KNOWLEDGE TRANSLATION IN HEALTH CARE

Moving from Evidence to Practice

Edited by

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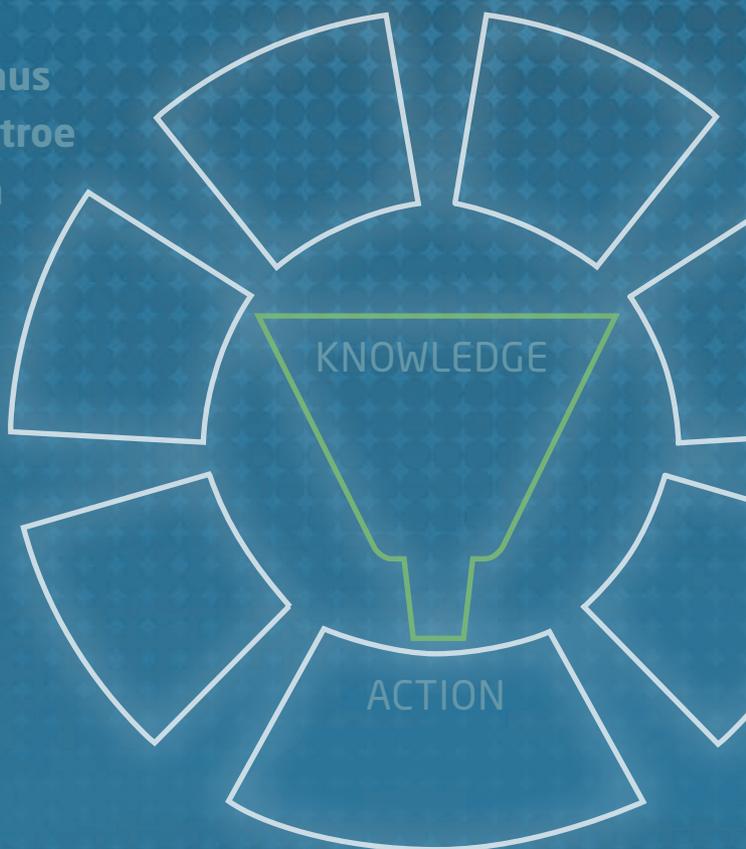
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Knowledge Translation in Health Care

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Moving from Evidence to Practice

SECOND EDITION

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Section 1 **Introduction**

Chapter 1.1 **Introduction**

Knowledge translation: What it is and what it isn't

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Key learning points

- Gaps between evidence and decision making occur across all decision makers including patients, health care professionals, managers, and policy makers.
- Knowledge translation is the synthesis, dissemination, exchange, and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system.

Globally health care systems are experiencing the challenges of improving the quality of care and decreasing the risk of adverse events [1]. Health systems fail to optimally use evidence (i.e. underuse, overuse, misuse of therapies, system failures) with resulting inefficiencies and reduced quantity and quality of life [2, 3]. For example, McGlynn and colleagues found that US adults received less than 55% of recommended care [4]. Simply providing evidence from clinical research (such as through publication in journals

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or presentation at scientific meetings) is necessary but not sufficient for the provision of optimal care or decision making. Indeed, the "know–do" gap in health care practice and health systems management creates an "ethical urgency" for both the practice and science of knowledge translation (KT) to answer these challenges and to optimize the return on investment in research. The growing emphasis on KT (and recognition that our knowledge about how to achieve KT is incomplete) has created interest in KT which we define as the methods for closing the knowledge-to-action gaps.

What is knowledge translation?

There have been many terms used to describe the process of putting knowledge into action [5]. In their work to create a KT search filter, McKibbon and colleagues have so far identified more than 100 terms for research use which may contribute to confusion about what KT is and thus, hinder its advance [6]. In the UK and Europe, the terms implementation science or research utilization are commonly seen in this context. In the USA, the terms dissemination and implementation, research use, knowledge transfer and uptake are often used. In Canada, the terms knowledge transfer and exchange and knowledge translation are commonly used. The term knowledge translation has largely been adopted in Canada because the Canadian Institutes of Health Research (the federal health research funding agency) has translation of research embedded in its mandate. In this book we use the terms knowledge translation and knowledge to action interchangeably.

For those wanting a formal definition of KT, the Canadian Institutes of Health Research (CIHR) defines KT as "a dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products and strengthen the healthcare system" [7]. This definition has been adapted by the US National Center for Dissemination of Disability Research and the World Health Organization. The common element to these different terms is the move beyond simple dissemination of knowledge and into actual use of knowledge. It is clear that knowledge creation (first generation research), distillation (creation of systematic reviews or second generation research), and dissemination (appearance in journals) are not usually sufficient on their own to ensure appropriate knowledge use in decision making.

We would also like to note the distinction between the concept of knowledge translation and research translation, where the later refers exclusively to the communication and use of research findings and the former encompasses all ways of knowing. By using the term "knowledge" we are

recognizing that there are many forms of evidence, including research data, local (e.g. administrative) data, evaluation findings, organizational priorities, organizational culture and context, patient experience and preference, and resource availability.

We should also clarify what KT isn't. Some organizations may use the term knowledge translation synonymously with commercialization or technology transfer but this is a very narrow view and does not consider the various stakeholders involved or the actual process of using knowledge in decision making. Similarly, some confusion arises around continuing education versus knowledge translation. Certainly educational interventions (such as journal clubs and educational outreach) are a strategy for knowledge implementation but it must be kept in mind that the audience for knowledge translation is larger than the health care professionals who are the targets for continuing medical education or continuing professional development. KT strategies may vary according to the targeted user audience (e.g. researchers, clinicians, policy makers, public), and the type of knowledge being translated (clinical, biomedical, policy) [2].

What is end of grant KT?

We have found it helpful to categorize KT activities into end of grant and integrated KT research (http://www.cihr-irsc.gc.ca/e/45321.html, accessed September 2012). End of grant KT refers to the development and implementation of a plan for making knowledge users aware of the results of a research project. There is a spectrum of end of grant KT activities; it can range from the typical dissemination and communication activities undertaken by most researchers such as publication of journal articles and presentation of research at relevant meetings to more intensive dissemination and implementation activities. For example, dissemination activities can include activities that tailor the message and medium to specific knowledge user audiences. More interactive approaches focused on knowledge implementation can also be considered such as small group educational sessions with patients or policy makers.

When considering end of grant KT activities, it is critical to consider the strength of the evidence and its significance and tailor our strategies as appropriate. For example, we shouldn't develop an elaborate, multicomponent strategy to disseminate and implement the results of a study involving just 20 people. The initial question to consider when planning our strategy is whether we want to focus on dissemination and/or implementation. If dissemination is the goal, we should consider which audience we want to target namely other researchers, clinicians, funders, managers,

members of the public or policy makers. When targeting dissemination to researchers we can consider which journal audiences we want to target. Similarly for presentation of research at meetings we consider which target audiences would be interested in our research. If implementation is our goal, we need to decide if we want to use the knowledge to promote change in attitudes, behavior or influence decision making.

There are challenges to consider when crafting our end of grant KT approach. First, when we are submitting a grant for funding and are drafting its end of grant KT plan, we don't know the results of the research. Therefore, we must anticipate the results and provide flexibility in our approach. Second, we need to ensure that we don't overestimate the potential impact of our research and create an overly ambitious and impractical plan. We like to use "common sense KT" as our mantra☺. See Chapter 2.4 for more detailed discussion on how to develop an end of grant KT plan.

What is integrated KT research?

Integrated KT research is an approach to conducting research that applies the principles of KT to the entire research process. It is a collaborative or participatory approach that engages knowledge users in the research and shares similarities with participatory research, action oriented research, co-production of knowledge approaches and Mode 2 knowledge production. Integrated KT research reflects a spectrum of activity from engaging the knowledge user in development or refinement of the research questions, selection of the methodology, data collections and tools development, selection of the outcome measures, interpretation of the findings, crafting of the message, dissemination, and implementation of the results (http://www.cihr-irsc.gc.ca/e/45321.html, accessed September 2012). The idea behind this approach is that if knowledge users are involved with the research, the research will be more solutions focused and more likely to yield results that they will use in decision making. Chapter 1.2 describes in greater detail the relatively new research paradigm of integrated KT research or engaged scholarship. In most chapters, the authors provide suggestions on how the content of their chapters might be used in integrated KT research.

Why is KT important?

Failures to use research evidence to inform decision making are evident across all decision maker groups including health care providers, patients, informal carers, managers, and policy makers, in developed and developing countries, in primary and specialty care and in care provided by all

disciplines. Practice audits performed in a variety of settings have revealed that high-quality evidence is not being consistently applied in practice [8]. For example, although several randomized trials have shown that statins can decrease the risk of mortality and morbidity in post-stroke patients, statins are considerably underprescribed [9]. In contrast, antibiotics are overprescribed in children with upper respiratory tract symptoms [10]. A synthesis of 14 studies showed that many patients (26% to 95%) were dissatisfied with information given [11]. Lavis and colleagues [12] studied eight health policymaking processes in Canada. Citable health services research was used in at least one stage of the policymaking process for only four policies, and only one of these four policies had citable research used in both stages of the policymaking process. Similarly, evidence from systematic reviews was not frequently used by WHO policy makers [13]. And, Dobbins and colleagues observed that while systematic reviews were used in making public health guidelines in Ontario, the recommendations were not adopted at the policy level [14].

Increasing recognition of these knowledge to action gaps has led to attempts to effect behavior, practice or policy change. Changing behavior is a complex process requiring evaluation of the entire health care organization including systematic barriers to change (such as lack of integrated health information systems) and targeting of all those involved in decision making including clinicians, policy makers and patients [2]. Efforts must be made to close the knowledge-to-practice gaps by effective knowledge translation interventions and thereby improve health outcomes. These initiatives must include all aspects of care including access to and implementation of valid evidence, patient safety strategies, and organizational and systems issues.

What are the determinants of KT?

Multiple factors influence the use of research by different decision maker groups [15–19]. A common challenge that all decision makers face relates to the lack of knowledge management skills and infrastructure (the sheer volume of research evidence currently produced, access to research evidence, time to read and skills to appraise, understand and apply research evidence). For example, if a general internist wanted to keep abreast of the primary clinical literature relevant to this field, she would need to read 17 articles daily [20]. Given that this study was completed in the 1990s and that more than 1000 articles are indexed in MEDLINE per day, the number of articles necessary to read today would be double this estimate. In one study of clinicians' use of evidence, it took more than two minutes to

identify a Cochrane review and its relevant clinical bottom line and thus this resource was frequently abandoned in "real-time" clinical searches [21]. Lack of skills in appraising evidence has been a challenge to all stakeholder groups because until recently, this skill set has not been a traditional component of most educational curricula [18, 22]. For example, Sekimoto and colleagues found that physicians in their study felt a lack of evidence proving effectiveness was equivalent to the treatment being ineffective [23]. Public health decision makers also identified a lack of skill in critical appraisal of evidence [24]. Finally, the content of evidence resources is often not sufficient for the needs of the end-users. While criteria have been developed to enhance reporting of systematic reviews [25], their focus has been on validity of evidence rather than applicability. For instance when trying to use evidence from systematic reviews for clinical decision making, Glenton and colleagues identified a lack of detail about the intervention, its accessibility, and risk of adverse events [26]. Shepperd and Glasziou observed that of 25 systematic reviews published over 1 year in the *EBM Journal* only 3 systematic reviews contained an adequate description of the intervention to allow clinical decision making and implementation [27]. This was even true for "simple" interventions such as medications.

Better knowledge management is necessary but this is insufficient to ensure effective KT given other challenges that may operate at different levels including the: health care system (e.g. financial disincentives), health care organization (e.g. lack of equipment), health care teams (e.g. local standards of care not in line with recommended practice), individual health care professionals (e.g. knowledge, attitudes and skills), and patients (e.g. low adherence to recommendations) [19]. In a review of barriers to physician implementation of guidelines, Cabana and colleagues identified more than 250 barriers to adherence including lack of awareness, lack of agreement with the guidelines and presence of external barriers to following the recommendations [15]. Frequently multiple challenges operating at different levels of the health care system are present. Knowledge translation interventions and activities need to keep abreast with these challenges and changes in the health care sector.

What is KT research?

The science of KT research, also referred to as implementation research, is still in its infancy and there are many gaps in the evidence base. KT research includes work to: explore measurement of gaps in decision making; improve knowledge synthesis and distillation (such as determinants of when systematic reviews and guidelines should be updated or how to

enhance implementability of guidelines); enhance diagnosis and measurement of determinants of knowledge uptake; and determine effectiveness and sustainability of different KT approaches and effect modifiers. In the development of a national research strategy to enhance KT capacity, we identified four core competencies for KT researchers including understanding of the models of KT and KT research; capacity to conduct systematic reviews to address KT questions (such as realist reviews); capacity in qualitative methods to examine factors that influence use of evidence (such as document analysis or interview research); and, capacity to evaluate the impact, effectiveness and sustainability of KT strategies (including cost effectiveness) in different settings [28].

What is the practice of KT?

The practice of KT focuses on implementing research evidence and evaluating its impact. It is very much focused on the "doing" of KT and while the science of KT can be advanced alongside, it is not essential. We find the "doing" of KT requires a unique skill set including an understanding of the health care context and how to effect change in addition to the ability to develop relationships with relevant stakeholders in the implementation process. Moreover, the evaluation of this process requires an understanding of qualitative and quantitative methods.

The knowledge to action framework: a model for knowledge translation

There are many proposed theories and frameworks for achieving knowledge translation which can be confusing for those responsible for it [29–33]. A conceptual framework developed by Graham and colleagues, termed the Knowledge to Action cycle, provides an approach that builds on the commonalities found in an assessment of planned-action theories [5]. This framework was developed following a review of more than 30 planned action theories which identified their common elements. They added to the planned action model a knowledge creation process and labeled the combined models the knowledge to action cycle. It has been adopted by the CIHR as the accepted model for promoting the application of research and a framework for the process of KT http://www.cihr-irsc.gc.ca/e/39033.html, accessed September 2012.

In this model, the knowledge to action process is an iterative, dynamic, and complex process, both concerning knowledge creation and the knowledge application (action cycle) with the boundaries between the creation
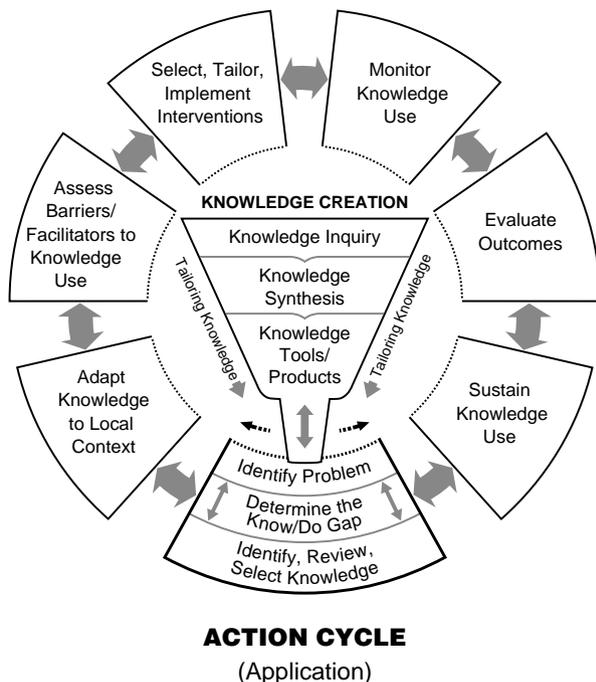
Figure 1.1.1   The knowledge to action cycle.

and action components being fluid. Figure 1.1.1 illustrates the knowledge creation funnel and the major action phases comprising model.

Knowledge creation

Knowledge creation, or the production of knowledge, is composed of three phases: knowledge inquiry (first generation knowledge), knowledge synthesis (second generation knowledge), and creation of knowledge tools and/or products (third generation knowledge). As knowledge is filtered or distilled through each stage in the knowledge creation process, the resulting knowledge becomes more synthesized and potentially more useful to end-users. For example, the synthesis stage brings together the disparate research findings that may exist globally on a topic and attempts to identify common patterns. At the tools/products development stage, the best quality knowledge and research is further synthesized and distilled into decision making tools such as practice guidelines or algorithms.

The action cycle

The seven action phases can occur sequentially or simultaneously and the knowledge phases can influence the action phases at several points in the cycle. At each phase there are multiple theories from different disciplines which can be brought to bear. The action parts of the cycle are based on planned action theories that focus on deliberately engineering change in health care systems and groups [29, 30]. Included are the processes needed to implement knowledge in health care settings namely identification of the problem; identifying, reviewing and selecting the knowledge to implement; adapting or customizing that knowledge to the local context; assessing the determinants of knowledge use (barriers and supports); selecting, tailoring, implementing, and monitoring KT interventions; evaluating outcomes or impact of using the knowledge, and determining strategies for ensuring sustained knowledge use. The knowledge to action framework can be used in multiple ways. Those generating the knowledge and those implementing the knowledge can work independently of each other, which is probably the most common case. For example, practice guideline developers synthesize the relevant research and make recommendations for practice that become knowledge tools and those in practice settings decide whether the guidelines are relevant and should be implemented. The framework can also be used in an integrated KT research fashion where researchers and knowledge users work collaboratively creating and implementing research (see Chapter 3.7a for an illustration of this). However the framework is used it is essential to consider the various stakeholders who are the end-users of the knowledge that is being implemented.

In this book, we attempt to provide an approach to the science and practice of knowledge translation. We will describe the role of synthesis and knowledge tools in the knowledge creation process as well as present the key elements of the action cycle and outline strategies for successful KT targeted to relevant stakeholders, including the public, managers, clinicians, and policy makers amongst others. Each chapter was created following a focused or systematic search of the literature and appraisal of individual studies for validity. Gaps in the literature are identified; the science of KT is a relatively new field and to reflect this, we highlight future areas of research which we hope will be of particular help to trainees interested in this field. Each chapter will provide suggestions for how an integrated KT research approach can be incorporated. This book is supported by a website which has additional resources for KT, including slide decks describing the key points in each chapter (www.ktclearinghouse.ca, accessed September 2012); if there are additional resources you would find useful or you would like to

make available on this website, please contact us via the email addresses on the website.

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Chapter 1.2 **Integrated knowledge translation**

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Key learning points

- While the "knowledge to action" gap is most often explained as a problem of "*knowledge transfer*"; knowledge translation research provides good evidence that this gap is often the result of a failure in "knowledge production."
- To promote knowledge use, potential knowledge users must be engaged in appropriate and meaningful ways from the beginning of the research process – strategies for involvement will vary based on many factors.
- While engaged scholarship is rooted in participatory research, and knowledge transfer in a biomedical paradigm, an integrated knowledge translation research approach can help integrate the two paradigms.

As outlined in Chapter 1.1, the gap between what we know and what we do – in either health care practice or health system management – is contributing to the critical challenges faced by the health care system. Many strategies have been adopted to promote the movement of knowledge into action: requirements for researchers to incorporate a knowledge translation (KT) plan in their funding proposals; dedicated funds for KT research; making information available in accessible and user-friendly formats (e.g.

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knowledge syntheses); development of knowledge products and tools such as clinical practice guidelines and decision support tools; research training opportunities for executives and managers; and funder requirements that clinicians and managers justify funding requests by demonstrating use of evidence in planning and priority setting.

While increasing numbers of researchers, policy makers, managers and providers are giving support to the concept of "knowledge translation," the same term is used to apply to many different – and often contradictory – approaches. The next section outlines two very different paradigms on which KT strategies are based (see Table 1.2.1).

Table 1.2.1 The KT paradigms

The knowledge transfer paradigm	The engagement paradigm
Biomedical roots	*Social science roots*
Researcher unilaterally makes decisions about:	Coproduction of knowledge: researchers and users collaboratively make decisions on:
• the research question	• the research question
• study design	• study design
• data collection approaches	• data collection approaches
• outcome measures	• outcome measures
• analysis of results	• analysis of results
• relevance of findings	• relevance of findings
• dissemination of findings	• dissemination of findings
Users are subjects or collaborators to achieve researchers' goals	Researchers and users share decision making power: they are equal partners
Research skills needed	Research and other professional skills and experiential knowledge needed and equally valued
Recipients use research results	Collaborative engagement between researchers and users facilitates assessment of results and their applicability
Focus on generic findings, applicable in all contexts	Recognition of non-research sources of evidence; importance of synthesis and application of research results in context
KT goal: more availability of research	KT goal: increased application of research through better quality, relevant research
Focus on communication and dissemination	Focus on partnership, power sharing, and mutual respect
• Information transmission: one way transfer from expert to users	• Knowledge exchange: mutual learning
Focus on single issue	Focus on change in how business done (research and health organizations)
Focus on content	Focus on process
Emphasis on increasing user capacity to use results	Emphasis on change management

The KTA gap as a "knowledge transfer" (dissemination) problem

The "knowledge to action" (KTA) gap is most commonly interpreted as a *knowledge transfer* problem: it is assumed that knowledge is not used because there has been a failure to transfer it effectively to the intended audience. A number of KT theories are based on this assumption, beginning with Rogers' diffusion of innovations [1] and subsequent theories based on researcher "push" (active and focused dissemination of research); and user "pull" (responding to the needs of users). Knowledge brokering theories are based on the assumption that skill and resources are needed to transfer knowledge between the very different cultures of research and decision making [2]. More recently, researchers have focused on the importance of interaction between researchers and knowledge users in predicting uptake of research (partnership theories) [3].

Analysis of this knowledge transfer paradigm reveals several underlying assumptions:

1   Researchers should be the ones to conduct research. Involvement of knowledge users potentially risks objectivity and "rigor" of research.
2   There is research available to guide the challenges facing the health care system.
3   The major challenges in knowledge uptake are appropriate communication and user "readiness" or "capacity" to take up the new knowledge.

The "knowledge transfer" approach has been bolstered by the evidence-based medicine (EBM), more recently referred to as the evidence-based practice (EBP) movement. Defined as "*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*" [4]. EBM is promoted as a critical factor in achieving better patient care and health outcomes. However, potential limitations of the EBM movement are suggested by an alternate definition proposed by Greenhalgh and Donald: "*the use of mathematical estimates of the chance of benefit and the risk of harm, derived from high-quality research on population samples, to inform clinical decision making*" [5]. Not only does the common definition of "evidence" as quantitative data produced in response to specific and focused questions about effectiveness oversimplify the complex nature of health care delivery (and health management and policy making) [6], clinical researchers responsible for "producing" the evidence for EBM often have a simplistic view of how to achieve action on the research syntheses generated – often focusing simply on dissemination.

Limitations of the knowledge transfer approach are becoming more evident [7]. Take, for example, the question of implementation of clinical

practice guidelines (CPGs). CPGs are the result of rigorous and systematic reviews of the literature, synthesized into practical guidelines for clinicians. A number of creative strategies are used to disseminate guidelines, including publication in specialty journals, interactive websites, paper and electronic distribution, computerized decision-support, academic detailing, feedback, and audit. However, uptake remains problematic. For example, one pilot study integrating CPGs into a computerized decision support/ordering system, found that only 2% of advice given from this decision support system resulted in canceled or changed orders [8]. Analysis of the results highlighted the limitations of CPGs if context for implementation is not taken into account and the importance of including users in early stages of intervention design to ensure that decision support tools meet their needs. Even greater challenges are experienced when this knowledge transfer paradigm is applied to population and public health issues, or to the fields of health policy and management – where differences are found in the culture of decision making, type of decisions, importance of context, timelines for decisions, and types of evidence considered credible [9].

The KTA gap as a "knowledge production" problem

There is an alternate interpretation of the cause of the KTA gap, reflecting a very different paradigm: the KTA gap is viewed not as a failure of *knowledge transfer*, but rather of knowledge *production*. Potential users fail to use research results not simply because these results have not been effectively disseminated, but because the research itself does not address the priority questions facing clinicians, managers, and decision makers. Engaged Scholarship (defined as a form of collaborative inquiry between academics and practitioners that leverages their different perspectives to generate useful knowledge) is based on the belief that higher quality, more relevant research results from true collaboration and from integrating the diverse perspectives of multiple stakeholders [10] Proponents of Engaged Scholarship argue that dissemination is too late if the questions that have been asked are not of interest to users [11]. Unlike the "knowledge transfer" approach, this paradigm is rooted in participatory research.

Integration of the two paradigms

As described in the previous chapter, the Canadian Institutes of Research (CIHR) which is the national funding agency for health research in Canada recognizes two forms of knowledge translation: (a) "integrated" KT research where research is designed to be a collaborative venture between

researchers and knowledge users as well as (b) end-of-project KT – dissemination activities (http://www.cihr-irsc.gc.ca/e/45321.html, accessed September 2012). While end of project KT addresses the problem of *knowledge transfer*; "integrated KT" research (iKTR) or "engaged scholarship" defines the problem as one of *knowledge production* [12, 13]. The CIHR model therefore, helps integrate the biomedical and the action research paradigms.

Implications for practice

1 *The need for clarity of terminology and concepts.* Although researchers, KT practitioners and knowledge users may use similar "KT" terminology, their concepts and practice may be based on very different assumptions. Teams must invest time to clarify their approach and assumptions.

2 *The need to address the growing skepticism about the value of KT.* The dominance of the knowledge transfer paradigm contributes to common cynicism about exhortations to adopt evidence-based practice [14], often referred to by decision makers as the "do we have a solution for you!!" approach. Health system managers are frustrated at being treated as passive recipients of research, and recognize the limitations of research to address the complex challenges facing them. And research is supporting their concerns: there is increasing evidence that simply disseminating knowledge to potential users after research has been complete is likely to be of limited effectiveness – even if multiple and creative methods are used [15]. A critical factor predicting research use is the engagement of knowledge users in prioritization, definition, interpretation and application of research [16].

3 *The need for a range of examples of participatory approaches.* While the principles of engagement are commonly accepted and practiced by researchers in some fields and for some problems (e.g. community-based participatory research), the potential of engagement in many diverse forms of research is only now being explored. Engagement (in the context of clinical, health services or even laboratory based research) is often expressed very differently than in grassroots community engagement activities: there is no one strategy (template) that can be applied in every situation. Many researchers and practitioners (a) have limited experience with participatory methods; (b) may view such as approaches as irrelevant – or even contradictory–to the work they do; and (c) do not have practical examples of how knowledge users could be appropriately engaged in the kind of research they are conducting. Both researchers and KT practitioners need concrete examples of engagement in a number of different areas:

- *Example of engagement in research using secondary data:* A study in one Canadian Health region used administrative data to identify potential patient safety concerns – but failed to include the Regional Health Information staff in the process. As a result, some definitions used to calculate adverse events were inappropriate, and major contextual issues (e.g. lack of systematic coding of palliative patients) were not taken into account. As a result, there was no confidence from regional staff in the findings. If those with appropriate expertise had been included from the beginning, a better quality document could have been produced. As importantly, such collaboration would have provided opportunities for researchers to learn about the patient safety issues of most concern to the region, and other sources of data to help inform the questions of concern. This also highlights the need for more clinical researchers who bring credibility to both the research and clinical domains.
- *Example of engagement in systematic reviews.* A recent review has found that the public involvement can contribute to systematic reviews by: refining the scope of the review; suggesting and locating relevant literature; appraising the literature; interpreting the review findings; and writing up the review [17]. For example, patients and clinicians can help focus the research on questions of most importance to them, and help identify methodological inadequacies, thus affecting both the focus of the review and the resulting recommendations.

As these examples illustrate, meaningful involvement does not necessarily require an intensive amount of preparation or time – from either researchers or knowledge users. It does not assume that knowledge users take on research roles; rather there is respect for the distinct expertise that practitioners, managers, and researchers bring to a specific problem. It does, however, require, a reorientation to research: a respect for the contributions of other kinds of expertise to the research (or KT) process; and willingness to adapt (or even change) the research (or KT activity) one has in mind to better meet the needs of potential users. A key concept, whatever the strategy adopted, is to ensure that knowledge users are *decision makers* in the research planning, implementation and interpretation process. They must not be treated simply as data sources, advisors, or (even more cynically) a means to a funding end.

4 *The importance of clarifying "knowledge users."* It is easy be confused about who one should engage with – not all those who are interested or affected by an issue will be in a position to take action on it. For example, in health care, patients are often the parties most affected by a decision, but those in a position to effect needed change are often managers.

Depending on the focus of the research, users may be policy makers; health system managers; clinicians; or clients/patients themselves. In some cases, (such as in the area of prevention) whole communities may be the intended knowledge users.

5 *The importance of selecting appropriate strategies for the KT challenge.* There is no silver bullet. KT strategies must reflect the targeted level of decision making, whether this is clinical, program management or health/social policy. It is also critical to determine the phase of decision making: is the challenge to understand and frame the problem? to get an issue on the agenda? to inform a response? to inform implementation?; to change practice?; or to maintain support for decisions already made? [18].

6 *The need to understand KT within a larger societal context.* The focus on KT is occurring alongside other challenges to traditional research approaches. In contrast with traditional forms of research which are often driven by the interests of academics and conducted in disciplinary silos, an alternate paradigm of research (referred to as Mode 2) has been proposed. Mode 2 research – issue-driven research that generates knowledge in response to societal needs – both recognizes and requires engagement with a diversity of stakeholders in the research process [19, 20].

There is increased recognition of the complexity of the challenges we face: it is argued that one of the reasons we do not make progress in addressing problems within health care is that we continue to treat all problems as simple, linear ones, when in fact most are complicated or complex [21]. While knowledge transfer activities may be effective in addressing simple, linear problems, they will be inadequate in addressing complex health issues. Complex problems do not have a clear cause–effect relationship, and cannot be solved by researchers working in discipline-specific silos, or without the insight and expertise of those working within the system, or the patients the system is attempting to help. There is also increased recognition of the many different sources of "evidence," other than research, that must legitimately inform decisions [22]. In addition, attention has shifted from a focus on individual behavior, to a focus on organizational level factors and interventions to support evidence use and research uptake [23, 24].

Summary

In spite of evidence on the importance of the participation of intended users in the research process, many KT initiatives fail to engage users, and

rely simply on dissemination strategies. These "research transfer" strategies too often fail to acknowledge or reflect the complexity involved in changing clinical or management practice, resulting in continued failure to effectively address the "knowledge to action" gap.

Researchers must recognize that if their research is to be useful and used, it must answer important questions of concern to knowledge users; and integrated with contextual evidence. Only in this way will it be actionable in a specific setting. There must be greater recognition that decisions – at clinical, managerial, and policy levels – are not based simply on research evidence but should reflect the complexities of the specific environment, and other legitimate sources of evidence such as local evaluation data, population profiles, provider expertise, local resource availability, and patient preferences. This integration of research with contextual knowledge can only be accomplished if there is genuine participation of knowledge users – managers, practitioners, and patients – from the beginning of the research process.

Future research

There are many research gaps including what are the most effective strategies for developing and sustaining researcher–knowledge user partnerships and how can research evidence be optimally integrated with contextual evidence. Finally, little is known about the impact of integrated knowledge translation approaches on clinical or health care system outcomes.

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Section 2 **Knowledge Creation**

Chapter 2.0 **Introduction**

The K in KT: Knowledge creation

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In the centre of the knowledge to action cycle is the knowledge funnel which represents knowledge creation [1]. As knowledge moves through the funnel, it is refined and, ideally, becomes more useful to end-users of the knowledge which can include researchers, health care professionals, policy makers, and the public. During each phase of knowledge creation, knowledge producers tailor their activities to the needs of these end-users. First generation knowledge is that derived from primary studies such as randomized trials and interrupted time series for example. Knowledge synthesis represents second generation knowledge and scoping and systematic reviews are examples of this knowledge product and are described in Chapter 2.1. Third generation knowledge includes tools and products such as decision aids, clinical practice guidelines, and educational modules whose purpose is to present knowledge in user friendly, implementable formats and are outlined in Chapter 2.2. Each of these formats can be tailored to the needs of the end-users of the knowledge.

Chapter 2.3 reviews some strategies for identifying research findings, specifically knowledge syntheses and practice guidelines. For people interested in the science and practice of KT, it is also helpful to understand how to search the literature for articles about KT. While searching the literature around any topic can be challenging, searching for KT literature has several distinct challenges including the varying terminology that is used to describe KT. Tetroe and colleagues have found 33 different terms used to describe KT including implementation science, research utilization and knowledge exchange and uptake [2]. Cognizant of these challenges, we also

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provide an approach to searching for KT literature in this chapter. Finally, Chapter 2.4 describes an approach to knowledge dissemination including traditional passive strategies as well are more interactive and tailored approaches.

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Chapter 2.1 **Knowledge synthesis**

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Key learning points

- Knowledge synthesis is used to interpret the results of individual studies within the context of global evidence and bridges the gap between research and decision making.
- There are various approaches to knowledge synthesis and many new methodologies are being developed.
- In health care, the most common type of knowledge synthesis is systematic reviews.
- Systematic review validity is dependent on the risk of bias of the included primary studies and the review process itself. Transparency in reporting will help readers assess review validity and applicability, increasing its utility.
- Given the magnitude of the existing literature, the increasing demands on systematic review teams, and the diversity of approaches, continuing methodological effort will be important to increase the efficiency, validity and applicability of systematic reviews.
- Future research should focus on matching the review question and the needs of the user to the most appropriate knowledge synthesis approach, understanding how best to update reviews, and increasing the uptake of knowledge synthesis.

Knowledge synthesis is a term used to describe the method of synthesizing results from individual studies and interpreting these results within the context of global evidence [1]. These methods can be used to understand inconsistencies across studies and identify gaps in the literature for future research endeavors. With the advent of evidence-based decision-making, knowledge synthesis has become increasingly important within health care [2].

Knowledge translation focusing on the results of individual studies may be misleading due to bias in their conduct or random variations in findings [3]. As such, knowledge synthesis should be considered the base unit of knowledge translation [4]. Syntheses provide the evidence base for knowledge translation tools, such as policy briefs, patient decision aids, and clinical practice guidelines [4] (see Chapter 2.2). Additionally, granting agencies, such as the Canadian Institutes of Health Research and the Medical Research Council in the United Kingdom, require knowledge syntheses to justify the need to fund and conduct randomized controlled trials [1]. Knowledge synthesis is central to knowledge translation, bridging the gap between research and decision making [5].

Over the past few years, a proliferation of methods has emerged to synthesize the literature [6]. Examples of these methods can be found in Table 2.1.1 and a few will be highlighted here. Realist reviews aim to determine which interventions work in particular settings. Meta-narrative reviews are used to explain complex bodies of evidence to uncover unfolding storylines. Meta-ethnography reviews are used to identify new theories to explain research findings. The terminology used to describe these methods often overlaps and is not always user-friendly, leading to confusion in the field. In addition, there has been little methodological research validating these methods. Efforts to better understand these often disparate knowledge synthesis methods are currently underway [6, 7], and will likely shed light on these approaches in the coming years.

Within health care, knowledge synthesis activities have focused on methodologically rigorous systematic review methods, such as those proposed by the Cochrane Collaboration [8] and these will be the focus of this chapter. The main components of systematic reviews according to the Cochrane Collaboration include "1) a clearly stated set of objectives with pre-defined eligibility criteria for studies; 2) an explicit, reproducible methodology; 3) a systematic search that attempts to identify all studies that would meet the eligibility criteria; 4) an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and 5) a systematic presentation, and synthesis, of the characteristics and findings of the included studies" [9]. A list of the steps involved with the conduct of a systematic review can be found in Table 2.1.2.

Table 2.1.1 Examples of innovative knowledge synthesis methods

Type of review	Type of evidence	Type of question	Example of question	Example of methods used to synthesize the literature
Meta-narrative review [10]	Qualitative	How best can one explain complex bodies of evidence?	How best to explain the diffusion of innovation in evidence-based medicine? [10]	• Questions: framed in broad, open-ended format • Searching: involves browsing relevant perspectives and approaches, finding seminal conceptual papers by tracking references of references • Analysis: involves mapping and comparing storylines
Realist review [11]	Mixed qualitative and quantitative	How do complex programs work (or why do they fail) in certain contexts and settings?	Which aspects of school feeding programs in disadvantaged children determine success and failure in various situations? [12]	• Question: scope of the review involves additional steps, such as identifying key theories to be explored • Literature search: involves searching for theories explaining why the program works • Data abstraction: includes contextual data, such as theory, process detail, and historical aspects of the study • Analysis: often involves an iterative process
Meta-ethnography review [13]	Qualitative	How can qualitative evidence explain why certain interventions work and others don't?	What are the types of factors that could influence adherence to tuberculosis treatment from the patient's experience? [14]	• Question: question must be answerable with qualitative research • Literature search: involves searching electronic databases beyond the medical domain as well as searching books and theses • Data abstraction: involves abstracting metaphors, quotations, and common themes • Analysis: focuses on narrative summary of the evidence, data may be arranged in a matrix to show the commonalities of themes across studies

Table 2.1.1   (*continued*)

Type of review	Type of evidence	Type of question	Example of question	Example of methods used to synthesize the literature
Meta-synthesis [15]	Qualitative	How can general theories be used to interpret findings from qualitative research?	In patients with leg ulceration, what is their experiences with neuropathic pain and sequelae? [16]	• Question: begin with a conceptual framework • Literature search: goal is to identify all literature in the field and involves searching a number of sources, such as electronic databases, books, and theses • Data abstraction: involves abstracting themes • Analysis: entails re-interpreting findings from individual studies into an overarching framework
Critical interpretive synthesis [17]	Mixed qualitative and quantitative	How can context be used to produce a theoretical model to explain phenomena?	What are the perspectives of patients, caregivers, professionals, and researchers about participation in end of life care research? [18]	• Question: question usually focuses on experience or perspective • Literature search: goal is to be comprehensive • Data abstraction: involves quality appraisal • Analysis: entails an interpretive synthesis
Mixed studies review [19]	Mixed qualitative and quantitative	How can qualitative, quantitative, and mixed studies be used to better understand a health problem?	What is the impact of clinical information retrieval on physicians? [19]	• Question: needs to be answered by all types of data – qualitative, quantitative, and mixed quantitative/qualitative • Literature search: goal is to be comprehensive • Data abstraction: abstract both qualitative and quantitative data, tool has been developed to appraise quality of mixed qualitative/quantitative studies • Analysis: entails both meta-analysis and narrative description of qualitative findings

Table 2.1.2 Conducting a systematic review

- Develop the review question using: Population of interest, Intervention to examine, Comparator(s), Outcome of interest, Study design(s), and Time limitations (PICOST) criteria
- Develop a review protocol
  - Outline the background
  - Define/clarify objectives and eligibility criteria
  - Develop search strategies
  - Identify methods to assess risk of bias
  - Describe the data to be abstracted
  - Pre-specify outcomes and analysis methods
  - Register the protocol with the PROSPERO database [this is an optional step]
  - Publish the protocol in an open access journal (e.g., Systematic Reviews). This is an optional step
- Plan literature search
  - Peer review literature search using the Peer Review of Electronic Search Strategies (PRESS) checklist
- Locate studies
  - Search electronic databases
  - Use other methods, if applicable (e.g., trial registers, hand searching, contacting experts)
- Select studies
  - Pilot-test eligibility criteria
  - Broad screen of citations (two reviewers in duplicate are recommended)
  - Strict screen of full-text articles (two reviewers in duplicate are recommended)
- Assess risk of bias in included studies
  - Use risk of bias instrument outlined in protocol (two reviewers in duplicate are recommended)
- Abstract data
  - Develop data abstraction form
  - Pilot test data abstraction form
  - Abstract data for primary and secondary outcomes outlined in protocol (two reviewers in duplicate are recommended)
- Analyze results
  - Assess clinical, methodological, and statistical heterogeneity
  - Synthesize the results quantitatively (e.g. meta-analysis) or qualitatively, if appropriate
- Present results
  - Present screening results (e.g., flow diagram)
  - Include a narrative synthesis of main findings, patient and study characteristics, and risk of bias results
  - Present quantitative data (e.g., forest plot) and/or qualitative data (e.g., thematic matrix)

Table 2.1.2 (*continued*)

- Interpret and discuss results
  - ○ Consider quality, strength, and applicability of results
  - ○ Discuss relevance of the findings to key stakeholders
  - ○ Describe study-level and review-level limitations
  - ○ Carefully derive conclusions
- Disseminate results
  - ○ For example, through peer-reviewed journals, media, reports, conference presentations

Groups that conduct systematic reviews

Many groups worldwide conduct systematic reviews (see Chapter 2.3). The Cochrane Collaboration, for example, often answer questions regarding the efficacy and effectiveness of an intervention [9]. They place a strong reliance on synthesizing evidence from randomized controlled trials (RCTs). However, some Cochrane entities support review questions that include different types of study designs, including qualitative research (Qualitative Research Methods Group), diagnostic test accuracy studies (i.e., Diagnostic Test Accuracy Working Group), and prognosis studies (Cochrane Prognosis Methods Group). Examples of other organizations that conduct systematic reviews include the Campbell Collaboration [20] which addresses questions related to crime and justice, education, and social welfare; [11] the Centre for Reviews and Dissemination, York University, which provides information about the effects of health and social care interventions and undertakes systematic reviews evaluating the research evidence on health and public health questions of national and international importance [21]; and the Joanna Briggs Institute, which conducts reviews on health issues of interest to the nursing profession [22]. These groups use different templates for conducting systematic reviews.

The review team

Prior to beginning a review, a systematic review team should be identified. The optimal team required is determined by the type of question being addressed and generally consists of clinical or content experts with extensive knowledge of the review topic, methodologists with expertise in systematic reviews, a librarian to help search the literature comprehensively [23], and epidemiologists or other researchers with

experience in conducting primary research on the topic. The funder or commissioning agency may help inform the context of the question and a statistician may be consulted if statistical synthesis (i.e. meta-analysis) is being considered. Some review teams also involve end-users of the review, including policy makers, health care professionals or patients, in the review process. This form of integrated knowledge translation [24] can be very informative to the systematic review conceptualization, conduct, and interpretation. It may also facilitate the uptake of review results.

How do we formulate the question, eligibility criteria and protocol?

Developing a clear and concise question is the first and one of most important steps in conducting a systematic review, as this will guide the review process. To formulate the systematic review question, the Population, Intervention, Comparators, Outcome, Study design, and Time period (PICOST) framework has been proposed to structure this process [25]. This approach defines the population, participants or problem (P); the interventions, independent variables or index test (for diagnostic reviews) (I); the comparators (C; e.g., placebo or standard of care or context, in the case of qualitative studies); and the dependent variables, endpoints or outcomes of interest (O) for the review question. The systematic review may also be limited to certain study designs (S), such as RCTs or cohort studies, and to studies of particular durations (Time – T). While this framework will not be suitable for all systematic review questions, it may be a useful guide. For example, systematic reviews of epidemiological studies may substitute *Intervention* with *Exposure.*

The eligibility criteria of studies to be included in the synthesis should extend from the PICOST components. Other characteristics that might be considered in developing eligibility criteria include publication status (i.e., published versus unpublished material) and language of dissemination. Limiting the review to published literature is cautioned against, as published studies have a greater tendency of having positive results [26, 27]. The effect of limiting the review by language of reporting of primary studies has yielded mixed results [28–30]. Regardless of the choices made, eligibility should be thoroughly considered, properly defined, and transparently reported to avoid ambiguity in the review process and to inform the validity of the review.

Once the review team has been assembled and the objectives defined, a protocol pre-specifying the systematic review methods, should be

developed to guide the process for the review team. Protocol use may decrease the likelihood of biased post-hoc methodological changes and selective outcome reporting [31]. Important elements of the review protocol include details on the methods used for search, retrieval and appraisal of the literature, and data abstraction.[9] Guidance is currently being developed on reporting items for systematic review protocols (*Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols*) [32]. The systematic review process may be iterative and the protocol may change over time; this is especially the case for qualitative reviews [17]. Changes to the review protocol are acceptable; however they should be transparently described in the final report.

Some groups have recently advocated for prospective registration of systematic reviews [31, 33]. Similar to trial registration [34], the rationale for systematic review registration is to help decrease publication and outcome reporting bias and avoid duplication [35]. An international registry for systematic reviews, PROSPERO, was launched in 2011 and contains over 700 records, attesting to its growing credibility within the systematic review community [36]. In addition, some researchers choose to publish their systematic review protocols in an open-access journal, such as *Systematic Reviews* [37].

How do we find relevant studies?

The review question or PICOST components are used to guide the location of relevant studies, usually entailing bibliographic database searches and other methods. The scope of the database and the review should be considered in order to select the most relevant databases for the review; searching more than one database is highly recommended in order to overcome potential indexing biases [38]. Commonly searched electronic databases for locating health-related research are MEDLINE [39]. EMBASE [40] and the Cochrane Central Register of Controlled Trials [8]. Reviewers may also search content-specific databases, such as the Cumulative Index of Nursing and Allied Health (CINAHL) or geographical databases, such as the Latin American Caribbean Health Sciences Literature (LILACS). Qualitative evidence is catalogued in a variety of different databases, making searching for such research challenging.[17] Consulting a librarian with experience in developing search strategies helps ensure that the search strategies are comprehensive. Feedback from a second librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist [41] might increase the likelihood that the literature search is valid and reliable, which is particularly helpful for groups updating existing reviews.

Systematic reviewers often use other sources to supplement their searches, such as hand searching journals, searching the reference lists of included studies or searching trial registries. Researchers should consider searching for grey literature (i.e., difficult to locate or unpublished material) which may include searching websites from funding agencies, health policy groups, and ministries of health, amongst others. Extensive guidance on searching for grey literature has been produced by the Canadian Agency for Drugs and Technologies in Health [42].

How do we select studies for inclusion?

Systematic reviewers generally separate the study selection process into two stages: (1) a broad screen of the titles and abstracts of the citations retrieved from the literature search, and (2) a strict screen of the full-text articles passing the broad screen to select the final included studies. Both phases of this selection are facilitated through the use of eligibility criteria. Pilot-testing the eligibility criteria on a random sample of citations/full-text articles can be conducted to ensure that study relevance is assessed consistently across reviewers. Having two or more reviewers screen the material independently helps ensure that potentially relevant studies are not excluded. Results are then compared and conflicts may be resolved by discussion or with the involvement of a third reviewer. Agreement between reviewers can be reported statistically using the kappa statistic [43].

The process of identifying and selecting studies requires detailed record keeping because it must be reported in sufficient detail for the end-user to determine validity. The ratio of reports to studies is not always 1 : 1, as some reports will describe multiple studies and some studies are described in more than one report; duplicate publications are not always obvious [44, 45]. Authors should attempt to identify such duplicate data, especially when considering meta-analysis. Using data from the same participants more than once may exaggerate the estimated treatment effect in meta-analysis [45]. The reviewers should first decide which study is the major publication for data extraction (e.g. based on primary outcome of the review, study with longest duration of follow-up or largest sample size) and the companion report(s) should be consulted to obtain supplementary information.

How do we assess the risk of bias of included studies?

The validity of the results of a systematic review will greatly depend on the risk of bias in the individual studies. Risk of bias assessment can be

completed using scales, checklists, or components and many tools are available [46]. For example, the Cochrane Collaboration has developed a tool to assess the risk of bias of RCTs, which was developed using informal consensus and evaluated through focus groups [47]. One study found that the Cochrane tool reliably categorized studies by the risk of bias [48], yet the reliability and validity of this tool have not been widely examined. A validated tool does not exist for assessing bias in observational studies [49], but the Newcastle Ottawa Scale is commonly used for cohort and case control studies [50]. Assessing the risk of bias for qualitative research is widely debated, although numerous tools have been developed, including the Critical Appraisal Skills Program's tool for qualitative studies [51]. Regardless of the instrument used, the individual components for each risk of bias item should be reported for each study. Simply reporting a score from an assessment scale is not as helpful to the end-user because there is insufficient detail to understand the sources of bias. Excluding studies from a review based on their risk of bias is not advisable. Rather, the impact of this potential bias can be addressed through sensitivity analyses, which explore whether results of the review are robust to differences across the studies, such as methodology (for example examining studies with and without concealed allocation separately) and study populations.

How do we extract data from the individual studies?

At the time of protocol development, the information sought from the included studies should be considered. The outcome(s) of primary importance (e.g. clinical, patient or policy relevant) should be differentiated from the "secondary" outcomes. Surveys have found that authors of randomized trials modified primary outcomes between the protocol and the final report approximately 40–62% of the time [52] and that the outcomes selectively reported in final reports were significantly more likely to be statistically significant than those omitted [53, 54]. Therefore, if a review is limited only to variables that are reported in the included studies rather than identifying those considered important at the outset, the review risks being subject to outcome reporting bias. In assessing outcome reporting bias, the Cochrane Collaboration recommends identifying the study protocol and comparing the outcomes that were reported in the protocol compared to the final study publication [47]. Another approach is to compare the outcomes reported in the methods and make sure that they are consistent with those reported in the results [47].

It is advisable to develop a data extraction form *a priori* including the variables to be collected and clear definitions for them. The form can be

pilot-tested by review team members to increase the reliability of the data extraction process. Having two or more people extract study data independently decreases the potential for error [55]. Reviewers should consider contacting authors to verify assumptions made for missing or unclear information.

How do we analyze the data?

The analysis method will depend on the question(s) being asked and the type of data collected; however, all systematic reviews should at least include a narrative synthesis describing the results and risk of bias in the included studies. For a typical intervention review including quantitative data, standard effect measures will need to be chosen, if possible, to compare studies (e.g., odds ratio, standardized mean difference, hazard ratio). The next step usually involves determining whether statistical synthesis (i.e., meta-analysis) is possible and appropriate. This step entails determining whether the studies are sufficiently homogenous regarding clinical aspects (e.g., patient populations), methodological characteristics (e.g., risk of bias), and statistical characteristics (e.g., range of effect sizes). Clinical and methodological heterogeneity are explored using clinical and methodological insight. Statistical heterogeneity is examined by visualizing the range of point estimates and 95% confidence intervals presented in forest plots and by calculating the I^2 statistic [9] and/or Cochran Q [9], which determines if the results from each study are more different from each other than one would expect due to chance alone. Extensive guidance on effect measures, approaches to detect heterogeneity, and meta-analysis techniques have been produced [9, 56, 57]. Qualitative approaches of analysis differ from quantitative methods. For example, qualitative data may be inputted into matrices or tables to allow comparison across studies [58]. Some knowledge syntheses will include both qualitative and quantitative data for which a variety of methods are available. Examples include a quantitative case survey, where qualitative data are converted into quantitative form and analyzed statistically (e.g., through meta-analysis) [58] and Bayesian meta-analysis, which allows the incorporation of qualitative research into a quantitative synthesis to provide policy-makers with decision support [56, 60]. Network meta-analysis is another form of meta-analysis that has gained increased interest by various stakeholders. This methodology can be used to compare interventions that have not been evaluated in head-to-head studies and ranks the effectiveness of each individual treatment [61]. Specifically, if one trial compares intervention A versus intervention B and another trial compares intervention B versus intervention C, the network of

evidence can be used to yield an indirect comparison of interventions A versus C.

How can we present the results of the review?

Results of knowledge syntheses may be presented in numerous ways. The screening process may be described in the text and/or presented as a flowchart (Figure 2.1.1) [62]. Many journals are requiring this information to facilitate transparency of the process. Characteristics of included studies, such as descriptions of study designs, participant populations and interventions, are generally presented by study in tabular form and/or synthesized textually. The results of risk of bias assessments may also be presented in a table or text and sufficient detail should be presented to allow the end-user to be able to determine the potential threats to validity.

Quantitative data should be presented as summary data (e.g. 2×2 tables of counts, means and standard deviations) and effect estimates (e.g. odds
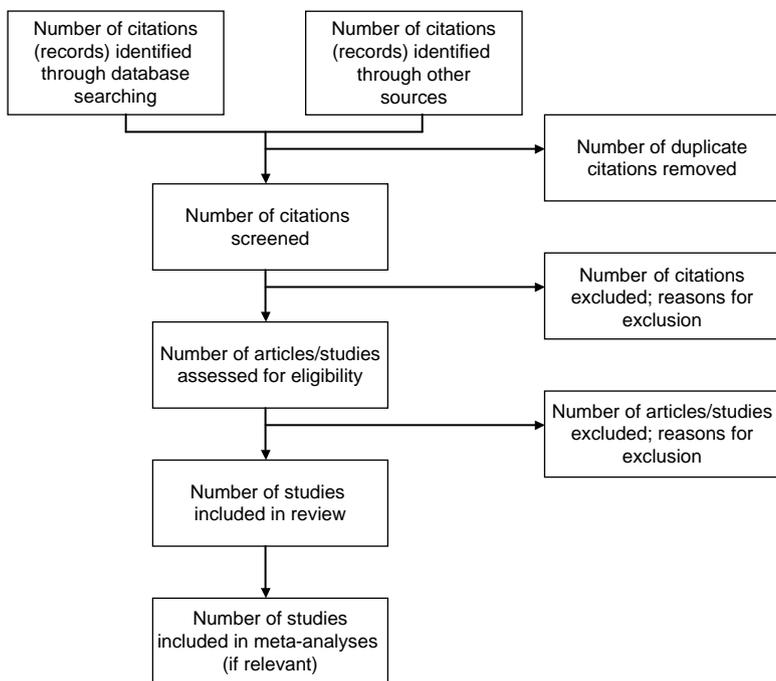
Figure 2.1.1   Flow diagram documenting literature retrieval.

Description	Tetracycline-rifampicin n/N	Tetracycline-streptomycin n/N	Relative risk (fixed) (95% CI)	Relative risk (fixed) (95% CI)
Acocella 1989	3/63	2/53		1.26 (0.22 to 7.27)
Ariza 1985	7/18	2/28		5.44 (1.27 to 23.34)
Ariza 1992	5/44	3/51		1.93 (0.49 to 7.63)
Baylndir 2003	5/20	6/41		1.71 (0.59 to 4.93)
Colmenero 1989	7/52	5/59		1.59 (0.54 to 4.70)
Colmenero 1994	2/10	0/9		4.55 (0.25 to 83.70)
Dorado 1988	8/27	4/24		1.78 (0.61 to 5.17)
Ersoy 2005	7/45	4/32		1.24 (0.40 to 3.90)
Kosmidis 1982	1/10	2/10		0.50 (0.05 to 4.67)
Montejo 1993	6/46	4/84		2.74 (0.81 to 9.21)
Rodriguez Zapata 1987	3/32	1/36		3.38 (0.37 to 30.84)
Solera 1991	12/34	3/36		4.24 (1.31 to 13.72)
Solera 1995	28/100	9/94		2.92 (1.46 to 5.87)
Total (95% CI)	501	557		2.30 (1.65 to 3.21)

Total events: 94 (tetracycline-rifampicin),
 45 (tetracycline-streptomycin)

Test for heterogeneity: $\chi^2 = 7.64$, df = 12, P = 0.81, $I^2 = 0\%$

Test for overall effect: z = 4.94, P < 0.001

0.1 0.2 0.5 1 2 5 10

Favours tetracycline-rifampicin   **Favours tetracycline-streptomycin**

Figure 2.1.2   Example of forest plot.

ratio, difference in means) with confidence intervals for each study, where possible. This data may be presented for each outcome in a table or in a forest plot, with the combined effect estimate of the meta-analysis, if relevant (Figure 2.1.2). Qualitative data may also be presented visually, for example through a conceptual framework. Results of all other analyses, such as assessment of publication bias, should also be reported. This essential information is often missing from reports of meta-analyses [63].

How can we interpret the results?

Reviewers should discuss the quality, strength, and applicability of the evidence for each main outcome when summarizing the results. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is a framework that can be used to facilitate interpretation of results [64], and has been endorsed by the Cochrane Collaboration [9]. Qualitative evidence may also help interpret how the intervention works, whether it could work in different settings, identify facilitators and barriers to implementation of the intervention, and highlight subjective experience of patients receiving the intervention [22]. Further guidance on interpreting systematic reviews have been published previously [65]. In addition, the relevance of the results should be considered for key stakeholders (e.g., policy makers,

patients, health care providers) because this will help increase the applicability of the results for these groups. As mentioned above, involving these groups at the outset of the review (e.g. in defining the research question, choosing eligibility criteria and outcomes) will increase applicability of the results.

Reviewers should consider both study and review-level limitations. If the conduct or reporting of included studies is poor, the review conclusions may be biased and this should be stated explicitly. Furthermore, systematic reviews themselves can be susceptible to bias [66]. Evidence suggests that systematic reviewers should try to avoid bias in their review by including relevant unpublished material, hand searching for additional material, searching more than one electronic databases, assessing for publication bias, and periodically updating the systematic review [66].

Despite efforts to decrease bias in systematic reviews, some limitations might persist. The Assessment of Multiple SysTemAtic Reviews (AMSTAR) tool can be used to identify limitations in the systematic review process [67], which should be noted.

Finally, reviewers should carefully draw conclusions based on the available evidence. Conclusions may include specific recommendations for decision-making or for research [68]. If conclusions can't be drawn due to insufficient reliable evidence, this should be stated as it may indicate the need for further research.

How do we update systematic reviews prior to publication?

The systematic review process can take six months to two years to produce results [69], and the literature search might be out-of-date by the time the review is ready for publication. Indeed almost a quarter (23%) of reviews were shown to be out of date by two years and 7% were out of date by the time of publication [70]. Review teams should consider updating their search using the same search strategy prior to journal submission and even after journal submission when the peer review process is lengthy. Guidance on when and how to update systematic reviews has been published previously and this is an area for further study [71, 72].

How do we disseminate the results of our review?

The final step in the review process is making the results accessible. The most common form of passive dissemination is publication in peer-reviewed journals, with recent estimates suggesting 11 systematic reviews are published per day [73]. Publishing in open access journals offers

broader readership, especially to low- and lower-middle-income economy countries; it also enables authors to retain copyright of their paper. Other forms may include targeted dissemination via media for the public [74] brief reports for health care providers, policy makers and consumers [75], and creation of knowledge tools such as decision aids for patients [76]. Uptake of the results of systematic reviews may be impeded by many factors, but one that is in the author's control is the quality of the review report. Transparent descriptions of the review methods and results allow readers to assess the methods, risk of bias of the included studies and the review, and inform them of the applicability of the review.

Evidence suggests that reports of systematic reviews are not optimal [77]. The PRISMA (*Preferred Reporting Items for Systematic reviews and Meta-Analyses*) Statement was developed to improve the reporting of systematic reviews and meta-analysis [62]. Similar initiatives are also available for reviews of observational studies [78]. The Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network website contains a comprehensive list of other reporting guidelines, some of which have received major health care journal endorsement [79].

How do we increase the uptake of our review results?

There is limited evidence to support how systematic reviews should be presented to enhance uptake in decision-making. Despite advances in the conduct and reporting of systematic reviews (and recognition of their importance in knowledge translation), current evidence suggests that they may be used infrequently by clinicians, patients and others to make decisions. For example, a systematic review of the information seeking behavior of physicians found that textbooks (many of which do not rely on evidence from systematic reviews) are still the most frequent source of information followed by advice from colleagues [80].

