She managed the project to produce the series until 2023.

Editorial Team

Sonja Marjanovic

RAND Europe

Sonja is Director of RAND Europe's healthcare innovation, industry, and policy research. Her work provides decision-makers with evidence and insights to support innovation and improvement in healthcare systems, and to support the translation of innovation into societal benefits for healthcare services and population health.

Tom Ling

RAND Europe

Tom is Head of Evaluation at RAND Europe and President of the European Evaluation Society, leading evaluations and applied research focused on the key challenges facing health services. His current health portfolio includes evaluations of the innovation landscape, quality improvement, communities of practice, patient flow, and service transformation.

Ellen Perry

THIS Institute (The Healthcare Improvement Studies Institute) Ellen supported the production of the series during 2020–21.

Gemma Petley

THIS Institute (The Healthcare Improvement Studies Institute)

Gemma is Senior Communications and Editorial Manager at THIS Institute, responsible for overseeing the production and maximising the impact of the series.

Claire Dipple

THIS Institute (The Healthcare Improvement Studies Institute)

Claire is Editorial Project Manager at THIS Institute, responsible for editing and project managing the series.

About the Series

The past decade has seen enormous growth in both activity and research on improvement in healthcare. This series offers a comprehensive and authoritative set of overviews of the different improvement approaches available, exploring the thinking behind them, examining evidence for each approach, and identifying areas of debate.

Cambridge Elements

Improving Quality and Safety in Healthcare

Elements in the Series

Reducing Overuse
Caroline Cupit, Carolyn Tarrant, and Natalie Armstrong

Simulation as an Improvement Technique Victoria Brazil, Eve Purdy, and Komal Bajaj

Workplace Conditions

Jill Maben, Jane Ball, and Amy C. Edmondson

Governance and Leadership
Naomi J. Fulop and Angus I. G. Ramsay

Health Economics

Andrew Street and Nils Gutacker

Approaches to Spread, Scale-Up, and Sustainability Chrysanthi Papoutsi, Trisha Greenhalgh, and Sonja Marjanovic

Statistical Process Control
Mohammed Amin Mohammed

Values and Ethics
Alan Cribb, Vikki Entwistle, and Polly Mitchell

Design Creativity
Gyuchan Thomas Jun, Sue Hignett and THI P. John Clarkson

Supply Chain Management Sharon J. Williams

Measurement for Improvement
Alene Toulany and Kaveh G. Shojania

Learning Health Systems
Thomas Foley and Leora I. Horwitz

A full series listing is available at: www.cambridge.org/IQ