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Quality improvement

QUALITY IMPROVEMENT

EDITORIALS

ANALYSIS

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Lessons in quality improvement

The Health Foundation and The BMJ introduce a collection of articles to support quality improvement measures

For 30 years, quality improvement approaches and tools have been used to improve the way in which healthcare is organised and delivered. In the UK, use of systematic improvement approaches, such as PDSA (plan, do, study, act) cycles or Lean,[1][2] is now relatively common, and many clinicians are introduced to quality improvement concepts at an early stage in their training.

Many quality improvement interventions have benefited patients—for example, by standardising care processes and pathways and removing delays and duplication.[3] They have given clinicians and other professionals the opportunity to consider the problems in care quality that matter most to them and their patients. However, not every quality improvement intervention is successful.

Some fail to achieve their desired outcomes or are not sustained.[4] This is not surprising given the experimental nature of quality improvement, and often the learning from this experience better prepares participants for their next intervention. Other interventions fall short because those involved are taking part under obligation and are unconvinced of the interventions' purpose and value. Meanwhile, some interventions may implement a solution that runs counter to standard practice elsewhere, causing a safety risk or creating unintended consequences in another part of an organisation or system, and so actually have a negative effect on patient care.

To help teams and organisations maximise their chance of planning and delivering successful and sustained quality improvement interventions, *TheBMJ*, in partnership with and funded by the Health Foundation, has created a collection of essays, analysis, and education articles on key quality improvement topics (https://www.bmj.com/quality-improvement). The collection highlights the skills and knowledge needed to do quality improvement well, and the relational, cultural, infrastructural, and strategic challenges that have to be addressed for improvement to flourish in healthcare settings and beyond.

One of the most important insights to emerge from the collection is that no improvement intervention should be conducted in isolation.[5] A weakness of much quality improvement work to date is that it tends to be carried out as a "highly local, almost artisan activity" focused on discrete "small, time limited projects." Such projects often absorb considerable amounts of time, effort, and energy but may make only a marginal, and sometimes fleeting, difference to patient care. To avoid this, any intervention needs to be integrated and aligned with the overarching strategic approach to improvement of the organisation or system in which it is set. Moreover, the job of improving care should not rest solely with frontline clinical teams: it requires active and consistent leadership from within the organisation and system, engaged and supportive managers, and the involvement from the start of patients and citizens as coproducers of improvement. This is happening in some places but is still far from being the norm.

Another challenge for healthcare systems highlighted in the collection is how to marshal and deploy the collective improvement expertise and knowledge of those doing improvement to identify and tackle quality issues that require a pathway or system-wide response. One solution is to create and resource networks and platforms that bridge organisational and sectoral boundaries and give people the space to come together and share ideas and expertise, learn from each other, and tackle quality challenges collaboratively. With interest in employing quality improvement approaches at population health level now on the rise, the need for such large scale engagement platforms, together with people who can act as "system integrators"[6] is becoming ever more apparent. With patients and carers often the only people who experience care across the system, it is critical to integrate them as a "vital source of different perspectives"[7] in healthcare improvement.

Working at organisation or system level is not easy. It is for this reason that so much improvement to date has taken place within specific teams and services. Organisations such as hospitals are complex entities with multiple and overlapping subgroups. And while some "cultural attributes are widespread and stable," "others may be shared only in subgroups or held only tentatively."[4] Equally, many processes and pathways are not stable but are in a constant state of flux.[8]

For anyone involved in improvement, an understanding of the social and cultural complexity of healthcare organisations, coupled with a recognition of how change happens in complex systems, is likely to be an increasingly valuable skill. After all, no other public or commercial sector is as intricate or has as many "moving parts" or clients whose needs are as complicated. It is not surprising that many of the people at the vanguard of efforts to plan and deliver system wide change have a background in systems design and engineering.[8]

What this shows is that to deliver improvement it is not enough to have a good grasp of how to apply quality improvement approaches and tools. Good relational skills matter just as much, if not more, as does the capacity to navigate the system and to build relationships and alliances with key stakeholders. Partnership working, therefore, is at the heart of all effective improvement interventions.

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Prioritising quality improvement

QI is a team sport, best played by those making the improvements

In almost every part of our lives we are inundated with information. The working lives of primary care doctors and their managers are no different. In 1964 Bertram Gross, professor of political science at Hunter College in New York, defined the concept of information overload:

"Information overload occurs when the amount of input to a system exceeds its processing capacity. Decision makers have fairly limited cognitive processing capacity. Consequently, when information overload occurs, it is likely that a reduction in decision quality will occur."[1]

The quality of the care we provide is measured, benchmarked, and reported back to us by a multitude of organisations. In England, primary care doctors can compare their patient experience scores with those of the practice down the road through the National GP Patient Survey.[2] They can see how well they are achieving screening targets on the public health websites[3] and compare their prescribing on openprescribing.net.[4]

Commissioning organisations send practices data on referring behaviour, rates of unplanned admissions, or how much their patients use the emergency department. Some aspects of performance can affect practice income through performance related pay,[5] including targets for treatment and follow-up of patients with long term conditions. Regulators use much of this information to guide judgments of services provided.[6]

Where to start?

With so many possible areas where improvements might be made, it can feel like an impossible task to choose which should take priority. Improvement often needs several iterative cycles before solutions that work emerge. Sustained improvement takes time and effort, and it is easy to get demoralised if practices or individuals take on too many projects and can't follow them through. It is tempting to prioritise the areas that affect practice income or please regulators rather than projects that matter more to patients and staff.

High quality care develops when an organisational culture promotes curiosity, experimentation, and continuous small cycles of change, particularly when changes are designed and driven by the people delivering care, in full collaboration with patients.[7] Quality improvement is a team sport and is played best when owned by those making the improvements. Projects work best when priorities are set locally unless external benchmarking data show problems with patient safety or quality of care or practice viability is being affected by poor performance in financially driven targets.

Primary care doctors have an important role in quality improvement. They need to be aware of practice performance data and find ways to present it to the practice team and patients in a meaningful way—for example, by taking into account variations in practice demographics and list turnover.

The increase in primary care workload without a matched increase in funding limits the time available for practice development and improvement.[8] Although there has been some attempt to rectify this, until the effects are felt at the frontline, practices must prioritise improvements that focus on working more effectively and efficiently. This is in line with the NHS sustainable improvement programme Time for Care.[9] Feedback from participants of the programme indicates that it has improved job satisfaction and teamwork and embedded basic quality improvement methods that practices can apply to other aspects of care such as patient outcomes and access.

Improvement won't happen unless people take action. The importance of "starting with why" has been recognised in many workplace environments,[10] and healthcare delivery and improvement is no different. If people working in a practice have a strong sense of purpose and know why they do what they do, they will notice when current performance isn't delivering their aspirations. This can generate improvement priorities that resonate with the values, vision, and purpose of the team and the organisation. Using these priorities to create broad themes over time creates a coherent and meaningful improvement plan that everyone understands and can work towards.

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Creating space for quality improvement

Clinicians already have the motivation; now they need time, skills, and support

Last year *The BMJ* and the Health Foundation launched a joint series of papers exploring how to improve the delivery of healthcare (https://www.bmj.com/quality-improvement).[1][2] The series aims to discuss the evidence for systematic quality improvement, provide knowledge and support to clinicians, and ultimately to help improve care for patients.

Stories of a disordered system abound in healthcare: the notes or test results that don't arrive, the overbooked clinic, the frail patient who wastes hours travelling to and from an appointment that the hospital had rescheduled but failed to communicate. At the front line the problems frustrate, waste time, and add avoidable risk; at national level, they add up to slow progress on quality, wasted resource, and severely dented staff enthusiasm and public trust in the NHS.

Leaving aside the human cost of poorly managed care, the aggregate loss of value each year is high. In today's NHS, the pressure—from rising demand and a financial squeeze in the NHS and social care—is intense, with staff working flat out to do their best for patients, in many cases at great personal cost. Suggestions to those working at the front line that things could be done differently can be met with a chorus of: "But we have no time to think/no support/no power/no resources," sometimes followed by "the organisation or government must do something."

But some clinical teams do carve out the space to discover what needs to change, then design and make improvements to the services they are responsible for.[3] There is no substitute—only clinicians, patients, and carers at the front line can see clearly every day what needs to change.

In making these improvements doctors have gone beyond their primary remit of practising medicine. If disordered care is to improve then we need more clinicians to view their role as bigger than the traditional scope of medicine taught at medical school. Just as doctors learn to assess, diagnose, and treat clinical conditions they also need to learn how to design improvements to

services, including communicating and negotiating better within and beyond their teams on the best way forward. Like studying the science of medicine, to make improvements doctors need to apply scientific principles to the practice of everyday work and to test changes, analyse results, and adapt accordingly. This broad approach is loosely called quality improvement in healthcare.

The task ahead is not necessarily to turn doctors into managers, but the first step must be to equip doctors and other clinicians with formal skills to make continuous improvements to the quality of the services they provide. This means new technical and relational skills and behaviours.

Despite substantial debate, multiple initiatives to equip clinicians with quality improvement skills, and advances in defining the role of a doctor,[4] medical training still does not help enough doctors to develop these skills. Audit (sometimes rebranded as quality improvement) is increasingly mandated as part of postgraduate clinical training but doctors are largely unsupported to do it, which risks quality improvement being viewed as a tick box exercise needed to get through annual appraisal.

While some royal colleges in the UK are making progress in introducing postgraduates to quality improvement,[5-7] many places of work either do not recognise the need or offer no support. There is a widespread view, and implicit hope, that improvements to care occur at the front line by a kind of osmosis or, worse still, only through new technologies or "management," without careful ongoing systematic effort of clinical staff. A good time to excite doctors on this agenda should be early in their career. But junior doctors are on short rotations, have limited time to do anything, and may feel they are transient workers with no authority to improve existing practices.

No surprises then that juniors become cynical, senior clinicians don't know about or are sceptical about quality improvement approaches, and both may run a mile from a management perceived to be focused on financial control. Rather than try to

improve a service, committed doctors may turn their energies elsewhere—to academic work, medical training, committee work, private practice—in fact, anywhere other than bettering everyday clinical work.

Yet there is plenty of evidence that systematic quality improvement makes a difference, not just for patients but for staff too.[8][9] And despite everything many doctors in the wider NHS are motivated to reach beyond the boundaries of traditional medicine and improve care. The intrinsic motivation of healthcare professionals to improve care for patients could undoubtedly be put to more effective use with more knowledge, careful planned development of clinicians, and practical support. Our aim is that this series will contribute to these important goals.

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Better healthcare must mean better for patients and carers

Their perspectives are essential to all successful healthcare improvement

Quality improvement in healthcare is a team effort[1] and most effective when it includes people using services and their carers, families, and advocates. These people bring direct expertise in matters of health from their personal experience of illness as well as skills from lives beyond the healthcare system.

Some aspects of healthcare undeniably need to be improved, but the quality deficit needs to be clearly described from every angle. We can do things better or we can do better things, but both usually mean acting differently. Patients, carers, and their advocates are a vital source of different perspectives in healthcare.

The invitation to patients to get involved needs to be both timely and respectful. In a board meeting discussing quality indicators, for example, it is demeaning to refer to the participating parent as "mummy." Looking at someone through this lens blinds us to the other life experiences they may have had in their professional career. We need to respectfully acknowledge all the attributes, qualities, and skills that people bring to the table, whether gained through their patient experiences or other personal or career experiences.

In healthcare improvement we are asking patients to play a range of roles in an invisible script, from telling their story, to being representative of a broader group, to partners in coproduction. It's not always clear which of these roles patients are asked to play.[2] Patients can find themselves stuck in limbo between two expected roles or trying to second guess what is required. In this situation, doing better means improving the relevance and practical impact of every contribution.

The level of patient involvement will differ according to the requirements of projects and the preferences of individuals. At all levels, quality of input trumps quantity. Patients and carers already provide solicited and unsolicited insights into their experiences of services. "Feedback fatigue" can set in if the purpose of further feedback requests isn't clear. New information isn't always better information, as criticism of the NHS friends and family test has recently explored.[3]

Paying attention to the quality of language is the foundation for successful dialogue and everyday collaboration. Many patients and carers can describe the pain caused by a single word they encountered while being treated. Especially with new words and labels, it is important that we are respectful towards their owners. For instance, only people with experience of dementia can verify which services are indeed dementia friendly.

In recent years, we have seen a qualitative expansion of the boundaries of the traditional patient-doctor relationship.[4] Patient advocates are becoming more confident when exchanging knowledge with clinicians and researchers about medical conditions, bringing in their knowledge from outside the medical arena. But we still have some way to go before all clinicians welcome every patient contribution, either during consultations or in discussing service improvements. One example of better healthcare might be that we no longer hear patients, carers, or healthcare professionals say, "I was too afraid to ask or say…"

Beyond these personal encounters, patients also have a key role in organisational change to improve healthcare. The delicate balance of sometimes competing drivers such as speed, volume, integration, and specialisation all directly affect people who use health services, so their perspectives need to inform this bigger picture too. Models already exist to involve people, their carers, families, and advocates in all aspects of organisational improvement.[5] The common thread across these is timeliness—involvement early is always better.

Any quality improvement effort can produce unintended collateral damage for patients if the "improvement" is one dimensional. The flaws of improvement initiatives will be invisible until users miss the refuge of a kitchen with a toaster in a children's ward or the comfort of a biscuit during regular intravenous treatments.[6] Proper collaboration early in the change process can give insight into what these unintended consequences might be and how to avoid them. Collaboration works both ways. With a deeper connection and appreciation of the rationale for decisions and the constraints that we all operate under (organisational, clinical, personal) we can learn together—and that is always better.

For people using services, better healthcare is personal, as we juggle self managing an illness with the practicalities of daily life. Often, better actually means choosing the least worst of a limited menu of options. To judge what is better from a patients' point of view, we must remember that the starting point is a profoundly disruptive life event. Living through illness gives individuals a unique insight of enormous value to quality improvement efforts. These efforts must recognise the qualitative nature of patient experience and give it equal priority with the experience of healthcare professionals providing clinical services. The two elements fit hand in glove, even if our language and systems don't always reflect it.

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Improving together: collaboration needs to start with regulators

Nicola Burgess and colleagues argue for a move away from top-down regulation to a new approach that facilitates rather than hinders learning across organisations

The regulatory landscape in the UK is changing again. From 1 April 2019 NHS England and NHS Improvement became what is effectively a single organisation with far reaching responsibility for the oversight of the system. The structural features of this change, which will eventually require legislative reform, have been widely debated, not least by those affected by plans for a collaborative approach to improvement in the NHS.[1][2] But there has been less discussion about the style and approach to regulation that might be best suited to drive improvement in the NHS as set out in the long term plan.[3] We contend that a major change is required in the way the system interacts with service providers if we are to be successful in developing a new service model for the 21st century.

Currently the NHS relies on positional authority—a hierarchical system in which regulators use their power and leverage to drive change. Drawing on organisational theory we contend that structural change in the regulatory landscape is insufficient to drive interorganisational learning for improvement. Specifically, we argue that regulation needs to shift towards a more relational form of governance in which informal social systems foster learning across organisations. This relational authority emerges through interpersonal relationships characterised by trust and mutual respect and has to be earnt over time.[4] To support our argument we draw on our experience analysing a major experiment in delivering service transformation in five NHS hospital trusts in partnership with NHS Improvement and the Virginia Mason Institute in the US (box 1).[3]

Interorganisational learning

Organisational learning describes the process of assimilation and embedding new knowledge in an organisation underpinned by social interactions between individuals and groups. Cross-organisational networks are becoming more common and offer considerable potential for organisational learning. Like learning within organisations, learning across organisations is facilitated through frequent and structured dialogue underpinned by high levels of trust and information sharing.[5][6] Such reciprocity and trust, however, requires long term commitment from collaborating parties, with regular, meaningful face-to-face interactions.[6-8]

Interorganisational learning is best supported by networked forms of governance—that is, when governance is shared between a group of autonomous organisations—rather than by a hierarchical approach. Where accountability is hierarchical, provider organisations are driven to ensure compliance[9][10]; by contrast, networked governance motivates autonomous organisations to work together, learn together, and improve together.[11]

As with interorganisational learning, networked governance is relational, emerging from informal social systems characterised by solidarity among network members, a shared goal, and frequent knowledge exchange.[7][11][12] Although NHS policy enshrines the building blocks for more collaborative approaches to improvement through integrated care systems, pervasive top-down regulation may stymie action on the ground. Policy emphasis on managing performance can mean that staff focus on meeting targets, reducing the energy for interorganisational learning.[13]

How do we build a relational approach to governance?

Moving from top-down regulation to networked governance requires a radical change from mechanisms that rely on positional authority to mandate change, to mechanisms that employ relational authority. The partnership between NHS Improvement and the Virginia Mason Institute shows how a relational approach to governance can be nurtured. The partnership is a five year collaboration to transfer learning from a US hospital with an enviable reputation for patient safety and quality to the English NHS (box 1). Part of this commitment was to establish a transformation guidance board to enable the five participating trusts to support one

KEY MESSAGES

- If collaboration between organisations is to drive improvement, regulators need to reconsider their approach to the exercise of power and authority
- Top-down governance forces organisations to seek rapid short term solutions that do not address complex problems
- Effective collaboration requires investment in developing relationships between organisations characterised by trust and reciprocity
- A relational approach between the regulator and service providers can foster interorganisational learning and governance

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Box 1: NHS-Virginia Mason Institute partnership

In 2015 a five year partnership was established between the NHS and US based Virginia Mason Institute, a non-profit organisation specialising in transforming healthcare. After a competitive tendering process, five NHS trusts were selected to form the partnership and develop localised versions of the Virginia Mason production system.

The production system is an adaptation of that used by the Japanese car manufacturer Toyota. Based on principles commonly known as Lean, the system makes patients central to all activity; any activity that doesn't add value to the patient is "waste" and should whenever possible, be eliminated.

Although the centrality of patients may seem obvious, many healthcare processes are designed around the needs of the service provider rather than patients. The partnership seeks to build skills in quality improvement within and across the five NHS trusts so that they can redesign processes to ensure the highest quality of care while reducing the cost of delivering the service. Crucially, the partnership shares a goal to support development of a sustainable culture of continuous improvement.

another, learn together, and foster ongoing dialogue among all partners.

The transformational guidance board is an example of a goal directed, interorganisational network,[7] where all network members are working towards a shared goal. Its members comprise chief executives of the five NHS partner trusts, senior members of NHS Improvement, and senior improvement specialists from Virginia Mason. NHS Improvement leads the administration of the network and is an active participant. The board provides two key mechanisms that combine to foster relational authority—a protected relational space and a "compact" (non-binding informal contract[14]) on expected behaviours and commitments. These mechanisms allow interorganisational learning and network governance to emerge.

Protected relational space

A protected relational space is an area where people can work collaboratively towards establishing new norms and roles that challenge institutional practices.[15] All stakeholders are included but individuals must support the aim to change processes; it does not include people motivated to defend the status quo. A protected relational space is crucial for fostering frank and honest dialogue about how to lead change (box 2). All stakeholders must feel psychologically safe to share the challenges they face as well as their successes; this is particularly important when relationships are characterised by a legacy of power imbalance, as in the case between a regulator and provider organisation.

Create a compact

Moving from positional authority towards relational authority requires a radical change in behaviour. In our example, the first step towards achieving relational authority for interorganisational learning occurred through collective structuring and negotiation of a compact— a process in which the expected behaviours and reciprocal commitments of the regulator and the chief executives are explicitly negotiated and formalised.

Members of the transformational guidance board spent almost 12 months developing the compact. Broad categories of partner responsibilities outlined in the compact include creating the right environment; fostering excellence; listening, communication, and influencing; focus on patients; focus on staff; and a focus on leadership (box 3). In the event that the compact is disrupted—for example, if a chief executive wasn't sufficiently supported in line with the terms of the compact—a frank and honest discussion takes place about what the board should have done differently.

Shifting attitudes

Dialogue is central to interorganisational learning.[16] When relationships are hierarchical, interaction commonly veers towards "skilful discussion" designed to keep the relationship with a more powerful actor at arm's length. A protected relational space allowed our stakeholders to come together regularly, engage in honest reflection, and develop collective thinking towards a shared goal. To our surprise we regularly heard representatives from the regulator claiming they were reflecting on their behaviours as a regulator and how those behaviours inhibit the improvement capability the network seeks to build.

In tandem, the continued commitment of the trust chief executives both within their organisations and to the transformational guidance board is testament to network governance. Chief executives rarely miss a meeting or prepare inadequately. This is partly because of the value that they associate with the meeting and partly because of the social norms firmly embedded across the group. The chief executives all prepare reports of progress and challenges to share at the meetings and they engage in dialogue that supports one another towards improvement goals. For example, one trust showcased its "heat map" of training—a document that visually depicts where trained individuals are located within the organisation. The document can be used to identify concentrations of trained individuals to inform future training plans and improvement efforts. The heat map was deemed an excellent idea and subsequently adopted by the other four trusts.

Box 2: What does relational space and relational authority look like?

The most striking feature of the NHS-Virginia Mason partnership is the quality and quantity of time invested in face-to-face meetings. All five chief executives travel to London from various parts of the UK to meet with the same senior executives of NHS Improvement and senior representatives from Virginia Mason every month. The meeting lasts for six hours, during which there are no laptops open, no phone calls taken, and dialogue is fluent, reciprocal, and supportive.

Spending six hours in a windowless room in London with senior representatives of the regulator may sound like punishment, but after more than three years these chief executives told us it was "the best day of the month." This is because discussions are frank, honest, and reciprocal and there is an air of friendship and friendly rivalry, with an overwhelming sense that all organisational partners are learning together. Relational investments of this nature are uncommon in the NHS; trusts typically compete against each other for business and reputation, and in-person interaction with the regulator is usually a sign a trust is in trouble.

One chief executive explains:

"It's quite remarkable really ... Regulators are usually regulators; they're usually telling you you're not doing something very well. But actually, this is different. It's really important in terms of how you are allowed to create the space to learn and develop, and even when things aren't going so well, there's a dialogue to be had. So, it's a different relationship."

Box 3: Compact between NHS Improvement and partner trusts

A compact was created to set down the reciprocal commitments of NHS Improvement and the partner trusts in working collaboratively towards their shared vision. The compact states:

"We aspire to fulfil these commitments and will be open to respectful communication from our partner(s) about how well we do in that regard. We accept that this is a developmental journey for all of us." Some of the responsibilities included are listed below.

NHS Improvement responsibilities
- Behave in a positive, respectful, and consistent way at all levels of interaction with trusts and be open and transparent
- Maintain integrity of positive partnership working even when under external pressure and show empathy with trust issues
- Be candid in offering constructive criticism and receptive in receiving it—always assume good intent

Trust responsibilities
- Act in a way that is respectful, open, and transparent with a commitment to early warning and no surprises
- When under pressure on wider delivery look to the method as part of the solution not a barrier
- Work with the wider system so everyone understands the methods, process, and what is required to maximise benefits

Can the approach be extended across the NHS?

The role of regulator is changing towards a more facilitative improvement role.[17] To date, attempts to transform the NHS have mainly focused on structural change and tightening up regulatory processes that serve to reinforce the positional authority of the regulator. Our analysis suggests that network governance can be more effective at fostering collaboration for improvement, and that such governance occurs through development of relational authority. We acknowledge that the partnership represents just one example of a networked governance approach and this particular example is limited to a collaboration with just five NHS provider organisations. The challenge will be how to replicate this approach across the broader system.

To reiterate our earlier contention, relational authority is earned over time. We have identified a safe relational space and the process of creating a new compact as important conditions to bring about interorganisational learning and network governance. A different approach to governance is plausible, possible, and desirable.

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Spreading and scaling up innovation and improvement

Disseminating innovation across the healthcare system is challenging but potentially achievable through different logics: mechanistic, ecological, and social, say **Trisha Greenhalgh and Chrysanthi Papoutsi**

The general practitioner in the surgery, the nurse manager on the ward, and the policy maker in the boardroom would be forgiven for losing track of all the new technologies, care pathways, and service models that could potentially improve the quality, safety, or efficiency of care. Yet we know that innovations rarely achieve widespread uptake even when there is robust evidence of their benefits (and especially when such evidence is absent or contested).[1] The NHS Long Term Plan points out that every approach prioritised in the plan is already happening somewhere in the NHS but has not yet been widely adopted.[2]

There are common sense reasons why spreading an innovation across an entire health system is hard. Achieving any change takes work, and it usually also involves—in various combinations—spending money, diverting staff from their daily work, shifting deeply held cultural or professional norms, and taking risks. Simplistic metaphors ("blueprint," "pipeline," "multiplier") aside, there is no simple or universally replicable way of implementing change at

scale in a complex system. A technology or pathway that works smoothly in setting A will operate awkwardly (or not at all) in setting B.

Given these realities, what insights does the rapidly growing research literature on spread and scale-up offer the busy clinician, manager, commissioner, or policy maker? How—if at all—does this literature speak to the patient?

"Spread" generally means replicating an initiative somewhere else and "scale-up" means tackling the infrastructural problems (across an organisation, locality, or health system) that arise during full scale implementation,[3] though in practice the one blurs into the other.

In this rapid review (the methods of which are described in box 1) we found that scholars of spread and scale-up had used many different theoretical lenses. We have chosen to discuss three—implementation science, complexity science, and social science, each of which is based on a different logic of change (mechanical, ecological, and social, respectively; table 1). Many successful spread and scale-up programmes draw predominantly on one of these lenses but include elements of the other two.

Implementation science: spread and scale-up as structured improvement

Implementation science, defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence based practices into routine practice" (page 2),[16] developed from the evidence based medicine movement in Europe and North America. It is perhaps best known for the sequential, structured (and somewhat top-down) method of spreading focused improvement techniques.[10 16]

The first phase of this approach (after initial set-up and orientation) is the development of a clearly defined intervention, the components of which are optimised to reflect the evidence base (especially relating to how to change individual behaviour) (fig 1). There is then a small scale trial of this intervention in

one or a few selected settings, followed by a systematic effort to replicate it in other settings, partly by identifying and dealing with barriers (which get in the way of the implementation effort) and facilitators (which potentially support it).

Patient input can be harnessed very productively in this effort, though careful attention needs to be paid to power dynamics, the kinds of data that are collected, and how and by whom those data are analysed.[15]

Although the sequence depicted in figure 1 is often promoted as the key to quality improvement, one systematic review showed that nearly half of all successful scale-up initiatives had not followed it.[10]

Implementation science approaches tend to draw heavily on quality improvement methodology. Barker and colleagues describe this methodology as an "engine" that uses rapid cycle change to drive spread of an innovation, with some potential to adapt to different contexts.[3]

In recent years, implementation science has matured as a field in a way that has paralleled developments in the Medical Research Council's guidance for developing and testing complex interventions.[17] Both have shifted from a highly structured and narrowly experimental approach based on mechanical logic (which emphasised standardisation and replicability) to a more adaptive approach that recognises the need to think flexibly, understand and respond to local context, use qualitative methods to explore processes and mechanisms, and adapt the intervention to achieve best fit with different settings.[18] This shift resonates with the complexity science approach described in the next section.

An example of spread using an implementation science logic is shown in box 2.

Complexity science: spread and scale-up as adaptive change

A complex system is a set of things, people, and processes that evolve dynamically and

KEY MESSAGES

- Spread (replicating an intervention) and scale-up (building infrastructure to support full scale implementation) are difficult
- Implementation science takes a structured and phased approach to developing, replicating, and evaluating an intervention in multiple sites
- Complexity science encourages a flexible and adaptive approach to change in a dynamic, self organising system
- Social science approaches consider why people act in the way they do, especially the organisational and wider social forces that shape and constrain people's actions
- These approaches may be used in combination to tackle the challenges of spread and scale-up

can be defined in terms of their relationships and interactions.[4 18] Such systems are characterised by uncertainty, unpredictability, and emergence. They adapt through self organisation (such as continuous adaptations initiated by frontline staff to allow them to complete tasks given local contingencies and availability of resources), attention to interdependencies (how the parts of the system fit together), and sensemaking (the process by which people, individually and collectively, assign meaning to experience and link it to action).[4]

To study the ecological (that is, emergent, interdependent, adaptive) properties of complex systems, researchers and evaluators use multiple methods, particularly ethnographic observation, in real world settings. Such studies are usually written up as richly described case studies incorporating both quantitative and qualitative data and including a narrative of how and why things changed over time.

Complexity can be hard to square with spread strategies that seek to replicate a "blueprint" innovation in a standardised way across widely different settings. The plan-do-study-act engine depicted in figure 1 might work for small scale improvement initiatives, but spreading and scaling up major innovations across a health system requires attention to the underlying logic of complex systems, which is ecological rather than mechanical.[4 5 7 8]

Lanham and colleagues, for example, recommend the following principles when planning major change programmes in conditions of complexity[4]:

- *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 it 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 sensemaking*—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.

To this list, we would add:

- *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 judgments 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 view conflicting perspectives as the raw ingredients for multifaceted solutions.

These principles underpin the concept of the learning health system, defined as one "in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience" (page 17).[20] A

Table 1 | Different approaches to spread and scale-up in innovation and improvement	Implementation science	Complexity science	Social science
Main focus	Evidence based interventions in practice	The evolving and emergent properties of systems	Social study of individuals, groups, and organisations
Contribution	Provides a concrete, planned approach to the delivery and study of spread and scale-up	Ecological view that emphasises the system's inherent unpredictability and need for adaptive change at multiple, interacting levels	Foregrounds patterns of social behaviour and interaction, professional beliefs and values, and organisational routines and structures
Key mechanisms of spread and scale-up	Uncertainty reduction, emphasis on fidelity and contextual influences	Emergent properties of an interacting system—self organisation, management of interdependencies, and sense making	Social, professional, and organisational influences that shape (and are shaped by) individual and collective action
Preferred methods for achieving spread and scale-up	Use structured, programmatic approaches to develop and replicate a complex intervention across multiple settings	Gain a rich understanding of the case in its historical, sociopolitical, and organisational context. Use multiple methods flexibly and adaptively. Expect surprises and handle them creatively. Develop individuals and organisations to be creative and resilient	Develop and apply theories of how individuals' behaviour and actions are influenced by interpersonal, material, organisational, professional, and other factors
Preferred methods for researching spread and scale-up	Metrics for measuring improvement (quantitatively) and systematic approach to exploring processes and mechanisms (qualitatively)	Case study approach using multiple qualitative and quantitative methods. Narrative can be used as a synthesising tool to capture complex chains of causation	Ethnography, interview based methods, and case narratives to provide insights into social interactions and contexts
How success is measured	Replication of a particular service model or approach in multiple contexts ("fidelity")	Nuanced narrative about what changed and why, including (where relevant) how the intervention was adapted or why it was abandoned	Theoretically informed and empirically justified explanations about human and organisational behaviour
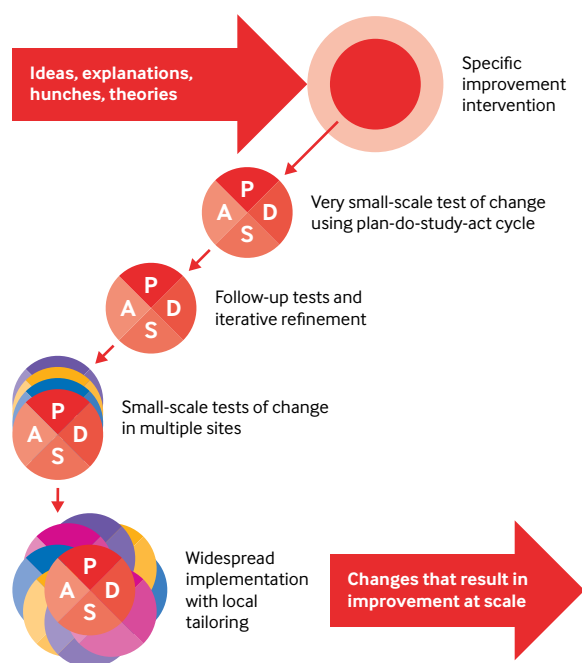
Fig 1 | Rapid cycle test of change model of spread used in implementation science. Drawing on insights and a previous diagram in a review by Barker[3]

learning health system is characterised by participatory culture, distributed leadership, engaged patients, shared and evidence based decision making, transparent assessment of outcomes, and use of information and technology for continuous learning. Innovation, improvement, spread, and scale-up will all occur more readily in such a system.[20]

There are numerous specific models of spread and scale-up that embrace (implicitly or explicitly) ecological logic and the learning health system; some are listed in table 2.

An example of a complexity science approach to scale-up and spread is shown in box 3. It shows that although the success of an initiative based on implementation science can be measured by fidelity of its replication across a range of contexts, success of a change effort in different parts of a complex system is better measured by a nuanced account of what changed and why.[22]

Social science: spread and scale-up as social action

Social science approaches seek to identify and explain social mechanisms, such as what people believe and feel; why people act as they do; how they interpret material artefacts and other people's actions; and how they draw on programme resources to achieve their goals (or why they refuse or are unable to do so).

As the previous section emphasised, staff in organisations implement change creatively and adaptively rather than mechanically. They experiment with innovations, develop feelings (positive or negative) about them, worry about them, adapt them to particular tasks, "work around" them, and try to redesign them.[1] Efforts to standardise the replication of an intervention across multiple settings therefore rarely go to plan.

Social science approaches to scale and spread generate theories about why and how programmes of change diverge from initial plans over time: explanations that answer the question, "What did people do in this particular case and why did that have the effect it did?" A programme theory is expressed at a very low level of generality (that is, it may apply only to the case being analysed and closely comparable settings)—for example, "The nurses did not engage because of a staffing crisis." Social scientists also develop more general ("substantive") theories to explain why spread and scale-up did or did not happen—for example, theories of behaviour change (individual level), absorptive capacity (organisational level), or interorganisational influence (supra-organisational level). Usually, a social science explanation of a spread or scale-up effort requires both substantive theory (or theories) and a more specific programme theory.[11 13 23]

Shaw and colleagues synthesised various substantive theories (summarised in the supplementary file) that have been used to analyse the spread and scale-up effort as social practice.[13] These theories—which include normalisation process theory, actor-network theory, and structuration theory—help researchers and change agents to tap into (with a view to influencing) the organisational and societal influences that shape and

Box 2: An implementation science approach to spread and scale-up

McKay and colleagues followed the full sequence of efficacy, effectiveness, and implementation trials to develop, test, and scale up an intervention of physical activity and healthy eating in elementary schools in British Colombia, Canada.[19] In the first phase, the multifaceted intervention (consisting of resources, training for teachers, school facilitators, and a regional support team) was developed through participatory research with schools, communities, and other stakeholders, taking account of contextual realities, behaviour change, and social-ecological theories.

Efficacy was evaluated in a cluster randomised controlled trial in 10 schools, which measured four outcomes: school based opportunities for physical activity; actual physical activity levels; students' chronic disease risk factors (such as obesity) and academic performance; and students' self reported consumption of vegetables and fruit. Process evaluation captured contextual and operational issues that led to refinement of the intervention, which was then evaluated for effectiveness under real world conditions in a larger cluster randomised controlled trial.

In the implementation and scale-up phase, a further 348 schools were supported to adopt and embed the intervention (with attention to fidelity of key components) and evaluate its effect locally. At the time of publication, 225 trained regional trainers had delivered over 4000 workshops to train over 80 000 teachers, reaching approximately 500 000 students. The programme, which took six years to develop and pilot, was sustained over 10 years.

This is a rare example of a predominantly top-down (structured and programmatic) spread and scale-up strategy that achieved widespread coverage and measurable improvements in some but not all outcome measures. Its success, however, is also likely to be attributable to the use of participatory research and social-ecological theories and to a positive policy context, strong professional buy-in, generous resourcing, and long timescale.

Table 2 | Specific models for applying complexity science to spread and scale-up

Name of model (author, year)	Key components	Comment
Participatory adaptation (Øvretveit, 2010)[7]	In the context of international health, use of decentralised planning, pragmatic modification, and improvement facilitators to adapt the operational details of an intervention to local circumstances	Proposed as a flexible way of achieving standardisation, replication, and accountability while also respecting emergence and adaptation at the local level
Facilitated evolution (Øvretveit, 2010)[7]	Local sites are supported to develop the capacity to find, adapt, and develop practices and models of care that tackle the challenges they face, with no external expectation placed on how problems are framed or which solutions are to be adopted. Draws on the concept of resilience (defined as a system's capability to withstand and recover from internal tensions and external shocks)	More radical approach than participatory adaptation. In one example, the goal of preventing HIV/AIDS in a low income African community was achieved through a community development initiative, which provided women with independent income
3S scale-up infrastructure (Øvretveit, 2011)[5]	A combination of strategic leadership, innovation culture, high quality data capture systems, and adaptive facilitation	These should not be viewed as mechanical tools to be applied deterministically to "solve" complexity (though formulaic versions of the breakthrough collaborative model exist). Rather, they are broad approaches that might be used creatively and reflexively to manage complexity
Breakthrough collaboratives (Øvretveit, 2011)[5]	Provision of resources, infrastructure, and impetus for inter-organisational exchange of resources, stories, and ideas oriented to achieving an improvement goal—typically through periodic collaborative workshops	
Experience based co-design (Bate and Robert, 2006)[21]	In collaborative workshops and in preparatory and follow-up work, patients work together with staff to identify emotional "touch points" in the patient journey and redesign the service in a way that centres on improving the patient experience	Not explicitly focused on complexity but follows many of the principles of effective change in complex systems—notably self organisation, collective sensemaking, and harnessing conflict productively

constrain individuals' actions. What do patients expect? What do different professional groups define as the gold standard of excellence? What do different professionals on the team expect of each other? What is thought to be legally sanctioned (whether or not correct)?

Many social scientists view the organisation as a "meso" level world that mediates between the individual (micro) and societal (macro). Individuals' actions in organisations are seen as shaped not only by practical and material realities but also by what are known as scripts or routines—that is, expected or required patterns of behaviour defined by formal roles, regulations, and standard operating procedures as well as by informal customs, practices, and traditions.[24] Organisational routines, in turn, are strongly influenced by external social forces including professional norms, public expectations, laws and policies, and commercial and other vested interests.