Given that systematic reviews of randomized trials are less susceptible to bias than the opinions of experts and observational data, why are they used so infrequently? There are many answers to this question, which can be broadly categorized into the relevance of the questions the reviews are addressing, the lack of contextualization and the format of presentation. While much attention has been paid to enhancing the quality of systematic reviews, relatively little attention has been paid to the format for presenting the review. Because the reporting of systematic reviews tends to focus on methodological rigor more than clinical context, they often do not provide crucial information for clinicians. In one study, only 15% of systematic reviews published in the *ACP JC* and *EBM Journal* (journals of secondary

publication) provided sufficient information for clinicians and policy makers to implement the intervention being examined [80]. Efforts are underway to improve the utility of systematic reviews [81, 82]. The Cochrane Collaboration provides patient-friendly user summaries for each systematic review, which is written in lay language to increase uptake [9]. Clinical Evidence provides evidence-based summaries for clinicians [83]. Rx for Change [84] and the Program for Policy Decision-making [85] provide evidence-based resources for policy-makers and managers.

Future research

Future research is needed to advance the knowledge synthesis field. Although numerous innovative knowledge synthesis methods have emerged, how best to match a review question to the most appropriate approach is yet to be determined. Furthermore, sorting through the terminology and methods that have emerged to synthesize the literature is required. Although research exists on the importance of updating systematic reviews [41, 70, 86], and suggested frequency and methods of updating [71, 72] more research in this topic is warranted. Furthermore, research is required to identify formats for knowledge synthesis that can increase their uptake, as well as determining the utility of resources to improve the uptake of reviews (e.g., Clinical Evidence [83], Rx for Change [84], Program in Policy-Making [85].

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Chapter 2.2 **Knowledge translation tools**

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Key learning points

Clinical practice guidelines
- translate evidence into clinical practice recommendations to assist with decisions by patients, providers, and policy makers
- impact quality of care and system performance
- can be developed, reported and quality appraised using AGREE II (Appraisal of Guideline Research and Evaluation II).

Patient decision aids
- translate evidence to inform patients on their options, help patients clarify the value they place on benefits and harms of options, and guide them in the process of decision making
- improve patients' participation in decision making, knowledge of options, and agreement between patients' values and their chosen option
- can be developed and quality appraised using the International Patient Decision Aid Standards (IPDAS) instrument.

In Chapter 2.1 we outlined that knowledge syntheses can form the base unit of KT tools such as clinical practice guidelines and patient decision

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aids which are discussed in this chapter. Clinical practice guidelines and patient decision aids are knowledge tools designed to facilitate evidence-based/evidence-informed decision making. However, the processes of developing and evaluating these knowledge tools can also serve as an effective integrated knowledge translation strategy because it requires the active collaboration among, and involvement of, methodologists, content experts, and knowledge users. To achieve a completely integrated approach, the process would start by end-users (e.g. patients, clinicians, policy makers) determining the need for the tool (i.e. identifying the clinical or decision issues of particular relevance), and encouraging participatory processes that involve end-users in the development process such as including them on development panels and obtaining broad end-user feedback on the tool to ensure relevance, usability, and implementability. We will demonstrate how these tools integrate scientific methodological rigor and social engagement to reflect vital elements of the knowledge creation and action components of the knowledge-to-action-cycle [1].

Knowledge translation using clinical practice guidelines

What are clinical practice guidelines?

Evidence-based clinical practice guidelines are knowledge tools defined as systematically developed statements aimed to assist in making decisions about appropriate health care for specific clinical circumstances [2]. Targeted originally for physicians, they are used by patients, health care policy makers, and clinical managers [3, 4]. The definition is important as it articulates what clinical practice guidelines are and what they are not. They are tools and, in addition to many other factors (values and preferences of patients, providers and society; costs, etc.) aim to assist decision making, but not supplant it. They are not dictum or formulaic tactics to drive patient care. Indeed, clinical practice guidelines have capacity to promote high quality practice informed by evidence, enable appropriate resource allocation, and advance research by identifying research gaps and areas where additional research will not advance knowledge further.

How are clinical practice guidelines developed?

Well-articulated systematic and rigorous methodologies exist to ensure high quality clinical practice guidelines are created. Guideline development requires a combination of both methodological rigor and social engagement (Table 2.2.1). Methodologically, clinical practice guidelines begin with a clinical question informed by a clinical or health care problem. As

Table 2.2.1 Clinical practice guidelines: common elements

- Establish multidisciplinary guideline team
- Identify, report, and manage conflict of interests of guideline team
- Identify purpose and goals of the guideline. Start to define dissemination and implementation goals and strategies
- Identify clinical question that explicitly defines the patients, intervention/exposure, comparisons (if relevant), outcomes of interest and setting
- Conduct a systematic review of evidence
- Appraise and interpret evidence and come to consensus on its meaning
- Draft guideline recommendations that align with evidentiary base. Where appropriate, consider other issues besides the evidence that influence the implementability of the recommendations (e.g. values, preferences, resource considerations)
- Complete an external review of draft report among intended users and key stakeholders.
- Revise the guideline in response to external review
- Read the final guideline report for distribution and dissemination
- Continue dissemination and implementation strategy

mentioned in Chapter 2.1, the PICO format (or some derivation of it) can be used to formulate the question. Starting with a good question is fundamental as it then informs the specific inclusion and exclusion criteria that will be used to design and execute the systematic review of the relevant research evidence. The evidentiary base serves as the foundation upon which to make the clinical recommendations. The recommendations that are made should explicitly link to the evidence that supports them with some indication of its quality, completeness, and risk of bias. This process can be achieved with formal systems (e.g., GRADE [5, 6], Risk of Bias tool [7]) or using language to explicitly describe the evidentiary base and study designs upon which they are based. There are pros and cons to both strategies [8, 9].

The next step is an external review of the draft clinical practice guideline by key stakeholders and the intended users of the recommendations. This review can improve the quality of clinical practice guidelines by identifying evidence that was missed and enabling stakeholders to endorse the interpretation of the evidence made by the developers or offer alternative interpretations. In addition, the review provides an opportunity to explore the "implementability" of recommendations, including an analysis of barriers and enablers to their application by clinicians and administrative and system leaders involved in the organization of health care services [10]. A transparent report of the external review strategy, the actions taken by the guideline development group in response to the feedback, and the final recommendations conclude the development process.

From a social engagement (or integrated KT) perspective, clinical practice guidelines can facilitate a culture of stakeholders who are receptive to evidence, understand evidence, and can apply evidence. To this end, the highest quality and most effective clinical practice guidelines are those in which the development group is comprised of a multidisciplinary team of stakeholders including clinical and content experts, methodologists, and other users including patient representatives, researchers, policy makers, and funders. External review is also a form of social engagement. It creates a system of accountability between developers and the intended users of the clinical practice guidelines, and provides a forum from which to engage target users endorsement of, and intentions to use, the recommendations. It is only with the engagement of relevant stakeholders that a viable strategy for implementation of the guidelines can be developed. A participatory approach to guideline development requires attention to processes for reporting and managing conflicts of interest (real and perceived) that may influence how evidence is appraised and interpreted and the recommendations that result [11, 12]. Skilled facilitation is an essential ingredient in this process.

There are several resources available to guide in the development of clinical practice guidelines [12–14], including the AGREE (Appraisal of Guidelines Research and Evaluation) II [15–17]. In addition, methods exist to enable clinical practice guidelines from one jurisdiction or context to be adapted for use in another [18] and this is discussed in Chapter 3.2.

Do clinical practice guidelines work?

The impact of clinical practice guidelines on practice and outcomes is complex. Systematic reviews and studies by Grimshaw and others suggest that interventions to implement clinical practice guidelines, or similar statements, can influence both the processes and the outcomes of care, although the effect sizes tend to be modest [19–23]. Interventions for implementation ranged from mass media interventions to use of local opinion leaders and include interventions targeted towards the public, health care professionals, and managers amongst others. Building recommendations into information systems and patient systems (e.g. electronic medical record) have been shown to be effective at facilitating uptake of desired behavior. A limitation in understanding the impact of guidelines is that studies often focus on process outcomes rather than clinical endpoints. For example, Grimshaw and colleagues found in their review of 235 studies, that the majority of studies used process outcomes for primary endpoints despite only 3 guidelines being explicitly based on evidence! [19]

The potential benefits of clinical practice guidelines are only as good as the quality of clinical practice guidelines themselves. There is good evidence demonstrating the role of guidelines as a tool to facilitate system and policy decisions [3, 4, 24, 25]. For example, in Ontario, Canada, guidelines are required as part of the information used by policy makers to determine which cancer drugs will be paid for in the publicly funded system [25]. This approach has expanded to an inter-provincial initiative, pan-Canadian Oncology Drug Review (p-CODR) [26].

While faithfulness to evidence-based principles is important, other factors believed to influence guideline uptake include adopters' perceptions of the guidelines characteristics and messages, perceptions of the development process, and factors related to norms and context [15, 19–23]. An implementation strategy, that includes analysis of enablers and barriers (Chapter 3.3), selection of appropriate and feasible KT interventions (Chapter 3.4a), and indicators to measure impact (Chapter 3.5) increases the likelihood of success. Considering these issues at the onset of guideline development, rather than at its conclusion, can be a more useful approach.

How do we determine the quality of clinical practice guidelines?

In reality, the quality of clinical practice guidelines can be extremely variable and often fall short of basic standards. For example, Graham and colleagues appraised the quality of 217 Canadian drug therapy clinical practice guidelines produced between 1994 and 1999 and found that less than 15% of the those reviewed met half or more of the 20 criteria assessing the rigor of development; the overall mean score was 30% [27].

In response to this challenge, the AGREE Instrument (2003) was designed to evaluate the process of guideline development and the quality of reporting [28]. Building on this, the AGREE Next Steps Consortium conducted a program of research to further test and refine the measurement properties of the Assessment Instrument (reliability and validity), ensure its utility across different stakeholder groups, and improve the supporting documentation to help users implement the Instrument. The result of these efforts is the AGREE II – the new standard for guideline development, reporting, and evaluation [15–17]. The AGREE II is composed of 23 items targeting 6 quality domains (see Table 2.2.2), one global rating scale, and a User's Guide. It has been used to inform other guideline development resources, such as the Institute of Medicine quality standards for guidelines [29]. Brouwers *et al.* evaluated English-language 602 cancer guidelines using the AGREE II and found the mean domain score of Stakeholder Involvement was only 43% and only 26% of guidelines that were assessed

Table 2.2.2 AGREE instrument domains

- Scope and purpose
- Stakeholder involvement
- Rigor of development
- Clarity and presentation
- Applicability
- Editorial independence

included all aspects of a researchable question used to develop the evidentiary base (Rigor of Development domain) [30]. Clearly, more work is required.

While the AGREE II provides important criteria upon which to evaluate clinical practice guidelines, the clinical validity, appropriateness of recommendations, and thorough analysis of the capacity to implement recommendations are factors not within its scope. This is the continued work of the AGREE Research Enterprise through the AGREE-REX (Recommendation Excellence) Research Team [31] and other international collaborators including GIRANet (Guideline Implementability Research and Application Network; [32]), the DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) Collaboration [33], and the GLIA (Guideline Implementability Assessment) tool team [34, 35]. The ADAPTE tool (Chapter 3.2) also provides criteria to evaluate the clinical fidelity of recommendations and their link to evidence [19].

Translating knowledge for patients using decision aids

What are patient decision aids?

Patient decision aids are interventions/tools that are designed to translate evidence into patient friendly resources. At a minimum, these tools make explicit the decision to be made, inform patients on their options, help them clarify the value they place on benefits versus harms, and guide them in the process of decision making [36]. Evidence included in patient decision aids is defined as up-to-date scientific information on options, benefits and risks of options, and associated probabilities [37]. Formats for these tools include paper-based booklets, video/DVDs, decision boards, and internet-based materials. Patient decision aids are used as adjuncts to practitioner counseling for decisions where the best choice depends on how patients weigh the benefits, risks and scientific uncertainty (e.g., birth control, genetic testing, breast and prostate cancer treatment, options for

menopause symptoms, back pain, osteoarthritis, level of care at end of life). They differ from educational materials by not only providing option information but also making explicit the decision and guiding patients to express their personal values. Some decision aids tailor the information to the patient's clinical risk profile. Figure 2.2.1 provides a sample page from a patient decision aid. Others are available on the website: http://decisionaid. ohri.ca/, accessed July 2012.

In addition to being KT tools, patient decision aids can be used as patient-mediated KT interventions (Chapter 3.4f) to increase use of

1.0 Patient decision aid presentation of outcome probabilities

Blocks of 100 faces show a "best estimate" of what happens to **100 people** who choose different options [**specify time period**]. Each face [☺] stands for one person. The shaded areas show the number of people affected. There is no way of knowing in advance if you will be the one who is affected.

Benefits

✱ [Fewer/More] people get a if they [insert option] ....→

Describe what it is like to experience this
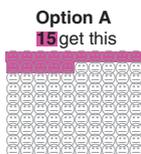
	Option A **15** get this	Option B **4** get this
	85 avoid this	**96** avoid this

Risks and side effects

✱ More people who [insert option] have risk/side effect a ....→

Describe what it is like to experience this
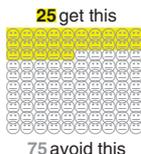
	25 get this	**52** get this
	75 avoid this	**48** avoid this

✱ Platinum or ✦ Gold symbols mean stronger study results; ☆ Silver or ✚ Bronze mean weaker results.

2.0 Patient decision aid exercise to clarify patients' values for outcomes

Common reasons to choose each option are listed below.
Check✓ how much each reason matters *to you* on a scale from 0 to 5.
'0' means it is **not** important to you. **'5'** means it is **ver**y important to you*.

Reasons to choose **Option A**	**Not** **important**				**Very** **important**
How important is it to you to [get the benefit of option A]?	⓪ ① ② ③ ④ ⑤				
How important is it to you to [avoid a risk/side effect/inconvenience] of the option B]?	⓪ ① ② ③ ④ ⑤				
Reasons to choose **Option B**	**Not** **important**				**Very** **important**
How important is it to you to [get the benefit of option B?	⓪ ① ② ③ ④ ⑤				
How important is it to you to [avoid a risk/side effect/inconvenience] of the option A]?	⓪ ① ② ③ ④ ⑤				

Figure 2.2.1 Example of selected components of a patient decision aid.

Table 2.2.3 Patient decision aids: common elements

- Makes explicit the decision to be made
- Evidence-based information on the condition, options, and outcomes including benefits and harms;
- Risk communication on the chances of outcomes and the level of scientific uncertainty (optional)
- Values clarification to ascertain which benefits, harms, and scientific uncertainties are most important to the patient
- Structured guidance in the steps of deliberating and communicating with practitioners and significant others

evidence in shared decision making. However, two systematic reviews of interventions to increase shared decision making found that to be more effective as patient mediated KT interventions, patient decision aids should be combined with interventions targeting practitioners such as training [38, 39].

How are patient decision aids developed?

High-quality patient decision aids are developed using a systematic process and explicit guidelines are available elsewhere [37]. Their development highlights the integrated KT approach, specifically engaging the end-users throughout the process. The first step is to determine the decision making needs of potential users (e.g., patients and practitioners). Needs assessments focus on the users' perceptions of the decision (options, outcomes, values), perceptions of others involved in the decision (decisional roles, opinions, pressures) and resources needed to make and/or implement the decision [40]. Second, the patient decision aid is based on an syntheses of the evidence and includes elements outlined in Table 2.2.3. To minimize bias and improve patients' ability to understand the chances of outcomes, there are evidence-based criteria for displaying probabilities within patient decision aids (Table 2.2.4). Third, the decision aid is reviewed by a panel of experts,

Table 2.2.4 IPDAS criteria for presenting probabilities of option outcomes

- Use event rates specifying the population and time period
- Compare outcome probabilities using the same denominator, time period, scale
- Describe uncertainty around probabilities
- Use multiple methods to view probabilities [words, numbers, diagrams]
- Allow patient to view probabilities based on their own situation
- Place probabilities in context of other events
- Use both positive and negative frames (of 100 people, 57 have less pain, and 43 have no change in their pain)

external to the development process. The panel may include clinicians, researchers, and patients amongst others. Finally, the patient decision aid is evaluated by end-users. Defining a "good decision" is a challenge, when there is no single "best" therapeutic action and choices depend on how patients value benefits versus harms. The International Patient Decision Aids Standards Collaboration (IPDAS) has reached consensus on the criteria for judging decision quality (informed, preference-based) and processes leading to decision quality (recognize that a decision needs to be made; know options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in preferred ways) [41]. These standards are available at http://ipdas.ohri.ca, accessed July 2012.

Do patient decision aids work?

A review of 10 systematic reviews of patient decision aids showed that these knowledge tools improve patients' participation in decision making, knowledge of options, and agreement between patients' values and the subsequent treatment or screening decisions [36, 42]. However, impact on clinical outcomes is less clear [36]. When probabilities of outcomes are presented, patients have more realistic expectations of the chances of benefits, harms, and side effects. The use of elective surgery (e.g., hysterectomy, prostatectomy, mastectomy, coronary bypass surgery, back surgery) decreased in favor of more conservative options without apparent adverse effects on health outcomes or anxiety. Finally, there appears to be a positive effect on communication with their health practitioner and a variable effect on the time required for this consultation.

A systematic review of 38 studies found that barriers to implementing patient decision aids in clinical practice include practitioner perception of patients' readiness to use them, forgetting to offer them to patients, content practitioners thought was too complex or too simple, time required to make them available, outdated evidence, cost, and limited accessibility [44]. This review also found that patient decision aids are more likely to be used when there are positive effects on patient outcomes and/or the clinical process, when patients prefer to actively participate in decision making, and health professionals are motivated to use them.

How do we determine the quality of patient decision aids?

Although many patient decision aids are available, as with clinical practice guidelines, they are of variable quality [43]. As a result, the IPDAS Collaboration was established to reach agreement on criteria for developing and

appraising their quality [37, 41]. The IPDAS checklist has domains that include: (a) content (providing information, presenting probabilities, clarifying values, guiding deliberation and communication); (b) development (systematic development process, balanced presentation, evidence base, plain language, disclosure); and (c) evaluation (decision quality and decision making process). The IPDAS checklist is used to appraise available patient decision aids in the Cochrane Inventory at a publicly available website (http://decisionaid.ohri.ca/, accessed July 2012); its validity and reliability have been established [41].

Future research

Research focused on developing strategies to enhance implementation of guidelines and patient decision aids would be useful. More work is also needed to show the impact of patient decision aids on adherence to chosen option, clinical outcomes, cost-effectiveness, and use with lower literate and culturally diverse populations.

Summary

In view of findings from systematic reviews, clinical practice guidelines may improve patient outcomes and patient decision aids improve decision quality. Both knowledge translation tools show promise in decreasing practice variations and preventing overuse or under-use of health care options. Important in the development of high-quality clinical practice guidelines and patient decision aids is the systematic synthesis of the evidence to be used within these tools, and the systematic iterative process of obtaining feedback from potential users. Ideally, systematic reviewers of clinical interventions should consider using these knowledge translation tools as end products for communicating their findings for use in clinical practice.

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Chapter 2.3 **Searching for research findings and KT literature**

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Key learning points

- KT practitioners need to identify published and unpublished material related to many elements of the KTA cycle. This material can be summaries of existing knowledge, demonstration projects and other summaries of successful and unsuccessful KT interventions, and material related to the theory of KT (e.g., models and frameworks).
- Many resources must be used to identify this material. Bdzel and colleagues have produced a document that provides assistance to those who want material important to KT practice.
- Search filters developed for KT literature are good at retrieving KT articles from large databases, but still return many false-positive articles for screening.
- Many internet sites are available that include resources and tools useful for general and more focused KT areas. This abundance of sites makes finding material both easier and harder as the documents and resources one needs will be in multiple places.
- The varied terminology across disciplines and geographic areas complicates retrieval. Standardization of definitions and acknowledgment of equivalent terms will make finding material easier.

Searching for evidence in the health literature is difficult for almost any topic because of the volume of literature and its complexities. The major problems of searching center around the time it takes, knowing the most promising resources to use, and how best to use the resource once it is chosen [1]. The knowledge-to-action cycle prescribes the need to identify studies, research, syntheses and knowledge tools that comprise the knowledge creation funnel as well as the need to identify literature on the KT process itself (e.g., KT theories, KT interventions).

People involved in KT research and practice benefit from using information from diverse resources. We need to identify quality evidence and summaries of evidence (e.g., systematic reviews, clinical practice guidelines, health technology assessments [HTAs]); to produce the knowledge syntheses which form the basis of guidelines as discussed in Chapters 2.1 and 2.2; and to identify information on successful KT interventions – the evidence showcasing successful or unsuccessful KT applications that can be used to model projects. Information describing the theoretical basis (e.g., models or frameworks for KT) is also important for those interested in designing and evaluating KT projects [2].

This chapter has several purposes. First, we want to describe where to find the information important to KT. Second, we want to provide the vocabulary that can be used to search resources that you might encounter. We have incorporated information from Bzdel *et al.*'s very useful web resource [3]. Although this document was published in 2004, we encourage consulting this guide as a starting point for almost any KT project or proposal.

Getting started: how do we find knowledge syntheses?

Summaries or syntheses of evidence provide the foundation of KT interventions. Busy practitioners do not have time to summarize the total evidence on important questions; researchers starting studies can also benefit from using existing summaries. It is much more efficient to use or build upon existing well-done summaries of evidence than to produce new summaries. These summaries are even more useful if they are published in specific, multiple formats for such various audiences as the public, patients, physicians, nurses, and policy staff. Several categories of evidence summaries exist and their identification varies by category. The largest category of summaries is systematic reviews including meta-analyses. These are often published and indexed in the large bibliographic databases such as Medline and CINAHL (Cumulative Index to Nursing and Allied Health Literature)

or other smaller databases. The health-evidence.ca site (http://www.health-evidence.ca/, accessed September 2012) provides systematic reviews in the area of public health useful to decision makers. The Cochrane and Campbell collaborations produce high-quality clinically important systematic reviews on all areas of health care (http://www.thecochranelibrary.com/view/0/index.html, accessed September 2012) and social science (http://www.campbellcollaboration.org/, accessed September 2012). The Joanna Briggs Institute in Australia produces systematic reviews in nursing and other health disciplines and provides access to many health-discipline specific resources (http://www.joannabriggs.edu.au/, accessed September 2012). Reviews related to KT are also available from the Canadian Agency for Drugs and Technology Health in their Rx for Change database (http://www.cadth.ca/resources/rx-for-change, accessed September 2012). The UK Centre for Reviews and Dissemination at York University (http://www.york.ac.uk/inst/crd/index_databases.htm, accessed September 2012) produces databases that include a broader range of reviews (Database of Reviews of Effects or DARE), economics studies (National Health Service Economic Evaluation Database), and HTAs (HTA Database). A searching guide for HTAs and similar material (HTA on the Net: A Guide to Internet Sources of Information) can be found at http://www.ihe.ca/research/health-technology-assessment/infopapers/, accessed September 2012. The Canadian Partnership for Against Cancer has produced a guide on searching for guidelines (http://www.cancerview.ca/idc/groups/public/documents/webcontent/can_implement_library_sup.pdf, accessed September 2012).

As mentioned in Chapter 2.2, clinical practice guidelines can be thought of as summaries of evidence that also include directions or recommendations for patient care. The largest site for guidelines is the National Guidelines Clearinghouse, produced by the US Agency for Healthcare Research and Quality, (at http://www.guideline.gov/, accessed September 2012). Although the title indicates national coverage, many guidelines from other countries are included. The Canadian Medical Association provides links to Canadian guidelines (CMA infobase http://mdm.ca/cpgsnew/cpgs/index.asp, accessed September 2012). NICE (UK National Institute for Health and Clinical Evidence) produces UK guidelines (http://www.nice.org.uk/, accessed September 2012 and Chapter 2.2). GIN or the Guidelines International Network brings together individuals and organizations committed to developing high-quality guidelines (http://www.g-i-n.net/, accessed September 2012). However, most of these guidelines are not appraised for quality and it is

useful to develop skills in appraising them for validity and importance prior to deciding on implementation.

What should we do next: how do we search large databases?

If we cannot find a summary of the evidence in the sources just listed or if we need original study results we may need to go to such databases as Medline, the large bibliographic database for all health care with emphasis on medicine or CINAHL for material important to nursing and allied health professions. The Bzdel Resource Guide [3] describes other databases and evidence resources important for KT. Librarians can help with searching or provide training on searching. Many online tutorials also exist. For example, the tutorial for PubMED, the easy-to-use, free Medline searching system is located at http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/, accessed September 2012.

Searching for articles on KT interventions or KT theory or frameworks is difficult. With funding from CIHR, we've produced searching "filters" to identify KT material in Medline and CINAHL more easily [4, 5]. These filters were developed to retrieve general KT content articles, KT applications, and KT theory, and are available at http://hiru.mcmaster.ca/hiru/HIRU_KT_MEDLINE_Filters.aspx, accessed September 2012. The filters have good sensitivity-retrieval of KT articles, but poorer specificity i.e. retrieval of false positive articles. In the future, the filters will be refined, but in the meantime they still retrieve a large amount of non-KT content due to issues with terminology in the field. Other similar filters exist as PubMed clinical queries that retrieve other content such as randomized controlled trials and systematic reviews (http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml, accessed September 2012), and qualitative, quality improvement, and health services research (http://www.nlm.nih.gov/nichsr/hedges/search.html, accessed September 2012).

A relatively easy way to use the filters in PubMed or Ovid Medline is to copy the filter from the HIRU website. In the searching window use this approach for Pubmed:

(your search terms) *and* (copied terms from your chosen KT filter)

Your search, or content, terms are typed or copied inside the first set of parentheses and the KT filter content is copied inside the second set of parentheses. In Ovid Medline, the search filter can be copied in the search window and the resulting citations can be "ANDed" with your content terms. More information on how to use the filters is included on the HIRU website (http://hiru.mcmaster.ca/hiru/HIRU_KT_MEDLINE_Filters.aspx, accessed September 2012). If you're searching for a specific KT intervention,

Figure 2.3.1   Screen shot of using Ovid Medline to retrieve studies of using computer communication methods for adolescents and young adults with diabetes.

we suggest that you look at search strategies employed in systematic reviews of the intervention to guide selection of your content search terms. These can be combined with the KT filters to further refine your retrieved result. As this looks complicated here is a screen shot of OVID Medline searching using the KT filters to find material on adolescents or young adults with diabetes when the KT intervention is any of several computer communication devices. Search statement 1 at the top of Figure 2.3.1 is the KT filter strategy with the highest sensitivity (91%) for retrieving studies of KT interventions.

Should we search the internet?

The internet can provide access to technical reports and other non-journal material related to KT. Google and its companion site, Google Scholar (a set of more scholarly documents than full Google), are good places to start. A summary of many of the other non-Google search engines is located at http://searchenginewatch.com/showPage.html?page=2156221, accessed September 2012. In addition, some websites allow you to search in multiple databases and resource collections with one searching window. One such resource that consolidates much information that is useful to KT practitioners and researchers is TRIP – Turning Research into Practice website: http://www.tripdatabase.com/index.html, accessed September 2012. These federated searches search multiple databases and content providers at one time. The ACCESSSS federated search, powered by McMasterPlus, conducts literature searches simultaneously in several different evidence-based information services (online evidence-based texts, and pre-appraised journal publications), and presents searching retrieval hierarchically based on

the principles of evidence-based medicine (http://plus.mcmaster.ca/ACCESSSS/Default.aspx?Page=1, accessed September 2012).

What are some existing collections of KT material?

Several sites collect and present KT material, tools, or both (see Table 2.3.1).

How do we search the grey literature?

Grey literature is information that is not under the jurisdiction of commercial publishers. This material is often published by all levels of government, academic centers, and businesses for example. The material is in electronic or paper format and is often very difficult to identify and obtain and no validated filters or search processes exist for this literature. Grey literature is especially important to those involved in public health KT. A number of university libraries provide guides on how to search for unpublished literature (e.g., http://guides.mclibrary.duke.edu/greyliterature, accessed September 2012; http://guides.lib.umich.edu/greyliterature, accessed September 2012). The New York Academy of Medicine collects grey literature related to health services research and public health which is searchable from their site at http://www.nyam.org/library/, accessed September 2012. European grey literature is available through SIGLE (System for Information in Grey Literature in Europe, http://opensigle.inist.fr/, accessed September 2012) and information about searching for grey literature related to HTAs and economics studies is at the HTAi Vortal: http://www.htai.org/index.php?id=579, accessed September 2012.

Searching for literature about knowledge translation

Searching for material related to KT interventions and theory has several characteristics that make searching even more difficult. KT is a new field that interrelates with several existing disciplines. It includes an evolving and varied vocabulary with multiple terms for the same concept. For example Canadian researchers use the term knowledge translation while US and UK researches may use the terms research utilization, implementation, translation, or diffusion. Those in business use terms related to marketing, advertising, and change management while engineers speak of technology transfer. Individual clinicians deal with adoption of new techniques and evidence-based practice while policy makers speak of evidence-informed decisions. Table 2.3.2 provides a list of

Table 2.3.1   Sites that provide KT material, tools, or both

Site name and web location	Material contained
Cochrane Effective Practice and Organization of Care Group, University of Ottawa, http://www.epoc.cochrane.org/en/index.html. Accessed September 2012	Collection of articles to support their goals: "The focus of EPOC is on reviews of interventions designed to improve professional practice and the delivery of effective health services. This includes various forms of continuing education, quality assurance, informatics, financial, organizational and regulatory interventions that can affect the ability of health care professionals to deliver services more effectively and efficiently."
KT+, McMaster University, http://plus.mcmaster.ca/kt/Default.aspx. Accessed September 2012	"**KT**+ provides access to the current evidence on 'T2' knowledge translation (i.e., research addressing the knowledge to practice gap), including published original articles and systematic reviews on health care quality improvement, continuing professional education, computerized clinical decision support, health services research and patient adherence. Its purpose is to inform those working in the knowledge translation area of current research as it is published."
US National Center for the Dissemination of Disability Research Library, http://www.ncddr.org/ktinfocenter/. Accessed September 2012	"The KT Library is designed to provide information to NIDRR grantees and interested members of the public about a wide spectrum of knowledge translation and evidence-based resources" (disability research KT).
Research Transfer Network of Alberta (RTNA) Alberta Heritage Foundation for Medical Research, http://www.ahfmr.ab.ca/rtna/index.php. Accessed September 2012	This group collects and makes available their publications including conference reports, proceedings, and water cooler discussions. The site includes casebooks from 2010-onwards which highlight KT projects underway in Alberta.
Research Utilization Support and Help (RUSH) Southeastern Educational Developmental Laboratory, Austin, TX, http://www.researchutilization.org/index.html. Accessed September 2012	This site has a KT tool box of resources associated with disabilities and rehabilitation. Also a nice list of demonstration projects. The work concluded on May 31, 2009 and resources are not being updated.

Table 2.3.1 (*continued*)

Site name and web location	Material contained
CIHR KT Clearinghouse, University of Toronto http://ktclearinghouse.ca/. Accessed September 2012	Another site of tools for all areas of KT practice and research.
National Coordinating Centre for Methods and Tools. Public Health Agency of Canada http://www.nccmt.ca/. Accessed September 2012	A set of tools and methods concentrating on public health in Canada and elsewhere.
Keenan Research Centre – Research Programs Joint Program in Knowledge Translation – Literature, http://www.rdrb.utoronto.ca/. Accessed September 2012	"RDRB (Research and Development Resource Base) is a literature database focusing specifically on continuing education, continuing professional development and knowledge translation in the health disciplines." This resource is comprehensive and covers many years.
Health Systems Evidence-Program in Policy Decision-Making at McMaster University, Canada, http://www.mcmasterhealthforum.org/healthsystemsevidence-en. Accessed September 2012	"Health Systems Evidence is a continuously updated repository of syntheses of research evidence about governance, financial and delivery arrangements within health systems, and about implementation strategies that can support change in health systems. Over time Health Systems Evidence will also contain a continuously updated repository of economic evaluations in these same domains, descriptions of health system reforms, and descriptions of health systems."
Health evidence.ca, http://health-evidence.ca/. Accessed September 2012	A free, searchable online registry of systematic reviews on the effectiveness of public health and health promotion interventions.
http://www.nlm.nih.gov/hsrinfo/implementation_science.html. Accessed September 2012	This page contains selective links representing a sample of available information. Items are selected for their quality, authority of authorship, uniqueness, and appropriateness.
Implementation Science, http://www.implementationscience.com/. Accessed September 2012	An open access, peer-reviewed online journal that aims to publish research relevant to the scientific study of methods to promote the uptake of research findings into routine health care in clinical, organizational or policy contexts.

Table 2.3.2 Terms used by various stakeholder groups for KT activities/components

Applied dissemination
Applied health research
Best practices adoption
Capacity building
Change implementation
Changing provider/physician/doctor behavior
Collaborative development
Competing
Complex interventions
Complexity science/studies
Continuing (medical/nursing/dental) education
Cooperation
Co-optation
Crossing the quality chasm
Diffusion of innovations
Diffusion(s)
Dissemination
Effective dissemination
Effectiveness research
Evaluation research
Evidence uptake
Evidence based medicine/nursing/practice
Feedback and audit (audit and feedback)
Gap analysis
Gap between evidence and practice
Getting knowledge into practice
GRIP
Guideline implementation
Impact
Implementation
Implementation research/science
Implementation science interventions/strategies
Implementing research evidence
Information dissemination and utilization
Innovation adaptation/adoption/diffusion
Know-do
Know-do gap
Knowledge adoption/brokering
Knowledge communication/cycle
Knowledge development and application
Knowledge diffusion/dissemination
Knowledge exchange/management
Knowledge mobilization
Knowledge synthesis
Knowledge to action

Table 2.3.2 (*continued*)

Knowledge transfer/transformation/ translation
Knowledge uptake/utilization
KSTE
Knowledge synthesis, transfer and exchange
Linkage and exchange
Opinion leaders
Patient education
Patient safety
Popularization of research
Professional behavior change
Quality assurance
Quality improvement
Research capacity
Research implementation
Research into action/practice
Research mediation
Research transfer/translation
Research utilization
Science communication
Teaching
Technology transfer
Third mission
Third wave
Total quality assurance
Total quality improvement
Transfer of technologies
Translating research into practice
Translation research
Translational research/science
Transmission
Turning research into practice
TRIP
Utilization

terms related to KT that we have identified in our attempt to develop a search filter for KT material. The terms themselves are very useful to include in search strategies. A wiki (http://whatiskt.wikispaces.com/, accessed September 2012) includes these terms and their definitions and we invite you to enhance this site with your knowledge and experience. Bzdel *et al.* [3] provide insights for searching for KT theories and frameworks. Additionally, the use of the named theories (e.g., the technology acceptance model [TAM] or the theory of planned

behavior) can be searched on the internet and in the large databases. The KT filters described above also help to identify these papers.

Summary

Searching for existing knowledge and evidence is a major foundation of the knowledge to action cycle. Producing and summarizing existing evidence from multiple sources to address knowledge or action gaps is the one of the first tasks of any KT work. Once summaries are identified or done, those involved in KT work also need to learn about methods and tools that have been used in previous KT projects and how best to build new programs based on theoretical constructs of KT. Searching for evidence to summarize, existing summaries in various formats, and knowledge about KT programs and theory are difficult for many reasons including vocabulary and its multidisciplinary nature. In addition to using the resources outlined in this chapter, contacting librarians and others experienced in searching will also help you on your road to successful searching.

The main areas in health research in the area of searching for material important to KT researchers and practitioners include production of effective searching filters for Medline and CINAHL. We need more data on proven retrieval methods for internet-based resources. Related to searching is also the need to come to consensus on or an accepted understanding of definitions and mapping of KT terms across disciplines (e.g., is technology transfer in engineering equivalent to T1 research for the US National Institutes of Health or knowledge translation for CIHR?). We also may be able to develop search engines or strategies that can search effectively across the many KT resources and sites (Table 2.3.1).

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Chapter 2.4 **Knowledge dissemination**

End of grant knowledge translation

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Key learning points

- The strength and significance of the research findings should determine the magnitude and extent of the knowledge translation (KT) plan. Judicious KT should be the first principle in end of grant KT.
- Dissemination activities target research findings to specific audiences.
- Dissemination activities should be carefully and appropriately considered and outlined in a KT plan focused on the needs of the audience who will use the knowledge. The proposed plan should be updated when the findings of the project are known.
- Researchers should engage relevant knowledge users to craft and tailor messages and help disseminate research findings.

The dissemination of research findings is a critical component of the knowledge translation (KT) process and is frequently thought to occur somewhere between the generation and synthesis of knowledge and its application or use. Researchers are often asked to consider their knowledge translation/dissemination strategy when preparing grant applications and then put these plans into action when their research findings become known. Traditional end-of-grant or project KT typically involves publication in peer-reviewed

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journals or presentation of results at appropriate meetings. While in some circumstances traditional end-of-grant knowledge translation is highly appropriate [1], in cases where the potential users of the research are not academics or researchers, this approach may not be the most effective strategy for encouraging awareness and uptake of findings by knowledge users.

This chapter draws heavily on a scoping review of conceptual frameworks for disseminating findings [2], an overview of knowledge translation of research findings [3], the Canadian Institutes of Health Research guide to planning knowledge translation [4], and the Rx for Change Database (http://www.cadth.ca/resources/rx-for-change, accessed September 2012).

When is knowledge ready for dissemination?

Decisions about the extent and ambitiousness of KT plans should be guided by the reliability, validity, strength, and significance of research findings. The general advice is not to place excessive emphasis on the results of single small studies, studies of poor methodological quality, or ones where the strength of the evidence is low. For example, it would not be prudent to have an elaborate multi-component KT strategy to disseminate findings from a pilot study. The research findings should also be considered of major significance to knowledge users before extra-ordinary means of dissemination are employed. In other words, judicious KT should be the focus of all KT plans. In addition, Grimshaw and colleagues [3] argue that knowledge synthesis where the results of individual studies are interpreted within the context of the global evidence should be the basic unit of knowledge translation. As they note, "greater emphasis on the results of systematic reviews would increase the 'signal to noise' of knowledge translation activities may increase the likelihood of their success" (p. 3). The threshold for dissemination may be different for different knowledge user groups.

What is knowledge dissemination?

Lomas [5] provides a useful taxonomy of KT activities that groups them into three conceptually distinct types: diffusion, dissemination, and implementation. He defined *diffusion* as those efforts that are passive and largely unplanned, uncontrolled and primarily horizontal or mediated by peers. Diffusion can be thought of as "let it happen" [6]. Publishing in peer reviewed journals or presenting research results to peers at an academic conference are examples of this type of dissemination. In this category of knowledge translation activities, the onus is on the potential adopter to be able to formulate a question they may have, know how and where to search for the

relevant knowledge that may answer their question, be able to access knowledge when they identify it, critically appraise it and then apply it to their issue or problem. This is expecting a lot from potential knowledge users!

Dissemination of knowledge, also known as knowledge transfer and end of grant knowledge translation [1, 7], focuses primarily on communicating research results by targeting and tailoring the findings and the message to a particular target audience [8]. For their scoping review, Wilson and colleagues define dissemination as "a planned process that involves consideration of target audiences and the settings in which research findings are to be received and, where appropriate, communicating and interacting with wider policy and health services audiences in ways that will facilitate research uptake in decision making processes and practice" [2]. Dissemination can be thought of as "helping it happen."

As we move along the KT continuum and want to reach audiences other than academics and researchers, more active dissemination approaches may include: tailoring the message and medium to the specific audience; linking researchers and knowledge users through linkage and exchange mechanisms, such as small workshops focused on the dissemination of a synthesized body of knowledge or those focused on developing a user-driven dissemination strategy; engaging media; using knowledge brokers; or creating networks or communities of practice involving both researchers and knowledge users (e.g.).[9–14]

Whether passive or more active dissemination activities are called for, researchers (and their knowledge user partners, where relevant) are encouraged, and increasingly required, to develop dissemination plans as part of their grant proposals (such as at the Canadian Institutes of Health Research [CIHR]). Such plans should describe the plan for disseminating the outcomes of the project and consider what knowledge should be transferred, to whom, how and with what effect; these are described in more detail later in this chapter.

Finally, the last category in Lomas' taxonomy, *implementation or application* is an even more active process than dissemination and involves systematic efforts to encourage adoption of the research findings by identifying and overcoming barriers which are discussed further in later chapters. Implementation is about "helping it happen."

What are the fundamentals of end of project KT/dissemination?

For their scoping review of conceptual frameworks for disseminating research findings, Wilson and colleagues [2] searched 12 electronic

databases (including MEDLINE, EMBASE, CINAHL, and PsycINFO) and individual funding agency websites to identify potential documents for inclusion. Documents were included in the review if they presented an explicit framework or plan either designed for use by researchers or that could be used to guide dissemination activity. Nearly 14,000 records were identified and 33 frameworks described in 44 papers meeting their inclusion criteria. Twenty of the frameworks were designed for use by researchers. Aspects of the theoretical approaches of persuasive communication, diffusion of innovations theory, or social marketing underpin 28 of the frameworks.

Common elements of many frameworks were: the message(s) (including the content of what is to be disseminated and tailoring or contextualizing the message to the audience); the target for message dissemination (including characteristics of the target audience); who is disseminating the message (s) (sources/messengers, credibility of messengers); and, the medium for dissemination (communication channels/dissemination strategies). Other elements included in fewer frameworks included: the setting or context for dissemination; identification of barriers and facilitators; the researcher–user relationship; evaluation of the effectiveness of dissemination efforts; budget description; and, planning activities.

Wilson and colleagues concluded that there is a large amount of theoretical convergence among the frameworks, many of the frameworks appear more participatory than simple messenger-receiver models, there is recognition of the importance of context, and there is emphasis on the need for interaction between researcher and the end-user.

The CIHR has published a guide to KT planning that offers a useful worksheet for designing a dissemination plan (the guide also has a section on developing an integrated KT project) [4]. The guide is in part based on the work done by Suzanne Ross, Paula Goering, Nora Jacobson and Dale Butterill commissioned by the CIHR, the Canadian Health Services and Research Foundation, the UK National Institute for Research Service Delivery and Organization, and the Netherlands Organization for Health Research and Development. The Ross guide was based on KT literature and piloted with applicants and reviewers from three of the four partner organizations. It was then adapted considerably to fit with CIHR's KT framework and strategic funding opportunities, illustrative examples added and the guide peer reviewed. The guide identifies five key factors to consider when planning end of grant KT: goals, audience, strategies, expertise, and resources which are outlined in detail below.

Goals

Determining what the KT goals are helps facilitate choosing dissemination strategies most likely to achieve the goals. It is important to determine whether the KT goals are to:

- increase awareness/knowledge?
- inform future research?
- inform/change attitudes?
- inform/change behavior?
- inform/change policy?
- inform/change practice?
- inform/change technology?
- or something else?

Key questions related to the goals are: Are the KT goals clear, concrete and well justified? Are the KT goals appropriate to the potential research findings and the target knowledge-user audiences (keeping in mind that the goals may be different for each audience and may also vary depending on the results of the study)? The stated goals should drive the dissemination strategies considered.

Audience

This element is about identifying and understanding the target audience. This can be done by asking: Who are the potential target audiences? Are they community-based and not-for-profit organizations, general public, health care professionals/service providers, health system administrators/managers, industry/venture capital group, media (print, TV, etc.), patients/consumers, policy makers/legislators, private sector, research funders, researchers, others?

Key questions to consider are: Does the plan consider all potentially relevant knowledge-user audiences? Are the audiences precisely defined in terms of their sector, roles, responsibilities, and decision making needs/opportunities? Does the plan demonstrate an understanding of the proposed target audiences, including their knowledge needs in the research area and their preferences for using knowledge?

Strategies

Diffusion strategies include traditional interventions such as conference presentations, non-peer-reviewed publications, peer-reviewed publications (open-access journal/archive), and web-based activities (e.g. postings, wikis, blogs, podcasts).

Dissemination strategies include: patient decision support aids, development of new educational materials/sessions, events and courses, interactive small group meetings, plain language summaries, summary briefings to stakeholders, reminders, social media (e.g. Facebook and Twitter), knowledge broker involvement, media release/outreach campaign, networks and networking, patient mediated interventions, performance feedback, champions/opinion leaders, financial interventions, arts-based KT activity (e.g. development of music video to share research message), audit and feedback, and communities of practice amongst other approaches.

The key questions for this element of the plan are: Are the messages clearly identified? Are the strategies appropriate to achieve the KT goals? Does the plan take into consideration the context in which the knowledge is to be used? If appropriate, is there a plan to adapt the knowledge to each specific audience? Have mitigating factors been considered that might affect the applicability of the research findings or the effectiveness of the planned KT activities? Does the plan consider barriers and facilitators to knowledge use?

Expertise

This element is about considering what expertise is required to execute the KT plan. Does the team have the required expertise and include individuals in the following roles (if relevant): knowledge broker, community leader, KT specialist, communication specialist, health care managers, public relations expert, volunteer, website developer/IT expert, writer/editor/copy editor/videographer, others?

The questions related to this element are: Are all the necessary knowledge users involved to achieve the stated goals? Is there a sufficient description of the team's ability to execute the proposed strategies? Where appropriate, does the team plan to collaborate with members of the target audience?

Resources

Several resources need to be considered including personnel such as graphic design/layout experts, KT specialists, knowledge brokers, and writers as well as consumables such as mailing/postage, open access publishing fees, teleconferences/travel, web-related costs, and workshops/meetings/networking costs. The key question about resources is: does the budget allocate adequate financial support to implement the plan? Since the end of grant KT plan may change over the duration of the project and as results are produced, this can be challenging and should be mentioned explicitly in the proposal.

Given that when the grant proposal is submitted to the funding agency the study findings have yet to be determined (although a researcher may have a hypothesis about what they may be), it is usually not possible to identify the dissemination messages or the intended audiences with certainty. For this reason the End of Grant KT plan should help the grant reviewer understand how the researcher is approaching KT rather than providing specific details about the "message." Once the study findings become available, it is important to review the KT plan that had been proposed at the beginning of the project and reconsider the KT goals in light of the findings, identify and tailor the messages to the intended target audiences, review the dissemination strategies and make necessary course corrections and consider whether there is still adequate resources for the KT plan or whether the plan needs scaling up or back and whether additional resources might need to be sought.

What is known about effective dissemination strategies?

The Rx for Change Database comprises synopses of reviews of the effectiveness of KT strategies directed at professionals and consumers. Grimshaw and colleagues [3] recently provided an overview of KT of research findings. The overview synthesized the findings from trials and studies to provide median absolute improvement rates where possible. Both sources reveal that there is considerable evidence about the effectiveness of dissemination strategies directed at professionals (almost exclusively physicians), although many areas remain under explored (e.g. how best to tailor messages for optimum effectiveness), considerably less evidence about how to influence consumers' uptake of research knowledge, and little evidence about effective strategies to influence use of research by policy makers and senior health service managers. Table 2.4.1 provides a very brief summary from these two sources of the effectiveness of some of the more common diffusion and dissemination strategies identified in this chapter (for fuller discussion of many of these strategies please refer to chapters on KT interventions later in the book).

What is an integrated KT approach to dissemination?

Given that knowledge users understand the context and culture in which research findings are to be applied, there may be considerable value in engaging knowledge users in developing and executing KT plans. They can help craft the research messages so that they are in a language and format suitable for the intended audience, offer insights into who might be credible

Table 2.4.1 Summary of effectiveness of disseminating strategies drawn from the Rx for Change Database and Grimshaw *et al.* [3]

KT strategy	Definition	Target of strategy	Effectiveness	Considerations
Distribution of educational material	Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials, and electronic publications	Professionals	50 reviews identified. Of these, 4/4 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to be generally effective (Rx for Change Database) 12 randomized trials, 11 non randomized trials – median absolute improvement: 4.3% (range –8% to 9.6%) [3]	Costs related to printing and distributing material – generally low cost
Mass media	Varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets, alone or in conjunction with other interventions; targeted at the population level	Professionals	4 reviews that examined the effectiveness of mass media interventions were identified. Of these, 1/1 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to be generally effective (Rx for Change Database)	Cost may be low to considerable if required to buy print/air time, may require engagement and collaboration of media
Access to reviews and tailored messages	Providing reviews, providing access to systematic reviews via online registry, providing access to registry + tailored messages	Policy makers and senior health service managers	1 review with 1 randomized and one non-randomized trial. None of the interventions showed a significant effect on global evidence-informed decision making, tailored messages plus access to the online registry of systematic reviews showed a positive significant effect on public health policies and programs [3]	Main cost is setting up and maintaining registry and the process for selecting, appraising knowledge and tailoring and disseminating messages

Educational meetings	Health care providers who have participated in conferences, lectures, workshops or traineeships.	Professionals	70 reviews identified. Of these, 2/6 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to generally effective whereas 3/6 reviews had mixed results. (Rx for Change Database) 81 randomized trials, median absolute improvement: 6.0% (interquartile range 1.8% to 15.3%) [3]	Main costs are for developing teaching materials, instructors, and release time for learners
Educational outreach (academic detailing)	Use of a trained person who meets with providers in their practice setting to give information with the intent of changing the providers' practice.	Professionals	69 randomized trials, median absolute improvement: prescribing behaviors: 4.8% (interquartile range 3.6% to 6.5%) [3] Other behaviors: 6.0% (interquartile range 3.6% to 16.0%) [3]	Main costs are for developing materials and for the detailers
Providing information or education	Strategies to enable consumers to know about their treatment and their health. Interventions include those to educate, provide information, or to promote health or treatment. Interventions can be provided to individuals or groups, in print or verbally, or face to face or remotely.	Consumers	4 reviews identified. Overall there is insufficient evidence to support the use of interventions that provide information or education as a single component to improve adherence, knowledge or clinical outcomes – they are generally ineffective (Rx for Change Database) Written information – 25 randomized trials, insufficient evidence to say whether written medicines information is effective in changing behaviors related to medicine taking [3]	Costs relate to development of materials and instructors – typically low cost

(*continued*)

Table 2.4.1 (*continued*)

KT strategy	Definition	Target of strategy	Effectiveness	Considerations
Acquiring skills and competencies	Strategies focusing on the acquisition of skills relevant to medicines use. Interventions aim to assist consumers to develop a broad set of competencies around medicines use and health, such as medicines management or monitoring; or training consumers in the correct use of treatments or devices to deliver treatment	Consumers	There is some evidence that strategies which focus on the acquisition of skills and competencies may improve adherence, medicines use and clinical outcomes, but results are mixed (Rx for Change Database) Self-management programs – 17 randomized trials, small (clinically insignificant) short-term improvements in pain, disability, fatigue and depression were found. Positive effects on confidence to manage and self-rated health were found. There was no effect on quality of life or use of health services [3]	Costs related to development of training materials, instructors, and professionals if ongoing contact with consumer involved
Local opinion leaders	Use of providers nominated by their colleagues as "educationally influential"	Professionals	18 randomized trials, median absolute improvement: 12.0% (interquartile range 6.0% to 14.5%) [3]	Costs related to identifying the opinion leader, training of the opinion leader and the opinion leader's time

Local consensus processes	Inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate.	Professionals	8 reviews that evaluated the effectiveness of local consensus process were identified and none were assessed as being of high quality or a key review (Rx for Change Database)	Costs mainly related to professionals' time to be able to participate
Linkage and exchange	Connecting and developing of relationships between researchers and knowledge users for the purpose of collaboration or exchange	Policy makers and senior health service managers	1 review including 16 studies. Two factors emerged with some frequency as being important to policy makers' use of research evidence: interactions between researchers and policy makers in the context of policy networks such as advisory committees and in the context of informal relationships; and research that matched the beliefs, values, interests, or political goals and strategies of elected officials, social interest groups, and others [3]	Costs mainly related researchers' and policy makers' time to engage, knowledge broker if one is involved, cost of research that may be conducted for policy makers

Table 2.4.1 (*continued*)

KT strategy	Definition	Target of strategy	Effectiveness	Considerations
Consumer system participation	Strategies to involve consumers in decision making processes on medicines prescribing and use at a system level, such as in research planning, formulary and policy decisions	Consumers	A single review indicates there is some evidence that medicines information materials developed with consumer involvement can increase knowledge and side-effect recognition, without increasing anxiety – they are generally effective (Rx for Change Database)	Costs relate to consumers' time to participate
Reminders	Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information	Professionals	59 reviews that evaluated the effectiveness of general reminders were identified. Of these, 2/2 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to be generally effective (Rx for Change Database) 28 randomized trials, computerized reminders- median absolute improvement 4.2% (0.8% to 18.8%) [3]	Cost varies across delivery mechanisms
Audit and feedback	Any summary of clinical performance of health care over a specified period of time	Professionals	35 reviews that evaluated the effectiveness of audit and feedback were identified. Of these, 2/2 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to be generally effective (Rx for Change Database) 118 randomized trials, median absolute improvement 5% (interquartile range 3% to 11%) [3]	Costs of data collection, analysis, and dissemination. Maybe less expensive is systems permit electronic mining of health records

| Patient mediated | New clinical information (not previously available) collected directly from patients and given to the provider e.g. depression scores from an instrument | Professionals | 14 reviews that evaluated the effectiveness of patient-mediated interventions were identified. Of these, 1/2 high quality/key reviews with a sufficient number of studies to draw conclusions found this intervention to be generally effective (Rx for Change Database) | Cost related to development of instruments/tools, data collection and analysis |
| Facilitating communication and decision making | Strategies to involve consumers in decision making about medicine. Interventions that aim to help consumers make decisions about medicines use, such as interventions for consumers to express their beliefs, values and preferences about treatment and care; communications with consumers about medicines use and related issues | Consumers | 18 reviews were identified, 15 of high quality. While some individual strategies are promising, the evidence on strategies facilitating communication and / or decision making is mixed overall (Rx for Change Database) Decision aids – 86 randomized trials, improved knowledge and accuracy of risk perception; reduced the proportion of people who were passive in decision making; resulted in higher proportion of patients achieving decisions informed and consistent with their values; reduced the number of people remaining undecided; reduced decisional conflict; decreased the choice of major elective surgery in favor of conservative options [3] | Costs are variable and related to development and testing of decision aids, risk screening tools, development of process and staff to administer decision aids, council about risks or coach about communicating with professions. There may also be costs related to sustaining these strategies. |

(*continued*)

Table 2.4.1 (*continued*)

KT strategy	Definition	Target of strategy	Effectiveness	Considerations
			Personalized risk communications – 22 randomized trials, weak evidence, consistent with a small effect that personalized risk communication increases uptake of screening tests [3] Communications before consultations – 33 randomized trials, increased question asking during consultation. They may also increase patient participation in consultation and improve patient satisfaction [3]	

messengers, suggest potentially useful KT strategies attractive to their colleagues, and even have existing communication channels to reach them (e.g. newsletters, meetings, etc). All studies can adapt an integrated KT approach to the KT plan regardless of whether the actual study falls under the rubric of integrated KT research or not.

Future research

Areas for future research include: how to tailor the dissemination and implementation strategies to different audiences, the role of e-media, including social media as dissemination vehicles, and the sustainability of different dissemination approaches. More research is needed on the effectiveness of strategies directed toward professionals other than physicians, consumers and policy makers and senior health service managers.

Summary

In keeping with the suggestions offered in the CIHR guide to KT planning, we have found the following list of questions to be useful when developing a more interactive and tailored approach to dissemination:

- What are the goals of the KT plan?
- Does the strength and significance of the new knowledge justify the KT goals?
- Who are the end-users of the research and who will be interested in knowing the results?
- What are the key messages from the research? Note these may be different for different end-users (e.g. different key messages likely necessary for policy makers and clinicians). How might end-users be engaged in helping to craft the key messages?
- Who are the principal target audiences for each of these messages?
- Who is the most credible messenger for these messages and how do we engage them in communicating these messages? We as the researchers may not be the most appropriate person to engage all relevant end-user groups. For example, a basic scientist may not be the person who should engage a clinician on the results of relevant research.
- What might be the barriers and facilitators to research uptake?
- What KT strategy(ies) will be used to promote research uptake? The decision should be based on evidence of what works.
- How will we evaluate the impact of our KT strategy?
- What resources are necessary for this end of grant KT strategy?

Table 2.4.2 Example of a KT plan from a biomedical project

KT Plan in project proposal	Modifications to the KT plan following analysis of results
Goals • Increase knowledge/awareness • Inform further research	None
Audience • Researchers in genetics and microbiology	Audience • General public • Sales for in scientific supply company
Strategies Diffusion • Peer-reviewed publications • Conference presentations	Strategies Dissemination • Presentations to non-academic audiences
Expertise Human resources • Research experience • Publication experience • Presentation experience	None
Resources • Open access publication fees • Conference registration fees • Travel costs	None

Table 2.4.3 An example of a KT plan from a clinical research project

KT Plan in project proposal	Modifications to the KT plan following analysis of results
Goals • Increase knowledge/awareness • Inform/change practice	None
Audience Cerebral palsy service providers • Physiotherapists • Professional associations • Clinical administrators/decision makers	None
Strategies Diffusion • Web posting of project findings • Clinical conference presentations and workshops	Strategies Dissemination • Interactive small group teleconferenced meetings • Follow-up interviews with site contacts

Table 2.4.3 *continued*

KT Plan in project proposal	Modifications to the KT plan following analysis of results
Dissemination • Plain-language summary • Electronic teaching materials • Knowledge broker involvement	Application • Tailored messages directly to hospital administrators and posed on web for all stakeholders • Interactive interventions to promote exchange and use
Expertise Multidisciplinary research team • Experience academics • Clinicians/knowledge brokers • Health care administrators	None
Resources • Knowledge brokers • Production/printing • Conference registration fees	Resources • Dissemination even grant • Research coordinator • IT/web support • Teleconferencing/printing

We create a table with the above questions and use this to develop our end of grant KT activities along with a potential timeline. We also mention potential barriers to the plan which allows us to explain what happens if the results are positive or negative for example and how this will alter the plan. When the results of the study are available or have been peer reviewed, we then revisit our table and make the necessary course corrections.

Tables 2.4.2 and 2.4.3 are examples drawn from the CIHR guide to KT planning [4], one reflecting a biomedical project and the other a clinical project. Please refer to the guide for a complete explanation of the examples and to see other examples representing health services and population health projects.

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Section 3 **The Action Cycle**

Chapter 3.0 **Introduction**

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The action cycle is the process by which knowledge is implemented. The action phases were derived from a review of 31 planned action theories [1]. Planned action theories focus on deliberately engineering change in health care systems and groups (although many policy maker targeted interventions may also focus on facilitating their access to research on short timelines, not just efforts to bring knowledge to their attention and to support action based on this knowledge). Included are the processes needed to implement knowledge in health care settings namely problem identification and identifying the relevant research; adapting the research to the local context; assessment of determinants of KT; selecting, tailoring, implementing; monitoring and evaluating KT interventions; and determining strategies for assessing and ensuring sustained knowledge use.

