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Article

Translating research on quality improvement in five European countries into a reflective guide for hospital leaders: the 'QUASER Hospital Guide'

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Abstract

Objective: The aim was to translate the findings of the QUASER study into a reflective, dialogic guide to help senior hospital leaders develop an organization wide QI strategy.

Design: The QUASER study involved in depth ethnographic research into QI work and practices in two hospitals in each of five European countries. Three translational stakeholder workshops were held to review research findings and advise on the design of the Guide. An extended iterative process involving researchers from each participant country was then used to populate the Guide.

Setting: The research was carried out in two hospitals in each of five European countries.

Participants: In total, 389 interviews with healthcare practitioners and 803 hours of observations.

Intervention: None.

Main outcome measure: None.

Results: The QUASER Hospital Guide was designed for leadership teams to diagnose their organization's strengths and weaknesses in the eight QI challenges. The Guide supports organizational dialogue about QI challenges, enables leaders to share perspectives, and helps teams to develop solutions to their situated problems. The Guide includes extensive examples of QI strategies drawn from the data and is published online and on paper.

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Conclusions: The QUASER Hospital Guide is empirically based, draws on a dialogical approach to Organizational Development and complexity science and can facilitate hospital leadership teams to identify the best solutions for their organization.

Key words: Quality improvement, hospital care, patient safety, quality improvement guide, translational research, leadership

Introduction

Although healthcare quality improvement (QI) has been high on policy agendas in most countries for well over a decade, there is frustration that quality and safety problems continue to cause harm to patients and that progress in achieving change is slow [1]. Understanding how to improve the quality of care is therefore a pressing problem. In this paper we describe the translational research and development of a guide for senior hospital leaders to enhance their organization's QI strategy.

Few studies have attempted to translate findings about factors that influence QI [2] into practical QI strategies and there is a gap between research findings and their translation into usable products. Although there are technical guides available for specific problems, such as the Institute for Healthcare Improvement's Targeted Solutions Tool to improve hand hygiene [3], and the structured communication tool SBAR [4], there is little guidance for hospital leaders about how they can set in motion key research findings for improving quality throughout a whole organization.

More recently, there has been increased interest in the role of hospital leaders and boards in the quality of care [5–10]. Management or executive boards of hospitals are responsible for setting strategy, advising on management, evaluating performance and exercising oversight and control [11]. In England, the Mid Staffordshire hospital failings highlighted the crucial role of hospital boards in providing leadership for quality [12, 13]. Other countries have experienced similar crises that have framed hospital leaders as central to QI [14].

A recent study of 15 organizations in England found that organizations with high QI maturity had boards that prioritized QI, balanced short-term priorities with long term investment in QI, used data for QI not just quality assurance, engaged staff and patients in QI, and encouraged a culture of continuous improvement [15]. Thus, the importance of hospital leaders and boards for QI is now well recognized but the necessary tools for integrating hospital wide strategies have not been developed.

As the methods and detailed findings of the QUASER study have been published elsewhere [16–18], we aim here to provide a brief overview of the study methods and main findings before describing in detail the design and process of translating the research findings into practical strategies for organizations and from this, developing the guide.

Overview of QUASER concepts, methods and fieldwork findings

Conceptual framework

Quality was defined as clinical effectiveness, patient safety and patient experience [19]. The QUASER study built on and extended the findings of the "Organising for Quality" study [20]. It found that high-performing hospitals recognized and had been successful in addressing six common challenges and the QUASER study took these results as a starting point. The six challenges were:

- Structural-organizing, planning and co-ordinating quality efforts
- Political-addressing and dealing with the politics of change surrounding any QI effort
- Cultural-giving 'quality' a shared, collective meaning, value and significance
- Educational-creating a learning process that supports improvement
- Emotional-engaging and mobilizing people by linking QI efforts to inner sentiments and deeper commitments and beliefs
- Physical and technological-design of physical systems and technological infrastructure
 - The QUASER study extended the framework to eight challenges, and included;
- Leadership for quality improvement
- External demands managing external demands in relation to quality improvement.

In the QUASER study framework, leadership and external demands were conceptualized as separate challenges in order to explore these organizational factors fully during the data collection and analysis. This final set of eight challenges that organizations must address as they seek to improve quality formed the conceptual basis of the study (see Fig. 1 adapted from [20])

Methods

QUASER was carried out in five European partner countries: England, the Netherlands, Norway, Portugal and Sweden, selected because they represent a range of healthcare systems and approaches to QI. Data were collected at macro (national or regional policy level), meso (organizational/hospital level) and micro (clinical) levels and integrated before being analysed and translated into a user guide for hospital senior leaders. Detailed methods for the empirical research can be found in the published QUASER study protocol [16]. At macro level and in two hospitals within each country, a total of 389 interviews and 803 hours of observation (including 207 meetings) were conducted.