Organisational change can thus be viewed as inherently transgressive, because doing things differently violates the norms, expectations, and rules that are inscribed in organisational routines. Yet because routines are carried out by creative, thinking individuals rather than automatons, they contain the scope for adaptation and change.[24] Leaders—clinical, managerial, and perhaps most importantly hybrid leaders who bridge both these roles—have a crucial part in creating the preconditions in which staff will feel confident to innovate and improve (for example, by setting a climate of risk taking and collaborative learning rather than one of playing safe and covering one's back).[3 12] An example of how social science has informed a study of spread and scale-up is shown in box 4.

Conclusion

We have presented three different logics through which spread and scale-up can be approached: mechanistic (implementation science), ecological (complexity science), and social (social science). We have separated them for analytic purposes, but there are substantial synergies and overlaps between them. These approaches can inform the design and implementation of spread and scale-up programmes from small quality improvement interventions to system-wide transformational change and can offer insights to frontline teams about how and why particular change efforts are effective (or not). Empirical studies of spread

Box 3: A complexity science approach to spread and scale-up

Eaton and colleagues used a combination of systematic review and national stakeholder interviews to build up an international case study of challenges to the spread of evidence based mental health programmes in low and middle income countries.[8] Although every country had its own unique problems, some inter-related challenges recurred: limited financial resources and government commitment; overcentralisation of services in large psychiatric hospitals along with a weak, underfunded primary care sector; scarcity of trained mental health personnel; and low public health expertise among mental health leaders.

In the context of such widespread problems, the term scale-up was extended to refer to several linked goals: increase coverage (the number of people receiving mental health services); increase the range and appropriateness of services offered; increase the extent to which these services were evidence based (using service models that had been tested in comparable settings); and strengthen the mental healthcare system through policy formulation, implementation planning, and financing. Also key to the spread and scale-up effort were mobilising political will and reducing the stigma of mental health conditions among both lay people and health professionals. Seen through a complexity lens, all these goals are interdependent and mutually reinforcing.

Numerous approaches were taken in different countries at national level (including attempts to influence the prioritisation, planning, and resource allocation for mental health services; challenging the tertiary care focus; developing and disseminating evidence based guidelines; developing human resource policies and programmes) and local level (support for service restructuring; training programmes for primary care staff in common mental disorders; engagement and education of patients, families, and communities; and strengthening systems for evaluation and monitoring). Many settings were found to have weak data systems. By improving the quality of routinely collected data, developing reliable metrics of success that fed into system planning in a timely way, and developing links with academic researchers, the potential for system learning was greatly improved, though the spread and scale-up effort was more successful in some settings than others.

In contrast with the example in box 1, a highly programmatic top-down approach emphasising fidelity of an intervention would not have worked in this case. An adaptive approach, combining national policy efforts with bottom-up strengthening of local services, was needed to take account of the precarious political and economic context in many low and middle income countries and the multiple interdependencies in the system.

Box 4: A social science approach to spread and scale-up

A good example of how researchers used social theory to explain both spread and non-spread of innovations are Dixon-Woods and colleagues' studies of national efforts to reduce catheter associated infections in intensive care units in the United States[23] (highly successful) and United Kingdom (less successful).[25]

The US investigators had initially concluded (using an implementation science lens) that a technical checklist, introduced in over 100 intensive care units, had dramatically reduced rates of central venous catheter infection by making the care process more systematic, rational, consistent, and evidence based. Dixon-Woods and her colleagues undertook post hoc interviews, reanalysed the data, and came up with a new theory of spread that was predominantly social rather than technical.

They showed, for example, that the US programme came to be seen as something a "good" intensive care unit should be signing up to, perhaps because it was led by respected opinion leaders from a university. Relations between participating units strengthened as a result of participation, resulting in extensive interorganisational networking and lateral support. As the initiative evolved, it took on the characteristics of a grassroots social movement in which responsible clinicians and managers identified strongly with the programme and wanted to be involved.

A later ethnographic study by the same team[25] used a different programme theory to explain why the same intervention largely failed to spread in UK intensive care units, despite a nearly identical phased model of implementation. In the UK, the intervention was seen as top-down and driven by government rather than professionally led and collaborative; the initiative was introduced in parallel with other major infection control policies so had a less distinct identity; there was limited lateral support between participating units; and in low performing units there appeared to be a history of under-resourced improvement initiatives that had resulted in change fatigue.

This case took a social science approach in the sense that a detailed programme theory was developed to explain both high and low success in different contexts, though the original design had been a conventional (largely behavioural) implementation science intervention.

and scale-up can, and perhaps should, combine more than one perspective. As a rule of thumb, the larger, more ambitious, and more politically contested the spread challenge, the more ecological and social practice perspectives will need to supplement (or replace) "mechanical" efforts to replicate an intervention.

For further reading on the interface between implementation science, complexity science, and social practice, we recommend Braithwaite and colleagues' recent theoretical synthesis.[26]

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Supplementary file: Reviews and theoretical syntheses of spread and scale-up in healthcare

Changing how we think about healthcare improvement

Complexity science offers ways to change our collective mindset about healthcare systems, enabling us to improve performance that is otherwise stagnant, argues **Jeffrey Braithwaite**

For all the talk about quality healthcare, systems performance has frozen in time. Only 50-60% of care has been delivered in line with level 1 evidence or consensus based guidelines for at least a decade and a half[1-5]; around a third of medicine is waste, with no measurable effects or justification for the considerable expenditure[6-9]; and the rate of adverse events across healthcare has remained at about one in 10 patients for 25 years.[10-13] Dealing with this stagnation has proved remarkably difficult—so how do we tackle it in a new, effective way?

We need to understand why system-wide progress has been so elusive and to identify the kinds of initiatives that have made positive contributions to date. Then we can ask what new solutions are emerging that may make a difference in the future and start to change our thinking about healthcare systems.

Why change is hard

The overarching challenge lies in the nature of health systems. Healthcare is a complex adaptive system, meaning that the system's performance and behaviour changes over time and cannot be completely understood by simply knowing about the individual components. No other system is more complex: not banking, education, manufacturing, or the military. No other industry or sector has the equivalent range and breadth—such intricate funding models, the multiple moving parts, the complicated clients with diverse needs, and so many options and interventions for any one person's needs. Patient presentation is uncertain, and many clinical processes need to be individualised to each patient. Healthcare has numerous stakeholders, with different roles and interests, and uneven regulations that tightly control some matters and barely touch others. The various combinations of care, activities, events, interactions, and outcomes are, for all intents and purposes, infinite.

When advocates for improvement seek to implement change, health systems do not react predictably; they respond in different ways to the same inputs (staff, funding, presenting patients, buildings, and equipment). In the language of complexity science, this is "non-linearity." The sheer number of variables and the unpredictability of their interactions make it hard to impose order. And health systems are indeterministic—meaning that the future cannot be predicted by extrapolating from the past. They are also fractal and self similar, often looking alike in, for example, organisational culture in different places and at different points in time.

How then is a system as complex and seemingly dynamic as healthcare typically in a steady state, with entrenched behaviours, cultures, and politics? Because the total of the negotiations, trade-offs, and positioning of stakeholders pulls strongly towards inertia.[14 15] No one person or group is to blame; but a complex system clearly does not change merely because someone devises and then mandates a purpose designed solution. Studies of concerted improvement efforts, for example in North Carolina, USA,[16] and in the NHS,[17] show

KEY MESSAGES

- The key measures of health system performance have frozen for decades—60% of care is based on evidence or guidelines; the system wastes about 30% of all health expenditure; and some 10% of patients experience an adverse event
- Proponents of change too often use top down tools such as issuing more policy, prescribing more regulation, restructuring, and introducing more stringent performance indicators
- We must move instead towards a learning system that applies more nuanced systems thinking and provides stronger feedback loops to nudge systems behaviour out of equilibrium, thereby building momentum for change
- Effective change will need to factor in knowledge about the system's complexity rather than perpetuate the current improvement paradigm, which applies linear thinking in blunt ways
- Yet we should recognise how truly hard this is in the messy, real world of complex care

Box 1: Selected attractors and repellents of change

Systems can change when:

- Stimulated by medical progress—eg, new diagnostic tests and treatments, imaging technology, or surgical advances
- Incontrovertible evidence shows public benefit—eg, immunising infants or reducing smoking rates in developed countries
- New models of care emerge—eg, the shift to day only surgery or providing GP advice remotely via apps, teleconferences, or telemedicine
- Clinical practices alter by necessity or because of professional acceptance—eg, laparoscopic techniques
- Sources: Thimbleby, 2013[19]; Farmanova et al, 2016[20]; Westerlund et al, 2015[21]; Watt et al, 2017[22]

Systems can reject change when:

- The primary or sole strategy is to mandate solutions from the top down
- The change is not supported by parties with power to resist or reject, such as the medical profession or the media
- The initiative encounters entrenched bureaucracy, particularly in organisations such as public hospitals
- More policies and procedures are issued on top of a multiplicity of existing policies and procedures
- Attempts to alter deep seated politics or cultures are superficial
- Sources: Coiera, 2011[15]; Braithwaite et al, 2017[23]; Khalifa, 2013[24]

Box 2: Initiatives to change the system's hardware

- *Restructuring organisations*—The boxes on the NHS organisation chart have regularly been redrawn to little benefit. Although such reorganisations do produce structural change, they do not greatly alter entrenched cultures, much less downstream clinical outcomes.[25] Two studies assessing structural change showed that merging NHS trusts[26] and restructuring Australian hospitals[27] produced no measurable gains and put things back by 18 months or more.
- *Capital investments*—New buildings and new equipment or technology are necessary changes that can contribute to better, more modernised models of caring. Technology supporting new diagnoses and treatments, tests, and clinical techniques can instigate important gains. These initiatives, however, are mostly left to research and development departments, researchers, or clinicians, while politicians and managers focus on organisational charts, opening new hospitals, and prescribing policy.
- *Financial models and targets*—Studies from the US Commonwealth Fund and international experience indicate that no one financial model is better than any other,[28] [29] and perverse outcomes and gaming often result from imposed targets and key performance indicators.[30]

this. Instead, the system alters over time and to its own rhythm (idiosyncratically and locally).[18]

This raises further questions: what circumstances can precipitate changes in complex health systems, and what circumstances frustrate progress? Box 1 summarises selected initiatives. Attractors enable or create sufficient change for the system to be nudged before it settles into a new state. Resisters or repellents hold the status quo or reject change.

A key message from the examples in box 1 is that change is accepted when people are involved in the decisions and activities that affect them, but they resist when change is imposed by others. Policy mandated change is never given the same weight as clinically driven change.

Systems hardware and software

Much has been written about the many efforts to initiate change in health systems around the world, most of which seems to presuppose two familiar pathways. One is to alter the system's "hardware" by restructur-ing the organisation chart, upgrading the infrastructure, or changing financial models or targets, for example (box 2). The NHS and other systems have invested heavily in many such efforts. But the gains have been modest, and the extent to which such changes have contributed to better patient care is unclear. The other approach is to change the "software" of the system by tackling the culture of clinical settings (and the quality of leadership offered by managers and policy makers) and using implementation and improvement methods (box 3).

Changing our collective mindset

Instead of using the metaphor of hardware and software, we could change our thinking. We need to recognise three problems. Firstly, implementing and securing acceptance of new solutions is difficult, even when armed with level 1 or other persuasive evidence—this is the take-up problem. Secondly, disseminating knowledge of an intervention's benefits across the entire system is hard—this is the diffusion problem. Thirdly, even if a new model of care, technology, or practice

is successfully taken up and widely spread, its shelf life will be short—this is the sustainability problem. The pace at which new ideas are being generated, and previous ones discarded, is accelerating, particularly so over the past 20 years.

So paradoxically, although nothing lasts, genuine transformational improvement remains frustratingly elusive. Adding to the challenge, as Contandriopoulos and colleagues remind us, knowledge (even level 1 evidence) is unevenly distributed, poorly understood, and always contested.[38]

Accepting this reality is uncomfortable for those promoting improvement. "Agents of change" tend to prefer optimism or even the delusion that their new policies or initiatives are widely adopted.[14] This dichotomy has been described as "work-as-imagined" by policy makers and managers and as "work-as-done" by the clinicians at the coalface.[39] Policy makers and managers try to instigate change remotely; clinicians try to deliver care proximally. This leads to much antagonism—or merely ignorance of the other's role.

Understanding emergence and resilience

How do we move forward? Whatever solutions we choose must reflect the complexity of the system and respect its resilient features.[40] We must change our approach to understanding health systems and their intricacies.[41 42]

One way is to break with the NHS's pattern of attempting systems improvement from the top down. Complex adaptive systems have multiple interacting agents with degrees of discretion to repel, ignore, modify, or selectively adopt top down mandates. Clinicians behave how they think they should, learning from and influencing each other, rather than by responding to managers' or policy makers' admonitions. Frontline clinicians in complex adaptive systems accept new ideas based on their own logic, not that of those in the upper echelons. Healthcare is governed far more by local organisational cultures and politics than by what the secretary of state for health or a remote policy maker or manager wants.

Change, when it does occur, is always emergent. This is when features of the system, and behaviours, appear unexpectedly, arising from the interactions of smaller or simpler entities; thus, unique team behaviours emerge from individuals and their interactions.

Those on the frontline of care (clinicians, staff, patients) navigate change through their small part of the system, adjusting to their local circumstances, and responding to their own interests rather than to top down

Box 3: Initiatives to change the system's software

- *Enhancing organisational and workplace culture*—A systematic review found a consistent association in over 62 studies between organisational and workplace cultures and patient outcomes across multiple settings.[31] Encouraging positive organisational cultures to promote better patient outcomes seems time well spent. But these are localised solutions.
- *Implementation science and improvement studies*—Studies have tested models for creating implementable interventions and for getting more research evidence into routine clinical practice.[32 33] Ideas have emerged—such as the PARiHS framework[34] and models that take a more system-wide view[32]— that identify important ingredients in change such as context, persuasiveness of the evidence, and active facilitation. But applying such models to systems has shown the limits of progress. For any intervention, the effect size that can be secured when successful (and many interventions yield no or little benefit) is modest; perhaps around 16% on average.[35-37]

Table 1 | Twenty complexity oriented enablers and insights[41 47-56]

Enabler (what to do)	Insight (why to do it)
For policy makers:	
Take multiple evaluations of what's going on	Different stakeholders have distinguishable views on what's happening in complex systems
Use system tools to uncover the system's features	Causal loop diagrams, social network analyses, role plays, and simulation can provide insights into a system's characteristics
Customise change to local contexts	Culture is unique to the context: tailoring change to the circumstances is crucial
Work with, not against, trends	Going against the currents of change is possible, but is fraught with frustration and risk—the trend is your friend
Balance standardisation and variety	There is constant tension between the push for uniformity and the need for local initiatives
Use the informal system, not just the formal system	Organisational chart thinking only gets people so far; use the informal system and its cultural and political attributes
Take every opportunity to bolster communication, trust, and interpersonal relations	Care is delivered as a system of systems, with multiple interacting networks of people at its heart—communication, trust, and relationships are key to any progress
For managers and improvement teams:	
Model the system's properties	Systems diagrams and models, computer based or hand drawn, can illuminate the dynamics of the system
Use multimethod research and improvement techniques	Randomised controlled trials or single method data gathering approaches rarely expose sufficient dimensions of complex problems
Appreciate less is more in interventions	Resist aiming to control the system through improvement strategies, projects, and change initiatives: spend more time learning about the effects of interventions than obsessing about intricate designs
Leverage complexity thinking	Immerse local teams in complexity science and systems thinking
Focus less on the individual and more on the system	It's much harder to change individuals—seek instead to nudge or perturb the system
Develop and apply feedback to people involved at every opportunity	Change and improvement is a set of feedback loops, not an event or a linear process
Look for things going right as well as those going wrong	This promotes a more balanced view of the system
For frontline clinicians:	
Adopt a new problem solving focus based on systems thinking rather than obsessing with finding "a" way forward	Search for interconnections rather than getting stuck on any one solution
Look for behavioural patterns in the system and listen to the language people use	The rich behaviours and practices of others, and the signals and messages they convey, are full of beneficial cultural and systems information
Beware excessively causal logic	Take care in attributing cause and effect—overgeneralising causation is a common error
Trade-off between constant turmoil and implementing changes before they are ready	All systems sit not far from the edge of chaos: ride the boundary, and remember the old lesson that much in clinical practice and systems is uncertain
Understand that adaptation is almost always micro and granular	Big picture transformational change is rare and is expressed differently in different settings when it does occur
Appreciate that humans have a social brain	Organisational participants are perennially tuned in to the behavioural repertoires of others: use this expertise, and be attentive to others' needs and motivations

instructions. Thus, healthcare is naturally resilient, always buffering itself against change that does not make sense to those who are on the ground, delivering care.

Towards a nuanced appreciation of change?

Here are six principles on which a new approach to change might be built. Firstly, we must pay much more attention to how care is delivered at the coalface. Bureaucrats and managers, among others, will not improve the system or make patients safer by issuing swathes more policy, regulating more avidly, introducing more clunky IT systems, or striking off doctors.[43]

Secondly, all meaningful improvement is local, centred on natural networks of clinicians and patients.[44] One size fits all templates of change, represented by standardisation and generic strategies, too often fail. We must encourage ideas from many sources; care processes and outcomes will vary whatever we do.

Thirdly, we must acknowledge that clinicians doing complex everyday work get things right far more than they get them wrong. We focus on the 10% of adverse events while mostly overlooking the 90% of care that has no harm.[40] Understanding errors is critical, as is seeking to stop outmoded, wasteful, or excessive care. But,

if we also better appreciate how clinicians handle dynamic situations throughout the day, constantly adapting, and getting so much right, we can begin to identify the factors and conditions that underpin that success.

This leads to a fourth, related, point. A recent book[45] looking at achievements in healthcare delivery across 60 low, middle, and high income countries showed us that every system can tell multiple success stories. These range from organ donation and transplantation in Spain to early warning systems for deteriorating patients in Australia and Qatar, implementing minimum required standards in Afghanistan, making improvements in information technology in Taiwan, and embracing community based health insurance in Rwanda. These apparently disparate achievements have four common factors: begin with small scale initiatives and build up; convert data and information into intelligence and give this openly to the appropriate decision makers; remember the lone hero model does not work and that collaboration underpins all productive change; and always start with the patient at the centre of any reform measure.[46] Such inspiring ideas reflect complexity thinking and are not necessarily predicated on reductionist, cause-effect logic.

Fifthly, we could simply be more humble in our aspirations. Putting the myth of inevitable progress aside, we should recognise that big, at-scale interventions sometimes have little or no effects and that small initiatives can sometimes yield unanticipated outcomes.[47] We must admit to ourselves that we cannot know in advance which will occur.

Sixthly, and most importantly, we might adopt a new mental model that appreciates the complexity of care systems and understands that change is always unpredictable, hard won, and takes time, it is often tortuous, and always needs to be tailored to the setting. Table 1 shows 20 ways to exploit these principles. These enablers and insights need practice but can be used by anyone, including patients. For ease of application, they have been separated into complexity approaches for policy makers, managers and improvement teams, and frontline clinicians.

Conclusion

We need to turn healthcare into a learning system, with participants attuned to systems features and with strong feedback loops to try to build momentum for change. If we construct a shared outlook and draw on new thinking paradigms, perhaps we

can move beyond today's frozen systems performance. A final note of caution goes to the proponents of today's most popular strategies: it's time to stop thickening the rule book, reorganising the boxes on the organisation chart, and introducing more key performance indicators—and to do something more sophisticated.

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Understanding organisational culture for healthcare quality improvement

Russell Mannion and Huw Davies explore how notions of culture relate to service performance, quality, safety, and improvement

If we believe the headlines, health services are suffering epidemics of cultural shortcomings. Extensive enquiries into failures and scandals in the NHS over several decades have indicated aspects of hospital culture as leading to those failings.(box 1).[1 2] The recent report into over 450 premature deaths at Gosport War Memorial Hospital mentions culture 21 times.[3] After such reports, widespread and fundamental cultural change is typically prescribed as the remedy (box 1).[4 5]

Ideas of culture are also central to quality improvement methods. From basic clinical audit to sustained improvement "collaboratives," business process re-engineering, Lean Six Sigma, the need for cultural reorientation is part of the challenge.[6] Yet although the language of organisational culture—sometimes culprit, sometimes remedy, and always part of the underlying substrate at which change is directed—has some immediate appeal, we should ask deeper questions. What actually is culture in health services? How does culture relate to healthcare quality, safety, and performance? And can changing culture lead to improvements in care and organisational performance?

Greater specificity around both culture and performance enables us to understand more precisely the possible relations between them: quality improvement work is ill served by broadbrush accounts of culture and service quality. We seek to move past the use of culture as simply a rhetorical tool used by politicians and in policy edicts. Instead, we outline a more nuanced account of the social dynamics of healthcare services.

What is culture in this context?

Healthcare organisational culture (from here, just culture) is a metaphor for some of the softer, less visible, aspects of health service organisations and how these become manifest in patterns of care. The study of organisational practices derives from social anthropologists' approaches to the study of indigenous people: both seek to unravel the dynamics of unfamiliar "tribes." The view that culture can be managed to remedy past deficits and produce desirable future outcomes is often smuggled in through this re-application of the ideas of culture to organisations. This view needs some critical scrutiny,[5] one that explores a more nuanced account of organisational culture in healthcare.

In one common framing,[7] the shared aspects of organisational life—the culture—are categorised as three (increasingly obscured) layers (box 2). First, and most visible, are the physical artefacts and arrangements, as well as the associated behaviours that get things done. These visible manifestations of culture are seen in how estate, equipment, and staff are configured and used, and in the range of behaviours seen as normal and acceptable. These include the embedded and accepted care pathways, clinical practices, and communication patterns, sometimes referred to as "the way things are done around here."

The second level is the shared ways of thinking that are used to justify the visible manifestations (box 2). This includes the beliefs, values, and arguments used to sustain current patterns of clinical practice. In this way, the local clinical culture is expressed not only through what is done, but also how it is talked about and justified.

Deeper still, and thus much less overt and accessible, are the largely unspoken and often unconscious expectations and presuppositions that underpin both dialogue and clinical practice (the shared assumptions; box 2). Such attitudes may be formed early, go deep, and be less amenable to modification.

These three levels are linked, of course, but not simply. Some of the deeper values and assumptions are taught in early professional education (the so-called

KEY MESSAGES

- Organisational culture represents the shared ways of thinking, feeling, and behaving in healthcare organisations.
- Healthcare organisations are best viewed as comprising multiple sub-cultures, which may be driving forces for change or may undermine quality improvement initiatives
- A growing body of evidence links cultures and quality, but we need a more nuanced and sophisticated understandings of cultural dynamics
- Although culture is often identified as the primary culprit in healthcare scandals, with cultural reform required to remedy failings, such simplistic diagnoses and prescriptions lack depth and specificity

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Box 1: Centrality of culture to healthcare scandals: from Kennedy to Francis

From Ian Kennedy's review of the failings in paediatric cardiac surgery in Bristol during the 1980s and 90s[2] to Robert Francis's inquiry into the systemic failings at Mid Staffordshire Hospital Trust over a decade later,[1] culture has been implicated.

Culture as culprit

"There was an insular 'club' culture [at Bristol], in which it was difficult for anyone to stand out, to press for change, or to raise questions and concerns" (p302)[2]

"Aspects of a negative culture have emerged at all levels of the NHS system. These include: a lack of consideration of risks to patients, defensiveness, looking inwards not outwards, secrecy, misplaced assumptions of trust, acceptance of poor standards, and, above all, a failure to put the patient first in everything done" (p2357)[1]

Culture as remedy

"The culture of healthcare, which so critically affects all other aspects of the service which patients receive, must develop and change" (p277)[2]

"The extent of the failure of the system shown in this inquiry's report suggests that a fundamental culture change is needed" (p65)[1]

Visible manifestations of healthcare culture include the distribution of services and roles between service organisations (such as the long established divides between secondary and primary care and between health and social care), the physical layouts of facilities (receptionists behind desks and doctors in consulting rooms), the established pathways through care (including the ubiquitous outpatients appointment), demarcation between staff groups in activities performed (and the tussles that challenge or reinforce these), staffing practices and reporting arrangements, dress codes (such as different coloured scrubs for different staff groups in emergency departments), reward systems (pay and pensions, but also the less tangible rewards of autonomy and respect), and the local rituals and ceremonies that support approved practices. Visible manifestations of culture (sometimes called artefacts) also include the established ways (both formal and informal) of tackling quality improvement and patient safety, the management of risk, and the accepted ways of responding to staff concerns and patient feedback or complaints.

Shared ways of thinking include the values and beliefs used to justify and sustain the visible manifestations above and their associated behaviours, as well as the rationales put forward for doing things differently. This might include prevailing views on patient needs, autonomy, and dignity; ideas about evidence for action; and expectations about safety, quality, clinical performance, and service improvement.

Deeper shared assumptions are the (largely unconscious and unexamined) underpinnings of day-to-day practice. These might include ideas about appropriate professional roles and delineations; expectations about patients' and carers' knowledge and dispositions; and assumptions about the relative power of healthcare professionals—collectively and individually—in the health system.

hidden curriculum), reinforced through ongoing professional interactions, and then made visible as accepted practices. Other cultural manifestations are created or shaped externally, perhaps by the macro policy environment (for example, service configurations or reward systems), but over time these can influence shared ways of thinking and even deeper assumptions (about who or what is valued, for example). As healthcare becomes more global, with regular movement of care staff across national borders, major shapers of the cultural aspects of care may also include national, ethnic, or religious cultures.

Organisational culture, then, covers how things are arranged and accomplished, as well as how they are talked about and justified—that is, the stories and narratives about what is done and why, and the presuppositions that underpin these. Taken together these can reflect a shared and commonly understood view of hospital life manifested in patterns of care, safety, and risk. Although we focus on the hospital environment here, these arrangements and narratives are found (albeit in different forms) across all healthcare organisations from general practices to community trusts. Those wishing and situated to improve services need a sophisticated understanding of the social dynamics and shared mental schema that underpin and reinforce existing practices and inform their readiness to change.

An important additional layer of complexity is that shared mental schema may be confined to subgroups within care

services, with important implications for patient experience and service delivery.

One culture or many subcultures?

Healthcare organisations are notoriously varied, fractured by specialty, occupational groupings, professional hierarchies, and service lines. Some cultural attributes might be widespread and stable, whereas others may be shared only in subgroups or held only tentatively. Important subcultures are delineated most obviously, as professional groups, and the faultlines are most obvious as these groups compete for resources and status.[9] Other subcultures can emerge over time. Some staff groupings may excel at articulating and enacting desirable values and practices, which may be helpful to organisational goals; for example, specialist teams or centres of excellence. Less helpfully perhaps, other subgroups may actively work to undermine changes promoted from external sources (often construed as countercultures). Whether such countercultures reflect unwarranted resistance to change or a more appropriate defence of enduring values may be hard to discern and depends on both perspective and context.

Hospitals, then, are a dynamic cultural mosaic made up of multiple, complex, and overlapping subgroups with variably shared assumptions, values, beliefs, and behaviours. Two of the major professional groupings concerned with quality improvement—doctors and managers—may differ in several important ways, for example. Doctors may focus on patients as individuals rather than groups and

view evidence through a positivist natural sciences lens. Managers may be more concerned with patients as groups and value a social science based experiential perspective.[10] These cultural divergences have important implications for collaborative work, especially for people in hybrid roles who may either retain a cultural allegiance to their base group or seek to adopt the cultural orientations of their new role. They also form an important target for purposeful cultural reform, which might sometimes seek to strengthen current trends or at other times to inhibit them.

In sum, specific subcultures may be powerful catalysts for innovation and improvement or defenders of the status quo (for good or ill); they can be useful safeguards against risk or covert countercultures quietly undermining necessary reforms. Making sense of this subcultural diversity should be an essential part of any cultural "diagnosis" in seeking quality improvement.

Can culture be assessed and managed?

There are two distinctive views of culture. The first is optimistic about the potential for purposive cultural management, seeing culture as something that an organisation has— an attribute that can be assessed and manipulated to improve care. By contrast, the second view is more concerned with securing insights about organisational dynamics, without focusing on whether they can be manipulated. It sees organisational culture as something the organisation simply is—an account of local dynamics not readily separable from the organisational here-and-now.

These two perspectives take us down different routes of assessing and managing local healthcare cultures. The first emphasises the use of metrics to assess the prevalent organisational culture around a performance domain, such as patient safety. This approach assumes that a strong "safety culture" is associated with better outcomes for patients. Such measures may identify targets for managed change, and repeated measurement may be used to gauge progress against cultural objectives, with the hope that improvements in care will follow (for example, the Safety Attitude Questionnaire; box 3). Many such tools exist to assess different aspects of culture, although the science behind them is often weak[11] and their reliability and validity are questionable.[12]

The second view seeks to explore local cultural dynamics, often working through dialogue and perhaps using images and narratives rather than measurement instruments. This view is more modest about

the potential for manager-led purposeful change but may still see cultural assessment as part of an overall influencing strategy (for example, the Manchester Patient Safety Framework; box 3).

Although both perspectives draw on assessment tools, they do so for different reasons: the first emphasising quantitative measurement to identify targets for change and to track progress (a summative approach); the second using qualitative insights more discursively to prompt reflection, learning, and shared actions (a more formative strategy). In practice, many researchers, organisational leaders, and quality improvement specialists will seek insights from across these approaches, despite the (at times uncomfortable) accommodations needed between their divergent assumptions.

Does culture matter?

It seems obvious that the shared, cultural aspects of organisational life must have some bearing on organisational outcomes. Yet because of the complexity of healthcare cultures and the ambiguity around health service "success," establishing such links through research is not easy.[13] Nonetheless, the most recent systematic review of work in this area found a "consistently positive association . . . between culture and outcomes across multiple studies, settings, and countries."[14] So, culture does seem to matter. Individual studies can also offer important actionable insights, such as on the importance of leadership, the need for balanced cultures, and on the contingent nature of the relationships between culture and performance (box 4).

Clearly, the relations between culture and quality, safety, or efficiency are unlikely to be straightforward. Culture, although important, offers no "magic bullet"—the challenge becomes one of understanding which components of culture might influence which aspects of performance.

Moreover, any relations between culture and health service outcomes are likely to be mutual and recursive: that is, perceived performance is as likely to shape local healthcare cultures as culture is to shape local healthcare performance. Virtuous circles of high performance leading to reinforcing cultures of high expectations may be seen, as can spirals into decline where perceived performance failings lead to demoralisation and resignation to those poor standards.[20] In these arguments, we can see how narrative practices about performance can have important effects on local cultures and that this has implications for clinician leaders, managers, and policy makers in how

they talk about and manage performance and improvement.

Conclusions

Too often the term culture is used as a metaphor for something the organisation is thought to have. But acknowledging that culture is a complex construct can allow more judicious application of the concept. Paying greater attention to the multilayered and multifaceted complexity underlying the term—and recognising that many and varied cultural subgroups make up our healthcare organisations—opens new avenues for

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Box 3: Two examples of culture assessment tools directed at patient safety

The **Safety Attitude Questionnaire (SAQ)** is a major (quantitative) assessment tool developed in the United States and widely used in the NHS to help organisations assess their safety culture and track changes over time. The SAQ is a reworking and refinement of a similar tool widely used in the aviation industry. There are various versions of the SAQ, but these typically comprise some 60 survey items, designed in the form of five point Likert scales, in six safety related domains: safety climate; team work; stress recognition; perceptions of management; working conditions; and job satisfaction. Completed by individuals, scores are then aggregated to give an indication of the overall strength of the organisation's extant safety culture.

The **Manchester Patient Safety Framework** is a facilitative (qualitative) educational tool. It aims to provide insight into safety culture and how it can be improved among teams and organisations. The tool explores nine dimensions of patient safety and describes what an organisation would look like at different levels of patient safety. Assessment is carried out in facilitator-led workshops, and the assessments can be used to prompt reflections, stimulate discussions, and understand strengths and weaknesses.

Box 4: Insights from empirical study of the links between culture and care

The importance of leadership

A recent intervention study (Leadership Saves Lives) focused on leadership actions to promote positive changes in organisational culture in 10 hospitals in the US. It found that changes in culture over a two year period varied substantially between hospitals.[15 16] In the hospitals that experienced substantial and positive cultural shifts, changes were most prominent in specific domains, such as perceptions of the learning environment, senior management support, and psychological safety. Hospitals with marked positive shifts in culture also experienced significant decreases in risk-standardised mortality rates (in this case for treatment of acute myocardial infarction). These findings from the US show which elements of culture need attention from hospital leaders—in particular, fostering a learning environment, offering sustained and visible senior management support to clinical teams, and ensuring that staff across the organisation feel "psychologically safe" and able to speak up when things are felt to be going wrong.

The need for balanced cultures

Research has shown that, in addition to cultural types, the balance between different cultures is important. Shortell, for example, found that, in a sample of chronic illness management teams, balance among team members relating to the cultural values of participation, achievement, openness to innovation, and adherence to rules and accountability was positively associated with both the number and depth of changes aimed at improving the quality of care.[17]

The appearance of contingent relationships

The research indicates that there is no single "best" culture that always leads to success across the full range of performance domains. Instead, the aspects of performance valued in a given culture are enhanced in organisations with strong congruence with that culture. Early studies in Canadian, UK, and US hospitals found, for example, that hospitals with inwardly oriented cultures that emphasised managing through informal interpersonal relationships performed significantly above average on measures of employee loyalty and commitment than those with outward looking cultures.[18] Conversely, hospitals with outward looking cultures and procedural management performed better on measures of external stakeholder satisfaction. More recently, large scale longitudinal research in English NHS hospital trusts[19] replicated some of these findings.

The influence of the wider organisational environment

A qualitative case study of six NHS hospitals found clear differences in the cultural profile of "high" and "low" performing hospitals in terms of: leadership style and management orientation; accountability and information systems; human resource policies; and relations with other organisations in the local health economy.[20] Each of these provides potentially important targets for purposeful cultural change aimed at performance improvement.

understanding the deeply social and discursive nature of complex organisations.

How these insights are used in quality improvement depends on both other conceptual framings of the healthcare setting, the aspect of service quality or performance to be improved, and on the precise nature of the quality improvement methods to be used.[6] For some framings and improvement methods, culture is key; for others, cultural aspects are in the background. Our view is that the cultural dimensions of organisations are an important substrate on which improvement focused change is being sought and that, although never fully manageable, cultures can be better understood and must be purposefully shaped.

Finally, the cultural framing of healthcare organisations draws attention to specific aspects of organisational life: the shared patterns of feeling, thinking, talking, and accomplishing that underpin local practice. In doing so, other equally important aspects of organisational life may be marginalised or neglected, such as individual skill, attitude, and responsibility; governance and performance management arrangements; the macro structural arrangements within which local service lines are embedded; the incentives spread across the system; and the availability of material resources, human capital, and knowledge. Each of these aspects interacts with and can sometimes overwhelm cultural features, with a resultant effect on the ability to shape and improve culture and services. The choice to focus improvement efforts on healthcare culture to the exclusion of, say, policy frameworks or resource constraints, inevitably has political ramifications, and these should be dealt with rather than ignored. Cultural reform in healthcare is no substitute for adequate resourcing. That said, the cultural perspective outlined here provides an insightful way of thinking and a practical set of tools to support wider quality improvement work in healthcare.

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Can we import improvements from industry to healthcare?

Healthcare has more to learn from other industries, including aviation—but it's more complex than we think argue **Carl Macrae and Kevin Stewart**

Exhortations to learn from other industries have been common in the world of healthcare improvement since the inception of the discipline.[1] These are not always helpful. Recounting oversimplified improvement examples from other industries (often aviation) can provoke considerable frustration and scepticism among clinicians exposed to the unique challenges and everyday complexities of trying to improve healthcare. Patients are not aeroplanes, and hospitals are not production lines. Nonetheless, many successful efforts to improve the quality and safety of healthcare have taken inspiration from other industries. Here we re-examine some familiar exemplars from the aviation industry to show what is (still) to be learnt, even in areas that have made substantial improvements.

No simple solution

From simulation training[2] to patient handover[3] to structured communication[4] to quality improvement itself,[5] many healthcare improvement interventions have been adapted from industrial settings as diverse as civil aviation, nuclear power, and car manufacturing. Initially, learning from other industries seems to offer a simple shortcut to anyone trying to improve healthcare. Other industries have spent decades developing tools, methods, strategies, and techniques to improve quality and safety: why not just apply these in healthcare?

Of course, it is not that simple. Translating and adapting improvement techniques to healthcare is hard and has had varied results. Some interventions, such as those aimed at reducing infections related to central venous catheters, have proved popular and successful[6]; others, such as incident reporting systems, have met with frustration and failure.[7] Initial enthusiasm for oversimplified, large scale attempts to apply a new improvement technique often quickly gives way to confusion, complication, and criticism.[8 9]

Despite these difficulties and frustrations, looking to other industries for ideas and inspiration still has value, just as other industries are increasingly looking to learn from healthcare.[10] But to do this well requires a more sophisticated approach centred on three principles.

Firstly, efforts to translate improvement strategies from one setting to another need to be based on a sophisticated understanding of the contextual, practical, and structural differences (and similarities) between those settings.[11] Secondly, translational efforts need to pay close attention to the cultural and organisational arrangements that support the particular improvement intervention. Thirdly, any translational effort needs to be based on a process of careful adaptation and intelligent reinvention, not simply importing and applying a readymade tool.

Lost in translation

Why is learning from other industries so hard? One of the main reasons is obvious: caring for patients is radically different from making cars or flying aeroplanes. Healthcare is unique in the intimacy, complexity, and sensitivity of the services it provides as well as the trust, compassion, and empathy that underpin it.[12] Healthcare is also enormously varied: elective surgery, community mental health, emergency medicine, and palliative care are very different in terms of the work, knowledge, and activities involved— and the ways they need to be organised and managed.