A group may start the knowledge to action process by determining the evidence to practice gap (Chapter 3.1). The knowledge relevant to this problem is then adapted to the local context (Chapter 3.2). Adapting the knowledge to local context extends to assessing barriers and facilitators to knowledge implementation (Chapter 3.3). The action cycle continues with selecting, tailoring and implementing the KT intervention (Chapter 3.4). Strategies for monitoring knowledge use and evaluating its impact on relevant outcomes are then be developed (Chapter 3.5) along with a plan for monitoring and optimizing sustained knowledge use. (Chapter 3.6) It must be noted that the action cycle is a dynamic and iterative process with each phase informing the others and the knowledge creation funnel potentially informing each phase. We also provide examples of implementation strategies and tips on implementation in Chapter 3.7.

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Chapter 3.1 Identifying knowledge to action gaps

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Key learning points

- Identifying the knowledge to action gap is the starting point of knowledge implementation and this can be done using a number of tools and techniques while actively involving relevant stakeholders.
- Strategies for needs assessments depend on the purpose of the assessment, the type of data, and the resources that are available. Needs assessments can occur from the perspective of the population, the provider organization, or the health care provider.

What is a "gap?"

One of the first steps in knowledge implementation is to assess the need for knowledge implementation or to measure the "gap" between the evidence and actual practice or policy making [1, 2]. By evidence, we mean the best available research evidence [3]. Ideally, this evidence should come from high quality practice guidelines or systematic reviews.

Quality indicators can be used as a basis for assessing gaps [4]. Interest in quality indicators has been stimulated through work done by the Institute of Medicine on patient safety [5] as well as studies highlighting inadequate quality of care [6]. The Institute of Medicine has outlined that health care should be safe, effective, patient-centered, timely, efficient, and equitable [7].

Quality indicators are measures used as a guide to monitor, assess, and improve the quality of care and organizational functions that affect patient outcomes. Donabedian proposed a framework for considering quality of care that separates quality into structure, process, and outcome that can be used to categorize quality indicators [8]. Important components of a quality indicator include: a descriptive statement; data elements that construct and report this measure; detailed specifications describing how the data elements are to be collected; the population on whom the indicator is constructed; the timing of data collection and reporting; the analytic models used to construct the measure; the format in which the results will be presented; and the evidence in support of its use [9]. As with any measurement tool, quality indicators should be valid, reliable and feasible. While many countries have instituted national strategies to collect quality indicators for benchmarking purposes in a performance measurement setting [10], there is little agreement on optimal quality indicators across countries. Quality indicators can measure structure, process, and outcome related elements within the health system.

Quality indicators should be developed through careful consideration of the best available evidence such as that from systematic reviews and the use of an appropriate rating process. However, before embarking on the development of a new quality indicator, we should ensure that a valid indicator has not already been developed; a scoping review can help with this process. For example, Salmond and colleagues [11] completed a systematic review of evidence determining which organizational factors contribute to positive practice environments for nursing staff within acute hospital settings and found a number of key staff, organizational, and patient indicators that could be used. Additionally, many researchers have explored what they call "nurse sensitive measures" (for example, patient clinical outcomes that are directly linked to nursing actions). These include patient safety (falls, infections) and skin integrity [12].

Another approach that can be used when there is a lack of existing evidence to inform the quality indicators is to use a process such as the Delphi technique [13]. The process involves rounds of anonymous ratings on a risk–benefit scale and in-person discussion between rounds [4, 14]. The goal is to include all relevant stakeholders and this is probably one of the key factors in successful development of quality indicators. This process should be followed by a test of the indicator in real practice settings [14]. A similar process for development of quality indicators is through the use of evidence-based practice guidelines. In this method, a panel of relevant stakeholders develops indicators based on the guideline recommendations. We refer readers to a series in the *Journal of Clinical Epidemiology* which

Table 3.1.1 Criteria for identifying gaps in clinical practice

Criteria for topic selection (identifying gaps in practice) Yes, No, N/A
Instructions
For each clinical topic area your group has identified, go through the following questions and answer either yes, no, or N/A (not applicable). Identify the top five topics with the most "yes" responses.
Is it an area of clinical concern?
Is it an area of concern to older people?
Do guidelines/best practice/standards/evidence exist that you could use?
Is baseline data available to indicate what performance is like currently?
Is there sufficient interest from the multidisciplinary team to support work on this topic?
Does the topic have a local champion?
Does the topic have support from management?
How does this initiative align with other local, regional or national initiatives?
Would doing something be:
Feasible
Practical
Achievable
Desirable

provides a detailed description of the methods for developing quality indicators [15, 16].

While many gaps in practice and policy making could be identified in various settings, it is important to establish a process for selecting which ones to target (Table 3.1.1) [14]. Strategies include consideration of the burden of disease including morbidity, mortality, quality of life, and cost. And, these discussions should involve all relevant stakeholder groups. A modified Delphi process can be used to facilitate this process and in particular, using technology such as Wikitechnology to achieve consensus across colleagues internationally [17]. Active facilitation of identifying the gaps in practice and processes is a skilled task requiring both knowledge of technical processes such as evidence synthesis and indicator development as well as good interpersonal and group process skills [18–21].

While we're not going to provide substantial detail on the methods for indicator development and selection, we would like to highlight the importance of engaging the end-users. We encourage readers to carefully consider the membership of the expert panel involved in quality indicator development and in selection of which care gaps to target. This panel should include representation from each of the relevant stakeholders including patients, families, clinicians, and managers. Whether you are working at

national, organizational or local level, the principles are the same: make sure you draw on evidence from a range of perspectives (patient and stakeholder perspectives, research evidence and local audit data) as well as involving stakeholders in both the identification and prioritization of the gap in knowledge.

How can we measure the gap?

There are a number of ways that the size and nature of the "gap" can be measured. These include needs assessments (such as whole community health needs' assessments) using routinely collected patient data; the use of clinical datasets to identify patterns in service utilization; local audit data to monitor activity and the use of quality and safety data sets to show trends, in particular data on falls, infections, and other adverse events. We will briefly outline how these sorts of data sets can be used and illustrate them at different levels of the health system.

Needs assessments are a systematic process for determining the size and nature of the gap between current and more desirable knowledge, skills, attitudes, behaviors, and outcomes. The strategies for needs assessment depend on the purpose of the assessment, the type of data and the resources that are available. Classification of needs include felt needs (what people say they need), expressed needs (expressed through action), normative needs (defined by experts), and comparative needs (group comparisons) [22]. We can consider this issue from the perspective of the population, the provider organization, or the health care provider and whether the needs are subjectively versus objectively measured [23].

Measuring the gap at the population level

At the population level, we can consider the needs of the population using epidemiological data which are objective assessment measures. Administrative databases are sometimes called claims databases and are a byproduct of administering and reimbursing health care services [24]. Typically they include information on diagnosis (International Classification of Diseases, 10th Revision, Clinical Modification or ICD-10), procedures, laboratory investigations, billing information, and some demographic information. Many administrative databases exist which we can use for this purpose ranging from regional databases (such as those provided by the Ontario Ministry of Health and Long-term Care [25]) to national databases (such as Medicare Provision and Analyses Review [MedPAR] Files). Databases such as these have been used to identify undertreatment of cardiovascular

risk factors in patients with diabetes [26] and overuse of benzodiazepines in elderly patients [27]. However, there are some limitations to these databases that must be considered. First, they were not developed for research use and thus may not contain all the information that would be useful for gap analysis including data on severity of illness [28]. Second, coding may be incomplete because there may be limited space for secondary diagnoses and therefore they may not include all relevant information on important comorbidities [24]. Third, we can only find events for which there are codes [24]. Fourth, the databases may not include the entire population. For example, the Medicare files include only those patients eligible to receive Medicare which includes people 65 and older, some people under 65 with disabilities and all people with endstage renal disease requiring renal replacement therapy.

These limitations to routine databases were addressed within a population health study in South Australia [29]. The LINKIN project has undertaken a population census to determine the extent of health need in the community and map this against the actual expressed use of the health services. By comparing the health needs with service utilization, the research team will work with the local stakeholders to begin to redesign core health service areas [30, 31].

Clinical databases can also be used to perform gap analyses. Clinical databases include registries of patients who have undergone specific procedures or who have certain diagnoses. Examples include the National Cardiac Surgical, Vascular, and Colorectal cancer databases in the UK [32]. These registries may have data that is complementary to that included in administrative databases including more information on secondary diagnoses and comorbidities. Therefore, clinical databases can sometimes be used in combination with administrative databases to provide additional detail on practice gaps [32]. However, some studies have shown lack of agreement between administrative and clinical databases [33]. Limitations exist with use of these databases including lack of accuracy of information.

Measuring the gap at the organization level

Needs assessments at the organization level may be done at the level of the hospital or clinic. Hospitals in many countries are required by accreditation bodies (such as the Joint Commission on the Accreditation of Health Care Organisations [JCAHO]) to collect information on infection control, mortality, and restraint use for example [34]. This data source could be used to collect information on gaps. With the growing use of computerized health

care records in hospitals and community settings, these tools can also be used to extract data for gap assessment [35]. Chart audits can be done to review and assess health records using preset standardized criteria. In chart audits, documented clinical care is measured against review criteria, defined as, "a systematically developed statement that can be used to assess the appropriateness of specific health care decisions, services and outcomes" [36]. Ideally review criteria should be based on valid evidence for the quality indicator and include objective measures such as achieving target levels of blood pressure and blood glucose in patients at elevated risk of a vascular event.

The Donabedian framework for considering quality of care that separates quality into structure, process, and outcome can also be used when considering a chart audit [8]. For example, if we want to look at the issue of prophylaxis against deep vein thrombosis (DVT) in patients admitted to the intensive care unit, structural measures would include the availability of DVT prophylaxis strategies at the institution. Process measures include prescription of DVT prophylaxis strategies such as heparin in the critical care unit. And, outcome measures include risk of DVT in these patients. Assessing frequency of DVT in these patients would require a much larger sample size than would be required if we looked at process measures, highlighting one of the advantages of using process measures. Other strategies for consideration when completing a chart audit are available from NorthStar which is a European initiative focused on quality improvement [37]. Table 3.1.2 shows an approach that we can consider when completing a baseline measurement.

Paper health records remain more common than electronic health records but they may not be as accurate. Rethans found that while they commonly report information on diagnostic tests, they often omit details on counseling [38]. Moreover, paper records are prone to lack of standardization and illegibility [39]. Computerized health records may have more accurate data on medications and diagnostic tests [40]. The advent of personal health records provides another potential source of data; however, patients may not provide access of this data to researchers or clinicians. Moreover, this data may have limited detail [41]. Finally, a key issue to consider when planning a chart audit is to consider the privacy and security of the health information obtained. Privacy regulations for using data from health records varies regionally and nationally. In some institutions, audit is considered part of standard care and thus is not subject to institutional review requirements. The need for ethics review of the audit process should be determined before any project is started.

Table 3.1. 2 Questions to consider when beginning a chart audit

Questions about comparing actual and desired clinical practice	Yes / No / Not sure
Before you measure	
• Have you secured sufficient stakeholder interest and involvement?	
• Have you selected an appropriate topic?	
• Have you identified the right sort of people, skills and resources?	
• Have you considered ethical issues?	
What to measure	
• Should your criteria be explicit or implicit?	
• Should your criteria relate to the structure, process or outcomes of care?	
• Do your criteria have sufficient impact to lead to improvements in care?	
• What level of performance is appropriate to aim for?	
How to measure	
• Is the information you need available?	
• How are you identifying an appropriate sample of patients?	
• How big should your sample be?	
• How to choose a representative sample?	
• How will you collect the information?	
• How will you interpret the information?	

Source: Reproduced from NorthStar (www.rebeqi.org) [37], with permission from the Health Services Research Unit, University of Aberdeen, UK.

Measuring the gap at the care provider level

At the level of the care provider, several strategies can be used for needs assessment including chart audits [39] observation, competency assessment and reflective practice. Direct observation of provider performance can be completed through use of standardized patients [42] or videorecording [43]. Similarly, competency assessments including knowledge question-naires can be completed such as those done as part of certification require-ments for the American Board of Internal Medicine [44] or through completion of clinical vignettes [45]. Finally, reflective practice whereby cli-nicians use their own clinical experiences to highlight learning opportuni-ties or learning portfolios which also support the identification and recording of needs from clinical experiences can be considered [46]. Sibley and colleagues observed that clinicians tend to pursue education around topics that they already know while avoiding areas in which they are

deficient and this has also been found in systematic review of self-assessment by physicians [47, 48].

Why do gaps exist?

While performing audits is a method for obtaining information about practice gaps, it must be cautioned that it is easy to use practice gaps to hold clinicians accountable for the gaps but in reality evidence to action gaps often reflect systems issues and not solely provider performance [49, 50]. It is for this reason that we need to look beyond the evidence of a practice gap to determine the "why." In accounting for this, we have drawn on classic theories that explain what happens to individuals when they learn to do tasks and then stop consciously thinking about this. Paradoxically, theories of routinization (or normalization process theory as it is called) are being used to explain how new ideas are introduced into practice. May and colleagues [50] state that it is when new practices are embedded into the routine that they are no longer challenged and are sustained.

Van de Ven [51] argues that in our quest to develop knowledge and translate it into practice, we underestimate what we already know about human behavior; namely, that human beings have problems paying attention to non-routine tasks. Also, it is well established empirically that most individuals find dealing with complexity and remembering complex information challenging [52, 53]. By contrast, most individuals are efficient processors of routine tasks. They do not concentrate on repetitive tasks, once they are mastered. Skills for performing repetitive tasks are repressed in our subconscious memory, permitting individuals to pay attention to things other than the performance of the repetitive task [54]. The consequence is that what most individuals do most frequently is what they think about the least. If they do not have ways of evaluating the impact of these routine tasks, then we can imagine the "drift" that could take place in terms of performance to acceptable standards, norms, and knowledge bases.

March and Simon [55] state that dissatisfaction with existing conditions stimulates people to search for improved conditions and they will cease searching when a satisfactory result is found. Satisfactory results are conceptualized as a function of a person's aspiration level (i.e. their internal value system) and the culmination of all the past successes and failures that they bring to bear on their work experiences [56]. There is another problem that has to be addressed from the social and cognitive psychological literature – that of the individual's tendency to unconsciously adapt to slowly changing environments which lead them to tolerate extreme (and possibly dangerous) variations in a process without becoming aware of it [55]. This

unconscious adaptation to deteriorating conditions is a feature of all systems such as workers' thresholds to tolerating discomfort (moral or physical). Dissatisfaction (with relationships, behaviors, attitudes, self-worth) is exacerbated to a point where they do not move into action to correct or alleviate their situation because they can no longer see how far they have drifted from their original starting point. Opportunities for new ideas or the introduction of new knowledge are not recognized, problems become critical situations and at the extreme, catastrophes are the inevitable consequence of a system that has drifted so far away from its ability to get feedback on its routine tasks [57].

   At the group and organizational levels the problems of inertia, conformity, and incompatible preferences are added to the range of individual limitations. [59] Processes and systems within large organizations become the "rules" against which teams working within these organizations evaluate their behavior. If no one in the hierarchy objects to the behavior, the declining status quo is legitimized. Such stark descriptions of the entropic nature of organizations are becoming more commonplace and accepted within organizational theory literature [58, 59]. However, in the professionally driven health care system, we may not be aware of the pervasive and potentially negative effects of routinized thinking and our inability to think creatively and objectively about our everyday procedures. We should acknowledge three realities:

- Most people (professionals included) operate on "automatic pilot" spending least reflective thinking time on the tasks they spend most of their working time doing. How then can we build in reflective time to clinical routines in order to optimize discussion, debate and dialogue, and critical inquiry?
- Most individuals will unconsciously adapt to worsening conditions or tolerate a gradual lowering of standards to a "lowest common denominator" situation effect. Unchecked, this phenomenon can lead to unsafe and unethical practices condoned by people in a system who are unaware that their actions and behaviors have shifted into a potentially hazardous zone. What checks and balances can be put in place at individual, team, and system level to identify when situations and /or cultures are starting to become "unhealthy" or hazardous for both patients and staff?
- Active strategies must be put into place to counter these natural trends – namely acknowledging that routinization of tasks leads to uncritical activity and that within an uncritical, unquestioning working climate individuals and teams will unconsciously adapt to worsening conditions. What proportion of work time should be devoted to active improvement activities that involve the whole workforce?

Future research

Areas for further research include: testing how routine data can be used to stimulate the identification of gaps in service delivery and how a population's health needs assessment can be mapped onto service utilization and then the gaps and duplications in service addressed; exploring how teams and whole systems can develop and maintain a culture of continuous learning and thus reduce the impact of "mental stagnation."

Summary

Identifying the gaps in care is a starting point for knowledge implementation. There are a range of structural requirements such as access to reliable, valid and comprehensive data sets to direct assessments between the desired actions (as outlined by the evidence) and actual activity (as described by the routinely collected data). Such data is the starting point but it is not without its own limitations in terms of quality, comprehensiveness, and ease of access.

In addition to the structural data requirements, there are also a number of process challenges. These include the level at which the data is collected (at national, system or local level; condition or population specific) and the different perspectives sought from key stakeholders. Data always needs to be interpreted and this very fact means that it is a social process with multiple stakeholders needing to be involved in the process. When people in systems are given more freedom to get involved in local problem solving and in being able to make autonomous decisions they more actively engage in finding creative solutions to routine problems [49] and to implementing knowledge in care settings. This requirement helps to ensure that the knowledge to action gap is a dynamic dialogue between multiple stakeholders, united to improve patient care and their own experience of working together.

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Chapter 3.2 **Adapting knowledge to local context**

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Key learning points

- Guideline adaptation is a way to start evidence implementation in practice, and serves to develop the product (a local protocol), and provide a process to align external evidence to a local context.
- ADAPTE provides a methodological template for adaptation and CAN-IMPLEMENT is a substantive guide for guideline adaptation and implementation including process and facilitation elements.

Why should we adapt clinical practice guidelines for local use?

Using the best available evidence is a fundamental aspect of providing high quality health care and clinical practice guidelines (Chapter 2.2) are an important tool to inform evidence-based practices. Good quality guidelines are viewed as valuable tools to improve the quality of care. They provide

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synthesized evidence that has been translated into specific practice recommendations. Since the early 2000s guideline production has been promoted and supported by governments and professional organizations. Many countries have infrastructure at the national and/or regional level dedicated to synthesizing evidence and producing guidelines and incentives designed to support practices guided by current guideline recommendations [1]. The background and goals of these initiatives differ depending on the political context and the health care system. For instance, in the United Kingdom, the National Health Service (NHS) has infrastructure and incentives built to deliver care guided by current guideline recommendations. National bodies such as NICE (National Institute for Health and Clinical Excellence) in the UK are dedicated to synthesizing evidence and producing guidelines for use within the NHS. To assess the uptake and adherence to guideline driven care, auditing functions are utilized across regions in the NHS. Despite these efforts, evaluation of implementation strategies show that overall conformity of practices lags behind expectations [2].

Although guidelines may be seen as necessary, their existence alone is clearly *not sufficient* to ensure practices and decisions are evidence-based. The uptake of evidence at the point of care is a complex and challenging endeavor. It does not occur with simple dissemination of information but requires a substantive proactive effort and additional translation for use at the point of decision making [3]. The gap between having valid guideline recommendations and delivering care based on them may be widened by numerous factors. For example, health care providers may not have the requisite skills and expertise to implement a recommended action or the setting may not have the mandatory equipment or staff time to deliver a guideline's recommendation. Additional challenges include recommendations not being acceptable to the local patient population or providers due to cultural or other factors. Even though guidelines provide evidence in a more usable form for practitioners and health settings than a plethora of primary studies, an important and additional necessary step is adaptation of the guideline to the context of use.

While national and international bodies have made major efforts to improve the quality and rigor of guidelines [4–6], less investment has been made in understanding how guidelines can be better targeted to the local context of care. Customizing a practice guideline for a particular setting may be helpful in improving acceptance and adherence. Active involvement of the targeted guideline end-users in this process has been shown to lead to significant changes in practice [7–9]. As a consequence, the local–regional adaptation of (inter)national evidence-based practice guidelines has received interest from organizations in many countries and has become

mandatory in some jurisdictions [10–15]. For many provincial/territorial jurisdictions, de novo guideline development is simply not feasible because of lack of time, expertise, and resources. It makes sense to take advantage of existing high-quality guidelines as an alternative to de novo guideline development [16–18].

Adaptation of existing high quality guidelines for local use is an approach targeted to reduce duplication of effort and to enhance applicability. The applicability and changes required in the organization of care to apply the recommendations are unique to its local context [19]. Importantly, the process of guideline adaptation is a first step in implementing evidence in practice and one that promotes local uptake of evidence through a sense of ownership by the targeted end-users. It is an action-oriented and concrete element of facilitating implementation of evidence. However, customizing a guideline to local conditions bears the risk that the adapted guideline departs from its evidence-base putting into question the quality and validity of the recommendations. This chapter outlines a systematic, participatory (integrated KT) approach for evaluating and adapting available guidelines to a local context of use while ensuring the quality and validity of the guideline. Whether evidence is provided in the format of knowledge syntheses, patient decision aids or clinical practice guidelines, end-users must consider how it should be adapted to the local context. The same principles can be applied to ensure local factors are considered prior to implementation of the evidence.

How do we adapt clinical practice guidelines for local use?

Guideline adaptation is a first step toward implementation of evidence in practice. Through an active process, existing guidelines are evaluated and customized to fit local circumstances while preserving the integrity of the evidence-based recommendations. Albeit supported by the same body of evidence, there may be differences in organizational, regional, or cultural circumstances that could legitimately lead to variations in guideline recommendations [4, 5, 16–18, 20]. In the process of adapting a guideline, specific health questions relevant to a local context of use, specific needs, priorities, legislation, policies, and resources in the targeted setting are considered and addressed.

Ideally, guideline adaptation is a systematic and participatory approach for evaluating and adapting existing guidelines. By its nature, it provides the potential to inform local practitioners, in a tangible and meaningful manner, about the principles of evidence-based health care services. External evidence is assessed with local data and circumstances in mind such as the size and characteristics of the population, the scopes of practice within

their health services, and the fit with existing delivery models and services. This local "evidence" is instrumental in promoting improved uptake and use of the guidelines.

With the exception of a few Canadian studies [7, 18], no validated process for the adaptation of guidelines has been documented [20]. The Canadian work [17] in this area was integrated with an international initiative known as the ADAPTE collaboration (www.ADAPTE.org, accessed September 2012) [20]. This group of researchers, guideline developers, implementers and users collaborated to enhance the use of research evidence through more efficient development and implementation of practice guidelines. The ADAPTE process was developed to facilitate creation of efficient, high-quality adapted guidelines that are likely to be implemented into practice. While users and prospective users of the process have been surveyed about their perceptions of the process [21], it has not been formally field-tested.

A Canadian cancer care initiative undertook a field study of the ADAPTE methodology with multiple groups. The process engaged end-users in the guideline adaptation process to address specific health questions relevant to their context. The exercise was premised on the goal of establishing a standard of being transparent, rigorous and replicable according to the following core ADAPTE principles:

- respect for evidence-based principles in guideline development [7]
- use of reliable and consistent methods to ensure the quality of the adapted guideline [5]
- participation of key stakeholders to foster acceptance and ownership of the adapted guideline, and ultimately promote its use [10]
- consideration of context during adaptation to ensure relevance for local practice and policy [22]
- use of transparent reporting to promote confidence in the recommendations of the adapted guideline [4, 23]
- use of a flexible format to accommodate specific needs and circumstances [1, 24]
- respect for and acknowledgement of source guideline materials.

What is the adaptation process?

Table 3.2.1 presents the 24 steps in adaptation as outlined in the ADAPTE process. Building on and transforming the ADAPTE process based on the experiences and needs of user groups led to the development of the CAN-IMPLEMENT Resource http://www.cancerview.ca/cv/portal/Home/TreatmentAndSupport/TSProfessionals/ClinicalGuidelines/GRCMain/GRCGD/GRCGDGuidelineAdaptation, accessed September 2012. This method has

Table 3.2.1 Guideline adaptation using ADAPTE

	Phase 1: set-up
	Preparation module
Step	1 Establish an organizing committee and working panel, resource team
	2 Select a topic using criteria
	3 Check if adaptation is feasible
	4 Identify necessary resources and skills
	5 Complete tasks for set-up phase inc. terms of reference, declaration of conflicts of interest, consensus process, endorsement bodies, guideline authorship, dissemination and implementation strategies
	6 Write the adaptation plan
	Phase II: adaptation
	Scope and purpose module
Step	7 Determine/clarify the health questions using PIPOH
	Search and screen module
Step	8 Search for guidelines and other relevant documentation
	9 Screen retrieved guidelines – record characteristics/content
	10 Reduce a large number of retrieved guidelines using AGREE instrument
	Assessment module – using tools provided:
Step	11 Assess guideline quality
	12 Assess guideline currency
	13 Assess guideline content
	14 Assess guideline consistency
	15 Assess acceptability and applicability of recommendations
	Decision and selection module
Step	16 Review assessments
	17 Select between guidelines and recommendations to create an adapted guideline
	Customization module
Step	18 Prepare draft adapted guideline
	Phase III: finalization
	External review and acknowledgement module
Step	19 External review – target audience of the guideline
	20 Consult with endorsement bodies
	21 Consult with source guideline developers
	22 Acknowledge source documents
	Aftercare planning module
Step	23 Plan for aftercare of the adapted guideline
	Final production module
Step	24 Produce final guideline document

Table 3.2.2 Guideline adaptation and implementation planning using CAN-IMPLEMENT

Phase 1	*Identification and clarification of the practice issue*
Step 1	• Call to action
Step 2	• Guideline development plan
Step 3	• Search and screen guidelines/evidence
Step 4	• Assess and select
Step 5	• Draft, revise and endorse (adapted) recommendations
Phase 2	*Solution building*
Step 1	• Align knowledge to local context (practice and system)
Step 2	• Assess innovation, adopters and practice environment for barriers and supports
Step 3	• Select and tailor implementation interventions
Phase 3	*Implementation, evaluation and sustainability*
Step 1	• Monitor knowledge use and evaluate implementation process
Step 2	• Evaluate outcomes (patient, practice, and system)
Step 3	• Nurture change and sustain knowledge use

been reformulated and streamlined while maintaining the essential tasks and rigor of the original ADAPTE process. CAN-IMPLEMENT approaches guideline adaptation in a stepwise process comprising three phases (Table 3.2.2): Phase 1: Identification and Clarification of the Practice Issue; Phase 2: Solution Building; and Phase 3: Solution Implementation, Evaluation and Sustainability). The 24 ADAPTE Steps were consolidated as 4 principal activities in Phase 1 and a distinct new element, the "Call to Action" was added to the beginning of the process to assist newly formed groups to clarify the driving force behind a proposed guideline initiative and examine its organizational context. A compelling need for assistance with implementation planning and evaluation prompted the development of two additional phases: Phase 2 provides an explicit focus on context alignment and Phase 3 addresses the assessment of guideline uptake and outcomes. In addition to reframing the process, CAN-IMPLEMENT includes many new and supplementary tools and templates, an expanded discussion on the essential role of facilitation, as well as search strategy fundamentals for novice developers or those without access to library science specialists. CAN-IMPLEMENT also adds a managerial dimension to the process by expanding the *tactical support* available to leaders and managers of guideline adaptation initiatives, i.e., it describes not only what to do but acknowledges the importance of infrastructure and underscores *"how-to"* proceed with tasks. User supports include a printable Guide, Quick Reference Guide,

Toolkit, and Library Supplement. An interactive tutorial version is also available on the Cancerview e-learning site at: http://www .cancerview.ca/cv/portal/Home/ParticipateAndConnect/PCProfessionals/ Collaborating/eLearningTools, accessed September 2012.

These three phases are embedded in the broader Knowledge-to-Action process framework, an application cycle (Figure 3.2.1). Knowledge Adaptation begins when this external knowledge/evidence enters the knowledge-to-action "application cycle." This transfer is usually activated by a practice issue or problem. In Phase 1 of CAN-IMPLEMENT, a rigorous process is employed to identify, appraise and adapt existing knowledge to meet a specified practice gap. In Phase 2, the selected knowledge is further aligned with the local practice environment/context. After adaptation, knowledge activation refers to the phase where the adapted knowledge (e.g., guideline recommendations) becomes integrated within the targeted practice and system. Critical barriers and facilitators are assessed and identified challenges are mitigated by the implementation and adjustment of strategies tailored to the circumstances of the local context. In Phase 3, levels of uptake are

ACTION CYCLE
(Application)
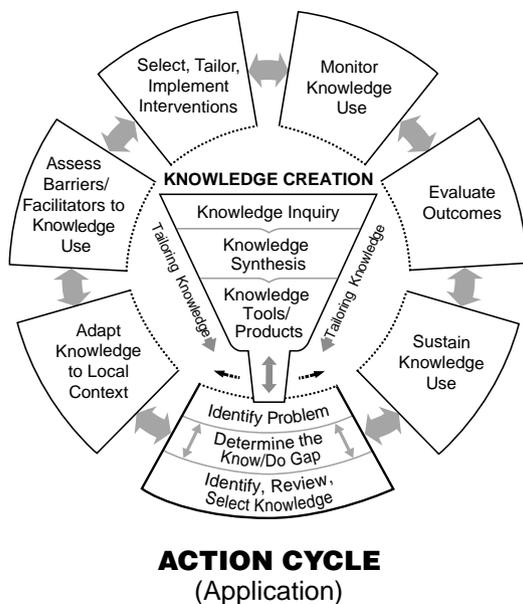
Figure 3.2.1   Knowledge to action process with guideline adaptation and implementation integrated. Reproduced from Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, Robinson N. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof.* 2006; **26**(1): 13–24, with permission from John Wiley and Sons.

monitored and, once a targeted threshold of use is reached, outcomes can be evaluated. During guideline adaptation there is opportunity to "think forward" and plan for this last phase to implementation. The resources and opportunities in the context are usually well identified in Phase 1 and 2 to appropriately plan and execute the implementation. In our field study groups took up to 24 months to adapt a guideline. In large part this was due to their working on the adaptation in addition to their regular workload and their lack of experience in the process, during which a great deal of implementation thinking and planning was occurring which reaped benefits as the adapted guideline was moved forward.

Summary

This chapter describes processes for adapting guidelines to the local context. The same principles could be used when considering implementation of knowledge syntheses or patient decision aids. The ADAPTE methodology offers an approach for straightforward guideline adaptation especially with experienced, resourced guideline panels. The CAN-IMPLEMENT process offers a more in-depth process and methodology for more field-based adaptation initiatives that includes the needed facilitation and methodological support, additional tools to manage and document the process and an explicit dissemination and implementation planning component. It would be useful for groups less experienced in guideline adaptation particularly for those working at the point-of-care undertaking a local adaptation. A significant benefit of using the ADAPTE or CAN-IMPLEMENT processes is that they break down a rather complicated process into discrete and manageable phases and steps. CAN-IMPLEMENT is an integrated KT approach to guideline adaptation. Its participatory nature promotes the adoption of the best evidence-based recommendations *along with* consideration of local needs, circumstances, and the opportunity to begin implementation planning. A guideline evaluation process should be rigorous, systematic, and structured to be inclusive of stakeholders when evaluating the guidelines as well as in reviewing the local adaptation of them. All decisions and their rationale are documented, along with important details of the methodology and process (e.g. the search strategies, results of the guideline appraisal, content analysis of the recommendations, and stakeholder feedback) to ensure that the process is transparent and reproducible.

As an organization works through adaptation of guidelines, an additional benefit is the development of consensus among relevant stakeholders including practitioners, policy makers and others. The process itself may serve as a non-threatening, instructive and updating experience for those

involved in reviewing existing guidelines or providing feedback on the local draft guideline. Adaptation, using a method such as ADAPTE or CAN-IMPLEMENT, helps to avoid departures from the evidence base and stresses the process of aligning the evidence to the local context. It directs users to identify potential local barriers in applying research evidence to clinical or policy practice. By actively engaging the targeted users in reviewing guideline recommendations and discussing any organizational changes required, an environment for communication and collaboration among health professionals, managers and decision making is fostered. This culture is crucial to overcome barriers to implementation.

Generally there are a number of potential challenges to guideline adaptation including a lack of high quality source guidelines, limited applicability of guidelines beyond the setting in which they were developed, acceptance of the process by different targeted user groups, or complexity of the adaptation process in the event of a large number of guidelines with potentially differing recommendations. Additional barriers may include lack of expertise and clinician availability.

Future research

The ADAPTE process is being used internationally and research should be conducted to understand users' experiences as well as to determine its usefulness and effectiveness in facilitating guideline adaptation in different contexts (i.e., among guideline developers, frontline providers, etc.). CAN-IMPLEMENT is a participatory, integrated KT approach to guideline adaptation and implementation. Its participatory nature requires engagement of end-users in all the steps in the process. This encourages their understanding and valuing the adaptation steps and willingness to implement the adapted guideline. By encouraging their buy-in of the adapted guideline it initiates the implementation process. CAN-IMPLEMENT and its resources will also require ongoing testing and refinement. Methods to effectively and efficiently provide orientation and training with both ADAPTE and CAN-IMPLEMENT will require evaluation e.g., online, workshop and other formats.

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Subsection 3.3 **Barriers**

Chapter 3.3a **Barriers and facilitators**

Strategies for identification and measurement

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Key learning points

- Barriers and facilitators to knowledge use are among the most important elements to be considered by those interested in knowledge implementation.
- A number of taxonomies/frameworks and instruments for assessing barriers and facilitators have been developed and should be used when developing a knowledge-to-action project.
- There is a need for a consensus on existing taxonomies/frameworks and instruments to support valid comparison between diverse contexts.

Introduction

The need for the effective knowledge translation in clinical practice is essential if we want to address the following challenges: (a) increased availability of health information [1]; (b) the expanded role of patients in clinical decision making [2]; (c) management of expectations regarding new treatments and technologies [3]; and (d) enhanced patient safety [4].To date, there is consensus in the implementation research community that efforts to translate knowledge at the clinical level have met with little success [5]. Although each phase of the knowledge-to-action cycle is important for ensuring the effective translation of knowledge, the aim of this chapter is to highlight the specific challenges associated with the assessment of barriers and facilitators to knowledge use. The observations in this chapter are based on a search of the Knowledge Translation Resource Clearinghouse of the Keenan Research Centre, a joint program of St. Michael's Hospital and the University of Toronto's Faculty of Medicine (http://ktclearinghouse.ca/tools/science, accessed September 2012).

The first section of this chapter addresses the importance of barriers and facilitators to knowledge use in health care. The second section briefly presents the evolution of a few models in this field in order to highlight the relevance of using conceptual models to assess barriers and facilitators. The next section reviews relevant instruments for measuring barriers and facilitators, and the last section of the chapter summarizes the lessons learned from the various research initiatives cited and identifies areas in need of further research.

Why are barriers and facilitators to knowledge use important?

A search in PUBMED up to August 7, 2012 using the search terms "barriers" and "barriers AND implementation" produced 57,665 and 4359 hits, respectively. The literature often refers to barriers and facilitators to knowledge use in the context of "beliefs about capabilities," of which they are key determinants. "Beliefs about capabilities" includes the concept of perceived behavioral control, a determinant of behavior proposed by the theory of planned behavior (discussed in Chapter 4.2) [6]. In a review of 78 studies using social cognitive theories (theories where individual cognitions/thoughts are viewed as processes intervening between observable stimuli and responses in real world situations) to identify factors influencing health professionals' behaviors, the authors found that the cognitive factors most consistently associated with predicting health care

professionals' intention and behaviors were beliefs about capabilities and intention [7]. Their results led the authors to propose an integrated theoretical framework for the study of health care professionals' behavior and intention, that is based on beliefs about capabilities. They hypothesized that in cases of non-volitional behavior, beliefs about capabilities have the potential to directly influence both intention and behavior. Moreover, a recently published Cochrane Review concluded that "interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or dissemination of guidelines" [8]. In other words, among all the existing socio-cognitive constructs, "barriers and facilitators to knowledge use" is one of the variables that best predicts both health care professionals' behavior and intention.

What are some of the conceptual models for assessing barriers and facilitators to knowledge use?

Conceptual models represent sets of concepts (words describing mental images of phenomena) and the propositions (statements about the concepts) that integrate the former into a meaningful configuration [9]. They may include general guidelines for research, practice, and education. Every world view that has become conventional engenders theories with a narrow focus that must be experimentally refuted [10]. Thus, conceptual models are rarely static and should evolve as new evidence emerges. In the context of barriers and facilitators to knowledge use in health care, relevant conceptual frameworks should help researchers move beyond conventional wisdom on the topic by identifying research questions, generating testable hypotheses, assessing outcomes with valid and reliable instruments, and making inferences from their study results. A useful framework would ensure that researchers can elaborate theory-based interventions with the potential for increasingly effective implementation of knowledge into clinical practice [11].

One of the conceptual frameworks often cited regarding barriers to knowledge use in health care is the Clinical Practice Guidelines Framework for Improvement [12]. This framework was based on an extensive search of the literature about barriers to physician adherence to clinical practice guidelines and was designed to measure physicians' knowledge, attitudes, and behavior [6]. Based on a systematic approach to evidence [13], clinical practice guidelines are defined as systematically developed statements to assist practitioners and patients with decisions about appropriate health care in specific circumstances [14]. Out of a total of 5658 potentially eligible articles, Cabana and his colleagues (1999) identified 76 published studies

describing at least one barrier to adherence to clinical practice guidelines. Taken together, the articles that were included reported a total of 293 potential barriers to physician guideline adherence, including awareness of the existence of the guideline (i.e. ability to correctly acknowledge the existence of the clinical guideline) (n = 46), familiarity with the guideline recommendations (i.e. ability to correctly answer questions about the guideline content) (n = 31), agreement with the recommendations (i.e. consenting to the recommendations) (n = 33), self-efficacy (i.e. feeling one is able to carry out the recommendations) (n = 19), outcome expectancy (i.e. perception that one's performance following the use of the recommendations will lead to improved patient outcome or process outcome) (n = 8), ability to overcome the inertia of previous practice (i.e. feeling one is able to modify one's routine) (n = 14), and absence of external barriers to following recommendations (i.e. perception of factors external to oneself that would impede the use of the recommendations) (n = 34) [12].

The Clinical Practice Guidelines Framework for Improvement has been extended further by researchers assessing barriers to knowledge use in specific clinical contexts [15, 16]. For example, in one study, barriers were defined as factors that would limit or restrict implementation of shared decision making in clinical practice. Each type of barrier was given a specific definition and potential facilitators of knowledge use were added [16]. Facilitators were defined as factors that would promote or help implement shared decision making in clinical practice. The consideration of facilitators was an important development because we tend to forget that the same factor may sometimes be identified both as a barrier and as a facilitator to knowledge use, demonstrating the importance of developing a more comprehensive understanding of both at once [17, 18]. Table 3.3a.1 presents the definition of each of the potential barriers and facilitators to knowledge use (in this case, shared decision making) in the health care context. This list can be used to guide a content analysis of individual interviews or focus groups collected during qualitative studies on research utilization.

Another conceptual framework frequently mentioned with regard to barriers and facilitators to research knowledge use in health care is "Promoting Action on Research Implementation in Health Services" (PARiHS). The PARiHS framework includes the three core elements of evidence, context, and facilitation, each positioned on a continuum from high to low. The proposition is that for implementation of evidence to be successful, there needs to be clarity about the nature of the evidence being used, the nature of the context, and the type of facilitation needed to ensure a successful change process. It was initially published in 1998 as an unnamed framework inductively developed from the authors' experience with practice

Table 3.3a.1 Taxonomy of barriers and facilitators to knowledge use (in this case, shared decision making) and their definitions[a] [16]

Knowledge	
Lack of awareness	Inability to correctly acknowledge the existence of shared decision making (SDM)
Lack of familiarity	Inability to correctly answer questions about SDM content, as well as self-reported lack of familiarity
Forgetting	Inadvertently omitting to implement SDM [49]
Attitudes	
Lack of agreement with specific components of shared decision making	
• Interpretation of evidence	Not believing that specific elements of SDM are supported by scientific evidence
• Lack of applicability	
Characteristics of the patient	Lack of agreement with the applicability of SDM to practice population based on the characteristics of the patients
Clinical situation	Lack of agreement with the applicability of SDM to practice population based on the clinical situation
• Asking patient about his/her preferred role in decision making	Lack of agreement with a specific component of SDM such as asking patients about their preferred role in decision making
• Asking patient about support or undue pressure	Lack of agreement with a specific component of SDM such as asking patients about support and/or undue pressure
• Asking about values/clarifying values	Lack of agreement with a specific component of SDM such as asking patients about values
• Not cost-beneficial	Perception that there will be increased costs if SDM is implemented
• Lack of confidence in the developers	Lack of confidence in the individuals who are responsible for developing or presenting SDM
Lack of agreement in general	
• "Too cookbook" – too rigid to be applicable	Lack of agreement with SDM because it is too artificial
• Challenge to autonomy	Lack of agreement with SDM because it is a threat to professional autonomy
• Biased synthesis	Perception that the authors were biased
• Not practical	Lack of agreement with SDM because it is unclear or impractical to follow

(*continued*)

Table 3.3a.1 (*continued*)

• Overall lack of agreement with using the model (not specified why)	Lack of agreement with SDM in general (unspecified)
Lack of expectation	
• Patient outcome	Perception that performance following the use of SDM will not lead to improved patient outcome
• Health care process	Perception that performance following the use of SDM will not lead to improved health care process
• Feelings	Perception that performance following the use of SDM will provoke difficult feelings and/or does not take into account existing feelings
Lack of self-efficacy	Belief that one cannot perform SDM
Lack of motivation	Lack of motivation to use SDM or to change one's habits

Behavior

External barriers

• Factors associated with patient

Preferences of patients	Perceived inability to reconcile patient preferences with the use of SDM

• Factors associated with shared decision making as an innovation

Lack of trialability	Perception that SDM cannot be tested on a limited scale
Lack of compatibility	Perception that SDM is not consistent with one's own approach
Complexity	Perception that SDM is difficult to understand and to put into use
Lack of observability	Lack of visibility of the results of using SDM
Not communicable	Perception that it is not possible to create and share information with one another in order to reach a mutual understanding of SDM
Increased uncertainty	Perception that the use of SDM will increase uncertainty (for example, lack of predictability, of structure, of information)

Not modifiable/way of doing it	Lack of flexibility to the extent that SDM is not changeable or modifiable by a user in the process of its adoption and implementation
• Factors associated with environmental factors	
Time pressure	Insufficient time to put SDM into practice
Lack of resources	Insufficient materials or staff to put SDM into practice
Organizational constraints	Insufficient support from the organization
Lack of access to services	Inadequate access to actual or alternative health care services to put SDM into practice
Lack of reimbursement	Insufficient reimbursement for putting SDM into practice
Perceived increase in malpractice liability	Risk of legal action is increased if SDM is put into practice
Sharing responsibility with patient[b]	Using SDM removes responsibility from the health professional because it is shared with patient

[a]Revised in 2009 by author.
[b]Only for the facilitator assessment taxonomy.
Source: Modified from [16] Legare F, O'Connor AM, Graham ID, *et al.* Primary health care professionals' views on barriers and facilitators to the implementation of the Ottawa Decision Support Framework in practice. *Patient Educ Couns* 2006; 63: 380–90 with permission from Elsevier. Copyright © 2006, Elsevier.

improvement and guideline implementation efforts [19]. In 2002, the original authors published a refined version of this framework containing the first published use of the PARiHS label. A conceptual exploration of evidence was published in 2004 [20], which rounded out the PARiHS team's review of their framework's three core elements. Kitson and colleagues published a further clarification of PARiHS in 2008 [21, 22] which focused on the need to develop diagnostic and evaluative tools based on PARiHS [22]. PARiHS has since been put into practice in instruments built to assess barriers and facilitators during implementation planning as well as to determine the effectiveness of intervention strategies [23–25].

More recently, based on a systematic review of 19 frameworks, Michie, van Stralen, and West proposed a Behavior Change Wheel which represents another attempt to establish a comprehensive framework for identifying the factors promoting behavior change [26]. Unlike other taxonomies, the Behavior Change Wheel uses broader categories and provides suggestions about interventions for addressing identified factors affecting behavior change. The three essential conditions at the centre of the Behavior Change Wheel are capability, opportunity, and motivation (what the authors term the "COM-B system"). The middle circle represents nine overarching intervention functions: education, persuasion, incentives, coercion, training, restriction, environmental restructuring, modeling, and enablement. The outer circle represents seven policy categories: fiscal measures, guidelines, environmental/social planning, communication/marketing, legislation, service provision, and regulation. This framework captured the full range of mechanisms that may be involved in behavior change, including those that are internal (psychological and physical) and those that involve changes to the external environment [26].

What are some methods and tools for assessing barriers and facilitators to knowledge use?

Although interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or dissemination of guidelines, the authors of the recently published Cochrane Review on this topic also highlighted the need for further development of the methods used to identify barriers and tailor interventions to address them [8]. To identify barriers and facilitators (also called determinants) to knowledge use, researchers frequently use qualitative study methods, such as one-on-one and/or focus group interviews with health professionals or other relevant knowledge users [27–31]. Various other methods include workshop discussions, observation of facilitators, internet surveys,

brainstorming by implementation researchers, reviews of records, analysis of the barriers and facilitators, and consensus of opinion leaders [8, 32]. Most of these studies use one or two qualitative methods to assess the barriers and facilitators; primarily they use methods oriented toward understanding phenomena rather than measuring them. Data collection of interviews and focus groups are often designed to be open-ended so that research participants feel free to express themselves in their own words. Some studies identify and validate barriers and facilitators in their respective knowledge-use contexts using the Delphi procedure [33, 34]. Some quantitative methods, such as survey questionnaires associated with multivariate analysis, may also use observational datasets to identify barriers and facilitators to knowledge use with respect to potential determinants [35, 36]. Meta-analyses that statistically analyze potential determinants accounting for the heterogeneity of effects across studies may also be helpful in identifying barriers and facilitators of knowledge use [8]. Each knowledge use environment presents organizational, professional, individual, and cultural particularities. The identification of specific barriers and facilitators represents an approach for identifying the determinants of knowledge translation to practice and decision making. It is in this context that there is considerable interest today in developing instruments that can perform valid and reliable assessments of barriers and facilitators to knowledge use that can be used by various end-users trying to implement knowledge.

Based on the Clinical Practice Guidelines Framework for Improvement, a tool named Attitudes Regarding Practice Guidelines to assess barriers to adherence to hand hygiene guidelines was developed and tested on a group of 21 infectious disease clinicians [37]. The tool uses a 6-point Likert scale and has two sections: attitudinal statements about practice guidelines in general and specific statements regarding the Hand Hygiene Guideline. The survey was administered twice, at two-week intervals. The tool was found to have a test-retest reliability coefficient of 0.86 and a standardized Cronbach alpha of 0.80 [37]. However, the authors concluded that their tool needed further testing and adapting if it were; old english needed here to measure potential barriers to adherence to clinical practice guidelines in general [37].

Wensing and Grol reported the development of another instrument designed to assess barriers and facilitators to knowledge use [38]. This instrument was applied to 12 different implementation studies in the Netherlands [38]. First, they used literature analyses and focus group interviews with implementation experts to identify possible barriers to change. Second, they performed validation studies to test the psychometric characteristics of the questionnaires. Questions pertained to characteristics of the innovation (i.e. clinical practice guidelines), care provider characteristics,

patient characteristics, and context characteristics. In a study on the prevention of cardiovascular diseases in general practice involving 329 physicians, they found that the self-reported barriers identified using their questionnaire explained 39% of the self-reported performance. This instrument is available in Dutch and English.

In the mental health field, G.A. Aarons has explored the role of attitudes in acceptance of innovation and proposes a model of organizational and individual factors that may affect or be affected by attitudes toward adoption of evidence based practice (EBP) [39]. This Evidence Based Practice Attitude Scale (EBPAS) includes four domains: attitudes related to the appeal of an EBP, requirements to adopt an EBP, openness to innovation in general, and perceived divergence between current work processes and those required by an EBP [40]. The overall Cronbach's alpha reliability for the EBPAS is good (alpha = 0.77) and subscale alphas range from 0.90 to 0.59 [39].

In nursing clinical practice, the BARRIERS scale was developed to assess barriers to research utilization based on four key dimensions: (a) nurse, (b) setting, (c) research, and (d) presentation [41]. The scale is composed of 29 items and is comprised of four subscales that map the four key dimensions. Each subscale is labeled in accordance with the theory of diffusion of innovation: (a) characteristics of the adopter (i.e. the nurse's research values, skills and awareness); (b) characteristics of the organization (i.e. barriers and limitations of the setting); (c) characteristics of the innovation (i.e. qualities of the research); and (d) characteristics of the communication (i.e. presentation and accessibility of the research). The BARRIERS scale has been translated and tested in German, Thai, Korean, French, Turkish, and Swedish [42, 43]. Interestingly, the group of researchers who translated this scale into Swedish added an additional item that covers the English language as a barrier for Swedish nurses, thus pointing out the need for cultural adaptation of barrier assessment tools. The scale is methodologically useful as it identifies some types of barriers to research utilization, but the barriers identified are general and wide-ranging, making it difficult to apply in specific knowledge use contexts [42]. In addition, it does not identify organizational barriers, while organizational context is widely considered to be an important influence on the successful implementation of research evidence in health care settings [20, 44].

C. A. Estabrooks and her collaborators developed another instrument based on the PARiHS framework, the Alberta Context Tool (ACT), an eight-dimension measure of organizational context for health care settings. An initial validation of the English version of ACT was completed by 764 nurses (752 valid responses) working in seven Canadian pediatric care

hospitals. ACT has two versions with 5- and 6-point Likert responses for each item; the original version includes 76 items and a reduced version includes 56 items. The eight core context dimensions of ACT include: (1) leadership, (2) culture, (3) evaluation, (4) social capital, (5) structural and electronic resources, (6) formal interactions, (7) informal interactions, and (8) organizational slack (comprised of three sub-concepts: staffing, space, and time resources) [45]. Cronbach's alpha for the 13 factors included in ACT ranged from 0.54 to 0.91 with four factors performing below the commonly accepted alpha cut off of 0.70. Each factor also showed a trend of increasing mean score ranging from the lowest level to the high-est level of instrumental research use, indicating construct validity. The tool's strengths are its brevity (allowing it to be completed in busy health care settings) and its focus on dimensions of organizational context that are modifiable [24].

In 2007, J. Wright and colleagues presented an instrument to identify contextual indicators that enable or hinder person-centered continence care and management in rehabilitation settings for older people [46]. In 2009 this instrument was named the Context Assessment Instrument (CAI) [23]. CAI contains 37 items with a 4-point Likert response format. A total score is calculated to represent an environment's receptivity to change. The five domains of CAI include collaborative practice, evidence-informed practice, respect for persons, practice boundaries, and evaluation. The Cronbach's alpha score for the complete questionnaire was estimated at 0.93. All five factors achieved a satisfactory estimated level of internal con-sistency in scoring, ranging from 0.78 to 0.91. Test–retest scores indicate reliability of the findings, and the feedback from focus group participants suggests that the instrument has practical utility [23].

The Organizational Readiness to Change Assessment (ORCA) is also worthy of mention. ORCA contains 77 items with 5-point Likert responses for each item. It was developed for use in quality improvement activities by researchers from the Veterans Affairs Ischemic Heart Disease Quality Enhancement Research Initiative to assess site readiness. Also based on the PARiHS framework, ORCA includes three domains: evidence, context, and facilitation. With a few exceptions, adequate estimates of reliability and validity were reported for most factors and subscales [25]. Cronbach's alphas for scale reliability were 0.74, 0.85 and 0.95 for the evidence, context and facilitation scales, respectively. Low reliability was observed for three evidence subscales [25, 45].

Assessing for barriers and facilitators through direct input from knowl-edge users about their perceptions of the determinants of knowledge use is considered an integrated KT approach because of: (1) the participatory

nature of the exercise, and (2) the desire to understand and appreciate the knowledge users' perspectives. Taking the process a step further may involve asking potential knowledge users to suggest interventions they think might address the barriers and facilitators they have identified. This input could be used to help map the intervention and is further described in Chapter 3.3b.

Future research

Although numerous current research initiatives focus on assessing determinants of knowledge use in health care practices, many challenges remain that will require rigorous research. Firstly, the use of multiple frameworks and tools may hamper the ability of researchers to make valid comparisons between diverse contexts. Therefore, there is a need to standardize the reporting of barriers and facilitators to translating research into practice and decision making [12, 47, 48]. We also need to distinguish between "barriers and facilitators to knowledge use" understood as beliefs about capabilities, a specific socio-cognitive construct, and understood as any factors influencing knowledge use. Secondly, models that identify barriers alone are not sufficient, since a factor perceived as a barrier can be identified as a facilitator at the same time. Thirdly, implementation researchers should use standardized, valid and reliable instruments in their assessments of barriers and facilitators to knowledge use. However, there is still a need to adapt and test existing instruments in diverse clinical as well as cultural contexts. Lastly, in line with the Behavior Change Wheel, more research is needed on choosing the right intervention for addressing a specific barrier and/or facilitator. Only then will the gap between research and practice be adequately addressed.

Summary

Of all the existing socio-cognitive constructs, "barriers and facilitators to knowledge use" may be the factor that can best predict both health care professionals' behavior and intention. Although there are many current research initiatives assessing determinants of knowledge use, the reporting of barriers and facilitators to translating research into clinical practice urgently needs to be standardized. Also, implementation researchers should consider using standardized, valid and reliable instruments in the assessment of barriers and facilitators to knowledge use. Further research is needed on how to choose the right intervention to address a specific barrier and/or facilitator and the work initiated by the Behavior Change Wheel may provide an interesting avenue.

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Chapter 3.3b Mapping KT interventions to barriers and facilitators

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Key learning points

- Mapping barriers to intervention components is a critical step in the knowledge to action cycle.
- Effectively mapping barriers to interventions can play a role in understanding why an intervention does or does not work.
- Few systematic approaches for mapping barriers to interventions exist.

In Chapter 3.4a Wensing and colleagues outline some of the challenges inherent in selecting and tailoring interventions to barriers and facilitators for behavior change. Despite these challenges, addressing barriers and facilitators is one of the most crucial steps in the knowledge-to-action process [1]. The linking of identified barriers to specific intervention components in order to address, alleviate, or reduce the impact of the barrier is a key aspect of facilitating knowledge use in health care. Likewise, identified facilitators should be linked to intervention components in order to promote and maximize their impact. KT interventions typically include multiple components to ensure that the various barriers and facilitators that might impact on the effectiveness of the intervention are addressed.

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Another rationale for explicit mapping of intervention components to barriers and facilitators is to ensure an understanding of the hypothesized causal pathways of change that are anticipated as the result of the intervention. Without a clear understanding of the changes that were anticipated and why the selected interventions components may create this change, it will be difficult to learn from (successful and unsuccessful) interventions and be able to develop a more effective intervention the next time around [2, 3]. A poorly planned intervention might also succeed by chance and the success could lead to incorrect assumptions and conclusions for the effectiveness of the intervention. While it is generally agreed that the intervention components needs to address the key barriers and facilitators, it is far less clear how to do so.

Consider as an example the use of evidence-based practice in the field of rehabilitation. Systematic reviews indicate that the adoption of best practices for stroke care by rehabilitation therapists is poor [4, 5]. Studies specific to occupational therapy in stroke care indicate desired assessment use rates from 1% [6] to 27% [7] and rates of desired intervention adherence from 15% [6] to 58% [7]. Numerous barriers to the adoption of stroke best practices have been identified such as a lack of confidence in the ability to use research and a limited skill base for understanding research [8]. The challenge is designing an intervention that will have an effect on therapists' confidence and skill. A systematic review on strategies to move stroke evidence into rehabilitation practice provided limited evidence on best approaches to KT but indicated that active, as opposed to passive, KT interventions were more likely to be effective [8]. Although helpful, this type of summary does not provide us with ideas for specific intervention components nor does it provide guidance on ensuring that our intervention addresses the key barriers and facilitators. A systematic approach to linking intervention components to barriers is required and often this information is not available in systematic reviews of interventions that usually lack detail on the components of the intervention, potential barriers, and facilitators to its uptake, or the context in which the interventions were deployed.

Regardless of which approach for mapping barriers and facilitators to intervention components is used, when designing the intervention it is important to establish a hypothesized pathway with three clear elements: what barrier and/or facilitator the component of the intervention is meant to address, why the intervention component was selected, and how it is expected to create change [3]. Choosing an intervention solely because it has been done before, or is judged to be feasible, is not recommended [9], and likely will not result in an optimized intervention. Colloquially referred to as the ISLAGIATT (it seemed like a good idea at the time) principle, this approach is unlikely to lead to generalizable interventions that have been

shown as effective [9]. Additionally, barriers and facilitators can exist at multiple levels. Depending on whether the barrier occurs at the level of the patient, provider, team, or organization, the intervention will need to be designed to target a level consistent with the level of the barrier.

Multiple planning models exist for intervention development [10, 11]. As an example, French *et al.* developed a useful and generic process for intervention development [11]. In their study, a systematic 4-step process to intervention development is outlined: (a) determine who needs to do what differently; (b) Use a theoretical framework to determine which barriers and facilitators need to be addressed; (c) Choose intervention components that will overcome barriers and enhance facilitators; (d) Determine how to measure behavior change. This chapter will focus on unpacking Step 3 of this process by providing a description of four approaches to mapping barriers and facilitators to intervention components.

The concepts of "tailoring interventions" and "mapping interventions to barriers and facilitators" are very similar. In the most recent Cochrane update on tailored interventions, the authors define tailoring as "strategies to improve professional practice that are planned taking account of prospectively identified barriers to change" [12]. In Chapter 3.4a, Wensing and colleagues extend the concepts involved in tailoring to include stage and intensity of tailoring, but remain consistent with the general definition of tailoring provided in the Cochrane review. This chapter will use the term "mapping interventions to barriers and facilitators" but consider this synonymous to tailoring.

What are the key concepts for mapping interventions to barriers and facilitators?

The approaches described in this chapter map intervention components to identified barriers and facilitators, and are described with the assumption that the barriers and facilitators have already been identified, using approaches such as those described in Chapter 3.3a. Several of the outlined approaches, however, offer comprehensive intervention development that includes barrier/facilitator identification as well as mapping to intervention components. This is stipulated where appropriate but the focus of the description is placed on the step that involves mapping interventions to barriers and facilitators.

Methods for mapping interventions to barriers and facilitators are in their infancy in the KT field. Few systematic approaches exist and scant evidence is available on the effectiveness or the superiority of specific approaches [12]. The approaches outlined here were chosen based on

prevalence in the literature and the presence of a reasonably defined proce-
dure. Four approaches to mapping interventions to barriers and facilitators
will be outlined; two are common sense [13] and two are theory-based.
Although many different classification approaches are used to describe KT
intervention design methods in the literature — for example, implicit the-
ory [9], common sense [14], theory-based [15], exploratory [16], prag-
matic [17, 18] – the terms common sense and theory-based were chosen
to describe the approaches in this chapter. Common sense methods are
those which use varying degrees of implicit theory and sound practical
judgment to specify relevant barriers and facilitators but do not explicitly
embed a guiding theoretical framework into the process [17, 18]. Theory-
based approaches explicitly use theories and their associated explanations
and predictions to guide the development of the intervention [3]. Both
common sense approaches described are participatory in nature and the
two theory-based methods are more researcher-driven.