Standardized frameworks for collecting, analysing and reporting data were used in all countries. Five country specific case study reports were produced written with a common structure, reporting the findings in relation to the research questions. A cross-case analysis was then conducted to synthesize the results and identify content for the guides.

Findings of QUASER study of QI in European hospitals

Initial scoping work to identify whether and how existing QI guides were used in each country clearly showed that the implementation and spread of QI was highly complex and dependent upon the structure of the healthcare system, the intermediary organizations and policies in each country, and the internal context and needs of the hospital. A technical QI guide that specified the actions to be taken

to improve quality was unlikely to be feasible or helpful. The complexity and variety of healthcare system contexts meant such a specific guide would not apply universally. A guide could, however, support QI work by focusing on the process of guiding senior hospital leaders as they navigated this complexity. The implication of this, inspired by Weick's idea of using verbs instead of nouns to focus on processes and emergence [21], was to move from developing a guide to focus on the process of guiding. This has much in common with advances in organizational development (OD) which

have seen a shift from searching for and supplying solutions developed by experts, to a dialogic approach, which aims to facilitate change organically [22].

The findings of the cross-case analysis showed that, despite differences in national health policy in relation to funding and quality [17], most hospitals in the five countries focused on the structural, physical and technological, and cultural challenges, and external demands, with less emphasis on the leadership, educational, political and emotional challenges. Table 1 summarizes the recommendations

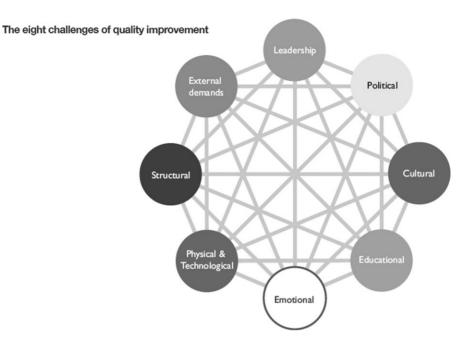


Figure 1 Eight challenges of Quality Improvement (adapted from Bate et al., 2008).

Table 1 Summary of findings from QUASER empirical study

Challenges

Structural/physical and technological/ political/cultural	•	Ensure a strong centralized quality strategy embedded in the hospital's social and physical infrastructure. Think about making use of hierarchies in order to foster an integrated approach towards QI but avoid the pitfall of creating an overly centralized system that marginalizes certain groups and is over-bureaucratic and slow.
Political/structural/physical and technological	•	Create spaces for informal negotiations and collaborative reflections and use their results to adapt formal structures. Think of opportunities to establish networks between individuals, professional groups, units, different organizational levels, and between patients and staff.
Political and cultural	•	Facilitate formal and informal dialogue to ensure different opinions are heard, and to establish shared understandings of QI through dialogue. Think about ways to recognize and value difference in a way that strengthens, rather than fragments.
Cultural/physical and technological/external demands	•	Reflect regularly on assumptions about quality that are based on quantifiable quality data such as indicators by taking softer issues into account and allow space for adaptation according to continuously changing circumstances.
Structural/cultural/physical and technological/external demands	•	Reflect on the balance between efforts to comply with external targets and improvement efforts that address internal needs of specific services. Reflect on whether the collected information is used to improve services and whether governance structures effectively connect individuals, professional groups and units, or whether they are rather serving administrative purposes.
Educational/structural	•	Foster ongoing/embedded learning support for staff at all levels. Think about learning strategies that are not only re-active but rather pro-active and lead to double-loop learning and integrate QI efforts and responsibilities into daily work routines.
Emotional	•	Think about engendering emotional reactions into quality work to strengthen the focus on patients.
Leadership (combining tactics to address all challenges)	•	Try to combine different leadership styles to be able to attune to the demands of various groups inside and outside the hospital

Recommendations for senior leaders

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Table 2 Translational workshop participants, aims, topics, findings and design implications