Healthcare is better understood as perhaps 20 different industries, many of which need to seamlessly interact at critical junctures throughout a patient's journey.[13] What works in one part of healthcare may not work in another. It is therefore unsurprising that what works in an entirely different industry, such as car manufacturing, may not easily and directly transfer to all healthcare settings. The diversity of healthcare means that it is almost meaningless to compare it with nuclear power or aviation.

Another rarely recognised consideration is that work in other industries is also diverse. In the healthcare literature, for example, "aviation" is often translated as "pilots flying aeroplanes"[14]—which overlooks the considerable differences between the operational work of flight crew, the diagnostic work of engineers, the physical repair work of maintenance technicians, the design work of system analysts, and the myriad other activities that constitute any complex industry.

When attempting to transfer improvement lessons, it is important to understand the precise nature of the work in different healthcare settings as well as in other industries. For instance, it might be useful to draw parallels between the technical, process oriented, monitoring activities of anaesthesia and similar types of activities in the control rooms of nuclear power plants.[10] Likewise, the complex diagnostic tasks, multiple handovers, and relatively isolated working patterns of maintenance engineering may be a useful analogue for some elements of primary care.

In addition, successful translation from other industries into healthcare typically depends on considerable adaptation and reinvention of the original improvement techniques. This can be seen in three areas of healthcare improvement that have drawn heavily on techniques pioneered in other industries.

Incident investigation and analysis

Analysing and investigating adverse incidents has been a cornerstone of improving patient safety for many years. The pioneering reports that established the discipline drew

directly on the experience of other industries, primarily aviation,[15][16] and incident reporting systems have subsequently become one of the most widely implemented improvement strategies across modern healthcare. The English National Reporting and Learning System currently collects data on over two million incident reports each year[17] and root cause analysis techniques have been widely adopted.[8]

However, the translation of these approaches into healthcare has often missed or misconstrued some of the most important elements seen in other industries. Incident investigations in industries such as nuclear power[18] are typically conducted by dedicated in-house teams of professionally trained investigators; routinely incorporate rigorous human factors and systems analysis; are separated entirely from any management processes that seek to allocate blame; and typically produce actions that focus on strong, systemic safety improvements such as redesigning equipment.

In contrast, the fundamental organisational systems and structures needed to effectively learn from incident investigations remain relatively underdeveloped in many healthcare settings. Investigations can get tangled up with political processes of blame, there is limited expertise, and resulting improvement actions are not always robust.[8] There has also been a heavy focus on collecting and recording large quantities of incidents. Reporting incidents has almost become an end in itself, whereas in other industries incidents are used merely as a starting point to investigate and improve work systems.[19]

Growing frustration[7] has recently led to a reappraisal of the focus on reporting, with attention increasingly shifting back to the practical work of investigating and improving healthcare.[20][21] Notably, several national healthcare systems are developing the capacity for routine, system-wide safety investigations (box 1).

Many healthcare organisations still have a long way to go before they can reliably transform incidents into improvements. Revisiting the organisational and cultural principles that support this in other industries still offers salient lessons, primarily the need for well resourced safety teams led by experts that allow systematic examination of practical work and the development of robust system level improvements in contexts removed from fear and blame.[24]

Checklists and cognitive aids

One of the highest profile improvement interventions adopted from other industries are safety checklists[25] and other cognitive aids such as emergency manuals.[26] Checklists provide a set of structured and practical instructions that either prompt, or serve to verify, a series of actions at key stages of a healthcare process—such as the sign-in process before surgery[9] or during an anaesthetic emergency.[26] Checklists draw directly on those used in other industries—aviation in particular—and the approach has been widely popularised.

However, in the process of being imported into healthcare, checklists have taken on several functions beyond those in other industries. For example, in healthcare checklists are often intended to prompt communication and facilitate team functioning. In other industries, the collective use of checklists depends on the prior creation of cohesive and well functioning teams through building stable cultural norms and expectations, routinely training for simulated emergencies, and establishing standard protocols for reliable communication,[3][26] rather than aiming to create effective teams through the use of a checklist.[9]

In other industries, checklists are just one element of a carefully designed sociotechnical system built to support processes for high reliability and effective human performance. Some areas of healthcare, such as maternity care, have emulated this successfully.[27] But in many healthcare settings the checklist may be the only element of an entire process that has been actively designed with reliability and safety in mind.[9] This brings both risks and opportunities. One risk is that an over-reliance on checklists, coupled with unrealistic expectations regarding their application, leads to well meaning people with limited expertise developing cognitive aids that are poorly designed or ineffective and therefore distract more than they support.

Box 1: System-wide, learning focused, safety investigation

What?

In April 2017 England became the first country to establish a dedicated, system-wide safety investigation organisation for healthcare: the Healthcare Safety Investigation Branch. Norway is launching a similar organisation in 2019 (the National Investigation Board for the Health and Care Services), and other countries are exploring the idea.[22]

Why?

The objectives of these new organisations are translated directly from other industries, including railways, shipping, and aviation: to undertake rigorous, non-punitive, and systematic investigations into serious patient safety risks that span the healthcare system to develop system-wide recommendations for learning and improvement.[21]

How?

Uniquely, the organisations are independent of all other parts of the healthcare system. They can therefore investigate and issue recommendations to all parts of the healthcare system—from frontline practice, to the design of equipment, to the regulation of services. Importantly, the investigation processes are focused solely on learning and are entirely separate from systems that seek to allocate blame, liability, or punishment. Information collected for the purposes of safety investigation will be used only for safety improvement and cannot be used by other organisations for punitive purposes. Ensuring this independence requires strong legislative protections to prevent safety information from being used inappropriately.[23]

What's different in healthcare?

The principles of investigation are common across all industries, but the practical specifics will need to be reinvented to deal with the unique challenges of healthcare. In particular:

- Healthcare practices draw on cutting edge and ever changing medical science and so investigations will need to engage with scientific evidence and will probably need to regularly recommend further scientific inquiry
- Health systems are much more complex than any transport industry and encompass a wide range of highly specialised professional groups, skilled activities, and advanced technologies
- Healthcare investigations must sensitively engage patients and families throughout the process; they are often the only people who see the entire trajectory of care
- Healthcare organisations routinely capture few data relevant to safety—there are no "black box" flight data recorders as in aviation—and the data that are collected may be difficult to collate and are often qualitative
- Healthcare processes are less specified and less standardised than in other industries, meaning there may be few benchmarks against which to identify deviation

Healthcare could learn further from the strategic use of cognitive aids and checklists as part of more integrated approaches to designing processes and improving reliability. For instance, considerable effort goes into supporting in-the-moment professional decision making by mapping out the complex conditions under which it is safe for an aircraft to depart and when it is not (box 2).

Quality improvement and systems design

Healthcare quality improvement owes its existence to other industries. Process re-engineering and systems improvement tools such as lean production,[29] plan-do-study-act cycles,[5] statistical process control,[30] and failure modes and effects analysis[31] have been imported into healthcare almost wholesale.

Many of these methods may seem simple[5] but are actually highly sophisticated and challenging techniques that require considerable expertise to implement well. Reviews suggest that they are not always consistently or effectively applied in healthcare.[5 31] This might be partly because individuals and teams are not appropriately trained or experienced in the particular method.[5] But more fundamentally, it points to the importance of having appropriate organisational systems, resources, and culture in place to support the systematic application of improvement methods.

One of the hidden assumptions that underpins many process improvement methods is that there are stable processes in place to improve. However, as the reliability of systems such as those for inpatient prescribing and theatre equipment availability has been found to be about 80%,[28] this can be a bold assumption. Activities in many areas of healthcare have often grown up organically over many years, so the most fundamental step in many healthcare improvement projects is often simply to design a process to begin with.

To date, the improvement approach in healthcare has largely focused on initiating large numbers of locally led improvement projects. This approach can work to optimise processes that already exist but is less suited to tackling the large, complex problems of system design.[32] Again, insights from other industries are still highly relevant to healthcare, such as the importance of systems engineering.

One of the defining features of many industries is the importance of "systems integrators," who oversee and coordinate the design of complex systems. In aviation, for example, major manufacturers—such as Boeing or Airbus—fulfil this function by designing the core of the aircraft,

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Box 2: Integrating systems analysis, decision making, and cognitive aids

What?
The routine operational decisions that are made in airlines that determine whether a commercial airliner is airworthy and safe to fly are governed by a minimum equipment list (MEL).

Why?
At any point in time, any aircraft is likely to have some equipment that is faulty or inoperable. The MEL can be more than 400 pages, mapping out the conditions and contingencies under which an aircraft is safe to fly and providing the basis for sophisticated professional judgments by engineers and flight crews regarding whether an aircraft is safe to operate or not. Essentially, the MEL maps out for most conceivable scenarios that "If this is broken then it is safe to fly if A and B are operational and you don't do C."

How?
The core requirements are determined by aviation regulators, documented by aircraft manufacturers, incorporated into airline operators' procedures, and implemented by engineers and flight crew. MELs are highly systematised decision support tools that capture a deep body of technical knowledge and present it in a way that supports expert judgment and professional accountability. These sophisticated cognitive aids aim to support cautious and balanced decisions about risks: ensuring that airworthiness and safety are maintained at all times and core regulatory requirements are met, while avoiding unduly inconveniencing passengers or affecting airline revenues by removing serviceable aircraft from operation.

What's different in healthcare?
The need to balance safety and productivity pressures, and to structure shared decision making, are common to many healthcare settings, but the specifics of how such an approach might be incorporated into healthcare would need detailed analysis:
- In which healthcare contexts might it be useful to develop more extensive, systems oriented cognitive aids equivalent to a MEL, and when might such tightly structured decision making be inappropriate or overly constraining?
- How might a healthcare equivalent of a MEL be designed and implemented in surgical settings given that around 20% of surgical procedures start with missing equipment,[28] and what adaptations might be required for different types of surgical procedure?
- To what extend might the principle of deep standardisation that underpins MELs conflict with new efforts to standardise healthcare processes, such as the National Safety Standard for Invasive Procedures in England, which encourages considerable variation in the local development and implementation of procedures and checklists?

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coordinating with all the component manufacturers (from engines to flight computers), designing the maintenance processes, and defining the procedures for operating and maintaining the aircraft—even down to specifying that on certain types of twin engine aircraft on certain types of operations, the same engineer may not conduct the same maintenance task on both engines, in case the same error is made.

Healthcare has much to learn from other industries about integrating complex technical, operational, and organisational systems. Recent examples include the systems engineering work undertaken to integrate technologies, processes, and systems in intensive care units[33 34] and efforts to apply safety case techniques from the nuclear and chemical process industries to analyse, map, and improve the reliability of health systems.[35] There are likely be new lessons to learn from developments in user-led design[36] and the organisation of resilient organisational systems.[27] But above all, perhaps one of the most striking

and fundamental lessons for healthcare is the extent to which other industries allocate considerable resources and dedicated staff to systems analysis and quality improvement.[24]

From translation to exploration

Learning from other industries is neither simple nor straightforward but it remains an important part of improving the quality and safety of healthcare. Adapting quality improvement tools from elsewhere requires a deep understanding of the mechanisms and systems that underpin an improvement technique in one industry; closely examining the context, practices, and challenges inherent in a particular setting in healthcare; and then carefully adapting and reinventing the improvement technique to work in healthcare. At the core, the process of learning from other industries is really a process of learning more about our own.

KS has longstanding experience in system-wide quality improvement initiatives and national improvement programmes. This article arose from discussions at an international quality conference. CM drafted the article and KS reviewed and helped revise it. CM is guarantor.

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How organisations contribute to improving the quality of healthcare

Naomi Fulop and Angus Ramsay argue that we should focus more on how organisations and organisational leaders can contribute to improving the quality of healthcare

Improving the quality of healthcare is complex.[1][2] Frontline staff are often seen as the key to improving quality—for instance, by identifying where it can be improved and developing creative solutions.[3][4] However, research and reviews of major healthcare scandals acknowledge the contributions of other stakeholders in improving quality, including regulators, policy makers, service users, and organisations providing healthcare.[5][6]

Policies on the role of organisations in improving quality have tended to focus on how they might be better structured or regulated. However, greater consideration is required of how organisations and their leaders can contribute to improving quality: organisations vary in both how they act to support improvement[7][8] and the degree to which they provide high quality healthcare.[9]

Some earlier studies suggest that high performing organisations share several features reflecting organisational commitment to improving quality. These include creating a supportive culture, building an appropriate infrastructure,

and embedding systems for education and training.[10][11] Subsequent reviews of quality inspections[12] and reviews of evidence on factors influencing quality improvement,[9] and board contributions[13] indicate that organisational leadership is crucial in delivering high quality care.

We discuss how organisational processes such as development of a strategy and use of data can be used to drive improvement, the characteristics of organisations that are good at improvement, and what to consider when thinking about how organisations can help improve quality of healthcare and patient outcomes.

We present evidence on the role of organisations in improvement drawn from acute hospital settings in the UK and other countries. Although contexts may vary—for example, in whether health policy is made at regional or national level, or in the form and function of healthcare organisations—the lessons have potential relevance to all settings.

Placing healthcare organisations in their context

Health systems operate at three inter-related levels: macro, meso, and micro (box 1). Research suggests that an organisation—

through its leadership and processes—can bridge these levels to influence the quality of care delivered at the front line.[14-16]

A key macro influence on organisations performing their role in improving quality is the way the healthcare system is governed and regulated. Regulation provides accountability to the wider system and therefore has a potentially strong influence on how healthcare organisations approach improvement. For example, multiple regulators in healthcare systems, as is the case in England, can lead to "regulatory overload,"[17] making it hard for organisations to focus on quality improvement rather than quality assurance[18] because of the need to respond to different (and potentially conflicting) regulatory approaches, priorities, incentives, and sanctions.[17][19][20]

How can organisations contribute to improving quality?

Organisations can use various levers and processes to translate external inputs (such as policy and regulatory incentives) and internal inputs (such as local assurance systems providing data on performance and capacity) to support quality improvement.[7][18][21] Organisations can facilitate improvement by developing and implementing an organisation-wide quality improvement strategy[9][22][23] that includes the following actions:

- Using appropriate data to measure and monitor performance[20][21][22]
- Linking incentives (both carrot and stick) with performance on quality[16][22]
- Recruiting, developing, maintaining, and supporting a quality proficient workforce[21]
- Ensuring sufficient technical resources and building a culture that supports improvement.[9][16]

Many of the key organisational activities important to improving quality, such as setting strategy and agreeing performance measures, are defined at organisational level by the board.[13] Bottom-up, clinician-led improvement is often seen as the answer to

Box 1: Macro, meso, and micro contributions to the quality of healthcare[14]

Macro (national health systems)
- Regulatory system
- Finance
- National priorities and policies
- Accreditation

Meso (hospitals)
- Strategies
- Systems
- Processes
- Cultures
- Practices
- Structures

Micro (departments, teams)
- Relational issues
- Communication
- Professional work
- Competence

Fig 1 | Leading and implementing system-wide change across organisations: centralising acute stroke services in London and Greater Manchester[25 27 28]

the quality challenge, and it is an important part of successful quality improvement.[3 24] However, relying solely on frontline staff to lead improvement is risky because professional self interest can shape or limit the focus of improvement activity.[22 25 26] Furthermore, lack of system-wide or organisation-wide agreement on objectives might result in variations at system level, reflecting localised priorities rather than what is likely to provide the best care for patients. As well as empowering staff and supporting system-wide staff engagement in activity around improving quality[4 20] organisational leaders must challenge localised professional interests, tribalism, and resistance to change.[18 22]

The reorganisation of acute stroke services in the UK (fig 1) shows how leadership can play a pivotal role in managing professional and organisational resistance to changes that aim to improve quality of care. Importantly in this case, leaders cited external organisations' priorities and public consultation responses when holding the line against local resistance to change.[25]

The culture of organisations is commonly considered important in improving quality,

as discussed elsewhere in this series.[20 29 30] Although the relation between culture and quality is complex, organisations can use formal and informal managerial processes to influence culture and thus improve quality of care.[30]

What helps organisations contribute to quality?

As set out in box 1, the relationship between a healthcare organisation and its external environment (especially regulators) is important in that organisation's contribution to quality.[18 23] A qualitative study of hospitals and their external environments in five European countries showed how some were better able to align multiple financial and quality demands.[7] Figure 2 shows contrasting organisational responses to external demands and the features of both the external demands and the organisations that contributed to these different responses.

Organisations can also contribute to improving quality through participation in (or leading) major system change, working beyond their own catchment areas across their local system—for example, integrating health and social care services[31] or centralising specialist acute services

across multiple hospitals in a given area.[32 33] Evidence suggests that how such changes are led and implemented influences the impact of the changes, including on patient outcomes (fig 1).

What do organisations that do well in improving quality look like?

Research suggests that organisations that deliver high quality care show high commitment to improving quality, reflected for instance in how organisations are led (eg, senior management involvement) and managed (eg, use of data and standards). As an illustration, fig 3 contrasts the approaches taken by US organisations with high patient mortality from acute myocardial infarction with those that have low mortality.

Some recent research has developed the concept of maturity in relation to how boards of organisations govern for quality improvement and what organisational processes accomplish and sustain it.[18]

More mature boards tend to use data to drive improvements in quality rather than merely for external assurance,[18 20] and they combine hard quantitative data on performance with soft data on personal experiences to make the case for improvement.[22] They also engage with relevant stakeholders (including patients[18] and the public), translate this into strategic priorities,[9-11] and have processes for managing and communicating information with stakeholders.[8 9 18] They value learning and development[4 7 22 34]—for example, drawing on external examples of good practice to achieve initial improvement then focusing on local, creative problem solving for continued improvement.[34] Finally, these organisations are outward facing, engaging with and managing their wider environment, including payers and other provider organisations.[7 13 29 34]

By contrast, organisations with lower levels of such capabilities (such as lack of coherent mission, high turnover of leadership, and poor external relationships) appear to slow or limit improvement.[18 35 36] Some interventions have been identified to help organisations struggling to improve quality.[35] Furthermore, research on organisational turnaround provides evidence of organisational leaders harnessing crises, such as major safety issues or financial difficulties, to drive radical change and improvement.[36 37] Key changes to turn round organisations have included refocused accountability systems (eg, making quality a key performance indicator, devolving accountability to clinical teams[11 38]), introducing processes to facilitate improvement (eg, dedicated

Fig 2 | How hospitals respond to external finance and quality demands[7]

improvement roles,[36 38] increased training opportunities, and sharing timely data on quality and cost with clinical teams[11 36 38]), supporting culture change (eg, increasing collaboration between clinicians and management[11 36 38] with clinicians leading on quality and management supporting them), and learning from the experience of other organisations.[11 36 38] However, for such interventions to have a chance of success, organisations need both sufficient space to think and the people to make change happen.[23]

The composition of senior leadership seems to influence how well organisations deliver on quality. Having clinicians on the board has been associated with better organisational performance,[23 39] through enhanced decision making, increased credibility with local clinicians (facilitating frontline uptake of policy), and making organisations more likely to attract talented

clinicians.[39] Active discussion of strategy is enhanced by independent challenge by non-executives who are well versed in quality issues; this is likely to enh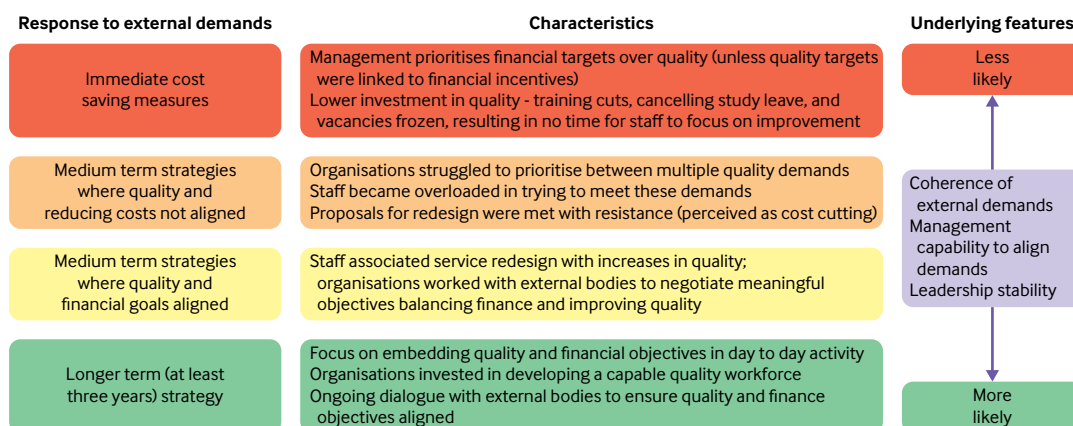ance focus on quality at board level, ensuring it is at the heart of an organisation's vision and strategy.[13] As noted elsewhere, focus is growing on service users guiding improvement.[40] However, it has been challenging to involve service users meaningfully at senior leadership level.[1 41]

What can we conclude?

Although organisations are central to improving quality, there is much variation in how they contribute, both locally and at system level. We have described ways in which organisations can contribute to improvement in terms of their processes (such as how they develop strategy and use data to drive improvements in quality), their leadership (such as how leaders

engage with and manage both their external context and local professional interests), and underlying features (including coherence of external demands and leadership stability). Box 2 summarises these themes. However, the balance of priorities among these is unclear: organisations will want to analyse how they can maximise their contribution to improving quality taking account of their particular context.

Regulators and policy makers also need to consider how they can better facilitate healthcare organisations' role in improving quality. Organisations are more likely to deliver quality improvement effectively if externally set objectives are clear and manageable, and there is time and resources with which to meet these. Regulators should seek to avoid generating regulatory overload and contradictory demands; and they should strengthen organisational leadership's hand by giving them headspace
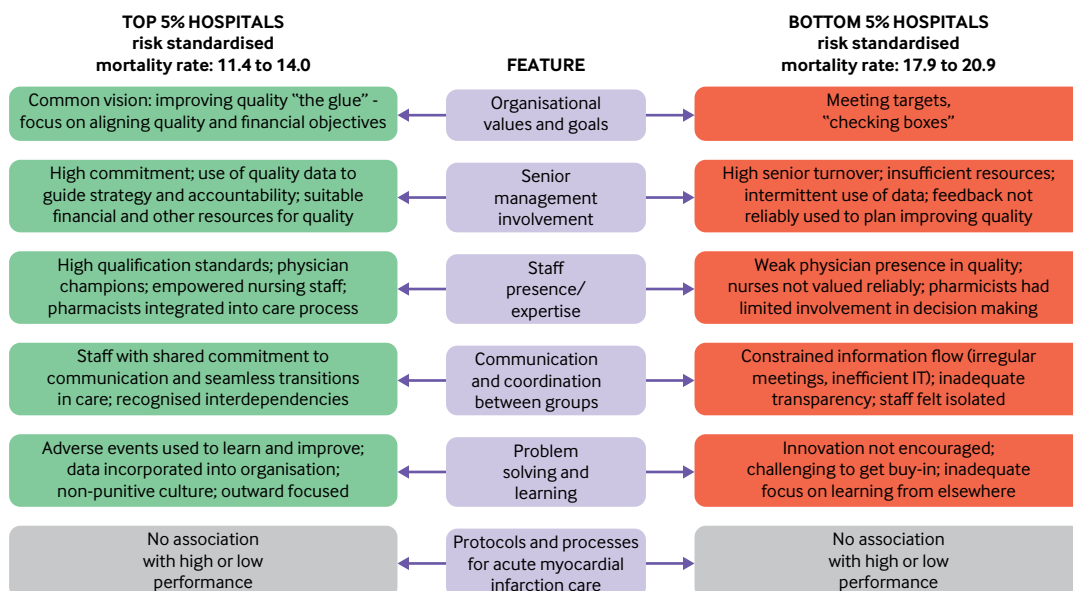

Fig 3 | Contrasting organisational approaches in US healthcare organisations with the top and bottom 5% risk standardised mortality for acute myocardial infarction in 2017[8]

Box 2: What helps organisations contribute to quality?

Organisational process
- An organisation-wide quality strategy to shift from external assurance to prioritising improvement
- Combine hard and soft data to drive quality
- Engage and communicate with stakeholders, including patients and carers, staff, and external partners
- Build culture of trust, supporting innovation and problem solving

Organisational leadership
- Support system-wide staff engagement in improving quality
- Be outward facing, to learn from and manage external context
- Challenge local professional interests where necessary
- Feature a strong clinical voice and independent challenge, especially on the board

Underlying features
- Space to think about improving quality
- Resources to implement improvements
- Coherent external requirements: avoid regulatory overload and contradictory demands
- Stability of leadership

to look beyond compliance and prioritise improving quality.

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Adapting Lean methods to facilitate stakeholder engagement and co-design in healthcare

Quality improvement approaches drawn from industry can go beyond traditional concepts of value and deliver improvements in healthcare services, argue **Iain Smith and colleagues**

Healthcare systems internationally face quality and productivity challenges and calls have been made for them to focus on delivering better value.[1-3] However, in healthcare, value is a debated concept. Value is often viewed in terms of health outcomes per spend for a given population[4] or in terms of clinical efficacy, focusing on interventions with a robust evidence base and reducing the use of interventions of low benefit.[2] But it can also be considered at the level of the microsystem, and systematic quality improvement (QI) approaches can help provide better value through action on quality, safety, and productivity.[1]

The Lean method is one approach that is being increasingly used to enhance value in healthcare.[5-7] In the UK, for example, NHS Improvement (which regulates NHS care providers) has embarked on a programme to embed Lean in English NHS trusts—some with support from the Virginia Mason Institute, a US based healthcare consultancy,[8] and others with support from an NHS Improvement consulting team.[9] Lean has drawn criticism for assuming that production efficiency techniques can apply directly to healthcare[10 11] and for lacking methods to integrate clinical knowledge and expertise with patients' preferences and needs in defining value.[12] We examine how it can be used to engage stakeholders in both defining value and designing systems and processes to deliver value.

What is Lean?

Lean is derived from the practices of Japan's automotive industry, specifically the Toyota production system.[13] It is a systematic improvement approach that conceptualises work as processes that can be continuously improved by emphasising customer value and eliminating waste.[6 13] Although it was developed for industry, it has been used successfully to improve quality and safety in acute, primary, and mental healthcare contexts (box 1).

The goal of Lean is to improve customer value.[13 20] Defining value in customer terms is the first step. The Lean ideal is then to design systems and processes that deliver customer value without waste, delay, or errors. This is achieved through iterative application of the Lean principles (box 2), which set out the steps for continuous improvement towards the ideal.[13 22]

Contextual and cultural differences must be taken into account when importing improvement approaches from other industries.[23] Differences must be well understood to adapt the approach to the specific requirements of the new context.[23] Therefore, delivering value for

healthcare using a Lean approach requires understanding of how Lean views customer value, how this concept should be translated to the healthcare context, and practical methods for engaging stakeholders in defining and delivering value.

Translating Lean value principle to healthcare

Lean value definitions typically emphasise a commercial, production perspective. Customer value is related to manufacturing processes that convert raw materials into finished products, such as a car, ready for sale.[24] Customers will not pay for defective vehicles, so to deliver value these processes must be performed correctly first time.[7] Production activities that are not adding value are deemed to be waste and targeted for elimination.[13]

US advocates applying Lean to healthcare have tended towards definitions of value in terms of the customer's willingness to pay[20] and its corollary that "anything in the process that the customer would be unwilling to pay for is waste."[25] Although this logic may be appropriate for the US system of hybrid payment healthcare, it is less relevant in national health insurance systems like the NHS.[26-28]

Unlike manufacturing, healthcare services are generally intangible and are characterised by simultaneous production

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KEY MESSAGES

- Quality improvement approaches used in industry, such as Lean, consider value from a customer perspective, focusing on productivity
- Healthcare requires a more holistic, multistakeholder view of value to target improvement that benefits patients as well as clinicians and management
- Lean also has methods that enable healthcare stakeholders (including staff and patients) to engage in the definition of value and the design of processes
- Early involvement of all stakeholders through these methods can optimise the outcomes

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Box 1: Examples of Lean in healthcare

- Western Sussex Hospitals NHS Foundation Trust has developed its patient first improvement system based on Lean principles. The system has been credited as contributing to the trust being rated outstanding by the Care Quality Commission.[14 15] It is also credited with improving timeliness of patient observations, fall rates, response rates for friends and family tests, and theatre start times, as well as many more small improvements that make a difference to the everyday experience of patients or staff.[16 17]
- NHS England's General Practice Development Programme has saved thousands of hours of clinical time by applying Lean principles through its "time for care" and "productive general practice" programmes. This involved identifying and implementing high impact changes to reduce waiting times and increase available GP time. Examples include redirecting patients not requiring a GP appointment to see other healthcare professionals such as nurse prescribers.[18]
- A cross-organisational collaborative in North East England used Lean methods to improve dementia care and nurse-led liaison mental health services for older adults. This included rapid improvement events that resulted in changes that reduced wait times, readmission rates, and length of hospital stay and made qualitative improvements such as increased confidence of staff and calmer ward environments.[19]

Box 2: Five core principles of Lean in healthcare[21]
- *Value*—Understanding value from the customer's perspective (usually the patient)
- *Value streams*—Identifying all the steps (both helpful and unhelpful) in the pathways of care that patients experience as they move through the system
- *Flow*—Working along care pathways to align healthcare processes to facilitate the smooth flow of patients and information
- *Pull*—Creating processes that direct value towards the patient such that every step in the patient journey pulls people, skills, materials, and information towards it, as needed
- *Perfection*—an ideal to be pursued through the ongoing continuous improvement of processes

and consumption.[29] Value is not created through transformative production steps in a remote factory. Rather, the value of the service is co-created with the customer (or end user)[29-31]; patients are not customers at the end of a production process but right in the middle of it throughout their pathways of care. Some believe that the principles of Lean have therefore been misunderstood and a more service oriented view is required that assumes value in healthcare is co-produced with patients.[26 30]

Although it may seem obvious that the patient should be considered the customer and value defined from their perspective,[32] there are other customers and stakeholders in healthcare whose needs and value perspectives must also be considered.[32 33] Young and McClean[33] proposed a framework to help do this by defining three critical dimensions to healthcare value—clinical, operational, and experiential. The clinical dimension of value relates to delivering effective care that achieves the best clinical outcome.[33 34] The operational dimension relates to the effectiveness of care relative to the cost of care.[2 4 33] The experiential dimension relates to how patients experience the care they receive and can be related to their interactions with staff as well as the care environment.[2 20 33] The various healthcare stakeholders (such as patients and carers, clinical and non-clinical staff, managers, and regulators) may place different emphasis on these dimensions of value.[33]

Lean QI methods to engage healthcare stakeholders

Arguably, most applications of Lean to healthcare have been limited by a largely operational view of value, where the focus has been on reducing costs rather than a more holistic, multistakeholder view.[11 33] However, through various workshop formats, Lean does have methods that enable definition of value and enhance customer participation.[35]

Lean rapid improvement events are already commonly used in healthcare to make incremental changes to processes.[6 36] Other Lean workshops include value stream analysis, which focuses on end-to-end pathways at high level to define strategic improvement plans,[37] and the production preparation process (3P), which focuses on developing new products and production facilities.[25] These Lean workshop formats differ in emphasis but all offer the opportunity to involve patients and service users in identifying value adding activities and eliminating waste.[35] The question is how can people leading health service improvement use these methods in practice?

Box 3 presents an example from the NHS in North East England, which adopted Lean using knowledge from Virginia Mason.[45] The Lean 3P method was used to involve stakeholders in simultaneously designing healthcare facilities and service systems.[38 43 44 46] The example illustrates challenges to participation that may be generally applicable (specifically the perception that patients are unable to contribute because of a lack of knowledge or ability).

The 3P method engaged stakeholders to articulate and share their value perspectives. Most importantly, this included service users, who shared their experiences and views on how these could be improved. Their experience was combined with staff experience to design care pathways (value streams) to deliver the desired user value. Staff contributed clinical experience and professional knowledge to ensure this could be done safely and effectively. The treatment rooms and other facilities were located to ensure steps in the pathway lined up with the physical layout to facilitate good flow. The service user, carer, and staff flows were mapped and simulated at each cycle of the design process. Information on how pathways would work was discussed by stakeholders, which helped facilitate improvement.

To improve the overall experiences of care, participants applied a service oriented approach in which "every step in the patient journey [pulls] people, skills, materials and information towards it, one at a time, when needed."[21] This helped stakeholders design more innovative models of care that could respond flexibly to changing circumstances. Services could then be

Box 3: Using Lean 3P in healthcare: the design of space project

The design of space project used the Lean 3P method to help NHS stakeholders such as patients, clinicians, and architects design two endoscopy units, a maternity unit, and a paediatrics unit in North East England.[38]

Previous reports of applying Lean 3P to design healthcare facilities have limited patient involvement to consultative walkthroughs[39] or not included them.[40] Furthermore, earlier research into stakeholder participation in the design of healthcare facilities identified scepticism from professional designers about the ability of patients to contribute.[41 42] Negative beliefs about users' ability included feelings that they are "meddling" in areas they know nothing about[41]; practical barriers in interpreting drawings and perceiving them spatially in three dimensions[41]; and concerns regarding understanding of professional issues such as construction costs and material options.[42]

The project showed that Lean 3P design workshops can provide an effective process for engaging a wide range of stakeholders[43] and a structured approach for corporate and clinical staff to work together with patient representatives.[44] The Lean concept of end-user value contributed to the design process by drawing out the perspectives (clinical, operational, and experiential) of multiple stakeholders in terms of what mattered most to them. Stakeholders were engaged in activities that stimulated discussion and debate and encouraged sharing of their requirements and preferences. In particular, the process gave patient and service user voices greater influence in designing the pathways and how delivery would be facilitated by the layout of the physical environment—for example, the location, layout, and size of treatment rooms. They were also able to contribute to the design of facilities for partners, family members, and carers; creation of family friendly environments; and an emphasis on sound privacy.

Simple Lean tools, such as spaghetti charts, were used to engage stakeholders in mapping out the pathway (value stream) and flows that patients and staff would follow. Flows were also designed to minimise the burden on patients (in terms of movement and anxiety) and direct staff and equipment towards the patient to deliver care.

"pulled" towards patients as required (for example, by bringing a clinician to a patient in a treatment room rather than moving the patient to the clinician in a different location, reducing patient movement). Through multiple cycles of design, the Lean 3P method helped participants move towards an optimised service model and design.[44 46]

Effective collaboration

The example shows that QI approaches such as Lean can be adapted to include important dimensions of service led value and quality, such as patient experience and satisfaction. In translating such methods to healthcare, it is important to identify both the primary customer and other service stakeholders to define value and target improvement. The 3P method facilitated conversations across multiple stakeholder groups (including patients, clinicians, and managers) that considered value in a more holistic way. For example, the clinical dimension of value involved stakeholders considering the effectiveness of treatments; the operational dimension involved stakeholders considering the efficiency and productivity of service delivery; and the experiential dimension involved stakeholders considering patients' preferences and needs. Stakeholders, including patients, articulated and shared their value perspectives, tested their ideas, and co-designed healthcare facilities and systems to deliver users' requirements. Stakeholder conversations about the different dimensions of value could also be facilitated in other workshop formats such as rapid improvement events and value stream analysis.

When patients are asked to participate in QI initiatives, their role needs to be relevant and have a practical impact. Proper collaboration early in the change process can help avoid the unintended consequences of overlooking experiential details that matter to patients. To achieve this, the qualitative nature of patient experience must be recognised and given equal priority to that of healthcare professionals.[47] It is therefore important to involve patients, clinicians, and managers early in the improvement initiative and select methods that allow them to work together on improvement. This includes facilitating conversations between stakeholders about what matters to them and creating opportunities for practical and tangible improvement activities such as small scale tests of change, working through the plan-do-study-act cycle, or creating prototypes together. In this way, QI approaches such as Lean will begin to

fulfil their potential to deliver greater value in healthcare.

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Revitalising audit and feedback to improve patient care

Audit and feedback are widely used in quality improvement. **Robbie Foy and colleagues** argue that their full potential to improve patient care could be realised through a more evidence based and imaginative approach

Healthcare systems face challenges in tackling variations in patient care and outcomes.[1][2] Audit and feedback aim to improve patient care by reviewing clinical performance against explicit standards and directing action towards areas not meeting those standards.[3] It is a widely used foundational component of quality improvement, included in around 60 national clinical audit programmes in the United Kingdom.

Ironically, there is currently a gap between what audit and feedback can achieve and what they actually deliver, whether led locally or nationally. Several national audits have been successful in driving improvement and reducing variations in care, such as for stroke and lung cancer, but progress is also slower than hoped for in other aspects of care (table 1).[4][5] Audit and feedback have a chequered past.[6] Clinicians might feel threatened rather than supported by top-down feedback and rightly question whether rewards outweigh efforts invested in poorly designed audit. Healthcare organisations have limited resources to support and act on audit and feedback. Dysfunctional clinical and managerial relationships undermine effective responses to feedback, particularly when it is not clearly part of an integrated approach to quality assurance

and improvement. Unsurprisingly, the full potential of audit and feedback has not been realised.

Clinical, patient, and academic communities might need to have more sophisticated conversations about audit and feedback to achieve substantial, data driven, continuous improvement. They can also act now. There are ways to maximise returns from the considerable resources, including clinician time, invested in audit programmes. These include applying what is already known, paying attention to the whole audit cycle, getting the right message to the right recipients, making more out of less data, embedding research to improve impact, and harnessing public and patient involvement.