Common sense approaches

Semi-structured interview methods

Semi-structured interview methods use individual interviews, brainstorm-
ing, and/or focus groups to map barriers and facilitators to intervention
components. While not purely qualitative, this approach resembles qualita-
tive participatory methods. These types of approaches are used widely in
practice although clear guidance on undertaking these methods is lacking
[16]. Wensing and colleagues are completing a project aimed at developing
and validating semi-structured interview methods to map barriers and
facilitators to interventions in chronic diseases [18]. The international proj-
ect targets five different chronic diseases in five different countries: cardio-
vascular disease in the Netherlands, obesity in England, depression in
Norway, chronic obstructive pulmonary disease in Poland, and multi-mor-
bidity in Germany. The project utilizes both structured and unstructured
group interview methods that gather input from various stakeholders
including implementation researchers, quality improvement staff, and cli-
nicians. The specific methods used are: (a) Open interview methods (indi-
vidual and group) in which potential KT interventions are identified and
assessed by the participants, given the known barriers and facilitators to
practice; (b) Structured interview methods, guided by checklists that sum-
marize barriers and facilitators to practice, research evidence, and templates
that link possible KT interventions to known barriers and facilitators. A key
aspect of this approach is the strong knowledge user input into the process
of mapping interventions to barriers and facilitators. A challenge is the lack

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Box 3.3b.1 Example: semi-structured interview methods [19]

This study team developed an intervention for Veterans Affairs substance abuse disorder clinics to increase the adoption of evidence-based guidelines for the recognition and treatment of depression. Designed specifically for providers at the clinic, this project was a part of a Quality Enhancement Research Initiative (QUERI) series. Following the determination of site-specific barriers and facilitators, the development of the intervention was achieved using development panels. These panels consisted of carefully selected local individuals who were deemed to be supportive, enthusiastic, respected, and likely to be engaged. The Principal Investigator of the study in collaboration with a local sponsor chose the individuals. The panels met on numerous occasions over 5 months. Together with the study principal investigator, the intervention was developed through discussion and iterative problem solving. The panels were provided with instructions on how to proceed and the discussions were guided by the study aims, the barriers/facilitators, and empirical evidence related to KT interventions for depression management as well as the evidence base for treatment of depression. The primary investigator played a key role in facilitating the panel discussions and incorporated information that was gathered by the research team in key informant interviews and site observations that occurred earlier in the process when determining the local barriers and facilitators. These interviews occurred with local staff, implementation experts, clinical experts, and patients. The final intervention was augmented by expert opinion that occurred outside of the panels. Efforts to determine an effect of this intervention are ongoing but initial studies indicate increased researcher and stakeholder involvement in the process [20].

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of a systematic approach to utilizing these methods including no clear guidance on how to present the intervention options (see Box 3.3b.1).

Plan-Do-Study-Act approach

Plan-Do-Study-Act (PDSA) is a rapid cycle approach that was developed in the field of Continuous Quality Improvement [21, 22]. The emphasis is placed on continuous cycles of improvement that are multi-disciplinary, focused on comprehensive and local input into intervention components, and aimed at adapting processes within an organization to elicit change. Based on the Langley Model of Improvement [22], the process starts with considering three key questions: what is to be accomplished, how will we know that a change is an improvement, and what changes can we make that will result in the improvement? The last question is answered in large part by the PDSA cycle: Plan (set objectives, predictions, who will do what), Do (undertake the plan, document), Study (analyze, compare, summarize what happens), Act (what changes need to be made, what cycle should come next). The mapping of interventions to barriers and facilitators is less

explicit in this approach but does occur through the process of end-users (the multi-disciplinary team) engaging in dialogue to plan objectives, predictions, and the associated activities to meet them. Careful attention needs to be placed on the team members involved and their understanding of the barriers preventing change in the organization. Small changes in rapid cycles are encouraged, as is evaluation of whether change was achieved, why or why not, and then decisions are made as to how to proceed through another cycle. The cycles continue until the desired change is achieved. With the PDSA approach, one knows quickly if something is or is not going to work and thus, large-scale mistakes are less likely. Another benefit is that the method incorporates end-user involvement in the intervention design process. A challenge is that the process requires strong multi-disciplinary engagement to be effective and end-users must have a thorough and accurate understanding of the barriers and issues that are preventing change and the facilitators that would promote change. Additionally, the rapid and multiple cycles of change could limit the strength and power of evaluation and make it more difficult to ascertain change and/or attribute any change to a specific intervention. The approach also tends to place more importance on the tacit knowledge of end-users than on evidence about effective interventions (see Box 3.3b.2).

Box 3.3b.2   Example: Plan-Do-Study-Act approach [23]

This study utilized the PDSA approach for an improvement project aimed at achieving a 48-hour target for processing repeat prescriptions for patients in a UK community practice of 14000 patients. The authors outlined the process they undertook using the three key improvement questions and PDSA framework as a structure, making it very clear as to how they used the approach and what occurred at each step. A multi-disciplinary group of individuals including one practice partner, the practice administrator, three receptionists, and an external facilitator were chosen to participate. All individuals were invested in the issue to be addressed and fully understood the existing limitations in office processes and procedures. Their first task was to establish a joint aim. Next, four brainstorming sessions were held over three months in which multiple flowcharts of the existing processes for repeat prescriptions were created, and then evaluated with a focus on key problem areas and potential solutions. This stage was augmented with an audit of their existing performance for repeat prescriptions. Based on these brainstorming sessions, four key areas were determined that would provide the basis for knowing that a change had occurred. A three-pronged strategy was developed to address the four issues that consisted of computer support to manage prescriptions, efforts to priorize prescribing processes, and moving key prescribing paperwork closer to the point of care. Positive results were achieved and their target was met with a total of three PDSA cycles.

Theory-based approaches

Intervention Mapping

Intervention Mapping [24, 25] was initially developed for evidence-based health promotion programs. On the basis that a health promotion program is more likely to succeed if guided by theory, the approach emphasizes the use of theories from social and behavioral science. The process involves five iterative steps presented in a linear approach. Step 1 is developing program objectives that are linked to their related barriers (typically there are multiple objectives for each barrier), step 2 is selecting theory-based intervention methods and related practical strategies designed to meet the program objectives, step 3 is operationalizing the methods and strategies into a coherent and feasible intervention, and steps 4 and 5 include anticipating the process of adoption, implementation, sustainability, and evaluation. In steps 2 and 3 intervention components are mapped to barriers. These two steps involve selecting relevant intervention components that are supported by theory that is deemed by the participants as most relevant to the barriers or issues for behavior change, linking these techniques to practical strategies to change the barriers related to the targeted health behavior, and then integrating these techniques and strategies into a coherent intervention. For example, a theory-based intervention technique that can effect self-efficacy could be modeling (providing an example to observe), and a practical strategy using this method could be making a video of peers as models [24].

Kok suggests three approaches to choosing the theory that will help explain the behavior change problem: (a) *issue approach*: search the literature for theories specific to the issues for behavior change; (b) *concept approach*: start with a provisional list of explanatory factors from the literature related to the problem and then link that list to theories that appear useful; (c) General Theories approach: consider general theories that may be important for the problem at hand.

Intervention Mapping provides a guided step-by-step process of intervention design that defines important barriers and links them to intervention strategies using theory. While the process of theory utilization will likely encourage barrier as well as facilitator identification, the focus of objective setting in Intervention Mapping is placed on barrier identification. One of the difficulties of Intervention Mapping is that the suggested approaches to choosing the theory are rather general and it remains a challenge to choose the theory that will accurately identify the key problems (see Box 3.3b.3).

> **Box 3.3b.3** Example: Intervention Mapping [26]
>
> This chapter outlines a detailed description of how Intervention Mapping was used to develop a locally tailored program to address secondary stroke prevention. The authors chose this approach as they felt it was a useful mix of theoretical considerations with the practicalities of intervention design. In order to guide intervention development and map intervention components to barriers, this team used a chronic care model as a guiding framework combined with the Theory of Planned Behavior (TPB), a theory of social psychology. The chronic care model guided system-based decisions like access to community-based resources and the incorporation of patient self-management principles. The TPB was used to target intervention components at social norms and perceived behavior control. The resulting multi-faceted intervention included clinical reminders, standardized provider checklists for patient training and education, and the development of patient support and peer programs. Supplemental files provide an excellent summary of each program objective matched to the theory-based techniques and practical strategies used to develop the intervention. For example, the objective of motivating patients to modify their lifestyle included techniques like role playing to improve provider skills (perceived behavior control) and the related practical strategies included training providers in motivational interviewing. An evaluation of this intervention is in progress but is not yet complete.

Behavior change technique matrix [27]

The behavior change technique matrix was designed to facilitate the development of theory-based interventions that have clearly articulated causal pathways between the intervention components and the barriers and facilitators [27]. The matrix is a list of 53 effective behavior change techniques, based on expert consensus and systematic review, mapped onto specific determinants of behavior (barriers and facilitators). The determinants of behavior are structured into 11 domains that were developed in previous work entitled "The Theoretical Domains Framework" [28]. The 11 domains represent a summary of determinants of behavior, and are based on expert consensus, and 33 constructs from 128 theories that are critical for behavior change. The domains are: knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; motivation and goals; memory, attention, and decision processes; environmental context and resources; social influences; emotion; behavioral regulation. The matrix maps effective interventions to these determinants of behavior or barriers. For example, if the barrier is related to social influences, the matrix suggests interventions of encouragement, pressure, support, and modeling of the behavior by others. If the barrier is related to one's beliefs about capabilities, the matrix suggests interventions of motivational interviewing,

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Box 3.3b.4 Example: Behavior Change Technique Matrix [11]

French *et al.* developed a systematic approach to designing an intervention that included four steps. The third step, mapping the intervention components to the barriers and facilitators, was achieved using the Behavior Change Technique Matrix. Called the IMPLEMENT trial, this intervention addressed guideline adherence for the management of low back pain in general practice and was designed with attention paid to theory, evidence, and practical realities. Unlike the majority of other approaches that focus mostly on barriers, this study pays an equal amount of attention to enhancing facilitators. Also, the authors considered whether barriers and facilitators were modifiable or not in their process of choosing which to address. French considered first the content of the intervention (what would be delivered) followed by the mode of delivery (how techniques would be delivered). Using their identified barriers and facilitators they used the matrix to design the building blocks of their intervention. This was then followed with further intervention development using the experience of various stakeholders on their research team (researchers and clinicians), and empirical evidence in support of interventions for the management of low back pain. The resulting intervention consisted of two facilitated interactive small group workshops that involved both didactic lectures and group discussion. A DVD was used to provide much of the intervention content to the providers who could not attend the workshops. The DVD innovatively included footage from the workshops. Results of this trial indicate improved adherence to the guideline in behavioral simulations [30].

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self-talk, self-monitoring, graded tasks, rehearsal, and feedback. While it is not necessary to use the Theoretical Domains Framework to determine barriers and facilitators in order to use the matrix, not doing so can present challenges. Any barrier/facilitator identification needs to be first aligned to the 11 domains in the Theoretical Domains Framework and a systematic process for doing this is not evident [27]. The Theoretical Domains Framework has since been expanded to include 14 domains [29] but the intervention matrix is still based on the original 11 domains. This approach simplifies the vast science of behavior change into a taxonomy of behavior change techniques that can be used to design complex interventions that have well articulated causal pathways (see Box 3.3b.4).

What are the challenges of intervention design?

Mapping barriers and facilitators to intervention components will typically result in building blocks for an intervention, but rarely will it provide a comprehensive intervention ready for implementation. The types of resulting building blocks will in part depend on which approach to mapping interventions to barriers and facilitators was utilized. For example, using

the behavior change technique matrix will result in a list of behavior change techniques such as role playing, modeling, or verbal persuasion. Semi-structured interview techniques could result in a list of potential interventions such as audit and feedback or education. Having a list of recommended methods or techniques is useful, but one still needs to determine how these methods will be operationalized into an intervention. For example, knowing that the intervention should focus on modeling is a significant first step to intervention design; however, one must still determine when, how much, by whom, and for what behavior? Some approaches to intervention design include the step of incorporating intervention components into a feasible and practical intervention [24] but rarely is there clear guidance on how to do this.

KT interventions tend to be complex involving a combination of multiple intervention components all potentially hypothesized to work with multiple causal mechanisms [30]. These interventions also tend to have many components being delivered by many individuals adding to the complexity [31]. This is in part due to the increased likelihood of multiple barriers and facilitators necessitating multiple intervention components to address them. The systematic mapping of barriers and facilitators to interventions thus becomes crucial in order to adequately design, report, and learn from studies of KT interventions. A valuable approach to take when developing and then reporting the intervention is to consider mode of delivery (the format and source of the intervention) [32], as well as the active ingredients (the basis for the causal pathway to change). Improved reporting of intervention components could be achieved with increased use of the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations [3] but this will not necessarily help with the challenge of effectively linking interventions to barriers and facilitators.

Future research

While several approaches to mapping interventions to barriers and facilitators exist, it is likely that a wider range of intervention design approaches for a wider range of contexts will be needed. Certainly, more systematic approaches are required for mapping interventions to barriers and facilitators: both common sense and theory-based. Equally as important, evidence is needed as to whether these methods yield efficacious interventions along with comparative evaluations on which approaches to mapping interventions to barriers and facilitators are more efficacious, and in which contexts. While general evidence exists as to whether certain approaches are efficacious (for an example see a systematic review of diabetes care and

Continuous Quality Improvement [33]), specific evidence related to any of these individual approaches is not evident making endorsement challenging. Best approaches to integrating knowledge user input into mapping interventions to barriers and facilitators are needed as are studies examining how we might consider combining common sense approaches with theory-based approaches. Studies need to include measurement of the barriers and facilitators targeted by the intervention so that their relevance can be assessed and more guidance is needed on determining which barriers and facilitators are the most important to target and how many can be adequately addressed in an intervention. The field would also benefit from consistent terminology related to the building blocks of an intervention: a comprehensive listing of the components that constitute an intervention would facilitate both design as well as reporting.

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Subsection 3.4 Selecting KT interventions

Chapter 3.4a Developing and selecting knowledge translation interventions

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Key learning points

- Knowledge translation (KT) interventions need to be tailored to specific determinants of practice, similar to a clinical treatment which is tailored to a diagnosed health problem.
- Research evidence on KT interventions can provide some guidance, but not decisively show what intervention should be implemented.
- The selection of knowledge translation (KT) interventions remains an "art," which can be supported by structured methods for outlining the objectives of the KT process, identifying relevant determinants of practice, and linking KT interventions to these factors.
- Tailored KT interventions have not been found to be consistently effective, partly because the tailoring methods varied widely across studies.
- Multi-component KT interventions are likely to address a range of determinants of practice, but the definition of what is a multi-component KT intervention is unclear.

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Major variations in chronic heart failure treatment have been repeatedly found. For instance, beta-blocker use in primary care ranged from 10% to 50% between countries, and use of angiotensin converting enzyme inhibitors (ACE-I) ranged from 50% to 75% [1]. Differences in national guideline recommendations were not sufficient to explain this variation [2]. Co-morbidity explained some of the variation in treatment, but 14% of prescriptions were related to patient characteristics that were not in line with evidence [3]. A study of determinants of adherence to heart failure guidelines found that many family physicians found it difficult to change treatment initiated by a cardiologist [4]. Titrating the ACE-I dose was seen as difficult and initiating ACE-I in patients already using a diuretic or stable on their current medication was perceived a barrier [4]. Suppose that these findings can be generalized to a targeted clinical setting, how would we try to improve primary care for chronic heart failure? How would we select interventions to translate the knowledge from practice guidelines and research into practice?

We may think of interventions to facilitate uptake of research to include such things as training for physicians (e.g. to learn about titrating ACE-I dose) or using opinion leaders to influence prescribing patterns of cardiologists. We may also consider providing financial incentives to physicians for each heart failure patient who is treated according to guideline recommendations. Or we could better inform the patient and his family about appropriate heart failure care, hoping that they will ask for this treatment in their future consultations with health professionals. Ideally, the selection of the KT intervention is guided by research evidence on the effectiveness and efficiency of the various interventions. However, this evidence cannot explicitly guide our decisions in all situations and circumstances and so in addition to "science" we will need some "art" to choose or design the KT intervention (Box 3.4a.1) [5].

It is beyond the scope of this chapter to review the evidence on KT interventions and instead we summarize other syntheses [5, 6]. Many KT interventions have been evaluated, but the rigor and quality of studies is mixed and the generalizability of findings across patients, providers and health care systems is often an issue. The research evidence suggests that the impact of KT interventions is variable and, on average, effect size is moderate. Thus, current research evidence on the effectiveness of KT interventions can only partly guide the implementer on the best choice of intervention. The following general conclusions can be drawn from the literature:

• Much of the available research evidence focuses on professional interventions, such as various educational programs, audit and feedback, and

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Box 3.4a.1   A lifestyle program "Lively Legs" [19]

This project aimed to develop a lifestyle program designed for patients with ulcus cruris who visit dermatology departments of Dutch hospitals. A core feature of the program was the availability of a specialized nurse who had a counseling role and helped the patients identify options for lifestyle improvements. The researchers used Intervention Mapping for the development of the program, a technique from the health promotion field. Since preliminary results of the effects of the program were promising, the researchers anticipated wide-ranging implementation and decided to invite the steering group for a brain-storming session to identify possible obstacles to implementation of the program at Dutch dermatology wards and to develop strategies to overcome these. Two sessions were held that included six people of varying disciplines that were involved with this patient group. Sessions lasted an hour and a half. Participants were asked to individually consider possible relevant factors at several levels: the level of the patient, the level of the nurses, the level of social interaction, the level of the organization, and finally, the level of broader structures such as legislation, using a pre-structured sheet. After all factors were collected on the blackboard, targets were formulated for the factors that were considered of most importance and modifiable. To define which factors were considered most important, participants had to divide three points among the factors. Examples of factors considered important were the lack of knowledge about ulcus cruris among nurses and the poor communication between nurses and support services. Subsequently, participants brainstormed to identify implementation strategies that looked most promising to overcome the barriers selected and thereby to achieve the targets chosen. Although both groups identified targets at varying levels, educational strategies were predominantly chosen to address these factors.

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computerized decision support. The overall absolute change of professional performance is usually not more than 10% on selected outcomes, but such change can be clinically or economically relevant.

- Passive educational interventions, such as written guidelines, didactic lectures and conferences, are unlikely to change professional behavior if used alone. Active educational interventions, such as outreach visits and quality circles of professionals, are more likely to induce change. Use of modern technology in educational programs (e.g. for distance learning) can be effective as well, but data on impact on clinical process and outcomes are scarce.
- Professional interventions that bring information close to the point of decision making, such as decision-support, are likely to be effective, particularly in the areas of prevention and test ordering.
- Patient directed interventions, such as pre-consultation questionnaires or decision aids, can support quality improvement in some cases, but insight into the effects of these interventions on quality of care is limited.

- Organizational interventions, such as enhanced patient care teams and integrated delivery systems, can influence clinical outcomes and efficiency in some cases. But their impact on knowledge translation is unclear and they seem particularly to improve efficiency and patient satisfaction.
- Changes in the financial incentives for patients or professionals influence volumes of health care use, which may be relevant for quality improvement (e.g. volume of preventive services). Their effect on appropriateness of clinical decisions and practice patterns is less clear. Moreover, evidence around sustainability of these interventions is limited.

The "art" of selecting a KT intervention can use structured procedures, at least partly. Many implementation experts suggest that a structured approach at various levels is needed to address professionals, patients, teams, organizations, and wider health care systems [6]. Structured approaches for planning change have been developed in various scientific disciplines and include: intervention mapping, marketing, precede/proceed, quality cycle, change management, organizational development, community development, and health technology assessment [7]. Whether these structured approaches result in better knowledge uptake, and which of their constituent components are most relevant, remains unknown. The planning models for change propose more or less the same steps or stages, although their number of steps varies widely [8, 9]. The aim of this chapter is to provide an overview and guidance on methods to select KT interventions, which are tailored to relevant determinants of practice.

Getting started: what are the objectives for knowledge translation?

An important step in the selection of KT interventions is the choice of specific objectives for the KT program. Goal setting may contribute to effective behavioral change [10]. It is usually not possible to analyze and address each objective in substantial detail, so a prioritization of objectives has to be undertaken. Ultimately, the objectives should be related to outcomes for patients, populations, and society. For instance, the objectives for improving heart failure treatment could include higher survival rates (e.g. resulting from better use of ACE-inhibitors and beta-blockers) and lower health care costs (e.g. resulting from fewer hospital admissions). Many KT objectives have been defined in terms of specific changes in treatments or other aspects of health care delivery (e.g. more prescribing of ACE inhibitors and beta-blockers). The expectation is that such changes result in better outcomes. Ideally, strong research

evidence supports this expectation, but in reality often such evidence has limitations. For instance, much of the evidence on effectiveness of heart failure treatment is based on hospital patients and may not be applicable to heart failure patients in primary care.

Several methods can be used to select the objectives for KT, such as a Delphi procedure [11]. For instance, a study showed that about 30% of children seen in primary care with diagnosed urinary tract infection had not received antibiotics [12]. Therefore we invited nine family physicians to consider what aspects of primary care for these patients needed to be targeted in a KT program. A Delphi procedure was used, in which they first received a written questionnaire on 22 potential objectives. They were asked to rate the clinical relevance of these objectives and to comment in their own words on the objectives. In a second round we reported the results of the first round and offered a number of revised objectives. This procedure resulted in a final set of seven objectives, including "all children aged less than six months old with a (suspected) UTI are referred to secondary care for treatment" and "all children with a UTI have to have a follow-up contact within three to five days after finishing the antibiotic treatment, in which the urine is tested by using a dipstick or urine culture."

What are the indicators that can be used to measure implementation?

The objectives need to be defined in terms of specific indicators that can be used to measure the degree of implementation. Clinical guidelines or other recommended practices can be analyzed to identify such indicators. The indicators should have good measurement properties, support from key stakeholders, and high feasibility in use. Quality indicators are addressed in detail in Chapter 3.1a. Current best practice is a structured Delphi procedure with panels of stakeholders who review available evidence, followed by a test in real practice [8]. For example, a European project on cardiovascular risk management in primary care, used a two-stage Delphi procedure to select indicators [13]. A total of 101 family physicians from 9 countries (80% of those invited) was involved in both rounds of this procedure. From an initial list of 650 indicators, 202 indicators were derived, of which 44 were rated as valid (22%). These indicators covered lifestyle (8), clinical performance (27) and organizational aspects (9) of care. Instruments were developed for measuring these indicators including abstraction tools for medical record audit and a questionnaire for the family physicians [14].

What are potential determinants of practice?

Once the objectives have been identified, most planning models suggest that the implementer analyze each chosen objective with respect to determinants of practice (also labeled: barriers or obstacles for change). There is a wide range of methods for the identification of determinants of practice [8], which are discussed in Chapter 3.3. Briefly, they can be broadly divided into two categories. A first category comprises methods to identify determinants of practice, as reported by professionals, patients and others including interviews, questionnaires, and group methods. It can be done relatively simple or more systematically, but a disadvantage is that the reported factors may in reality have little or no impact on knowledge translation. An example was the study on determinants for changing heart failure treatment, described above, which was based on semi-structured questionnaires [4]. This study found that family physicians perceived on average four determinants for prescribing ACE inhibitors or optimizing ACE inhibitor dose. However, no significant relationships were found between the determinants perceived by family physicians and ACE inhibitor prescribing.

A second category comprises the analysis of practice variation or changes over time with respect to its determinants. This approach requires large observational datasets and statistical methods for analysis of variation in health care delivery across patients. The study of variation in heart failure treatment in relation to co-morbidity was a good example of this [3]. Another example is an explorative meta-regression analysis of guideline implementation studies in hospital settings, which found some evidence for the influence of organizational factors on the effectiveness of the KT interventions [15]. A limitation of this approach is that usually only a few potential determinants of practice can be examined in a single study.

How can we link KT interventions to these determinants?

Once objectives have been chosen and determinants of practice have been identified, the next step is to link specific KT interventions to these barriers. This process is similar to a clinical treatment which is tailored to a diagnosed health problem [6]. For instance, a project which aimed to reduce inappropriate long-term use of proton pump inhibitors in patients with dyspepsia focused on one specific barrier: the routine provision of repeat prescriptions, without evaluation and discussion with the patient of its usefulness. We developed and successfully tested in a randomized trial a discontinuation letter for patients [16]. Another study found that some patients with non-specific low back pain resisted advice to stay physically

active and avoid passive physiotherapy. Therefore we developed and tested a training session for physicians which included communication skills training. A randomized trial showed that this had positive effects on professional behavior and patient satisfaction with care, but not on patients' functional status or sick leave [17].

Linking KT interventions to determinants is probably the most creative step in the design of KT programs, because it is challenging to provide clear guidance on how to proceed. The concept of "tailoring interventions to relevant determinants" is often used in a loose way, but it has in fact different dimensions. These include:

- *Intensity of tailoring:* matching interventions to determinants at population level (e.g. all participants in a national project), at practice level (e.g. outreach visits to all practices to assess needs), and clinician level (e.g. using some interviewing method).
- *Stage of tailoring:* matching interventions to determinants of change at the design stage of an improvement project (when planning interventions) and at the delivery stage of a project (when running the project)
- *Range of options considered:* choosing the primary type of implementation interventions (e.g. professional education or financial incentives) versus optimization of chosen interventions (e.g. content of professional education, budget involved in financial incentives)
- *Basis for inclusion or exclusion of the intervention as a component of the tailored intervention:* considering perceived impact/importance (why the intervention might have an important effect or not) and feasibility/cost of the component(s).

Both exploratory and theory-inspired methods can be used. Exploratory methods try to avoid implicit assumptions on what would work, but instead advocate using an "open mind." In many cases, some sort of brainstorming in a group is used to identify as many solutions as possible to a problem [18]. Box 3.4a.1 provides an example of this approach [19]. An alternative to the traditional brainstorming is online brainstorming, using internet platforms to allow members to enter their ideas anonymously while providing for the anonymous distribution of ideas to all participants. Our experience is that the type of implementation interventions suggested by participants can be unsurprising – they tend to mention what they know, such as continuing professional education and information technology solutions. The involvement of a wide range of stakeholders in this process could increase the successfulness of the KT program and promotes their engagement and interest in the initiative.

Alternatively, theory is used to understand the factors that determine practice variation and change [20, 21]. Box 3.4a.2 provides an example of

Box 3.4a.2 Tailored interventions to implement guidelines on depression [22]

This study aimed to determine whether methods tailored to overcome barriers to change using psychological theories are more effective than dissemination alone in the implementation of guidelines for depression among general practitioners. To test this hypothesis, 1239 general practitioners in England were invited to take part in the study. The practices of those who agreed to take part were divided into intervention and control practices. Each practitioner in the intervention group took part in an in-depth interview six weeks after disseminating the guidelines to identify their obstacles to implementing them. Interviews were recorded and transcribed. For every comment that related to obstacles to change, a psychological theory explaining aspects of individual behavior change was suggested by the reviewer and discussed among the researchers until consensus was reached about what specific theory best explained the observed obstacle. The theory was then used to select the implementation method, for example: "if a general practitioner reported anxiety about assessing suicide risk and uncertainty about the form of question to use, the theory identified would be self-efficacy. In this case, the implementation method might include the provision of scripts of questions for assessing suicide risk for the general practitioner to use in consultations." If a practitioner faced several obstacles he/she also received several implementation methods. The theories most commonly found to explain observed barriers were preparedness to change (many practitioners had not given thought to the need to change performance) and self-efficacy (which referred to the fact that practitioners did not feel able to ask about suicide risk or discuss compliance with medication). In the case of factors related to preparedness to change, feedback was given on the stage of contemplation that the practitioner was in. In the case of factors related to self-efficacy, educational outreach visits were organized, feedback was given as well as quotations from practitioners who did feel able to discuss suicide risk. Further, factors related to social influence theory were addressed through small group discussions with peers, educational outreach by an expert clinician as well as feedback to enable comparison of performance with others. Factors related to cognitive dissonance theory were addressed by educational outreach visits and feedback accompanied by a reminder of the evidence. Finally, organizational obstacles were mentioned (although the researchers did not ask for them) but could not be addressed in this study. The intervention did not increase adherence to all guideline recommendations.

this approach [22]. A "common sense" use of theories would be to consider the chosen objectives and decide what interventions various theories suggest to influence the determinants for change. This decision can be taken in a group, so that this method is actually close to the exploratory method described above. A structured approach has been proposed for interventions, which target individual clinicians, based on psychology theory [23].

After a KT intervention has been chosen, it may be refined on the basis of an "intervention modeling experiment" [24]. Modeling experiments aim to test one or more selected interventions in a simulated situation, using written scenarios and/or self-report measures of performance. Modeling uses real health professionals, but simulated measures (e.g. self-report questionnaires), and potentially also a subset of all intervention components.

There is no firm research evidence to suggest either approach. We suggest combining explorative and theory-based methods to select and tailor interventions. Explorative methods may help to consider issues which were not anticipated beforehand. The use of theory, however, might help to broaden the scope of factors considered, and would therefore reduce the chance of overlooking important issues.

What factors should we consider when deciding to use a single or multi-component KT intervention?

One of the important decisions concerns the use of a single KT intervention or a multifaceted KT intervention. The assumption is often that multi-component interventions addresses a larger number of determinants of practice, and are therefore more effective. However, the research evidence does not clearly support this claim [5]. A complicating factor is that the definition of what is a "single intervention" is unclear. For instance, outreach visits that include instruction, motivation, planning of improvement, and practical help hardly comprise a single intervention. A multi-component intervention that combines different types of professional education (e.g. lectures, materials, and workshops) still only addresses lack of knowledge. We suggest that multi-component interventions could be more effective than single interventions, if they address different types of determinants of behavior change. As they tend to require more resources, the efficiency (and feasibility and sustainability) of multi-component interventions needs to be evaluated.

Research that is needed to advance the field

There is a need for comparative research on methods for tailoring. For instance, in a large research project focused on chronic diseases, different methods for tailoring KT interventions to determinants of practice are planned to be evaluated [29]. Key areas of interest are (a) comparison of open interview methods versus interviews that are guided by structured (theory-orientated) templates and (b) comparison of different types of

participants, such as clinicians, KT experts, and others. Direct outcomes of these comparisons include the range and detail of KT interventions, acceptability of the methods, and resources involved. Ultimate outcomes concern the effects on clinical processes and outcomes of the tailored implementation interventions, which are based on the different methods for developing these interventions.

Summary

The choice of KT interventions remains an "art" informed by science, meaning that practice-based experience and creativity are important in the selecting of KT interventions. The science can however be complemented by structured methods, which help to consider a comprehensive range of determinants of practice and interventions, as well as relevant evidence on the effectiveness of interventions to implement knowledge.

It remains to be seen how comprehensive and systematic the analysis of determinants of change has to be. The added value of tailoring KT interventions has yet to be proven. A systematic review on the effectiveness of tailored versus non tailored interventions could not show the added value of tailoring interventions to determinants identified [25]. However, the main reason for this conclusion was the lack of sufficient details concerning how determinants assessed influenced the choice of interventions in the included papers. An explorative review that included some of the same studies [26] found that many KT interventions chosen focused predominantly on cognitive factors in health professionals, such as knowledge gaps, although a much wider range of determinants of practice was considered in the studies of determinants of change.

Many KT projects are pragmatic activities in busy environments and therefore they should aim to deliver an optimal effect at the lowest possible costs. KT interventions should not just aim at improving health care delivery, but also at sustaining improvements. Practitioners and managers have every reason to be critical about systematic, resource- consuming methods. More research is needed on how to design KT programs and particularly on the linkage between determinants of practice and choice of KT interventions. A challenge for researchers is to define testable hypotheses, even in situations that are to some extent unique and in complex KT programs which address multiple issues and stakeholders. Health policy makers face the short-term needs for improvement in health care delivery, and therefore design pragmatic KT programs. They should also invest in KT research to enhance the sustained impact of KT interventions [27, 28].

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Chapter 3.4b **Formal educational interventions**

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Key learning points

- "Education" is a broad and holistic term: while it conjures up a traditional didactic activity, the *effective* education of health professionals can be seen as an intervention, often with predisposing, enabling, and reinforcing strategies
- Large group sessions – the mainstay of traditional or formal continuing education (CE) – can also be made more effective by paying attention to rigorous needs assessments, and by increasing interactivity and engagement in the learning process
- Other interventions also show promise: small group learning, quality-driven activities, communities of practice, and distance education
- Finally, self-directed learning is increasingly better understood and may be assisted by the addition of portfolio learning and informed self-assessment exercises.

The term "education" has many meanings, though its gestalt – especially in continuing education (CE) – conjures the image of a large group session held in a hotel or conference setting, demonstrating little evidence of effect on clinician performance or health care outcomes. In fact, "education" is much broader than such large group, didactic sessions. For example, the American Medical Association (AMA) defines CE as "any and all ways by which physicians learn and maintain their competence" – clearly a much

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more fulsome construct than attending a short course [1]. This chapter describes educational interventions designed to promote the incorporation of best evidence into the practices of health professionals. It encompasses educational interventions more commonly considered as formal "CE" or continuing professional development (CPD). Other chapters build on the overview provided in Chapter 3.4a; they describe educational and KT interventions such as academic detailing (Chapter 3.4a), audit and feedback (Chapter 3.4d) and reminders (Chapter 3.4a), all of which are broadly "educational." While touched on here, a more complete discussion of educational theories is provided in Chapter 4.3.

In particular, this section comprises: a theoretical basis for physician* learning and education; an outline of effective large group methods; innovations in formal education employing high (and low) technology strategies; and finally, future trends in CE and health professional education.

What is the role of education?

The question of *why* health professionals learn is driven by many external forces. These include: the medical knowledge explosion, specialty society interest in CE, the use of CE "credit" to document maintenance of knowledge and competence, and a large interest by pharmaceutical and other commercial interests that recognize CE as a means to influence physician practice. Regulatory forces also exist: licensing and certification boards now require proof of participation on a regular basis; the process of recertification, at least in the USA, has given rise to a more active and effective form of continuing education [2]. There are of course many internal forces at work as well – including an innate sense of professionalism on the part of most health care workers.

The question of "*how*" physicians and other health care workers learn has also been extensively examined. For example, two decades ago, Fox and his colleagues asked over 300 North American physicians what practices they had changed and what forces had driven that change [3]. Physicians undertaking any change widely described an image of that change; for example, the general physician needing to be more comfortable with an ethnic population. The forces for change were varied. While changes arose from traditional educational experiences, many more were intrapersonal (e.g., a recent personal experience), or from changing non-medical external

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* In this section, reference is made most frequently to physician education, given that the majority of studies in this area have employed physicians. Where possible, reference is made to other health professionals.

factors, for example demographics (e.g., an increasingly aging patient population), patient demands, and other issues such as financial restraints or practice needs. Finally, the changes varied from smaller "adjustments" or accommodations (e.g., adding a new drug to a regimen within a class of drugs already known and prescribed) to much larger "redirections," such as adopting an entirely new method of practice.

Similar examples from seminal studies also reflect core learning principles. Schon describes the internal process of learning and "reflection," suggesting that a potent learning mechanism is secondary to self-appraisal and awareness built from clinical experiences, leading to a building of a new and expanded competency or "zone of mastery" [4]. Candy's description of the traits of the self-directed learner also deserves some elaboration [5]. These traits include: discipline and motivation; analytic abilities; ability to reflect and be self-aware; curiosity; openness and flexibility; independence and self-sufficiency; well-developed information seeking and retrieval skills; and good general learning skills. While these attributes may appear idealized, it is important for the knowledge translation process to bear them in mind as implementation plans are developed and executed.

Implementation strategies are about health professional and/or system change and have also been the subject of decades of research [6]. Rogers [7] referred to this as the decision-innovation process and Prochaska and Velicer [8] as the trans-theoretical model. Specifically focusing on physicians, Pathman [9] used a model comprising four stages – awareness–agreement–adoption–adherence – to describe how physicians progress as they learn about, agree with, begin to adopt, then fully adopt a new clinical process. These "stages" of learning are also important when considering the effect of educational interventions.

What is the process for education?

Education is one means to effect performance change and improve practice outcomes, thereby achieving translation of knowledge into practice. In the current context of relatively autonomous practice, it may afford the only means at the implementer's disposal to effect change. Green's PRECEDE model provides a highly useful construct to understand, develop, and deploy effective educational interventions [10]. The model incorporates elements characterized as predisposing (setting up the change), enabling (facilitating or supporting the change acquired in the predisposing phase), and reinforcing (supporting the change once it has begun to occur). In this model, predisposing methods may include mailed guidelines, didactic lectures, conferences, and rounds which may *predispose* the learner in

Table 3.4b.1 Examples of educational interventions in the context of stage of physician learning and change

Learning/change continuum	Awareness	Agreement	Adoption	Adherence
Elements of change:	Predisposing elements:	Enabling strategies:		Reinforcing elements:
Possible roles for educational interventions	Conferences, lectures, rounds, print materials	Small group learning activity; inter-activity in lectures	Workshops; materials dis-tributed at conferences; audit and feedback	Audit and feedback; reminders

knowledge uptake; patient education materials and other tools (flow charts, for example) which might *enable* the change; and finally *reinforcing strategies* including reminders or audit and feedback, useful in solidifying a change already made. At least one systematic review supports this construct [11] and allows us to consider aligning educational interventions to the stage of learning as shown in Table 3.4b.1. Similarly, Grol describes the potential of employing multifaceted interventions, for example, coupling more traditional methods (predisposing to change) with elements such as reminders facilitating and feedback (to either health professionals or patients) to reinforce changes [6].

Putting together these characteristics and the process through which the learner adheres to a new practice (Pathman's awareness/adherence model) provides a useful if inexact framework to strategize the deployment of educational interventions. First, several systematic reviews have identified that most didactic conferences [11, 12] or mailed materials [13], employing only one technique, are infrequent producers of change in performance. This finding, however, may undervalue such traditional modalities since they often play a crucial role in predisposing to change – but not in effecting change by themselves. For example, where health professionals are unaware of new evidence, conferences, print materials and rounds may alert them to a new finding, treatment modality, or guideline. Second, if learners are aware of a new finding or guideline but do not agree with it, small group learning, or increased interactivity in the conference setting exposes the learner to peer influence [14, 15], a strong predictor of increased discussion and possible consensus. Third, if the issue is one of adoption of a new manual or communication skill, or a complex care algorithm, more in-depth workshops or interactive, online learning experiences may facilitate the

change [15]. Finally, once the process has been adopted, system-based interventions such as reminders or audit and feedback may be considered to facilitate sustainability [16]. Table 3.4b.1 outlines these principles, based on an earlier model of implementation [17].

What educational interventions can we use to effect knowledge translation?

Large group sessions

Educational events for relatively large numbers of learners are commonplace although the evidence indicates that the purely didactic type of this educational intervention produces little, if any, performance change. However, several studies [11, 12, 18–20] have outlined relatively useful and effective strategies within the large group model to increase the impact on performance and health care outcomes. These strategies include: more refined and objective needs assessments [18]; increased interactivity [19]; and variation in the educational method [12].

Determining needs and setting objectives

There is ample evidence (and increasing awareness) that not only the needs of learners but also that of their patients or health care system should drive CE content [12]. However, considering *only* system or patient needs and ignoring health professionals learning styles and habits misses an understanding of the learning process and may fail to change professional performance. In contrast, CE planners frequently use solely subjective needs assessments despite evidence that clinicians may be poor self-assessors [21, 22] and that objectively determined gaps may more closely link the CE process to demonstrable outcomes. Subjective needs assessment strategies include questionnaires, focus groups, structured individual interviews and diaries or log books which are described in more detail in Chapter 3.1. To offset the self-assessment deficiencies inherent in these methods and to create a more balanced needs assessment strategy, objective tools can be used including standardized assessments of knowledge and/or skills, chart audits, peer review, observation of health professional practice, and reports of practice patterns and physician performance data [23, 24].

The results of these combined subjective and objective needs assessment can be used to produce objectives for educational activities. To progress the concept of knowledge translation, CE – along with undergraduate and (post)graduate education – has shifted from conceiving of these as learning objectives (what the learner should know at the end of the activity), to

behavioral objectives (what the learner should be expected to *do* as a result of what has been learned).

Formatting large group sessions

Several strategies can enhance the delivery of effective formal, large group CE. They include: increasing the interactivity of the sessions, employing multiple methods within the framework of the activity, and using other strategies to increase the reach and impact [12].

Multiple methods

As discussed in Chapter 3.4a, there is as yet no clear evidence suggesting benefit of multi-component interventions over single component interventions. However, there is reason to believe that multi-component interventions could be more effective than single interventions, if they address different types of barriers for change. Within the context of the formal CE event, most recent evidence demonstrates that multiple methods used within the context of the activity may promote uptake and translation into practice [12, 25]. The methods may be characterized in several ways. First, formal sessions may use a variety of presentation media (e.g., audio recordings to present heart sounds; actual or standardized patients or videos; panel discussions to present conflicting perspectives on one topic; debates to highlight issues where agreement is lacking; quizzes to determine learning needs or outcomes). Second, given that knowledge is a necessary but not sufficient condition for performance change to occur, practice "enablers" may be useful in the course of a standard CE event. Examples include patient care reminders, protocols, and flow sheets, patient education materials, wall charts, and other measures which may be used in the practice setting after the conclusion of the activity [12]. Third, CE activities may use clinical scenarios and vignettes in an attempt to increase relevance and applicability of educational material. Vignettes are frequently derived from actual clinical cases, modified to ensure patient confidentiality and used to exemplify details of history, diagnosis, or management [26]. They promote reflection and interaction. There are many methods to present such cases or clinical stories: short paper cases can use prompts for discussion of diagnosis or management; standardized patients can present highly credible clinical findings and histories; video and audio cases, role playing, and sophisticated simulation techniques may add relevance and increase potential for learning [12].

Staging a learning experience so that it is interrupted or sequenced also shows evidence of increased effect [12]. Two workshops of three hours each held a month apart, for example, (compared to a one-time 6-hour

workshop) allow the learners to absorb information from the first event, apply it in the work setting and then discuss this process with reinforcement of learning, during the second event. The weekly or monthly recurrence of clinical rounds provides a prime example of this interrupted learning process.

Interactivity

With fairly clear evidence for effect [19], interactivity increases the exchange between audience members, or between participants and the presenter. There are a number of ways in which this can be accomplished:

- *Interaction between the presenter and participants:* planners may increase the question and answer sessions of lectures, divide lectures into 10-minute periods of lecture followed by questions and answers [26] and/or use an audience response system [27]. The last option may employ technology to poll the audience for responses to projected questions or use low-tech options (though not so anonymous) employing color-coded cards.
- *Interaction between participants:* buzz groups – described by the noise they make in a normally quiet audience – allow participants to engage neighboring audience members in conversation. Pyramiding or snowballing builds on interactions between pairs of participants, to groups of 4 or 6, and eventually grows to involve all participants. An example is termed "think–pair–share," a method in which practice reflection first occurs (a quiet moment for participants to think of a particular case, for example), followed by discussing the idea with a neighboring participant, then sharing it with the larger audience.

Small group learning

Small group learning involving health professionals is one of many innovations created by the growth in problem-based learning methods in undergraduate education. This method uses groups of 5–10 individuals and employs many of the principles of effective CE (case vignettes, relevant group discussion, peer interaction, and high degree of interactivity). Groups meet regularly, usually without an expert and are led by one of their own membership, who acts as a facilitator. Common in Canada and in Europe, these groups have demonstrated impact on competence and performance, most likely a combination of their concentration on evidence-based materials, and on their heavy reliance on collegial influence [15, 28]. While some groups are informal and self-organizing, many others are a part of national maintenance of competence and CE programs such as professional licensing bodies [29].

Distance education techniques

While formal, in-person CE remains a primary knowledge transfer vehicle, there are other ways in which knowledge translation may be accomplished. For example, visiting speaker programs may use web-, video- or audio-casts. Not unlike their live counterparts, these activities must be interactive in order to engage the learner and improve impact and may employ inter-active cases and other methods to stimulate the learner to use critical think-ing and problem-solving. Recent studies have shown increases in physician knowledge and knowledge retention following participation in online CE courses [30] and if appropriately designed, they may be superior to live activities in effecting physician behavior changes [31].

Online communities of practice [32] are another potential KT interven-tion. Motivated by common interests and issues, groups of learners experi-ence audio conferences, case discussions, and follow up or support by electronic means using reminders, cases, and other means to promote net-working and consulting among peers. These groups or networks can assist in evaluating the effectiveness of the education as well as determining needs for new activities and can build both a community and a shared knowledge base. These groups make use of knowledge "brokers" – individuals or net-works of individuals able to disseminate and increase the uptake of best evidence [33].

Self-directed learning

Some health professionals possess a learning style preference or logistical need for more self-directed choices. These include traditional sources – such as textbooks, monographs, clinical practice guidelines, and journals – which provide clinical information. Important developments to aid self-directed learning have included the advent of printed or computerized self-assessment programs, which provide learners with feedback about their competence as they read materials and answer questions, receiving feedback.

Portfolio-based learning [34, 35] is also an important tool in self-directed learning, derived from the concept of the artist's or photographer's col-lection of his or her work. More complex than a simple accumulation of exemplary work, however, the portfolio is intended to document educa-tional activities undertaken by the clinician, quality documentation (chart reviews, procedure logs, or achievement of performance mile-stones), identified learning gaps, examples of learning plans, and objec-tives and resources used to meet them, and other data related to performance and health care outcomes. Portfolios can be used for self-reflection, self-assessment and learning, or may be employed in an

educational manner – providing grist for conversation with a peer or other mentor or applied to questions of relicensure, recertification, remediation, and other needs.

What are some current and future trends in CE?

Multiple trends and challenges exist in the construct, delivery, and use of CE leading to a more holistic and integrated role for this last and longest phase of clinicians' learning. They are important to understand in the context of knowledge translation and include:

- *The changing construct of "CE":* from a traditional understanding of CE as an information transfer vehicle to a more complete if complex understanding of the learning process and the complex health care world in which this occurs.
- *An increasing focus on health care outcomes and performance:* using performance measures to plan and evaluate CE. This shift moves CE planners to increase attention to Levels 4-6 of the Moore [36] evaluation schema (Table 3.4b.2), rather than its previous occupation with lower levels.
- *Maintenance of licensure and certification:* the traditional notion of "credit," linked solely to CE participation for physicians, is increasingly questioned by licensing boards, specialty societies and certifying boards citing evidence of the "failure" of traditional CE. While the traditional time-based credit hour has served to document CE participation, it falls short in demonstrating translation to maintained competence or improved performance. With the movement toward more informed self-directed, practice-based learning, critics have argued for a system that provides higher value credit for those activities that demonstrate improved practice.

Table 3.4b.2 Outcomes for continuing education/continuing professional development [36].

Level	Outcome	Indicator
1	Participation	Attendance
2	Satisfaction	Participant satisfaction
3a	Learning: declarative	Knows
3b	Learning: procedural	Knows how
4	Competence	Shows how; observed in educational setting
5	Performance	Changes in practice performance
6	Patient health	Changes in patient health status
7	Population health	Changes in population health status

This notion is incorporated into the movement to maintenance of licensure and certification in the USA and Canada [37, 38].

- *Increased use of electronic means of communication:* to replace and/or enhance health professional learning – online learning resources, social networking, blended practice and learning methods described by the American Medical Association as "Point of Care" Learning [39–41].
- *New and emerging disease states:* here the need for rapid response educational technologies exists in the face of serious pandemics such as, pan-flu and bioterrorism issues. In the event, such disease states speak to the need for technologies such as text messaging, fax networks, email, tweeting, and other means including the concept of "push" technologies, or point of care learning [42].
- *Interprofessional learning:* It is increasingly apparent that the traditional physician-only targets of most "CE" activities requires re-thinking and modification, given increasingly complex health care settings and the recognition that quality of care is clearly a multi-professional team activity [43]. In this case, accommodation for a variety of learning needs, styles, practice roles, and other unique dimensions of health professionals' roles requires careful consideration and attention. It can similarly be argued that – just as clinical guideline development increasingly employs engagement and the input of patients and public members – CE planning and development also requires this consideration.
- *Chronic disease management:* health researchers have outlined the need for improved management of chronic diseases, many with comorbidities, in an aging population. These needs show promise in driving the educational aspects of KT – creating meaningful interprofessional education initiatives, disseminating and incorporating complex care algorithms, point of care learning resources and other methods.

Future research

The study of health care delivery requires many research directions in which CE plays a significant role. Of these, several become important in an era of accountability and movement towards demonstrated competence and performance as the result of CHE participation. They include: questions about the learner (are self-assessment and self-directed learning core character traits or can they be taught? If the latter, how can this best be accomplished?); the communication vehicles (what knowledge translation vectors work best? For example, are mobile technology mediated educational messages more effective than formal educational ones); how does the context or setting of learning influence on learning and knowledge use (for example

how can learning be supported by remuneration pattern, or linkage to information technology and electronic health record resources?). Finally, a large question for CE research to undertake is the uptake of evidence in which the variables include questions about the nature, complexity, compatibility, and strength and quality of the evidence to be adopted.

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Chapter 3.4c Linkage and exchange interventions

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Key learning points

- There are a variety of linkage and exchange interventions that can be used to effect knowledge translation including audit and feedback and opinion leaders.
- There is limited evidence to support the use of knowledge brokers.
- Participatory research is a potential strategy for integrated knowledge translation.

Translating health research findings into action requires a complex system of linkage and exchange between those who create knowledge and those who must ultimately use or act upon it. This process can include researchers and service providers, services managers and other decision makers; researchers and health care or public health policy makers; researchers and patients, advocacy groups, community members or organizations; or a pragmatic mix of any or all of these stakeholders. The ultimate goals are effective and efficient programs, services, products, or procedures that meet the health needs of those they intend to benefit, the practice goals and needs of those who must administer them, or the programming goals of public policy makers.

Linkage and exchange interventions designed to increase knowledge uptake essentially fall into two categories: (1) integration of appropriate

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stakeholders within the knowledge creation process (integrated KT), and (2) engagement of stakeholders in knowledge translation activities related to existing knowledge (end of project KT). Integrated and end of project KT are described in more detail in Chapters 1.2 and 2.4 respectively.

What linkage and exchange interventions can be used to positively influence knowledge use?

Integrated knowledge translation research is as much an approach to undertaking research as it is a KT intervention. It involves assuring that intended knowledge users are implicated in the production of the action-oriented knowledge. Engagement with knowledge users can take place at the outset of knowledge creation, stemming from the identification of a gap or need by a particular stakeholder. The principles of participatory research drive the interaction between parties [1–3]. These include: the acknowledgement that all parties possess knowledge and expertise that will improve the quality of the knowledge produced or its effective translation; that the process is driven by the goals and needs of the knowledge-users; that relevant stakeholders have the opportunity to be equitably involved at all appropriate stages of the process from identifying the knowledge or practice gap, through designing the means of its addressing, to the interpretation of results and the implementation of findings within the target setting and their dissemination to other settings.

The participatory approach integrates knowledge translation within the knowledge creation process by assuring that those who have identified the gap are themselves taking ownership of the process of bridging it. Key drivers of the participatory process include knowledge to action (utilization) and stakeholder self-determination; and partnership stages include stakeholder engagement, formalization, mobilization, and maintenance [4]. To date there is a paucity of evidence regarding the impact of this integrated approach. There is early evidence from a systematic [5] and a realist [6] review that participatory approaches ensure culturally and logistically appropriate research processes and outcomes; enhance knowledge-user engagement; and generate professional capacity and competence of stakeholders. In addition, Jagosh and colleagues [6] document that participatory research generates productive conflicts between stakeholders resulting in useful negotiation to improve team functioning; increases of the quality of outputs and outcomes over time (for example, based on accumulated partnership synergy, barriers such as community resistance to RCT enrolment can be overcome); increases sustainability of outcomes beyond the intervention period; and creates system changes (such as health policy changes

beyond the original goals of the project) and new unanticipated activities (such as addressing new research topics including those arising from the partners), and formation of new coalitions. Quantitative data to support these summary statements are not available from these reviews.

Although the benefits of participatory approaches to the creation and translation of new action-oriented knowledge are well described, the mechanisms by which they occur and the myriad contexts in which these are activated are less well understood. The evidence needed is not easily come by owing to the complexity of the social interaction and heterogeneity of designs or contexts involved which does not lend itself easily to controlled experimentation [6, 7]. Further mixed-methods and (social-)theory-driven research exploring the contexts and mechanisms of stakeholder engagement are needed, and more standardized reporting procedures are required to allow better synthesis of emerging evidence.

Linkage and exchange interventions

Besides the integration of knowledge users into the production of new action-oriented knowledge, other linkage and exchange interventions exist to facilitate the use of pre-existing research. In the last edition of this book, Eccles and Foy summarized a number of intervention strategies to facilitate the implementation of research findings by making use of the interpersonal relationships and social influences between health care practitioners [8]. The strategies include the use of educational outreach and opinion leaders, which Eccles and Foy note can produce small but worthwhile changes in health care professional behavior; and knowledge brokers, the effectiveness of which is less clear. Grimshaw and colleagues (2012) examine these and other strategies, including cognitive cues such as audit and feedback and computerized reminders [9].

Educational outreach visits [10] (and see Chapter 3.4b) describe a personal visit by a trained person to health professionals in their own settings, also referred to as academic detailing or public interest detailing. Its key principles include surveys of practitioners to determine barriers to appropriate practice and the subsequent development of an intervention tailored to address those barriers using simple messages; targeting of practitioners with low compliance; and the delivery of the intervention by a respected person. The intervention often included feedback on existing practice. O'Brien and colleagues found that the median absolute improvement in adherence to desired practice was 5.6% (interquartile range (IQR) 3.0% to 9.0%) [10]. These improvements were highly consistent for prescribing (median 4.8%, IQR 3.0% to 6.5% for 17 comparisons), but varied for other

types of professional performance (median 6.0%, IQR 3.6% to 16.0% for 17 comparisons).

Opinion leadership [11] is the degree to which an individual is able to influence other individuals' attitudes or overt behavior informally, in a desired way with relative frequency. Eccles and Foy note that the most striking feature of opinion leaders is their unique and influential position in their system's communication structure; they are at the centre of inter-personal communication networks – interconnected individuals who are linked by patterned flows of information [8]. Opinion leaders appear to be different for different issues, and while it is possible to identify opinion leaders using a self-designating instrument, the effectiveness of such opinion leaders has not been rigorously tested in health care settings [12]. A systematic review of the effectiveness of opinion leadership [13] found that opinion leader interventions produced changes in compliance with desired practice ranging from an absolute improvement of 25% to a worsening of 6%. The overall median improvement was 10%.

Knowledge brokers. The Canadian Health Services Research Foundation has defined knowledge brokering as "all the activity that links decision makers with researchers, facilitating their interaction so that they are able to better understand each others' goals and professional cultures, influence each others' work, forge new partnerships, and promote the use of research-based evidence in decision-making." The idea of systematic knowledge brokering is much more recent than either opinion leaders or educational outreach and its effectiveness is unclear as it has not been subjected to the same degree of rigorous investigation.

Cognitive cues represent interventions to remind or prompt practitioners to take evidence-based action at appropriate times. Examples of intervention strategies include *audit and feedback* (see Chapter 3.4d in this volume) and *computerized reminders*. Grimshaw and colleagues (2012) report on a review of effectiveness of computerized reminders showing that the median absolute improvement of care of $\pm 4.2\%$ (interquartile range $\pm 0.8\%$ to $\pm 18.8\%$) [9, 14]. However, they note that most studies examined the effects of relatively simple reminders, while the results of more complex decision support systems have shown less success [9].

Future research

The effectiveness of these interventions has varied by strategy and by target end-user audience. The majority of evidence comes from clinical settings rather than community or population settings, and more often targets clinical end-users rather than health care policy makers and

senior managers [9] or communities and community-based organizations [15]. The complexity of knowledge translation underlies the difficulty in assessing the effectiveness of a particular strategy given the heterogeneity of settings, users and needs to which they are being applied.

Eccles and Foy [8] suggest future research could usefully examine a number of areas including: the role of outreach visitors in a wider range of settings; identification of contextual attributes of clinician/team behaviors that particularly lend themselves to the use of opinion leaders, knowledge brokers and educational outreach visits; clarification of the key conceptual attributes of knowledge brokers and studies of their effectiveness; and cost-effectiveness of each of these strategies [8].

In a review of changes in health policy, Mitton *et al.* [7] conclude that personal contacts and building trust are key elements of successful knowledge exchange, that one size does not fit all for the heterogeneity of policy institutions, and that there is "insufficient evidence for recommending 'evidenced-based' knowledge transfer exchange for health policy making" [7]. As a result they recommend that researchers learn the constraints of real-world decision making and recommend funding for formal and rigorous research designs to assess and evaluate successes of using research to inform policy changes.

Summary

Linkage and exchange must be fostered between those who create and those who use knowledge to support effective translation and action within a wide variety of settings. Linkage and exchange can be accomplished through the integration of appropriate knowledge-users within the knowledge production process. It can also be accomplished through interventions that use or alter the social environment to create and sustain bridges between producers and users. In either case, the sustainability of the intended action outcome requires that the needs of knowledge-users are met and that they take ownership over the production of new knowledge, programs, procedures and policies or the process of their translation into action. Both approaches require further evaluation. The contemporary effort by research funding agencies to support KT and integrated KT through targeted funding initiatives should as well be seen as an intervention with the goal of enhancing linkage and exchange [16]. The growing body of funded projects emanating from these efforts will ultimately produce the evidence needed to better understand the effectiveness of KT interventions.

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Chapter 3.4d **Audit and feedback interventions**

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Key learning points

- Measuring adherence to clinical practice recommendations can highlight important implementation gaps and inform subsequent priorities for knowledge implementation.
- Audit and feedback can be effective in improving professional practice although the effects on clinical practice are generally small to moderate.
- More research is needed on the effects of audit and feedback compared to other interventions, and the mechanisms by and contexts in which it works best

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There are recognized gaps and delays in the implementation of evidence based practice [1, 2]. Data from chart audits help to confirm or identify these gaps and are commonly incorporated into feedback interventions to promote implementation. Audit and feedback is defined as "any summary of clinical performance of health care over a specified period of time" given in a written, electronic, or verbal format [3].

Chart audits

In chart audits, documented clinical care is measured against a review criterion, defined as, "a systematically developed statement that can be used to assess the appropriateness of specific health care decisions, services, and outcomes [4]." Review criteria are often derived from clinical guideline recommendations, which should ideally have been rigorously developed based upon evidence from systematic reviews or from formal consensus processes where strong evidence is lacking as described in Chapter 00. Review criteria can be explicit or implicit [5, 6]. Explicit criteria aim to maximize the reliability and objectivity of measurement, e.g. patients under 80 years receiving treatment for hypertension should have a clinic blood pressure below 140/90 mmHg [7]. Implicit criteria involve peer or expert clinicians making judgments about the desired care. They therefore tend to be more subjective and less reliable than explicit criteria. Implicit criteria are mainly used to assess complex processes of care or adverse outcomes (e.g. maternal deaths related to childbirth).