	Participant type	Participant countries	Aims	Topics discussed	Main findings	Design implications
Workshop 1	National organizations 3 Hospital leaders 6 Payer organization 1	Denmark England Estonia Norway Portugal Spain Sweden Taiwan Netherlands Turkey	Identify differences between healthcare systems and organizations that would influence whether and how a guide would be used.	National context for quality and safety in each country represented, whether and how QI guides are used, recommendations for designing a guide and engaging with potential users.	There were major differences between countries in the way healthcare is resourced, organized and delivered and the way that quality is regulated, confirming the findings of the early QUASER scoping work [23].	Confirmed variability of healthcare systems and the impossibility of designing a guide for all contexts Confirmed the importance of guiding QI using a dialogic approach rather than a technical guide.
Workshop 2	National organizations 0 Hospital leaders 10 Payer organizations 6 Patient representatives 7	Belgium Denmark England Estonia Finland France Hungary Italy Lithuania Norway Romania Spain Netherlands	Gain in depth advice from stakeholders on the emerging design of the Guide (see Fig. 2).	In facilitated small groups participants reviewed and discussed the emerging structure and design of the Guide, needs of the user groups and how to organize and present the material.	 Confirmed importance of dialogic approach The guide should be dynamic and capable of being used as a planning tool, to record reflections on self-diagnosis, facilitate evaluation of whether what was implemented worked, and enable improvement over time to be tracked. It should be clear that it is not intended to be used to assess quality, or as a tick box exercise Its purpose as a dialogue tool to facilitate deep reflection should be clear, but this did not preclude self-diagnosis using rating scales Examples of successful QI strategies should be included together with contextual information Make the interactions between the challenges clear and explicit The Guide should not only be used by hospital leaders but has potential for facilitating dialogue within a hospital – vertically and horizontally. 	

Table 2 Continued

	Participant type	Participant countries	Aims	Topics discussed	Main findings	Design implications
Workshop 3	National organizations 0 Hospital leaders 5 Payer organizations 5 Patient representatives 4	Belgium Denmark England France Hungary Lithuania Norway Netherlands	Gain stakeholder feedback on a detailed prototype of the guide showing the proposed layout and with detailed text. The aim was to review the detailed text, not the structure of the guide	Feedback on layout, language, clarity, graphics, and the rating scales and radar plots to be used for diagnosing strengths and weaknesses	Confirmed the purposes and approach used in the guide Recommended broadening user group to include any one undertaking QI, not just senior leaders Recommended clearer definitions of challenges, strategies, and related terms throughout Recommended the use of graphics to illustrate that challenges are all important and are linked Confirmed the value of examples and these could be even more central in the guide Recommended the guide should include an action plan to document agreed actions and to include time, resources, people Confirmed the rating scale to diagnose current strengths and weaknesses was appropriate Confirmed the value of the radar plots to show the outcome of the organizational self-assessment Clearer links needed between the guiding text and the examples drawn from our empirical research.	Content was revised to incorporate this feedback

based on the findings from the QUASER study. We also collected examples of effective QI efforts and took note of successful strategies for overcoming the many challenges of QI.

Translational methods for designing the guide

In the QUASER study we conceptualized translation as an interactive process between the research and the potential users of the Guide [24] and therefore sought input from stakeholders throughout the study. Over a two-year period, a series of three translational day-long workshops was held with an expert group of stakeholders including hospital leaders, policy specialists, researchers, and payers/funders of healthcare from across Europe. The workshops were

publicized widely at conferences, events, via EU networks and directly to stakeholder organizations such as the European Hospital and Healthcare Federation and patient groups. Participants were selected purposively to obtain views from a wide range of quality improvement experts including payers, providers and patients, and from as wide a range of countries as possible. All participants were volunteers and travelling expenses were reimbursed. Table 2 summarizes the three workshops and shows the participant types, the aims, the topics discussed, the main findings and the design implications of each.

Participants were provided with a short briefing document in advance of each workshop. At the workshop an overview of the project, progress, and the aims of the workshop were presented. In G92 Anderson et al.

all workshops a focus group format was used with question and topic guides. Participants worked in small groups and plenary sessions facilitated by researchers to answer specific questions. Detailed notes were taken in parallel by several researchers. These were transcribed and circulated to the research team for further additions. A detailed report was then written summarizing the reflections of the participants and identifying the implications for the design of the guide.

The first workshop was held in the Netherlands and was important in highlighting variability across and within countries and organizations and confirmed our view that a guiding process was needed rather than a guide. The second workshop was held in England following completion of the fieldwork, but before completion of the cross-case analysis. The aim was to gain in depth advice from stakeholders on a draft of the guide (see Fig. 2). As shown in Fig. 2, the emerging guide had three parts; an overview of the eight challenges with a self-diagnostic process, strategies to address the challenges and a plan for addressing the diagnosed weaknesses.