Apply what is already known

Audit and feedback generally work. A Cochrane review of 140 randomised trials found that they produced a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in healthcare professionals' compliance with desired practice, such as recommended investigations or prescribing.[3] This is a modest effect, but cumulative incremental gains through repeated audit cycles can deliver transformative change. Audit and feedback also influence reach and population through scaled up national programmes, which other quality improvement approaches (such as financial incentives or educational outreach visits) might not achieve with similar resources; for example, social norm feedback (presenting information to show that individuals are outliers in their behaviour) from a high profile messenger can reduce antibiotic prescribing in primary care at low cost and at national scale (table 1).[7]

The interquartile range in the Cochrane review indicates that a quarter of audit and feedback interventions had a relatively large, positive effect of up to 16% on patient care, whereas a quarter had a negative or null effect. The effects of feedback can be amplified by ensuring that it is given by a supervisor or colleague, provided more

than once, delivered in both verbal and written formats, and includes both explicit targets for change and action plans.[3] A synthesis of expert interviews and systematic reviews identified 15 "state of the science," theory informed suggestions for effective feedback (box 1).[8] These are practical ways to maximise the impact and value of existing audit programmes.

Pay attention to the whole cycle

The audit and feedback process comprises one or more cycles of establishing best practice criteria, measuring current practice, feeding back findings, implementing changes, and further monitoring. This chain is only as strong as its weakest link. Feedback effects can be weakened by information-intention gaps (feedback fails to convince recipients that change is necessary), intention-behaviour gaps (intentions are not translated into action), or behaviour-impact gaps (actions do not yield the desired effect on patient care).[9] The success of national audit programmes depends on local arrangements that promote action as well as measurement.[10]

A synthesis of 65 qualitative evaluations proposed ways of designing audit programmes to better align with local capacity, identity, and culture and to promote greater changes in clinical behaviour.[11] Healthcare organisations have finite capacity, so audit programmes should be designed so that they require less work, make best use of limited local resources, and clearly state why any investment is justified. Clinician beliefs about what constitutes best practice can influence how they respond to feedback, so audit programmes need to consider these while also challenging the status quo. All aspects of audit programmes should be designed with a focus on the desired changes in behaviour by recipients to achieve better outcomes; for example, feedback tackling unnecessary blood transfusions could include suggested alternative approaches to minimise blood loss during surgery.[12] Because the purpose of an audit programme is not measurement

KEY MESSAGES

- Clinical audit and feedback entail reviewing clinical performance against explicit standards and delivering feedback to enable data driven improvement

- The impact of audit could be maximised by applying implementation science, considering the needs of clinicians and patients, and emphasising action over measurement

- Embedding research on how to improve audit and feedback in large scale programmes can further enhance their effectiveness and efficiency

Table 1 | Examples of national clinical audit programmes and randomised trials evaluating audit and feedback

Objective	Methods	Illustrative findings
National clinical audit programmes		
To measure and improve the structure, processes, and outcomes of stroke care	The National Clinical Audit for Stroke operates a prospective, continuous audit of the processes and outcomes of NHS funded stroke care and rehabilitation in acute and post-acute settings in England and Wales. It also reviews care at six months and beyond to assess how longer term needs are met	Stroke unit performance in key aspects of care improved over five years; eg, the proportion of patients assessed by a stroke specialist consultant physician within 24 hours rose from 74% to 83%, whereas the proportion of applicable patients screened for nutrition and seen by a dietitian by discharge rose from 66% to 81%.[4] However, significant gaps in provision remain; eg, fewer than one in three patients receive a six month review
To measure and improve care and outcomes for lung cancer	For the National Lung Cancer Audit, secondary and tertiary care NHS hospitals in England and Wales submit data via the National Cancer Registration and Analysis Service as part of the Cancer Outcomes and Services Dataset. The data are linked to Hospital Episode Statistics, the National Radiotherapy Dataset, the Systemic Anti-Cancer Dataset, pathology reports, and death certificate data	The proportion of patients alive at least one year after diagnosis rose from 31% in 2010 to 37% in 2017.[5] However, almost a third of patients still lack access to the benefits of specialist nursing support
Randomised trials of audit and feedback		
To assess the effect of adding an action implementation toolbox to electronic audit and feedback targeting quality of pain management in intensive care units[16]	21 Dutch intensive care units were randomly assigned to receive usual electronic feedback only or to feedback with an implementation toolbox suggesting practical actions staff could take to improve pain management	Over six months, the proportion of patient shifts with adequate pain management increased by 14.8% compared with 4.8% in the feedback only group
To assess the effects of feedback including "social norm" persuasive messaging and patient focused information on antibiotic prescribing in higher prescribing general practices[7][26]	1581 English general practices whose prescribing rate for antibiotics was in the top 20% for their locality were randomly assigned to receive feedback including a letter from England's chief medical officer highlighting the higher rate of antibiotic prescribing or to no communication. They were then randomly assigned to receive patient focused information promoting reduced use of antibiotics or to no communication	Over six months, the rate of antibiotic items dispensed per 1000 population was 127 in the feedback intervention group and 131 in the control group, representing an estimated 73 406 fewer antibiotic items dispensed. The patient focused intervention did not significantly affect prescribing

alone but using data to inform quality improvement, we need to understand existing barriers to desired change and have a plan for how feedback helps to tackle those barriers.

Without functioning local networks and systems, national audit programmes can become echo chambers, where good intentions and blame for limited progress reverberate. Audit and feedback will flounder if local quality improvement is based on repeated, unconnected, and inappropriately delegated projects conducted in isolation from mainstream pursuits and if any learning is dissipated in collective amnesia. Clinical and managerial leaders should ask questions about their organisational performance in response to feedback (box 2)[13] and set clear goals, mobilise resources, and promote continuous improvement.[14] Audit and feedback by themselves cannot solve ingrained deficiencies but can emphasise priorities for change, inform focused actions, and evaluate progress.

Get the right message to the right recipients

Feedback comparing performance among different healthcare organisations and clinicians can leverage competitive instincts. This might not always work as intended. Nobody likes being told they are getting it wrong, repeatedly. Yet this is how clinicians and organisations often experience feedback suggesting suboptimal performance. Low baseline performance is associated with greater improvement after feedback[3] but can elicit defensive reactions ("I don't believe these data"), especially if feedback does not align with recipient perceptions ("My patients are different"). Such responses are not uncommon given that clinicians tend to overestimate their own performance.[15] Continued negative feedback perceived as punitive can also be demotivating and risk creating burnout ("What else can I do?").

Giving feedback to professionals who take pride in their work requires careful thought. Consider, for example, providing feedback to high performers—will positive feedback lead to reduced effort or increase

Box 1: Questions for audit programmes and healthcare organisations to consider in designing, implementing, and responding to audit and feedback[8]

Nature of the desired action
- Can you recommend actions that are consistent with established goals and priorities?
- Can you recommend actions that can improve and are under the recipient's control?
- Can you recommend specific actions?

Nature of the data available for feedback
- Can you provide multiple instances of feedback?
- Can you provide feedback as soon as possible and data frequency informed by the number of new patient cases?
- Can you provide individual rather than general data?
- Can you choose comparators that reinforce desired behaviour change?

Feedback display
- Can you closely link the visual display and summary message?
- Can you provide feedback in more than one way?
- Have you minimised extraneous cognitive load for feedback recipients?

Delivering feedback
- Have you addressed barriers to feedback use?
- Can you provide short, actionable messages followed by optional detail?
- Have you addressed credibility of the information?
- Can you prevent defensive reactions to feedback?
- Can you construct feedback through social interaction?

Box 2: Questions that healthcare organisations can ask themselves about performance[13]
- Do we know how good we are?
- Do we know where we stand relative to the best?
- Do we know where and understand why variation exists in our organisation?
- Over time, where are the gaps in our practice that indicate a need for change?
- In our efforts to improve, what's working?

motivation? Should audit programmes switch attention to new topics where performance is poorer, at risk of inducing fatigue in higher performers? Given the law of diminishing returns, attempts to improve already high levels of performance might be less fruitful than switching attention to other priorities. Many clinical actions have a "ceiling" beyond which improvement is restricted because healthcare organisations or clinicians are functioning at or near their maximum capabilities.

A range of approaches can help tailor feedback to recipients' needs. First, feedback can include comparators that show like for like (such as similar types of organisations with similar case mixes) and set realistic goals for change relative to performance levels (such as lower but more achievable targets for poorer performers). Second, feedback can be delivered alongside a range of tangible action plans to support improvement; for example, an implementation toolbox improved pain management in intensive care units.[16][17] Third, new audit criteria need to be convincing, based on robust evidence and with scope for patient and population benefit.

Make more out of less data
Healthcare organisations and clinicians need to juggle competing priorities and therefore struggle to act on all feedback from national and local audit programmes. A 2012 snapshot identified 107 National Institute for Health and Care Excellence clinical guidelines relevant to primary care, resulting in 2365 recommendations.[18] Audit programmes can help to identify which recommendations have the greatest potential to benefit patients and populations.

One of the highest costs associated with audit programmes is the time and effort involved in data collection, particularly the manual review of patient records. The burden of this data collection can be compounded by temptations to add in more variables for analyses that marginally improve precision.[19] The resulting feedback might reinforce the credibility of data and enable recipients to explore associations in the data. Providing larger amounts of complex data, however, risks cognitive overload and distracting recipients from key messages. The diminishing returns of continuing efforts to perfect data come at the expense of focusing energy on improvement.[19]

The increasing availability of electronic patient record systems and routinely collected data on quality of care offer opportunities for large scale, efficient feedback programmes. Such approaches offer greater population coverage, which can overcome risks of biased sampling associated with manual review, such as the loss of records of patients with poorer outcomes. Routine data can also be collected and analysed in real time, thereby enabling faster, continuous feedback and countering objections voiced by clinicians ("These data are out of date").

Data quality is only as good as coding at the point of care. Validity checks and quality control of the data might compound the burden on clinical teams. Data linkage and extraction across different information requires compliance with data protection and information governance requirements. Even with all this in place, we must acknowledge Einstein's advice that not everything that counts can be counted, and not everything that can be counted counts.

Embed research to improve impact
Poor research design, conduct, and dissemination contribute to "research waste."[20] Implementation science aims to translate research evidence into routine practice and policy but is also affected by research waste. A cumulative meta-analysis of the Cochrane review of audit and feedback indicated that the effect size stabilised in 2003 after 30 trials.[21] By 2011, 47 more trials of audit and feedback versus control were published that did not substantially advance knowledge, many omitting feedback features likely to enhance effectiveness. This indicated a growing literature but "stagnant science."

Implementation laboratories offer a means of enhancing the impact of audit and feedback while also producing generalisable knowledge about how to optimise effectiveness.[22] A "radical incrementalist" approach entails making serial, small changes, supported by tightly focused evaluations to cumulatively improve outcomes.[23] It is already used in public policy and in business. Amazon and eBay randomly assign potential customers to see different presentations of their products online to understand what drives purchases. It is also applicable to healthcare[24] and can help answer many questions about how best to organise and deliver feedback (such as, does feedback on performance indicating an organisation's position against top performing peers stimulate more improvement than showing its position against average performance? What is the effect of shorter versus longer feedback reports? Does adding additional persuasive messages have any effect?). Embedding sequential head-to-head trials testing different feedback methods in an audit programme provides a robust empirical driver for change. Modifications identified as more effective than the current standard become the new standard; those that are not are discarded.

Harness public and patient involvement
Healthcare providers and researchers are still learning how to work meaningfully with patients and the public, and there are opportunities in audit programmes. This means moving beyond current models of involvement—typically advisory group roles to ensure accountability and contribute to strategy—towards active participation in feedback and service improvement.

Patients and the public are often surprised by the extent of unwarranted variations in healthcare delivery, which is the core business of audit programmes.[25] They express frustration at the difficulties in routinely measuring less technical aspects of care, such as consultation skills and patient centredness. Involving patients and the public, including seldom heard communities, early in the process of developing indicators is important. Audit programmes can be at the forefront of innovating and evaluating different approaches to involvement, asking questions such as, does incorporating the patient voice in feedback lead to greater improvement? Can feedback reports be better designed to improve understanding for both lay and professional board members of healthcare organisations? Patients and the public represent an underexplored and untapped force for change, which audit programmes can learn to harness.

Conclusion
Audit and feedback are widely used, sometimes abused, and often under-realised in healthcare. More imaginative design and responses are overdue; these require evidence informed conversations between clinicians, patients, and academic communities. It is time to fully leverage national audits to accelerate data guided improvement and reduce unwarranted variations in healthcare. The status quo is no longer ethical.

programmes in the UK and abroad and is a non-executive director at the Mid Essex Hospital Trust. JI has leadership and strategic management expertise of healthcare providers and charities in quality improvement, including clinical audit. DK has expertise in leading clinical, regulatory, executive participation in national clinical audit and patient outcome programmes driving local quality improvement in acute hospitals in the UK. RF and MS drafted the initial manuscript. All authors contributed to and commented on subsequent drafts and approved the final manuscript. RF is the guarantor.

Patient involvement: BM coauthored the manuscript and emphasised the need to focus on tackling unwarranted variations in healthcare delivery and involve a diverse range of patients and members of the public in improving national audit programmes.

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Quality improvement at times of crisis

Making rapid change during covid-19 has lessons for how to improve healthcare, argue **Amar Shah and colleagues**

Health systems across the globe have faced unprecedented strain and uncertainty during the coronavirus pandemic. Healthcare providers have had to respond rapidly, making major changes to all aspects of healthcare from moving to remote delivery of primary care services to creating covid "hot" and "cold" zones and developing innovations which are likely to have both short and long term consequences for the health of the population.

Quality improvement has been increasingly used globally over the past decade to change healthcare. Evidence of success is mixed.[1] Have such approaches added any value to healthcare service delivery during these unparalleled rapid changes? Are scientifically based approaches to complex system change, such as quality improvement, helping healthcare providers during a crisis?

Several authors have suggested ways in which quality improvement might be applied during the pandemic—for example, by generating rapid learning about which changes are effective when many changes are happening simultaneously[2] and through generating, testing, refining, and evaluating particular ideas speedily. Quality improvement could enhance workflow, provide a systematic approach to change, strengthen the system, and increase learning.[3 4]

This paper offers evidence based on personal experience of how quality improvement has been applied during the pandemic and how it has contributed to the response, and reflects on what we might learn.

Has quality improvement been used during the covid-19 pandemic?

A survey of 225 Q community members (people involved in improving health and care across the United Kingdom[5]) suggests that approaches to improvement have been used widely during the pandemic. Fifty one per cent of respondents said that quality improvement had been important during covid-19. A considerable number of respondents felt that the role of improvement tools, methods, approaches, or attitudes increased in their work (44% of all respondents), their team (45%), and their organisation (49%).

Below, we describe five ways in which attempts to improve quality have been made during the covid-19 pandemic.

Creating a common theory about how to tackle complex problems

Healthcare organisations and leaders have been faced with managing a disease with unknown clinical characteristics. Creating a coherent response within a health service was critical for a major and speedy reorganisation of service delivery and to protect staff from infection. Driver diagrams are a tool commonly used to describe the theory of change for solving a complex problem. These diagrams can help a diverse group of people, who may be working outside their established roles, to collaborate in developing change that will achieve a shared goal.[6]

East London NHS Foundation Trust, a UK provider of mental health, community health, and primary care, developed a driver diagram to help organise its response to phase 2 of the pandemic (fig 1). Developing the driver diagram involved a range of participants, including service users, clinicians, and senior leaders. Using an approach to tackling the problem which was already embedded in organisational practice provided people with a familiar method of dealing with complex problems, thereby providing continuity of approach. The driver diagram also helped leadership to communicate the way in which the organisation was planning its response.

The Albert Einstein Hospital in Sao Paulo, Brazil (fig 2), similarly developed a driver diagram. The hospital asked staff about barriers and fears during the pandemic to ascertain how the organisation could reduce harm for staff. As of April 2021, no deaths had occurred among the 14 000 staff of the hospital system.

Understanding and improving processes

Healthcare providers used process mapping and redesign as part of their response to the pandemic.[5] Flow charts can help to visualise steps in a process. Improvement often involves testing new ideas to simplify or redesign processes to make them more efficient, which can be particularly critical in emergencies when resources are stretched or new processes are needed.

Seventy per cent of respondents to the Q insight survey thought that improvement tools had been used to a great or moderate extent in rapidly reviewing and improving processes and practices.[6] Figure 3 shows an example from an East London trust which helped visualise, standardise, digitise, and automate the process for ordering personal protective equipment, and illustrates the way in which quality improvement can enable fast responses. In one day, the steps and decisions shown in figure 3 were mapped by staff, who identified a number of steps that required clarification or could be removed. A digital form was created, aligning with the new standard process, tested by one team, and then scaled throughout the organisation.

Improvement tools, such as flow charts, can help clarification of roles and steps at times of major change. With staff increasingly dispersed at home and work, and major changes to clinical work flow, this tool allows team members to create a shared approach to work, clarifying

KEY MESSAGES

- Quality improvement tools have been applied during the covid-19 pandemic in a range of healthcare settings to standardise and improve processes, to measure change, and to test and implement intervention
- An opportunity exists to build on the widespread change that has been led by healthcare staff at the point of care and embed the rigour of quality improvement without the jargon and bureaucracy that might have stifled past efforts
- Approaches to improvement offer valuable ways for dealing with complex problems, even in pressurised situations
- Sustained success is likely to require commitment to the chosen improvement method and for tools to be seen as part of a discipline of continuous improvement
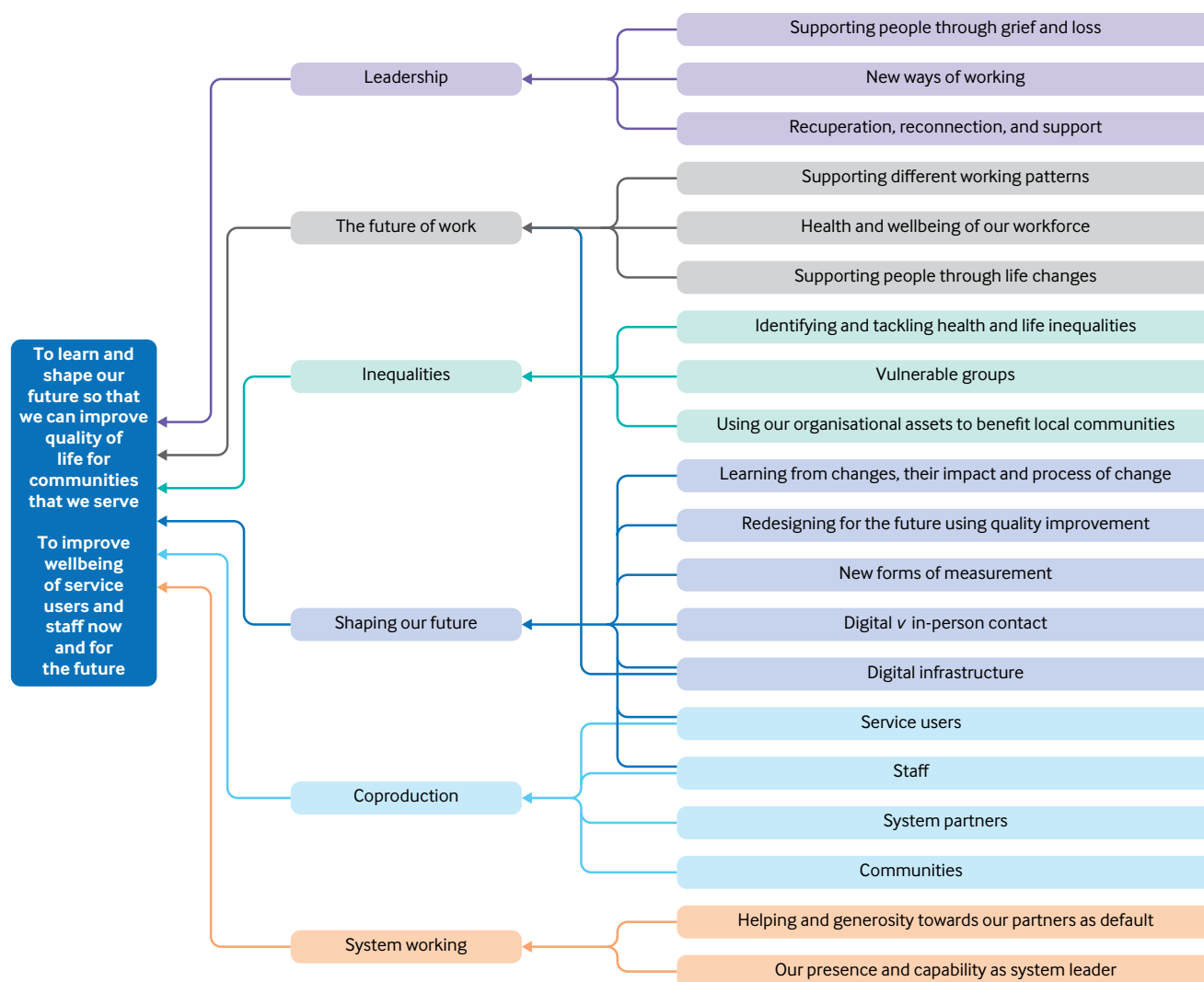
Fig 1 | Example of a driver diagram developed and used at the East London NHS Foundation Trust during the pandemic

uncertainties about roles and simplifying the process.

Measurement to inform decision making

To ascertain if changes have led to improvement, the data should be studied; this is a key aspect of quality improvement.[7] Undoubtedly, the pandemic presented challenges, with Q survey respondents describing the difficulties of systematic measurement of improvement during the pandemic, including reduced data collection, high levels of uncertainty about the situation, making it hard to know what to measure, and the speed at which decisions needed to be made. Nevertheless, real time measurement of improvement is particularly helpful when needing to test, learn, and make decisions rapidly.

The Institute for Healthcare Improvement and Associates in Process Improvement have developed modified Shewhart charts to learn from variation in reported deaths in an epidemic.[8] Albert Einstein Hospital set up a dashboard of key measures that was refreshed daily, to enable the interpretation of variation to guide decision making and to identify the effect of tests of change being carried out. An example of one measure tracked daily is illustrated in figure 4, which helped the hospital to understand the effect of their changes.

Plan-do-study-act (PDSA) cycles to test and scale rapidly

When a swift response to changing circumstances is required, rapid learning cycles, such as through the PDSA structure, can enable teams to adapt quickly with minimal risk and interruption to clinical work. Having a mechanism to try, and refine, ideas, and ensure that they are plausible before implementing them can support teams in responding to challenges which

have no known solution, as described by Fitzsimons.[2]

From the Q insight survey, PDSA cycles were seen to be especially useful owing to the increased need to consider what did and did not work well, especially at the start of the crisis. However, even the rapid iterative nature of PDSAs seemed too arduous for others, with people noting that they were sometimes applied incompletely with some stages missing. One respondent noted that "people are moving too fast to think about the learning generated before making their next plans."

Some organisations found PDSA useful for developing solutions during the pandemic. The Royal National Orthopaedic Hospital used a number of PDSA cycles to support rapid testing, learning, and scaling, to achieve their goal of 80% of consultations delivered virtually within six weeks.[9] Surrey and Sussex Healthcare

Provide physical security to employees

1. Offer, and train for use of, personal protective equipment
2. Employee clinic - directed and organised assistance to employees suspected of covid
3. Monitoring of covid confirmed with scheduled calls, online consultations, and face-to-face as needed
4. Hygiene kit for confirmed covid
5. Evaluation of employee's temperature before start of shift
6. Safety visits in areas with higher incidence of reviewers with covid-19
7. Analysis of cases of employees with covid-19 in partnership with occupational health team
8. Expansion of situational awareness and culture of institutional care
9. Flow to increase number of employees vaccinated for influenza

Reduce harm to SBIBAE employees to zero during pandemic

Provide psychological security to employees

1. OUVID programme - programme for listening to employees by psychologists
2. Programme to increase situational awareness and institutional care culture
3. Adequacy of social areas for restart of interactive activities
4. Balance and wellness practices: relaxing activities
5. Self-assessment system: system incorporated in APP Meu Einstein and blog Vida Saudável

Have initiatives that positively affect employee's journey and experience

1. Online event series
2. Daycare maintenance
3. Partnership with schools and volunteers to receive children from employees who have no one to leave them with
4. Rounds in social areas (canteen and spaces of employees)
5. Definition of guidelines and appropriateness of cafeteria employees and physicians in partnership with nutrition and facilities
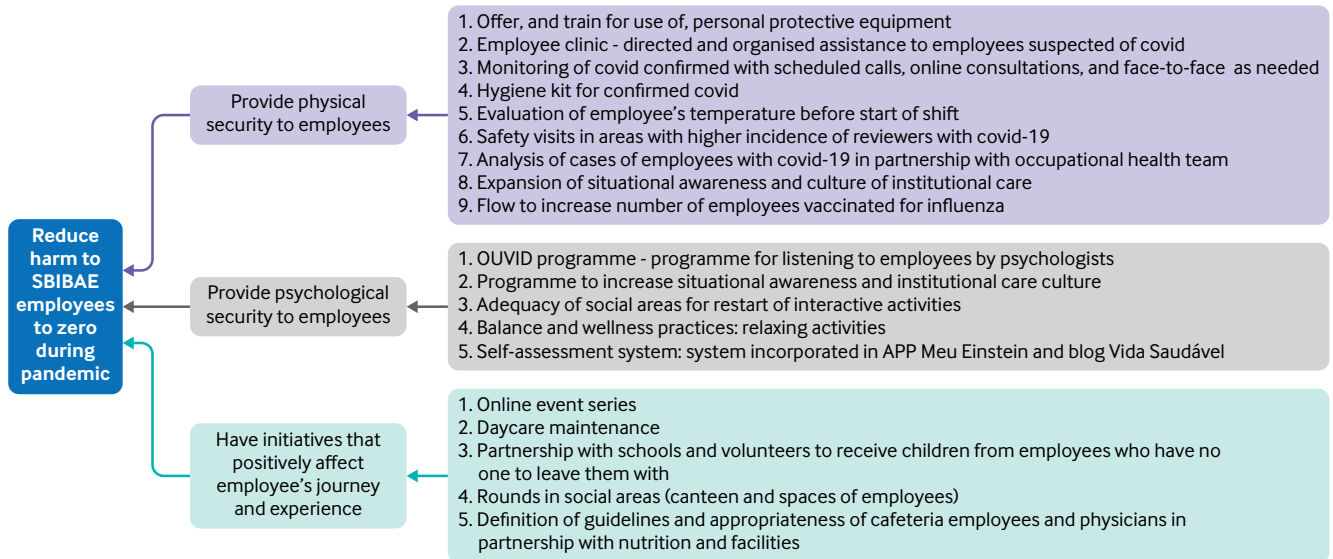
Fig 2 | Driver diagram created by the Albert Einstein Hospital, Brazil, to create a theory of change relevant to the covid-19 pandemic. SBIBAE=Sociedade Beneficente Israelita Brasileira Albert Einstein

Procurement

Processes for sourcing, ordering, and keeping two weeks supply of all key PPE

Complete "stock reconciliation" sheet on SharePoint form

Central fulfilment

Orders submitted via online form by 11am

Mile End Stores team look at SharePoint form for orders received

Is this a priority order based on service type? — No → Process priority orders first, then other orders

Yes ↓

Do you approve of quantities ordered? — No → Amend order and inform contact person by email

Yes ↓

Prepare bundle for service noting delivery address and if priority

Add bundle to stockpile for borough/directorate

Record on "order fulfilled" column of SharePoint form

Drivers collect combined stockpile for each borough/directorate

Local delivery

Driver delivers to borough/directorate hub

Named local link person takes delivery of combined stockpile

Prioritise sequence of deliveries by: priority, closing time for delivery address, location/route

Bundles for individual services handed over to local drivers

Packs delivered to named person/deputy in each service? — No → Bundle returned to borough/directorate hub
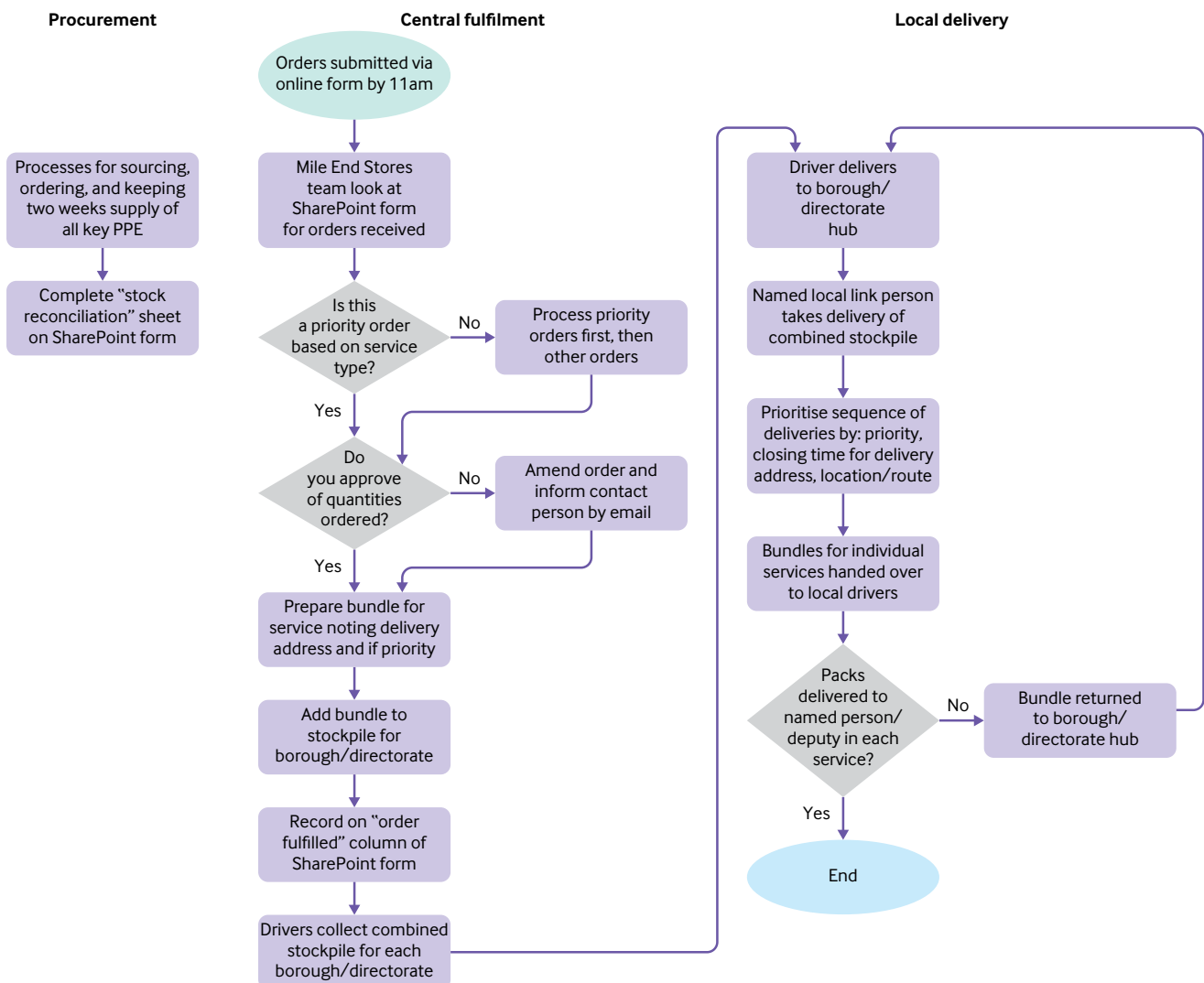
Yes ↓

End

Fig 3 | Flow chart to show the procurement and delivery process for personal protective equipment at the East London NHS Foundation Trust
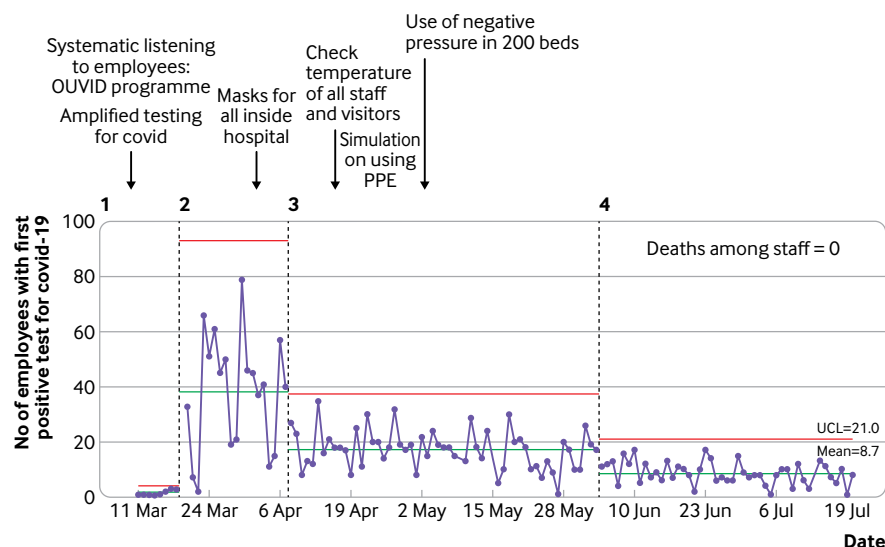
Fig 4 | Data tracked daily during the covid crisis using an annotated statistical process control chart at Albert Einstein Hospital. PPE=personal protective equipment; UCL=upper control limit

NHS Trust used several PDSA cycles to develop and implement a decontamination process which uses ultraviolet light to clean protective hoods worn by staff (consisting of a helmet, face shield, and neck cape). A diverse team developed a range of ideas, eventually discovering that hanging the hood from a disco ball motor and tipping at a 45° angle allowed the ultraviolet light to reach all areas for decontamination, achieving a 100% detection rate.[10]

Without a structured approach to experimentation, such as the PDSA cycle, we rely on expertise to design solutions, and implement them without the ability to learn and adapt from small scale to full scale, resulting in a greater risk of failure and less effective solution.

Supporting learning and redesign for the future

During the acute phase of the pandemic, considerable changes to service provision have taken place and we need to consider which have been helpful and should continue, and which aspects of routine service delivery need to be reinstated. Local and national improvement leaders have used the principles of quality improvement to consider this systematically.[11]

Examples include the musculoskeletal services within the Northern Care Alliance NHS Group, who were supported by the Advancing Quality Alliance through a 60 day innovation cycle to redesign the care pathway (personal communication). At East London Trust, a structured process has been provided for service users to understand the changes made and plan and redesign for the future.[12]

What does this mean for the future of quality improvement in healthcare?
Use of methods and measurement
The methods and tools of quality improvement have been used in a range of different contexts to deal with some of the specific challenges faced during the crisis. Sixty nine per cent of respondents to the Q survey reported that improvement efforts were enabled to a great or moderate extent by reduced bureaucratic constraints, quicker decision making, and fewer financial or procurement hurdles. Some respondents, however, found that the discipline and formal improvement structure was too restrictive during an emergency. Respondents prioritised service delivery over evaluation of the effectiveness of changes. The use of quality improvement often seemed to be characterised by short term goals, and many respondents questioned whether this might undermine the longer term sustainability of changes.

These replies should provoke us to learn how improvement and measurement can be legitimately streamlined while still accelerating testing and learning and reducing demand on clinicians. We have an opportunity to simplify language, avoid differentiating between improvement methods that have the same underpinning scientific roots, and creating too many requirements that stifle activity.

Quality improvement requires proportionate measurement to confidently improve systems and outcomes. We can simplify measurement by using routinely collected data available to teams in a way that allows interrogation and use. Provision of skilled support to teams can help with developing simple measurement plans. Using tools such as safety crosses or manually updated run charts can help teams to connect data collection and interpretation with proposed changes.[8]

Building improvement capability across the system
Many organisations have seen value in quality improvement tools during the pandemic, but few have demonstrated the full breadth of benefits described by Mondoux et al.[4] Organisations that have a culture of systematic experimentation and discovery, have trained their workforce, and coached their leaders are more likely to be able to deploy improvement methods effectively and on a larger scale during a crisis. Q members who said their organisation had a well developed approach to improvement before covid were more likely to say that improvement had had an important role during the pandemic. This group was also more likely to use improvement strategically to plan and to collaborate with others.[7] The unanswered question is whether organisations with this improvement capability achieved better outcomes than others without this expertise.

For many, quality improvement was used in light touch ways, with fuller rigour felt to be too slow during a crisis. This perception of quality improvement is likely to evolve with experience as people become more confident and learn how to apply it to influence their everyday approach to problem solving, with minimal extra work. For example, creating a process map might take an hour but save several hours of wasted activity in a system where roles and steps are not clear. PDSA cycles, conducted well, should save time and reduce waste, by testing rapidly and allowing adaptation to ensure that a solution works well under all known conditions. For those who are newer to the structured approach of quality improvement, their unfamiliarity with the method and tools might not have allowed rapid application to the fast moving environment of the pandemic, when the opportunity for guided learning and reflection is limited.

Quality improvement methods are not just effective for making rapid adaptations in a crisis but, properly supported, can also foster change in the longer term. Organisations with an established improvement culture might be better able

to leverage the learning from the changes that took place rapidly during the acute phase of the pandemic, to emerge more strategically equipped to improve outcomes in a way that is operationally sustainable.

Leadership for improvement

The opportunity for leaders is to ensure that the use of improvement tools and approaches during a crisis helps to embed improvement as a strategy for tackling the most complex future challenges. Health-care staff highlighted increasing autonomy to adapt to the changing circumstances, with 72% of Q survey respondents approving leadership approaches that have supported local decision making.[13] Conversely, those respondents who described facing greater challenges in drawing on improvement during the covid-19 pandemic often noted a "command and control" style leadership that stifled testing and innovation. These comments should reinforce our commitment to leadership approaches that provide top-down clarity and encourage bottom-up action.

Developing a deep understanding and application of quality improvement across our health and care systems will require us to continue using improvement tools for daily problem solving, while also using rigorous time limited quality improvement projects for more complex problems. We will need to continue building skills, incentives, and learning mechanisms. Lastly, because modern healthcare is interconnected, many opportunities for improvement will lie in applying quality improvement across boundaries. Thus we need to apply quality improvement over whole systems, as well as within individual organisations.