Review criteria can relate to the structure of health care delivery (e.g. the presence of calibrated devices for measuring blood pressure), health care processes (e.g. the prescription of anti-hypertensive medication), and patient outcomes. The latter can include short-term or surrogate outcomes (e.g. blood pressure levels) or long-term outcomes (e.g. stroke). Structural and process criteria must be valid, so that strong evidence exists that their improvement is associated with improvement in outcomes of care. Outcome criteria tend to be less sensitive at detecting changes in practice – because many factors may influence patient outcomes – and generally require more resources, larger sample sizes, and longer follow up to detect important changes. Target levels of performance can be set to guide subsequent decisions on whether implementation activities are worthwhile. Given the law of diminishing returns, attempts to improve already high levels of performance may not be as productive as switching attention to alternative priorities. For many clinical actions, there is a "ceiling" beyond which health care systems' and clinicians' abilities to improve performance are limited because they are functioning at or near their maximum capabilities [8]. There are other good reasons not to expect 100% adherence to targets. For example, eligible patients may prefer to avoid drug treatment or experience unacceptable adverse effects. There are a number of practical considerations in planning and conducting chart audits including sampling procedures, sample size, and data collection. An account of these can be found at NorthStar (http://www.rebeqi.org, accessed September 2012) [9]. Two related issues merit a brief comment. First, under-documentation of

clinical actions in medical records is recognized. However, this is becoming less tenable for evidence-based clinical actions considered by professional consensus to be sufficiently important to merit documentation. Second, the growing use of electronic patient records, from which clinical data can be extracted automatically, potentially offers a more efficient means than manual extraction. This can reduce the costs of chart audit but depends upon the reliability of clinical recording. Moreover different electronic records require creation of different data management algorithms to extract this data to optimize accuracy of the data retrieved.

Audit and feedback

The mechanism by which audit and feedback works appears self-evident; demonstrating the gap between actual and desired performance will motivate clinicians or health care systems to take action to address that gap. The most closely related theory to this is probably Self-Regulation Theory [10]. "Self-regulation" is a process of determining goals and then using these as reference values to bring existing states into line with those goals. The success of any desired change also depends upon individuals being able to change their behavior (e.g. clinical practice skills) or upon external influences on behavior (e.g. organizational factors). A Cochrane Review of 140 randomized trials concluded that audit and feedback leads to small but potentially important improvements in clinical practice [3]. Effectiveness was variable across the included studies. For example, when percentage adherence with desired practice was measured, the median improvement across 82 comparisons was 4.3% with an interquartile range of 0.5% to 16%. There are a number of explanations for this variation in effect which mainly relate to the different permutations in the provision of feedback, context, and the nature of targeted clinical behaviors. The delivery of feedback can vary according to:

- *type of format*, i.e. verbal, paper, or electronic
- *frequency and duration*, e.g. as a one-off step or continuously and often over a period of time
- *source*, e.g. whether from a supervisor or professional body
- *content*, e.g. information on health care processes or patient outcomes, use of identifiers to permit comparisons between individual professionals, teams or facilities
- *use of various sources* to deliver feedback, such as supervisors or professional bodies.

The review found that feedback may be more effective when the source is a supervisor or colleague, it is provided more than once, it is delivered in

both verbal and written formats, and when it includes both explicit targets and an action plan. The larger effects of such enhancements need to be weighed against any potential higher costs of their delivery [11]. There is limited evidence that combining audit and feedback with other strategies, such as educational meetings, is more effective than audit and feedback alone. However, effects are inconsistent and when or whether to use combined approaches remains a matter of judgment. Given the relative paucity of head to head comparisons of different methods of providing feedback and of comparisons of audit and feedback versus other interventions, it also remains difficult to recommend the use of one intervention strategy over another on empirical grounds. Contextual factors and the nature of the targeted behaviors may also influence effectiveness. The Cochrane Review found that the relative effects of audit and feedback were greater when baseline adherence with recommended practice was low [3]. An exploratory analysis found larger effects when prescribing was targeted compared with test ordering or chronic disease management; one interpretation is that prescribing is a relatively less complex clinical behavior and perceived as more important by clinicians. Clinicians' motivation to change practice may therefore influence change. Somewhat contrary to expectations, there is evidence that the effects of audit and feedback are greater for recommendations perceived by clinicians to be less compatible with current norms [12] and for tasks associated with lower motivation [13]. The broader context also matters. Audit and feedback is primarily used as a means to change the behavior of individual clinicians and teams. However, effective implementation often requires action across different levels of health care systems, such as securing senior leadership commitment to change [14].

Future research

Future research on audit and feedback could usefully focus on three questions. First, by what mechanism or mechanisms does audit and feedback exerts its effects? Second, which contextual features (e.g. setting, characteristics of health care professionals) and attributes of targeted clinical behaviors negate or enhance the effects of audit and feedback? Third, how does audit and feedback, by itself or in combination with other interventions, compare against other interventions to change clinical behavior?

Summary

There are only limited insights into how and when audit and feedback can be made to work more effectively [15]. Ultimately, its selection as a KTA

intervention is a matter of judgment based upon the current evidence base, a working "diagnosis" of the causes of an implementation gap, and the availability of supporting resources and skills [16]. In principle, getting the diagnosis right offers a rational basis for choosing an approach to delivering feedback. Hypothetically, if perceived peer pressure was identified as a key determinant of clinicians' practice or motivation to change for a given context, feedback could reasonably incorporate peer comparison [17].

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Chapter 3.4e **Informatics interventions**

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Key learning points

- Knowledge translation (KT) and informatics domains share many of the same basic components of collecting, summarizing, packaging, and delivering knowledge. KT concentrates on implementing published evidence while informatics interventions focus on providing patient- or population-specific knowledge and data.
- Many informatics applications can be effective KT tools, delivering evidence to health professionals, patients, and informal caregivers.
- Informatics interventions that speed KT can be found in the areas of patient and physician education, mobile health, communication and support, reminder systems, and computerized clinical decision support systems. They have been shown to change knowledge and behavior, improve adherence through reminders, efficiently collect and present data from multiple sources, and effectively support decision making. Their effects on health care costs and health outcomes have been less well demonstrated.
- Many of these effective informatics applications exist as demonstration projects or on a small scale. We have yet to harness the full potential of integration of the KT process with informatics applications.

Knowledge translation (KT) deals with the collection, summarization, and packaging of (research) *knowledge* and its delivery in a timely and appropriate format to those who can use it caring for patients and populations. Informatics does the same with (patient or population) *information*: collecting, summarizing, packaging, and delivering. Both domains share the theoretical foundation of epistemology: understanding and knowing the limits and validity of knowledge [1, 2]. KT and informatics are natural partners and the question for this chapter is how do, and which, informatics applications best support KT. Informatics interventions can support or implement knowledge use by making data collection and analysis easier and faster; enhancing communication with new devices; improving educational projects through multifaceted, individualized programs; and providing clinical support through reminders, clinical decision support, and order entry systems.

What sources of data can be used for planning and evaluating KT projects?

Electronic medical records (EMR), personal health records and other large clinical systems have data which can be analyzed to show evidence–practice gaps (needs assessment) and evaluate KT interventions. These systems can be used in audit and feedback, quality improvement, and many other KT projects. Hynes and colleagues [3] describe how the US Veterans Affairs health systems use informatics resources including EMR data in quality improvement. Quality improvement (see Chapter 4.5) may not be completely under the purview of KT but we can learn much from their work. Mobile health (e.g., cell phones and tablets and their apps and medical devices such as automated glucometers and step counters) is also fast becoming an important KT tool for both delivering care and data collection before, during, and after KT implementations [4]. These mobile devices are described further below. Personal health records systems are collections of health and wellness data kept by patients. Their roots are in paper records for patients, especially in areas such as charting and monitoring pregnancies and data related to children (e.g., immunizations and other health milestones). Personal health records systems, especially those tethered (e.g., can send data to and receive data from) clinician-kept or institutional EMR systems also provide opportunities for data collection and behavior based interventions [5, 6].

What informatics interventions might be effective in achieving KT?

Multifaceted educational interventions with new informatics tools (mobile health)

One of the areas where informatics may have the greatest effect on KT interventions is the use of the internet to educate and support clinicians, patients, and families in relation to health and wellness. (See also Chapter 3.4b for more information on education.) Pletneva and colleagues [4] report that half of their survey participants in Europe in 2011 used the internet at least weekly to seek health information. North American data are similar. The most effective use of the internet for educating and changing behavior is if the intervention has multiple components and includes such things as goal setting, individualized support or tutoring, communication with real or "electronic" personnel, and if it is ongoing. This pattern of success is shown in reviews by Neve and colleagues [7] on the effects of web based interventions on weight loss and maintenance, by Ramadas and colleagues [8] on web based interventions for patients with diabetes, and by Krebs and colleagues [9] who summarize the evidence on the effects of behavior targeted informatics projects on smoking cessation, healthy eating, physical activity, and mammography screening. Mobile health is defined as systems (often cell phones, tablets, or monitoring devices) with wireless connectivity that are consumer centered; record, monitor, and transmit health or wellness data; and often direct actions based on analyzed data. Mobile health is new and evolving and early evidence supports its spread and usefulness [4]. The caveat across these electronic knowledge domains, however, is that although the studies uniformly show important improvements, their methods are often weak and contain problems.

Computerized Clinical Decision Support Systems (CDSSs)

Computers are excellent at storing, synthesizing, and presenting data in an efficient and user-friendly format. CDSSs are electronic systems that aid clinical decision making by generating patient-specific assessments and recommendations through software algorithms that match individual patient data to a computerized knowledge database [10]. Such systems can "push" information to clinicians through alerts or reminders at the point-of-care, or through system-wide approaches such as evidence-based order sets. Alerts or prompts can either be active (requiring users to act on them) or passive (appearing without requiring user action) [11]. Alternatively, CDSSs can act as simple information repositories from which clinicians can "pull" context-specific knowledge as required [10].

CDSSs are superior to paper-based resources because they are more flexible and can rapidly retrieve vast amounts of data (e.g., test results), perform time-consuming calculations, and navigate complex care algorithms [12]. They can also present information "just-in-time," without overloading providers with unnecessary data. For example, British Columbia's PharmaNet is a simple CDSS which provides physicians with patients' prior prescription data at the point-of-care [13]. In a more sophisticated CDSS, the UK's National Institute for Health and Clinical Excellence (described in Chapter 2.2), has developed tagging specifications for guidelines so that their content can be electronically "matched" to individual patients in EMRs and suggestions can be presented to clinicians during clinical decision making [14]. Finally, CDSSs can improve care by giving clinicians performance feedback on quality indicators, enabling them to identify and bridge their own practice gap [10, 15].

CDSSs can address diagnostic, prevention or screening, drug dosing, and disease management decisions. They may be stand-alone systems functioning in parallel to an existing paper or EMR system, or may be integrated into an EMR, enabling direct and automated patient data import. They can also work on mobile devices, thus being well suited to clinicians delivering care in diverse locations. With the convergence of laptop, tablet, and Smartphone computing capabilities, and the fact that nearly two-thirds of physicians now own a Smartphone [12], barriers to introducing portable computing devices into the care milieu have been reduced. Not only do physicians already use Smartphones to access information to guide patient care, but many medical apps have rendered this task more efficient and user friendly [16]. This portability, ease of use, speed, accessibility, and abilities to support both patients and their families and clinicians are perceived by physicians to improve productivity and care [12]. For example, a handheld computer-based CDSS for patients with suspected pulmonary embolism increased clinicians' use of evidence-based pretest probability calculations, appropriateness of diagnostic testing, and guideline adherence, when compared to paper-based guidelines [17].

In a systematic review of the effectiveness of CDSSs, Bright and colleagues reported a significant improvement in process measures [10]. However, effects on clinical outcomes and cost-effectiveness were measured in a minority of studies and were inconclusive. Other caveats include potential for decreased clinician efficiency and increased workload, clinician "deskilling" due to task automation, and inadvertent deleterious effects on clinician performance and patient safety due to flawed system design [11].

CDSSs have been shown to improve care when they are used directly by patients. Patients can enter data into a CDSS which processes, transfers, and presents it directly to their physicians. Such systems can facilitate clinician decision making, and influence clinician decisions through patient-prompting (a form of patient-mediated KT, discussed in chapter 3.4f). Web-based and mobile-enabled CDSSs are increasingly accessible to patients. Other platforms include mobile phone-based short message service (SMS) system [18] or electronic information kiosks. For example, a web-based diabetes care tool enabling patients to upload and relay their monitoring data to care managers resulted in improved glycemic control, compared to education and usual care [19]. Alternatively, CDSSs may empower patients to self-manage chronic diseases, or to guide complex medical decision making. For example, in a randomized controlled trial, patients who managed their asthma through an internet-based CDSS had improvements in asthma control and lung function compared to those who received standard medical care [20]. Electronic patient decision aids can improve care by empowering patients to participate in their own health care decisions. For example, Protheroe and colleagues [21] used a randomized controlled trial to demonstrate that a self-directed, interactive computerized decision aid for women with menorrhagia reduced decisional conflict and improved menorrhagia-specific knowledge and quality of life, compared to information leaflets alone.

A large literature on clinician and patient reminder systems also exists and is summarized by Shojania and colleagues [22]. Similar to CDSSs this evidence summary on point of care reminders shows modest improvement in processes of care but often the systems did not meet expected targets of improved clinical outcomes. Although these reminder systems are thought to be useful their implementation still need enhancing if this usefulness is going to be achieved.

Summary

As the volume and breadth of research evidence continues to grow, a wide and advancing range of informatics interventions will assume an increasingly important role in ensuring the effective and timely translation of this new knowledge into clinical practice. Web 2.0, multifaceted individualized educational interventions, and mobile-based applications represent a particularly exciting future medium for KT interventions. Age is still a determining factor is the use of informatics applications for health information with more young people using them but this difference in use based on age is decreasing quickly

[23]. However, the use of informatics interventions, such as limited access to such large-scale information technology (IT) as EMRs in some developing countries, inconsistent EMR use, and a paucity of systems that integrate evidence with clinical data in a user- and work-flow-friendly format present some limitations. However, mobile health has made much progress in developing countries [24]. Successful intervention design will require an understanding of evolving eHealth literacy among both providers and patients [24]. Future studies should adhere to a standardized reporting format, in accordance with the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) statement [25].

Future research

Informatics interventions that support KT (e.g., mobile health, personal health records), IT interventions that are essentially KT interventions (e.g., SMS devices or computer tutors for weight loss), or IT tools (e.g.,CDSS, EMR systems) exist in many forms and locations, facilitating KT. Together they hold much potential for improving health care by supporting the information needs of patients, clinicians, and families. These systems also improve communication, identify health needs or trends, and engage clinicians, patients, and families to work towards patient empowered health and wellness care Many of these interventions, however, are demonstration projects or have been implemented only in local settings. Broadening the scope of these interventions remains an area for future research and development. This research should involve many facets and partners, including technology (improving information standards and enhancing system interoperability), social sciences (understanding individual needs and characteristics to design truly useful and easy-to-use interventions), business (managing system change with financial integrity), and methodologists (studies are often poorly done, poorly reported, or both) in addition to decision makers, health providers, and patients. Personal health records and mobile health are areas of great potential that require interdisciplinary research, both qualitative and quantitative, to obtain the best results for all stakeholders. We also need future research to assess the cost-effectiveness of informatics KT interventions, the sustainability of their effects, their effects on patient outcomes and good assessment of the unintended consequences of these new tools. To date, we have a good understanding of the effects of these interventions on process, but little evidence of their benefit on the outcome that matters most: patient health and well-being.

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Chapter 3.4f Patient-direct and patient-mediated KT interventions

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Key learning points

Patient-direct KT interventions
- Aim to actively engage patients to enhance their knowledge, experience, service use, health behavior, and health outcomes.
- Focus on health literacy, clinical decision making, self-care, and patient safety.
- Improve patients' knowledge and can have positive effects on their experience, service use, health behavior, and health outcomes.

Patient-mediated KT interventions
- Are targeted at patients but aim to change health professionals' behaviors through patient–provider interaction.
- Have not been evaluated adequately to determine their impact on changing health care practitioners' behavior.

Knowledge translation (KT) interventions should be tailored for the target audiences; one of which is patients. For patients, these interventions can be grouped into interventions designed to: (1) directly influence patient outcomes, here termed "patient-direct"; and (2) or interventions provided to patients but aimed at mediating health professionals' behaviors, here termed "patient-mediated" (see Figure 3.4f.1). Similarly, interventions

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KT Intervention
targeted to:

Intent to influence:

multifaceted interventions

| Patient | → direct → | Patient knowledge, skills, behaviour, and/or health outcomes |

mediated

| Healthcare professional | → direct → | Healthcare professional knowledge, skills and/or behaviour |
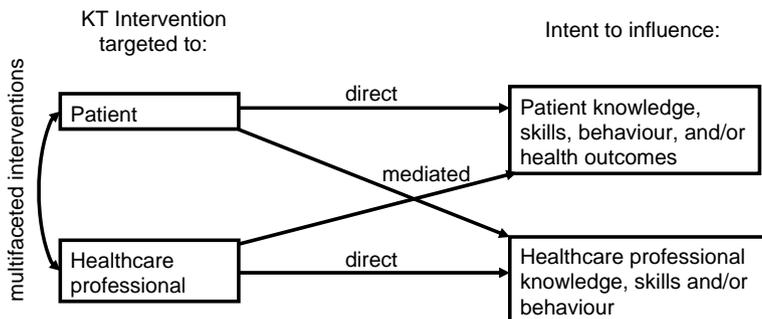
Figure 3.4f.1   Direct versus mediated KT interventions for patients and health care professionals.

targeting health professionals may influence their attitudes, knowledge, skills, and behavior directly and may also mediate patients' behaviors (see Chapter 3.4b). All of these interventions are used to increase uptake of evidence in clinical practice and self-care.

Interventions provided to patients for reducing the knowledge to care gap are premised on having an informed and activated patient [1, 2]. This chapter summarizes the state of the knowledge and research gaps regarding patient-direct and patient-mediated interventions used to enhance KT.

Patient-direct interventions

Patient-direct interventions aim to promote patients' involvement in implementing appropriate, safe, effective, and responsive self-care and health care (see examples in Table 3.4f.1). The framework of Coulter and Ellins [1, 3] is used to classify these strategies into four broad categories according to their intent to improve health literacy, clinical decision making, self-care, and patient safety.

A person who is *health literate* is able to access, understand, evaluate, and communicate information as a way to promote, maintain, and improve health in a variety of settings across the life-course [4]. Examples include written health information materials, alternative format information resources (e.g. video), targeted approaches for disadvantaged groups with lower health literacy (e.g. using non-written media such as pictograms, videos, interactive computer systems), and mass media campaigns to promote

Table 3.4f.1   Examples of patient-direct and patient-mediated interventions for KT

Patient-direct interventions	Patient-mediated interventions
• health information materials • mass media campaigns • question prompts • patient decision aids • self monitoring/self-administration • self-help groups, peer support • tele-care • enhancing adherence to treatment • patient reporting adverse events	• question cards to prompt asking questions of practitioners • coaching in preparation for consultation with health professionals • patient decision aids • patients providing reports to health professionals • communication skills training to patients and to professionals • patients reporting their results to the health professional (e.g. blood pressure readings, depression scores, blood glucose readings)

specific health behaviors or service use (e.g. television, radio, newspapers, posters, brochures).

Interventions focused on supporting patient involvement in *clinical decision making* includes patient decision aids (see Chapter 2.2), question prompts, health coaching, and training clinicians in communication skills [1, 3]. Health coaching is used to develop patients' skills in preparing for a consultation, deliberating about options, and implementing behavior change [5].

Self-care and self-management interventions aim to improve people's practices in maintaining health and managing disease. Examples include: self-management education to develop skills to cope with the condition and manage daily problems; self-monitoring and self-administered treatment; self-help groups and peer support; patient access to personal medical information; and patient centered tele-care. Many self-management education programs used the Lorig model which aims to help patients develop the skills needed to manage their chronic health condition [6, 7]. The Lorig model for self-management is a generic, lay-led, community-based course provided in six weekly sessions and includes cognitive skills, symptom management, healthy lifestyle, communication skills, managing medication, planning for the future and taking action, problem solving, making informed decisions, and working in partnership with the health care team. Patients exposed to this self-management program had short-term improvements in health behaviors, self-efficacy, and use of health services.

Patient-direct interventions whose aim is to improve *patient safety* include information about choosing safe providers, patient involvement in infection control, adherence to treatment, checking records and care processes, and patient reported adverse events.

Do patient-direct interventions work?

Coulter and Ellins [1, 3], identified 129 reviews of patient-direct interventions. Drawing on their findings, we report patient outcomes for knowledge, experiences, health service use and costs, and health behavior and health outcomes (see Table 3.4f.2 for specific outcomes in these categories).

Table 3.4f.2 Outcomes for patient-targeted interventions

Categories of outcomes	Outcome description
Knowledge, comprehension and recall of information	Knowledge of ○ the health condition ○ long term complications of the health condition ○ self care options ○ treatment options
Experience	• patient satisfaction • satisfaction with doctor-patient communication • quality of life • psychological well-being • self-efficacy • involvement with health care decision making and self care • empowerment
Use of health services and costs	• hospital admissions • length of hospital stay • number of visits to health professionals • costs • costs to patients • days lost from work or school
Health behavior	• health related lifestyles • self-care activities • treatment adherence
Health outcomes	• severity of disease or symptoms • physical and mental functioning • clinical indicators
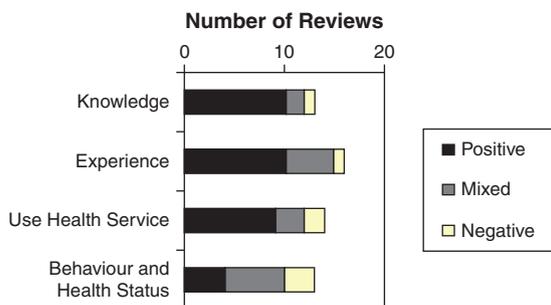
Figure 3.4f.2 Reviews of health literacy interventions (n = 25).

Patient-direct interventions to improve *health literacy* were the focus of 25 reviews [1, 3]. These interventions have the most consistent positive effects on knowledge and to a lesser extent on patients' experience and use of health services (see Figure 3.4f.2). Health literacy interventions alone do not have consistent positive effects on behavior and health outcomes. Written materials improve knowledge and recall particularly if personalized. Combined written and oral information can improve patient experience and sometimes use of health services. Other formats, such as websites, improve user satisfaction and some studies report positive effects on self-efficacy and health behavior. Although information adapted for disadvantaged populations who lack health literacy skills has shown positive effects on knowledge and behavior, fewer studies have examined effects on reducing inequities in health outcomes. Targeted mass media campaigns increase awareness often within 3 to 4 months, improve use of services (drugs, medical or surgical procedures, diagnostic tests), but have less effect on health behavior. Only two studies showed that mass media influenced smoking behavior among young people [8, 9].

There were 22 reviews on interventions to improve *clinical decision making* [1, 3]. The most consistent positive effect is on knowledge followed by use of health services (see Figure 3.4f.3). The reviews that examined question prompts and coaching found that these interventions have positive effects on patients' knowledge, information recall, and participation in decision making. Their effects on satisfaction and treatment outcomes were inconsistent. The reviews of patient decision aids indicated that they improve patients' participation, increase knowledge of their treatment options and outcome probabilities, and improve agreement between patients' values and subsequent treatment decisions. For example in one meta-analysis of 11 trials, the use of discretionary surgery decreased by 20% without apparent adverse effects on health outcomes [10].
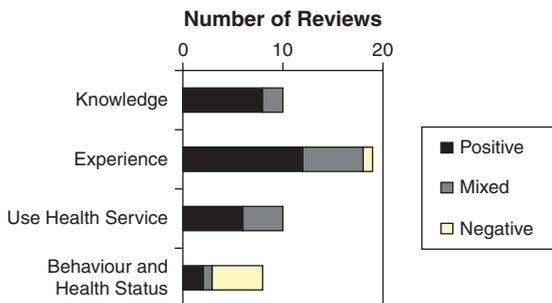
Figure 3.4f.3   Reviews of clinical decision making interventions (n = 22).

Coulter and Ellins [1, 3] synthesized 67 reviews of *self-care or self-management* interventions (see Figure 3.4f.4). Overall, findings revealed improved knowledge, patient experience, health behavior, and health outcomes. Although there were mixed effects across reviews, self-management programs improved knowledge, coping behavior, adherence, self-efficacy, and symptom management. Programs which included skill development were more effective than those which provided information alone. Health services use and cost sometimes were reduced and quality of life enhanced. There were beneficial effects on health behavior and health outcomes within 3 to 6 months, which tended to lessen over time. Quality-of-life effects tended to be sustained beyond the intervention period. For example, more multi-faceted programs (self-management program, regular health professional consultation, patient action plans) that targeted asthma improved service use. Specifically, there were fewer hospitalizations
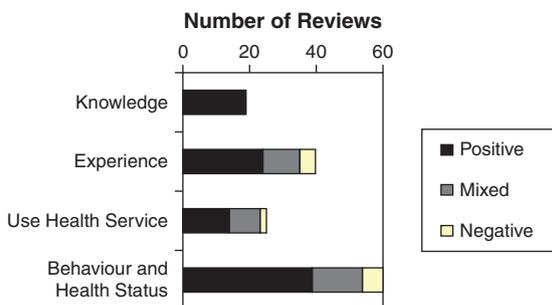
Figure 3.4f.4   Reviews of self-care and chronic disease self management interventions (n = 67).

(Relative Risk (RR) 0.64, Confidence Interval (CI) 0.56, 0.82), unscheduled visits (RR 0.68, CI 0.56, 0.81), quality of life (Standardized Mean Difference 0.29, CI 0.11, 0.47) and self efficacy (0.36, CI 0.15, 0.57). Children and adolescents also had moderate improvements in lung function measured with spirometry. In contrast, the effects of arthritis self-management education on pain (effect size range 0.12–0.22) and function (effect size range 0.07–0.27) have been small and short-lived. When diabetes self-management education was combined with other disease management strategies, blood glucose control was improved and diabetic complications were reduced. For patients with Type 2 diabetes, group education improved blood glucose and blood pressure. In summary, larger effect sizes were associated with self-management programs that focused on specific topics, used participative teaching methods, had multiple components including regular review by health professionals, involved family or other informal caregivers, and lasted at least 12 weeks.

There are fewer reviews of self-monitoring ($n = 8$), peer support groups ($n = 3$), patient-held medical records ($n = 4$), and patient centered tele-care ($n = 4$). Blood glucose self-monitoring in patients with diabetes has not been shown to be effective [11, 12]. In contrast, self-monitoring of blood pressure and anticoagulant therapy had similar outcomes to those of professionally managed care. In the case of hypertension, self-monitoring was cost neutral; for anticoagulation therapy, it was cost-saving. Self-help and support groups were viewed positively by participants in terms of sharing information, experiences, and problem solving. In the case of caregiver support groups, they improved confidence, coping, family function, and perceived burden of care. Patients found patient-held records useful and increased their sense of control. Recording consultations improves patients' recall, understanding, and uptake of information. Patient-centered tele-care in the home reduces patients' perceived isolation and improves self-efficacy, quality of life, patient empowerment, and psychological outcomes such as depression. Cost savings were evident when routine care was replaced by "virtual visits." Self-help, support groups, patient held medical records, and recording consultations did not affect health behavior or health outcomes.

Most of the 18 reviews by Coulter and Ellins [1, 3] focused on *improving safety* through better treatment adherence (see Figure 3.4.f.5). Overall safety KT interventions are effective in improving knowledge and patients' experience and to a lesser extent use of services, health behavior and health outcomes. The most effective strategy to optimize patients' treatment adherence is to simplify dosing regimens (8 to 19.6% improvement in 7 of 9 trials). Education and information provision was necessary but not sufficient to improve adherence. Little is known about the long-term effects of

Number of Reviews
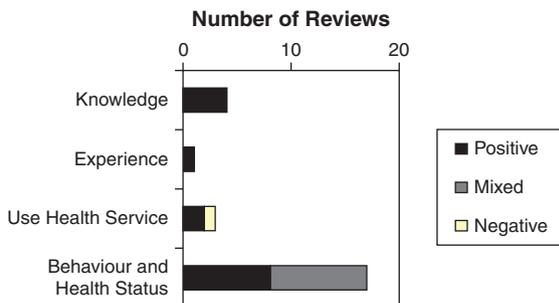
Figure 3.4.f.5 Reviews of safety interventions (n = 18).

treatment adherence interventions. One review of patient-oriented hospital infection control campaigns concluded that it increased compliance to hand hygiene when hand washing facilities were provided along with patient encouragement to ask health workers if they have washed their hands. Coulter and Ellins [1, 3] report that there have been no systematic reviews of patient reporting of adverse drug events. In individual studies, the evidence is mixed on the role of patient safety information in preventing adverse events. The effect of direct patient reporting into adverse event monitoring systems is unknown. The only review on equipping patients for safer health care reported one trial that provided patients with detailed information about their medications and another trial of a self-medication program. Both significantly reduced medical errors. There were some beneficial effects on patients' knowledge and confidence from an educational video. Personalized information on drugs had no effect on patients' experience of care. The effects from personalized information on error rates and adverse events were mixed so no conclusion can be made. Considering the surgical context, there are no reviews of asking patients to mark the site where their surgery will take place; however, single studies indicated that patients do not always follow through with requests to mark the correct surgical site.

Patient-mediated interventions

Patient-mediated interventions are targeted at patients but aim to change health professionals' behaviors through patient–provider interaction. According to the Cochrane Effective Practice and Organization of Care Review Group [13], patient mediated interventions are defined as new clinical information collected directly from patients and given to the provider

such as depression scores from an instrument (see Table 3.4f.1).We have expanded this definition to include any intervention targeting patients that aims to influence uptake of evidence by health care professionals. To scope out other potential interventions, we adopted the framework for organizing reviews used within the Cochrane Consumers and Communication Review Group. First, the framework organizes interventions by main direction of communication, in recognition of the multidirectional nature of communication and the central role of consumers to effective interactions and health care [14, 15]. Second, an intervention for communication and participation is defined as a "purposeful, planned and formalized strategy associated with a diverse range of intentions or aims. These interventions aim to inform, educate, communicate with, support, skill, change behavior, engage, or seek participation of people in all spheres of health – from individual to collective contexts [15]." While this therefore encompasses a wider range of interventions than are discussed here, the definition alerts us to the multiplicity of purposes of communication, including the indirect series of effects anticipated by interventions for consumers in changing the behaviors of professionals. According to this framework, other potential patient-mediated interventions include: (a) interventions for communication exchange between health care professionals and consumers (e.g. patient decision aids, communication skills training for consumers); or (b) interventions from the consumer (e.g. provider education by patient or family care representatives or civic participation interventions such as consumer involvement in developing health care policy, research, and clinical practice guidelines) [16].

Do patient-mediated interventions work?

Four systematic reviews evaluated the effect of interventions on communication exchange between health care professionals and consumers [10, 17–19]. In one review of 86 trials of patient decision aids, 11 trials measured patients' participation in decision making and 4 measured the effect on patient–health professional communication (see Table 3.4f.3) [10]. This review found a reduced proportion of decisions being made by the health professional alone (RR 0.61; 95% CI 0.49 to 0.77) and more communication about the decision occurring between the patient and their health professional when patients were exposed to decision aids compared to usual care. Two systematic reviews evaluated the effect of interventions on enhancing shared decision making in clinical practice [17, 18]. From a patient reported perspective, one review of 21 trials found that all 3 trials that improved shared decision making included a patient-mediated

Table 3.4f.3 Evidence for patient-mediated interventions (n = 4 systematic reviews)

Systematic review focus	Trials (n)	Summary of findings
Patient decision aids (86 trials) [10]	11 trials [26–36]	↑ Patient participation in decision making ↓ Practitioner controlled decision making
	4 trials [37–40]	↑ patient-health professional communication about the decision
Patient reported shared decision making (21 trials) [18]	3 trials [41–43]	↑ shared decision making (when decision aid given with training of health professionals)
Third party reported shared decision making (5 trials) [17]	2 trials [44, 45]	↑ shared decision making (when decision aid used in consultation and/or used with training of health professionals)
Shared decision making in mental health (2 trials) [19]	1 trials [41]	↑ shared decision making (when used a patient decision aid)

intervention (e.g. patient decision aid) combined with an educational session about shared decision making for health professionals [18]. From a third party observer perspective, a review of five trials found that the two positive trials improved shared decision making and both used patient-mediated interventions [17]. One trial compared a patient decision aid used within the consultation to a patient decision aid used in preparation for the consultation. The other trial compared usual care to an intervention that included patient decision aid, educational session on shared decision making and performance feedback. The fourth systematic review of interventions to enhance shared decision making in people with mental health conditions identified two trials; both of which used patient decision aids and both trials were included in reviews reported above [19].

Other patient-directed interventions such as question prompts, which use question cards to prompt patients to ask the practitioner questions, or coaching in preparation for the consultation, both have the potential to be patient-mediated interventions. However, reviews of these interventions have not discussed their effect on health professionals' behaviour [20, 21].

For interventions from the consumer, one systematic review evaluated the effect of methods of consumer involvement in developing health care policy and research, clinical practice guidelines, and patient information material [22]. However, this review did not identify any studies that evaluated the effect of patient-mediated interventions on health care professionals'

behavior. A narrative overview of systematic reviews of communication skills training directed to consumers identified that apart from consultation length, no health professional outcomes were reported [23]. Improvements for consumers included outcomes associated with participating in the consultation. Interventions directed to both professionals and patients had mixed results including improvements in physicians' communication styles.

Although other systematic reviews report including patient mediated interventions, it was difficult to identify their effect on outcomes because: (a) patient-direct interventions were used alongside patient-mediated interventions; (b) studies evaluated patient-mediated interventions as part of a multi-faceted intervention; (c) studies didn't report their impact on health professionals' behaviors; or (d) patient-mediated interventions were inadequately described. For example, patients remotely submitting their home glucose records to their health care team may have combined it with a patient education intervention and study outcomes focused on glycemic control [24]. Similar issues were identified in a synthesis of systematic reviews focused on interventions to enhance medication prescribing that included patient-mediated interventions [25].

Future research

Research gaps regarding patient-targeted interventions occur at the fundamental and implementation levels. There are fundamental questions about the underlying theoretical frameworks of the interventions, essential effective elements, required duration, and adaptation for disadvantaged groups. More focus is needed on cost, long-term outcomes, and impact on narrowing health inequities. In the case of interventions with established efficacy (e.g. patient decision aids), research on optimal strategies to address implementation barriers is needed. Finally, studies of patient-targeted interventions that have the potential to be patient-mediated interventions need to consider measuring the effect on health professionals' behavior.

Summary

In view of the findings from systematic reviews, patient-direct and patient-mediated interventions may improve uptake of evidence to change behaviors of patients and health professionals respectively. Patient-direct interventions that actively engage patients improve their knowledge and can have positive effects on their experience, service use, health behavior, and health outcomes. To change other outcomes, additional strategies are required such as increasing the specificity and personalization of information, combining interventions with professional or other social support and

extending the duration of the intervention when long term behavior change is required. Patient-mediated interventions such as patient decision aids have been shown to change health professional behavior; however, there is a need to provide some link between the patient and the health professional either by using the decision aid within the consultation or by training health professionals in shared decision making. Important in the development of high-quality patient-direct and -mediated interventions is the systematic synthesis of the evidence used to inform them and the iterative process of ensuring they are relevant to the targeted user.

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Chapter 3.4g **Organizational interventions**[1]

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Key learning points

- It is important to place empirical studies of Knowledge Translation (KT) in health care organizations in a broader theoretical perspective.
- A recent literature review suggests three alternative perspectives are of special interest: (a) the Resource Based View (RBV) of the firm; (b) Critical Theory, and (c) Organizational Form.

Health care organizations (such as a hospital or primary care practice/ organization) typically operate at the middle level between the micro level of clinical practice and macro level of health policy. This middle level is increasingly important with the move away from traditional clinical dominance over work practices and towards a more corporate perspective,

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implying a stronger management of clinical practice. In publicly funded health care, the middle level is charged by the national policy level with the implementation of organization-wide interventions to improve service quality. In more market orientated systems, privately funded hospitals adopt organizational interventions to improve their position in the market. Cycles of such interventions have appeared with greater intensity since the 1990s. Some (but not all) of them have been independently evaluated so that a knowledge base is emerging. This article offers an overview of this expanding field and suggests key messages for implementing knowledge within organizations.

Successive organizational change programs are evident in health care over the 1990s. We have moved from Total Quality Management [1, 2], through Business Process Engineering (BPR) [3] and Plan–Do–Study–Act (PDSA) cycles. Change management interventions (such as Organization Development or culture change programs) have been imported, as have clinical practice guidelines. We currently see the attempted redesign of care pathways using the principles of service improvement. These complex interventions seek to improve service quality but often run into implementation barriers.

What do we know about program "implementation" in health care? There is both conceptual and empirical knowledge. The concept of the *implementation process* comes from political science [4] and Organizational Behavior (OB). Political scientists see health care arenas as a bargaining process between various interest groups with differential power [5]. Organizational behavior scholars study themes of organizational culture and change management as well as the process of organizational change, seeing it as a combination of a "receptive context" [6] and appropriate action. These scholars distinguish between incremental, strategic and transformational modes of change. Non incremental forms of change are difficult to achieve in health care, as managers have little power and professionals more. The basic concept of professional dominance is important [7] but subject to contest and revision. Health care displays many co-located professions so innovations which cross the frontier between professions are vulnerable to blockage [8]. An empirical evidence base is developing, with some overviews on service redesign and on change management [9, 10].

This chapter summarizes the main messages from our recent structured literature review on knowledge mobilization [1, 2]. It moves beyond the conventional focus on empirical and substantive findings to provide stronger theoretical emplacement. We identified many different (and often incommensurable) academic literatures jostling for space on this topic.

Perspective 1: resource based view (RBV) of the firm

RBV is an influential perspective within generic strategic management and industrial economics [4, 5]. It sees a firm's competitive advantage as shaped by a bundle of internal "micro" resources (e.g. ability to mobilize knowledge, to learn and to change) which are valuable and difficult to imitate. It focuses on the internal capabilities of the firm and not the market structure of a sector, spawning related concepts such as "dynamic capabilities" and "absorptive capacity" [6, 7]. While initial work came from corporate settings, some authors recently used its key concepts within health care settings [8].

Market orientated reforms (e.g. in the UK NHS) may make RBV more applicable to decentralized and market orientated delivery units (the UK Foundation Trusts) which increasingly have strategic space. An intangible ability to mobilize knowledge effectively may promote enhanced performance ("performance" may be the public sector analogue of private sector competitive advantage). Statement 1 in our review asserted:

> Healthcare scholars and policy makers will wish to consider how the mobilization of knowledge can improve productivity, innovation and performance in more market driven systems. RBV has potential application.

Perspective 2: critical management studies

In contrast to unitary perspectives such as RBV, scholars from critical management studies see health care settings as characterized by power contests, attempts to impose managerial control, and professional resistance. The reaction of health care professionals to novel Knowledge Management (KM) systems may include rejection or adaptation as well as acceptance. Public sector settings are seen as distinctive from private firms so corporate KM systems cannot be simply imported [9]. Two broad streams of critical work can be distinguished: the labor process school [10] (seeing KM as a deskilling or work intensification process) and the expanding Foucauldian school [11] (examining the effects of the "gaze" on clinical behavior as including both surveillance regimes and self surveillance). The (non) implementation of KM systems is a strong possibility, given continuing professional power and conflict with management.

Statement 2 in our review asserted:

> Critical perspectives – especially labor process and Foucauldian perspectives – explain why many knowledge management systems fail in health care.

The importance of power contests amongst occupational groups in health systems makes it appropriate to temper positivistic and technical approaches to knowledge management with skepticism.

Perspective 3: organizational form

An organizational studies perspective suggests underlying organizational form shapes knowledge flows. In health care, alternative governance modes include hierarchy, (quasi) markets, and networks. Some literature [12] suggests network or laterally based modes of organizing stimulates organizational learning. There appears to be a meta shift in the private sector from large integrated firms (Fordism) to (post-Fordist) networked flotillas of smaller organizations (e.g. Silicon Valley from the 1970s onwards). Small, knowledge intensive, firms are nimble, better able to learn and innovate. More lateral forms may be emerging in the public/health care sector, such as managed networks, partnerships, and strategic alliances. Some relevant empirical health care studies on this theme have however been inconclusive [13].

Statement 3 from our review asserted:

> The organizational studies perspective argues that appropriate organizational forms support knowledge mobilization efforts. Theoretically, alternative partnership and network based organizational forms are seen as more effective in promoting knowledge sharing than markets or hierarchies, but we now need to review further studies in health care organizations to refine theory and match it with empirics.

Summary

These three statements have structured our analysis in a larger and follow-up literature review (Ferlie *et al.* [3]) project. We will shortly report on this project, placing the literature(s) in the broader theoretical context outlined here. To provide analytic focus, future review work [3] should concentrate on three contrasting perspectives – coming from alternative social science disciplines – summarized here.

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Chapter 3.4h **Shared decision making**

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Key learning points

- Shared decision making requires that both the best evidence, values and preferences of patients be considered.
- Shared decision making also relies on the relationship between the both members of the decision making dyad (patient and health care provider).

If we are serious about addressing the expanding role of patients in clinical decision making, we need to change the way we study knowledge translation in the healthcare context [1]. In clinical settings, the implementation of knowledge depends on the exchange of information between health care providers and patients, where research evidence is used to support clinical decisions [2]. The ideal pathway for knowledge translation in this context is the sharing of decisions between a health care provider and a patient, a process known as "shared decision making" (SDM) [2]. A systematic review that identified 31 components of shared decision making (SDM) and summarized the key ones in an integrative model posited that three elements must be present for SDM to occur: both the health care provider and the patient must acknowledge that a decision is needed, they must both know

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and understand the best available evidence concerning the risks and benefits of every option and, in making a decision, must consider not only the clinician's recommendations but also the patient's values and preferences [3]. The overlap between this definition and that of the practice of evidence-based medicine (which requires the integration of the best available evidence, sound understanding of pathophysiology and sensitivity to the patient's emotional needs [4]) is clear. In this way, we see that SDM requires not only that the best evidence be considered and the patient's values and preferences be taken into account, but also that the information exchange between members of the decision-making dyad (the health care provider and the patient) is two-way. Shared decision making does not assume that the health care provider is the only party who needs access to evidence in order for patients to experience evidence-based practice; rather, it assumes that both the health care provider and the patient need access to the best evidence [5]. Moreover, it assumes that beyond the individuals involved in the decision-making process, a new entity must be taken into account: the decision-making dyad.

SDM is an interpersonal process, i.e. the parties relate to each other. It is an interdependent process as well: each party influences the other's cognitions, emotions and behaviors [6], and they collaborate to come to decisions about the patient's health care [7–9]. In SDM, one party's perceptions can influence the perceptions of the other, and each party's perceptions have several layers. SDM considers clinician–patient interaction to be an interpersonal and reciprocal system, and the two participants need to be considered simultaneously. In one study, this dynamic was explored by applying the Actor–Partner Interdependence Model [10] within patient–physician consultations [11]. The authors assessed how patient factors influenced not only their own personal uncertainty about the decision to be made but also the personal uncertainty of their physicians. At the same time, the authors assessed how physician factors affected their personal uncertainty about the decision to be made and the personal uncertainty of their patients. They showed that the personal uncertainty of patients and physicians was influenced negatively both by each party's own knowledge deficits and by the knowledge deficits of the other member of the dyad [11]. Specifically, the less informed one party felt (physician or patient), the more personal uncertainty the other felt [12]. According to an earlier study, an unintended impact on the other member of the dyad can occur (collateral damage) when a knowledge translation intervention is applied to increase the knowledge of just one member of the dyad. Physicians and patients influence each other in unexpected ways [12]. According to the Actor–Partner Interdependence Model, one cannot take for granted that an

effective knowledge translation intervention for health care providers will benefit their patients or vice versa [10]. Recently, a randomized trial showed that, in a clinical encounter, when the physician has had communication skills training and the patient has had patient-activism training, compared to only one party having had the intervention, or to usual care, information exchange between patient and healthcare provider is enhanced, as well as patient perceptions of engagement in care, and systolic blood pressure among underserved primary care patients with uncontrolled hypertension may be improved [13].

Although examining the dyad's contribution to clinical decision making holds great potential, SDM research requires valid and reliable dyadic measures, i.e. standardized measures that can be administered to clinicians and patients concurrently and can be used to derive dyad-level indices. In turn, dyadic indices may provide valuable information on the unique contribution of the dyad paradigm to the decision-making process. A recent study to assess the psychometric properties of dyadic measures for SDM research [2] found that out of seven subscales for measuring six elements of SDM, four measures have acceptable psychometrics to be considered dyadic: the values clarification subscale, the perceived behavioral subscale, the information-verifying subscale, and the uncertainty subscale [14].

Future research

More knowledge translation theories inspired by social theories need to be explored for application in the healthcare field. The Interdependence Theory, for example, is "a dyad-level social psychological theory that was originally proposed to understand the interpersonal context of social situations, how individuals involved in a relationship respond to such situations, and the determinants of social interaction" [15]. Dyadic methodology is relatively new as applied to health services research. New methods to develop valid and reliable dyadic measures could be the focus of future research. Lastly, a dyadic approach to knowledge translation intervention is also still in its infancy and it is not clear if one single intervention applied at the level of the dyad will be more effective than tailored and individualized knowledge translation interventions at the level of the patient or the health provider.

Summary

A dyadic approach to SDM research may help us increase our understanding of the knowledge translation process during patient–clinician interaction [16, 12]. Dyadic measures have the potential to capture key

mechanisms of reciprocity and mutual influence in clinical encounters. These instruments also lay the groundwork for the design of valid and reliable dyadic indices. We expect that a dyadic approach to SDM research will help implementation scientists design or evaluate new types of intervention for effective knowledge translation and will steer SDM in new and exciting directions [17].

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Chapter 3.4i **Financial incentive interventions[1]**

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Key learning points

- Financial incentives are extrinsic sources of motivation that exist when an individual receives a monetary transfer which is conditional on acting in a particular way.
- There is limited and incomplete evidence for the effectiveness of financial incentives in changing the behavior of primary care physicians.
- There is no evidence that using financial incentives to change the behavior of health care professionals also improves patient outcomes.

Financial incentives are extrinsic sources of motivation that exist when an individual receives a monetary transfer which is conditional on acting in a particular way. Other kinds of incentives exist (e.g. resources, gifts), but are

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Knowledge Translation in Health Care: Moving from Evidence to Practice, Second Edition. Sharon E. Straus, Jacqueline Tetroe and Ian D. Graham.
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not considered here. Intrinsic sources of motivation for clinicians include the likelihood that patients' health will improve as a result of a course of clinical action, and satisfaction from performing a task well. Social and peer group norms, where certain actions, or failure to act, are met with approval or condemnation are other sources of motivation.

The ultimate goal of using financial incentives is to increase quality of care and by extension, improve patient outcomes, reduce costs, or improve access to care. To achieve this goal, financial incentives are increasingly used to persuade physicians to use evidence-based treatments and/or to change their clinical behavior with respect to preventive, diagnostic and treatment decisions. Examples of nation-wide reforms linking financial incentives to performance of certain clinical actions are the *Quality and Outcome Framework for Primary Care* in the UK [1–3] and the *Practice Incentive Program* in Australia [4].

What different types of financial incentives are there?

Although there are issues with nomenclature and definitions, the different types of financial incentives used in health care include:
1 *Salary or sessional payment:* a lump sum payment for working for a specified time period (e.g. a set number of working hours or sessions per week)
2 *Fee for service (FFS):* payment for each service, episode of care, or patient visit
3 *Capitation:* payment for providing care for a patient or for a special population
4 *Target payments and bonuses (pay for performance, PFP):* payment for providing a pre-specified level or change in a specific behavior or quality of care.
5 *Mixed or blended systems,* comprising more than one of the groups listed above

What is the behavioral response to financial incentives?

A financial incentive may create different types of behavioral response: it may be positive and result in the desired behavioral change, or it may be negative, thereby creating a "disincentive" resulting in either no response or a behavioral change in the opposite direction. This response, both in direction and magnitude, depends on a number of factors [5]. In some cases the strength of the incentive may have a bearing on its effect, e.g. a weak incentive to perform a highly valued behavior may be more effective

than a strong incentive to perform behavior regarded as unimportant. It has also been suggested that high intrinsic motivation (such as with health professionals), reduces the need for strong financial incentives [6].

How can financial incentives affect professional practice?

Financial incentives are likely to have the twin aims of increasing the quality and efficiency of care [7], but it is not automatically the case that an incentive promotes both. There may be tensions between intrinsic motivation and financial incentives. For instance, financial incentives may "crowd out" or reduce intrinsic motivation, thereby leading to negative consequences for the overall quality of care [8]. A financial incentive aimed at increasing the throughput of patients within an out-patient department, or using FFS payment generally, is likely to increase the number of patients seen but may not be compatible with providing high-quality care. Similarly, a capitation system pays a fixed amount per patient and provides incentives to minimize costs and only treat less complex and resource intensive patients (so called "cream-skimming"). Additionally, financial incentives may produce undesirable effects and unintended behaviors or changes in performance in other areas: e.g. if incentives are effectively used to improve care for patients within a certain disease area, other non-incentivized diseases may then be neglected, and so again may not be compatible with improving the net quality of care [9]. Another example would be improving or cheating on reporting rather than improving performance (so called "gaming") to increase the pay [10]. Authors have argued for blended payment schemes that reduce the impact of "extreme" incentives in FFS or capitation, alongside an element of PFP [11].

What is the evidence for the effectiveness of financial incentives?

In an overview of reviews [12], evaluating the effectiveness of financial incentives on professional practice, the results were mixed. *FFS*, *capitation* and *PFP* were all found to be "generally effective." *Mixed and other systems* showed "mixed" effectiveness, and *payment for working for a specified time period* was shown to be "generally ineffective" in terms of changing clinician behavior. For different categories of outcomes, financial incentives overall were "generally effective" in improving *processes of care*, *referrals/admissions*, and *prescribing costs*, but were of "mixed" effectiveness in improving *consultation/visit rates* and "generally ineffective" in improving outcomes related to *guideline compliance*. None of the reviews included in

the overview reported on the effects of FIs on patient outcomes. However, all of these results which are based on a vote-counting analysis of 32 studies from 4 reviews should be interpreted with caution, since it is a descriptive analysis and only the direction of effects and not the effect sizes are taken into account in the analysis

Another overview of reviews found limited evidence for the effectiveness and cost effectiveness of PFP in low- and middle-income countries (LMICs) [13]. A recent systematic review [14] concluded that the evidence is insufficient to support or not support the use of financial incentives to improve the quality of primary health care.

Future research

Future research should aim to evaluate the effectiveness of variable "doses" of financial incentives. A second area where there is little data is the effects of incentives on patient outcomes and on undesired or distorted behavior. Research in these areas will help to provide a more complete picture of the impact of financial incentives on health systems. In addition, the cost-effectiveness of financial interventions need further study. Studies evaluating the effectiveness of financial interventions applied in other contexts (e.g. in LMICs, and in secondary care), or to other categories of health care professionals than physicians, would improve the existing evidence base.

Summary

There are indications that *FFS*, *capitation* and *PFP* may be effective for improving selected processes of care, little is known about their possible negative effects. The effects on patient outcomes, undesired, or distorted behavior and the cost-effectiveness of financial incentives are understudied. The small and incomplete body of evidence is insufficient to support or not support the use of financial incentives within health care.

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Chapter 3.5 **Monitoring knowledge use and evaluating outcomes**

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Key learning points

- Knowledge use can be instrumental (concrete application of knowledge), conceptual (changes in understanding or attitude) or persuasive (use of knowledge as ammunition).
- While knowledge use is important, the impact of its use on patient, provider, and system outcomes is of greatest interest.
- Strategies for evaluating knowledge implementation should use explicit and rigorous methods and should consider both qualitative and quantitative methodologies.

Monitoring knowledge use

In the Knowledge to Action cycle, after the knowledge translation intervention has been implemented (Chapter 3.4), knowledge use should be monitored. This step is necessary to determine how and to what extent the

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knowledge has diffused through the target decision maker groups [1]. Measuring and attributing knowledge use is still in its infancy within health research. How we proceed to measure knowledge use depends on our definition of knowledge and knowledge use and on the perspective of the knowledge user.

There have been several models or classifications of knowledge use [2, 2–6]. Larsen described conceptual and behavioral knowledge use [2]. Conceptual knowledge use refers to using knowledge to change the way users think about issues. Instrumental knowledge use refers to changes in action as a result of knowledge use. Dunn further categorized knowledge use by describing that it could be done by the individual or a collective [3]. Weiss also described several frameworks for knowledge use including the problem solving model which she described as the direct application of the results of a study to a decision [4]. In this model she mentions that research can "become ammunition for the side that finds its conclusions congenial and supportive. Partisans flourish the evidence . . . to neutralize opponents, convince waverers and bolster supporters" [4]. Beyer and Trice considered this to be a different form of knowledge use and labeled it as symbolic knowledge use which they added to Larsen's framework [5]. Symbolic use involves the use of research as a political or persuasive tool. Estabrooks has described a similar framework for knowledge use including direct, indirect and persuasive research utilization where these terms are analogous to instrumental, conceptual and symbolic knowledge use respectively [6].

We find it useful to consider conceptual, instrumental and persuasive knowledge use [1]. As mentioned above, conceptual use of knowledge implies changes in knowledge, understanding or attitudes. Research could change thinking and inform decision making but not change practice. For example, based on knowledge that self-monitoring of blood glucose in newly diagnosed patients with type 2 diabetes mellitus is not cost-effective and is associated with lower quality of life [7, 8] we understand a newly diagnosed patient's concern about self-monitoring.

Instrumental knowledge use is the concrete application of knowledge and describes changes in behavior or practice for example [1]. Knowledge can be translated into a usable form such as a care pathway and is used in making a specific decision. For example, a clinician orders deep venous thrombosis (DVT) prophylaxis in patients admitted to the intensive care unit. This type of knowledge could be measured by assessing how frequently DVT prophylaxis is ordered in appropriate patients.

Persuasive knowledge use is also called strategic or symbolic knowledge use and refers to research being used as a political or persuasive tool. It relates to the use of knowledge to attain specific power or profit goals (i.e.

knowledge as ammunition) [1]. For example, we use our knowledge of adverse events associated with use of mechanical restraints on agitated inpatients to persuade the nursing manager on the medical ward to develop a ward protocol about their use.

All types of knowledge use can be partial or complete. For example, a clinician may be aware of and understand several of the recommendations in a clinical practice guideline but not of all of them (partial conceptual knowledge use); similarly, she may implement some of these recommendations in her own setting but may not be able to implement all of them (partial instrumental knowledge use).

How can knowledge use be measured?

There are many tools for assessing knowledge use. Dunn completed an inventory of tools available for conducting research on knowledge use [3]. He identified 65 strategies to study knowledge use and categorized them into naturalistic observation, content analysis, and questionnaires and interviews [3]. He also identified several scales for assessing knowledge use but found that most had unknown or unreported validity and reliability. Squires and colleagues completed a systematic review of the psychometric properties of self-reported research utilization measures [9]. The authors identified 60 unique measures but only 7 were assessed in more than 1 study. Most measures targeted health care provider use of knowledge. Only 6 measures reported validity from 3 or more sources (including content, response processes, internal structure, and relations validity). Four of these 6 measures target nurses, 1 targets allied health care professionals, and 1 targets public health decision makers. Overall, the review highlights substantive gaps in the literature supporting the validity of these measures.

Examples of questionnaires available to measure knowledge use include the Evaluation Utilisation Scale [10] and Brett's Nursing Practice Questionnaire [11]. This latter questionnaire focuses primarily on the stages of adoption as outlined by Rogers [12] including awareness, persuasion, decision, and implementation. Most frequently, knowledge utilization tools measure instrumental knowledge use [9, 13]. And, often these measures rely on self report and are subject to recall bias. For example, an exploratory case study described call centre nurses' adoption of a decision support protocol [14]. Participating nurses were surveyed about whether they used the decision support tool in practice. Eleven of 25 respondents stated that they had used the tool and 22 of 25 said they would use it in the future. The authors identified potential limitations to this study including recall bias and a short follow-up period (1 month) without repeated observation [14]. In a more

valid assessment of instrumental knowledge use, participants also under-
went a quality assessment of their coaching skills during simulated calls
[15]. Assessing instrumental knowledge use can also be done by measuring
adherence to recommendations or quality indicators. For example, Grol
and colleagues completed a series of studies involving family physicians in
the Netherlands who recorded their adherence to 30 national guidelines
[16]. A total of 342 specific adherence indicators were constructed and phy-
sicians received educational sessions on how to record their performance
on these indicators. Computer software was developed to relate actual per-
formance to clinical conditions to assess adherence. They were able to
determine that guidelines with lowest adherence scores included those for
otitis externa and diagnosis of asthma in adults while those with highest
adherence scores were those for micturition problems in older men and the
diagnosis of heart failure [16].

In addition to considering the type of knowledge use, we should also
consider who are the targets for knowledge use (i.e. the public, health care
professionals, policy makers). Different targets may require different strate-
gies for monitoring knowledge use. Assessing use of knowledge by policy
makers may require strategies such as interviews and document analysis
[17]. When assessing knowledge use by physicians, we could consider meas-
uring use of care paths or ordering of relevant medications. And, when
assessing knowledge use by patients, we could monitor adherence to exer-
cise or medication regimens for example.

What is the target level of knowledge use that we are aiming for? As men-
tioned in Chapter 3.1, this target will be based on discussions with relevant
stakeholders including consideration of what is acceptable and feasible and
whether a ceiling effect may exist. If the degree of knowledge use is found to
be adequate, strategies for monitoring sustained knowledge use should be
considered. If the degree of knowledge use is less than expected or desired,
it may be useful to reassess barriers to knowledge use. In particular, the tar-
get decision makers could be asked about their intention to use the knowl-
edge. This exploration may uncover new barriers. In the case study of the
use of decision support for a nurse call centre, it was identified through a
survey that use of the decision support tool might be facilitated through its
integration in the call centre database, incorporating decision support
training for staff, and informing the public of this service [14].

When should we measure knowledge use versus the impact of knowledge
use? If the implementation intervention targets a behavior for which there is
a strong evidence of benefit, it may be appropriate to measure the impact of
the intervention in terms of whether the behavior has occurred (instrumen-
tal knowledge) rather than whether a change in clinical outcomes has

occurred [18]. For example, we recently completed a study of a strategy to implement the Osteoporosis Canada guidelines in a northern Ontario community setting [19]. The primary outcome of this randomized trial was appropriate use of osteoporosis medications (instrumental knowledge) rather than patient fractures (clinical outcome). We felt that there was sufficient evidence in support of use of osteoporosis medication to prevent fragility fractures that we did not need to measure fractures as the primary outcome. In cases such as this study, outcome measurement at the patient level could be prohibitively expensive but failure to measure at the patient level does not address whether the intervention improves relevant clinical outcomes.