Following workshop 2, the structure of the guides was populated with content, using an extended iterative process that involved moving between the data and the emerging design in extended analysis meetings involving researchers from each participant country.

A detailed prototype of the guide was then produced for review in the final stakeholder workshop, which was held in England A professional copy editor and a designer were used to refine the text and layout. A paper copy of the guide was produced with high quality graphics and design.

Some examples of how the input of stakeholders contributed to the design can be provided from workshop 3. Stakeholders recommended: defining the challenges more clearly with examples; visualizing the challenges more clearly in a way that shows the equality and interlinking of the challenges; including the ability to compare QI progress over time; expanding the concrete examples of how others have improved in different contexts. This feedback resulted in the provision of examples of the challenges, the visual representation of the challenges shown in Fig. 1, the worksheets for teams to record

and compare their self-diagnosis over time, and the inclusion of a large compendium of contextualized examples. Table 2 summarizes the outputs from the workshops.

Results—the QUASER Hospital Guide

The final QUASER Hospital Guide is published in print and online https://www.ucl.ac.uk/dahr/pdf/study_documents/iQUASER_ Hospital_Guide_291014_press-ready_cs4.pdf). The Guide provides a comprehensive map, based on our empirical findings, of the areas hospital leaders need to address to improve quality by articulating common challenges faced by healthcare organizations. It provides a method for systematically identifying gaps in QI strategies, and a framework and a language for talking about QI. In keeping with the concept of QI as a human and social accomplishment, the process of using the Guide potentially enables hidden assumptions and priorities to surface and be resolved thus enabling focused and coordinated approaches to QI. The Guide contains introductory material, workbooks for teams to use to diagnose their own organization's progress in QI and document agreed strategies, and extensive examples of successful strategies from the QUASER empirical study, linked and cross referenced to the challenges. It thus provides structured evidence about QI strategies in other organizations to facilitate thinking and discussion. Although based on fieldwork in hospitals, the Guide was deliberately written in a general way such that it can be used in any healthcare organization, including acute care, mental health care, care homes, and diagnostic centres to formulate, implement and monitor organization-wide QI strategies.

Users first assess the progress of their organization or service on the eight challenges. Teams can complete this task as a group, or individually, coming together later to share perceptions, discuss differences and make plans. The worksheets in the Guide provide a description of each challenge and users are asked to rate the degree of progress already made on each challenge in the organization (on a scale of 1 low to 5 high), and to document the reasons for their rating. Ratings can be plotted on a radar plot provided in the

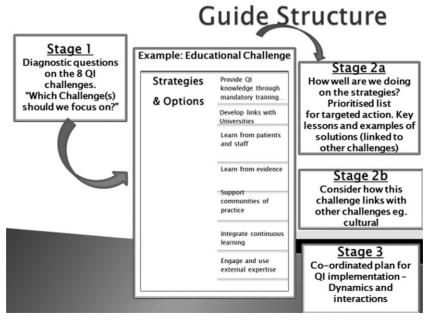


Figure 2 Emerging design of QUASER Guide presented at second translational workshop.

Table 3 Definitions of quality improvement challenges and associated strategies included in the Guide