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Accelerating population health improvement

Pedro Delgado and colleagues describe how applying improvement methods to working with populations could help close equity gaps

As the covid-19 pandemic shines a bright light on longstanding health equity gaps,[1] concerted action around social determinants of health to close these gaps continues to increase. Improvement methods (including shared tools and language) traditionally used in healthcare are agnostic in nature and can also be used in sectors such as education, local government, law enforcement, and others to improve social determinants of health. Such adoption could catalyse population health improvement efforts with and for the populations they serve.

Three related concepts are core to this article. "Population health" is defined as the health outcomes of a group of individuals in a specified population, including the distribution of such outcomes within the group. "Population health management" efforts seek to optimise the health of populations over individual life spans.[2 3] We did not find a common definition for "population health improvement," but we think this is an area that will start to generate more learning and evidence over the coming years. Ahead of such developments, we suggest an early definition: concerted, intentional, and systematic efforts by those working together towards measurable improvement of health and wellbeing outcomes, co-produced with and for the population in their locality.[1]

Actors jointly working to pursue better health for well defined populations (including citizens, healthcare providers at all levels, councils or municipalities, businesses, schools, fire services, voluntary sectors, housing associations, social services, and police) will benefit from having a shared method that includes a common language and tools and can be applied across four areas: defining the system, describing shared aims and the work required to achieve them, measuring systematically over time, and acknowledging that change happens. These four components form the foundation of the improvement method, and their systematic application[4] can bring health economy actors together in pursuit of better population health.

A common method to tackle shared challenges

People are living longer; technology is evolving rapidly; and the costs associated with lack of proactive, concerted actions to prevent and manage non-communicable diseases have the potential to bankrupt healthcare systems and affect other sectors of the economy. With these drivers as a backdrop, several trends have taken shape in healthcare, including a shift towards tackling upstream factors, prevention, and self-management of conditions.[5] Care models are shifting from specialized care to primary care, which has demanded the development of support systems, including use of technology to enable virtual care.[5 6] Similarly, healthcare providers' priorities are shifting from volume to value,[7] tackling quality and all of its dimensions[5] and ensuring access to high quality care for all, with increased attention to inequities in outcomes for distinct populations.

Healthcare provider organisations are focused on partnering with citizens and communities to improve health and with patients to improve care.[7] They are increasingly looking beyond the walls of their institutions to understand their effects more widely,[8] with a greater awareness of the bi-directional connection between environmental changes and health, combining the concepts of planetary health and sustainability.[9] There is a clear push towards health economy integration and place based health,[10 11] and organisations are making efforts to enhance the contribution of health systems as anchor institutions.[8]

Building on these trends, governments have been promoting strategies to pursue better care and better health at sustainable costs.[12-14] Health economies are therefore formally and informally fostering hands-on collaboration among traditional partners, such as healthcare institutions, and non-traditional partners, such as sectors related to the social determinants of health, to serve their local populations. In England, for example, the NHS is leading efforts to formalise collaboration by moving Integrated Care Partnerships into legislation by April 2022.[15]

As these partnerships form and evolve over time, a common improvement method (tools and language) provides a shared approach that stakeholders in and across sectors can use to translate strategy and evidence based changes, using local expertise, into measurable results.

Strategies for population health improvement

Box 1 shows priority areas and strategies for health systems to consider when undertaking population health improvement.

Define and co-design

Identify a group of people with similar needs or characteristics for whom a portfolio of interventions might improve outcomes. Start with the question, "Who is not thriving?" to identify broad populations, such as adult mental health or children and young people's health, and then select more specific population segments to focus improvement efforts by identifying an aim and changes to test, such as reducing suicide rates in men aged 16-24 in a particular geographical area. The King's Fund defines four interdependent pillars as the "system" of population health: individual health behaviour and choices; the places and communities that individuals live in and with; an integrated health and care system; and the wider determinants of health.[16] These can be used to help define the population. A three part data review is also useful for population stratification to better understand the needs and assets of the population, which then inform the design choices to improve outcomes.[17]

KEY MESSAGES

- Improvement methods traditionally used in healthcare can also be used by other actors outside healthcare working to improve population health
- The adoption of improvement methods by stakeholders working to improve population health has the potential to catalyse their joint efforts
- Using common implementation tools and language can help to achieve shared aims
- Population health improvement learning is likely to exponentially increase in months and years to come

Box 1: Strategies for successful population health improvement

Define the population and design accordingly
Develop bold ambitions and bold aims
Act with and for the population
Build a portfolio of projects focused on each population health aim
Segment for equity
Measure what matters
Embrace an asset based approach
Embrace humility to generate trust
Test your way into better partnership work, in pursuit of results
Make health improvement everyone's business and make improvement skills available to all

Bold ambitions for population health improvement need to be supported by aims that specify how much, by when, for whom, and where. Start by developing a bold purpose statement such as "being the best place to grow up."[18] Next, create more specific and measurable aim statements that relate to the population rather than the service; for example, under the "best place to grow up" the vision could be "90% of all children in each community planning partnership area will have reached all of the expected developmental milestones and learning outcomes by the end of primary school) by the end of 2021." Good aim setting will help identify opportunities to segment populations, establish relationships, and ensure that impact can be measured.

Co-design and co-production with individuals from the target population should be embraced at every step of the process. In population health improvement efforts, activating the agency of the population as well as that of those coordinating their care is fundamental. The process of working together towards the aim is as important as the aim itself and requires engaging key actors in the health economy (as described above), including citizens and service users, to design and adopt the changes needed to improve. People's health is heavily influenced by factors outside of their care such as their social and economic environment, physical environment, and individual characteristics and behaviours.[19] So individuals are protagonists in efforts to improve population health, not passive "receivers" of health. Activating people's agency is at the heart of the Institute for Healthcare Improvement's *Psychology of Change Framework*.[20] The framework describes methods and approaches around five inter-related domains of practice that organisations can use to advance and sustain improvement.

The complexity of the population health system is such that health economies will almost inevitably need a portfolio of projects occurring in parallel to make progress. Our experience emphasises the value of identifying key drivers for each aim and tackling them through targeted improvement projects, ensuring the efforts are also aligned with strategic priorities of these systems. "Think big and start small" is a mantra we often use.

Partnering for equity

There is no quality without equity. Stratifying data allows for better understanding of variation and gaps in outcomes, which in turn allows for tailoring strategies that respond to the specific needs of different populations to eliminate equity gaps.[21] If a differentiated approach is not adopted, the gap between people who have access to the best possible health and those who do not will widen, leading to avoidable suffering, intergenerational cycles of poor health, and high costs for health economies.[22] The World Health Organization defines equity as "the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically, or by other means of stratification it implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential."[23]

Between 2017 and 2019, the Institute for Healthcare Improvement ran an initiative with eight health systems in the United States to improve equity in access to and quality of care, as well as health outcomes, through the practical application of improvement methods, collaboration, and shared learning.[24] One key element was ensuring that health systems had the capacity to collect and stratify data to better understand which populations were benefitting and which ones were being left behind, including data about race, language, and ethnicity. This enabled health systems to create better solutions that took into consideration the specific needs and conditions of those left behind.[24]

Health systems should proactively partner with individuals, communities, and institutions within and beyond healthcare. There is a growing realisation that the historical approach to health and healthcare, which is largely dependent on professionally trained and qualified health and healthcare "experts," needs to be reconsidered. The most successful population health improvement efforts involve actors that are open and willing to value each other's assets (such as will, abilities, and resources) and understand that the whole is greater than the sum of its parts.

Integration will move forward at the speed of trust. In the earliest stages, health economies that are learning to work together will require humility to accept that the protagonist is the citizen, not any single actor, and will require designing systems that are organized around the needs of those citizens. This is hard to do and must be intentionally designed early in the process to create an environment of psychological safety, to develop a sense of community guided by a unified purpose, and to foster trust and a set of behaviours that build trust, instil purpose, and generate energy.[25] Municipal leaders from the Bridge for Better Health effort in Denmark have a performance indicator related to the quality of their relationships with partners as a way of focusing attention on humility and good collaboration.[13]

Measure and learn

Health systems should identify what matters most to the population of interest and develop measures to track progress. The large number of measures health systems are often required to track leads to diffusion of impact and exhaustion of staff, who find themselves collecting data for many indicators with little connection to the purpose of such efforts.[26] More importantly, tracking too many measures might not directly benefit the people that health systems serve. Population health improvement efforts often struggle because health economy actors do not feel ownership of broad aims, and it is difficult to define who is responsible for achieving outcomes when data are collected. We foresee a future in which health systems will start to include other aspects in their measurement efforts: relationships between partners in the health economy and the environmental effects of the carbon footprint resulting from more

home based health and care models, for example.

Avoiding planning paralysis is important. Too often, integration efforts in health economies dedicate a disproportionate amount of time and energy to establishing governance arrangements and idealised strategies and plans, without paying enough attention to how ambitions will be tested, implemented, and scaled up. Integration is frequently seen as an end in itself, when it's clearly a means to an end—measurable outcomes for better population health. We encourage testing and learning, from the integration process to implementing specific changes to improve population health. This iterative testing and learning approach enables refinement of the strategy and "the work" of improving population health, and it is a cornerstone of the improvement methods described above.

Improving population health starts and ends with each citizen. Making improvement everyone's business will create the opportunity to put improvement knowledge in their hands. We hope in the future that citizens will develop fluency in improvement methods and be able to design their personal health driver diagrams, to test changes in their own lives that are co-designed with members of their "life system," and to measure progress over time. The same principle applies to all health economy actors, who yield the benefit of having a common language for implementation to progress towards better population health. The jargon filled nature of improvement literature needs to be tackled to make the content accessible to citizens, families, health professionals, and other actors of health economies.

Conclusion

Covid-19 will continue to have a profound effect on the health of populations globally and is already challenging health systems to work agilely with local partners to better serve their communities. Our experience based reflections are offered as both a provocation and an invitation to stakeholders in population health improvement to adopt a common improvement method to accelerate progress. Furthermore, we think that clearly defining population health improvement as a field of learning can help those working towards better population health share lessons, successes, and opportunities from their efforts. We envision a future where systematic use of a shared improvement method will yield valuable lessons about improving population health, and a thriving population health improvement learning community will continue to grow in numbers and strength.

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Aiming beyond equality to reach equity: the promise and challenge of quality improvement

Quality improvement must move beyond only measuring average quality and change and focus on equity to support achieving the quality needed for effective universal health coverage, argue **Lisa Hirschhorn and colleagues**

Close to 20 years after the seminal Institute of Medicine report *Crossing the Quality Chasm*, the Lancet Global Health Commission on High Quality Health Systems found that poor quality care accounts for more deaths than lack of access to care. The most disadvantaged populations have the worst outcomes, reflecting how much work is needed.[1] We use the Institute of Medicine definition of quality, which emphasises equity as one of the six dimensions of quality,[2] to call for the quality improvement (QI) community to include equity more effectively as we work to ensure the quality needed to achieve the promise of universal health coverage. We believe that QI can be a powerful tool to achieving equitable high quality healthcare, but better methods and focus are needed.

The World Health Organization defines equity as "the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification."[3] But equity is often forgotten or not explicitly measured and targeted in interventions for health system improvement. Experience shows that traditional QI methods can maintain or worsen health inequities across subpopulations. These failings are exposed by the current covid-19 pandemic, where, unsurprisingly, inequities intrinsic in health systems and society are magnified for the most disadvantaged populations.[4]

There can be three possible outcomes of QI on equity: improvement for all but maintenance of the equity gap (equality in improvement); improvement more in the disadvantaged population (decreasing the gap); or improvement more in the advantaged population (widening the gap).[5] QI initiatives must prioritise equity in how they design and measure change among disadvantaged subpopulations and strengthen the evaluation needed to know which of these three outcomes they have achieved. For example, the US based Diabetes QI Collaborative improved care for white but not Latino patients, worsening inequity and widening the gap. Analysis found flaws in the programme design contributing to this outcome, such as English-only communication, absence of interventions to deal with barriers specific to the Latino population, and no disaggregation of data to detect changes by ethnic subgroup.[6] Similarly, pay-for-performance initiatives, which have gained popularity with global funders, can also result in worsening equity. For example, Medicare's Hospital Readmissions Reduction Program was associated with higher rates of readmission among black people for conditions not targeted by the financial scheme in safety net hospitals but not in more resourced hospitals.[7]

How can we do better?

These examples underscore the importance of proactive identification of drivers of inequities, and QI designed with clear equity related aims. This intentional integration into QI aims, intervention design, and programme evaluation is required to reduce inequities as quality is improved. This work will require expanding interventions to include the underlying political, social, and structural causes of health inequities.[5 8-10]

National health systems, payers such as insurance and donors, and QI implementers must also expand their scope to identify and tackle these factors outside the individual provider or facility, such as social determinants of health, governance, and health system design, which can happen only by engaging communities more deeply in identifying solutions.[1 10] Work is also needed to tackle the intrinsic and extrinsic biases within the health system and in the community, which can underlie ineffective QI design and implementation. Increasing the involvement of patients and community members in QI design, raising their expectations of health system performance, and prioritising measurement of patient reported outcomes and experiences are also improvement strategies needed to achieve equity.[1]

We also recommend that designers incorporate planned data disaggregation upfront to look at changes among commonly disadvantaged subgroups such as wealth, race, and location. Measurement should include implementation outcomes such as acceptability and adoption and data elements needed to understand the underlying factors associated with success or failure in reducing inequity as quality improves. Disciplines such as implementation sciences and disparities research offer tools and frameworks that can accelerate this work.[11 12]

While this broader approach to QI may seem daunting, we describe an initiative led by two of the authors (HM and AK) in Ethiopia and lessons learnt to inform how we can improve the way we design, implement, and define success of QI.

Equity focused QI: the Ethiopia healthcare quality initiative

The Ethiopia healthcare quality initiative began with the Institute for Healthcare Improvement supporting development by the Ethiopia Ministry of Health of a national

KEY MESSAGES

- Poor quality care accounts for more deaths globally than lack of access to care
- Work to achieve universal health coverage therefore needs to consider effectiveness and equity
- Without prioritisation of equity, population level improvements in healthcare may mask those left behind because of economics, gender, ethnicity, or location
- We suggest five key areas where strategies for quality improvement need to tackle inequity: stakeholder engagement, measurement, design, improvement work, and learning

healthcare quality strategy in 2015, setting the vision and leadership for a high quality equitable health system and the high priority interventions and policies needed to translate the strategy into action. This was supported by the building of QI competency at all levels of the health system to create local champions, who served as Ministry of Health employed QI experts, to sustain capability building in the country.

These steps were important in facilitating the co-design and testing with the Ministry of Health of a district-wide approach to managing and improving quality explicitly to support populations with the worst maternal and newborn health system experience and outcomes and show the impact of QI on maternal and newborn health. The Institute for Healthcare Improvement worked with the Ministry of Health to include equity in site selection, which led to inclusion of pastoralist communities, given their worse maternal and newborn health outcomes. This intentional inclusion of some of the hardest to reach and underserved ethnic groups deepened understanding of diverse population needs, preferences, and health system challenges and their impact on quality.

The initiative also prioritised broad stakeholder engagement, leveraging QI expertise and leadership within the federal and regional governments in the country. These strategies resulted in a cadre of embedded improvement leaders trained to prioritise equity who will continue the work beyond partner engagement. Federal and regional leaders supported district level leadership to build a culture of learning through improvement collaboratives and identify local contextual factors that needed to be tackled. Key stakeholders across the health system, including patients, community health workers, clinical providers, and data managers, convened in learning sessions to empower frontline providers with QI methods and to use their own data to identify problems in inequity of quality and access, create and test solutions, and spread positive change quickly.

Measurement and feedback were designed to increase the input of patients and communities as core to increasing equity by ensuring that they informed problem prioritisation and solutions. Patient experience was put at the centre of the improvement process through community engagement in the collaboratives and inclusion as a performance measure. In addition,

government quality unit leaders trained providers to use data to advocate effectively for solutions identified through this engagement but beyond their immediate resources, further increasing the involvement of patients and communities.

The Ethiopian healthcare quality initiative resulted in improved quality overall, with two thirds (67%) of facility QI teams reporting over 90% adherence to all labour and delivery bundles and almost 75% of these teams reporting improvement in at least one outcome of maternal and neonatal service coverage.[13] Importantly, inequity of quality was reduced for indicators such as antenatal care (equity gap reduced from 15 to 8 percentage points) and similar improvement was seen for new measures across regions, with some of the largest improvements found in the traditionally disadvantaged pastoralist areas.

How can the QI community increase equity of QI focus and outcomes?

We make the following recommendations, including which data we use and how we use them and how QI is designed, implemented, and monitored, to help accelerate the work to improve inequities through QI.[5 9] The appendix on bmj.com gives further details on how these recommendations were applied in the Ethiopia healthcare quality initiative.

Engage better

Ensure that you have identified your key stakeholders in and beyond the QI team to understand the root causes from perspectives within and external to the health system. This should include people representing the lived experience of inequities in quality and policy makers able to facilitate the system changes needed. Keeping these individuals as active participants as you design, test, and refine the QI will increase your understanding and more effectively tackle quality and inequity. This strategy was important in Ethiopia and has been seen in other improvement work. For example, participatory women's groups— used to identify and convene women often from marginalised subgroups—support their prioritisation, and problem solving at the household level has been effective in reducing neonatal mortality and reducing inequities.[14] While this approach may not be traditionally categorised as QI, the purposeful engagement of these women to join in a structured process of problem identification and resolution is an area where QI can increase impact on inequity.

Measure and use data better

Design and use your data to identify inequities from the start. In many contexts, the lack of relevant data may be part of the problem of continued neglect, implicit bias, and structural inequities. Programme designers may need to look beyond traditional health metrics, including qualitative measures to iteratively identify disparities and underlying causes, to inform the work to improve quality and close the equity gaps. Planning for disaggregation from the start, similar to that planned in the work in Ethiopia, is also critical. For example, the English NHS has included health equity indicators to identify disadvantaged neighbourhoods and impact of expanding primary care in equity of access.[15] Through disaggregation, covid-19 research has rapidly identified disparities in outcomes and identified the need to design QI to tackle underlying determinants as well as quality of care received.[12]

Design better

Prioritise tackling barriers identified through your stakeholders of groups least served by the health system. Reaching the most disadvantaged will take innovations in strategies and learning from other groups already showing progress in these areas. For example, the role of patient navigators to improve uptake of cancer screening among African American women has now been expanded to increase access and uptake in settings across Africa, Asia, and Europe for other conditions.[16 17] The use of community health workers to improve access and uptake of interventions to reduce child mortality among those in more remote areas is another example of equity focused interventions.[18]

Improve better

Move beyond conventional ways for improvement to include areas outside the scope of traditional QI and take a "whole quality management" approach. The work requires quality planning and leadership that intentionally prioritises equity; tackling gaps in the health system structure such as human resources, systems, health financing, and governance associated with disparities[1 19]; and moving beyond the health system to include social determinants of disease and factors such as female empowerment and education associated with better access and survival.[20 21] The work will require new partnerships and interdisciplinary approaches to deal with the often vast quality gaps and where root causes also go beyond the health sector.[22]

Learn better

A robust internal learning system is required to monitor QI implementation to iteratively adjust to ensure equity while increasing impact. Lessons from disciplines such as implementation science, disparities research, realist evaluation, and patient centred outcomes research to better understand contextual factors will need to be applied during QI, and those that will influence implementation strategies will also strengthen equity targeted QI. For example, in Bangladesh, recognition that strategies that improved access to family planning were ineffective owing to systems and culture barriers informed adaptation to strategies and improved uptake.[23] More effective dissemination of results of equity focused QI is also needed to move the focus beyond the already broad literature describing existing disparities. This approach will also help the QI community understand and learn how and why QI did or did not improve quality and if disparities were reduced or eliminated.[24 25]

Conclusion

QI impact is challenged by approaches that can ignore or even worsen inequities. As illustrated by the Ethiopia initiative, a participatory strategy to improve the design and implementation of solutions needs to go beyond the traditional clinical and individual focus and QI methods to include the broader systems, governance, and intersectoral responses needed to tackle underlying social determinants of access and health and structural inequity. Intentional stakeholder engagement from leadership through to frontline providers and, critically, the patient and community is needed to inform the design, ensuring the QI tackles root causes within and beyond the health system and support work throughout its implementation. Investment in measurements to monitor equity and increase patient involvement through experiential quality and patient reported outcomes is also needed. Changing what and how we measure will need commitment from funders, insurers, multilateral and bilateral institutions, policy makers, and other leaders who define metrics for accountability and payment, and will need to increase community engagement in this process. A multidisciplinary approach including implementation science, patient centred outcomes, and research can offer additional tools to QI to better understand context, strengthen stakeholder engagement, and create more generalisable knowledge to accelerate scale and adapt quickly to meet the needs of the most disadvantaged. While goals of scale and equity often conflict, health system leadership must act to transform this dynamic and achieve high quality care for all.

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Different approaches to making and testing change in healthcare

Greg Ogrinc and colleagues call for greater exploitation of the synergies between quality improvement and implementation science in improving care

Improving the quality of healthcare is complex. It requires input not just from healthcare providers but also from patients and families to identify gaps, develop meaningful interventions, and ensure that interventions improve care and outcomes, and consider value from their perspective.[1] Closing gaps in healthcare quality, improving workflows, and implementing evidence based interventions require change, but not all changes are successful, and most come with unintended consequences.

Numerous approaches are available to making changes in healthcare systems such as lean, six sigma, the model for improvement, healthcare delivery science, and implementation science. These are usually used in isolation, although there is some overlap in their approaches, particularly quality improvement and implementation science. When looking to build and disseminate knowledge about making change, collaboration between approaches might help create changes more successfully and efficiently.

Interdisciplinary tensions

Over the past several years we have recognised a tension and, at times, a competition between quality improvement (QI) and implementation science (IS), two commonly used systematic approaches to improve the quality, safety, and value of healthcare services and to disseminate what is learnt from those efforts. This tension is unnecessary and wasteful when so many gaps in healthcare quality need to be addressed. QI focuses on the highly relevant work within a particular context while IS focuses on framing the work to make findings generalisable. Both approaches are important, and there is considerable overlap from which each can learn. Failure to recognise the overlap can lead to replication of interventions, delay in the dissemination of effective interventions, and missed opportunities to work together to improve healthcare. Others have also recently noticed overlap in QI and IS such as the potential to use both to improve cancer care.[2]

The response of healthcare systems to the covid-19 pandemic exemplifies this challenge. Early in the pandemic, local systems experienced a rapid influx of patients with covid-19 and dwindling supplies of personal protective equipment (PPE). Institutions relied on sound QI methods to determine how to solve the particular problem of PPE in their particular context. While this was necessary and helpful, there was, perhaps, a missed opportunity. If IS methods had been used to help solve those problems, it might have been easier to share answers with others. Both QI and IS bring a rich base of knowledge and skills. Both are needed but their potential summative effects have been underused during the covid-19 pandemic, partly because these fields see themselves as competitors and not collaborators.

QI and IS approach change from different philosophical underpinnings, yet we feel they share similarities that suggest combining their lenses would be beneficial. While QI comes from system operations[3] and IS from behavioural sciences,[4] both recognise that changes occur in a specific context and are affected by the context itself, requiring that each context be considered unique. The outcomes of interest in QI are generally improving quality of care: safety, timeliness, effectiveness, equity, efficiency, and patient centredness.[5] The outcomes of interest in IS generally include the uptake and application of evidence based care with attention to acceptability, cost, and feasibility.[6] Both fields focus on disseminating findings to others through peer reviewed publications.[7 8] Overall, this tension has been accurately described as the work of moving evidence into practice.[9]

Different approaches to change

Making and documenting changes to interventions is difficult, and reporting of QI and IS varies, limiting impact.[10] The Standards for Quality Improvement Reporting Excellence (SQUIRE) were developed to improve the reliability of reporting among those using QI, IS, or any other of the approaches to improvement.[7]

The challenge of reporting is prominently manifest in how the intervention changes in response to the local context. An intervention has an initial structure, but the intervention is typically modified throughout the process of improvement or implementation to make it more effective in a particular context. Both fields use imperfect approaches to capturing the data related to these processes, and each has something to offer the other.

In QI, changes are widely promoted to be accomplished through "tests of change" to predict, test, and assess the effect in the local microsystem. Careful use of tests of change, such as through plan-do-study-act (PDSA) cycles, are viewed as key to learning about the microsystem and the context to inform the change process.[11] The strength of this approach is the importance placed on the microsystem and context, and in this way, it may inform the IS field, which does not strongly emphasise the use and reporting of recursive change.

In IS the concept for modifying the intervention is referred to as "adaptation" and is recognised as key to identifying how to spread effective interventions to new contexts, rather than on making

KEY MESSAGES

- Implementation science and quality improvement both use tests of change to adapt interventions in a particular context
- The context in which the changes are made affects the effectiveness of tests of change, irrespective of the methods that are used
- Fidelity in tests of change refers to both the faithful use of data to drive the iterations of the interventions as well as implementation of the intervention as designed
- The common features of implementation science and quality improvement can be used to improve the conduct and reporting of changes to interventions

the change work in one specific context. Making, assessing, and reporting these adaptations are viewed as an essential part of generating knowledge that can be readily shared with others.[12] The strength of IS is in the methods and approaches to the assessment and reporting of adaptations, and these could be usefully applied to QI, which does not emphasise spread to other contexts as strongly.[7 8]

PDSA versus adaptation

PDSA cycles are often used in QI for tests of change in a system. PDSA changes should be small, focused, and deliberate.[11 13] The goal is to try an intervention in a microsystem to learn about how the microsystem reacts. Sometimes the test of the intervention is successful and the system moves closer to its goal. Other times, the PDSA change may not be successful, and the team learns how the microsystem absorbs or ignores the intervention. Making successive changes in a system is often messy and complex. Key to successful PDSA projects is collecting data that clearly align with the goal and analysing each PDSA cycle.[11] Healthcare improvement teams may be frustrated when a step in a PDSA is unsuccessful or they may worry that testing a "small" change will not lead to the improvement that they seek. But although the overall objective is improvement towards the goal, PDSA is about learning and gaining insight into the system, from both the successes and the failures.[13]

In contrast, IS develops an initial, detailed plan for the implementation process. IS considers the contextual factors in the development of the initial implementation strategy to determine which may be facilitators and which may be barriers to the intervention.[14 15] Identifying these factors in advance allows the team to create implementation strategies that address the anticipated barriers; however, the best design and plans will always be confronted with a changing context. IS often addresses this by adapting the intervention. In IS, there may be tension between fidelity to the planned implementation strategy and adaptation. Adaptation, in some ways like PDSA cycles, plays a central role in the "fit" between the context and the intervention.

Fidelity in QI and IS

Understanding the fidelity of the intervention in both PDSA and adaptation is vital to successful execution of change. Haphazard execution is a risk during iterations and limits learning.[16] Fidelity in IS is the extent to which an intervention adheres to the planned protocol. The intervention may adapt, but the core elements are intended to be implemented as initially designed. In QI, interventions are expected to be modified through each PDSA cycle of change as the team gains insight into what works, for whom, and in what context. In QI, fidelity refers to both the adherence to the planned protocol within each PDSA cycle and to the faithful use of data to inform the next test of change.[17] This ensures that changes are driven by the findings of the previous iteration and lead to the accumulation of insights about the intervention, thus increasing the possibility that the intervention will be sustained within the system.

Context and change

The context changes in complex systems in response to alterations in processes, people, policy, or any other perturbation. Context and healthcare improvement interventions interact, so it is important to account for how the context and the intervention change over time to make the changes more sustainable. In QI, context is defined as the physical and sociocultural makeup of the local environment and the interpretation of these factors by the stakeholders in the environment.[7] It is considered fluid and consists of specific factors but also individuals' interpretation of the relationships between the factors.[18]

Context in QI may be identified and assessed through process analysis tools such as process flow, cause-effect, or workflow diagrams. These tools are used in the design of interventions to provide insights into the context, enabling the initial intervention to be tailored to the specific microsystem. The intervention is then modified through successive PDSA cycles, based on how the local context reacts to the intervention.

In IS, models such as the consolidated framework for implementation research (CFIR), provide a framework of domains of context.[19] These help inform the design of interventions and are especially useful for formative evaluations of change. CFIR domains, for example, are prespecified contextual factors and sub-constructs that include adaptability and trialability of the intervention. CFIR also recognises that PDSAs are one way to adapt the intervention to a specific context.[19] Importantly, both QI and IS note that there is bidirectional interaction, with the intervention affecting the context and the context affecting the intervention.

Learning from one another

The different origins of healthcare QI (systems operations[3]) and IS (behavioural change[4]) sometimes obscure their common goal of creating improvements in the quality, safety, and value of healthcare services in partnership with patients, families, and communities. Each field has much to offer the other in the work of initiating and evaluating change. Figure 1 lists the main characteristics of intervention modification in QI and IS, showing the substantial overlap between the intent and execution of change within each field. While each has a specific approach, there is much in common and much that can be learnt through collaborations. QI can learn from IS by incorporating framework driven approaches to development, planning, and evaluating outcomes that are helpful to make the work more easily generalisable. IS can learn from QI by incorporating data driven flexibility, needed to show how interventions can be successful in a wide variety of contexts.

Plan-do-study-act cycles (QI methods)
- Local microsystem driven to identify a problem and improvement strategy
- Context assessment for design and iteration of changes
- Iterate improvement (changes) based on findings of each PDSA cycle

Adaptation (IS methods)
- Framework driven design of implementation strategy
- Context and barrier assessment during formative evaluation
- Maintain core components of interventions

Common features
- Goal is to improve quality, value, and safety of healthcare services
- Moving evidence into practice is a priority
- Benefit from patient and family input, guidance, and participation
- Fidelity in use of data from each test of change to inform modifications
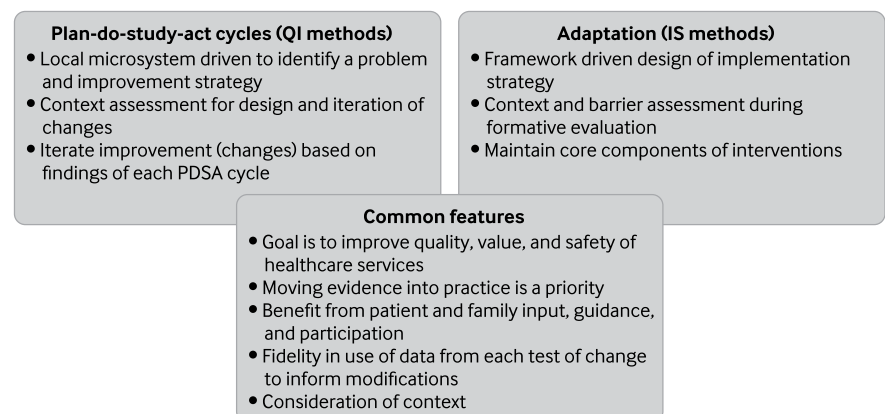- Consideration of context

Fig 1 | Characteristics and overlap of tests of change in quality improvement (QI) and implementation science (IS)

We see many opportunities for these fields to work together. Organisations that focus on QI should bring in IS strategies, specifically to learn what to measure to spread work to other microsystems and contexts. IS should expand the integration of QI within its work, perhaps by explicitly embedding PDSA cycles within IS sustainability efforts.

Funding organisations and journals have long recognised IS because of its similarity to the research model. Funders and healthcare journals should encourage use of QI and IS methods together. This would expand the study of both and speed the growth of knowledge about how to make and sustain change in healthcare. Neither of these fields has led to the healthcare system transformation that was hoped for, and the emerging improvers and researchers in health professions should be steeped in both. Perhaps this will lead to the emergence of a new set of knowledge and methods that will have a more lasting effect. By working together and combining knowledge and methods from both fields, QI and IS can develop a unified approach with more depth and effectiveness than either field has on its own.

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How to improve healthcare improvement

As improvement practice and research begin to come of age, **Mary Dixon-Woods** considers the key areas that need attention if we are to reap their benefits

In the NHS, as in health systems worldwide, patients are exposed to risks of avoidable harm [1] and unwarranted variations in quality.[2-4] But too often, problems in the quality and safety of healthcare are merely described, even "admired,"[5] rather than fixed; the effort invested in collecting information (which is essential) is not matched by effort in making improvement. The National Confidential Enquiry into Patient Outcome and Death, for example, has raised many of the same concerns in report after report.[6] Catastrophic degradations of organisations and units have recurred throughout the history of the NHS, with depressingly similar features each time.[7-9]

More resources are clearly necessary to tackle many of these problems. There is no dispute about the preconditions for high quality, safe care: funding, staff, training, buildings, equipment, and other infrastructure. But quality health services depend not just on structures but on processes.[10] Optimising the use of available resources requires continuous improvement of healthcare processes and systems.[5]

The NHS has seen many attempts to stimulate organisations to improve using incentive schemes, ranging from pay for performance (the Quality and Outcomes Framework in primary care, for example) to public reporting (such as annual quality accounts). They have had mixed results, and many have had unintended consequences.[11 12] Wanting to improve is not the same as knowing how to do it.

In response, attention has increasingly turned to a set of approaches known as quality improvement (QI). Though a definition of exactly what counts as a QI approach has escaped consensus, QI is often identified with a set of techniques adapted from industrial settings. They include the US Institute for Healthcare Improvement's Model for Improvement, which, among other things, combines measurement with tests of small change (plan-do-study-act cycles).[8] Other popular approaches include Lean and Six Sigma. QI can also involve specific interventions intended to improve processes and systems, ranging from checklists and "care bundles" of interventions (a set of evidence based practices intended to be done consistently) through to medicines reconciliation and clinical pathways.

QI has been advocated in healthcare for over 30 years[13]; policies emphasise the need for QI and QI practice is mandated for many healthcare professionals (including junior doctors). Yet the question, "Does quality improvement actually improve quality?" remains surprisingly difficult to answer.[14] The evidence fo`r the benefits of QI is mixed[14] and generally of poor quality. It is important to resolve this unsatisfactory situation. That will require doing more to bring together the practice and the study of improvement, using research to improve improvement, and thinking beyond effectiveness when considering the study and practice of improvement.

Uniting practice and study

The practice and study of improvement need closer integration. Though QI programmes and interventions may be just as consequential for patient wellbeing as drugs, devices, and other biomedical interventions, research about improvement has often been seen as unnecessary or discretionary,[15 16] particularly by some of its more ardent advocates. This is partly because the challenges faced are urgent, and the solutions seem obvious, so just getting on with it seems the right thing to do.

But, as in many other areas of human activity, QI is pervaded by optimism bias. It is particularly affected by the "lovely baby" syndrome, which happens when formal evaluation is eschewed because something looks so good that it is assumed it must work. Five systematic reviews (published 2010-16) reporting on evaluations of Lean and Six Sigma did not identify a single randomised controlled trial.[17-21] A systematic review of redesigning care processes identified no randomised trials.[22] A systematic review of the application of plan-do-study-act in healthcare identified no randomised trials.[23] A systematic review of several QI methods in surgery identified just one randomised trial.[56]

The sobering reality is that some well intentioned, initially plausible improvement efforts fail when subjected to more rigorous evaluation.[24] For instance, a controlled study of a large, well resourced programme that supported a group of NHS hospitals to implement the IHI's Model for Improvement found no differences in the rate of improvement between participating and control organisations.[25 26] Specific interventions may, similarly, not survive the rigours of systematic testing. An example is a programme to reduce hospital admissions from nursing homes that showed promise in a small study in the US,[27] but a later randomised implementation trial found no effect on admissions or emergency department attendances.[28]

Some interventions are probably just not worth the effort and opportunity cost: having nurses wear "do not disturb" tabards during drug rounds, is one example.[29] And some QI efforts, perversely, may cause harm—as happened when a multicomponent intervention was found to be associated with an increase rather than a decrease in surgical site infections.[30]

Producing sound evidence for the effectiveness of improvement interventions and programmes is likely to require a multipronged approach. More large scale trials and other rigorous studies, with embedded qualitative inquiry, should be a priority for research funders.

Not every study of improvement needs to be a randomised trial. One valuable but underused strategy involves wrapping evaluation around initiatives that are happening anyway, especially when it is possible to take advantage of natural experiments or design roll-outs.[31] Evaluation of the reorganisation of stroke care in London and Manchester[32] and the study of the Matching Michigan programme to reduce central line infections are good examples.[33 34]

It would be impossible to externally evaluate every QI project. Critically important therefore will be increasing the rigour with which QI efforts evaluate themselves, as shown by a recent study of an attempt to improve care of frail older people using a "hospital at home" approach in southwest England.[35] This ingeniously designed study found no effect on outcomes and also showed that context matters.

Despite the potential value of high quality evaluation, QI reports are often weak,[18] with, for example, interventions so poorly reported that reproducibility is frustrated.[36] Recent reporting guidelines may help,[37] but some problems are not straightforward to resolve. In particular, current structures for governance and publishing research are not always well suited to QI, including situations where

researchers study programmes they have not themselves initiated. Systematic learning from QI needs to improve, which may require fresh thinking about how best to align the goals of practice and study, and to reconcile the needs of different stakeholders.[38]

Using research to improve improvement

Research can help to support the practice of improvement in many ways other than evaluation of its effectiveness. One important role lies in creating assets that can be used to improve practice, such as ways to visualise data, analytical methods, and validated measures that assess the aspects of care that most matter to patients and staff. This kind of work could, for example, help to reduce the current vast number of quality measures—there are more than 1200 indicators of structure and process in perioperative care alone.[39]

The study of improvement can also identify how improvement practice can get better. For instance, it has become clear that fidelity to the basic principles of improvement methods is a major problem: plan-do-study-act cycles are crucial to many improvement approaches, yet only 20% of the projects that report using the technique have done so properly.[23] Research has also identified problems in measurement—teams trying to do improvement may struggle with definitions, data collection, and interpretation[40]—indicating that this too requires more investment.