Evaluating the impact of knowledge use

The next phase of the Knowledge to Action Cycle is to determine the impact of knowledge implementation [1]. In this phase we want to determine if the knowledge use impacts health, provider, and system outcomes. While assessing knowledge use is important, its use is of particular interest if it influences important clinical measures such as quality indicators.

Evaluation should start with formulating the question of interest. As mentioned in Chapter 2.2, we find using the PICO framework to be useful for this task. Using this framework, the "P" refers to the population of interest which could be the public, health care providers, or policy makers. The "I" refers to the KT intervention which was implemented and which might be compared to another group ("C"). The "O" refers to the outcome of interest which in this situation refers to health, provider, or organizational outcomes.

In the previous section we described strategies for considering knowledge use which can be used to frame outcomes. Donabedian proposed a framework for considering quality of care that separates quality into structure, process, and outcome. It can be used to categorize quality indicators and to frame outcomes of both knowledge use and the impact of knowledge use [20]. Structural indicators focus on organizational aspects of service provision which could be analogous to instrumental knowledge use. Process indicators focus on care delivered to patients and include when evidence is communicated to patients and caregivers. These indicators are analogous to instrumental knowledge use. Outcome indicators refer to the ultimate goal of care such as patient quality of life or admission to hospital. For example, if we want to look at the issue of prophylaxis against DVT in patients admitted to the intensive care unit, structural measures would include the availability of DVT prophylaxis strategies at the institution (instrumental

Table 3.5.1 Measures of knowledge use and impact of knowledge use

Construct	Description	Examples of measures	Strategy for data collection
Knowledge use			
• Conceptual	Changes in knowledge levels, understanding or attitudes	Knowledge attitudes; intentions to change	Questionnaires, interviews
• Instrumental	Changes in behavior or practice	Adherence to recommendations (e.g. change in prescribing, adoption of a new nursing practice or abandonment of existing practice)	Administrative database or clinical database
Outcomes			
• Patient	Impact on patients of using/applying the knowledge	Health status (morbidity or mortality); health related quality of life; satisfaction with care	Administrative database, clinical database, questionnaires
• Provider	Impact on providers of using/applying the knowledge	Satisfaction with practice; time taken to do new practice	Questionnaires, interviews
• System/society	Impact on the health system of using/applying the knowledge	Costs; length of stay; waiting times	Administrative database, clinical database

knowledge use). Process measures include prescription of DVT prophylaxis strategies such as heparin in the critical care unit (instrumental knowledge use). And, outcome measures include risk of DVT in these patients in the intensive care unit. Table 3.5.1 provides a framework for differentiating knowledge use from outcomes.

In a systematic review of methods used to measure change in outcomes following a KT intervention, Hakkennes and Green grouped measures into 3 main categories [18] which we have modified to focus on impact of knowledge use:

1 Patient level
(a) Measurement of an actual change in health status such as mortality or quality of life
(b) Surrogate measurement such as length of stay in hospital or attitudes towards an intervention.

2 Health care provider level
(a) Measurement of provider satisfaction.

3 Organizational or process level
(a) Measurement of change in health care system (e.g. wait lists) or costs.
Hakkennes and Green found that of 228 studies evaluating strategies for guideline implementation, 93% measured outcomes at the level of clinician and 13% used surrogate measures at the level of the provider [18]. Less than one-third of studies used patient level outcomes. In a review of 53 guideline implementation studies in nursing and allied health professions, 86% of the studies included provider outcomes, 43% included patient outcomes, and 38% of the studies had system level outcomes [21].

We encourage readers to look at the Grid-Enabled Measures (GEM) Database [22] which is a project initiated by the Canada Research Network Cancer Communication Research Centre at Kaiser Permanente in Colorado and the National Cancer Institute's Division of Cancer Control and Population Sciences. The goal of GEM is to provide a database of standardized and validated KT measures. Each item in the repository includes the name of the tool, the construct it measures, its content area, target population and mode of administration. Links to the tool and ratings by those who have used it are also available.

Methods for evaluating KT interventions

After formulating the question, we need to match it to the appropriate evaluation design. When developing an evaluation, we need to consider rigor and feasibility. By rigor we mean the strategy for evaluation should use explicit and valid methods. Both qualitative and quantitative methodologies could be used. By feasible, we mean the evaluation strategy is realistic and appropriate given the setting and circumstances. As with any evaluation, the strategy should be ethical.

Selection of our evaluation strategy also depends on whether we want to enhance local knowledge or provide generalizable information on the validity of the KT intervention. As mentioned in Chapter 5.1, those interested in local applicability of knowledge (i.e. whether an intervention worked or not in the context in which it was implemented) should use the most rigorous study designs feasible. These may include observational evaluations whereby the researcher does not have control over allocation of study participants to the intervention or a comparable control. Those interested in generalizable knowledge (i.e. whether an intervention is likely to work in comparable settings) should use the most rigorous research evaluation

design that they can afford such as randomized trials (or experimental evaluation). A third form of evaluation to consider is process evaluation. Process evaluation may involve determining the extent to which target decision makers were actually exposed to the intervention or the dose of the intervention. It may also include a description of the experience of those exposed to the intervention and potential barriers to the intervention. For example, a study designed to evaluate the effectiveness of an educational intervention on the use of radiography for diagnosis of acute ankle injuries revealed no impact of the active dissemination of the Ottawa Ankle Rules. However, less than a third of those receiving the intervention were physicians who had authority to order X-rays, raising the question about whether the intervention was not effective or simply not directed to the appropriate target decision makers [23]. This type of evaluation is also useful to allow corrections to the intervention or implementation strategy based on what is revealed. We believe that process evaluation should occur alongside observational and experimental evaluation.

Qualitative methods of evaluation can be helpful in exploring the "active ingredients" of a KT intervention and thus are particularly useful in process evaluation. In a randomized trial of a comprehensive, multifaceted guideline implementation strategy for family physicians, no changes in cholesterol testing were noted after a 1 year intervention [24]. This finding led to completion of interviews with family physicians who expressed concern about the extra workload associated with implementation of the guidelines and suggested revisions to the diagnostic algorithm [25]. Triangulation should be considered in qualitative studies whereby a variety of strategies for data collection (e.g. interviews, surveys, focus groups) are used to enhance validity. Qualitative research can also be useful for identifying unintended impacts of the intervention. For a more comprehensive description of qualitative research methods we encourage readers to review the textbook by Denzin and Lincoln [26].

Quantitative evaluation methods included randomized and quasi-experimental studies. Randomized trials are more logistically demanding but provide more reliable results than non-randomized studies. Non-randomized studies can often be implemented more easily and are appropriate when randomization is not possible. For complete description of these strategies, we refer you to Chapter 5.1.

Mixed methods can be used to evaluate KT interventions and are particularly helpful in the evaluation of complex KT interventions. We propose that the evaluation phase is also an opportunity to explore factors that can contribute to sustainability of the intervention. Both quantitative and

qualitative evaluation strategies can help identify factors that can influence sustained knowledge use. Sustainability is further discussed in Chapter 3.6.

Future research

There are several areas of potential research including the development and evaluation of tools for measuring knowledge use, outside of instrumental knowledge use. And, enhanced methods for exploring and assessing sustained knowledge use should be developed.

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Chapter 3.6 **Sustaining knowledge use**

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Key learning points

- Sustained knowledge use refers to the continued implementation of innovations over time and depends on the ability of workers, organizations, and health care delivery systems to adapt to change.
- A tension exists between routinization of one innovation and receptivity to subsequent innovations.
- Sustainability planning is recognized as a critical aspect of introducing innovations in systems.
- There is an increasing research base about sustainability. Based on systematic reviews and our experience in the field, six factors are identified: Health needs and expected benefits; effectiveness of the system to monitor progress; adaptability and alignment of the improved process; multi-level and collective leadership; financial and human resources; and community stakeholder support.
- Planning for sustainability should be initiated early in the knowledge to action cycle, when interventions to implement innovations are being designed.
- Addressing sustainability requires planning for both the spread and scaling up of knowledge use in health systems.

What determines whether and how a health care provider, inter-professional team, hospital or a health system will continue to sustain, spread, or substitute a new evidence-informed innovation? Examples include: whether to continue to order specific medications, for whom to sustain policies for

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minimum restraint use, how to provide mental health community services for vulnerable populations or the best methods to use to continue to implement continuous quality improvement cycles. These questions about the sustained use of existing or new knowledge are of vital importance in order to achieve optimal health outcomes. Both researchers and policy makers are challenged with "accelerating health care improvement and transformation as well as converting evidence and innovative practices into actionable policies, programs, tools, and leadership development" [1]. The creation of new knowledge through research may or may not lead to implementation of that knowledge or innovation. Deciding whether or not and also how to sustain implementation of new knowledge and innovations into practice are critical components of the science and practice of knowledge translation [2].

What is sustainability?

Sustainability is commonly defined as "*The degree to which an innovation continues to be used after initial efforts to secure adoption is completed*" [3]. A systematic review of the growing number of recent studies on sustainability of new programs and innovations found that sustainability was the most common term used in 77 of 125 studies (62%) yet only 29% of all studies used an operational definition of sustainability [4]. Two other terms used were long-term follow-up implementation (10%) and institutionalization (5%). The measurement timeframe for most studies (64%) was two years or more after initial implementation. Partial sustainability was reported as the most frequent result across these studies about medical care, mental health, and public health promotion programs. The authors conclude that there is a need for prospective research guided by the conceptual literature on sustainability with attention to interactions at multiple levels to better understand what influences, enhances, or challenges sustainability [4].

It is important to acknowledge that assessing sustainability warrants a more sophisticated approach than the longitudinal follow-up of intervention implementation. Elements of sustainability that researchers are beginning to address include system readiness for integration [5]. Glasgow outlines the need for research that tests approaches to scaling up and sustaining effective interventions by focusing on five core values: rigor, and relevance, efficiency, collaboration, improved capacity, and cumulative knowledge [6]. There are several inter-related concepts about sustainability and some authors use terms inter-changeably. Table 3.6.1 provides a list and brief description of selected terms.

Table 3.6.1 Terms related to sustainability or lack of sustainability

Sustainability

Routinization: When an innovation becomes entrenched into regular activities and loses distinct identity [3].

Institutionalization: The "staying power" or relative endurance of change in an organization [40]. The change becomes part of everyday activities or normal practices in an organization.

Re-Invention: Adapting the innovation to fit with a local situation or the degree of modification by the adopters [3].

Spread: "The process through which new working methods developed in one setting are adopted, perhaps with appropriate modifications, in other organizational contexts" [8].

Expanded: In addition to sustaining knowledge use over time, there is a broader implementation to transcend disciplines, organizational units of care, health care sectors, and/or communities (e.g. service, academic) [18].

Scalability "the ability of a health intervention shown to be efficacious on a small scale and or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population, while retaining effectiveness [41].

Lack of sustainability

Improvement evaporation, initiative decay or erosion: Decreased application of the innovation over time [8].

Discontinuance: A decision to de-adopt or stop the implementation of an innovation [3].

Relapse: Reverting to previous ways of operating [35].

What sustainability models are available to inform knowledge translation?

In a 2010 review of 31 models or frameworks about knowledge translation, 11 described a step that was separate and subsequent to the step of evaluation, which was labeled as maintain change or sustain ongoing knowledge use [7]. There are also an increasing number of models specifically focused on sustainability [8–10] but to date few rigorous evaluations of these models have been conducted to assess their ability to predict actual implementation sustainability and sustainability of the outcomes.

One well developed sustainability model with a diagnostic structured questionnaire and a weighted scoring system is available along with tools and guides for leaders from the NHS Institute for Innovation and Improvement in the UK [9]. This NHS Sustainability Model revolves around three core elements of process, staff, and organization. Factors in the process domain are: benefits beyond helping patients; credibility of evidence; adaptability; and monitoring progress. For the staff domain, factors are: training and involvement; behaviors; senior leadership engagement and support;

and clinical leadership engagement and support. Finally, for the organization domain, factors are: fit with goals and the culture and infrastructure.

The NHS Sustainability Model is being used in research in the USA, South Africa, and in Canada [10–14]. An issue with the diagnostic questionnaire is that factors include multiple dimensions. For example, the element entitled "senior leadership engagement and support" includes aspects of involvement, visibility and communication. Participants report that it is difficult to score this aspect with an overall single rating. Nevertheless, leaders and staff at nine Canadian health care settings were receptive to sustainability action planning with outcome tracking for the implementation of evidence-informed guidelines over three years [13]. Steering committee members reported that questionnaire responses helped them to better understand the attitudes and values of different disciplines. Low scores prompted some leaders to implement additional implementation strategies such as more education, equipment, and human resources. In a second study, a research team in South Africa reported that all 17 project teams were willing to use a revised NHS tool created with mutually exclusive yes/no 2×2 tables [14].

How can sustainability-oriented action plans be developed?

We are suggesting six factors to consider in the development of sustainability-oriented action plans. These factors are derived from the Maher *et al.* model (2010) [9], systematic reviews published in 2008 [15] and 2012 [4] as well as from our own 12-year experience in knowledge translation cycles [12, 13, 16–21].

1 *Health needs and expected benefits*: Is there a well-defined need and a priority for the knowledge/innovation that is being implemented and sustained? Is there consensus about what knowledge needs to be sustained and the related benefits across inter-professional and stakeholder groups and most importantly the patients or communities themselves?

2 *Effectiveness of the system to monitor progress*: Is there an evaluation system that will be sustained to provide ongoing quantitative and qualitative data to inform formative learning and determine evidence of outcomes and impact? Have interactive feedback processes with potential knowledge users been put in place? Are communication systems available to inform patients, staff, the organization and the community about indicators and outcomes?

3 *Adaptability and alignment of the improved process*: Will the improved process resulting from the ongoing implementation of an innovation be adaptable as other organizational or socio-political changes occur over

the long term? What management decision making processes need to be considered when determining how to align the ongoing implementation of current and future innovations?

4 *Multi-level and collective leadership*: What actions might senior leaders, clinical leaders, and champions take to support the sustainability of the new innovation and ongoing knowledge use? Are there champions for the change at various system levels (health care provider peer mentors, team leaders, senior management)? Who is responsible for continued implementation of the innovation and making modifications as new knowledge or contextual changes in the setting occur? Who will be accountable for the monitoring process to ensure that progress towards the relevant outcomes is being assessed and acted upon?

5 *Financial and human resources*: What funding is required to implement and sustain the innovation? What funding is available for spreading and scaling up the implementation? Are efficiencies gained through a scaling up process? Can lower-cost yet effective strategies be used in the future to maintain the core elements of the innovation? Are human resources and staffing systems supportive for ongoing implementation of the innovation for the long term?

6 *Community stakeholder support*: Who are the stakeholders and how might their power or support be leveraged over the long term?

Sustainability tensions

Tension exists between the routinization of one idea and the receptivity to a subsequent good idea [5]. Sustainability is not always a desirable outcome when the decision to modify or cease an innovation is evident. As research results and subsequent innovations are continuously being produced, sustainability strategies need to allow for the integration of new insights emerging from the production and application of new research knowledge. Moreover, because it is not uncommon for health care systems to change models of care delivery; sustainability strategies for knowledge implementation must have the flexibility to respond to these and other important contextual shifts.

Tension also exists about whether to pilot a good idea (i.e. innovation) in one or two places first in order to develop and evaluate potential implementation strategies (e.g. educational programs, determine necessary equipment, assess the impact on staffing). Alternatively, is it a better approach to spread an innovation as widely and quickly as possible, so that saturation contributes to sustainability [8]? An ethical tension arises when high-quality research evidence exists about a treatment or an education

program yet is only accessible to a few pilot sites or sub-group of the relevant patient population.

How should KT interventions be scaled up and spread?

Two closely related concepts in the sustainability literature are spread and scaling up. Rogers in 1995 described spread as less intentional or a less formal process through which innovations are adopted [22]. Greenhalgh in 2004, one of the early authors to note the absence of scientific literature about sustainability described characteristics of centralized versus decentralized networks for spread and indicated that elements of a social marketing program should be applied when spread is centrally driven [5].

Scaling up implies a much more deliberate "push" approach to change and refers to a "systematic programme to bring effective treatment, diagnosis or care approaches to wider populations, or to improve in other ways disease and programme specific services" [23]). There is no ready-made formula that allows one to determine timing or appropriateness of scaling up an innovation. Nonetheless, the use of explicit criteria to gauge these decisions is important. For instance, what is the expected cost and benefits of scaling up of this innovation relative to others; and are the benefits of spread likely to reduce inequities in health services and outcomes?

Lessons learned from scaling up effective practices are described in a paper that differentiates horizontal or broad based scaling up from vertical scaling up. Vertical scaling up requires working at different system levels [24]. For instance, introducing mental health innovations among practitioners in primary care settings, putting in place supporting policies at provincial levels and incorporating innovations in accreditation programs. Each of these innovations and policies work at a different level within the health care system.

Scaling-up takes knowledge translation beyond the realm of individuals and organizations that are early adopters. This requires concerted efforts to normalize evidence-informed approaches and to create the system structures that will recognize, support and reward these approaches. As is the case for sustainability, scaling up considerations should be considered early in the process; indeed, KT interventions should not be undertaken without consideration of sustainability. Conditions that are critical for scaling up include adequate human capacity; and supportive financial, organizational, governance and regulatory structures [25, 26]. Decision-support tools, such as simulation modeling are needed to help estimate what will be required to scale up interventions across a broader range of contexts [27, 28]. Such tools could be used to aid the design of research and pilot interventions

that may be feasible. Without systematic ways to address the scalability of interventions when research is planned, we may end up with "proven" interventions that hold little or no potential for system sustainability due to their inherent scaling up limitations. For example, anti-retrovirals for the treatment of HIV and AIDS have demonstrated efficacy and effectiveness. But scaling up these regimens at a national level in lower-income countries has been challenging due, in part, to issues of human resource capacity within the health care system [28]. Within Canada, we have similar issues of scalability when considering differences between northern nursing stations and large academic teaching institutions.

What models exist for spreading and scaling up KT Strategies?

It is time to consider the boundaries of the knowledge to action process and think more on a population approach as well as an individual, organizational, and regional approach. If a health system does not "approve" of an organizational approach to the implementation and sustainability of evidence-informed innovations then sustained practice changes beyond specific funded research projects will be difficult on many levels. The science of spread is discussed in American NIH and AHRQ reports [6, 29, 30]. A position paper prepared for the New Zealand Ministry of Health describes an action plan for the spread of proven health innovations [31].

How should KT interventions be adapted and sustained?

Perhaps the most intriguing issue underlying sustainability is the nature of the complex adaptive systems into which innovations are placed [15, 32]. This makes sustainability inherently difficult to predict and also tells us that sustainability ultimately comes down to adaptability of both the innovation and the system [32]. Complex adaptive systems theory explains how dynamic and ongoing changes at one level of the system may eventually influence changes (both intended and unintended) at another system level [33]. Simply put, adaptation theory tells us that there are continuous dynamic change processes at work within each level of the system. Thus, even when an innovation is introduced at one system level, it invariably has the potential to impact on or to be influenced by factors at the same and other system levels. For example, introducing evidence-informed best practice guidelines for asthma management by nurses has implications for care provision by other members of the health care team. The changes that the other health care team members make to support or thwart this shift

in practice will influence whether or not these changes in nursing practice are sustained.

Over time, change processes at one system level may lead to change processes at the next system level. Continuing with our asthma example, changes at other system levels might include a shift in policies and procedures for asthma management, the inclusion of new practices in orientation sessions for new nursing staff, and changes in patient referral and follow-up procedures. However, if these sorts of structures at the next level do not fundamentally change to accommodate the innovation, practitioners will have a tendency to revert to the former ways of doing things, and implementation of the innovative practice may not be sustained. There are many inter-system factors that may support these changes. Notably, vertical social connections (e.g. nurses being formal members of organizational decision making committees) facilitate synergistic and multi-level adaptation processes. There are also factors that tend to maintain the status quo. These include power hierarchies among professional groups, institutionalized routines, and established governance structures that yield unequal benefits or burdens for one social group relative to another [33, 34].

Sustainability: not an all or nothing phenomenon

Monitoring systems and data feedback mechanisms are needed to determine relevant process and outcome factors to assess sustainability. While some relapse or reversion to previous practices is to be expected, a decision will be necessary to determine how much relapse is acceptable to claim that sustainability is achieved [35]. Sustainability assessment is not an all or nothing phenomenon. One Canadian research team describes four degrees of sustainability from absent, precarious, or weak to the ultimate sustainability level that involves routinization [36]. There are major limitations to assessing the extent of the sustainability of one specific evidence-based innovation because there are multi-level considerations and an ever-changing evidence base so that a fixed practice or routinization may not be what is best for all.

Future research

There remains much to be learned about the multi-faceted construct of sustainability in the knowledge to action process. We recommend the use of available definitions and theoretical models for sustainability, spread, and scaling up processes. Researchers need to be clear in their distinctions of underlying theories which may include generic knowledge translation models, specific sustainability models or other models such as those published

in the complex adaptive systems literature. In addition, there is a need for measures, building on the valuable work of the NHS sustainability diagnostic questionnaires and other tools [9, 35, 37–39], so that there is more consistency in measures used across studies allowing for more direct comparisons across diverse settings.

Tensions exist about whether to conduct small-scale innovations or to plan for scale up deliberately from the start [8]. Tensions also exist about whether to focus research on fidelity of the innovation and/or adaptation mechanisms. We recommend research related to the development and evaluation of interventions for scaling up frontline and organizational innovations that address inequities and emerging trends. There is a need for sustainability-oriented programs of research and not just isolated single knowledge to action projects. We also recommend the creation of networks of researchers and decision makers to work together over time to learn from evidence-informed system change successes and failures.

Summary

Sustaining knowledge use is an essential element of the knowledge to action process. While the knowledge to action framework visually depicts the sustainability phase after the evaluate outcomes phase, many authors, including those of the K2A cycle, advocate planning for sustainability as early as possible, such as when the interventions for knowledge use are being selected, tailored, and implemented. Sustainability and adaptation models are available to help with planning. Numerous potentially relevant factors have been documented in the literature. Six key factors are: health needs and expected benefits; effectiveness of the system to monitor progress; adaptability and alignment of the improved process; multi-level and collective leadership; financial and human resources; and community stakeholder support. These factors based on systematic reviews and our own experiential data are vital for thoughtful planning in order to continuously strive for better health for all and a better health care system, Sustainability, spread and scaling up need to be considered from a health care provider, interprofessional team, hospital/community, and health systems perspective.

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Subsection 3.7 **Case examples**

Chapter 3.7a **Ilustrating the knowledge to action cycle**

An integrated knowledge translation research approach in wound care

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Key learning points

- A planned action model can provide a useful framework to guide implementation.
- Knowledge to action requires meaningful collaboration between implementation researchers and those wanting to implement best practice.
- Implementation can be complex (e.g. requiring new allocations of practice responsibilities, redesign of service delivery models) and takes time and careful planning.
- Scoping the evidence to practice gap, adapting the knowledge to the context, assessing barriers to using the knowledge, selecting and tailoring interventions, monitoring knowledge use, and evaluating outcomes of implementation efforts contribute to sustainability.
- Methodological rigor must be balanced with timely, practical and doable approaches in the real world.

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Sharon E. Straus, Jacqueline Tetroe and Ian D. Graham.
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Table 3.7a.1 Description of the knowledge to action cycle

Knowledge to action cycle steps	Activities and data sources
Knowledge creation	
Knowledge inquiry	From as early as the second century a variety of wound care approaches particular to leg ulcers have been reported in the literature. Throughout the same period, the evidence for the effectiveness of compression therapy for venous leg ulcers mounted, although RCTs have only become common since the 1980s
Knowledge synthesis	The first meta-analysis of randomized controlled trials of compression bandages was released in the late 1990s (2;3)
Knowledge products and tools	Numerous clinical practice guidelines were developed around the world with varying levels of quality (4–8)
Action cycle	
Identifying the Problem	Initially, experiences of homecare managers revealed increasing costs for leg ulcer care. The team conducted a formal needs assessment using a mixed methods approach to produce local evidence about the problem. This involved undertaking a regional prevalence and profile study (9;10), an analysis of the gap between current practice and best practice (11), a systematic review of venous leg ulcer prevalence studies (12), an environmental scan of expenditures (13), knowledge-to-action gap analysis including a practice audit, and Knowledge, Attitudes and Practice (KAP) surveys of nurses and doctors (14;15)
Adapting knowledge to local context	Being aware of numerous international guidelines and not sure how to adapt them for local use, the team developed and refined the Practice Guidelines Evaluation and Adaptation Cycle to guide the process for adapting existing guideline to the local context (16–19)
Assessing barriers to knowledge use	The team conducted a proactive assessment of barriers and facilitators related to the guideline, potential adopters, and the practice environment using the Ottawa Model of Research Use (20;21) as a framework. Data for the assessment derived from the KAP surveys, feedback on the draft guideline from community nurses and family physicians, discussion with managers at the community nursing agency and home care authority
Selecting, tailoring and implementing interventions to promote knowledge use	Based on the identified barriers, a community leg ulcer service was developed to support implementation of the guideline. The intervention essentially consisted of the new service staffed with dedicated nurses with special training in leg ulcer care and the adapted guideline

Table 3.7a.1 *continued*

Knowledge to action cycle steps	Activities and data sources
Monitoring knowledge use	Chart audits undertaken pre- and post-guideline implementation were used to assess adherence to key elements of evidence-based leg ulcer care (12)
Evaluating outcomes	A pre-post-study design with multiple points of data collection was used to assess changes in healing rates, nursing visits, and supply costs (19). At the end of the project, the nurses on the leg ulcer service were also surveyed about their experiences participating in the project
Sustaining knowledge use	The leg ulcer service is now been operating since the early 2000s. The leg ulcer guideline protocol has been adopted in two other regions in the province with success. The team went on to conduct a randomized controlled trial of the benefits of home versus clinic (23) care and are currently conducting a 10 site randomized controlled trial of two compression technologies commonly used in community care (24)

In this chapter we present a case study of an implementation and research program to illustrate the elements of the Knowledge to Action Cycle to show how it can guide health system and practice change. The focus of the program was directed at increasing the application of evidence-based recommendations for community care of individuals with venous leg ulcers. Leg ulcers are a common, costly, and complex condition to care for and manage and represent a chronic, debilitating, and isolating condition [1]. Table 3.7a.1 presents the steps in the knowledge to action cycle and briefly describes how each were addressed.

Context for the case study

To close the gap between evidence and practice in the field of wound-care, managers and clinicians from the Ottawa Community Care Access Centre (OCCAC), and the then Ottawa Victorian Order of Nurses (now known as Carefor) and researchers from Queen's University (Kingston, Ontario), the University of Ottawa, partnered to implement a planned-action model for knowledge translation (KT), focusing on improving health outcomes (i.e. healing rates), and quality of life for individuals with leg ulcers. This collaborative interdisciplinary or integrated KT approach, born out of a community-researcher alliance, fostered a 7-year program of implementation and research [2].

Knowledge creation: a brief history of the evidence for compression therapy

As mentioned in Chapter 2.1, knowledge syntheses are often the base unit of implementation activities. In this case, meta-analyses of randomized controlled trials of compression technologies found that high compression bandages were more effective at healing venous leg ulcers than low compression bandages [3, 4] To varying degrees this evidence was subsequently used in creating the third generation of knowledge by producing practice guidelines for management of venous leg ulcers [5–9].

The action cycle

Identifying the Problem

In the late 1990s, based largely on their experience, regional home care managers in Ontario, Canada, voiced concern about supply costs, amount of nursing time, and frequency of visiting for clients with leg ulcers. Nursing time was becoming a scarce resource, and the regional health authority responsible for providing home care services had limited understanding of the leg ulcer population and outcomes of care at a regional level. They approached the researchers (MBH, IDG) for help.

An important element to the success of this program was the formation of an alliance between the researchers and clinicians (community nurses, specialist physicians including a vascular surgeon, a dermatologist, and a hematologist) with the health care decision makers at the regional health authority and community nursing agency to plan, design, and conduct a needs assessment on the regional level. Family physicians and home care nurses were also engaged via surveys. The assessment involved consideration of the patient population, the health care providers, and their scopes of practice, the practice environment and service delivery model, and gaps between the evidence about effective care and current practice. We used mixed methods to produce *local evidence* about the problem and conducted: a regional prevalence and profile study [10, 11], an analysis of the gap between current practice and best practice [12], a systematic review of venous leg ulcer prevalence studies [13], an environmental scan of expenditures [14], a knowledge-to-action gap analysis including a practice audit, and Knowledge, Attitudes and Practice (KAP) surveys of nurses and doctors [15, 16]. Many of these activities occurred simultaneously and took from 3 to 12 months to complete. These data provided important baseline and planning information about the current state of affairs in the region and where changes would be required to implement best practice.

The regional prevalence and profile study [10] and secondary analysis of these data [11] revealed important local information for planning the implementation. Three- quarters of the individuals with leg ulcers in the region were over 65 years of age. However the majority were independently mobile. Many (60%) suffered from four or more co-morbid conditions and nearly two-thirds were experiencing a recurrent venous ulcer (i.e. had reported having a previous ulcer that had healed). The ulcer problem was longstanding with 60% having their ulcer for over 6 months' duration while one-third of people had endured it for over a year. Some 40% of people had two or more ulcers. The practice audit revealed that etiology was identified on admission to home care in only half of the cases, and less than half of the patients were assessed appropriately with an Ankle Brachial Pressure measurement prior to receiving compression therapy. Most importantly it was found that only 40% of the individuals with venous disease were treated with compression therapy.

The environmental scan [14] concluded that an average of 19 *different* nurses saw any one client in a month. Some 40% of clients received visits daily or twice a day; thus the estimated cost for 192 cases or 4 weeks equaled $1.26 million in nursing and supply expenditures. The KAP surveys [15, 16] confirmed that home care nurses' knowledge about the evidence for effective care of venous leg ulcers was less than optimal but was greater than that of the family physicians in the region. It also revealed that nurses and physicians had positive attitudes about caring for people with leg ulcers and were enthusiastic about improving care.

Adapting knowledge to local context

To determine what the local protocol for caring for venous leg ulcers in the community should be, the homecare authority, researchers, and health care providers convened a regional task force to review existing practice guidelines. As many of the guidelines were from international bodies, the task force was sensitive to the need to adapt the existing guidelines to the local context. This took about a year to complete. They were also confronted with numerous guidelines from which to choose. During the project we developed and refined the Practice Guidelines Evaluation and Adaptation Cycle to guide the process for adapting existing guideline to the local context. Details about the cycle and its validation are reported elsewhere [1, 17–19]. The use of the Practice Guideline Evaluation and Adaptation Cycle assures that the local guideline for best practice has been derived using a rigorous process, the recommendations have been quality assessed, and are useful

and feasible to implement locally, have been properly endorsed, revised, and updated if necessary.

The task force developed a practice algorithm which condensed the local guidelines on one page for easy access by home care nurses [17]. Other tools developed for the nurses were paper based assessment and documentation tools. To streamline the assessment process and facilitate application of evidence-based care, documentation forms were revised to collect information about the etiology of the ulcer with venous symptoms and history on one side of the page and arterial symptomology on the other. This practical enhancement provided an amalgamation of important clinical data to support evidence-based decision making.

Assessing barriers to knowledge use

Despite having a well-tailored and evidence-informed local guideline, barriers to guideline use exist. A proactive assessment related to the guideline, potential adopters, and the practice environment may help identify barriers to the uptake of a guideline [20]. Using the Ottawa Model of Research Use [20, 21] as a framework to guide local barriers assessment, we directed attention to: assessing barriers and supports to the use of the guideline related to providers' perceptions of attributes of the guideline, aspects of the potential adopters and the practice environment.

A number of data sources were used to identify potential barriers to adoption of best practice: the KAP surveys, feedback on the draft guideline from community nurses and family physicians, and discussion with managers at the community nursing agency and home care authority. This work was largely funded by the regional health authority. The surveying took between 3 and 6 months to complete. Some of these potential barriers were identified during the needs assessment phase (see Table 3.7a.2). In summary, there was support to proceed with an evidence-based approach to care and service delivery; however, significant barriers were uncovered.

Selecting, tailoring, and implementing interventions to promote the use of the guideline

Once the team developed an understanding of potential impediments to using the best practice guideline, it selected or developed interventions to address these barriers (see Table 3.7a.2). For example, it was not feasible to provide individual additional training to each nurse on venous leg ulcer management. However as a group, continuing education was something the nursing organization was willing to support. With the researchers'

Table 3.7a.2 Identified barriers to use of the leg ulcer guideline and intervention selected to overcome the barriers

Data source	Identified barrier or support	Intervention
Potential issues related to the guideline		
The draft of the adapted guideline was sent for external review to a random sample of 96 family physicians, a focus group of home care nurses, and relevant health care administrators to judge potential acceptance of the guideline and to identify issues that might discourage its eventual use. Three international leg ulcer experts were also sent the guideline to assess whether the adaptation remained true to the original guideline use (16)	Some family physicians were not familiar with ultrasound doppler assessment of ankle brachial pressure and wanted to know where they could send patients for this	Messaging for family physicians was developed explaining that the leg ulcer service would provide the ABP assessments. The messaging also emphasized that the community nurses would be keeping the family physician informed of treatment plans and referrals to specialists
	Others were concerned that the application of the guideline by community nurses might mean that they would not be informed about their patients' care	
Adopter level		
Knowledge Attitudes, Practice survey of 170 community nurses and 348 family physicians (14;15)	Knowledge about the evidence of the effectiveness of compression therapy was very low for family physicians but somewhat better for community nurses	Providing the adapted leg ulcers guideline to family physicians and community nurses for feedback offered an opportunity to increase their knowledge about best practice for leg ulcer care

(continued)

Table 3.7a.2 *continued*

Data source	Identified barrier or support	Intervention
	Nurses lacked training in leg ulcer care including expertise with compression bandaging	The research team arranged for about a dozen nurses to obtain additional training in wound care in the form of a university level distance course from the UK. The instructors were flown in to provide in-person master classes at the beginning and end of the course
	Both nurses and family physicians held quite positive attitudes about caring for individuals with leg ulcers	Local training in performing doppler assessments and compression bandaging was also provided to the nurses
Organization level		
Discussions with home care managers, community nursing agency management and nurses, consultant physicians	The existing service delivery model had all community nurses providing wound care yet few nurses had specialized expertise required to deliver high compression	The service delivery for evidence-based leg ulcer care was redesigned. The home care authority decision makers along with the service providers and researchers established a working group to develop a service delivery model that would enable evidence-based practice. It involved developing and deploying a dedicated leg ulcer care team composed of nurses, providing care in either the home or a nurse-run clinic, and acquisition of the necessary equipment for care (e.g. hand-held dopplers). The project arranged for the nurses to take a distance

The existing remuneration arrangement between the nursing agency and home care authority did not support the required thorough patient assessment that would be necessary prior to initiating treatment

The existing referral process to specialists prevented nurses from directly contacting consultant physicians about specific patients

The documentation system did not facilitate collection of all relevant clinical data for evidence-informed decision making

graduate course from a UK university on care of leg ulcers and the instructors were flowing in to do master classes with the nurses on bandaging techniques

The research team negotiated with the home care authority to adjust time and reimbursement allowed for 1st visits to complete the necessary comprehensive assessments upon admission to the leg ulcer service.

Standing orders from the nursing agencies medical director were develop to permit nurses to contact specialists directly

Decision making tools were developed during the guideline adaptation process. These assessment, documentation tools, and care algorithm served as implementation interventions by being reminders to collect the necessary clinical information to process with the evidence-based decision tree

Table 3.7a.3 Comparison of the old and new services for wound care

Old model	New model
Referrals made to several nursing agencies on a rotational basis. Nurses providing care to patients worked in any of several agencies	Referral to a regional wound service run by one agency
Mixed staffing model (registered nurses and registered practical nurses)	All-registered nurse service, focused on wound care, trained in leg ulcer assessment and care
Centrally based manager responsible for leg ulcer group and all other cases in one geographic locale	Primary nurse service team: team reports to a practice-based, clinical leader who in addition to providing care, is responsible for orientation, continuing education, and quality control (Clinical Nurse Specialist function/Manager role)
Care based on individual physicians' orders	Care based on evidence-based protocol, individual physician orders were the exception
Consultations: nurses work through family physicians	Consultation: streamline links to specialist physicians for referral. Notification to family physicians of the referral
Initial assessment and follow-up variable. No specific timing but typically < 40 minutes	Standardized comprehensive, evidence-supported initial assessment and documentation 1–1.5 hour initial assessment, follow-up every 3 months for 1 year

contacts, the UK program was undertaken and the physicians involved provided opportunity for local hands-on assessment in their clinics. Use of the KAP data and the team's knowledge of the local physician group aided in selecting the best method of communication of the changes. A major intervention was the development of a community leg ulcer service with dedicated nurses with special training in leg ulcer care and the adaptation of a leg ulcer guideline [22]. Table 3.7a.3 describes the changes made to the delivery of community care.

Monitoring knowledge use (i.e. guideline recommendations adherence)

Once a guideline or protocol has been "implemented," it is vital for implementers to monitor its use to determine whether it is in fact being used, has been abandoned or reinvented. In our case, chart reviews of 66 clients over 9 months [12] indicated that documentation of ulcer etiology increased

from 53% to 100% following introduction of the local guideline, the proportion of patients having an Ankle Brachial Pressure Index measurement prior to initiating compression increased from 47% to 95%, record of serial ulcer measurement increased by 11% to 88%, compression bandage initiated for venous ulcers increased from 66% to 86%, and pain assessment documentation increased from 15% to 90%. The adapted guideline, nurse training, and organizational restructuring produced an overall increase in documentation, precision in assessments, and provision of evidence-based care.

Evaluating outcomes

The Knowledge to Action Cycle emphasizes the importance of evaluating outcomes that result from applying or using the evidence in practice. In this case, in addition to improving the quality of venous leg ulcer care, the implementation of the locally adapted guideline produced a considerable increase in healing rates. In the year prior to the implementation of the leg ulcer service the ulcer healing rate at 3 months was 23%, in the year following the launch of the leg ulcer service and implementation of the evidence-based care protocol, the 3 month healing rate was 56% ($p < 0.001$) [19]. During the same period, nursing visits decreased from a median of 3 (IQR $2–4.8) to 2.1 (IQR $1.6–2.4) per week ($p = 0.005$) and daily nursing visits decreased from 38% to 6% (Pearson X^2 test 60.1, $p < 0.001$). Supply costs also decreased from a median of $1923 (IQR $395–$1931) per case to a median $406 (IQR $219–$920) per case ($p = 0.005$) [1].

At the end of the project we surveyed the nurses on the leg ulcer service about their experiences participating in the project. In response to an open-ended question, a few indicated that participation in the project had generated their interest in participating in other research and one nurse disclosed that her involvement in the project had caused her to rethink her decision to retire early from nursing. Another outcome was nurses' and the home care authority's interest in participating in other studies of direct relevance to them, specifically, an evaluation of clinic versus home delivery of evidence based care and a trial to evaluate the effectiveness of two compression technologies.

Sustaining knowledge use

The leg ulcer service has now been operating since the early 2000s with continued positive results. Despite the success story, the sustainability of the leg ulcer service is an ongoing concern as is often the case in health care

delivery. In follow-up with the team leader, local data indicated that healing rates continue to improve with ∼30% healed by 30 days and 70% healed by the target of 84 days with venous leg ulcer population (personal communication K. Lorimer).

There have been indications of sustainability of knowledge use; the use of the adapted guideline was expanded to three other regions and successfully adopted in two of them. The team conducted a randomized controlled trial of the benefits of home versus clinic care [23] and a 10-site randomized controlled trial of two compression technologies commonly used in community care [24, 25]. Our original clinical and health services partners are involved in the research and participating as investigators. The research questions from these trials emanated from the initial evidence-based implementation reorganization.

Summary

Effective solutions for longstanding, complex health care issues are possible through integrated KT research focused on promoting knowledge to action. The iterative process of using external evidence and producing local "evidence" for planning, and using a planned action model to guide knowledge implementation grounds the approach for both successful implementation and improved outcomes. Our experience demonstrates that successful implementation requires strategic and collaborative alliances between researchers and the health setting, a foundation based on sound population health principles, needs-based (rather than organization based) planning, and working in tandem at both the practice and health services levels [26]. Working through the elements of the Action Cycle provides an implementation road map.

In this case, the results of undertaking integrated KT research resulted in more effective and less costly care than usual care. The quality of wound care provided in the region increased substantially. Scarce nursing resources were used more efficiently. More individuals were cared for with the same allocation of home care dollars. Because of the collaborative approach, the researchers played an integral role in bringing evidence to all the discussions and ensuring the process was rigorous, studying the change as a natural experiment, and at times facilitating implementation of the change. They were instrumental in creating and facilitating strategic alliances and solutions-focused collaborations due to their perceived "neutrality" as scientists. They brought the "science of synthesis" into practice, used rigorous methods for each step (organizational planning, guideline appraisal and adoption, evaluation of implementation), and a conceptual framework that

underpinned current and future research. The knowledge user partners contributed to the relationship by identifying the study issue, bringing their practice-based knowledge and experience to bear and actively participating in the research by providing human and financial sources. Most importantly, they applied the findings when they became available.

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Chapter 3.7b **Tips on implementation**

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Key learning points

- Knowledge Translation (KT) approaches must be adapted to the gap(s) in quality of care and the context.
- KT is a continuous and iterative process that involves reassessment of goals, barriers and facilitators, and implementation and sustainability strategies.

Introduction

Clinicians and health care managers face a barrage of demands, limited resources, and usually no additional funding to support change. They wonder when, if, and how they can follow the recommended actions for effecting behavior change. The aim of this chapter is to consider some of the aspects that might be considered the art of implementations and provide "tips" on moving through the phases of the Knowledge-to-Action cycle from the "real world" clinical perspective.

Where do we start?

"Don't miss good while waiting for perfect!" Be systematic and as rigorous as possible while being realistic and not missing "good." Clinical and administrative evidence-informed decisions must be made but we may not always need 95% certainty about the evidence. A policy analyst, asked how much certainty he needed for advice to the Minister, responded "anything better than 50/50 is good" (personal communication, September, 1999).

Evidence from multiple studies (even without strong designs) or national standards is usually better than ideas from a few colleagues.

Prepare Plans A, B, and C for implementation of evidence! Address each phase of the knowledge-to-action cycle and create a plan that is specific, and that identifies objectives and related activities, persons responsible, resources required, and timelines along with milestones. "Action-oriented" health care providers often think planning takes too much time. They often feel the pressure of time to "fix" an urgent problem and do not take time to plan prior to implementation. Without that investment, the change process often takes more time or fails. For example, in a large hospital, an inter-disciplinary working group assumed that implementing a new decision algorithm and practice change for treatment of hypoglycemia required only an education session. They stated there was no time to develop a formal plan to address, for example, the KTA framework phases. They mobilized resources and educated 90% of the more than 3000 nursing staff. One year later, practice had changed very little. Only the least experienced clinicians considered the protocol to be at all useful and planned to follow it only until they gained more experience! Consider the following ideas in your planning process:

- Include relevant stakeholders in your working group and set clear mandates for the initiative and the working group on which the team agrees. Stakeholders include those who will be affected by the change and whose input is required to effect the change. Implementation is not an individual endeavor. Designate a leader who will be the spokesperson and project manager.
- Pay attention to issues of language. Stakeholders may use the same word or terms differently. For example, the definition of "evidence" is not universal across disciplines. Kitson and Straus (Chapter 3.1) are clear that they are referring to "evidence" as "the best available research evidence." However, for others, the definition includes many types of knowledge such as patient preferences, clinical expertise [1, 2].
- Define clear goals and targets for your change. Setting "perfect" targets, such as 100% compliance with recommendations, may be essential in high risk situations such as medication administration. But, moving from a 0% to a 100% rate of the desired practice is unlikely in all situations [3, 4].
- Be specific about the goal of the change and what/how/when you will measure whether you achieve it (e.g. within 24 hours of admission, all patients will be assessed using the "X" scale for pressure ulcer risk.). In some situations, there may be established, and ideally, evidence-based, standards and indicators that will guide you (e.g. timing of administration of treatment for pneumonia after arrival at hospital; standards set by Accreditation Canada). Measure current practice and the gap between

that and your target. Assess barriers and facilitators to establish why that gap exists. It is tempting to "jump to the solution." Instead, ensure that the goals and targets for your change are established and that you have a good understanding of determinants of evidence uptake in your context before you move on to developing the implementation strategy.

- There are many possible approaches to stating goals and targets. One is the "PICO framework" (Population, Intervention, Comparison, Outcomes; Chapter 3.2). Harrison, *et al.* (Chapter 3.2) describe using PIPOH (Population, Intervention, Professionals/Patients, Outcomes, Health Care Setting) as a tool to consider more elements in a range of health care issues. Another approach is to set "*SMART*" goals and objectives [5]:
    - *S*pecific: Who, what, where?
    - *M*easureable: How will I know when it is accomplished? How will I measure?
    - *A*ttainable: Can the goal be accomplished?
    - *R*elevant: Does the goal matter? How much?
    - *T*ime-bound: When? What can be accomplished in a specific period?

How far can we go in adapting the knowledge to the local context?

Adapt recommendations to the local context. Be careful not to make decisions that violate the evidence but consider the "fit" of the recommendations within your setting. In this phase, you can continue assessing barriers and facilitators to implementation using a variety of strategies such as interviews, focus groups, surveys and workflow analysis as outlined in the next section. Many issues may influence decisions about "fit" and adaptation of the knowledge:

- Is the evidence from populations like your populations?
- Does your setting have the resources needed to implement the recommendations (e.g. time, enough skilled staff?)
- Which recommendations are "mandatory"? Which are "negotiable"?
  Revisit the adaptation issues in later phases of the implementation process, especially when unanticipated challenges arise. For example, a guideline recommends every 48-hour re-assessment of a hospitalized patient's risk for pressure ulcers. The recommendation is based on very low-quality evidence. Nurses involved with the proposed implementation questioned the recommended frequency and argued that such practice was not a good use of resources. Those reactions made clear that the uptake of any of the recommendations would be jeopardized by requiring automatic reassessments every 48 hours. The implementation working group created a protocol that did not include that recommendation

that was the source of concern. However, they used their education workshops, discussion of case situations during unit coaching visits, and reminder strategies to raise awareness of the types of changes in patient condition that should lead to re-assessment of risk. In short, they "did not miss good while waiting for perfect."

How do we organize an assessment of barriers and facilitators?

Your assessment of barriers and facilitators (Chapter 3.3) will guide your decisions. Finding barriers does not mean that the implementation of a practice change should stop. Rather, that knowledge can inform your choice of implementation strategies.

There is evidence of increased success when implementation strategies are tailored to address specific barriers or facilitators in the setting [6] or determinants of behavior change [7]. This assessment helps to set priorities about changes and select appropriate implementation interventions. Be alert to the following considerations:

- Individuals' perceptions/beliefs about evidence-based practice, the attributes of a practice, or the evidence to support changing practice vary across disciplines and may have an impact on willingness to adopt recommendations [8–10]. For example, despite evidence that nurses do not accurately predict which patients are at risk for pressure ulcers, they believe that their assessments *are* accurate and that they do not need a risk assessment tool [11]. Physicians may value the evidence base for any practice recommendations more highly than other disciplines [12, 13].
- Hidden practices that have developed over time but are not widely recognized beyond a single group or at a higher administrative level, and "urban myths" may be barriers to practice change or lead to incorrect assumptions. For instance, a team leading an initiative to improve the consistency of nurses' practices related to administering insulin to patients with diabetes according to a "sliding scale" undertook a barrier assessment. They discovered a longstanding "hidden practice" of doing the capillary blood glucose assessment up to 3 hours prior to the insulin administration. Another team trying to improve patient admission processes reported a "consensus" about a key barrier. However, more careful assessment revealed that only one person, who complained frequently, had created an "urban myth" about this proposed barrier to implementation.

- Identify "early adopters" and "laggards" [10]. In any situation, some people are more receptive to change than others and "early adopters" in one situation may be "resistors" or laggards in another. "Resistors" sometimes occupy 95% of your time! Try spending 95% of your time with those who are eager to adopt the change [14]. However, it is helpful to listen carefully to "resistors"; their concerns may lead to important implementation strategies.
- While doing assessments of the determinants of knowledge uptake, remember that you are not doing a research project or producing "generalizable" knowledge. Be systematic and use valid assessment approaches, but you need only enough data to make informed choices about implementation strategies in your context.
- Different assessment strategies may be appropriate for different contexts, professionals, or clinical issues. Use a prepared list of barriers and facilitators (Chapter 3.3). Some of the strategies that can work in a busy clinical setting include:
  - Brief surveys about perceptions of barriers/facilitators/motivators for current practice or the proposed change. For example, survey physicians after they have ordered a specific diagnostic test to indicate their reasons for ordering it [15].
  - Formal or informal interviews to elicit clinicians' views and brainstorming activities to generate perspectives.
  - Review of data from pre-existing databases (where they exist).
  - Have stakeholders "vote" on the most important barriers/facilitators or practice changes using a "dots" voting system.
  - Remember that each of these strategies have pros/cons; it is often helpful to use multiple strategies to assess barriers to uptake to determine the most important barriers.

How do we "connect" the phases and choose implementation strategies?

As you plan your implementation strategies for a specific practice change, consider the sustainability of your strategies and of the practice changes. A plan that requires significant resources (e.g. multiple "experts") to mobilize the interventions may be considered a "boutique" intervention and result in "evaporation" of the practice change because those resources cannot be sustained.

"Connect" the components of your planning process by creating a table to provide a clear picture of the problem, current state of practice, its indicators and how they are measured (what are the markers

of "success"?), specific targets or objectives, key barriers and facilitators and related implementation strategies. Again, "don't miss good while waiting for perfect." You will almost always encounter limitations of time, finances and resistance. Keep your plan as simple and pragmatic as possible. Consider interventions that will enable clinicians to embed the practice in their routines.

Tailor the implementation strategies to your setting. This will require creativity and attention to the barriers and facilitators. Take care to use the best available evidence. Sometimes teams "brainstorm" solutions (a specific change in practice) for practice problems without considering the available evidence about those solutions or effective implementation strategies [16]. This may result in wasted time and ineffective practices. For example, a group of clinicians decided to "brainstorm" to find a solution to increase the frequency of pain assessments performed with patients. They spent time developing a new "pain scale" without consulting the evidence or local experts beyond their own work area. However, their time was wasted because there was evidence that the type of approach they proposed is ineffective. In another situation, a team decided to develop a "discharge checklist" to assist them in preparing a patient for discharge from hospital. They did not consult the literature and missed important information about checklists that have already been developed and tested elsewhere. Ideas that emerge from "brainstorming" may already have been tested in a number of areas – teams should take time to assess the quality of the evidence about them and whether there are effective implementation strategies rather than using resources to recreate tools and strategies.

Two frequent implementation strategies in health care are creating evidence-informed policies/protocols and "educating" the clinicians. There is some moderate-quality evidence that policies/protocols result in sustained guideline implementation [17] and that clinicians use policies/protocols, *provided* they know about them and believe they are appropriate [18]. For example, during a discussion about the evidence base for a hospital's policy about a particular practice, only one person knew the policy existed; no others believed the evidence. All too often, educational strategies (Chapter 3.4b) may waste time because they do not focus on the real barrier to practice change. Strategies that address knowledge are useful only if lack of knowledge is the barrier! There is evidence, for example, that, even when nurses' have good knowledge about pain care, other factors influence their performance of the related practices [19].

Match evidence-based implementation strategies with specific barriers/ facilitators in your context (Chapter 3.3b). For example:

- *Barrier:* information overload, "forgetting."
  - *Intervention: implementing reminders* (e.g. leaders regularly issue reminders or reminders are sent electronically as part of a computerized decision support or prescriber order entry system).
- *Barrier:* lack of awareness of current performance.
  - *Intervention: embedding audit and feedback* (e.g. audit the practice, communicate results, and discuss actions for change).
- *Barrier:* habit - some "entrenched" practices may be related to "automatically activated habits" [20].
  - *Intervention*: c*reating "disturbances"* or contextual changes that disrupt routines and create new habits such as by introducing visual reminders or new levels of monitoring that cause a disruption and redirect the clinician toward the desired habit [20].
- *Barrier:* lack of (and resistance to purchase) required equipment.
  - *Intervention*: *submitting a business case* to persuade management of the need for the equipment. Brief statements about what the change (that will result from using the new equipment) will accomplish can highlight issues that "matter" to people with budget responsibility. For example, a business case for falls prevention equipment revealed fewer falls injuries would "produce" a net saving by year two. When the equipment arrived, the clinicians felt "the administration" had paid attention and signaled that prevention was "important."
- *Barrier:* lack of leadership engagement. Leaders need to support implementation work and create a culture that supports change and innovation [15, 16, 21].
  - *Intervention*: *create strategies* to help formal leaders to be visible and active in ways that do not take excessive time (e.g. using language or asking questions to provide reminders and communicate clear expectations) [16, 21].
  - *Intervention*: *identifying* and engaging opinion leaders (i.e. staff influencing team members) [22], champions (key local people supporting proposed changes, disseminating information to other staff, etc.) [9], knowledge brokers or change agents [23].
  - *Intervention*: *engaging* formal facilitators (educators, practice developers) [24, 25].

What if the implementation plan does not work?

Moving the plan into action is challenging. Despite great efforts, early results may reveal new barriers (e.g. the practice is more difficult to learn than anticipated) or facilitators (e.g. the practitioners quickly recognize the

benefits and adopt the new practice). In such cases, you may need to move to Plan B or C!

Start small and "test" your strategies. With small "trials" you can assess what works, discard some strategies, and mobilize others. Be practical, action oriented, and, at first, focus on the individuals who want to try the practice change. One approach to make the change process more manageable is to engage in "small tests of change" and rapid cycle improvements using PDSA (Plan Do Study Act) cycles [26]. You can do a cycle, reassess, modify, and try again with frequent cycles within just a few days. Always consider the evidence base for both the practice changes and implementation strategies.

As you spread the change to more clinicians, consider whether and how you will modify your plan for a wider practice area. Some useful "tips" include:

- *Be flexible*. You may discover that, in your setting, the strategies are not effective and need modification.
- *Change takes time*. Set firm timelines – avoid setting timelines that take many months or years unless that is appropriate for the project (such as looking at sustained impact of an intervention); make modifications to the interventions when appropriate, using the data you are collecting as a guide.
- *Monitor and evaluate changes* during and after the implementation process.
- *Don't get discouraged*. Consider lessons learned from things that were and were not successful.
- *Get patients/families/informal caregivers engaged* in designing and promoting the change [27].

We have taken actions to select, tailor and implement change strategies: Now what?

Keep the specific goals, targets and measures in view! Your early decisions and baseline measurements now provide direction for monitoring the knowledge use (what change happened?) and the outcomes (did you get the expected/targeted patient results?) Some implementation strategies may help you monitor your outcomes. The "audit and feedback" intervention can inform clinicians about their practice/patient indicators and provide you with "outcomes data." A recent review [28] found that feedback may be more effective when certain components, including verbal and written formats and provision of clear targets, and an action plan, are present. The Institute of Healthcare Improvement recommends that graphic

representation of change over time with such approaches as run charts helps clinicians understand the data and provides information about patterns of change (www.IHI.com/knowledge/pages/howtoimprove, accessed September 2012). Choose your monitoring strategy carefully to match your resources and to use what will be sustainable. Be sure to look for unintended consequences or impacts of the change (positive and negative) and when necessary address the negative impacts.

There are reports of "improvement evaporation" in up to 70% of change initiatives [29–31]. Ovretveit [32] states that the challenge is not starting, but continuing after the initial enthusiasm has diminished. Plan early for sustaining changes. Consider which of the factors that may influence sustainability (Chapter 3.6) are most crucial. Some specific strategies to consider when planning for sustainability include:

- Be careful about the language you use from the beginning (e.g. using the term "project" conveys that the work is meant to be short-term; referring to the practice change work as a "program" conveys something more permanent).
- Repeated, routine assessments remind clinicians that the practice is still important.
- Plan for competing priorities and rapid pace of introduction of new equipment, care challenges, and other practice changes in the clinical environment. Can some new practices be "bundled" to decrease the perception of multiple, disconnected changes?

Finally, remember that the knowledge to action cycle is . . . a cycle! It does not follow a tidy, linear process, and each phase informs others.

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Section 4   Theories and Models of Knowledge to Action

Chapter 4.1 **Planned action theories**

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Key learning points

- Data on the validity and transferability of planned action theories are limited.
- Using a planned action theory can focus implementation efforts and provide all stakeholders with a common script or understanding of the action plan.

There has been growing focus on moving research into practice in recent years and alongside, interest in theories of knowledge implementation has been increasing. For example, the idea of using conceptual models to help nurses implement research evidence gained strength in the 1970s and 1980s when a number of models were tried [1–3]. Conceptual models of implementing knowledge are essentially models or theories of change. Change theories fall into two basic kinds: classical and planned [4]. Classical theories of change (sometimes referred to as descriptive or normative theories) are passive; they explain or describe how change occurs. An example of a classical theory of change is Rogers' diffusion theory [5, 6] or Kuhn's [7] conceptualization of scientific revolutions. These theories describe change but were not specifically designed to be used to cause or guide change in practice. Other implementation theories falling within this category are the models that have been proposed as ways of thinking about or researching knowledge translation such as Lomas' Coordinated Implementation Model [8, 9].While classical theories of change can be quite informative and helpful for identifying the determinants of change, researchers, policy makers, and change agents tend to be more interested in planned change theories that are specifically intended to be used to guide or cause change [4].

A planned change theory is a set of logically interrelated concepts that explain, in a systematic way, the means by which planned change occurs, that predict how various forces in an environment will react in specified change situations, and that help planners or change agents control variables that increase or decrease the likelihood of the occurrence of change [10, 11]. Planned change, in this context, refers to deliberately engineering change that occurs in groups that vary in size and setting. Planned change theories are also referred to as prescriptive theories [4]. Those who use planned change theories may work with individuals, but their objective is to alter ways of doing things in social systems. This chapter describes our review and analysis of planned action models.

We undertook a focused literature search of the social science, education, management, and health sciences literature which has been documented elsewhere [12]. All searches were restricted to literature published in English or French. The literature search yielded 78 articles that were subject to data abstraction by two reviewers. This involved abstracting the key or core concepts of each model/theory, determining the action phases, and deciding whether each fit the inclusion/exclusion criteria around the planned action theory/model/framework.

Thirty-one planned action theories (see Box 4.1.1) were identified and subjected to a "theory analysis," which is a useful process for determining the strengths and limitations of theories and to determine similarities and

Box 4.1.1 List of planned action theories in the database

Ashford J, Eccles M, Bond S, Hall LA, Bond J. Improving health care through professional behaviour change: introducing a framework for identifying behaviour change strategies. *British Journal of Clinical Governance* 1999; 4(1): 14–23.

How: Information was sought from books, articles, and "grey literature." Prominent current researchers in different areas relating to change were also approached for their advice regarding relevant texts, reviews, and articles. Searches were made in several disciplinary databases including social science, psychology, and education. Articles were included if their context was pertinent to change in health care.