Challenges	Definition	Associated Strategies
Leadership	Provide clear, strategic direction for the organization to meet the quality improvement challenges and develop quality improvement leaders throughout the organization	 Translating national targets into local QI initiatives Aligning QI work that your hospital has to do with priorities for QI that emerge locally Securing commitment to QI in your staff Developing your staff for QI Implementing long term QI strategies Encouraging both top down and bottom up approaches to
Political	Address internal organizational politics, engage people effectively, ensure they have a shared understanding of quality and obtain their support for QI efforts	 QI Managing tension between external demands and internal needs Establishing a shared understanding of quality improvement in your hospital Identifying quality improvement priorities with your patients Identifying quality improvement priorities with your staff Managing tensions and the politics of change Enabling multi professional working
Cultural	Create an organizational culture in which quality is a shared value that is central to clinical work and underlies all aspects of the organization's activities	 Establishing a broad, shared understanding of quality and QI in your hospital which encourages buy in from all professional groups Allowing local adaptation of initiatives within a broader strategic framework Embedding QI in the culture Establishing the relevance and importance of change
Educational	Continuous learning process supported and nurtured by the organization, identification of the skills and knowledge required and the development of structures and processes to train staff, formal and informal learning, individual and organizational	 Reflecting on quality in your hospital and your QI journey Encouraging spaces for reflection for staff to think about and discuss QI Learning continually from your patients Integrating QI into educational activities Importing and adapting strategies from other hospitals nationally and internationally Enabling staff to learn about QI from outside your hospital Linking the learning from different QI projects Embedding processes for capturing and reflecting on lessons learnt at the end of all QI projects and taking lessons forward to future QI Using a range of data sources and tools to understand QI Encouraging multi-professional learning and sharing about OI
Emotional	Inspire people about QI, engage their emotions and build passion and excitement for QI. Effectively mobilize ideas, resources and energy for QI	 Making the most of all the potential resources for QI in your hospital by framing quality in different ways to different audiences Establishing quality and QI as the goal of clinical work Paying attention to the social as well as the technical aspects of QI Energise staff over the course of QI initiatives by understanding and responding to their beliefs and values Listening to your staff and patients Making quality improvement visible
Physical and technological	Effective IT systems to enable monitoring and benchmarking. Physical environment should be conducive to QI efforts	 Measuring and monitoring your hospital's performance over time Designing the physical environment in support of QI Benchmarking and checking how your hospital is doing compared to others Sharing information about QI amongst your staff
Structural	Organizational structures should support ongoing improvement work and include, for example, roles and responsibilities, committees, lines of authority and reporting, incentives and rewards, development of organization-wide quality strategies'	 Integrating QI into the daily routines of staff Building QI capacity within your hospital Co-ordinating QI efforts in your hospital Capturing and embedding the learning from QI Linking staff at all levels who are interested in QI with relevant expertise and resources

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Table 3 Continued

Challenges	Definition	Associated Strategies
External demands	Respond to broader social, political, economic and contextual factors that influence the hospital and devise strategies to manage them	 Actively managing the demands of your external environment Using external demands as a means of increasing focus on and supporting QI Establishing a positive working relationship with payers and regulators

Table 4 Examples from data showing linked challenges, strategies and prompts

Selected examples from data	Linked to challenges and strategies	Prompts to be used in developing strategies
Formal and informal learning In Sweden Hospital A, links with external knowledge and learning centres are encouraged. There are links with a range of universities which collaborate in developing QI courses that integrate into and support professional training. Close collaboration with centres of learning is promoted by employing hospital staff with hybrid responsibilities covering clinical and university lecturing responsibilities	Leadership challenge – Developing your staff for QI strategy Cultural challenge – Reflecting on quality in your hospital and your QI journey Educational challenge – Enabling staff to learn about QI from outside your hospital Structural challenge – Building QI capacity within your hospital	How can leaders show their commitment to QI? Think about the cultural challenge around making QI an integral part of the culture of your hospital. How can leaders identify key goals and priorities for staff training in QI? How can your hospital locate and build networks and collaboration with external knowledge and learning centres for QI? Think about the educational challenge of resourcing QI learning. How can you enable staff to access external support for QI?
Using patient experiences and stories In Norway Hospital A service users are represented in a user panel, the Quality Committee and in the steering committee of the QI programme. Patient representatives are also expected to be included at each step of QI projects. There are patient surveys and a mailbox to collect patient experiences on the wards.	Political challenge – Identifying QI priorities with your patients Educational challenge – Learning continually from your patients Emotional challenge – Listening to your staff and patients	How do you currently capture and use patient experiences to inform your QI efforts? How can you involve patients and carers closely in your QI projects, working alongside staff as partners in the improvement process? How are patients' views represented on key committees and decision-making bodies in your hospital?

worksheet to easily visualize areas of weakness and to assist comparison of individual ratings.

The Guide then describes suggested strategies for meeting each of the eight challenges. Users rate the progress that has been made in each strategy in a similar way to their rating of the challenges. Users then meet to discuss their different perspectives and interpretation of the organization's success in meeting the QI challenges and are guided to develop strategies to identify improvements and an implementation plan. The Guide includes a compendium of examples, drawn from the empirical data, showing how other hospitals have addressed the challenges. Prompts are included to facilitate reflection and discussion. Table 3 summarizes the eight challenges and their associated strategies. Table 4 shows two examples from the data together with the linked challenges and strategies and the prompts that are intended to facilitate reflection on potential actions. Users document their actions for each challenge, including naming a responsible person, the timeline, and the resources required.