Improvement research is particularly important to help cumulate, synthesise, and scale learning so that practice can move forward without reinventing solutions that already exist or reintroducing things that do not work. Such theorising can be highly practical,[41] helping to clarify the mechanisms through which interventions are likely to work, supporting the optimisation of those interventions, and identifying their most appropriate targets.[42]

Research can systematise learning from "positive deviance," approaches that examine individuals, teams, or organisations that show exceptionally good performance.[43] Positive deviance can be used to identify successful designs for clinical processes that other organisations can apply.[44]

Crucially, positive deviance can also help to characterise the features of high performing contexts and ensure that the right lessons are learnt. For example, a distinguishing feature of many high performing organisations, including many currently rated as outstanding by the Care Quality Commission, is that they use structured methods of continuous quality improvement. But studies of high performing settings, such as the Southmead maternity unit in Bristol, indicate that although continuous improvement is key to their success, a specific branded improvement method is not necessary.[45] This and other work shows that not all improvement needs to involve a well defined QI intervention, and not everything requires a discrete project with formal plan-do-study-act cycles.

More broadly, research has shown that QI is just one contributor to improving quality and safety. Organisations in many industries display similar variations to healthcare organisations, including large and persistent differences in performance and productivity between seemingly similar enterprises.[46] Important work, some of it experimental, is beginning to show that it is the quality of their management practices that distinguishes them.[47] These practices include continuous quality improvement as well as skills training, human resources, and operational management, for example. QI without the right contextual support is likely to have limited impact.

Beyond effectiveness

Important as they are, evaluations of the approaches and interventions in individual improvement programmes cannot answer every pertinent question about improvement.[48] Other key questions concern the values and assumptions intrinsic to QI.

Consider the "product dominant" logic in many healthcare improvement efforts, which assumes that one party makes a product and conveys it to a consumer.[49] Paul Batalden, one of the early pioneers of QI in healthcare, proposes that we need instead a "service dominant" logic, which assumes that health is co-produced with patients.[49]

More broadly, we must interrogate how problems of quality and safety are identified, defined, and selected for attention by whom, through which power structures, and with what consequences. Why, for instance, is so much attention given to individual professional behaviour when systems are likely to be a more productive focus?[50] Why have quality and safety in mental illness and learning disability received less attention in practice, policy, and research[51] despite high morbidity and mortality and evidence of both serious harm and failures of organisational learning? The concern extends to why the topic of social inequities in healthcare improvement has remained so muted[52] and to the choice of subjects for study. Why is it, for example, that interventions like education and training, which have important roles in quality and safety and are undertaken at vast scale, are often treated as undeserving of evaluation or research?

How QI is organised institutionally also demands attention. It is often conducted as a highly local, almost artisan activity, with each organisation painstakingly working out its own solution for each problem. Much improvement work is conducted by professionals in training, often in the form of small, time limited projects conducted for accreditation. But working in this isolated way means a lack of critical mass to support the right kinds of expertise, such as the technical skill in human factors or ergonomics necessary to engineer a process or devise a safety solution. Having hundreds of organisations all trying to do their own thing also means much waste, and the absence of harmonisation across basic processes introduces inefficiencies and risks.[14]

A better approach to the interorganisational nature of health service provision requires solving the "problem of many hands."[53] We need ways to agree which kinds of sector-wide challenges need standardisation and interoperability; which solutions can be left to local customisation at implementation; and which should be developed entirely locally.[14] Better development of solutions and interventions is likely to require more use of prototyping, modelling and simulation, and testing in different scenarios and under different conditions,[14] ideally through coordinated, large scale efforts that incorporate high quality evaluation.

Finally, an approach that goes beyond effectiveness can also help in recognising the essential role of the professions in healthcare improvement. The past half century has seen a dramatic redefining of the role and status of the healthcare professions in health systems[54]: unprecedented external accountability, oversight, and surveillance are now the norm. But policy makers would do well to recognise how much more can be achieved through professional coalitions of the willing than through too many imposed, compliance focused diktats. Research is now showing how the professions can be hugely important institutional forces for good.[54 55] In particular, the professions have a unique and invaluable role in working as advocates for improvement, creating alliances with patients, providing training and education, contributing expertise and wisdom, coordinating improvement efforts, and giving political voice for problems that need to be solved at system level (such as, for example, equipment design).

Conclusion

Improvement efforts are critical to securing the future of the NHS. But they need an evidence base. Without sound evaluation, patients may

be deprived of benefit, resources and energy may be wasted on ineffective QI interventions or on interventions that distribute risks unfairly, and organisations are left unable to make good decisions about trade-offs given their many competing priorities. The study of improvement has an important role in developing an evidence-base and in exploring questions beyond effectiveness alone, and in particular showing the need to establish improvement as a collective endeavour that can benefit from professional leadership.

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Getting more health from healthcare: quality improvement must acknowledge patient coproduction

Modelling healthcare as either a product or a service neglects essential aspects of coproduction between doctors and patients. **Paul Batalden** shares his learning from 10 years of studying change

All clinicians experience moments when the healthcare system in which they work makes it difficult for them to deliver good care for their patients.[1] Healthcare increasingly seems to include frustrating processes and unmanageable administrative burdens that reduce the time available for patient care, with negative effects on health outcomes.

Clinicians are also increasingly called on to improve the quality of the systems of care that they deliver. Many participate in improvement efforts, from experiencing large scale, top-down organisational change to making small changes that improve the ways their team works and cares for patients. Some will have taken courses on audit, the Model for Improvement,[2] Lean,[3] and more.

For many clinicians, however, the underlying question, "What is quality improvement, and how can it transform healthcare?" remains unanswered.[4] Full appreciation of what it means to get more health from healthcare demands as full an understanding as possible of the systems to be improved. Fortunately, the past decade has afforded many opportunities to fundamentally challenge thinking about how healthcare actually works and how it contributes to health.

Healthcare as a product: an oversimplified model

In 2007, a colleague and I described a frame for thinking and working to improve and transform healthcare.[5] This involved a substantial shift in the way we thought about healthcare; the shift became widely used as one definition of quality improvement. Through asking the question, "How might system-wide improvement strategies and efforts usefully improve healthcare?" we began to think in terms of systems and processes, considering how to integrate improvement efforts with daily clinical operations and professional development.

Our models were taken from manufacturing, with products ranging from electronics to cars. This had led us to assume that "making a product" and "making a service" were similar—they were both systems for "making"—and that we could think in either way as we developed and tested changes to improve healthcare.

Product dominant thinking sometimes fits well with healthcare: consider an older patient with pain and limited mobility because of hip osteoarthritis who receives the product of a new hip. Through this improvement approach we could understand the elective surgery process, improving how quickly patients progressed and achieved a pain-free outcome.

Sometimes, however, the fit was awkward and it was necessary to include a service model as well as a product model—for example, a patient supplied a need (a painful hip); service processes transformed the need into an output (analgesia); and patients received a benefit that could be measured as outcomes (reduced pain and increased mobility).

Using this language, we could consider the clinician-patient relationship as a "supplier and customer partnership." Yet this also didn't seem quite right: patients are both suppliers and customers. Patients with heart disease, for example, consume healthcare in the form of drugs and check-ups but they also are potential suppliers of activities that improve their health, such as exercise and eating a healthy diet.

Thinking about "supplier-customer partnerships" taught us new aspects of the transactions involved in professional activities, such as the exchange of a symptom (less mobility and pain) for a treatment and an outcome (more mobility and less pain). It's important to remember, however, that this focus on transactions also potentially diminished the nature of the human relationships between a patient and a health professional, and their contribution to health. These ways of thinking failed to encompass the "swampy lowlands" of healthcare, such as physical pain as an expression of loneliness or psychological anguish.[6]

Over time, as we saw thousands of teams improving system performance, we noticed how often ways of product dominant thinking framed how healthcare was perceived. Professionals were increasingly seen as "making" healthcare actions using resources of time and materials, such as requesting investigations or generating prescriptions. Productivity was measured as the number of actions produced in each unit of time—such as the number of patients seen a day in an outpatient clinic—and the amounts of other resources consumed. Furthermore, what had been introduced as "improvements"—such as shorter waits and delays, better documentation, altered work processes, and measured outputs—were instead increasingly seen as inimical to the joy and mastery of real professional work. Professionals and patients were increasingly frustrated.

Making services differs from making products

In his groundbreaking book, *The Service Economy*, the health economist Victor Fuchs noted that making a service in retail or banking was different from making a product. Unlike for a product, two parties are always involved in making a service.[7] The economists Elinor and Vincent Ostrom later suggested that public services were "coproduced."[8] More recently, management researchers have observed that people making public services (social work, healthcare, education, police services, and others) have often been encouraged to adopt a "product dominant" logic.[9]

In product making, one party makes and then conveys that product to a second party, the consumer. For example, a car manufacturer makes a vehicle and sells it to a customer. If we adopt that "product" logic for making a healthcare service, the professional "makes" the service and then sells it to a consumer-patient. But by confusing the logic of product making with service making we risk distorting our understanding of some of the elements of health services that actually contribute to health. If we look at quality

improvement solely through a product dominant lens we will focus on processes, actions, and outputs, which risks neglecting relationships, outcomes that are less easy to measure, and, most importantly, individual patient preferences. Rethinking healthcare as a coproduced service adds depth to our understanding of how we might better design and make services, improve them, and ultimately increase their contribution to better health.

To help us shift to a "service dominant" mindset we created a model of healthcare service coproduction[10] based on the work of Wagner[11] and Coulter.[12] Coproduction of health describes the interdependent work of users and professionals who are creating, designing, producing, delivering, assessing, and evaluating the relationships and actions that contribute to the health of individuals and populations. At its core are the interactions of patients and professionals in different roles and degrees of shared work.

On an individual level, according to this model, a healthcare service is usually composed of a relationship and an action. When a trusted health professional explores a patient's need, a relationship is formed. This relationship is key to agreement and to shared actions that might follow, such as procedures or drugs. Patient and professional are held together by knowledge, skill, habit, and a willingness to be vulnerable.

Trustworthiness, respect, and trust make this relationship possible. Both parties bring their knowledge, skill, and habits to the service making task. A willingness to be vulnerable arises from being fully present and able to fully engage another person. This idealised model does not always exist in practice, but conceptualising it helps us to focus on those elements of the relationship that typically require improvement; they grant professionals important permission to be vulnerable and to value more fully the knowledge and skills patients bring to making health services.

In some interactions, the focus may be more on the action than the relationship, such as properly immobilising a fractured limb. Even within these apparently product dominant interactions, however, practising within a contextualising "service making" frame allows professionals to pay attention to the patient's lived reality, assets, social support, and aims. These might include a patient's caring responsibilities for an elderly parent, or the role of their stress relieving weekend basketball game. Attending to such experiences is not simply a matter of courtesy but recognising what is necessary to do the real, shared work of

limiting the burdens of illness and treatment and optimising health.

How has our understanding changed the way we think about healthcare systems?

Eleven years after our first publication, it is clear that generating sustainable improvement in a coproduced system entails several elements absent from our initial taxonomy:

- *Health*—The aim of these elements and their interaction is the improvement of health. Our earlier emphasis on better outcomes becomes more specific: better health. Health "belongs" to the individual whose health it is. It is their responsibility and difficult to "outsource," even to a professional. In the context of daily healthcare services, health usually includes minimising the burdens of illness and treatment.

- *Network or system*—The operating organising structure is more than a building, and its performance must be characterised by quality, safety, and good benefit for money spent to deliver value. Earlier we separated better system performance from learning. Today we acknowledge the benefit of integrating system performance with learning into a network that reflects active learning and never ending change for improvement. It includes the development and use of knowledge to offer standardised responses to common needs, customised responses to particular needs, and flexible responses to emergent needs. Although some commentators have described continuous learning as the hallmark of

a "professional," learning for patients or users is important as well.

- *Patient participation*—Coproduced healthcare services always include patient participation in some way. Active participation makes it possible to understand the assets and social support that patients contribute to the service and their health. Patient participation is built on trust and relationships.

- *Professional development*—Health professionals capable of service coproduction understand and use several analytical frames: science informed practice, the experiences of individuals, and knowledge that integrates good design principles and daily practice. These professionals also bring their knowledge, skill, and habits to the interdependent work of service coproduction. Their way of work can contribute to a sense of trustworthiness. Coproducing professionals further recognise that when they work as whole people they may become vulnerable as they work to create a trusting, effective, interpersonal relationship. Joy and reflection on their own lives helps sustain these professions in the never ending confrontation with some of life's boundaries.

- *Assessment and measurement*—Measuring the process and results of a coproduced service invites attention to how the patient's goals were elicited, how they were addressed, and whether they were attained. It also must assess the effectiveness of the professionals' interventions and practice. Good

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Example characteristics of knowledge elements

- *Patient aim*—Reason for seeking help, grounded in the reality of the patient's life. The circumstances surrounding that aim matter: a "well" patient may have different requirements for a coproduced service than a "sick" one

- *Generalisable, science informed practice*—Observations and evidence from others and other contexts. This usually reflects empirical study of specific individuals in defined settings.[13] Benefit for a particular person may be difficult to predict given the ways in which the generalisable information was constructed

- *Particular context*—The dynamic interactions among people and groups reflect the enormous complexity of human environments.[14] These physical, social, and cultural realities are expressed in the processes, systems, and dispositions of the local setting. This knowledge is constructed from the current state, its processes and systems, the "coproduction" of knowledge, skills, dispositions of the parties involved, the relationships of the parties, and their assets and social supports

- *Measurable improvement*—Assessment of the degree to which the patient's aim was understood and achieved as well as the effect of the scientifically informed intervention. It usually includes a balanced set of measures to reflect performance over time

- *Connecting patient aim and science informed practice in design of intervention*—Working from the patient's aim, scientifically informed interventions are sought, explored, and matched

- *Contextualising the planned change*—Matching the possible interventions with the enabling and limiting features of the local setting as it changes

- *Testing the change*—Mobilisation of the strategic, operational, and human resource realities that contribute to making changes happen

measurement becomes a means to create new knowledge about service development.

What knowledge do we need to improve healthcare systems?

Previously we recognised the multiple knowledge systems involved in designing and testing a change for improvement:

Generalisable scientific knowledge + Particular context → Measurable performance improvement

Today, in addition, we make explicit the contributions of patients and professionals, who each bring different expertise, knowledge, and experience to their shared interactions in the coproduction of a service:

(Patient aim + Generalisable, science informed practice) × Particular context → Measurable improvement

This modified improvement formula seeks to describe the coproduced world of healthcare service. Each element is driven by a different knowledge system (box).

What do we need to do next?

The different knowledge systems invited by these perspectives require scientific and experiential learning. We have learnt a great deal in a decade of studying the improvement process and building the science of improvement. Now, explicitly extending this scholarly approach to understand healthcare service coproduction and its limits is likely to help us to maximise the health we get from healthcare still further.

Readers should note the service dominant or product dominant thinking in their organisation, assessment, improvement of services and in professional education. Acts of noticing can be important reminders to consider all knowledge elements, including the important domain of patient aim.

Whether clinicians are working in a coproduced healthcare service or designing and improving health services, thinking in this new way about the elements that

Biography

Paul Batalden is a senior fellow of the Institute for Healthcare Improvement and an active faculty member at Dartmouth and the Jönköping University. He previously developed the Institute for Healthcare Improvement, the US Veteran Administration National Quality Scholars programme, the General Competencies of the Accreditation Council for Graduate Medical Education (ACGME), the Dartmouth leadership preventive medicine residency, the annual health professional educator's summer symposium, the SQUIRE publication guidelines, the improvement science fellowship programme of the UK Health Foundation, and the Vinnvård Improvement Science fellowships in Sweden.

produce health means undertaking professional development that goes beyond generalisable, science informed practice or improvement tools. Clinicians need to learn in ways that encompass all of the forms of knowledge described here, including eliciting a patient's immediate and long term aims. On an individual level, this can be described as shared decision making. On a system level, this way of thinking and practising may enable us to transform healthcare to improve health for our patients and populations.

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Why healthcare leadership should embrace quality improvement

Making quality improvement a core tenet of how healthcare organisations are run is essential to ensuring safe, high quality, and responsive services for patients, write **John R Drew and Meghana Pandit**

Healthcare staff often have a positive experience of quality improvement (QI) compared with the daily experience of how their organisations are led and managed.[1] This indicates that some of the conditions and assumptions required for QI are at odds with prevailing management practices. For QI to become pervasive in healthcare, we need to change leadership and management.

At a QI event, we listened to an experienced nurse explaining a QI project to improve patient flow. The most striking thing was not her description of the project or what she had learnt or the benefits for patients, but instead how it had made her feel "valued and respected."

A manager's job is to achieve organisational goals. In the NHS, this includes meeting emergency and elective targets, such as the referral to treatment target, cancer and diagnostic standards, and the emergency department standard. Clinicians often perceive managerial interactions as authoritarian and lacking patient centredness and see QI as inclusive, bottom-up engagement.[2] Staff appreciate non-hierarchical approaches.

QI can be defined as "a systematic approach that uses specific techniques to improve quality."[2] It requires infrastructure—systematic and disciplined ways to eliminate waste from processes, improve outcomes and experiences for patients, and eradicate mistakes. It requires organisational patience and a culture that empowers staff to achieve positive change. Organisations that foster continuous improvement might say that all staff have two jobs: first, to do their job; second, to improve it.

The nurse we spoke to said that the main difference when working on the QI project was having the time and the "permission" to make improvements in her own work. Staff engagement scores indicate that many NHS clinicians increasingly feel trapped in a flawed system with little prospect of changing it.[3]

Understanding why there is a gap between the predominant management practices and culture of the NHS and the "microclimate" associated with local QI activities, and how to close that gap, is vital. Staff often report two contributors to this gap: a lack of "headspace" and feeling like a cog in a machine.[4]

Rising demand for healthcare and an estimated 8% vacancy rate[5] in the clinical workforce make it difficult to find time for QI. Some leaders have committed to protecting time for QI because it generates a return in improved quality and productivity.[6] But this is still rare. Without long term strategic commitment, expecting people to find time for their second job is unrealistic. There is growing recognition that this needs to change.[7 8]

Increased demand has been compounded by a rise in transparency and regulation, especially in publicly funded health systems, placing managers and leaders under greater pressure. Regulators often require improvement plans to be developed quickly, making meaningful staff engagement difficult. Recent changes in contracts, such as job planning, and pension tax rules in the UK have led many doctors to think that their employment has become more transactional. This, combined with top-down target setting and a narrative of "grip and control," might explain why staff increasingly feel insignificant.

QI as the basis of management

QI depends on engaging and empowering the teams delivering care and equipping them with the tools and skills they need to improve care pathways. Ultimately, it means trusting professionals' knowledge and judgment of what patients need and allowing them to make decisions, including the allocation of resources, with appropriate accountability. This requires a shift in managerial and leadership thinking (box 1).

QI needs to become the basis of how organisations are led and managed, replacing traditional, hierarchical structures and incentives. Regulators already recognise this; the Care Quality Commission's report on quality improvement in hospital trusts, for example, says that when leaders and frontline staff work together it creates a powerful sense of shared purpose.[6] This is often present in the NHS trusts that it rates "outstanding," it says. Dido Harding, chair of NHS Improvement, has said, "If all of the boards in the NHS chose to take culture and people management more seriously and put it on a level footing with financial and operational performance, we'd see a huge improvement in culture and outcomes for patients as well."[9]

The profound shifts in leadership and management needed for QI to thrive sometimes run contrary to traditional approaches for optimising short term performance. The recent average tenure of an NHS chief executive is 2-3 years, undermining the sustainable culture change needed for QI.[10] Burgess and colleagues describe a different type of governance that fosters learning, citing the partnership of NHS Improvement and five trusts with the Virginia Mason Institute in the United States.[11] Creating a compact with regulators enables a change in attitudes and allows organisations to grow and learn, they say. This promotes board longevity, which is a requirement for continuous improvement.[6]

When do QI and good management coalesce?

The most senior leaders might have the greatest challenge; their roles would shift from being responsible for all performance to a devolved model of collective, inclusive, and compassionate leadership. Embedding QI can challenge senior leaders' fundamental beliefs and management practices. Safe healthcare depends on defining and following standards, but an emphasis on engaging frontline staff to develop, apply, and improve those standards is often lacking. Instead, standards are implemented rapidly in a top-down, non-negotiable fashion.[12]

The language of QI often reflects nature, describing organisations as ecosystems to cultivate or living systems to keep healthy rather than machines to optimise. Human factors (such as relationships, trust, and healthy multidisciplinary teams), talent management, succession planning, and assurance are central to this way of working.

Senior leaders must be role models. Their behaviour is amplified throughout the organisations they lead, whether they recognise it or not. Staff will judge what is important by where and how leaders spend their time rather than by what they say.

The Virginia Mason Institute partnership was enabled in 2015 by the secretary of state

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Box 1: Cycles of continuous improvement

All QI activities need to start small and then scale up. The transition to full implementation requires constant plan-do-study-act cycles with user involvement and feedback. One QI activity that changed organisational culture received the HSJ National Patient Safety Team Award in 2018.

The process began with the team members asking themselves, if they were a patient, what would they like to happen after a clinical harm incident in a hospital. The team then defined the current state and future vision. Eight frontline staff participated in a five day workshop to define the key steps that would help achieve the desired outputs. They tested the approach over the next few weeks and agreed metrics that were reported to executives at 30, 60, and 90 days. The workshop included patient representatives. Several changes resulted in increased incident reporting and user feedback, introduction of safety huddles, and the creation of an innovative patient safety response team.

Making such changes stick requires constant and consistent messaging and leading by example. Appreciating the efforts of frontline workers, and saying "thank you," is vital.

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for health and social care to adopt "lean thinking" (a method developed by Toyota to deliver more benefits to society while eliminating waste) in the NHS. The trusts' progress is being evaluated, but some trusts already report having developed a "golden thread" of QI that is visible to all, leading to improvements in CQC ratings and staff engagement.

Translating QI endeavours into operational and financial success takes time, and caregivers, providers, and regulators need to hold their nerve to see lasting performance improvement. Other healthcare providers have embraced QI methods without formal partnerships with international organisations and have delivered strong long term results. A key feature in most of these cases has been coaching for the most senior leaders and managers (for example, with a "lean" coach, usually people with experience from other industries who have moved into healthcare or consultants) so that they understand the changes they need to make in their own behaviours and practices. This has been described in the motor industry.[13]

So is QI just good management?

Management, leadership, and QI are distinct but overlapping. Some leaders are not managers, and vice versa. Some, but not all, leaders and managers will undertake QI, which can be performed in isolation from leadership and management. But integrating all three is likely to optimise outcomes. Broadly, management is controlling a group or team to accomplish a goal. Leadership is influencing others to contribute towards success. Management requires "grip" (staying on top of details, intervening quickly, and giving orders or instructions if performance is below expectations), and QI often requires a deliberate loosening of that grip. This could create conflict unless management has QI as a fundamental principle.

One could argue that QI requires more people to behave like leaders and fewer to behave like managers. In the most radical forms of QI (such as those described in *Reinventing Organisations*[14]), many of the roles and responsibilities of management become shared among well functioning, trusted frontline teams. The sense of "them and us" between frontline workforce and management vanishes.

The chairman of the Japanese electronics company Matsushita famously issued a challenge: "The essence of management is getting ideas out of the heads of the bosses and into the heads of labour . . . Business, we know, is now so complex and difficult, the survival of firms so hazardous in an environment increasingly unpredictable, competitive, and fraught with danger, that their continued existence depends on the day-to-day mobilisation of every ounce of intelligence."[15]

How can we help leaders get on this path?

Embedding QI in any organisation requires a new narrative from regulators and boards, strategic intent, investment in training leaders and staff, a more distributed leadership model that empowers frontline teams, and a meaningful role for patients so that improvement activity is aligned to what they most need and value.[6][16]

It also requires courage and patience from the most senior leaders as they commit to new management practices. Their incentives must depend not only on delivery of top-down targets but also on building a culture conducive to long term quality improvement, which could be personally uncomfortable for them.[17]

Quality management systems have an important role.[18] Taichi Ohno, architect of the Toyota Production System (popularised as "lean"), would instruct managers to spend hours "watching" from within a chalk circle on the factory floor. He wanted managers to learn to see waste and opportunities to improve quality and flow.

Learning good management in healthcare includes not only learning to see opportunities to improve healthcare processes but also noticing the experience of frontline staff, and consequently leading in ways that engage and empower them to "mobilise every ounce of intelligence."

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How to get started in quality improvement

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Quality improvement (box 1) is a core component of many undergraduate and postgraduate curriculums.[1-5] Numerous healthcare organisations,[6] professional regulators,[7] and policy makers[8] recognise the benefits of training clinicians in quality improvement.

Engaging in quality improvement enables clinicians to acquire, assimilate, and apply important professional capabilities[7] such as managing complexity and training in human factors.[1] For clinical trainees, it is a chance to improve care[9]; develop leadership, presentation, and time management skills to help their career development[10]; and build relationships with colleagues in organisations that they have recently joined.[11] For more experienced clinicians, it is an opportunity to address longstanding concerns about the way in which care processes and systems are delivered, and to strengthen their leadership for improvement skills.[12]

The benefits to patients, clinicians, and healthcare providers of engaging in quality improvement are considerable, but there are many challenges involved in designing, delivering, and sustaining an improvement intervention. These range from persuading colleagues that there is a problem that needs to be tackled, through to keeping them engaged once the intervention is up and running as other clinical priorities compete for their attention.[13] You are also likely to have competing priorities and will need support to make time for quality improvement. The organisational culture, such as the extent to which clinicians are able to question existing practice and try new ideas,[14-16] also has an important bearing on the success of the intervention.

Box 1: Defining quality improvement[1]

- Quality improvement aims to make a difference to patients by improving safety, effectiveness, and experience of care by:
- Using understanding of our complex healthcare environment
- Applying a systematic approach
- Designing, testing, and implementing changes using real time measurement for improvement

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WHAT YOU NEED TO KNOW

- Participation in quality improvement can help clinicians and trainees improve care together and develop important professional skills
- Effective quality improvement relies on collaborative working with colleagues and patients and the use of a structured method
- Enthusiasm, perseverance, good project management skills, and a willingness to explain your project to others and seek their support are key skills

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This article describes the skills, knowledge, and support needed to get started in quality improvement and deliver effective interventions.

What skills do you need?

Enthusiasm, optimism, curiosity, and perseverance are critical in getting started and then in helping you to deal with the challenges you will inevitably face on your improvement journey.

Relational skills are also vital. At its best quality improvement is a team activity. The ability to collaborate with different people, including patients, is vital for a project to be successful.[17 18] You need to be willing to reach out to groups of people that you may not have worked with before, and to value their ideas.[19] No one person has the skills or knowledge to come up with the solution to a problem on their own.

Learning how systems work and how to manage complexity is another core skill.[20] An ability to translate quality improvement approaches and methods into practice (box 2), coupled with good project and time management skills, will help you design and implement a robust project plan.[27]

Equally important is an understanding of the measurement for improvement model, which involves the gradual refinement of your intervention based on repeated tests of change. The aim is to discover how to make your intervention work in your setting, rather than to *prove* it works, so useful data, not perfect data, are needed.[28 29] Some experience of data collection and analysis methods (including statistical analysis tools such as run charts and statistical process control) is useful, but these will develop with increasing experience.[30 31]

Most importantly, you need to enjoy the experience. It is rare that a clinician can institute real, tangible change, but with quality improvement this is a real possibility, which is both empowering and satisfying. Finally, don't worry about what you don't know. You will learn by doing. Many skills needed to implement successful quality improvement will be developed as you go; this is a fundamental feature of quality improvement.

How do you get started?

The first step is to recruit your improvement team. Start with colleagues and patients,[32] but also try to bring in people from other professions, including non-clinical staff. You need a blend of skills and perspectives in your team. Find a colleague experienced in quality improvement who is willing to mentor or supervise you.

Next, identify a problem collaboratively with your team. Use data to help with this (eg, clinical audits, registries of data on

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Box 2: Quality improvement approaches

Healthcare organisations use a range of improvement methods,[21 22] such as the Model for Improvement, where changes are tested in small cycles that involve planning, doing, studying, and acting (PDSA),[23] and Lean, which focuses on continually improving processes by removing waste, duplication, and non-value adding steps.[24] To be effective, such methods need to be applied consistently and rigorously, with due regard to the context.[25] In using PDSA cycles, for example, it is vital that teams build in sufficient time for planning and reflection, and do not focus primarily on the "doing."[26]

Box 3: Clinical audit and quality improvement

Quality improvement is an umbrella term under which many approaches sit, clinical audit being one.[33] Clinical audit is commonly used by trainees to assess clinical effectiveness. Confusion of audit as both a term for assurance and improvement has perhaps limited its potential, with many audits ending at the data collection stage and failing to lead to improvement interventions. Learning from big datasets such as the National Clinical Audits in the UK is beginning to shift the focus to a quality improvement approach that focuses on identifying and understanding unwanted variation in the local context; developing and testing possible solutions, and moving from one-off change to multiple cycles of change.[34]

patients' experiences and outcomes, and learning from incidents and complaints) (box 3). Take time to understand what might be causing the problem. There are different techniques to help you (process mapping, five whys, appreciative inquiry).[35-37] Think about the contextual factors that are contributing to the problem (eg, the structure, culture, politics, capabilities and resources of your organisation).

Next, develop your aim using the SMART framework: Specific (S), Measurable (M), Achievable (A), Realistic (R), and Timely (T).[38] This allows you to assess the scale of the intervention and to pare it down if your original idea is too ambitious. Aligning your improvement aim with the priorities of the organisation where you work will help you to get management and executive support.[39]

Having done this, map those stakeholders who might be affected by your intervention and work out which ones you need to approach, and how to sell it to them.[40] Take the time to talk to them. It will be appreciated and increases the likelihood of buy in, without which your quality improvement project is likely to fail irrespective of how good your idea is. You need to be clear in your own mind about the reasons you think it is important. Developing an "elevator pitch" based on your aims is a useful technique to persuade others,[38] remembering different people are hooked in for different reasons.

The intervention will not be perfect first time. Expect a series of iterative changes in response to false starts and obstacles. Measuring the impact of your intervention will enable you to refine it.[28] Time invested in all these aspects will improve your chances of success.

Right from the start, think about how improvement will be embedded. Attention to sustainability will mean that when you move

Quality improvement in action: three doctors and a medical student talk about the challenges and practicalities of quality improvement

This box contains four interviews by Laura Nunez-Mulder with people who have experience in quality improvement.

Alex Thompson, medical student at the University of Cambridge, is in the early stages of his first quality improvement project

We are aiming to improve identification and early diagnosis of aortic dissections in our hospital. Our supervising consultant suspects that the threshold for organising computed tomography angiography for a suspected aortic dissection is too high, so to start with, my student colleague and I are finding out what proportion of CT angiograms result in a diagnosis of aortic dissection.

I fit the project around my studies by working on it in small chunks here and there. You have to be very self motivated to see a project through to the end.

Anna Olsson-Brown, research fellow at the University of Liverpool, engaged in quality improvement in her F1 year, and has since supported junior doctors to do the same. This extract is adapted from her *BMJ Opinion* piece (https://blogs.bmj.com/bmj/)

Working in the emergency department after my F1 job in oncology, I noticed that the guidelines on neutropenic sepsis antibiotics were relatively unknown and even less frequently implemented. A colleague and I devised a neutropenic sepsis pathway for oncology patients in the emergency department including an alert label for blood tests. The pathway ran for six months and there was some initial improvement, but the benefit was not sustained after we left the department.

As an ST3, I mentored a junior doctor whose quality improvement project led to the introduction of a syringe driver prescription sticker that continues to be used to this day.

My top tips for those supporting trainees in quality improvement:
- Make sure the project is sufficiently narrow to enable timely delivery
- Ensure regular evaluation to assess impact
- Support trainees to implement sustainable pathways that do not require their ongoing input.

Amar Puttanna, consultant in diabetes and endocrinology at Good Hope Hospital, describes a project he carried out as a chief registrar of the Royal College of Physicians

The project of which I am proudest is a referral service we launched to review medication for patients with diabetes and dementia. We worked with practitioners on the older adult care ward, the acute medical unit, the frailty service, and the IT teams, and we promoted the project in newsletters at the trust and the Royal College of Physicians.

The success of the project depended on continuous promotion to raise awareness of the service because junior doctors move on frequently. Activity in our project reduced after I left the trust, though it is still ongoing and won a Quality in Care Award in November 2018.

Though this project was a success, not everything works. But even the projects that fail contain valuable lessons.

Mark Taubert, consultant in palliative medicine and honorary senior lecturer for Cardiff University School of Medicine, launched the TalkCPR project

Speaking to people with expertise in quality improvement helped me to narrow my focus to one question: "Can videos be used to inform both staff and patients/carers about cardiopulmonary resuscitation and its risks in palliative illness?" With my team I created and evaluated TalkCPR, an online resource that has gone on to win awards (talkcpr.wales).

The most challenging aspect was figuring out which tools might get the right information from any data I collected. I enrolled on a Silver Improving Quality Together course and joined the Welsh Bevan Commission, where I learned useful techniques such as multiple PDSA (plan, do, study, act) cycles, driver diagrams, and fishbone diagrams.

to your next job your improvement efforts, and those of others, and the impact you have collectively achieved will not be lost.[41 42]

What support is needed?

You need support from both your organisation and experienced colleagues to translate your skills into practice. Here are some steps you can take to help you make the most of your skills:

- Find the mentor or supervisor who will help identify and support opportunities for you. Signposting and introduction to those in an organisation who will help influence (and may hinder) your quality improvement project is invaluable
- Use planning and reporting tools to help manage your project, such as those in NHS Improvement's project management framework[27]
- Identify if your local quality improvement or clinical audit team may be a source of support and useful development resource for you rather than just a place to register a project. Most want to support you.
- Determine how you might access (or develop your own) local peer to peer support networks, coaching, and wider improvement networks (eg, NHS networks; Q network[43 44])
- Use quality improvement e-learning platforms such as those provided by Health Education England or NHS Education for Scotland to build your knowledge[45 46]
- Learn through feedback and assessment of your project (eg, via the QIPAT tool[47] or a multi-source feedback tool.[48 49]

Quality improvement approaches are still relatively new in the education of healthcare professionals. Quality improvement can give clinicians a more productive, empowering, and educational experience. Quality improvement projects allow clinicians, working within a team, to identify an issue and implement interventions that can result in true improvements in quality. Projects can be undertaken in fields that interest clinicians and give them transferable skills in communication, leadership, project

management, team working, and clinical governance. Done well, quality improvement is a highly beneficial, positive process which enables clinicians to deliver true change for the benefit of themselves, their organisations, and their patients.

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Using data for improvement

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We all need a way to understand the quality of care we are providing, or receiving, and how our service is performing. We use a range of data in order to fulfil this need, both quantitative and qualitative. Data are defined as "information, especially facts and numbers, collected to be examined and considered and used to help decision-making."[1] Data are used to make judgements, to answer questions, and to monitor and support improvement in healthcare (box 1). The same data can be used in different ways, depending on what we want to know or learn.

Within healthcare, we use a range of data at different levels of the system:

- Patient level—such as blood sugar, temperature, blood test results, or expressed wishes for care)
- Service level—such as waiting times, outcomes, complaint themes, or collated feedback of patient experience
- Organisation level—such as staff experience or financial performance
- Population level—such as mortality, quality of life, employment, and air quality.

This article outlines the data we need to understand the quality of care we are providing, what we need to capture to see if care is improving, how to interpret the data, and some tips for doing this more effectively.

What data do we need?

Healthcare is a complex system, with multiple interdependencies and an array of factors influencing outcomes. Complex systems are open, unpredictable, and continually adapting to their environment.[3] No single source of data can help us understand how a complex system behaves, so we need several data sources to see how a complex system in healthcare is performing.

Avedis Donabedian, a doctor born in Lebanon in 1919, studied quality in healthcare and contributed to our understanding of using

Sources and selection criteria

This article is based on my experience of using data for improvement at East London NHS Foundation Trust, which is seen as one of the world leaders in healthcare quality improvement. Our use of data, from trust board to clinical team, has transformed over the past six years in line with the learning shared in this article. This article is also based on my experience of teaching with the Institute for Healthcare Improvement, which guides and supports quality improvement efforts across the globe.

WHAT YOU NEED TO KNOW

- Both qualitative and quantitative data are critical for evaluating and guiding improvement
- A family of measures, incorporating outcome, process, and balancing measures, should be used to track improvement work
- Time series analysis, using small amounts of data collected and displayed frequently, is the gold standard for using data for improvement

Box 1: Defining quality improvement[2]

Quality improvement aims to make a difference to patients by improving safety, effectiveness, and experience of care by:
1. Using understanding of our complex healthcare environment
2. Applying a systematic approach
3. Designing, testing, and implementing changes using real-time measurement for improvement

outcomes.[4] He described the importance of focusing on structures and processes in order to improve outcomes.[5] When trying to understand quality within a complex system, we need to look at a mix of outcomes (what matters to patients), processes (the way we do our work), and structures (resources, equipment, governance, etc).

Therefore, when we are trying to improve something, we need a small number of measures (ideally 5-8) to help us monitor whether we are moving towards our goal. Any improvement effort should include one or two outcome measures linked explicitly to the aim of the work, a small number of process measures that show how we are doing with the things we are actually working on to help us achieve our aim, and one or two balancing measures (box 2). Balancing measures help us spot unintended consequences of the changes we are making. As complex systems are unpredictable, our new changes may result in an unexpected adverse effect. Balancing measures help us stay alert to these, and ought to be things that are already collected, so that we do not waste extra resource on collecting these.

How should we look at the data?

This depends on the question we are trying to answer. If we ask whether an intervention was efficacious, as we might in a research study, we would need to be able to compare data before and after the intervention and remove all potential confounders and bias. For example, to understand whether a new treatment is better than the status quo, we might design a research study to compare the effect of the two interventions and ensure that all other characteristics are kept constant across both groups. This study might take several months, or possibly years, to complete, and would compare the average of both groups to identify whether there is a statistically significant difference.