Bartholomew LK, Parcel GS, Kok G, Gottlieb NH. *Intervention mapping: designing theory and evidence-based health promotion programs.* Montain View: Mayfield Publishing Company, 2001.

How: N/A

Benefield LE. Implementing evidence-based practice in home care. *Home Healthc Nurse* 2003; 21(12): 804–9.

How: N/A

Craik J, Rappolt S. Theory of research utilization enhancement: a model for occupational therapy. *Can J Occup Ther* 2003; 70(5): 266–75.

How: The conceptual foundation of this study builds upon the theoretical stages of research utilization presented by Knott and Wildavsky 1980 (Knott J, Wildavsky A. If dissemination is the solution, what is the problem? Knowledge, Creation, Diffusion, Utilization 1980; 1(4): 537–78). The model of research utilization in occupational therapy builds upon the existing theoretical concepts and stages of clinical-decision making as outlined in the occupational performance process model by Fearing et al., 1997 (Fearing G, Law M, Clark J. An occupational performance process model: fostering client and therapist alliances. Canadian Journal of Occupational Therapy 1997; 64(1): 7–15) and the stages of research utilization by Knott and Wildavsky (1980).

Dearing J. Improving the state of health programming by using diffusion theory. *Journal of Health Communication* 2004; 9: 21–36.

How: Draws on Diffusion of innovations by Rogers 1983 (Rogers EM. Diffusion of innovations. New York: Free Press, 1983), especially concepts of attributes, opinion leadership, and clustering, in order to create steps for planned diffusion.

DiCenso A, Virani T, Bajnok I, Borycki E, Davies B, Graham I, *et al.* A toolkit to facilitate the implementation of clinical practice guidelines in health care settings. *Hosp Q* 2002; 5(3): 55–60.

How: Over 8 month period, panel reviewed and critiqued research on dissemination, transfer, uptake of clinical practice guidelines

Dixon DR. The behavioral side of information technology. *Int J Med Inform* 1999; 56(1–3): 117–23.

How: N/A

Doyle DM, Dauterive R, Chuang KH, Ellrodt AG. Translating evidence into prac-
tice: pursuing perfection in pneumococcal vaccination in a rural community.
Respir Care 2001; 46(11): 1258–72.

*How: References a British survey on GP's perceptions of the route to EBP which
influenced the authors' perception of the need for behavioral methods to overcome
real/ perceived barriers.*

Tracy S, Dufault M. Testing a collaborative research utilization model to trans-
late best practices in pain management. *Worldviews on Evidence-based Nursing*
2004; 1(S1): S26–S32.

*How: Based on Rogers (1983) Diffusion of innovation theory, and Havelock and
Havelock (1973) (Havelock RG, Havelock MC. Training for change agents:
a guide to the design of training programs in education and other fields.
Chicago: Center for Research on Utilization of Scientific Knowledge, University of
Michigan, 1973).*

Feifer C, Ornstein SM. Strategies for increasing adherence to clinical guidelines
and improving patient outcomes in small primary care practices. *Joint Commis-
sion Journal on Quality & Safety* 2004; 30(8): 432–41.

*How: During the PPRNet-TRIP study, practices experimented with new approaches
to practice operations and care delivery. Documented the activities and structures
that emerged in each practice as part of the trial's process evaluation. One aim of
this evaluation was to develop a model of improvement strategies that might serve
as an example for others. Used grounded theory – an analysis style that yields cate-
gories and theories grounded in a given social situation – to develop the PPRNet-
TRIP Improvement Model from qualitative data gathered in 10 intervention group.*

Fooks C, Cooper J, Bhatia V. *Making research transfer work: summary report from
the 1st National Workshop on Research Transfer Issues, Methods and Experiences.*
Toronto: ICES, IWH, CHEPA, 1997 Feb.

*How: In the fall of 1996, staff at three Ontario based research organizations felt a
workshop to address the issues and experiences of research transfer in Canada
might be of some benefit to those in the field. "We had four questions in mind–
what is research transfer, who is doing it and if so, how?"*

Graham ID, Logan J. Innovations in knowledge transfer and continuity of care.
Can J Nurs Res 2004; 36(2): 89–103.

*How: Adaptation of model published in Science Communication 1998; 20(2):
227–46: "Toward a comprehensive interdisciplinary model of health care research
use." Elements are primarily drawn from the literature related to research utiliza-
tion, the diffusion of innovations, physician behavior change, and the development
and implementation of practice guidelines (1998). The OMRU was refined through
discussions with participants in workshops we conducted for the Ontario Health
Care Evaluation Network, conference presentations, and clinical education rounds
(1998). Derived from theories of change, from the literature, and from a process of
reflection. Captures characteristics and important social factors related to
Donabedian's (1988) germinal work, but not explicitly linked (2004).*

Green LW, Kreuter MW. Health promotion planning: an educational and eco-logical approach, 3rd edn. Mountain View: Mayfield Publishing Company, 1999.

How: Built on Andersen's model of family use of health services and original work on use of family-planning services, hypertension, and asthma self-management. Later work in community health promotion grants and health services

Grol R, Grimshaw J. Evidence-based implementation of evidence-based medi-cine. *Joint Commission Journal on Quality Improvement* 1999; 25(10): 135–40.

How: In this article, propose a general framework for changing practice, based on theoretical approaches for translating evidence into clinical practice and on empiri-cal evidence about the effectiveness of different implementation strategies (1999). Reviews theoretical approaches to change and integrates these into a framework for changing clinical practice

Grol R, Wensing M. What drives change? Barriers to and incentives for achiev-ing evidence-based practice. *Med J Aust* 2004; 180(6 Suppl): S57–S60.

How: Integrating various stages of change theories, we have compiled a 10-step model for inducing change in professional behavior.

Herie M, Martin GW. Knowledge diffusion in social work: a new approach to bridging the gap. *Soc Work* 2002; 47(1): 85–95.

How: The project integrated theory and research in knowledge diffusion and social marketing to develop a dissemination model for moving these clinical tools and techniques into the direct practice arena.

Hickey M. The role of the clinical nurse specialist in the research utilization pro-cess. *Clinical Nurse Specialist* 1990; 4(2): 93–6.

How: N/A

Hyde PS, Falls K, Morris JA, Schoenwald SK. *Turning knowledge into practice*. Boston: Technical Assistance Collaborative Inc., 2003.

How: There are substantial bodies of knowledge underlying this manual: the clini-cal interventions or practices themselves, the process and structure of change man-agement, and the increasingly complex issues of financing services and supports for people with disabilities. To develop practical help to clinicians and administrators in provider organizations.

Kraft JM, Mezoff JS, Sogolow ED, Neumann MS, Thomas PA. A technology transfer model for effective HIV/AIDS interventions: science and practice. *AIDS Educ Prev* 2000; 12(5 Suppl): 7–20.

How: Starting with a review of diffusion of innovations and technology transfer literature, we offer a technology transfer model for HIV interventions. We identify participants and activities directed toward the use of effective interventions by prevention services providers (e.g. health departments and community-based organizations) in each phase of technology transfer. To identify potential ele-ments for the model, we reviewed the literature, developed a draft model, and sought feedback from prevention services providers and researchers.

Lavis JN, Robertson D, Woodside JM, McLeod CB, Abelson J. How can research organizations more effectively transfer research knowledge to decision makers? *Milbank Q* 2003; 81(2): 221–2.

How: We conducted a qualitative review of both systematic reviews and original studies across the five questions, four target audiences and full range of disciplinary perspectives and methodological approaches. Surveyed directors of applied health and economic/social research organizations regarding how their organizations transfer research knowledge to decision makers.

Lundquist G. A rich vision of technology transfer: technology value management. *Journal of Technology Transfer* 2003; 28: 265–84.

How: By addressing 7 distinct lines of description/questions: why?, who?, where?, when?, what?, at what cost?, and how? (Lundquist comments: The 7 sections simplify content for readers. The real key is that the authors start with the core definitions, then put those concepts into context of a multi-faceted view of technology transfer.

Motwani J, Sower VE, Brashier LW. Implementing TQM in the health care sector. *Health Care Manage Rev* 1996; 21(1): 73–82.

How: N/A

Moulding NT, Silagy CA, Weller DP. A framework for effective management of change in clinical practice: dissemination and implementation of clinical practice guidelines.

Qual Health Care 1999; 8: 177–83.

How: Draws on social and behavior theory, diffusion of innovation theory, transtheoretical model of behavior change, health education theory, social influence theory, social ecology theory

National Health and Medical Research Council. *How to put the evidence into practice: implementation and dissemination strategies*. Canberra: Commonwealth of Australia: National Health and Medical Research Council, 2000.

How: Developed by a multi-disciplinary committee and approved by the NHMRC.

Pape TM. Evidence-based nursing practice: to infinity and beyond. *J Contin Educ Nurs* 2003; 34(4): 154–61.

How: N/A

Proctor EK. Leverage points for the implementation of evidence-based practice. *Brief Treatment and Crisis Intervention* 2004; 4(3): 227–42.

How: Drawing on literatures on knowledge diffusion, innovation, and quality improvement, this paper proposes a conceptual framework for the multiple tasks, participants, and leverage points required for the adoption of EBP.

Roberts-Gray C, Gray T. Implementing innovations: a model to bridge the gap between diffusion and utilization. *Knowledge: Creation, Diffusion, Utilization* 1983; 5(2): 213–32.

How: Assembled around 5 essential elements of programmed implementation. Parts based on Lewin's theory of social change (1947)

Rosswurm MA, Larrabee JH. A model for change to evidence-based practice. *Image J Nurs Sch* 1999; 31(4): 317–22.

How: The model is based on theoretical and research literature related to evidence-based practice, research utilization, standardized language, and change theory. The authors developed and tested the usefulness of the model as they mentored nurses in defining and integrating evidence-based practice protocols at a regional medical center.

Simmons R, Brown J, Diaz M. Facilitating large-scale transitions to quality of care: an idea whose time has come. *Stud Fam Plann* 2002; 33(1): 61–75.

How: Review of literature (social science, family planning, political science, reproductive health, policy and organizational sciences) 61–62, 66

Stetler C. Updating the Stetler Model of research use to facilitate evidence-based practice. *Nursing Outlook* 2003; 49: 272–9.

How: First developed in 1976 with Marram as a pragmatic tool to fill a void re how to go from a traditional research critique to application. The model was refined in 1994 with conceptual underpinnings and a set of assumptions... plus additional detail related to critical thinking based on current science re knowledge and research utilization plus review of and experience of CNS's with the model. And then in 2001... the model has been further refined on the basis of a related utilization-focused integrative review methodology, targeted evidence concepts, and continuing experience through use of the model with, primarily but not exclusively, clinical nurse specialists.

Titler MG, Kleiber C, Steelman V, Goode C, Rakel B, Barry-Walker J, *et al.* Infusing research into practice to promote quality care. *Nurs Res* 1994; 43(5): 307–13.

How: Outgrowth of the Quality Assurance Model Using Research

differences. The steps in a theory analysis [13] are to: (a) determine the origins of the theory (i.e. Who developed it? Where are they from? What prompted the originator to develop it? Is it inductive or deductive in form? Is there evidence to support or refute the development of the theory?), (b) examine the meaning of the theory (what are the concepts and how they relate to each other?), (c) analyze the logical consistency of the theory (Are there any logical fallacies?), (d) define the degree of generalizability and parsimony of the theory, (e) determine the testability of the theory, and (f) determine the usefulness of the theory. The complete categorization and synthesis of the theories is available at http://www.iceberg-grebeci.ohri. ca/research/kt_theories_db.html. Accessed September 2012.

The 31 theories identified in our search were published between 1983 and 2006. Of these, 16 were interdisciplinary, 6 were from nursing, 2 were from medicine, 2 from social work, and one each were from HIV/AIDS prevention

occupational therapy, family planning, health education and health informatics literature. The intended foci for these theories were: health care, social work, and management. The theories were most commonly derived from the literature, followed by research, or the experience of the originators. Most (21/31) of the identified theories have not yet been tested empirically. The model by Graham and Logan [14] has demonstrated face and content validity in unpublished studies and implementation projects, as has Green's model [15], which was used to conduct systematic baseline-diagnostic interviews with asthma patients treated in the emergency room or as out-patients [16].

We examined all of the components in each of the theories in order to determine commonalities and to develop a framework to compare the focus of each. This exercise resulted in ten action phases with some phases having sub actions (see Table 4.1.1). Each theory was analyzed as to whether or not it addressed each action category. Planned action theories generally outline the following phases to deliberately engineer change (n = the number of models that include that particular phase):

1 Identify a problem that needs addressing (n = 19)
   - Identify the need for change (n = 22)
   - Identify change agents (i.e. the necessary participants to bring about the change) (n = 15)
   - Identify target audience (n = 13)
   - Link to appropriate individuals or groups who have vested interests in the project (n = 15)
2 Review the evidence or the literature (n = 21)
3 Adapt the evidence and/or develop the innovation (n = 11)
4 Assess barriers to using the knowledge (n = 18)
5 Select and tailor interventions to promote the use of the knowledge (n = 26)
6 Implement the innovation(n = 22)
7 Develop a plan to evaluate use of the knowledge (n = 14)
   - Pilot test (n = 11)
   - Evaluate the process to determine whether and how the innovation is used(n = 19)
8 Evaluate the outcomes or impact of the innovation (n = 20)
9 Maintain change: sustain ongoing knowledge use (n = 11)
10 Disseminate results of the implementation process. (n = 7)

No theory included all of the action phases and no action phase was included in all of the theories. Some theories focus more on evaluation, while others focused on identification of the problem and their barriers to implementation. In choosing a planned action theory to guide implementation efforts, we would advise careful review of the component elements and

Table 4.1.1 Elements of planned action theories

	Ashford	Bartholomew	Benefield	Craik	Dearing	DiCenso/RNAO	Dixon	Dufault	Doyle	Feifer	Fooks	Graham/Logan	Green	Grol/Grimshaw	Grol/Wensing	Herie	Hickey	Hyde	Kraft	Lavis 2003	Lundquist	Motwani	Moulding	NHMRC	Pape	Proctor	Rosswurm	Simmons	Stetler	Titler	**Total / 30**
Identify problem	x		x	x	x	x			x	x		x	x	x			x	x	x		x				x	x			x	X	**19**
Identify need for change	x	x	x	x	x				x	x	x	x	x		x	x	x			x	x	x	x		x	x	x	x	x	X	**22**
Identify change agents	x				x			x	x	x	x					x	x	x	x	x	x	x			x		x			X	**15**
Identify target audience	x		x	x					x	x		x			x		x	x		x	x				x		x		x		**13**
Link(age)		x			x	x		x		x	x			x	x	x	x	x	x						x		x		x		**15**
Review evidence/literature	x		x	x	x	x		x	x	x		x		x		x	x	x	x	x	x				x	x	x	x		X	**21**
Adapt/	x		x		x			x		x		x		x							x				x			x	x	X	**11**
Assess barriers			x			x	x	x	x		x	x	x	x			x	x	x		x	x		x	x	x			x	x	**18**
Tailor/develop intervention		x	x	x	x			x	x	x	x	x		x	x	x	x	x	x		x	x	x	x	x	x	x	x		X	**26**
Implement			x			x	x	x		x	x	x	x	x	x	x	x	x	x	x	x			x	x	x			x	X	**22**
Develop evaluation plan	x	x			x			x		x			x				x	x			x		x	x	x				x	X	**14**
Pilot test		x			x			x	x	x				x	x	x	x	x			x								x	X	**11**
Evaluate the process	x			x	x			x			x	x	x				x	x	x	x	x			x	x	x	x	x		X	**19**
Evaluate outcomes	x		x		x		x	x		x	x	x					x	x	x	x	x	x	x	x	x	x			x	X	**20**
Maintain change			x			x	x		x		x			x	x			x									x	x	x		**11**
Disseminate			x					x						x	x												x	x		X	**7**
Total no. of elements: 16	7	5	10	5	9	12	3	10	9	7	11	11	6	8	7	8	11	12	11	8	10	7	4	14	9	7	10	9	12	12	

how they have been coded into action categories and determine which theory is the best fit for the context and culture in which individuals are working. Regardless of the selected theory (or whether we choose to use the list of action categories as a kind of "meta-theory" along the lines of the Knowledge to Action Framework [17, 18]) documenting experiences with the model will advance understanding of its use and provide information to others who are attempting a similar project.

Future research

An important area for research in the coming years will be to empirically test planned action theories. More research is also needed to determine if there are advantages of using one theory over another.

Summary

We believe that theory driven implementation will further the study of knowledge translation by providing a framework in which we can understand the change process and see which implementation components were successful and which were not. At each action category of the knowledge to action cycle, there may be a host of theories from multiple disciplines that can be drawn on when planning to move knowledge into action.

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Chapter 4.2 **Cognitive psychology theories of change in provider behavior**

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Key learning points

- Cognitive psychology theories related to motivation, action, stages of change, and decision making have been influential in the field of knowledge translation.
- These theories provide a framework for examining, measuring, and understanding research use behavior.
- According to cognitive psychology theories, interventions designed to influence individual cognitive characteristics can be used to mediate/moderate individual behavior.
- A limited but growing body of empirical evidence exists to validate the theoretical assumptions of cognitive psychology theories.

Cognitive psychology theories have predominantly been used to examine and understand the determinants of health-related behaviors of the *individual*, and in particular the role of cognitive factors in predicting behaviors such as smoking, exercise, eating habits, and vaccination adoption. These theories have the potential to aid understanding of and predict the use of research. As such, some KT scholars have applied these theories to inform research design and to guide intervention development to influence adoption of research evidence in practice. Like health-related behaviors, health professionals' research-use behavior is considered to be, in part, within the

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individual's control. Furthermore, social cognitive factors, including beliefs, attitudes, and knowledge, are considered to be more amenable to change than factors such as personality. These features underlie the premise that interventions designed to influence individual cognitive characteristics can be used to mediate/moderate individual behavior [1].

Theories related to *motivation*, such as social cognitive theory [2], and the theory of planned behavior [3]; theories related to *action*, such as implementation intentions theory [4] and the theory of operant conditioning [5]; and theories related to *stages of change*, such as the transtheoretical model of change [6] have been influential in the field of KT. Such theories offer frameworks for examining and understanding determinants of behavior and potential mechanisms to promote behavior change. Most of these theories assume that individuals make rational decisions based upon systematic analysis of the information available to them [1]. Failure to consider external factors and the social construction of knowledge are potential limitations of these theories. A brief description of the aforementioned theories and their application to KT follows.

Theories related to motivation

According to motivational theories, behavior is determined and, therefore, predicted by motivation. Two theories in this area are examined. First, social cognitive theory [2, 7] assumes that behavior is determined by incentives and expectations related to situation-outcomes (beliefs about anticipated consequences if the individual abstains from the respective behavior); action-outcomes (beliefs about the likelihood of certain outcomes occurring as a result of the behavior); and perceived self-efficacy (beliefs about the extent to which the behavior is within the individual's control). Bandura [2, 7] hypothesizes that four sources of information influence self-efficacy and expectations: performance accomplishments, vicarious experience, verbal persuasion, and physiological feedback. Performance accomplishment is the most influential information source and results from personal or professional experience, for example, acquisition of the necessary skills to conduct a physical examination. Vicarious experience arises from observing the behavior of, and outcomes achieved by, others such as mentors, role models or opinion leaders. Verbal persuasion includes nurturing individuals' self-confidence in their ability to accomplish a specific behavior and persuading them of the benefits of that behavior. This could be achieved through academic detailing and continuing education (see Chapter 3.4). For health professionals interested in translating knowledge into practice, physiological

feedback resulting from a particular behavior is the least relevant of Bandura's sources of information.

Second, according to the theory of planned behavior [3], the determinants and, therefore, potential predictors of behavior are the *intention to engage in*, and *perceived control over*, the behavior. Intention is a function of *attitudes* towards the behavior, *subjective norms* (beliefs about the opinions of others with respect to the behavior), and *behavioral control* (perceived ease of engagement in the behavior). Attitudes are determined by perceptions of the consequences of the behavior. Subjective norms are based on normative beliefs, that is, perceptions of the preferences of others for the individual to adopt the specific behavior. Consideration of normative beliefs is balanced against the individual's desire to comply with the perceived expectations of the group. An individual's behavior may be influenced by patients, managers, and other members of the multidisciplinary team, including those who are persuasive, respected, or in positions of power. Behavioral control, a construct derived from the notion of self-efficacy in social cognitive theory, is influenced by perceived access to resources and opportunities to engage in the behavior, balanced by the capacity of each of these to enable or impede the behavior. Behavioral control includes factors such as time, the existence of necessary equipment or staff, or patient preferences, all of which may influence the course of action pursued by a health professional.

The theory of planned behavior has been employed in a number of studies to predict health professionals' behavior with respect to the uptake of specific research evidence [8, 9]. The demonstrated predictive power of the constructs – attitudes, subjective norms, and behavioral control – offers some evidence for their value in informing the development of interventions to influence behavior [8, 10]. In general populations, intention to act has been identified as one of the most important determinants of behavior [11–13]. In the case of clinical practice guideline implementation, for example, an education intervention may be designed to address negative attitudes towards the guidelines. In the case of limited perceived behavioral control, academic detailing might be implemented to enhance confidence in skills, and/or constraints identified within the environment may be removed to promote the guideline uptake. The theory of planned behavior and social cognitive theory have been successfully used to guide development of interventions to influence primary care physicians' antibiotic prescribing behavior for patients presenting with sore throats [14,15]. Further, the theory of planned behavior has been used to guide a process evaluation within a randomized trial of knowledge translation strategies. Test-requesting behavior of primary care physicians was highly correlated with behavioral

intention, attitudes and subjective norms [16]. The findings of this study led the authors to conclude that the theory of planned behavior is appropriate to guide process evaluations to understand causal mechanisms of KT strategies when adoption of the intervention is thought to be influenced by theory of planned behavior constructs.

Theories related to action

Theories of action focus on predictors of behavior in individuals who are motivated to change. The theory of implementation intentions [4], proposes that intentions to engage in a behavior are distinct from the intention of achieving a certain goal. Specifically, implementation intentions relate to the logistics surrounding when, where, and how the behavior will be carried out to achieve a goal. Hence, when certain conditions are met the individual is mentally committed to specific behavior to accomplish the particular intentions. The process of planning for a change is premised to increase the likelihood of an individual adopting the behavior [17]. According to this approach, interventions designed to facilitate planning and preparation may help promote the adoption of specific behavior.

The operant conditioning theory [5] proposes that positive feedback, such as a reward or incentive in response to certain behavior, is likely to encourage repetition of the behavior. Such repetition over time may result in the behavior becoming part of routine practice. In contrast, negative feedback, such as a reprimand or a financial disincentive, is likely to discourage the behavior. Interventions may be targeted to either encourage or discourage certain behavior. An expanding body of evidence suggests that the theory of operant conditioning helps in understanding and predicting health professionals' behavior [9, 18].

Theories related to stages of change

The transtheoretical model of change is one stage of change theory. It comprises five stages through which an individual progresses over time: precontemplation, contemplation, preparation, action, and maintenance [6]. In the *precontemplation* stage the individual does not plan to adopt the behavior in the foreseeable future. When the individual is intending to adopt the behavior within the next 6 months they have advanced to the *contemplation* stage. The *preparation* stage is reached when the individual intends to adopt the behavior within the ensuing month. The *action* stage is reached when the individual has been using the behavior for the previous 6 months. The

maintenance stage involves actively working to maintain the change. Finally, the *termination* stage is attained when the behavior is firmly entrenched; individuals are not tempted to abandon the behavior, and are entirely confident of their self-efficacy in carrying out the behavior. One of the assumptions of the transtheoretical model of change is that interventions targeted to specific stages on the change continuum will facilitate transition along the continuum [6].

Progression from precontemplation to the contemplation stage involves changes in knowledge or attitudes and is sensitive to strategies designed to enhance awareness and re-evaluate values. Such strategies may include continuing education, educational outreach, exposure to consensus statements, and performance feedback [19], which are described in Chapter 3.4. Movement from the contemplation stage to preparation and action stages involves changes in the way individuals think about the particular behavior and their beliefs about their capacity and ability (self-efficacy) to make the change. Strategies useful in promoting *action* include the provision of appropriate resources and support. Reminder systems and prompts (which are described in Chapter 3.4e) and the provision of appropriate equipment can be used to facilitate progression and promote adherence to the *action*. To progress from preparation and action to maintenance involves change in the environment and may include the provision of social support, incentive schemes, and audit and feedback [19]. There is limited evidence in support of stages of change theories. Stage of change was not a predictor of behavior when applied in the study of health professionals' use of clinical practice guidelines [18]. However, in the general population stages of change were useful in detecting barriers to certain behavior, matching interventions and predicting outcomes [20].

In 2008, Godin and colleagues published a systematic review of studies using social cognitive theories to explore health professionals' behaviors and intentions [21]. The authors found that the theory of reasoned action or its derivative, the theory of planned behavior, was the most frequently used theory to predict behavior. Further, studies using this theory demonstrated significantly greater power to predict behavior when compared with studies using other theories. While the theory of reasoned action or the theory of planned behavior was the most frequently used theory to predict intention, studies using the theory of interpersonal behavior had significantly greater power to predict intention.

In a recent study, the usefulness of motivational theories (e.g., social cognitive theory, the theory of planned behavior), action theories (e.g., implementation intention theory, the theory of operant conditioning) and stage

of change theories, in predicting health professionals' use of research, was examined according to scenario decision making and behavioral intention [22]. Variance in scenario decision making was explained by the theory of planned behavior (31%), social cognitive theory (29%), implementation intention theory (7%), and the theory of operant conditioning (30%). Significant variance in decision making was not explained by the action theory of self-regulation, the common sense self-regulation model, or the stage model. Variance in behavioral intention was explained by the theory of planned behavior (30%), social cognitive theory (25%), the theory of operant conditioning (58%) and by the common sense self-regulation model (27%). These findings led the investigators to conclude that cognitive behavioral theories can be used to help understand and predict health professionals' behavior.

Theories related to decision making

In the previous edition of this book the cognitive continuum theory [23, 24] was discussed. However, due to a lack of research using this theory to justify or explain health professionals' decision making and/or substantiate the theory, elaboration of the theory is not included in this chapter.

Constructs common to psychological theories

There is considerable overlap or commonality of constructs contained in psychological theories. To promote the success of KT research in explaining as well as predicting behavior change Michie and colleagues [25] identified key theoretical constructs embedded in psychological theories. Through a process of brainstorming and prioritizing they identified 12 theoretical domains to explain behavior change. Following validation, a series of domain-specific interview questions were generated to assess behavior change. In addition, the researchers developed an instrument to map each theoretical domain to techniques that can be employed to promote behavior change within the respective domain [26]. More recently, a study to examine the content validity of the framework [27] has supported refinement of the framework to include 14 theoretical domains (Table 4.2.1). This framework is designed to help researchers and health professionals diagnose and explain failed attempts to move knowledge to action and to guide the design of interventions to promote successful KT. The framework has been used to assess for barriers and enablers of KT (see Chapter 3.3a). It has also been used in the development of behavior change interventions (see Chapter 3.3b).

Table 4.2.1 Theoretical domains

Domains
1. Knowledge
2. Skills
3. Social/professional role and identity
4. Beliefs about capabilities
5. Optimism
6. Beliefs about consequences
7. Reinforcement
8. Intentions
9. Goals
10. Memory, attention and decision processes
11. Environmental context and resources
12. Social influences
13. Emotion
14. Behavioral regulation

Source: Reproduced from [27] Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Impl Sci* 2012; 7: 37. © 1900 Cane *et al.*; licensee BioMed Central Ltd.

Future research

Future research in this field should be undertaken using a programmatic approach to systematically and incrementally develop and test theory-based interventions and to validate their theoretical assumptions. Consistent with this approach a process modeling method, based on the UK Medical Research Council Framework for Trials of Complex Interventions (discussed in Chapter 5.2) [28], has been adopted to examine interventions underpinned by psychological theory [17, 29]. According to this framework, theory should be used to guide the selection of interventions to maximize the uptake of research evidence. Importantly, the use of theory will facilitate understanding of how and why the intervention worked under certain conditions [14,15]. The theory selection phase should be followed by a modeling phase comprising theory-informed identification of measurable components of the intervention and their mechanisms of action. These constructs can then be measured and used to understand and predict outcomes. Exploratory studies should then be conducted to assess the feasibility and guide refinement of the intervention. This phase precedes the conduct of definitive randomized controlled trials to test the effectiveness of the intervention, which should then be followed by replication studies in different settings. The adoption of such an approach will help strengthen

the evidence base and promote understanding of how, why, and under what circumstances interventions underpinned by cognitive psychological theory work. Importantly, detailed reporting of research methodology and intervention design and refinement is necessary for the conduct of replication studies and to maximize intervention fidelity.

Summary

Cognitive psychology theories can be useful for identifying cognitions that are amenable to change and providing a theory-based rationale for, and guiding development of, strategies to increase the adoption of relevant research evidence by health professionals. Such theories also offer a theoretical foundation for research designed to explore, measure, and understand health professionals' research use behavior and to study the effectiveness of interventions designed to influence such behavior.

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Chapter 4.3 **Educational theories**

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Key learning points

- Cognitive, affective, and psychomotor domains as well as individual learning styles should be taken into consideration when designing an educational intervention.
- Behaviorist, cognitivist, constructionist, humanist, and social learning perspectives can be used to inform choice of educational interventions.
- Baseline assessment of learning needs, facilitation of social interaction between learners, provision of opportunities to practice newly acquired skills, and the inclusion of a series of multifaceted educational interventions have been shown to improve performance.
- Despite strong theoretical foundations, there is a limited evidence base for educational theories.

In Chapter 3.4b, it was suggested that where there are knowledge deficits around specific and relevant research evidence, educational interventions can be used to enhance practitioners' learning, understanding, and ability to apply the evidence. Educational theories are useful for explaining the effectiveness of educational interventions and for developing frameworks to design and test new educational interventions [1]. There are a number of education theories and principles to guide the development of educational interventions [1–3]. In this chapter we will discuss educational theories targeted at the individual level and how they can be used to inform the development of interventions to move knowledge to action.

Learning domains

Educational theorists identify three broad areas of learning: the *cognitive*, *affective*, and *psychomotor* domains [2, 4]. The *cognitive* domain involves the acquisition of academic knowledge and reflects teaching methods directed towards the delivery of information which are traditionally used in the education of health professionals. Educational interventions that are typically used to promote this form of learning include didactic lectures, academic detailing and computer-based modules [2]. The *affective* domain of learning involves adoption of attitudes, values and beliefs, which are important precursors to behavior change. Educational interventions such as group interaction, self-evaluation, role play, use of case studies, and simulation are recommended to advance this form of learning [2]. Finally, the *psychomotor* domain refers to psychomotor skill acquisition and development, and interventions such as demonstration followed by supervised skill performance and practice can be used to develop skill mastery [2]. All three domains are fundamental to health professionals' knowledge, skill development, and ability to deliver high quality health care and should be taken into consideration when designing an educational intervention.

Learning styles

A range of learning styles among health professionals, including *activist*, *reflective*, *theoretical*, and *pragmatic* styles, have been described [5, 6]. The *activist* prefers to learn through experience, enjoys group work and discussion, readily adopts an innovation but has a tendency to become bored with the process of implementation and therefore quickly rejects the innovation. The *reflective* learner is systematic in collecting information on all the available options before acting but can be indecisive, resulting in delayed innovation adoption. The *theoretical* learner prefers to analyze the information and develop models of cause and effect before deciding to act. The *pragmatic* learner is more inclined to base his or her behavior on practical experience with an innovation. To engage the learner and maximize learning outcomes, the individual learning styles of health professionals should be considered when designing educational interventions. Inclusion of a range of teaching techniques can be used to satisfy the styles of all learners [7].

Motivation to learn

An understanding of motivators for behavior change is important when designing interventions to promote learning. Sources of motivation are

considered to be intrinsic or extrinsic [8]. Intrinsic motivation comes from within the individual and relates, for example, to their personal interest in acquiring new knowledge or to their desire to advance or contribute service to the community. Extrinsic sources of motivation for learning include conditions such as employment requirements, career advancement requirements, or a directive from a higher authority. Intrinsic sources of motivation, such as the desire for professional competence, are considered to provide a more powerful impetus for behavior change than external sources [8].

Learning theories

Five perspectives from which we can understand learning have been described: behaviorist, cognitivist, constructionist, humanist, and social learning [9]. These theoretical approaches to learning and how they can inform choice of educational interventions are discussed in turn.

Behaviorist approaches

According to behavior theorists, the context in which an individual works influences their behavior. Behavior theorists are interested in observable and measurable behavioral responses to certain stimuli [9]. The notion of behavior reinforcement is seen as an important aspect of learning. Hence, individual feedback is perceived to be important to the success of education interventions [3]. The instructor's role is to create an environment which encourages desirable behavior and discourages undesirable behavior [9]. Behavior theory can be used in the design of interventions including regular performance appraisal, the setting of behavioral learning objectives and plans, peer review, the use of competencies and standards against which to measure performance and computer-based learning modules.

Cognitivist approaches

Cognitive theorists study the processes used to acquire, interpret, store, and use information to formulate awareness, understanding, and meaning [9]. Modeling behavior based on observation of others' behavior is one mechanism through which cognitive theorists believe learning occurs. Cognitive theory has helped describe the process of problem solving and how skills acquired to solve one problem can be applied to new situations [3]. The use of mentorship or preceptor programs and role models to support training of novice learners is an example of use of cognitive theory. Problem-based learning approaches have also emerged as a method for teaching

health professionals. This approach typically involves the use of small groups, self-directed learning, tutorial instruction, examination of a relevant and realistic problem, and skill development. It has been recommended because knowledge acquisition as a result of problem solving is thought to result in sustained and readily accessible knowledge [2]. Numerous systematic reviews and meta-analyses (e.g., [10–15]) have been conducted to examine the effectiveness of problem-based learning on social and cognitive learning outcomes. The results, however, have been inconclusive or conflicting and have ignited debates about the effectiveness of problem-based learning. Criticism of the evidence base has been leveled at attempts to compare various different implementation methods and models of problem-based learning, potentially confounding the findings because differences in models should result in different types of learning outcomes [16].

Constructivist approaches

Constructivist theorists believe that learning is based on experience, from which meaning and understanding are constructed [9]. Constructivism draws on the notion of reflection on practice and the potential for learning through reflection and evaluation of past experience. Schon [17] was influential in highlighting the importance of reflection to professional practice and Mezirow's [18] theory of transformative learning focuses on the concepts of experience and critical reflection. According to Mezirow, change in beliefs, attitudes, and behavior requires critical reflection on experiences to transform an individual's perspective. Schon [17] also advocated for coaching by senior professionals to facilitate learning in novice professionals. Benner [19] argues that clinical practice experience is essential to the development of critical thinking skills and reflective practice. Promotion of opportunities for reflective practice, reflective journaling, evaluation of information such as quality reports and critical incident debriefing reflect the use of constructivist theory. Further, preceptorship programs can be employed to coach learners and stimulate reflective practice.

Humanist approaches

According to humanist theorists, learning is a function of growth; humans have control over their future, will actively work towards improvement, and have unlimited learning potential [9]. Humanism focuses on learning through experience and stresses the importance of autonomy and individual responsibility to achieve betterment [9]. Benner's work [19], is situated in the intuitive-humanistic paradigm [20] and draws on the Dreyfus model

Table 4.3.1 Principles of adult learning theory

Adults are self-directed – they need to decide what they want to learn

Adults have acquired a range of experiences and knowledge – learning can be more meaningful when prior knowledge can be integrated with new knowledge

Adults are goal-directed – encountering situations that require certain knowledge stimulates readiness to learn

Adults are relevancy-oriented – they require new knowledge to be relevant

Adults focus on acquiring practical knowledge – they need to know that new knowledge is applicable and beneficial

Adults want to be treated with respect

Source: Adapted from Leib 1991 [32].

of skill acquisition to understand how nurses learn. According to this model the learner progresses through five stages of proficiency: novice, advanced beginner, competent, proficient, and expert. Benner [19] contends that practitioners reach the expert level as a result of gaining over time, a combination of sound knowledge base and extensive practical experience.

Adult learning theory is a dominant perspective amongst the humanist theories. Knowles [21, 22] introduced the term *andragogy* to describe adult learning and proposed a number of oft-cited principles of adult learning (Table 4.3.1). These principles can be used to guide planning for educational interventions directed at adults and have had considerable influence on the delivery of education for health professionals [8, 23]. Adult learning theory is based on the assumptions that adults have already acquired a range of life experiences and knowledge, are more motivated to learn something that is immediately relevant to their needs, and are self-directed in their learning style. This approach differs from the pedagogical approach, in which education involves instruction, most commonly using traditional teacher-centered methods, and learning is perceived as a passive process with the learner being the recipient of instruction [9].

According to Knowles [21, 22], adults are goal-oriented and they want to know how an educational session is going to assist them to achieve their objectives. To address this need, the teacher should provide clear objectives at the beginning of any educational session so the learner is informed and has realistic expectations of the session [7, 22]. Adults are motivated by realistic practical problems or issues in preference to abstract or conceptual issues [8]. In addition, adult learners want to integrate new knowledge with their existing knowledge. Learning activities should, therefore, allow for different knowledge levels and provide opportunities for the learner to integrate prior learning with new knowledge. Furthermore, adult learners want the new knowledge to be relevant and readily transferable to their practice.

Based on the premise that adult learners are self-directed they should be allowed to discover new knowledge with the guidance of a facilitator. The learning atmosphere should foster interaction and challenge learners to consider new ideas [2]. Timely, regular, constructive, and sensitively delivered feedback is important to successful learning and skill acquisition [7].

The principles of Adult Learning Theory can be used to inform the design of education interventions to maximize knowledge translation (KT) in health care. Specifically, the intervention should include an assessment of the health professional's learning needs, acknowledgement of their existing knowledge in relation to the subject [7], the provision of clear objectives that are relevant and meaningful to the health professional's practice, and the use of creative interventions or activities to engage them in the learning process. The interventions may involve approaches such as self-directed learning, small group work and discussion forums, problem solving, use of case studies, practice sessions, computer-based modules and simulation, academic detailing, and educational outreach visits as discussed in Chapter 3.4d. Formal feedback sessions should be factored into the intervention design. Opportunities to provide informal feedback should also be used when appropriate.

Social learning approaches

Social learning theorists concentrate on understanding how learning occurs through social and environmental interaction [9]. Learning, according to this theory, can result from observation of others' behavior and the consequences of their actions [24]. Drawing on elements of behaviorist, cognitivist, and humanist theory, social learning theory views experience, motivation, self-direction, setting of objectives, and observation as important aspects of learning [3]. Role modeling appropriate behavior has been identified by social learning theorists as an important mechanism to facilitate learning [3]. Further, mentorship models to promote learning through social interaction are strongly grounded in social learning theory [9].

Evidence for educational theories and interventions

Although educational theories have strong theoretical foundations, the evidential base for these theories is limited [2]. Research efforts to validate the theoretical assumptions underlying these theories have been hampered by methodological limitations, practical, and ethical issues [2]. Acknowledging these limitations, scholars continue to argue vigorously for the use of theory to guide the design of educational interventions and to make

recommendations for continued research to test the theoretical assumptions of educational theories [2].

Considerable research has been undertaken to study the effectiveness of educational interventions in influencing knowledge use [25, 26]. Research in the field of continuing education has demonstrated that traditional passive, non-interactive, teaching methods have had minimal effect on the behavior of health professionals and they have had no discernible effect on clinical outcomes [2, 27]. A review of systematic reviews revealed that the most commonly used approaches to physician education, didactic teaching, and dissemination of printed material, were the least effective approaches to changing physician behavior [28]. However, as outlined in Chapter 3.4d, evidence in support of the effectiveness of educational interventions, including interactive education sessions [29], academic detailing [28, 30] and educational outreach visits [25, 28–31] on the behavior of health professionals and on patient outcomes does exist. From research examining the effectiveness of continuing education efforts, some factors have consistently been shown to be effective in improving physician performance [27]. These include baseline assessment of learning needs, facilitation of social interaction between learners, provision of opportunities to practice newly acquired skills, and the inclusion of a series of multifaceted educational interventions. Although the evidence suggests that educational interventions have the potential to influence the uptake of knowledge, it appears such interventions alone are unlikely to be sufficient.

Future research

Future research to test the effectiveness of educational interventions should promote generalizability, be underpinned by educational theory, and be carefully designed and conducted with rigor to avoid methodological limitations such as unit of analysis error. Such research is required to test and validate the assumptions of educational theories as well as determine the effectiveness of the intervention. Reporting should include careful and detailed description of the intervention as well as a detailed description of the education, if any, received by the control group, in the event that a control is employed. Such description would enable systematic reviews of interventions such as problem-based learning to control for different delivery models and implementation processes. Hung [16] recommends that such description addresses: (1) the learning needs addressed, (2) characteristics of the students, (3) the

problem-based learning model used, (4) the rationale for the model selected, (5) the learning outcomes measured, and (6) the types of assessment used. In addition, rich description of the context in which the research is conducted will help assessment of the generalizability of the findings. Finally, detailed economic evaluation will enable decision makers to make informed decisions about the suitability and feasibility of the intervention.

Summary

Theory-informed educational interventions can be used to facilitate research use when they are tailored to individual learning styles and needs, matched to the skills of the learner, relevant to practice, problem- and goal-oriented, and when they enable the integration of new knowledge with existing knowledge and experience. They should be delivered in a cooperative and respectful atmosphere, using teaching approaches designed to accomplish learning objectives, to allow active involvement and self-directed learning and to address key learning domains. Research to validate the assumptions of educational theories has been constrained by methodological limitations. However, evidence in favor of the effectiveness of some educational interventions in facilitating knowledge to action is promising and can be used to guide the design, implementation, and evaluation of such interventions.

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Chapter 4.4 **Organizational theories**

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Key learning points

- An organizational perspective on knowledge use focuses on enriching the organizational context.
- Three concepts are at the core of an organizational perspective on knowledge use: capabilities, process and codification.
- Specific strategies for knowledge use can be derived from each of these three concepts.
- Knowledge management in organizations can be based on the integration of these three conceptualizations of knowledge.

Our main objective in this chapter is to present an organizational perspective on knowledge use in health care organizations and systems. Taking an organizational perspective means we are scrutinizing the intellectual and system capabilities that organizations develop and nurture to improve their use of knowledge and, consequently, their performance, adaptation, and innovation [1, 2]. Broadly speaking, an organizational perspective addresses the concept of receptive capacity, which includes learning by organizational participants and their involvement in the creation and co-production of knowledge [3]. Organizations are resources capable of increasing the creation and use of knowledge.

The idea that organizations can develop strategies to increase knowledge use is based on extensive scholarly work on learning organizations [1, 4, 5] and evidence-informed management [6, 7] While the abilities to capture

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knowledge, to put knowledge into action, and to learn from experience is based on the behaviors, talents, and intellectual capacities of individuals, an organizational perspective on knowledge use emphasizes the steps organizations can take to stimulate closer connections among their decisions, operations, and emerging knowledge. Overall, we suggest that the net impact of strategies deployed to increase the use of research-based evidence in health care organizations and systems highly depends on the enrichment of organizational context. A recent review [8] on knowledge exchange processes in organizations and policy arenas supports this assumption by underscoring the importance of the roles played by institutional incentives and social structures in promoting knowledge use.

The problem of knowledge use in health care organizations and systems

Health care organizations have been traditionally defined as professional bureaucracies [9] in which work processes are in the hands of highly qualified experts and where managers and support services are somewhat at the service of those experts. It is through the autonomy delegated to experts within the operating core of these organizations that the mobilization of up-to-date knowledge is ensured. It is also through the interactions of well-trained professionals within and around the clinical core that complex problems should be resolved. However, the practices of autonomous and highly qualified professionals and organizations guarantee neither the quality and safety of care [10, 11] nor the adaptation or updating of practices to cutting-edge knowledge and technologies. If such things were guaranteed, concerns about how to generate more evidence-informed health care systems, organizations, and practices would not be an issue.

That expert organizations may at times underperform with respect to knowledge use is intriguing from an organizational perspective. This perspective posits three interrelated principles:

- Experts and knowledge cannot be dissociated; indeed, each empowers the other.
- Knowledge use is a process phenomenon whereby internal and external knowledge consolidates organizations by circulating through them.
- Codified knowledge plays a key role in sustainable organizational change.

We draw on these principles in our discussion of three key concepts that shed light on the potential of an organizational perspective to implement knowledge. The first concept emphasizes the organizational and system features that can foster knowledge use. The second focuses on the organizational processes involved in knowledge application. And the third examines

the use of codified knowledge to improve performance. These three concepts reflect a constant tension between the search for conformity between research-based evidence and organizational practices and the need for *in-situ* learning and adaptation in order to bring about quality and performance improvement.

Key concepts of knowledge use

Knowledge as capabilities

Understanding *knowledge as capabilities* requires awareness of the tangible and intangible assets that can increase the incorporation of knowledge in an organization's main operations and services [1, 12, 13], Capabilities are the properties that can stimulate attention to and use of knowledge. When knowledge is endogenous, the challenge is to ensure its diffusion to other organizational units. For example, if leaders of a given clinical program develop ways of improving the functioning of multidisciplinary teams, processes should be in place to ensure the sharing of that knowledge with other appropriate units to spread the innovation. When knowledge is exogenous, the challenge is to capture it rapidly and to translate it into innovative practices and/or services within the organization. A classic example of this challenge entails an organization's ability to assimilate and adapt new practice or clinical guidelines. In reality, both endogenous and exogenous sources of knowledge combine in an indistinct manner.

Several studies have created a solid conceptual starting point for identifying the major organizational capabilities that influence knowledge use [3, 19–22]. According to these studies, competition in the form of increased pressures for performance (e.g. benchmarking) and open policies regarding access to scientific knowledge (e.g. availability at non prohibitive cost of published scientific works and vigorous dissemination policies) increase pressure on organizations to use new knowledge [14].

An organization can improve its ability to manage knowledge if its structure, strategy, and culture have certain characteristics. Structurally, organizations that leverage their organic properties such as autonomy of decision making and flexibility are better prepared to capture and manage knowledge [15]. Organic properties emphasize decentralized decision making and authority in ways that foster customized solutions to emerging problems [1]. Decentralization in these types of organizations – which resemble the enabling bureaucracies described by Adler and Borys [16] – is coupled with clear strategies that value using knowledge to improve performance. In such organizations, incentive systems like group rewards foster group cohesion and performance. On the cultural front, a high level

of professional autonomy is considered desirable and viable as long as an organization is in a position to monitor and stimulate commitment and performance [1, 17]. Decentralization facilitates knowledge contextualization by giving a great deal of autonomy to the people in charge of resolving complex problems [18]. In these types of organizations some resources are provided to support innovative projects and to cover the risks of experimentation [14]. Support of knowledge use may also require the development of new organizational forms like networks [19–21]. Such networks play a mediating role between knowledge sources and practice settings and provide a space to share experiences and to activate the circulation of knowledge [22]. Individual capacities and new professional roles like knowledge brokers embedded in these networks and the status of actors and organizations involved will influence the impact of such organizational forms on knowledge use [23].

In addition to the type of organizational structure in place, research-based evidence must be accessible through various technical supports designed to increase its use in daily practices. Implementation of new roles such as knowledge brokers [24] are also part of the pool of capabilities organizations may consider although as outlined in Chapter 3.4, evidence in support of their use is limited.

The concept of knowledge as capabilities holds that organizations will excel in knowledge management if they manage the tension between the autonomy of a decentralized structure and the need to stimulate professionals to improve their performance [1, 15]. This tension will be constructive as long as professionals and other staff members have the resources to access new sources of knowledge and to develop local or customized strategies to put knowledge into action. Knowledge understood as capabilities also mandates that organizations must tolerate risk and accept that not all the initiatives that derive from the incorporation or dissemination of knowledge will be genuine innovations and will necessarily affect performance in a positive manner. Organizational mechanisms like systematic evaluation geared to identifying and selecting promising innovations or practices derived from new knowledge are key ingredients of an effective knowledge management strategy [25].

Knowledge as process

While the focus on capabilities emphasizes resources, design, and norms that organizations may put in place to foster knowledge use, *knowledge as process* looks at processes that condition knowledge's acceptability and potential. Knowledge is considered to be an innovation from the point of

view of potential users. Social processes that support the constitution and circulation of knowledge in networks of organizations are regarded as determining levels of use and application. From a process perspective, knowledge is a dynamic and ambiguous entity characterized by fluid boundaries [26]. Knowledge is used because it is transformed within networks of concerned individuals and organizations [27]. Accordingly, context is not something given to people but a social construct or phenomenon that results from day-to-day interactions [28].

The role of scientific evidence in spreading clinical–administrative innovations offers a good example of knowledge as process [29, 30]. Using a case study approach, this study tracks the spreading of innovations among clinical and organizational settings through interviews with key informants and analysis of secondary data available on the diffusion process. While in each of the four innovations they studied the authors identified a core of hard evidence (i.e., evidence that is less subject to controversies), they also identified a soft periphery for each innovation (a soft periphery is a space in which an innovation's boundaries are more negotiable, the notion of credible scientific evidence is much less settled, and the evaluation of an innovation in term of costs and benefits is much more controversial). For example, in their research, Denis and colleagues studied the case of assertive community treatment (ACT), a care-delivery model for patients with severe mental health problems. This innovation was subjected to various assessments by stakeholders regarding the value and credibility of scientific demonstrations of its benefits. Community health organizations looked for alternative approaches that place greater value on patient autonomy and they were somewhat reluctant to adopt a standardized approach that would impose control over patients' daily lives. ACT required adaptations in the organization of work, scheduling, and staffing. Denis and colleagues found that evaluations of gains and losses due to the intervention varied across promoters, patient representatives (e.g., community groups), and staff. Dissemination of ACT appeared to be contingent on the type of networks that developed around the innovation and on the ability to transform opponents into adherents or promoters of this new approach. In a similar initiative, Denis and colleagues studied cholecystectomy by laparoscopic surgery. They found that the procedure rapidly diffused throughout a network of physicians and patients. For surgeons, the procedure was the only way to keep pace with an expanding market; non-adopters risked being shut out of the sector or losing significant portions of their activity. For patients, the promise of rapid recovery with fewer visible traces on their bodies transformed them into supporters despite the risks associated with the procedure's rapid diffusion and extension of the scope of its indications.

The ACT and laparoscopic surgery examples reveal that a complex web of interactions and meaning systems determine both what will be considered knowledge and the credibility people will attach to innovations. From a process view of knowledge, these examples illustrate the fact that knowledge use is the customization or adaptation of knowledge to fit situations involving organizational pluralism.

Lehoux and colleagues' [31, 32] work on the social analysis of technology in health care illuminates another aspect of the key concept of knowledge as process. In her study of technological diffusion, Lehoux emphasizes the role of normative assumptions in the shaping and level of acceptability of these technologies [33]. Such assumptions – for example, beliefs about the kinds of innovations that are desirable for modern health care systems – are often tacit, but they determine how people and organizations regard new knowledge. Normative expectations are also embedded in a political economy of health wherein certain technologies, such as low-cost portable radiology equipment for primary care [34], have less chance of being diffused and adopted than others.

Knowledge is a social construct that at times transcends and, at other times, is circumscribed by professional and clinical boundaries [35]. People who engage in epistemic conversations develop various definitions of the forms that valid and useful knowledge can take. In such situations, knowledge is used when convergence arises among a plurality of people (including all the relevant stakeholders or knowledge users) and organizations. It is important to point out that this process of accommodation cannot be totally identified with pure political considerations where concerned actors promote a certain kind of knowledge to gain power and preserve their interests. From a process perspective, knowledge is used when it contributes to increasing individuals' problem-solving capacities, when it increases their sense of self-control over their working contexts and day-to-day practices [4], and when it reflects normative preferences of what an innovation should do.

Wenger's work [36] on communities of practice provides a basis for thinking about knowledge use within the context of networks. According to Wenger, communities of practice develop around three key components: identity, problem-sharing, and artifact development. Because of their organic and contextual nature, communities of practice link social dynamics and learning in forms that hold the potential of translating and appropriating knowledge processes within and across organizations. It must be noted, however, that learning processes in communities of practice are constrained or enabled by governance structures and normative frames embedded in organizational or social settings.

Knowledge understood as process suggests that organizations should go beyond the implementation of formal capabilities such as design, incentives, and accessibility and availability of knowledge. Instead, they should devise interventions that blend social processes, learning, and knowledge use [37–39]. The concept of knowledge as process suggests that the use of research-based evidence is contingent on the ability of people within an organization to agree on a common set of problems and to maintain cooperation and communication despite inevitable controversies.

Knowledge as codification

Polanyi [40] made the classic distinction between tacit and explicit – or codified – forms of knowledge. *Knowledge as codification* refers to knowledge that is embedded in formal and visible codes and well-circumscribed technologies. Codified knowledge in health care organizations includes clinical practice guidelines, quality indicators, performance management systems, information systems, and electronic patient records.

Current research on clinical governance underscores the importance of codified knowledge for improving organizational and clinical performance [41, 42]. In health care organizations the development of codified knowledge is often associated with a search for increased accountability and the need to open the black box of resource use. When undertaken in concert with the development of technological capacities, codified knowledge also plays a (growing) role in the governance of health care organizations and systems. The Canadian Institute for Health Information (CIHI), for instance, is dedicated to increasing the use of codified knowledge within the regulation of Canada's health care system. Organizations in the United Kingdom such as the National Institute for Health and Clinical Excellence (NICE) and the NHS Institute for Innovation and Improvement likewise promote elevated use of codified knowledge aimed at influencing the behaviors of health care decision makers and professionals. In the USA, meanwhile, the pivotal role of information systems in the Veterans Administration restructuring further illustrates the potential of codified knowledge to improve performance [43].

An organizational perspective on knowledge use sees both potential for and limits to the expansion of codified knowledge for governing health care organizations. Potential resides in the possibility of inducing desirable changes by providing information about processes and outcomes that support organizations in their improvement efforts. Studies of improvements and performance in health care organizations tend to emphasize this positive (instrumental) side of codified knowledge.

An organizational perspective, however, highlights the importance of paying attention to the limits of codified knowledge. Such limits are found in the undesirable dynamics that codified knowledge systems can stimulate. Such systems are populated with indicators that can be used to perform summary evaluations of activities and performance assessments. The gaming that often develops in order to comply with embedded expectations is a classic example of such effects. A recent review of the benefits of public reporting of performance in health care suggests that, in order to obtain the maximum benefits from such systems, the pressures providers feel to comply with standards of care in such contexts should be addressed [44]. Similarly as discussed in Chapter 3.4, financial interventions based on these performance measures can lead to gaming of the system.

Another limit (or risk) is found in the potential inadequacy of such systems when they are used to assess care quality and service performance. For example, there is a difference between assessing care quality in a hospital at a discrete point in time and evaluating it across a full episode of care that goes beyond a single organization's boundaries. Quality or performance appraisal systems may provide a reductionist view of activities and responsibilities and might leave aside important segments or dimensions of activities. In addition, codified knowledge systems can take on lives of their own and thereby reduce the agency of individuals and their ability to make adjustments or to take more desirable courses of action. A recent study [45] reported on this phenomenon in an empirical exploration of the use of indicators to restructure health care systems and to close facilities. The researchers found that decision makers used a limited set of indicators to target hospitals for closure. While in most cases the system of indicators seemed to support sound decision making, in the case of one hospital it was much less clear that the decision considered the role played by this organization and its dynamism. Despite that shortcoming, decision makers were unable to adjust their decisions about which hospitals to close, thereby becoming trapped by a system of indicators. Publicly recognizing the system's limits would have compromised the legitimacy of the indicators and, ultimately, the legitimacy of the entire decision making process involved in the restructuring project.

By using this example of contestable decision making we do not want to devalue the potential of codified knowledge systems. Rather, we suggest that the use of such systems will be more beneficial if one pays attention to the organizational dynamics that develop around the implementation of such tools (and thus watch for unintended consequences). While accountability issues are important and probably inevitable, studies of governance [46] suggest that accountability relations between various individuals and

organizations can be developed in an argumentative framework wherein people debate the quality and appropriateness of their behaviors and achievements. In such a process, codified knowledge is coupled with systems and actions that favor argumentation and deliberation, with a focus on continuous improvements instead of overemphasis on control. This position is also in line with recent studies of care safety that have promoted the need for a culture of learning instead of a culture of blaming [47].

Future research

Future research from an organizational perspective on knowledge use should look at the specific attributes and dynamics that transform codified knowledge into learning opportunities and improvements. There is a pressing need to better understand the interplay between formalized knowledge systems and more organic processes, as well as the ways both contribute to increased performance in health care organizations. We also must be more specific about certain organizational assets (e.g., technology, new organizational roles such as knowledge broker) that might contribute to learning and improvements. And, finally, there is still much to be discovered about how new organizational forms such as networks can assist knowledge exchange and about how to stimulate the development of networks across various organizational forms and health care systems in order to increase mutual learning.

Summary

Organizational perspective is useful for understanding the factors and processes that can impede or facilitate the use of research-based evidence to enhance decisions and practices. This perspective builds on three key concepts of knowledge: capability, process, and codification. Each of these concepts embodies different strategies for promoting the use of knowledge or research-based evidence in health care organizations and systems.

Knowledge as capability underlines the potential of organizational structures and resources to support people in their attempts to use knowledge. *Knowledge as process*, meanwhile, emphasizes flexibility in knowledge use and the need to contextualize knowledge in order to adapt to local settings and dynamics. Experimentation and trialability are, therefore, key to success. *Knowledge as codification* focuses on the potential of sophisticated information systems to govern health care organizations, an approach that is most beneficial when people confront their views on the information that can be extracted from such tools. Ideally, the search for increased accountability should not be conducted at the expense of learning.

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Chapter 4.5 Quality improvement theories

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Key learning points

- Quality improvement and knowledge translation have similarities, but they are not identical.
- Quality improvement and efforts to improve patient safety are increasingly linked in the literature.
- Quality improvement is by nature more local and less generalizable than knowledge translation.
- There are conceptual frameworks for quality improvement and patient safety which have strong overlap with conceptual frameworks for knowledge translation, but it is not clear how strong the theory base for quality and safety improvement is.
- There is a large published literature on quality improvement, including methods for doing quality improvement and reports of the processes and outcomes of quality improvement.

Defining quality improvement

The Institute of Medicine in the USA defines quality of care as "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"[1]. While there are other definitions of quality of care, most are consistent with this definition. It follows that quality improvement is the effort to increase or improve the degree to which health services

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increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Batalden and Davidoff define quality improvement as "the combined and unceasing efforts of everyone– health care professional, patients and their families, researcher, payers, planner and educators– to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [2]." Increasingly, quality improvement and patient safety are regarded as closely related concepts, with often overlapping mandates and activities [3].