A study of the implementation of the Guide in six hospitals in England has been completed (iQUASER see [25]), and a Norwegian version of the Guide (SAFE-LEAD [26] has been developed for use in nursing homes and home care and is currently being evaluated. Healthcare organizations in Ireland and the Netherlands are using the Guide. The results of these studies will provide valuable evidence about its impact.

Discussion

In this paper we have described the systematic translational research process of designing an innovative guide for QI based on in depth empirical data from 5 European countries. The Guide complements the search for innovative solutions to care quality problems being sought in different countries (for example, [27–29]). Many guides and toolkits approach QI as a set of technical tasks for improving quality at the microsystem level. In contrast, the aim of the QUASER Guide is to facilitate systematic and detailed discussions amongst senior hospital leadership teams about organization-wide strategies for improving QI, supported by examples from the fieldwork.

This approach is similar to the principles of dialogic organizational development which views organizations as socially constructed realities that are constantly changing in response to conversations, dialogues and interactions between their members [20]. It moreover acknowledges that there is not one solution to quality and that organizational members are often more than capable of coming to situated solutions if only given the tools to start reflexive dialogues [30]. According to this view, organizational change is possible when conversations are changed in ways meaningful to practitioners, and new ways of thinking emerge through discussion and dialogue. The QUASER Guide provides a structure within which such a dialogue can occur, and solutions can then be

found by those who have the most knowledge about the organization and how to change it [31].

The diagnostic self-assessment process was conceptualized to begin conversations and build consensus about what needed to be improved, in keeping with a dialogic approach. The importance of critical reflection as a mediator between experience, knowledge and action, and the need for tools to facilitate and support this process, has been recognized in the management literature [32], but health-care QI has been dominated by technical "how to" guides [16]. The QUASER Hospital Guide has been developed to fill this gap.

The Guide also draws on management thinking based on complexity theory. According to this perspective healthcare organizations can be characterized as complex adaptive systems in which the role of managers is to enable learning, innovation and adaptability in a dynamic and unpredictable environment [33]. A similar philosophy underpins new perspectives on safety [34]. The Guide aims to assist managers to handle this complexity by ensuring that the full range of challenges, both internal and external to the organization, are considered and addressed. The Guide seeks to expand the complexity of organizational responses to challenges and help leaders to match organizations' internal complexity with the complexity of the environment. This requisite complexity is theorized to be fundamental to an organization's ability to adapt to changing conditions [35].

The translational process using workshops with expert stake-holders was fundamental to the design of the study, in keeping with current thinking of translation as a continuous part of research [eg 24]. We found there was tension between engaging stakeholders early in the process with the aim of building engagement and ensuring tools are optimally designed, and the difficulty of gaining engagement and feedback on ideas rather than concrete artefacts or study results. Stakeholders were more engaged with the later workshops at which they could comment on a tangible product. It may be that even more intensive translational activities were needed at the end of the project when the user group was clearly defined.

Limitations

The QUASER Guide was based on extensive empirical work in consultation with expert stakeholders, but evidence for its effectiveness in practice is still developing [25] and more research is needed. It is not clear how and to what extent the Guide is transferable to different healthcare systems, with different funding and regulatory structures and having different QI traditions. The composition of the stakeholder workshops shaped the Guide and may have resulted in undue focus on specific aspects of quality improvement. However, we purposively selected participants who could help meet the aims of designing a reflective guide, and the size of the research group and the stakeholder groups mitigates this concern somewhat.

Conclusions

The QUASER Guide was deliberately designed to extend traditional approaches to quality improvement which view organizations mechanistically and focus mainly on the technical aspects of improvement work [16]. The Guide provides a structured process to identify strengths and weaknesses in QI strategies through self-assessment tools. Hospital managers may use the self-assessment, together with the research-based inspirations from other hospitals, to design a QI strategy to suit their organization. It is based on empirical work to identify common quality improvement challenges, but it is possible that the challenges are not comprehensive and may differ depending

on an organization's QI maturity. However, the Guide's function as an artefact to start conversations rather than to provide answers means that the nature of the conversations is as important as the content of the guide [36]. There is emerging evidence from a subsequent study of the use of the Guide with English hospital boards that it can serve to focus attention on quality improvement if the organizational context is receptive and is effective if adapted to suit the organization's objectives [25]. Further work to evaluate the impact of the Guide in different settings is underway [26] and the Guide is now available for use by healthcare managers.

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Competing interests

None declared.

Ethical approval

Ethical approval was given by the appropriate regulatory bodies in each participating country.

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