This approach is unlikely to be possible in most contexts where we are trying to improve quality. Most of the time when we are improving a service, we are making multiple changes and assessing impact in real-time, without being able to remove all confounding factors and potential bias. When we ask whether an outcome has improved, as we do when trying to improve something, we need to be able to look at data over time to see how the system changes as we intervene, with multiple tests of change over a period. For example, if we were trying to improve the time from a patient presenting in the emergency department to being admitted to a ward, we would likely be testing several different changes at different places in the pathway. We would want to be able to look at the outcome measure of total time from presentation to admission on the ward, over time, on a daily basis, to be able to see whether the changes made lead to a reduction in the overall outcome. So, when looking at a quality issue from an improvement perspective, we view smaller amounts of data but more frequently to see if we are improving over time.[2]

Box 2: Different types of measures of quality of care

Outcome measures (linked explicitly to the aim of the project)
- *Aim*—To reduce waiting times from referral to appointment in a clinic
- *Outcome measure*—Length of time from referral being made to being seen in clinic
  - *Data collection*—Date when each referral was made, and date when each referral was seen in clinic, in order to calculate the time in days from referral to being seen

Process measures (linked to the things you are going to work on to achieve the aim)
- *Change idea*—Use of a new referral form (to reduce numbers of inappropriate referrals and re-work in obtaining necessary information)
- *Process measure*—Percentage of referrals received that are inappropriate or require further information
  - *Data collection*—Number of referrals received that are inappropriate or require further information each week divided by total number of referrals received each week
- *Change idea*—Text messaging patients two days before the appointment (to reduce non-attendance and wasted appointment slots)
- *Process measure*—Percentage of patients receiving a text message two days before appointment
  - *Data collection*—Number of patients each week receiving a text message two days before their appointment divided by the total number of patients seen each week
- *Process measure*—Percentage of patients attending their appointment
  - *Data collection*—Number of patients attending their appointment each week divided by the total number of patients booked in each week

Balancing measures (to spot unintended consequences)
- *Measure*—Percentage of referrers who are satisfied or very satisfied with the referral process (to spot whether all these changes are having a detrimental effect on the experience of those referring to us)
  - *Data collection*—A monthly survey to referrers to assess their satisfaction with the referral process
- *Measure*—Percentage of staff who are satisfied or very satisfied at work (to spot whether the changes are increasing burden on staff and reducing their satisfaction at work)
  - *Data collection*—A monthly survey for staff to assess their satisfaction at work

What is best practice in using data to support improvement?

Best practice would be for each team to have a small number of measures that are collectively agreed with patients and service users as being the most important ways of understanding the quality of the service being provided. These measures would be displayed transparently so that all staff, service users, and patients and families or carers can access them and understand how the service is performing. The data would be shown as time series analysis, to provide a visual display of whether the service is improving over time. The data should be available as close to real-time as possible, ideally on a daily or weekly basis. The data should prompt discussion and action, with the team reviewing the data regularly, identifying any signals that suggest something unusual in the data, and taking action as necessary.

The main tools used for this purpose are the run chart and the Shewhart (or control) chart. The run chart (fig 1) is a graphical display of data in time order, with a median value, and uses probability-based rules to help identify whether the variation seen is random or non-random.[2] The Shewhart (control) chart (fig 2) also displays data in time order, but with a mean as the centre line instead of a median, and upper and lower control limits (UCL and
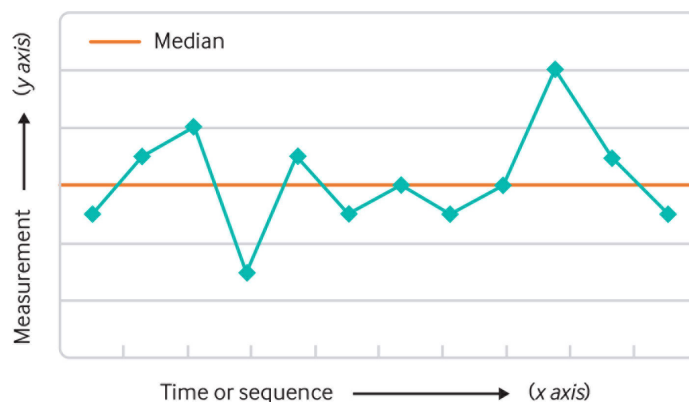

Fig 1 | A typical run chart

LCL) defining the boundaries within which you would predict the data to be.[6] Shewhart charts use the terms "common cause variation" and "special cause variation," with a different set of rules to identify special causes.

Is it just about numbers?

We need to incorporate both qualitative and quantitative data to help us learn about how the system is performing and to see if we improve over time. Quantitative data express quantity, amount, or range and can be measured numerically—such as waiting times, mortality, haemoglobin level, cash flow. Quantitative data are often visualised over time as time series analyses (run charts or control charts) to see whether we are improving.

However, we should also be capturing, analysing, and learning from qualitative data throughout our improvement work. Qualitative data are virtually any type of information that can be observed and recorded that is not numerical in nature. Qualitative data are particularly useful in helping us to gain deeper insight into an issue, and to understand meaning, opinion, and feelings. This is vital in supporting us to develop theories about what to focus on and what might make a difference.[7] Examples of qualitative data include waiting room observation, feedback about experience of care, free-text responses to a survey.

Using qualitative data for improvement

One key point in an improvement journey when qualitative data are critical is at the start, when trying to identify "What matters most?" and what the team's biggest opportunity for improvement is. The other key time to use qualitative data is during "Plan, Do, Study, Act"
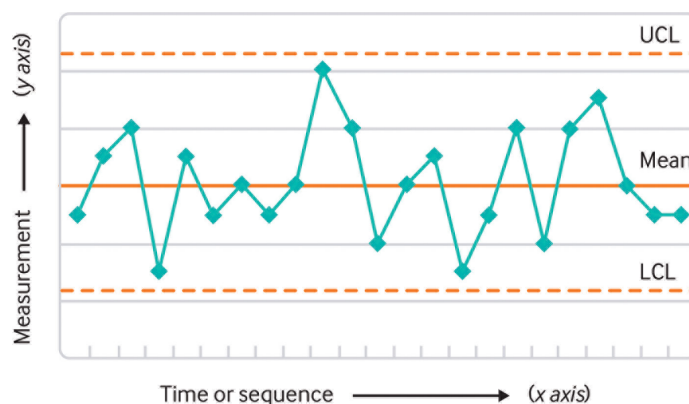
UCL = Upper control limit, LCL = Lower control limit

Fig 2 | A typical Shewhart (or control) chart

Table 1 | Different ways to collect qualitative data for improvement

Data collection method	Advantages	Disadvantages	Using the data
Free-text question in a survey	Quick and easy to create, on paper or electronic	Questions are pre-determined so cannot adapt based on answers Beware of survey fatigue	At the start of a project to capture opinions, ideas, and feedback from service users and staff
Interviews	Can be individual or group Can be structured, semi-structured, or unstructured Can explore deeper meaning	Time intensive Need to facilitate the interview and take notes or record the discussion Analysing large amounts of narrative requires skill	To help us understand the issue we want to work on in more detail with multiple perspectives To help us appreciate a deeper meaning behind people's views and theories
Observations	Able to see behaviour and impact of human factors in real-world setting Can be useful in understanding robustness of implementation	Time intensive Obtrusive, so risk of Hawthorne (observer) effect—knowing you are being observed affects how you behave	Useful to understand the system from another perspective Can be particularly helpful in monitoring whether implementation has been successful
Review of documents	Large amounts of documentation are usually available, and may yield useful information (such as complaints, incident forms, clinical documentation)	Can be time intensive May need a defined search and sampling strategy—you could ask your informatics or business intelligence team for help	At start of project to identify opportunities for improvement through analysing service user feedback, incidents. or complaints

(PDSA) cycles. Most PDSA cycles, when done well, rely on qualitative data as well as quantitative data to help learn about how the test fared compared with our original theory and prediction.

Table 1 shows four different ways to collect qualitative data, with advantages and disadvantages of each, and how we might use them within our improvement work.

Tips to overcome common challenges in using data for improvement?
One of the key challenges faced by healthcare teams across the globe is being able to access data that is routinely collected, in order to use it for improvement. Large volumes of data are collected in healthcare, but often little is available to staff or service users in a timescale or in a form that allows it to be useful for improvement. One way to work

Fig 3 | Example of a safety cross in use

around this is to have a simple form of measurement on the unit, clinic, or ward that the team own and update. This could be in the form of a safety cross[8] or tally chart. A safety cross (fig 3) is a simple visual monthly calendar on the wall which allows teams to identify when a safety event (such as a fall) occurred on the ward. The team simply colours in each day green when no fall occurred, or colours in red the days when a fall occurred. It allows the team to own the data related to a safety event that they care about and easily see how many events are occurring over a month. Being able to see such data transparently on a ward allows teams to update data in real time and be able to respond to it effectively.

A common challenge in using qualitative data is being able to analyse large quantities of written word. There are formal approaches to qualitative data analyses, but most healthcare staff are not trained in these methods. Key tips in avoiding this difficulty are (*a*) to be intentional with your search and sampling strategy so that you collect only the minimum amount of data that is likely to be useful for learning and (*b*) to use simple ways to read and theme the data in order to extract useful information to guide your improvement work.[9] If you want to try this, see if you can find someone in your organisation with qualitative data analysis skills, such as clinical psychologists or the patient experience or informatics teams.

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Evaluating the impact of healthcare interventions using routine data

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Interventions to transform the delivery of health and social care are being implemented widely, such as those linked to Accountable Care Organizations in the United States,[1] or to integrated care systems in the UK.[2] Assessing the impact of these health interventions enables healthcare teams to learn and to improve services, and can inform future policy.[3] However, some healthcare interventions are implemented without high quality evaluation, in ways that require onerous data collection, or may not be evaluated at all.[4]

A range of routinely collected administrative and clinically generated healthcare data could be used to evaluate the impact of interventions to improve care. However, there is a lack of guidance as to where relevant routine data can be found or accessed and how they can be linked to other data. A diverse array of methodological literature can also make it hard to understand which methods to apply to analyse the data. This article provides an introduction to help clinicians, commissioners, and other healthcare professionals wishing to commission, interpret, or perform an impact evaluation of a health intervention. We highlight what to consider and discuss key concepts relating to design, analysis, implementation, and interpretation.

What are interventions, impacts, and impact evaluations?

A health intervention is a combination of activities or strategies designed to assess, improve, maintain, promote, or modify health among individuals or an entire population. Interventions can include educational or care programmes, policy changes, environmental improvements, or health promotion campaigns. Interventions that include multiple independent or interacting components are referred to as complex.[5] The impact of any intervention is likely to be shaped as much by the context (eg, communities, work places, homes, schools, or hospitals) in which it is delivered, as the details of the intervention itself.[6789]

An impact is a positive or negative, direct or indirect, intended or unintended change produced by an intervention. An impact evaluation is a systematic and empirical investigation of the effects of an intervention; it assesses to what extent the outcomes experienced by affected individuals were caused by the intervention in question, and what can be attributed to other factors such as other interventions, socioeconomic trends, and political or environmental conditions. Evaluations can be categorised as formative or summative (table 1).

Approaches such as the Plan, Do, Study, Act cycle[11], which is part of the Model for Improvement, a commonly used tool to test and understand small changes in quality improvement work[12] may be used to undertake formative evaluation.

With either type of evaluation, it is important to be realistic about how long it will take to see the intended effects. Assessment that takes place too soon risks incorrectly concluding that there was no impact. This might lead stakeholders to question the value of the intervention, when later assessment might have shown a different picture. For example, in a small case study of cost savings from proactively managing high risk patients, the costs of healthcare for the eligible intervention population initially increased compared with the comparison population, but after six months were consistently lower.[14]

This article focuses on impact evaluation, but this can only ever address a fraction of questions.[15] Much more can be accomplished if it is supplemented with other qualitative and quantitative methods, including process evaluation. This provides context, assesses how the intervention was implemented, identifies any emerging unintended pathways, and is important for understanding what happened in practice and for identifying areas for improvement.[16] The economic evaluation of healthcare interventions is also important for healthcare decision making, especially with ongoing financial pressures on health services.[17]

What are the right evaluation questions?

An effective impact evaluation begins with the formulation of one or more clear questions driven by the purpose of the evaluation and what you and your stakeholders want to learn. For example, *"What is the impact of case management on patients' experience of care?"*

Formulate your evaluation questions using your understanding of the idea behind your intervention, the implementation challenges, and your knowledge of what data are available to measure outcomes. Review your theory of change or logic model[2122] to understand what inputs and activities were planned, and what outcomes were expected and when. Once you have understood the intended causal pathway, consider the practical aspects of implementation, which include the barriers to change, unexpected changes by recipients or providers, and other influences not previously accounted for. Patient and public involvement (PPI) in setting the right question is strongly recommended for additional insights and meaningful results. For example, if evaluating the impact of case management, you could engage patients to understand what outcomes matter most to them. Healthcare leaders may emphasise metrics such as emergency admissions, but other aspects such as the experience of care might matter more to patients.[523]

What methods can be used to perform an impact evaluation?

Randomised control designs, where individuals are randomly selected to receive either an intervention or a control treatment, are often referred to as the "gold standard" of causal impact evaluation.[24]

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WHAT YOU NEED TO KNOW

- What interventions have you designed or experienced aimed at transforming your service? Have they been evaluated?
- What types of routine data are collected about the care you deliver? Do you know how to access them and use them to evaluate care delivery?
- What resources are available to you to support impact evaluations for interventions?

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Table 1 | Impact evaluations

Formative	Summative	Examples
Conducted during the development or implementation of an intervention	Conducted after the intervention's completion, or at the end of a programme cycle	A formative evaluation of the Whole Systems Integrated Care (WSIC) programme, aimed at integrating health and social care in London, found that difficulties in establishing data sharing and information governance, and differences in professional culture were hampering efforts to implement change[10]
Aims to fine tune or reorient the intervention	Aims to render judgment, or make decisions about the future of the intervention	A summative impact evaluation of an NHS new care model vanguard initiative found that care home residents in Nottinghamshire who received enhanced support had substantially fewer attendances at emergency departments and fewer emergency admissions than a matched control group.[13] This evidence supported the decision by the NHS to roll out the Enhanced Health in Care Homes Model across the country[2]

In large enough samples, the process of randomisation ensures a balance in observed and unobserved characteristics between treatment and control groups. However, while often suitable for assessing, for example, the safety and efficacy of medicines, these designs may be impractical, unethical, or irrelevant when assessing the impact of complex changes to health service delivery.

Observational studies are an alternative approach to estimate causal effects. They use the natural, or unplanned, variation in a population in relation to the exposure to an intervention, or the factors that affect its outcomes, to remove the consequences of a non-randomised selection process.[25] The idea is to mimic a randomised control design by ensuring treated and control groups are equivalent—at least in terms of *observed* characteristics. This can be achieved using a variety of well documented methods, including regression control and matching,[26] eg, propensity scoring[27] or genetic matching.[28] If the matching is successful at producing such groups, and there are also no differences in *unobserved* characteristics, then it can be assumed that the control group outcomes are representative of those that the treated group would have experienced if nothing had changed, ie, the counterfactual. For example, an evaluation of alternative elective surgical interventions for primary total hip replacement on osteoarthritis patients in England and Wales used genetic matching to compare patients across three different prosthesis groups, and reported that the most prevalent type of hip replacement was the least cost effective.[29]

Assessing similarity is only possible in relation to *observed* characteristics, and matching can result in biased estimates if the groups differ in relation to *unobserved* variables that are predictive of the outcome (confounders). It is rarely possible to eliminate this possibility of bias when conducting observational studies, meaning that the interpretation of the findings must always be sensitive to the possibility that the differences in outcomes were caused by a factor other than the intervention. Methods that can help when selection is on unobserved characteristics include difference-in-difference,[30] regression discontinuity,[31] instrumental variables,[18] or synthetic controls.[32] Table 2 gives a summary of selected observational study designs.

Observational studies are often referred to as natural (for natural or unplanned interventions), or quasi (for planned or intentional interventions). Natural experiments are discussed to evaluate population health interventions.[41]

What's wrong with a simple before-and-after study?
Before-and-after studies compare changes in outcomes for the *same* group of patients at a single time point before and after receiving an intervention without reference to a control group. These differ from interrupted time series studies, which compare changes in outcomes for *successive* groups of patients before and after receiving an intervention (the interruption).

Before-and-after studies are useful when it is not possible to include an unexposed control group, or for hypothesis generation.

Table 2 | Observational study designs for quantitative impact evaluation

Method	Strengths and limitations
Matching[33] Aims to find a subset of control group units (eg, individuals or hospitals) with similar characteristics to the intervention group units in the pre-intervention period. For example, impact of enhanced support in care homes in Rushcliffe, Nottinghamshire[13]	Can be combined with other methods, eg, difference-in-differences and regression. Enables straightforward comparison between intervention and control groups. Methods include propensity score matching and genetic matching
Regression control[34] Refers to use of regression techniques to estimate association between an intervention and an outcome while holding the value of the other variables constant, thus adjusting for these variables	Can be beneficial to pre-process the data using matching in addition to regression control. This reduces the dependence of the estimated treatment effect on how the regression models are specified[35]
Difference-in-differences (DiD)[30] Compares outcomes before and after an intervention in intervention and control group units. Controls for the effects of unobserved confounders that do not vary over time, eg, impact of hospital pay for performance on mortality in England[36]	Simple to implement and intuitive to interpret. Depends on the assumption that there are no unobserved differences between the intervention and control groups that vary over time, also referred to as the "parallel trends" assumption
Synthetic controls[32] Typically used when an intervention affects a whole population (eg, region or hospital) for whom a well matched control group comprising whole control units is not available. Builds a "synthetic" control from a weighted average of the control group units, eg, impact of redesigning urgent and emergency care in Northumberland[37]	Allows for unobserved differences between the intervention and control groups to vary over time. The uncertainty of effect estimates is hard to quantify. Produces biased estimates over short pre-intervention periods
Regression discontinuity design[31] Uses quasi-random variations in intervention exposure, eg, when patients are assigned to comparator groups depending on a threshold. Outcomes of patients just below the threshold are compared with those just above, eg, impact of statins on cholesterol by exploiting differences in statin prescribing[38]	There is usually a strong basis for assuming that patients close to either side of the threshold are similar. Because the method only uses data for patients near the threshold, the results might not be generalisable
Interrupted time-series[39] Compares outcomes at multiple time points before and after an intervention (interruption) is implemented to determine whether the intervention has an effect that is statistically significantly greater than the underlying trend, eg, to examine the trends in diagnosis for people with dementia in the UK[40]	Ensures limited impact of selection bias and confounding as a result of population differences but does not generally control for confounding as a result of other interventions or events occurring at the same time as the intervention
Instrumental variables[18] An instrumental variable is a variable that affects the outcome solely through the effect on whether the patient receives the treatment. An instrumental variable can be used to counteract issues of measurement error and unobserved confounders, eg, used to assess delivery of premature babies in dedicated *v* hospital intensive care units[19]	Explicitly addresses unmeasured confounding but conceptually difficult and easily misused. Identification of instrumental variables is not straightforward. Estimates are imprecise (large standard error), biased when sample size is small, and can be biased in large samples if assumptions are even slightly violated[20]

Table 3	Commonly used routine datasets available in the NHS in England	
Dataset	**Dissemination and alternatives**
Hospital episode statistics (HES).[46] HES is a database containing details of all admissions, accident and emergency attendances, and outpatient appointments at NHS England hospitals and NHS England funded treatment centres. Information captured includes clinical information about diagnoses and operations, patient demographics, geographical information, and administrative information such as the data and method of admissions and discharge	HES is available through the Data Access Request Service (DARS),[47] a service provided by NHS Digital. Commissioners, providers in the NHS, and analytics teams working on their behalf, can also access hospital data directly via the Secondary Use Service (SUS).[48] These data are very similar to HES, processed by NHS Digital, and are available for non-clinical uses, including research and planning health services
Primary care data is collected by general practices. Although there is no national standard on how primary care data should be collected and/or reported, there are a limited number of commonly used software providers to record these data. Information captured includes clinical information about diagnoses, treatment, and prescriptions, patient demographics, geographical information, and administrative information on booking and attendance of appointments, and whether appointments relate to a telephone consultation, an in-practice appointment, or a home visit	Commissioners, and analytics teams working on their behalf, can work with an intermediary service called Data Service for Commissioning Regional Office to request access to anonymised patient level general practice data (possibly linked to SUS, described above) for the purpose of risk stratification, invoice validation, and to support commissioning. Anonymised UK primary care records for a representative sample of the population are available for public health research through, for instance, the Clinical Practice Research Datalink.[49]
Mortality data[50] The Office for National Statistics (ONS) maintains a dataset of all registered deaths in England. These data can be linked to routine health data to record deaths that occur outside of hospital	ONS mortality data are routinely processed by NHS Digital, and can be linked to HES data. These data can be requested through the DARS service. When deaths occur in hospital this is typically recorded as part of discharge information
The Mental Health Services Data Set (MHSDS)[51] contains record level data about the care of children, young people, and adults who are in contact with mental health, learning disabilities, or autism spectrum disorder services. These data cover data from April 2016	Like HES, MHSDS is available through the DARS service. Mental health data from before April 2016 have been recorded in the Mental Health Minimum Dataset also disseminated through NHS Digital

However, they are inherently susceptible to bias since changes observed may simply reflect regression to the mean (any changes in outcomes that might occur naturally in the absence of the intervention), or influences or secular trends unrelated to the intervention, eg, changes in the economic or political environment, or a heightened public awareness of issues.

For example, a before-and-after study of the impact of a care coordination service for older people tracked the hospital utilisation of the same patients before and after they were accepted into the service. They found that the service resulted in savings in hospital bed days and attendances at the emergency department.[42] Reduced hospital utilisation could have reflected regression to the mean here rather than the effects of the intervention; for example, a patient could have had a specific health crisis before being invited to join the service and then reverted back to their previous state of health and hospital utilisation for reasons unconnected with the care coordination service.

Various tools are available to evaluate the risk of bias in non-randomised designs due to confounding and other potential biases.[4344]

Where can I find suitable routine data?

Healthcare systems generate vast amounts of data as part of their routine operation. These datasets are often designed to support direct care, and for administrative purposes, rather than for research, and use of routinely collected data for evaluating changes in health service delivery is not without pitfalls. For example, any variation observed between geographical regions, providers, and sometimes individual clinicians may reflect real and important variations in the actual healthcare quality provided, but can also result from differences in measurement.[45] However, routine data can be a rich source of information on a large group of patients with different conditions across different geographical regions. Often, data have been collected for many years, enabling construction of individual patient histories describing healthcare utilisation, diagnoses, comorbidities, prescription of medication, and other treatments.

Some of these data are collected centrally, across a wider system, and routinely shared for research and evaluation purposes, eg, secondary care data in England (Hospital Episode Statistics), or Medicare Claims data in the United States. Other sources, such as primary care data, are often collected at a more local level, but can be accessed through, or on behalf of, healthcare commissioners,

provided the right information governance arrangements are in place. Pseudonymised records, where any identifying information is removed or replaced by an artificial identifier, are often used to support evaluation while maintaining patient confidentiality. See table 3 for commonly used routine datasets available in England.

Healthcare records can often be linked across different sources as a single patient identifier is commonly used across a healthcare system, eg, the use of an NHS number in the UK. Using a common pseudonym across different data sources can support linkage of pseudonymised records. Linking into publicly available sources of administrative data and surveys can further enrich healthcare records. Commonly used administrative data available for UK populations include measures of GP practice quality and outcomes from the Quality and Outcomes Framework (QOF),[52] deprivation, rurality, and demographics from the 2011 Census,[53] and patient experience from the GP Patient Survey.[54]

Are there any additional considerations?

It is essential to consider threats to validity when designing and evaluating an impact evaluation; validity relates to whether an evaluation is measuring what it is claiming to measure. See Rothman et al[55] for further discussion.

Internal validity refers to whether the effects observed are due to the intervention and not some other confounding factor. Selection bias, which results from the way in which subjects are recruited, or from differing rates of participation due, for example, to age, gender, cultural or socioeconomic factors, is often a problem in non-randomised designs. Care must be taken to account for such biases when interpreting the results of an impact evaluation. Sensitivity analyses should be performed to provide reassurance regarding the plausibility of causal inferences.

External validity refers to the extent to which the results of a study can be generalised to other settings. Understanding the societal, economic, health system, and environmental context in which an intervention is delivered, and which makes its impact unique, is critical when interpreting the results of evaluations, and considering whether they apply to your setting.[56] Descriptions of context should be as rich as possible.

Often, the impact of an intervention is likely to vary depending on the characteristics of patients. These can be usefully explored in subgroup analyses.[57]

Clear and transparent reporting using established guidelines (eg, STROBE[58] or TREND[59])to describe the intervention, study

population, assignment of treatment, and control groups, and methods used to estimate impact should be followed. Limitations arising as a result of inherent biases, or validity, should be clearly acknowledged.

Around the world, many interventions designed to improve health and healthcare are under way. An evaluation is an essential part of understanding what impact these changes are having, for whom and in what circumstances, and help inform future decisions about improvement and further roll out. There is no standard, "one size fits all" recipe for a good evaluation: it must be tailored to the project at hand. Understanding the overarching principles and standards is the first step towards a good evaluation.

Further Resources
See *The Health Foundation. Evaluation: what to consider. 2015*[60] for a list of websites, articles, webinars and other guidance on various aspects of impact evaluation, which may help locate further information for the planning, interpretation, and development of a successful impact evaluation.[5 23 55]

EDUCATION INTO PRACTICE

- What interventions have you designed or experienced aimed at transforming your service? Have they been evaluated?
- What types of routine data are collected about the care you deliver? Do you know how to access them and use them to evaluate care delivery?
- What resources are available to you to support impact evaluations for interventions?

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Quality improvement into practice

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The benefits to front line clinicians of participating in quality improvement (QI) activity are promoted in many health systems. QI can represent a valuable opportunity for individuals to be involved in leading and delivering change, from improving individual patient care to transforming services across complex health and care systems.[1]

However, it is not clear that this promotion of QI has created greater understanding of QI or widespread adoption. QI largely remains an activity undertaken by experts and early adopters, often in isolation from their peers.[2] There is a danger of a widening gap between this group and the majority of healthcare professionals.

This article will make it easier for those new to QI to understand what it is, where it fits with other approaches to improving care (such as audit or research), when best to use a QI approach, making it easier to understand the relevance and usefulness of QI in delivering better outcomes for patients.

How is quality improvement defined?

There are many definitions of QI (box 1). The *BMJ*'s Quality Improvement series uses the Academy of Medical Royal Colleges definition.[6] Rather than viewing QI as a single method or set of tools, it can be more helpful to think of QI as based on a set of principles common to many of these definitions: a systematic continuous approach that aims to solve problems in healthcare, improve service provision, and ultimately provide better outcomes for patients.

In this article we discuss QI as an approach to improving healthcare that follows the principles outlined in box 2; this may

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HOW PATIENTS WERE INVOLVED IN THE CREATION OF THIS ARTICLE P

This article was conceived and developed in response to conversations with clinicians and patients working together on co-produced quality improvement and research projects in a large UK hospital. The first iteration of the article was reviewed by an expert patient, and, in response to their feedback, we have sought to make clearer the link between understanding the issues raised and better patient care.

WHAT YOU NEED TO KNOW

- Thinking of quality improvement (QI) as a principle-based approach to change provides greater clarity about (a) the contribution QI offers to staff and patients, (b) how to differentiate it from other approaches, (c) the benefits of using QI together with other change approaches
- QI is not a silver bullet for all changes required in healthcare: it has great potential to be used together with other change approaches, either concurrently (using audit to inform iterative tests of change) or consecutively (using QI to adapt published research to local context)
- As QI becomes established, opportunities for these collaborations will grow, to the benefit of patients.

How this article was made

AB and FO are both specialist quality improvement practitioners and have developed their expertise working in QI roles for a variety of UK healthcare organisations. The analysis presented here arose from AB and FO's observations of the challenges faced when introducing QI, with healthcare providers often unable to distinguish between QI and other change approaches, making it difficult to understand what QI can do for them.

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be a useful reference to consider how particular methods or tools could be used as part of a QI approach.

What other approaches to improving healthcare are there?

Taking considered action to change healthcare for the better is not new, but QI as a distinct approach to improving healthcare is a relatively recent development. There are many well established approaches to evaluating and making changes to healthcare services in use, and QI will only be adopted more widely if it offers a new perspective or an advantage over other approaches in certain situations.

A non-systematic literature scan identified the following other approaches for making change in healthcare: research, clinical audit, service evaluation, and clinical transformation. We also identified innovation as an important catalyst for change, but we did not consider it an approach to evaluating and changing healthcare services so much as a catch-all term for describing the development and introduction of new ideas into the system. A summary of the different approaches and their definition is shown in box 3. Many have elements in common with QI, but there are important difference in both intent and application. To be useful to clinicians and managers, QI must find a role within healthcare that complements research, audit, service evaluation, and clinical transformation while retaining the core principles that differentiate it from these approaches.

Why do we need to make this distinction for QI to succeed?

Improvement in healthcare is 20% technical and 80% human.[22] Essential to that 80% is clear communication, clarity of approach, and a common language. Without this shared understanding of QI as a distinct approach to change, QI work risks straying from the core principles outlined above, making it less likely to succeed.

Box 1: Definitions of quality improvement

- Improvement in patient outcomes, system performance, and professional development that results from a combined, multidisciplinary approach in how change is delivered.[3]
- The delivery of healthcare with improved outcomes and lower cost through continuous redesigning of work processes and systems.[4]
- Using a systematic change method and strategies to improve patient experience and outcome.[5]
- To make a difference to patients by improving safety, effectiveness, and experience of care by using understanding of our complex healthcare environment, applying a systematic approach, and designing, testing, and implementing changes using real time measurement for improvement.[6]

Box 2: Principles of QI

- *Primary intent*—To bring about measurable improvement to a specific aspect of healthcare delivery, often with evidence or theory of what might work but requiring local iterative testing to find the best solution.[7]

- *Employing an iterative process of testing change ideas*—Adopting a theory of change which emphasises a continuous process of planning and testing changes, studying and learning from comparing the results to a predicted outcome, and adapting hypotheses in response to results of previous tests.[8 9]

- *Consistent use of an agreed methodology*—Many different QI methodologies are available; commonly cited methodologies include the Model for Improvement, Lean, Six Sigma, and Experience-based Co-design.[4] Systematic review shows that the choice of tools or methodologies has little impact on the success of QI provided that the chosen methodology is followed consistently.[10] Though there is no formal agreement on what constitutes a QI tool, it would include activities such as process mapping that can be used within a range of QI methodological approaches. NHS Scotland's Quality Improvement Hub has a glossary of commonly used tools in QI.[11]

- *Empowerment of front line staff and service users*—QI work should engage staff and patients by providing them with the opportunity and skills to contribute to improvement work. Recognition of this need often manifests in drives from senior leadership or management to build QI capability in healthcare organisations, but it also requires that frontline staff and service users feel able to make use of these skills and take ownership of improvement work.[12]

- *Using data to drive improvement*—To drive decision making by measuring the impact of tests of change over time and understanding variation in processes and outcomes. Measurement for improvement typically prioritises this narrative approach over concerns around exactness and completeness of data.[13 14]

- *Scale-up and spread, with adaptation to context*—As interventions tested using a QI approach are scaled up and the degree of belief in their efficacy increases, it is desirable that they spread outward and be adopted by others. Key to successful diffusion of improvement is the adaption of interventions to new environments, patient and staff groups, available resources, and even personal preferences of healthcare providers in surrounding areas, again using an iterative testing approach.[15 16]

If practitioners cannot communicate clearly with their colleagues about the key principles and differences of a QI approach, there will be mismatched expectations about what QI is and how it is used, lowering the chance that QI work will be effective in improving outcomes for patients.[23]

There is also a risk that the language of QI is adopted to describe change efforts regardless of their fidelity to a QI approach, either due to a lack of understanding of QI or a lack of intention to carry it out consistently.[9] Poor fidelity to the core principles of QI reduces its effectiveness and makes its desired outcome less likely, leading to wasted effort by participants and decreasing its credibility.[2 8 24] This in turn further widens the gap between advocates of QI and those inclined to scepticism, and may lead to missed opportunities to use QI more widely, consequently leading to variation in the quality of patient care.

Without articulating the differences between QI and other approaches, there is a risk of not being able to identify where a QI approach can best add value. Conversely, we might be tempted to see QI as a "silver bullet" for every healthcare challenge when a different approach may be more effective. In reality it is not clear that QI will be fit for purpose in tackling all of the wicked problems of healthcare delivery and we must be able to identify the right tool for the job in each situation.[25] Finally, while different approaches will be better suited to different types of challenge, not having a clear understanding of how approaches differ and complement each other may mean missed opportunities for multi-pronged approaches to improving care.

What is the relationship between QI and other approaches such as audit?
Academic journals, healthcare providers, and "arms-length bodies" have made various attempts to distinguish between the different approaches to improving healthcare.[19 26-28] However, most comparisons do not include QI or compare QI to only one or two of the other approaches.[7 29-31] To make it easier for people to use QI approaches effectively and appropriately, we summarise the similarities, differences, and crossover between QI and other approaches to tackling healthcare challenges (fig 1).

QI and research
Overview
Research aims to generate new generalisable knowledge, while QI typically involves a combination of generating new knowledge or implementing existing knowledge within a specific setting.[32] Unlike research, including pragmatic research designed to test effectiveness of interventions in real life, QI does not aim to provide generalisable knowledge. In common with QI, research requires a consistent methodology. This method is typically used, however, to prove or disprove a fixed hypothesis rather than the adaptive hypotheses developed through the iterative testing of ideas typical of QI. Both research and QI are interested in the environment where

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Box 3: Alternatives to QI

Research—The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.[17]

Clinical audit—A way to find out if healthcare is being provided in line with standards and to let care providers and patients know where their service is doing well, and where there could be improvements.[18]

Service evaluation—A process of investigating the effectiveness or efficiency of a service with the purpose of generating information for local decision making about the service.[19]

Clinical transformation—An umbrella term for more radical approaches to change; a deliberate, planned process to make dramatic and irreversible changes to how care is delivered.[20]

Innovation—To develop and deliver new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health. Health innovation responds to unmet needs by employing new ways of thinking and working.[21]
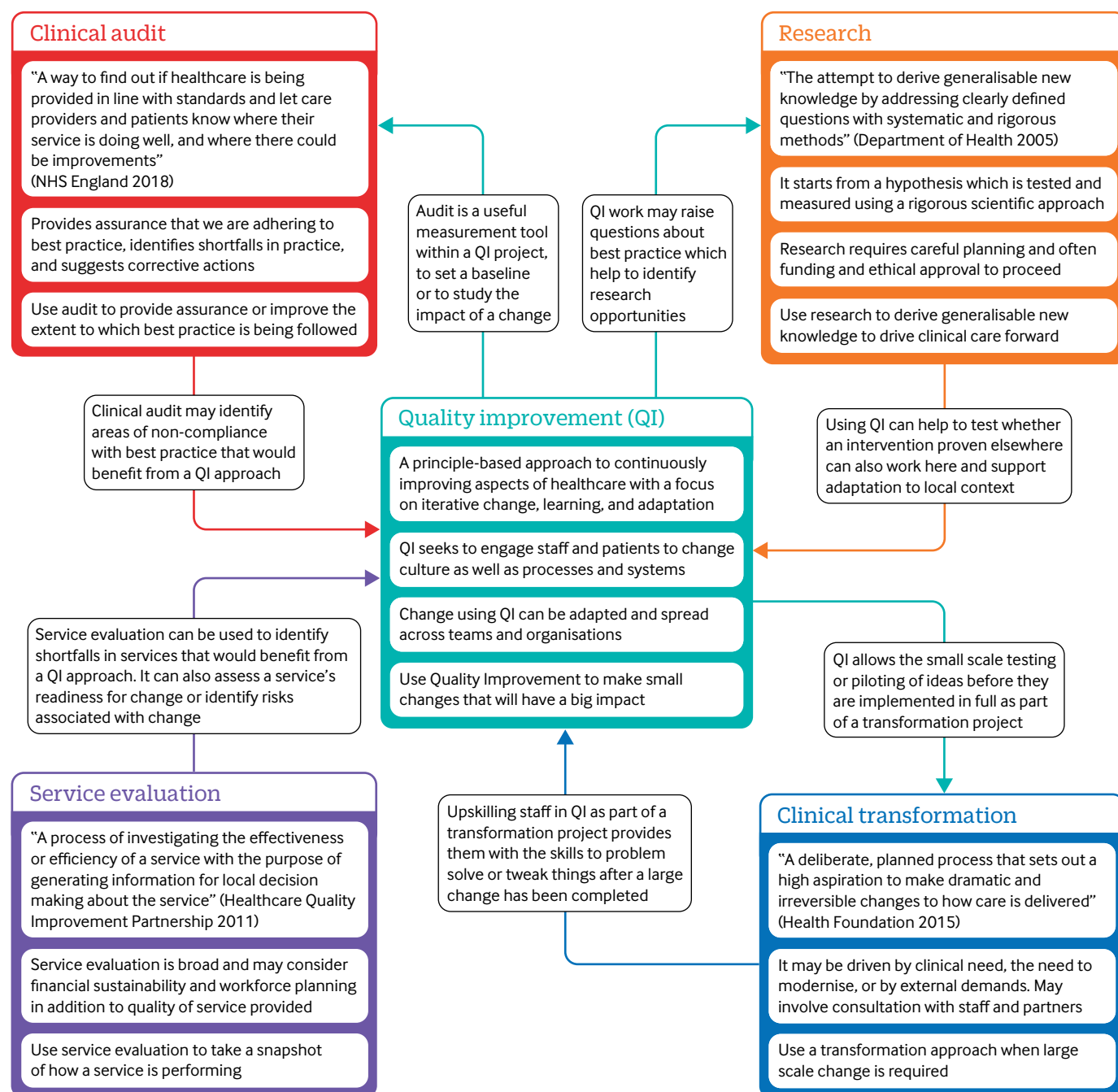

Fig 1 | How quality improvement interacts with other approaches to improving healthcare

work is conducted, though with different intentions: research aims to eliminate or at least reduce the impact of many variables to create generalisable knowledge, whereas QI seeks to understand what works best in a given context. The rigour of data collection and analysis required for research is much higher; in QI a criterion of "good enough" is often applied.

Relationship with QI
Though the goal of clinical research is to develop new knowledge that will lead to changes in practice, much has been written on the lag time between publication of research evidence and system-wide adoption, leading to delays in patients benefitting from new treatments or interventions.[33] QI offers a way to iteratively test the conditions required to adapt published research findings to the local context of individual healthcare providers, generating new knowledge in the process. Areas with little existing knowledge requiring further research may be identified during improvement activities, which in turn can form research questions for further study. QI and research also intersect in the field of improvement science, the academic study of QI methods which seeks to ensure QI is carried out as effectively as possible.[34]

QI and clinical audit
Overview
Clinical audit is closely related to QI: it is often used with the intention of iteratively improving the standard of healthcare, albeit in relation to a pre-determined standard of best practice.[35] When used iteratively, interspersed with improvement action, the clinical

audit cycle adheres to many of the principles of QI. However, in practice clinical audit is often used by healthcare organisations as an assurance function, making it less likely to be carried out with a focus on empowering staff and service users to make changes to practice.[36] Furthermore, academic reviews of audit programmes have shown audit to be an ineffective approach to improving quality due to a focus on data collection and analysis without a well developed approach to the action section of the audit cycle.[37] Clinical audits, such as the National Clinical Audit Programme in the UK (NCAPOP), often focus on the management of specific clinical conditions. QI can focus on any part of service delivery and can take a more cross-cutting view which may identify issues and solutions that benefit multiple patient groups and pathways.[30]

Relationship with QI
Audit is often the first step in a QI process and is used to identify improvement opportunities, particularly where compliance with known standards for high quality patient care needs to be improved. Audit can be used to establish a baseline and to analyse the impact of tests of change against the baseline. Also, once an improvement project is under way, audit may form part of rapid cycle evaluation, during the iterative testing phase, to understand the impact of the idea being tested. Regular clinical audit may be a useful assurance tool to help track whether improvements have been sustained over time.

QI and service evaluation
Overview
In practice, service evaluation is not subject to the same rigorous definition or governance as research or clinical audit, meaning

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Scenario: QI for translational research

Newly published research shows that a particular physiotherapy intervention is more clinically effective when delivered in short, twice-daily bursts rather than longer, less frequent sessions. A team of hospital physiotherapists wish to implement the change but are unclear how they will manage the shift in workload and how they should introduce this potentially disruptive change to staff and to patients.

• *Before continuing reading think about your own practice*—How would you approach this situation, and how would you use the QI principles described in this article?

Adopting a QI approach, the team realise that, although the change they want to make is already determined, the way in which it is introduced and adapted to their wards is for them to decide. They take time to explain the benefits of the change to colleagues and their current patients, and ask patients how they would best like to receive their extra physiotherapy sessions.

The change is planned and tested for two weeks with one physiotherapist working with a small number of patients. Data are collected each day, including reasons why sessions were missed or refused. The team review the data each day and make iterative changes to the physiotherapist's schedule, and to the times of day the sessions are offered to patients. Once an improvement is seen, this new way of working is scaled up to all of the patients on the ward.

The findings of the work are fed into a service evaluation of physiotherapy provision across the hospital, which uses the findings of the QI work to make recommendations about how physiotherapy provision should be structured in the future. People feel more positive about the change because they know colleagues who have already made it work in practice.

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that there are inconsistencies in the methodology for carrying it out. While the primary intent for QI is to make change that will drive improvement, the primary intent for evaluation is to assess the performance of current patient care.[38] Service evaluation may be carried out proactively to assess a service against its stated aims or to review the quality of patient care, or may be commissioned in response to serious patient harm or red flags about service performance. The purpose of service evaluation is to help local decision makers determine whether a service is fit for purpose and, if necessary, identify areas for improvement.

Relationship with QI
Service evaluation may be used to initiate QI activity by identifying opportunities for change that would benefit from a QI approach. It may also evaluate the impact of changes made using QI, either during the work or after completion to assess sustainability of improvements made. Though likely planned as separate activities, service evaluation and QI may overlap and inform each other as they both develop. Service evaluation may also make a judgment about a service's readiness for change and identify any barriers to, or prerequisites for, carrying out QI.

QI and clinical transformation
Overview
Clinical transformation involves radical, dramatic, and irreversible change—the sort of change that cannot be achieved through continuous improvement alone. As with service evaluation, there is no consensus on what clinical transformation entails, and it may be best thought of as an umbrella term for the large scale reform or redesign of clinical services and the non-clinical services that support them.[20 39] While it is possible to carry out transformation activity that uses elements of QI approach, such as effective engagement of the staff and patients involved, QI which rests on iterative test of change cannot have a transformational approach—that is, one-off, irreversible change.

Relationship with QI
There is opportunity to use QI to identify and test ideas before full scale clinical transformation is implemented. This

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Scenario: Audit and QI

A foundation year 2 (FY2) doctor is asked to complete an audit of a pre-surgical pathway by looking retrospectively through patient documentation. She concludes that adherence to best practice is mixed and recommends: "Remind the team of the importance of being thorough in this respect and re-audit in 6 months." The results are presented at an audit meeting, but a re-audit a year later by a new FY2 doctor shows similar results.

• *Before continuing reading think about your own practice*—How would you approach this situation, and how would you use the QI principles described in this paper?

Contrast the above with a team-led, rapid cycle audit in which everyone contributes to collecting and reviewing data from the previous week, discussed at a regular team meeting. Though surgical patients are often transient, their experience of care and ideas for improvement are captured during discharge conversations. The team identify and test several iterative changes to care processes. They document and test these changes between audits, leading to sustainable change. Some of the surgeons involved work across multiple hospitals, and spread some of the improvements, with the audit tool, as they go.

Scenario: QI and clinical transformation

An NHS trust's human resources (HR) team is struggling to manage its junior doctor placements, rotas, and on-call duties, which is causing tension and has led to concern about medical cover and patient safety out of hours. A neighbouring trust has launched a smartphone app that supports clinicians and HR colleagues to manage these processes with the great success.

This problem feels ripe for a transformation approach—to launch the app across the trust, confident that it will solve the trust's problems.

- *Before continuing reading think about your own organisation*—What do you think will happen, and how would you use the QI principles described in this article for this situation?

Outcome without QI

Unfortunately, the HR team haven't taken the time to understand the underlying problems with their current system, which revolve around poor communication and clarity from the HR team, based on not knowing who to contact and being unable to answer questions. HR assume that because the app has been a success elsewhere, it will work here as well.

People get excited about the new app and the benefits it will bring, but no consideration is given to the processes and relationships that need to be in place to make it work. The app is launched with a high profile campaign and adoption is high, but the same issues continue. The HR team are confused as to why things didn't work.

Outcome with QI

Although the app has worked elsewhere, rolling it out without adapting it to local context is a risk – one which application of QI principles can mitigate.

HR pilot the app in a volunteer speciality after spending time speaking to clinicians to better understand their needs. They carry out several tests of change, ironing out issues with the process as they go, using issues logged and clinician feedback as a source of data. When they are confident the app works for them, they expand out to a directorate, a division, and finally the transformational step of an organisation-wide rollout can be taken.

has the benefit of engaging staff and patients in the clinical transformation process and increasing the degree of belief that clinical transformation will be effective or beneficial. Transformation activity, once completed, could be followed up with QI activity to drive continuous improvement of the new process or allow adaption of new ways of working. As interventions made using QI are scaled up and spread, the line between QI and transformation may seem to blur. The shift from QI to transformation occurs when the intention of the work shifts away from continuous testing and adaptation into the wholesale implementation of an agreed solution.

EDUCATION INTO PRACTICE

Next time when faced with what looks like a quality improvement (QI) opportunity, consider asking:

- How do you know that QI is the best approach to this situation? What else might be appropriate?
- Have you considered how to ensure you implement QI according to the principles described above?
- Is there opportunity to use other approaches in tandem with QI for a more effective result?

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How to improve care across boundaries

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Integrated care is a healthcare approach focused around the patient perspective, which aims to promote better coordination and continuity of care across organisational boundaries.[1] Integrated care can improve patient experience[2] and reduce duplication.[3] However, structural and cultural differences between physical and mental health services and across the primary and secondary care divide can impede its delivery. Perverse financial incentives and outdated expectations of doctor and patient roles are further barriers to improving care across boundaries.[4] Changes in service commissioning and organisational culture may promote integrated care, but its delivery ultimately depends on the skills, behaviour, and engagement of healthcare workers.

This article will explore the rationale and evidence base for integrated care and highlight salient examples of quality improvement (QI) across organisational boundaries in the UK and beyond. We aim to provide clinicians with a practical guide to implementing locally relevant, sustainable, and patient-centred change across boundaries.

Why is it important to improve care across boundaries?

The consequences of ill health extend beyond physical symptoms. Disease can affect an individual's mental health, independence and family life. Patients want to receive responsive and holistic care from a trusted professional, in the right place and at the right time. Siloed and fragmented health systems encourage professionals to treat clinical problems in isolation; patients' wider health and social and spiritual needs may remain unmet. Integrated care moves beyond reductive and compartmentalised approaches towards cross-boundary, coordinated, and person-centred care.

In the UK, many primary and secondary care organisations are working at maximum capacity. Finding new ways of working that bridge traditional divides can improve patient experience without overburdening professionals. Clinicians can learn new skills from their colleagues, and, by engaging in genuine co-production, discover what really matters to patients and carers. This is especially pertinent to patients living with long term conditions, who require regular contact with healthcare services.

What is the evidence for integrated care?

Most integrated care evaluations have been performed in Western European and North American settings.[5] Several thousand studies have been conducted worldwide, and the volume of literature has expanded threefold since 2007.[6] Integrated care models have largely focused on adults with long term conditions, though specialty-specific models have been described.[7] Interventions are often complex and multifaceted. They include the introduction of joint clinics, multidisciplinary team meetings, staff education, and new financial models. Outcomes of interest include patient and staff satisfaction, health and social care resource utilisation and cost.[5]

High quality systematic reviews suggest that integrated care can deliver improvements in patient experience and access to healthcare.[5 8] Evidence for economic benefits and improvements in staff satisfaction is more equivocal.[9]

Most integrated care studies are small and descriptive and fail to account for the effects of local contextual factors on outcomes.[10] The absence of well matched control groups in many interventional studies has frustrated efforts to ascertain precisely what caused an intervention to succeed or fail, limiting generalisability and spread of best practice.[11] Successful implementation of change across boundaries seems to be context-dependent. Emerging evidence has identified organisational culture, motivation of front line professionals, and funding[12] as key factors influencing the delivery of integrated care.

What are the challenges and impediments to improving quality across whole systems?

Quality improvement (QI) across boundaries may form part of a wider strategy supporting integration of care at local, regional or national levels, or stem from grassroots initiatives conducted by small clinician and patient networks. These "top-down" and "bottom-up" approaches illustrate that there is no "one size fits all" method to achieve integrated care. None the less, several factors consistently promote (box 1) and impede improvement work.

Improving quality across organisational boundaries requires dedicated leadership from clinicians, managers, commissioners, and patients and carers. NHS Improvement estimates that 5% of an organisation's workforce must receive formal training in QI methodology to foster a culture of continuous improvement,[13] but providing time and space for QI is challenging in the current climate.[14]

Working across boundaries calls for cultivation of a shared vision between groups with potentially competing interests. Stakeholders must invest time and effort in building relationships,

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HOW PATIENTS WERE INVOLVED IN THE CREATION OF THIS ARTICLE

When planning this article, we asked a parent volunteer with experience of leading community based quality improvement (QI) work in North West London for her views on this topic. She said that sustained support from clinical staff was crucial in driving patient-led improvement efforts; her involvement in QI also allowed her to see the difference she could make to her local community. A second patient provided a written account summarising the benefits he had experienced as a result of improved coordination of care for his long term conditions. He also read through and commented on the final draft of this article.

WHAT YOU NEED TO KNOW

- Integrated care aims to improve coordination and continuity of care for patients across organisational boundaries
- There are many different approaches to improving care across boundaries
- Improving care calls for effective and accountable leadership, agreement on a shared vision of improvement, and sustained patient involvement

and larger organisations must convince smaller providers that integrated care will provide mutual benefits rather than one-sided financial returns.[15] Top-down approaches may necessitate changes in commissioning practices to provide financial incentives for collaboration.[1]

Separate computer systems in primary and secondary care frustrate clinicians' efforts to form a holistic impression of a patient's health needs and institute optimal treatment. Robust information governance frameworks and data sharing agreements are needed to promote confidence in using electronic shared records and other tools.

The patient perspective is central to all integrated care programmes. Where possible, patients should be involved in planning, conducting, and evaluating improvement work, with sufficient support to avoid tokenistic engagement.[16] Efforts must be made to reach vulnerable and disadvantaged patient groups to avoid the unintended consequence of building inequality into integrated care models.[17]

How to do it well

Clinicians, commissioners, and policymakers working across the health system need to understand which behaviour changes promote integrated care and how best to implement them. They are currently limited by a lack of high quality evidence.

Current evidence suggests that there is no universal method to improve care across boundaries. Strategic and grassroots approaches are not mutually exclusive and can be synergistic in driving change. Commissioning for improvement can remove financial barriers to collaboration, but commissioning alone may be insufficient to generate sustainable change.[18] Patient populations exhibit different behaviours and health beliefs, so we must canvass professionals and patients to identify locally relevant and tractable change ideas. The perspectives of general practitioners (GPs)—a group with substantial social capital[19] and a rounded

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Box 1: General principles supporting improvement across whole systems

Stakeholder engagement
- Identify and engage stakeholders affected by changes—patients and staff
- Identify and engage people who are central to the success of the project—senior clinicians, managers, and commissioners

Agree coordinated strategy
- Develop shared objectives
- Clearly assign professional responsibility for clinical and administrative tasks
- Establish provisional timeframe for interventions, analysis, and feedback

Effective and accountable leadership
- Flatten hierarchies to encourage staff feedback during periods of change
- Advocate for patient involvement

Maintain staff and patient involvement and momentum
- Inter-professional and patient education
- Building relationships within and between clinical teams
- Training and up-skilling healthcare professionals

Meaningful patient engagement
- Involve patients in all stages of QI from design to dissemination
- Measure outcomes that matter to patients
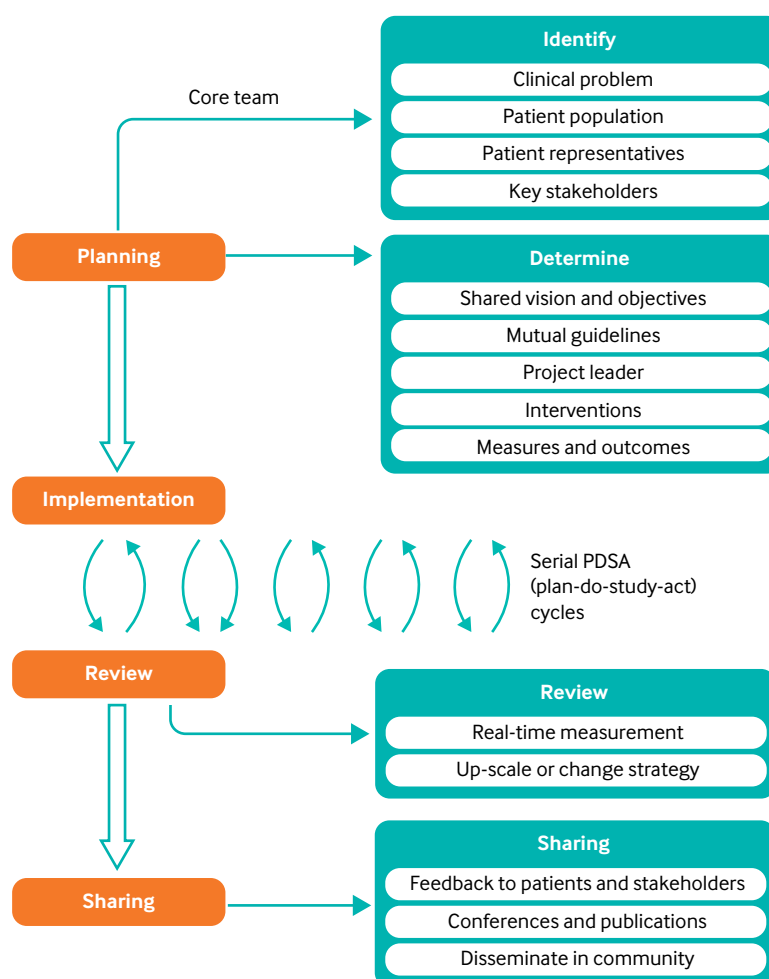- Assign clear roles and responsibilities and manage expectations

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understanding of patient problems—are therefore invaluable. Professionals must show leadership to build networks and give patients a voice; these skills can be honed through participation in QI forums and formal training programmes.

As those most affected by changes to health systems, patients should be placed at the centre of service redesign. Co-production allows professionals to see and learn from the patient's perspective, but patient involvement will be meaningful and sustainable only if patients are involved from the outset, clear on their responsibilities, and receive support from senior clinicians and managers. Careful thought should be given to involving vulnerable patients or their advocates to avoid exacerbating existing health inequalities.

In our experience, building relationships, maintaining patient involvement, and developing clinical leadership are essential (fig 1).[20] The following examples highlight approaches that clinical teams have taken to address these challenges in the UK and beyond. Table 1 shows a worked example of a QI project across organisational boundaries.

Building relationships

Connecting Care for Adults (CC4A), a team of hospital specialists based at Imperial College Healthcare NHS Trust, has developed a model that up-skills GPs caring for adults with long term conditions. This grassroots initiative was embedded within an overarching programme that seeks to deliver integrated care across North West London through service commissioning.[18] Specialists and GPs conducted joint virtual registry reviews for patients living with chronic illnesses such as heart failure. Clinicians used a digital shared care record integrating primary, secondary, and social care data from eight London boroughs to create personalised care plans. GPs felt more confident in supporting their patients; specialists received detailed feedback on their correspondence with primary care; and patients had their care optimised by a specialist physician without attending in person.[21]

The sustained success of this approach rests on the strength of the relationships built between GPs and specialists, rational use of digital tools, and inter-professional feedback and education. Box 2 contains a patient's account of the impact of this intervention on his experience of living with long term conditions.

Patient involvement

As those most affected by QI and clinical transformation projects, patients can and should play a role in their design. Several prominent examples of patient involvement in QI come from the Swedish region of Jönköping, which boasts a dedicated centre for innovation and improvement known as the Qulturum. This provides patients and healthcare professionals with training to enhance the patient voice and incorporate it into QI. Patients are invited to explore their experiences with clinicians at informal coffee mornings and contribute to simulations that seek to redesign clinical pathways around the patient experience.[22]

For example, one group of patients has worked with specialist nurses to develop a new method of dialysis that maximises patient autonomy and increases system capacity in an area with rising demand. Dialysis-dependent patients attending the county's Ryhov Hospital are trained to use and maintain dialysis equipment independently. In the words of Goran Henriks, chief executive of the Qulturum: "[Patients] no longer think of themselves as sick people, but as healthy people with a need for dialysis."[23]

Leadership

Several organisations now seek to provide clinicians with formal training in leadership and improvement science, while others

Fig 1 | Stepwise approach to delivering improved care across boundaries. Adapted with permission from Kvamme et al.[20]

promote collaboration between QI leaders to hasten the spread of ideas and best practice.

The adoption of "Big Rooms" across the UK represents a paradigm shift in the field of QI. These QI forums, which bring frontline staff together in structured weekly meetings, provide an environment in which QI can thrive. Trained "flow coaches" work with colleagues to develop a systematic plan for improvement of a patient pathway using QI techniques and tools including stakeholder engagement, logic models, and process mapping. Staff use plan-do-study-act (PDSA) cycles to evaluate small tests of change, and clinical data are displayed in statistical process control charts to monitor progress.[24]

The team behind the UK's first Big Room has now established a national Flow Coaching Academy in Sheffield. Frontline staff from across the UK undertake a 12 month programme that trains them to coach Big Rooms in their workplace. Big Rooms have already produced impressive results, such as a reduction in time to surgery in patients with acute cholecystitis and a reduction in sepsis related mortality among hospital inpatients.[25] The success of this model stems from multidisciplinary team working, strong leadership from coaches and clinicians, and sustained engagement of frontline staff, who can suggest and test locally relevant change ideas.

In primary care, emerging leadership initiatives such as "Next Generation GP" aim to provide trainees with the skills

Table 1 | Worked example of a project to improve the recognition and management of diabetic peripheral neuropathy in adult patients

Key stage	Specific example
Clinical problem	Management of diabetic peripheral neuropathy
Patient population	Patients >40 years of age living with type 1 or 2 diabetes and under the care of a single primary care network
Patient representatives	Invite 4-5 patients to participate—ideally from different GP practices and backgrounds and with different disease severity
Key stakeholders	Patients, carers, podiatrists, general practitioners, district nurses, specialist nurses, endocrinologists, orthopaedic and vascular surgeons
Shared vision or objective	Improved recognition, management, and prevention of diabetic peripheral neuropathy in primary and secondary care
Shared guidelines	Mutually acceptable guidelines for referral to secondary care
Nominate project leader	Diabetic specialist nurse, podiatrist, or general practitioner
Plan interventions	Multidisciplinary team meetings to facilitate personalised care planning. Joint clinics with specialist nurses or podiatrists in primary care. Peer mentoring sessions led by patients
Measures that matter to patients and clinicians	Outcome measures—Number of days per month when activity limited by symptoms; hospitalisation; number of amputations Process measures—Attendance at peer mentoring sessions

Box 2: Patient perspective on remote registry reviews for chronic disease

I am fortunate to be under the care of a clinic which has the benefit of virtual specialist support; many of my conditions are long term and require a high level of monitoring and care. My team at the clinic are [now] able to coordinate this so much better...leaving me to lead a healthier life with fewer outpatient appointments. I much prefer this to the standard approach in either the NHS or my private appointments, where it can take many months to find solutions and clearly my health would be at risk of deterioration.

A particular benefit is that I get specialist opinions about my conditions and treatment not only from the specialist consultants, whom I sometimes see privately, but also from the clinic's NHS consultants who see the results of my pathology and other tests and can discuss them with my team at the clinic. I would say that it has improved my relationship with my primary care team, and this can only be a good thing—the patient experience is much improved.

needed to shape the system around them. Trainees participate in regular workshops that empower them to enact change and provide a forum to share leaders' personal stories. This helps them to understand the opportunities and challenges faced by leaders in primary, secondary, and social care.[26] For those with more experience, the Health Foundation has established the Q Community, which aims to connect over 3000 QI leaders across the UK. This initiative allows clinicians to pool resources and expertise and promotes collaboration to extend the scope and reach of improvement work.[27]

Additional education resources

- NHS Improvement. Improvement Fundamentals. https://www.england.nhs.uk/sustainableimprovement/improvement-fundamentals/
  - Free online platform offering self directed mini-courses on quality improvement (QI) for health and social care professionals. Registration required
- NHS Leadership Academy. Edward Jenner programme. https://www.leadershipacademy.nhs.uk/programmes/the-edward-jenner-programme/
  - Free online courses targeted at early career professionals. Completion of Launch and Foundations modules leads to an NHS Leadership Academy Award in Leadership Foundations. Registration required
- Harvard University. Improving global health: focusing on quality and safety. https://www.edx.org/course/improving-global-health-focusing-on-quality-and-safety
  - Massive open online course developed by Harvard University. Free to enrol and participate; registration fee for final certificate
- Healthcare Quality Improvement Partnership. https://www.hqip.org.uk/
  - Independent organisation that supports development of QI. Free resources include guides to promoting involvement of patients and junior doctors in clinical audit and improvement work

Information source for patients

- The Health Foundation. Quality improvement made simple. https://www.health.org.uk/publications/quality-improvement-made-simple
  - This accessible guide from the Health Foundation provides an overview of the importance of QI in the NHS and overseas

Conclusion

Integrated care aims to improve patient experience by providing more holistic, coordinated, and person-centred care. Improving quality across whole systems requires stakeholder engagement, agreement on a shared vision, clinical leadership, and patient involvement. Policy levers, commissioning, and organisational culture can promote integrated care, but the different health beliefs and behaviours of patient populations dictate that there is no universal effective approach. Ultimately, the delivery of integrated care depends on skilled and motivated frontline professionals with adequate time, space, and support for innovation and improvement.

EDUCATION INTO PRACTICE

- Does your trust or general practice offer training in quality improvement (QI) methodology to staff?
- How can you empower your patient population to become involved in QI?
- What would you like to learn from your colleagues in primary or secondary care?

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How to embed quality improvement into medical training

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Training was recognised as a "bridge to quality" 20 years ago[1] and quality improvement is now integrated into appraisal for doctors in training[2] and outcomes for undergraduate medical education.[3] In the UK, expectations for training of doctors in their first two years after graduation are set by the UK Foundation Year curriculum, which states that FY2 doctors are required to contribute significantly to at least one quality improvement project and report their work in their e-portfolio.[4]

Two systematic reviews[5 6] found that teaching quality improvement and patient safety to trainees frequently resulted in changes in clinical processes. Subsequently, a realist review[7] and a systematic review[8] have focused specifically on the characteristics of quality improvement training that are associated with a positive, sustained impact on patient care outcomes and system performance improvement.

However, previous articles in this series have raised concerns that trainees in the UK are on short rotations, have limited time or support, and may perceive that they lack authority to persuade colleagues that problems need tackling.[9 10] This article describes an approach which applies evidence about successful quality improvement training (table 1) to a curriculum on healthcare improvement for doctors in their first two years of training, drawing on the authors' experiences. The article recommends principles to help integrate quality improvement into medical training.

This article was based on a literature search for systematic reviews about medical training in quality improvement and on the personal experiences of the authors in developing integrated curriculums for workplace based education.

Integrate quality improvement projects with clinical audit and service evaluation

Quality improvement education is more likely to report impact on clinical processes or patient outcomes when a quality improvement project is an explicit part of the curriculum.[7] However, identifying meaningful projects that can be completed within a short time is challenging. Near misses in practice are an important source of information about system errors.[7] Encouraging trainees to report weaknesses in the system and involving them in analysis of individual cases enables them to evaluate delivery of care and to critique themselves and their peers within clinical teams.[7]

Quality improvement has great potential to be used with other approaches to change, such as audit and service evaluation.[11] These may identify areas of non-compliance with best practice or shortfalls in services that would benefit from a quality improvement approach. Quality improvement can also assess a service's readiness for change or identify risks associated with change.

In NHS Tayside, the FY2 quality improvement project is preceded by training in problem finding and analysis and is part of a connected curriculum of workplace based learning in quality improvement for medical students and foundation year doctors (fig 1). From 2022 this training will be completed by all 235 medical school graduates and all 92 FY2 doctors.

Build capacity for quality improvement projects

Studies of quality improvement education are more likely to report impact on clinical processes or patient outcomes when there is evidence of interprofessional involvement.[8] Interprofessional teams may include administrative, finance, and management, as well as clinical staff.[7]

Successful approaches to quality improvement include learners participating in a clinical quality improvement team that incorporates more than one learner or individual projects. Challenges include ensuring a clearly allocated time to complete the work, competing priorities, and short periods in which the work must be completed.[7]

The FY2 year is a rotation through three posts. The UK Foundation Programme requires that FY2s have three hours a week of non-clinical professional self-development time. The intended use of this time will include preparing for specialty application and developing skills in quality improvement, teaching, and leadership.[12]

In the early years of our programme we focused on acute care (acute medicine, anaesthetics, and emergency medicine) because the high throughput of patients facilitated quality improvement projects in the limited time available, and these were priority areas in the Scottish Patient Safety programme which built capacity for engagement of frontline staff with improvement methods. Over eight years we have built capacity for quality improvement projects across the range of services where FY2 doctors work.

In the first three years of the programme, most FY2 quality improvement projects focused on problems identified by the foundation year doctors. Some of these projects resulted in structural changes that have been sustained since.[13 14] However, it was often difficult to sustain change that was perceived as increasing workload for other team members.[15] We learnt from quality improvement projects with students that involving them in problems identified by the clinical teams enables them to design and test solutions,[16] which can then be sustained and spread by the clinical teams. We still support projects focused on burning issues identified by foundation year doctors, but most projects now focus on problems identified by clinical teams.[17] This facilitates interprofessional learning from the start (box 1).

HOW PATIENTS WERE INVOLVED IN THE CREATION OF THIS ARTICLE Ⓟ

The authors have drawn on their experience in partnering with patients in the design and delivery of multiple healthcare improvement activities. Patients were not directly involved in writing this article.

WHAT YOU NEED TO KNOW

- From the start, medical training should involve identifying problems, analysing why they happen, and testing change
- Enable interprofessional learning by focusing on problems identified by multiprofessional clinical teams
- Support requires clinical and educational leadership, and individual support such as coaching

Table 1 Evidence about the impact of training in quality improvement for healthcare professionals on patient care outcomes or system performance improvements*

| Factor	Realist review[7] (39 studies of physician education in quality improvement)	Systematic review[8] (99 studies of quality improvement education for health professionals)
Project	Identifying educational and clinically relevant project topics is challenging. Consider having trainees choose their own project. Choose topics of clinical importance. Use near misses as a way to identify system errors	Quality improvement project in the curriculum OR 13.60 CI 2.92 to 63.29
Learners	Trainees are frontline providers and have deep insights into the clinical processes and the knowledge for improvement within the system. Quality improvement projects create opportunities for interprofessional engagement and education	Interprofessional learning OR 6.55 CI 2.71 to 15.52
Support	Successful quality improvement teaching in the clinical setting requires support from both educational and care delivery leaders and the work of the trainees. Programmes can be successful either by engaging all faculty around quality improvement or by having dedicated quality improvement faculty for teaching the subject within the clinical setting	Coaching OR 4.38 CI 1.79 to 10.94
Learning outcomes	Lack of clarity around whether educational and clinical outcomes are of equal importance. Sustainability is important for the clinical setting and the trainee	Most studies only assessed knowledge. A minority of studies reported impact on attitudes (13%) and behaviour change (3%)

CI=confidence interval
*The systematic review included a quantitative analysis of three pre-specified factors. The odds ratios (OR) in the systematic review are for association between three pre-specified curricular features and changes in clinical care processes or outcomes

Support quality improvement training

Quality improvement education is more likely to affect clinical processes or patient outcomes when learners are supported by coaching.[8] This requires commitment from academic, administrative, and clinical leadership.[7] Ideally, learners should be embedded in clinical environments where continuous improvement cannot be disentangled from daily work.[20] It is essential that they join a department that is primed, ready, and welcoming given the short duration of their attachment. At an organisational level it is therefore important to know where this expertise exists and commit to growing this resource.[20] Within each clinical specialty, our foundation year doctors have access to a named quality improvement coach who is an improvement adviser. In addition to improvement methods, the coaches help the foundation year doctors with forming a
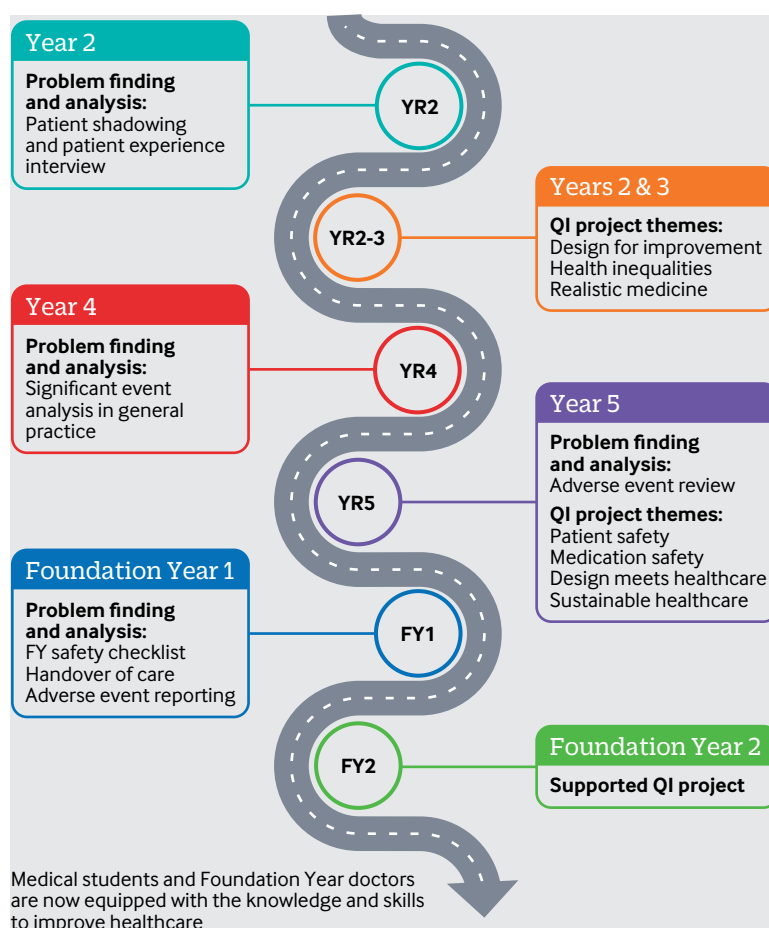
Fig 1 | Workplace based learning programmes on healthcare improvement in the undergraduate and foundation year (FY) curriculum. Foundation years are the first two years of postgraduate training

Box 1: Example of sustained improvement enabled by an interprofessional learning team[18]

Problem
Unreliable implementation of the COUGH[19]bundle in a surgical high dependency unit

Problem identification
Surgical high dependency unit team

Project leaders
FY2 trainee doctors

Interventions
Four interventions were implemented sequentially. Improvement occurred only after the fourth intervention
1. Education through staff emails
2. Two posters about risk scoring and detailed steps for junior doctors to take
3. Moving observation charts from filing cabinets to a wall space that was dedicated to quality improvement projects
4. Sticker placed in the admission notes by ward clerks

Lessons learnt
Lessons learnt from this project included the importance of encouraging and motivating all members of the team. The most successful intervention was the sticker, and this involved team work from the ward clerk, junior doctors, anaesthetists, physiotherapists, and nursing staff. New junior doctors rotate throughout the unit on a 4 monthly basis; therefore, it is vital that permanent members of the team are engaged so that the project can be sustainable

multidisciplinary team, which could include a finance representative and a sponsor with links to executive level for leadership support.

The Scottish Quality and Safety fellowship programme[21] has increased capacity for improvement methods in clinical services. It has been important to have a clinician appointed to a lead management role with responsibility for quality improvement in the organisation. Alignment of senior clinical leadership with the undergraduate and foundation year programmes enables trainee and student improvement to be targeted to areas of greatest need rather than towards vanity projects. Coordination allows the targeted use of trainees and students as an additional resource that can help stretched clinical teams.[22] This allows the organisation to connect with ideas being generated by frontline teams and with ideas from service users in a way that would not otherwise be possible. The knowledge gained from individuals closest to the point of delivery is vital when looking to improve a complex system.[23 24]

Box 2: Guidance on writing up a quality improvement project for foundation year doctors and their assessors, based on the assessment approach that we have developed and evaluated with medical students[28]

Suggested structure:
• Project aim
• Planned changes tested
• Predictions
• Measures—outcome, process, and balancing
• Summary of results, including run charts
• Analysis of data
• Project significance for local system and generalisable findings
• Reflections, including factors that promoted success, barriers to success, learning from project, and reflections on the role of the team

EDUCATION INTO PRACTICE

To enable doctors to make quality improvement in their first years of training, consider asking:
• How will you explain the concept of quality improvement in an engaging manner that encourages trainees to reflect critically on the service being provided in their area?
• How will you connect trainees with quality improvement experts, so they have support when designing their project, interpreting data, and presenting results?
• How will you ensure that the efforts of the trainee and their team are recognised to encourage future involvement and spread good practice?

RECOMMENDED RESOURCES/FURTHER READING

• Realistic Medicine. Shared decision making, a personalised approach to care, reduce harm and waste, reduce unwarranted variation, managing risk better, becoming improvers and innovators. https://www.realisticmedicine.scot
• Institute of Healthcare Improvement. Patient safety, leadership and person centred care—free access for students and trainees (trainees need to register as a resident to get free access). http://www.ihi.org/education/ihiopenschool/courses/Pages/SubscriptionInformation.aspx
• Quality improvement zone. Improvement Journey, project charter, model for improvement and quality improvement tools. https://learn.nes.nhs.scot/1262/quality-improvement-zone/qi-tools

Key learning outcomes are behavioural

Evidence about quality improvement education shows a lack of clarity around the relative importance of educational and clinical outcomes and a focus on assessment of knowledge, with only 3% of studies in one systematic review assessing impact on learner behaviour.[8] A recent evaluation of a quality improvement training programme reported that 62% of participants had implemented quality improvement projects at six months and 48% reported leading other quality improvement projects at 18 months after the programme.[25] Developing strategies to capture downstream quality improvement behaviour change is important because knowing something or even being skilled at doing something does not of itself lead to improvement.[26] In addition to leading quality improvement projects, learners should recognise how an isolated problem could be an opportunity for broader quality improvement, and take steps towards leading change.[20]

In the UK, assessment of successful progression through quality improvement training is part of the Annual Review of Competency Progression process and relies on objective measurable information from several sources, including workplace based assessment of e-portfolio and supervisors' assessments.[2] In addition, individual royal colleges are introducing exit assessment from training through national postgraduate examinations.[27] Existing assessment tools enable trainees to build evidence of progression in quality improvement, with the input of educational and clinical supervisors. This can be supported using tools such as a structured guide to good practice in reporting the quality improvement project (box 2). Encourage trainees to present their work to their peers, trainers, and clinical colleagues or to submit it for publication.[13-15 18 29-31]

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