Relating quality improvement to knowledge translation research

The overlap between quality improvement and knowledge translation is embedded in the desire to increase the degree to which health services are consistent with "current professional knowledge." However, despite this overlap, much of the work done as part of quality improvement may not be related to this goal, but instead is often related to efforts to address problems or issues that are perceived as affecting the degree to which health services "increase the likelihood of desired health outcomes" or are perceived as inefficient, harmful, or violating other precepts of high quality care, which include safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity [1]. All of these may be part of "desired health outcomes," but may not relate to whether professional knowledge and practice are current and effective. QI and KT may not share the same specific goals, although both are intended to improve care.

Frameworks for quality improvement

Avedis Donabedian traces the history of quality improvement models and proposals back to the early part of the twentieth century [4]. His proposed framework for understanding the factors influencing quality of care, and in particular outcomes of health services, is widely adopted in the literature on health care quality improvement. He proposed that *structure* of health services, which include the physical facilities in which health services are delivered, the types of services available (such as level of intensive care, availability of surgery or specialty services), and factors such as staffing levels or per capita ratios of key inputs to health services, (such as physicians per 1000 population) influence the *process* of care. Care processes include specific interventions such as surgery, prescribing medications, and monitoring processes of care [5], including monitoring vital signs during a

hospital admission. These factors, in Donabedian's framework, influence *outcomes*, which can be at several different levels, although his framework focuses on patient-level outcomes of care. These outcomes include whether a patient survives an episode of care delivered during an acute event, such as hospitalization following myocardial infarction, the quality of life someone has after receiving health services for some kind of health condition or problem (e.g. chemotherapy or radiation therapy for cancer care), and other sequelae both of the health condition and of the health services received. These sequelae may include iatrogenic or adverse events as a result of the health care services. It should be noted that although Donabedian is best known for the *structure–process–outcome* framework, he elaborated several additional principles to guide the improvement of quality in health care, many of which are similar to the six core principles outlined by the Institute of Medicine [6]. In addition to patient-level outcomes, he also focused on system-level outcomes such as cost and efficiency [7–9].

Negative outcomes–iatrogenic or adverse events as a result of health services delivered – have received a considerable amount of attention in recent years. In response, additional frameworks for conceptualizing health care quality improvement have been proposed. This strategy comes originally from manufacturing industries, and is credited to Joseph Juran and W. Edwards Deming separately, both of whom were engaged in quality improvement and the development of *total quality management* and *continuous quality improvement* processes and techniques [10]. The translation of these approaches to health care can largely be credited to the work of Donald Berwick. His work has resulted in the adoption of quality improvement principles in the hospital and health care organization accreditation procedures of the Joint Commission in the USA as well as in other jurisdictions; through the Institute for Healthcare Improvement (IHI), Berwick has had considerable influence in many different countries. The core framework for continuous quality improvement includes several tenets, which include the use of data and statistical analysis to identify processes and control of processes; the use of benchmarking for comparison with relevant groups; the use of teams to identify problems, processes, and solutions; and the use of some form of improvement process, usually described as a cycle: *plan*, *do*, *study* (or *check*), *act*. Following action, the cycle repeats with further planning, doing, studying, or checking results, and further action [11]. These tenets have been developed by IHI and others into processes called *collaboratives* in which several health care organizations come together over a period of 12–18 months and engage in activities designed to address specific problems, such as surgical wound infections [12–14]. In a recent project, quality improvement experts rated characteristics of quality improvement

projects – how we can recognize that a project was quality improvement. They found only a few points of consensus among the experts, making it difficult to know when a project is continuous quality improvement (CQI) and when it is not [15]. In a recent editorial, Berwick signals a cautionary note about attempts to classify quality improvement [16], suggesting that quality improvement may still be more of an art than a science. Despite these issues, particularly with respect to patient safety improvement, efforts are underway to increase the theory base used for improvement [17] and to create and evaluate frameworks for improving our understanding of patient safety practices [18].

Assessments of quality improvement as a means of knowledge translation or implementing evidence-based practice

There have been several systematic reviews addressing the degree to which quality improvement processes and techniques achieve their intended goals of improving quality of care [19–22]. Some of these reviews have attempted to assess the global impact of quality improvement initiatives, while others have focused on specific aspects of the way quality improvement is done. In a series of reports for the Agency for Healthcare Research and Quality, a group at Stanford University and the University of California at San Francisco evaluated effects of quality improvement activities on care for a series of chronic health conditions, including hypertension [19] and type 2 diabetes [20]. This latter review was recently updated [22]. They found that quality improvement initiatives spanned a wide variety of activities; and that overall, the results of quality improvement methods are mixed in terms of effectiveness. In a related paper, Shojania and Grimshaw reviewed the evidence base for quality improvement techniques, and found it problematic in that many of the methods used for quality improvement have little basis in evidence, produce mixed and inconsistent findings at best, and demonstrate a scattered approach [21]. Similarly, Øvretveit and colleagues found relatively little evidence for sustainability of quality improvement initiatives over time, suggesting that many quality improvement initiatives are limited in duration of effect, even when they demonstrate effectiveness in short-term projects [14, 23–25].

These reviews point out some substantive differences between some quality improvement and knowledge translation or implementation science efforts. Quality improvement initiatives tend to be quite local in nature. Problems are identified at a local level, and often do not generalize, particularly in their specificity, to other settings or organizations. In addition,

quality improvement efforts are geared to dealing with immediate prob-
lems, and to attempting to address concerns with how care is delivered in
real time to specific patients. Knowledge translation research often attempts
to derive generalizable knowledge through the systematic application of
research methods and principles, and to apply lessons learned from one
specific setting to another, or across a relatively large number of settings or
organizations.

Issues and concerns in quality improvement as a means of knowledge translation

Issues have been raised about the role of ethical or human subjects review
and protections for both patients and health care providers in quality
improvement activities. In research activities, there is no question about
the need for ethical or human subjects protection review, but this is rarely
considered an issue in quality improvement, even when very similar activi-
ties and interventions are used [26–28]. Concerns have been raised about
whether some forms of knowledge translation, particularly attempts to
implement evidence-based medicine or evidence-based care, might conflict
with attempts to engage in meaningful quality improvement activities [29–
32]. These concerns are echoed in terms of concern about the lack of an
evidence base of quality improvement activities, on one hand [21, 33], and
concerns about the standards used for evidence on the other [34]. Ques-
tions have also been raised about the evidence base that has launched the
current international focus on patient safety, particularly the evidence that
hundreds of thousands of hospital deaths in a country like the USA are pre-
ventable and related to medical error [35–38]; while there is little dispute
about the need for patient safety and quality improvement, measuring
adverse events accurately and appropriately is a necessary precondition for
effective and efficient response to these problems. Additional concerns
include how quality of care issues are identified and the role of professional
and individual lenses in identifying issues initially [39], and how different
health care professionals may rate the seriousness of quality issues [40, 41].
The highly localized nature of quality improvement may make these issues
more concerning than they might be for knowledge translation research,
with its broader scope and greater emphasis on generalizability.

Despite these concerns and caveats, quality improvement remains a
mainstay of efforts to improve the experiences that patients have when they
receive health care services. There is an increasing merger between the per-
spectives of quality improvement and knowledge translation research, evi-
denced by some large, multi-site quality improvement initiatives, including

approaches using collaboratives similar to those pioneered by IHI, as well as other approaches [42–46]. In some of these, attempts are being made to provide evidence for Donabedian's *structure-process-outcome* framework, bolstering the theory base for quality improvement activities [47]. Overall, there is an increasing convergence in viewpoint between proponents of evidence-based practice, knowledge translation, and quality improvement, which is likely to lead to improvements in the care patients and consumers receive from health care organizations and systems [48].

Future research

Given the nature and intent of quality improvement, it is not clear whether there is a need for a science of quality improvement, although there have been calls for developing such a science [48, 49]. There are, however, areas for improving the reliability and effectiveness of quality improvement interventions which depend on developing reliable and effective methods of improving quality of care. These methods are shared with implementation or knowledge translation science, and research related to quality improvement as well as quality improvement efforts themselves can contribute to building generalizable knowledge and reliable, effective interventions. One important approach that has been received little attention until recently is to attempt to synthesize the vast literature reporting the processes and outcomes of quality improvement efforts. This constitutes a long-term research agenda that would contribute substantively to our knowledge about methods for improving care. Recently, efforts have been made to try to bridge this gap in knowledge, although these are still early efforts [15, 50, 51]. Applying consensus standards to reporting quality improvement interventions [52] and patient safety improvement efforts [49, 53] would support these efforts considerably.

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Section 5 **Evaluation of Knowledge to Action**

Chapter 5.1 **Methodologies to evaluate effectiveness of knowledge translation interventions**

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Key learning points

- The evidence base for interventions to change clinical practice is modest but growing- we know several KT interventions which usually work, but not when or how.
- Given the cost of implementing KT interventions and their variable effect, they should be rigorously evaluated.
- Evaluations should be informed by a "theory of change" – ideas and assumptions about how desired organizational and behavioral changes are achieved – even if informal.
- Evaluation studies should strive for internal validity, the degree to which an observed outcome can be attributed to an intervention. Randomized controlled trials provide the highest degree of internal validity.
- Non-randomized designs provide less internal validity but may be easier to execute.
- The external validity is the degree to which results from a particular study are applicable to a regular practice setting. It is enhanced by choosing typical subjects and settings and widely practicable KT interventions.
- Qualitative methods should be used alongside quantitative ones to understand the effect of the context on outcomes and the mechanisms by which the intervention achieves (or fails to achieve) its effects, thus improving our understanding of the theory of change.

> "Evidence based medicine should be complemented by evidence based implementation."
>
> *Richard Grol*

The field of knowledge translation (KT) promotes the uptake of evidence-based practices, but often unproven KT interventions are used to promote these practices [1, 2]. On the one hand, there is pressure to urgently improve quality of care. On the other hand, there is insufficient information about which interventions actually work to improve quality [3], how, and under what circumstances. It is tempting simply to intervene using apparently "sensible" approaches [4], but many of these may not work, and some may be harmful. If every KT intervention was rigorously evaluated, we would quickly build up a reliable evidence base about which interventions do and do not work, and under what circumstances. This chapter is a call for routinely combining rigorous evaluation with every KT intervention.

Implementation research often operates at multiple levels, trying to affect patients nested within a provider's practice nested within a multidisciplinary team nested within a health facility, nested in local and national health care systems. The conceptual and methodological challenges are significant, especially since the impact is often modest [5]. Furthermore, we know little about what the most effective KT interventions approaches are for a given setting or how to apply them [6].

The Cochrane Collaboration has registered over 350,000 randomized controlled trials in clinical medicine and health care [1] but fewer than 1% of these are randomized trials of interventions to improve health care delivery, including KT interventions [7]. This gap in knowledge may be partly because treatments (medicines, technologies, procedures) are more heavily regulated than health care delivery or improvement strategies. The huge potential benefit of improving care warrants a shift in effort from developing new treatments to developing approaches to consistently deliver what is already known to work [8]. Given the limited evidence base, people involved in health care delivery and improvement have a responsibility to evaluate their efforts [9] not only because many interventions are ineffective and may lead to a waste of resources [10], but also because evaluation creates knowledge that may benefit others.

Evaluating the effectiveness of KT interventions may benefit from an integrated-KT (iKT) approach (Chapter 1.2), in which those who intend

to use the evaluation study results inform its design. Such an approach would start by ensuring that the evaluation questions are relevant to those who would use the study findings (managers, policy makers, funders, providers etc). Knowledge users can participate in decisions about the study design (including the setting, participant selection, outcome measures) as they understand the context of the setting and what they hope to obtain from the study results. They can also be involved in selecting or tailoring the KT intervention being studied (as described in Box 5.1.1). The intent would be to maximize the likelihood that the evaluation would provide relevant, useful and desired information the knowledge users need to make informed decisions.

Box 5.1.1 Evaluation of a theory-based intervention of a low back pain practice guideline [37]

Clinical practice guidelines are intended to communicate the best available scientific evidence about disease conditions and their treatment to practitioners to improve care and patient outcomes. However, clinical practice guideline uptake is notoriously low. For example, although most Australian primary care practitioners are aware of and agree with low back pain guidelines, many do not follow their recommendations. The IMPLEMENT study [37] is a cluster randomized controlled trial to evaluate a theory-based intervention intended to increase the uptake of low back pain guidelines by Australian family physicians. Randomization was at the practice level to minimize contamination. To design the intervention, a series of focus group interviews was conducted with general practitioners to explore barriers and enablers to guideline implementation. The team mapped the data from the focus groups onto the theoretical domains for understanding and facilitating behavior change. They developed the intervention based on these results. The intervention is an educational workshop designed to address the barriers and enablers to guideline uptake and consists of a combination of behavior change techniques chosen because they are considered the best approaches to address the particular barriers and enablers identified in the focus groups. For example, one of the barriers identified in the focus groups was a belief that following the guidelines would result in worse care for patients. To address this, the workshop focuses on the evidence base of recommendations and the balance between benefits and harms. To determine the effectiveness of the intervention, the team will measure outcomes at the provider level (referral for an X-ray for those presenting with low back pain) and at the patient level (low back pain disability).

The Canadian Institutes of Health Research (CIHR) has published a useful overview of evaluation in health research, which describes the differences between evaluation and research, different types of evaluation, and steps on how to design and conduct an evaluation [11]. In this chapter, we focus specifically on the methodological decisions and approaches most relevant to evaluating knowledge translation interventions. When considering how to evaluate the impact of an intervention, the first issue is whether we are interested in local or generalizable knowledge. The former is the concern of managers responsible for quality improvement in an institution and the latter of greater interest to KT researchers and those looking for effective KT interventions. This chapter will review several designs, and explain the benefits and disadvantages of each for managers and researchers.

How can theory inform the evaluation of a KT intervention?

KT scientists have argued that it is difficult to interpret the limited and varied effects of KT interventions, partly due to lack of explicit rationale for many intervention [12]. Greater understanding about *how* an intervention works should result in a better study design, including more appropriate methods of measuring its effect. The choice of implementation intervention should be influenced by the ideas and assumptions about the mechanism of the behavioral and organizational change(s) the intervention targets, or the "theory of change." In this case, theory describes "a set of highly general, logically interrelated propositions that claim to explain the phenomenon of interest" [13]. A theory of change describes the causal pathway of an intervention and the elements required to catalyze and sustain the change and it can be formal (obtained from the literature where it may have been validated in empirical research, such as the theory of planned behavior) or less formal (a personal theory, or commonly held explanation). Designing an evaluation based on a particular theory of change may improve the intervention, because it helps the implementation team to think clearly about *what mechanisms of change* they are trying to foster and how best to affect them in order to achieve the change [12].

Using a theory helps to ask "How can behavior change be measured and understood?" prompting the implementation designers to identify mediators of change to investigate the proposed pathways of change, and select appropriate and feasible measures accordingly [12]. Thus, theory-informed evaluation may help ensure that the right things are being measured and provides the researcher with proposed mechanisms to help explain why it did (or did not) work. Box 5.1.1 illustrates an example of how theory informed a KT intervention and evaluation.

Available resources and the need for local or generalizable knowledge drive most of the decisions in evaluation design for KT interventions. The most important goal in study design for intervention studies is internal validity, the degree to which an observed effect can, without bias, be attributed to the intervention under study. The next is external validity, applicability or generalizability, the degree to which the results of one study in a given setting can be applied to other settings [10]. If a study has poor internal validity (the relationship between intervention and impact has not been accurately measured), its generalizability is irrelevant, because the estimate of effectiveness is spurious. However, even if the finding is internally valid, it may not be broadly applicable if the study was conducted in an ideal practice setting, practitioner participants were selected to be optimum performers and patient participants were carefully selected to have higher than usual adherence in order to strengthen the relationship between intervention and observed impact. Thus an internally valid finding may not be generalizable to other settings, nor even applicable to the more typical practitioners and patients in the very setting the study was conducted. We will first discuss the elements of study design which establish internal validity and then elements which establish external validity.

How can internal validity of a study be established?

There are many reasons why an intervention may appear effective when it is not. For example, quality of care in a given department may improve after an intervention because the intervention was effective, or because quality had been improving consistently for some time due to external factors like increased resources, or because a national incentive program was started around the time of the intervention. Consider for example a major academic hospital that implemented a clinical pathway on the surgical service and looked at length of stay before and after its implementation. Length of stay was reduced by 67%; however, when length of stay was analyzed for the same procedures at other hospitals, the same or a greater decrease were found. The changes were likely due to external factors such as economic pressures to decrease length of stay, and this would have been missed if control site data had not also been considered [14]. Another reason that the intervention may appear effective when it is not is because the program selected poor performers who regressed to more usual performance by time outcomes were measured. This latter phenomenon is called "regression to the mean" and explains why variables that are extreme in their first measurement (i.e. poor performance) are more likely to be closer to the average when measured a second time. The purpose of impact evaluation studies is

to understand if any improvement in the outcome of interest was due to the intervention under study.

The two broad categories of intervention study design are randomized and non-randomized (or quasi experimental) designs. In randomized designs, the investigator has control over the allocation of the intervention to ensure that the group receiving it is comparable to a control group. In non-randomized designs, you can find a matched control group, or measure the outcome in the intervention group at multiple time points before and afer the intervention, both of which control for underlying trends. If the intervention allocation is determined by administrators and non-random, then there is a higher risk of bias [15]. In this section, we describe several variations of randomized trial designs and three non-randomized designs used for intervention studies: uncontrolled before and after, controlled before and after, and interrupted time series. We also discuss several approaches to analyzing available cohort data in an observational study with modern techniques for adjustment of confounding variables: propensity-matched cohort design, instrumental variable design, and multiple baseline design.

Randomized studies may require flexibility on the part of those in charge of the health system in which the study is taking place, and because they provide more reliable results, are increasingly favoured [16,17]. Non randomized studies may be administratively less challenging and are appropriate when randomization is not possible. We will describe the various design considerations in each type of study.

Randomized designs

Randomized controlled trials (RCTs) are considered the gold standard for evaluating the impact of an intervention [18]. As illustrated in Figure 5.1.1, we can randomize either individuals or larger aggregates of people in natural units such as family practices to be exposed to an intervention or usual care (the control). The most important (and unique) advantage of randomized trials is that they are likely to ensure balance between the control and intervention groups for unknown confounders. We seldom understand all of the factors which influence outcomes, and randomization itself ensures that even these unknown factors are likely to be evenly distributed between arms. In addition, randomization tends to ensure similar distribution of other factors that influence outcomes between arms. Finally, because of their statistical properties, randomized trials have a better basis for significance testing and confidence interval estimation (i.e. determining the
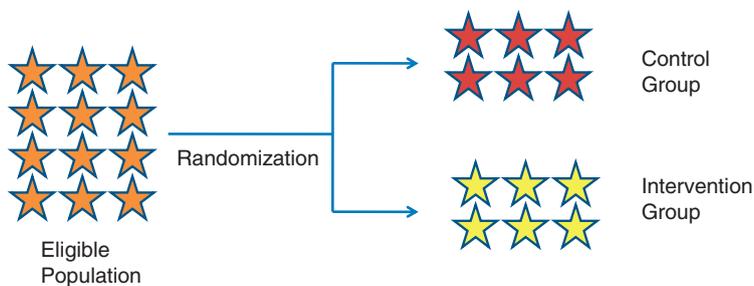
Figure 5.1.1   Design for a randomized controlled trial.

likelihood that the observed result was due to chance rather than the effect of the intervention) than non-randomized designs.

In all intervention designs, concealing the intervention from participants until they are irrevocably included in the study helps prevent bias. Although less important, blinding (where participants never know whether they receive the intervention or control) helps minimize bias in subjectively assessed outcomes [19]. Since it is rarely possible to conceal from practitioners, patients and those who measure the outcomes which arm of a KT trial they are in, choose objectively measurable outcomes where possible, in order to reduce this bias (patient reported measures like quality of life would be an obvious exception).

Randomized controlled trials are commonly used to test drugs, devices, and procedures. However, they are also particularly well suited to testing the effectiveness of KT interventions for a number of reasons. First, as noted in Chapter 3.4a, since the effects of most interventions are on the order of 10% [2], minimizing bias is important because imbalance between groups could overshadow the effect. Second, we often have a poor theoretical understanding of professional behavior and behavior change, so it is important to be quite certain that a KT intervention *does* work before we try to explain *how* it works (especially amid unwarranted assumptions of effectiveness) [20]. Third, we have a limited understanding of likely confounders (often we only know the impact of commonly considered confounders – age of providers, gender, organization of care), so it is much more likely that the study groups are balanced at baseline if they are randomized.

Despite the benefits of the RCT design, some argue that it is too rigid to evaluate complex interventions [21]. This view confuses rigid allocation

with rigid definition and monitoring of the intervention, which is not required. Modern pragmatic approaches to the design of RCTs [22, 23] allow and even encourage real world flexibility of the intervention, and thus maintain rigor and reliability of the evaluation of impact without sacrificing flexibility of the intervention. Choosing to use a randomized controlled trial to evaluate an intervention opens up a series of design choices around number of comparators, unit of randomization, and sample size.

Number of comparison groups (study arms)
There are multiple potential designs for randomized controlled trials, depending on how many interventions one cares to evaluate. Two arm trials (Figure 5.1.1) are the most common and they can determine if an intervention is better than carrying on with an alternative. In KT trials the control group is often the usual approach to delivery of care. Multiple arm trials allow for a comparison of different interventions and assess the relative effectiveness of different approaches. If we want to know whether two interventions are synergistic, they can be tested in a factorial design, which compares either intervention individually or in combination with a control (Figure 5.1.2).

Unit of randomization
In drug trials, patients are usually randomized to receive the study medication or a placebo (or active control). This approach may not be feasible in quality improvement studies. If the intervention is a change in organization of care such as introduction of an electronic medical record, then it would be difficult to include some patients and not others within the same facility. Similarly, if the intervention is an educational workshop for physicians, the

A + B	A
B	Neither A nor B

Figure 5.1.2   Design for a factorial trial.

physicians will not be able to apply the knowledge to some patients and not to others. Contamination is another concern and can occur when participants in the control group are affected by the intervention, usually through contact with people in the intervention group. It is often easier to randomize intact units (such as clinics or practices), not only for administrative convenience, but to reduce contamination and because it may be the natural level of application. These units are known as clusters and there is a large and useful literature on cluster randomized trials. For example, wards have been selected as the unit of randomization in trials evaluating inter-professional collaboration initiatives [24]. Alternatively, clinics, communities or health care providers may be the unit of randomization. Keep in mind that large units of randomization may facilitate implementation within a site, but it may not be feasible to recruit a large number of clinics or hospitals.

Sample size

To minimize the likelihood of observing a change in outcome due to chance alone, RCTs must include a sufficiently large number of patients or health care providers. When patients are randomized, this sample size estimation is straightforward, and depends on the size of the effect one is trying to detect, and the power of the study (the acceptable likelihood of not finding a difference if it is there).

Sample size calculation is slightly more complicated in trials where groups (rather than individuals) are randomized. Practitioners working at the same or nearby clinics are more likely to behave similarly, due to collegial interaction, the impact of organizational culture on care, and likely shared socio-cultural and economic backgrounds, in addition to likely similar patient rosters. Thus, each individual is not entirely independent, which increases the required sample size, since less information is contributed by each individual. The degree of similarity between subjects within a group is captured in the intra-cluster correlation coefficient (ICC), and the degree to which sample size is affected is called the inflation factor [25]. Generally speaking, more power is derived from adding clusters than from increasing the number of patients within each cluster, so the benefit of recruiting more than 50 patients per cluster is small [18].

Enrolment timing

Sometimes it is feasible to enroll all participants at approximately the same time. However, alternate designs are possible when this is not feasible. For example, in a stepped-wedge study design all participants (or clusters of participants) receive the intervention in a randomly selected sequential roll-out [26]. Outcome measures are collected for all participants (those

who have received the intervention and those who have not yet) from the beginning of the study adding the advantage of within subject or cluster pre-intervention data for better adjustment of estimates effect. This type of design is helpful when it is not feasible or wise to initiate the intervention with all participants at once.

Non-randomized designs
These designs are more prone to bias than randomized trials, but tend to require fewer resources and are more easily managed on a small scale.

Uncontrolled before-after study
Measuring quality of care at baseline and then at another point in time after an intervention without a control group is better than no measurement at all, and can assess if quality improved over the time period. However, it is not possible to know if the result was due to the intervention or whether it would work in another setting. It is possible to use rigorous designs with little additional effort.

Controlled before-after studies
If we are interested in testing an intervention in a single context, identifying a comparable control group will double the effort in terms of data collection, but provide a much more reliable answer (Figure 5.1.3). If there are multiple wards in a given hospital or clinics in a practice group, it may be possible to randomly select one to receive the intervention initially and the other to receive it at a specified time in the future, provided it was effective. This strategy has financial and logistical benefits, in addition to the obvious scientific ones. However, with a small number of units, it may not be possible to find groups that are comparable for measurable
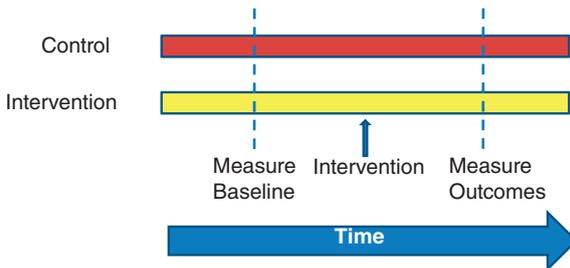
Figure 5.1.3 Design for a controlled before and after study.

(and, quite likely, immeasurable) confounders. If the groups are not comparable, the secular trend in the outcome of interest may be different between them, invalidating the control [18]. Nevertheless, a well-matched control should give a sense of secular trends and sudden changes, and should be attempted if a randomized trial or interrupted time series (below) is not possible.

Propensity-matched cohort design
When the units of intervention are heterogeneous or have complex characteristics, matching those exposed to the intervention with those not exposed may be difficult. In these cases, a propensity-matched cohort design may be an alternative. In this type of study design, participants are observed (not assigned) regarding whether they were exposed to the treatment. The difference in the treatment effect between the exposed and unexposed participants is calculated. The measurement of treatment effect may be biased by differences between the two groups. By determining the participants' propensity score (the probability of being exposed to the treatment), the evaluation team can perform calculations which model the effect with known confounders removed and provide a less biased estimate of the treatment effects. This type of design is most appropriate when the characteristics which influence propensity to receive the treatment (age, health status, geographic location, etc.) are well known. Because it is observational, it is a relatively inexpensive study design and simple to execute, but requires access to a large database with potential unexposed control participants. The major limitation to this type of study design is that it is vulnerable to bias, and requires an accurate estimate of the probability of being exposed to a treatment, which is difficult for new and understudied treatments.

Instrumental variable design
Since a propensity-matched cohort design cannot control for unmeasured variables, it is subject to bias. An instrumental variable design is a complex statistical technique which uses the relationship between an "instrumental variable" (a variable presumed not to be itself associated with the outcome) and the outcome as a surrogate for randomization. An ideal candidate for an instrumental variable would be one that is strongly associated with exposure to the intervention, but does not itself have any effect on the outcome, nor share a common cause with the outcome [27]. Although this design can theoretically minimize bias due to unknown confounders, there is no way of knowing that the chosen "instrumental variable" meets these criteria, and so the technique should

be viewed as a sophisticated way of adjusting an observational study, rather than as a form of randomized trial.

Interrupted time series

This design uses multiple measurements before and after an intervention to determine if it has an effect that is greater than the underlying trend [28]. For example, in the UK, the quality of care has been improving for several years, so when a "pay for performance" intervention was introduced, it appeared to be effective according to the post-intervention quality (points E and F), but in fact there was no change from the pre-existing rate of improvement (points A-D) [29] (Figure 5.1.4). These studies are particularly useful when assessing an intervention where a contemporaneous control group cannot be identified, such as a media campaign or policy that goes into effect simultaneously throughout a region, reaching everyone. An interrupted time series (ITS) requires multiple time points before the intervention to identify the underlying trend or any cyclical phenomena, and multiple points afterwards to see if there is any change in the trend measured previously. From an analytic perspective, the number of time points and the time between each one determines the stability of the estimate of the underlying trend. Time points that are very close to each other are more likely to be similar than those which are further apart, a phenomenon known as autocorrelation [18].

Though more reliable than unbalanced controlled before after trials, interrupted time series studies do not control for co-interventions or other outside influences on the outcome arising concurrently with the intervention [30]. ITS designs are most suited to settings where routine outcome data are available covering long time periods. Without this, an ITS would require collecting data for several months or years before starting the study, rendering it nearly as logistically difficult as an RCT.
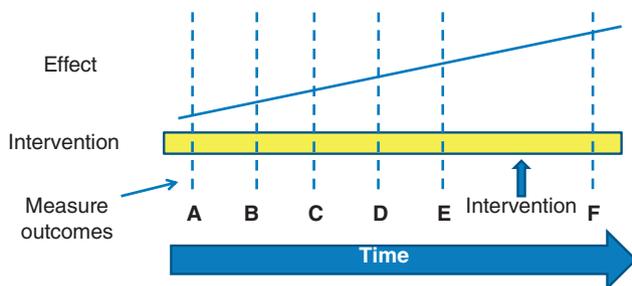
Figure 5.1.4   Design for an interrupted time series.

Multiple baseline design

This design is used to increase the confidence that an intervention was responsible for a change in the outcomes of interest. This design requires two or more groups to receive the intervention at different starting times. Multiple measurements are taken in all groups simultaneously over the whole period of study and so this can be thought of as a multiple ITS design. This approach is more sensitive than a single intervention site ITS in determining whether changes in the outcomes of interest were due to the intervention itself, and not a secular trend [30].

How can external validity be established?

Pragmatic designs

The study designs mentioned above vary in their ability to control for bias and to ascertain whether an observed effect is the result of the intervention in question. Consideration of validity involves having a sufficient sample size, blinding outcomes assessors, analysts, and participants (where possible) to group allocation, and using a placebo when feasible. These all increase internal validity. However, an internally valid study may or may not have high external validity [31]. Pragmatic study designs are intended to have high external validity because they are designed to estimate the effects of interventions under usual conditions; they maximize the relevance of results for real-world decision making, often for a broad range of settings [32, 33].

Quality improvement and KT studies are often conducted by enthusiasts in supportive environments, and if these conditions are essential to the intervention's success, the results may not be generalizable to settings. Maximizing study generalizability is necessary to ensure that the expansion of a successful pilot program produces similar results when scaled up in usual care settings.

Broad eligibility criteria – where a high proportion of providers or health facilities approached are recruited and analyzed – are a key feature of pragmatic designs. Box 5.1.2 illustrates one such study. Participants who drop out or who choose not to join studies may not be sufficiently motivated to follow through on labor-intensive interventions, so studies that only include enthusiastic groups may overestimate the impact in a general practice setting. Alternatively, motivated groups may have a high baseline quality, minimizing the intervention impact due to a ceiling effect. The terms "pragmatic" (also known as effectiveness) and "explanatory" (also known as efficacy) are used to describe trials designed to test therapeutic or programmatic options, while the latter is used to describe trials designed to

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Box 5.1.2　Does an educational intervention for vestibular rehabilitation help people with chronic dizziness? A three-armed pragmatic randomized controlled trial [38]

One in 10 people of working age and 1 in 5 people aged 60 or older have dizziness that interferes with daily activities, medical consultation, or medication use. Exercise treatment known as "vestibular rehabilitation" or "balance retraining" is the most effective means of managing dizziness due to vestibular dysfunction. However, in a recent study in a primary care setting only 3% of persons warranting the treatment had been offered it. This is because access to vestibular rehabilitation usually involves a costly and lengthy referral process. To increase the use of vestibular rehabilitation, an educational booklet was designed to teach patients how to perform the exercises, eliminating the need for lengthy and costly referrals to specialists. A study was conducted to determine the effectiveness of this intervention. A three armed RCT was conducted to measure the effectiveness of giving patients the self-management booklet, and giving patients the self-management booklet and vestibular specialist telephone support, versus routine medical care. Adults from 35 family practices across England (from rural, suburban, and urban primary practices) were invited to participate if they had complained of dizziness during the past two years and that dizziness was vestibular in nature. Patients who consented to participate were randomized to one of the three arms. Dizziness-related outcome measures were taken at baseline, 12 weeks post-treatment, and after 1 year. After 12 weeks there were no significant differences between the groups regarding reported dizziness symptoms. However, after 1 year patients allocated to booklet self-management (with or without telephone support) improved relative to those allocated routine care, by reporting greater subjective improvement, fewer symptoms related to dizziness, and a reduced handicap related to dizziness.

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test causal research hypotheses. Table 5.1.1 outlines the key differences between these two types. Since few trial designs are only pragmatic or only explanatory, Thorpe and colleagues [23] have developed a tool to help study designers and others assess the position of a trial within the pragmatic-explanatory continuum.

Pragmatic designs also increase the confidence with which one can extrapolate the results to other practice settings. Although the wide variation in implementation of interventions and practice settings is common in pragmatic designs, and is generalizable to most non-study settings, it is less clear what the results may mean for any particular institution, whose levels of, say, enthusiasm, may be known to be higher than usual [4]. For example, a simple surgical checklist was tested across eight sites and though the study found a 22% average improvement in select safety procedures, the improvements varied from 0.1% to 51% across sites [34].

Table 5.1.1 Comparing explanatory and pragmatic designs

	Explanatory/efficacy	Pragmatic/effectiveness
Purpose	To examine efficacy (measure of capacity for beneficial change due to a given intervention)	To examine effectiveness (measure of how well a given intervention works in practice)
Setting	"Ideal" conditions; environment monitored	Typical practice
Participant selection	Motivated practices or providers	Representative of regular practices or providers
	Careful selection of patients most likely to benefit	Any subject who would typically be receiving the intervention or usual care
Interventions	Strict enforcement and monitoring of adherence	Flexible application; suited to typical practice
Outcomes	Short-term surrogates or process measures	Outcomes of relevance to participants, funders, health care providers, decision makers, and other stakeholders
Relevance to practice	Indirect: little effort made to match trial design to needs of decision makers	Direct: efforts to link study design to everyday practice

Limited descriptions of context and the intervention itself make it difficult to reproduce the intervention in another setting [5]. To assist the interpretation of study results, qualitative and quantitative studies should be run alongside the trials to assess the degree to which the intervention was actually implemented and to give some insight into why an intervention was successful or not. This approach may entail surveying participants or interviewing key informants such as managers and team leads. It could also require participant observation to record the process and extent of implementation. For example, Brady and colleagues [35] found that including qualitative measures to evaluate the implementation of a complex KT intervention yielded important insights into aspects of the intervention which were not well received and staff perspectives of recruitment consistency.

We also suggest that qualitative studies can be used to test the theories of organizational and behavioral change behind an intervention, to learn why and how there was a treatment effect. This information will inform potential scaling up by helping the implementation team adapt the intervention to other settings or determine which settings may not be conducive to the intervention. In addition, it will add richness and context to KT science, furthering the field's understanding of the mechanisms of complex

interventions. Finally, mixed method studies can be used to measure the fidelity of implementation, by learning which components of the KT intervention were implemented as intended [36].

Summary

Given the time and resources necessary to implement knowledge translation interventions, there is a need to evaluate them rigorously. Complex strategies of this nature should be pilot-tested, and if promising, they should be evaluated in explanatory trials [31]. Randomized controlled designs are the least subject to bias, but require a large number of units (patients, providers, clinics), which may be logistically challenging. Non-random or quasi-experimental studies may be appropriate when randomization is not feasible. Pragmatic designs increase the confidence with which one can extrapolate to other practice settings. A concurrent qualitative investigation can assess the degree of implementation and provide insight into why an intervention was successful or not [5]. Moreover, it may provide deeper understanding about the mechanisms of change and the contextual factors which promote and inhibit change, assisting with spread to other settings.

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Chapter 5.2 Economic evaluation of knowledge translation interventions

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Key learning points

- Health care decision makers should explicitly include economic principles and evidence throughout the knowledge to action (K2A) cycle to ensure their knowledge translation (KT) activity represents value for money.
- Adding a deliberate reference to health economics at every step of the K2A cycle will enhance the effectiveness, equity and efficiency of KT.
- As there are significant barriers to using and applying health economics evidence at all levels the health system, this chapter provides a framework and practice points on how to plan, implement and evaluate KT activity through the lens of health economics principles and approaches.

Why should health economics be included in KT?

Since the resources available for health care are limited, health care managers, policy makers and clinicians will always have to make decisions that reflect the conscious or unconscious allocation of these resources.

As resources in most of the world's health systems are becoming increasingly stretched, there is an ethical and social imperative to include an economic perspective when developing policies, initiating new programs or interventions, implementing guidelines or trading benefits, and risks in clinical practice. Health economics evidence is not well understood, applied, or routinely translated in the best way possible [1–4]. This lack of understanding results in health care system inefficiency and poorer outcomes for patients [5]. In this context, those responsible for the design and implementation of KT activities also will find their own work increasingly scrutinized for value, impact, and cost. To prepare for this responsibility, this chapter guides those planning, implementing and evaluating KT to include health economics as a vital dimension to their application of the knowledge to action (K2A) cycle.

What health economic principles can guide decision making in health care?

There are two main economic principles critical to health care decision making [6]. The first principle states that allocating resources in one way means that there is a forgone opportunity to use them elsewhere: this is called "opportunity cost." Any KT activity will potentially cost money which could have been spent somewhere else in the health system. The second principle states that the allocation of resources should ensure maximal benefit gained from using the next unit of resources: this is referred to as "marginal analysis." If additional funds were available for KT, health care managers ought to invest in KT activity that would generate the most benefit in return for this investment [7].

Besides these two principles, it is generally accepted that societies benefit when resources are allocated in a fair and just manner across population groups (according to need) and particularly to avoid creating or exacerbating inequalities in health outcomes as a consequence [8].

What types of health economic evidence can be used in decision making?

In this chapter, we define health economics evidence as that relating to scientifically credible data or information about incremental resource use, costs and effectiveness that is generalizable to circumstances beyond that in which it was generated. In essence, this is relevant evidence about the cost and benefit between two alternative courses of action [9]. Health

economics evidence can be generated from Randomized Controlled Trials (RCTs) and other study designs using economic evaluation methods or existing economic evidence can be incorporated into decision analytic modeling or synthesized into a meta-analysis (Chapter 2.1). Although there are methodological challenges in generating valid and reliable economic evidence [10], guidelines have been produced to ensure the development and reporting of economic evaluations are more consistent, explicit and transparent [11, 12].

There are many barriers to being able to incorporate economic evidence at this organizational level however such as rigidities of health care budgets, context of decision making, politics, and organizational culture [1, 3, 4, 13].

The level of the health system in which economic evidence can apply must also be considered. At the *national* level, some countries have explicit mechanisms by which economic analysis occurs and is linked to health care decision making (e.g. the National Institute of Health and Clinical Excellence in the UK). At the level of a health care *organization* such as a Trust or Health Maintenance Organization (HMO), decisions on whether certain programs, services or interventions get funded or used usually lies with senior executive managers (e.g. policy makers, public health practitioners, or health service managers) who have the financial delegation to make choices and commit resources.

At the *patient or clinical* level, individual doctors and nurses will make choices that determine what treatments or services are offered to individual patients. Whilst published health economics evidence may be considered to some extent, often other factors prevail in this level of decision making e.g. patient preference and well-being, the social context, equity and willingness-to-pay in clinical practice [14]. Therefore, anyone designing KT activity should understand the level and the levers by which KT activity can be influenced by health economics evidence.

What economic issues should be considered when embarking on a KT activity?

KT aims to ensure more diligent use of evidence in health care decision making. Given the barriers to generating, understanding, and using economic evidence, we illustrate below how health care decision makers can introduce economic principles and approaches at each stage of the K2A cycle. We also present a case study at the organizational level to highlight practice points.

In the USA, hospital managers are required to address Hospital-Acquired Infection (HAI) rates [15]. There is increasing interest in guidelines, programs and interventions that will help reduce surgical, catheter and ventilator-associated HAIs rates in patient groups. There is an especially strong economic incentive to do this because the Centre for Medicare and Medicaid Services no longer reimburses hospitals for conditions that were not present at admission [16].

Identifying the knowledge gaps

At this first stage of the knowledge to action cycle, gaps in policy or practice that need to be addressed are identified and described systematically. In order to find evidence that might help decision makers understand the implications of the knowledge gap in terms of economics, there are an increasing number of web tools that assist in the searching and access to health economics evidence and some of these are mentioned in Chapter 2.3 [17–19].

When considering potential gaps in policy or practice, we suggest it is important to be clear whether a new intervention, guideline or service is being considered against an existing one, or whether the "gap" is about the balance or redistribution of existing services, programs or interventions. Next, it is necessary to conduct a needs assessment by auditing and/or costing current local practice or activity. For hospitals and other health facilities, local administrative data can be helpful in calculating or estimating the cost of current services or interventions and the demographics of local population; as well as the cost of the desired evidence-based practice that is the goal of the agreed KT activity. Defining these economic-related factors should help in the clarification of the knowledge gap that needs to be addressed.

The US Agency for International Development and Management Sciences for Health produced an Infection Control Assessment Toolkit [20] that helps health care managers to identify, assess, and review areas of concern (i.e. needs assessment) regarding nosocomial HAIs and suggests cost-efficient interventions for implementation according to national and international best practice guidelines for prevention and control of HAIs.

Adapting knowledge to a local context

At this stage of the KT cycle, it is essential to start engaging clinicians and health care managers in a discussion to help understand the local context.

For example, there is a need to understand whether the impetus for change comes externally to the local context such as through a national campaign or change in guidelines, or whether it is being driven by local need.

It is particularly important here that the principle of opportunity cost be kept at the forefront of further planning. There should be a discussion around direct costs (resources consumed by the intervention, e.g. cost of prescriptions, cost of equipment) – vs. indirect costs (cost as a consequence of the intervention e.g. staff time, monitoring the implementation) of implementing the change in policy or practice. One should also be mindful of the total budget within which decisions must be made. It may also be helpful to prepare a business case for consultation with relevant local decision makers about the cost of action vs. the unpaid cost and loss of benefit (i.e. patient health outcomes) from inaction or poor compliance with evidence-based practice – "the opportunity cost".

> The Society for Healthcare Epidemiology of America developed a guide on how to develop an economic business case for infection control in hospitals [21], including information on attributable costs (including direct and indirect costs) for HAIs and impact on patient outcomes. Such a resource prepares local decision makers to be able to discuss the potential burden of costs and loss of benefit from poor compliance with evidence-based practice.

Clinicians and health care managers should be engaged in a specific discussion about the economic principles and health benefits by which they might determine the value of a proposed KT activity.

Unfortunately, it might become clear to decision makers that there is no existing or appropriate economic evidence with which to inform further decision making. It should be considered whether an economic evaluation of the newly proposed KT activity is needed or alternatively whether existing economic evidence can be synthesized and adapted by conducting a meta-analysis or developing a decision analytic model to meet the demand for local contextualized economic evidence.

Assessing barriers or enablers to knowledge use

There are several studies across the UK, Europe, USA and Australia that repeatedly report similar barriers to using economic evidence in health care decision making [1, 3, 4, 13, 22–24] (Table 5.2.1). Generating receptivity to

health economic evidence at the local level is a key enabler for ensuring its integration in KT activity [4, 23]. Educating clinicians, health care managers and policy makers in basic economic principles and their application [1, 13, 22–25] will help facilitate use of economic evidence in health care decision making.

> Qualitative studies [26, 27] report barriers to implementing infection control guidelines or effective interventions in particular hospital settings. These typically relate to a lack of resources (e.g. lab equipment and staff), bed and isolation capacity in different hospital wards. Widespread perceptions about the "disconnect" between infection control activity and quality performance indicators is also a barrier.

Select, tailor and implement knowledge translation activity

At this stage of the K2A cycle, decision makers should develop and agree transparent decision making criteria based on economic principles, to facilitate the selection and implementation of KT activity at the local level. There are a number of available frameworks that can assist decision makers in this process (see Table 5.2.2). There should be a shared clarity about the anticipated benefits from implementing the intervention, service, or policy and how these would be valued. In addition to supporting intellectual rigor more overtly, such a step will enable stakeholders to *prioritize* intervention options according to costs (e.g. time and resources) and benefits. For example, an economic approach helps to clarify the benefits of system redesign compared with the costs.

> Graves [28] presents the underlying economic concepts that should be taken into consideration when deciding how much should be invested into HAI infection control programs by presenting a marginal analysis of the costs and benefits of different options. The paper guides decision makers on how to demonstrate which types of programs or interventions would potentially provide value for money.

Monitor and evaluate knowledge use

At this stage of the KT cycle, monitoring and measuring the impact of evidence uptake will verify whether the activity as implemented delivered the desired outcomes. When implementing any KT activity, the costs (direct vs. indirect) and benefits (e.g. reduced morbidity or increased quality of life for

Table 5.2.1 Barriers to using economics evidence in health care decision making

Barrier	Description	Citation
National or system level		
Rigidities of health care budgets	The structure and governance of health care financing at the regional and local level may restrict evidence-based approaches to resource allocation	[1, 3, 13, 22]
Culture, beliefs, and organizational objectives	Culture of the organization (particularly in relation to evidence-based practice), beliefs and strategic objectives all influence how and when economics evidence is used	[3, 4, 13]
Political context of organization	There is a need to conform to national regulation and policies and these may contradict or constrain the use of economic evidence at the local level	[3, 23]
Organizational or local level		
Lack of understanding of economic evaluation methods	Local decision makers may not have the knowledge or skills to be able to understand or interpret the economic evidence	[1, 13, 22–25]
Availability of locally relevant economic evidence	There is a disconnect between what economic evidence is published and what is needed locally by decision makers	[3, 4, 22]
Lack of time and timeliness in economic evaluation	Local decision making processes do not have sufficient time to incorporate all forms of evidence or discuss the full context. Economic evidence is often not available when needed	[3, 13, 23–25]
Context of local decision making processes	The nature of how decisions are made locally also influences whether economic evidence is used (i.e. local governance processes and communication)	[4, 23]
Patient or clinical level		
Decisions not solely based on economic principles or evidence	Resource allocation decisions should incorporate ethical principles, considerations of equity, and clinical autonomy at the patient level	[1]

Table 5.2.1 (*continued*)

Barrier	Description	Citation
Lack of generalizability of study results to the real world	The most common economic evaluation approaches tend to focus on specific diseases and interventions	[1, 13, 23]
Lack of integrity or transparency in published economic evidence	Quality of published studies is variable with a wide range of methodological approaches and there is a sense of mistrust of pharmaceutical industry funded evaluations	[1, 3, 13, 22, 24]

Table 5.2.2 Frameworks to embed economic evidence in health care decision making

Description	Advantages	Disadvantages	Citation
Discrete choice experiments			
DCEs involve conducting a choice survey with appropriate stakeholders to generate data about preferences for health care interventions. These preferences are then used to build and analyze a preference model for deriving other health outcomes (i.e. utilities etc.)	DCEs have frequently been used with patients to enable a discussion and analysis of trade-offs in eliciting preferences for health care products and programs	Technical difficulties in designing optimal choice sets and estimating sample size for surveys. DCEs not frequently used in outcome measurement for economic evaluation to date	[31]
Multi-criteria decision analysis			
MCDA offers a structured approach to measure and rank different intervention options against each other according to pre-agreed multiple assessment criteria	Allows for qualitative and quantitative analysis of each intervention option against the performance criteria	Gaining more traction in the health field in recent years	[32]
Program budget marginal analysis			
PBMA uses a set of practical steps to	PBMA relies upon an multi-disciplinary	Facilitated with organizational stability,	[7]

Table 5.2.2 (*continued*)

Description	Advantages	Disadvantages	Citation
guide an advisory panel through the process of judging and ranking the relative costs and benefits of health program or service options. Recommendations are then made on how to allocate the funds within the given budget (e.g. investment, reallocation, or disinvestment)	advisory panel to set priorities for resource allocation at different levels of the health service Practical guide to decision making based on explicit economic principles	leadership, and receptivity to economic principles. Requires costing and activity or health indicator data for successful application	

patients) should be agreed upon in advance to assist in ongoing monitoring and evaluation.

Conducting an economic evaluation of KT activity will be important in determining the overall cost (alone) or the cost per benefit (i.e. incremental ratios) of implementation. The perspective of the evaluation (i.e. patient vs. health care provider) will determine which costs and benefits are measured and reported from the evaluation.

> Graves *et al.* [29] make an argument for the explicit incorporation of economic information in decision making around HAI infection control programs. They discuss how to measure the cost burden of HAI for hospitals and the attributable patient outcomes and other benefits that arise from implementing an evidence-based infection control program. Hospitals can track a reduction in the rate of HAIs associated with cost savings from preventing the treatment and management of these infections.

Sustain knowledge use

To make KT activity sustainable over time in terms of cost *and* benefit, there is a need to embed health economics principles and evidence through the entire K2A cycle. This is essential if prolonged funding for existing KT interventions is desired and also when consideration is given to scaling up existing health interventions. Economic principles involved in generating and using costing data, including marginal analysis and economies vs. diseconomies

of scale, need to be continuously applied to the local context so that decisions about the long-term production and costs of health care interventions can be made [30].

Embedding an economic approach into the K2A cycle is also critical for any new innovation in health care, as KT activity will increasingly be challenged in the future on the grounds of cost-effectiveness. Although empirical studies are few, sustaining the influence of health economics in evidence-based practice at the local level will likely be maintained through changes in organizational culture, staff awareness and understanding of how health economics evidence is generated and used, as well as investments in more flexible financial and clinical information systems.

> Demonstrating a cost–benefit from implementing an infection control program or intervention to hospital managers or directors provides a convincing evidence-based argument for continued funding of such a program.

Conclusions

Health economics principles and evidence will boost the relevance and acceptability of the K2A cycle that has become the gold standard in planning, implementing and evaluating KT activity. By ensuring that health economics is conscientiously addressed at each stage, KT activity will continue to support a financially sustainable health service with a focus on patient health outcomes.

Further research

Empirical work from different countries to identify the organizational and individual factors that promote and sustain the use of health economics evidence in the K2A cycle would quickly build a stronger evidence base with which to improve the cost-effectiveness and defensibility of KT in circumstances challenged by resource constraints.

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Section 6 **Ethics**

Chapter 6.1 **Ethics in the science lifecycle**[*]

Broadening the scope of ethical analysis

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Key learning points

- Ethics considerations go beyond provisions for the protection of research participants and their personal information.
- Researchers at all careers levels and across disciplines are encouraged to think of the potential ethics considerations at every stage in the lifecycle of their work.
- Ethics considerations can be attended to through the critical analysis of the relations of power in any given situation and at any phase along the Knowledge-to-Action cycle.
- This chapter offers a simple framework to help structure thinking about ethics considerations in the lifecycle of scientific research.

Introduction

The unprecedented growth in the human and financial resources channeled toward the health research sector globally has given rise to commensurate

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expansion in the scope and breadth of research ethics as a professional activity [1]. As much a scholarly discipline as a set of standard operating procedures, research ethics has been shaped by contributions to the literature, by the development and use of international declarations, and by the evolving discussions of institutional review boards across the globe. Indeed, scholarly ethicists, applied ethicists, and review board members alike can attest to the dynamic and necessarily shifting landscape that constitutes research ethics, even while upholding long established principles.

For their part, scientists might attest to the challenges of understanding and applying research ethics principles, but would not deny the central place of ethics at the heart of their craft. Judging by the growing number of online training programs, and the content of their modules, the ethics review process itself holds a central place for researchers. In the fast-paced world of health research, efficiency dictates that investigators be well enough versed in the "rules" for protecting research participants and their private information to satisfy research ethics boards quickly in order not to delay the research. Indeed, within the scientific community, the enactment of research ethics is often thought to start and to end with the review of a research protocol.

Yet, ethics concerns are inherent at every stage of research, from conception of an idea to the real-world application of results. That these concerns may not always directly reflect issues related to the protection of human research participants should not diminish them. To the contrary, questions such as "who controls the research agenda?" or "who will be affected by the results of this research?" may have even more far reaching implications from an ethics perspective.

What is needed to address these implications is a simple tool to assist researchers in anticipating, identifying, and attending to the *ethics considerations at all stages of the scientific endeavor*. With the objective of fostering a culture of ethics in science, such a tool should broadly address any discipline and encompass holistically the knowledge creation and knowledge application aims of science. In this chapter, we propose a simple analytical framework designed to graphically represent a generic "lifecycle approach" to ethics in science. Drawing on the work of Graham *et al.* [2] we adapt the Knowledge-to-Action (KTA) cycle in two ways: (1) parsing the key phases in the knowledge creation component of the cycle to match the detail of knowledge application component and to highlight the iterative interaction between the two; and

(2) critically considering some of the ethical issues that arise at each phase.

What ethics for the science lifecycle?

Ethics can be and has been described in many ways, as any undergraduate curriculum might attest. Legalistic or religious approaches for instance, tend to contrast perceived opposites such as "right" and "wrong" according to given doctrinal or legal standards. Such approaches are based on sets of values that underpin their decision making processes. Whether these are the social values reflected by a democratic legislative framework or the values of received religious doctrine, a common challenge is that *all* value-based systems are time-bound and culturally derived systems. These systems are never universally representative. For instance, what is considered a crime will differ from country to country, just as what is considered a sin will differ from one religion to another.

It is this issue that can complicate the application if ethics to science, a sector for which the cornerstones are objectivity and experimental rigor. Though we might like to think of science as being value-free, arguably it is impossible for any human activity to be so. Yet science does occupy an exceptional position from the perspective of ethics. The ethics-based calculus of *values* (determining right or wrong, good or bad) does not apply to the scientific endeavor as it does to human or organizational behavior. Similarly, the established values-based principles of popular models of bioethics such as beneficence, non-maleficence and justice cannot simply be imported directly into research, as the experimental method would be impotent if it truly "did no harm." Nonetheless, ethical reasoning is central to knowledge creation and its application.

We argue that an ethical framework for the science lifecycle must be sufficiently broad and flexible to include not only the universal principles of human participant protection that are already long-established to govern scientific research, but also a critical analysis of the (unintended) consequences or hidden biases along the lifecycle. Thus, we propose a pragmatic approach to ethics in the science lifecycle that positions ethics as a *critical analysis of relations of power and context*. The following section describes this theoretical framework, using a practical example, the publication of H5N1 (influenza) research (Box 6.1.1).

Box 6.1.1   True case example: H5N1

For over a year, two separate research teams wanted to publish their results on the air-borne transmissibility of H5N1 influenza between mammals (ferrets). As per international standards of science, the "Materials and Methods" section of the manuscript included a detailed description of the process used to create this virus, to allow reproducibility of the results.

The situation ignited considerable debate among bloggers. Some strongly defended freedom of inquiry while others feared for public safety if the results were to be published, as the information could be used for nefarious purposes. Both labs created a transmissible form of H5N1; any release of this virus could trigger a pandemic in humans. The controversy around this issue was escalated and resulted in a hearing of the US National Science Advisory Board for Biosecurity in February 2012.

Finally, the papers in question were published in the internationally renowned journals *Science* (http://www.sciencemag.org/content/336/6088/1534.full, accessed September 2012) and in *Nature* (cont. below) (http://www.nature.com/nature/journal/v486/n7403/full/nature10831.html, accessed September 2012) in June 2012.

A critical analysis of relations of power and context

In the example (Box 6.6.1), it is not possible to make an ethics-based decision using the good/bad-right/wrong frames of reference. The traditional principles of beneficence, non-maleficence, autonomy, and justice – the tenets of health care ethics – cannot be applied in this case. These frameworks fail to capture the inherent risk in the scientific endeavor, while traditional research ethics frameworks do not capture the issues of greater social responsibility, beyond protection of human research participants. So the case is caught between two ethics frameworks, neither of which is sufficiently supple to capture both the short and longer-term consequences of the research and the translation of new knowledge acquired.

Consider that a researcher has the freedom to define his or her agenda and that this is an exercise of power. Society, through its institutions, has the right to regulate and fund research as it sees fit. This is also an exercise of power. If we evaluate the power struggle, we will gain a better insight about the risks and benefits involved in this particular case. For instance, proving the (previously rejected) possibility of airborne transmission would be a great benefit to science and public health, yet keeping society safe from potential nefarious uses of the new knowledge is equally important from a public health and safety perspective. In the end, researchers and public health officials in this particular case managed to prove that the knowledge

gained, although potentially harmful if applied inappropriately, would yield positive results for society.

As evidenced by the H5N1 influenza case, we can easily imagine knowledge to be at once good and bad or right and wrong. Similarly, we can easily place knowledge on both sides of the beneficent/maleficent fence. In fact the history of science is rife with examples of this ambiguity of impact. Consider António Egas Moniz, who was awarded the Nobel Prize for Medicine for his research on lobotomy, a procedure that was later fully discredited [3]; or think about Thalidomide which was intended to reduce a woman's nausea during pregnancy, but resulted in tragic consequences for the child. This drug is now making a comeback in the armamentarium for the treatment of some neoplasms and chronic inflammatory diseases [4].

It is because of this inherent ambiguity that the best ethics guidance for knowledge creation and knowledge application is not a directive that dictates a course of action, but rather simple tools that support *critical reasoning* through an analysis of power relationships over the immediate, medium, and long term. Researchers and other science stakeholders are thus encouraged to think critically about who has power and voice in a situation and who is (unintentionally) silenced; who benefits and who does not, and in what contexts? The goal of this approach is to consider each element in a situation and note the influences and potential consequences. The approach thus illuminates the ethical issues and can facilitate decisions on the most socially defensible course of action.

The Knowledge-to-Action Ethics Framework (KTA–E)

To facilitate the application of a practical approach to ethics throughout the science lifecycle, we have developed a graphical representation of the analytical framework. The Knowledge-to-Action Ethics (KTA-E) framework (Figures 6.1.1, 6.1.2, and 6.1.3) is designed to represent the interconnected and iterative relationship between the activities associated with knowledge creation and those of knowledge application. It builds on the Knowledge-to-Action (KTA) cycle developed by Graham *et al.* [2] and explores some of the ethics considerations at each phase in this process from the perspective of relations of power.

Deliberately generic, the framework is designed to apply across research disciplines and with any type of research methodology, from experimental trials to qualitative research. While the phases associated with the involvement of human participants in research are included in the framework (phases 5 to 7, Table 6.1.2), these phases can be invoked or ignored

depending on the type of research under analysis. These phases are high-lighted deliberately in Table 6.1.2 specifically to draw attention to the fact that conventional thinking often limits ethics analysis to these phases alone. The result is to effectively ignore the possibility of ethics concerns in research not involving humans (or animals). By contrast, the KTA-E framework demonstrates that even research that does not involve humans must be considered from an ethics perspective.

For the sake of visual clarity the graphic is broken down into a series of three parts (Figures 6.1.1, 6.1.2, and 6.1.3), though these should be considered interdependent and iterative, where attention to knowledge application is linked directly to activities in knowledge creation such as the development of research partnerships and forming research questions, for instance (what is known as integrated KT). As a visual cue that underscores this interdependence, knowledge creation and application are encircled within an integrated system that covers the full lifecycle of science.

At the same time, the segmented nature of the graphic can also facilitate more detailed analysis of the ethics considerations of knowledge creation or knowledge application processes independently.

It should be noted that other layers of analysis could be applied to this framework. For instance, gender-based issues or environmental impacts could be analyzed using the model.
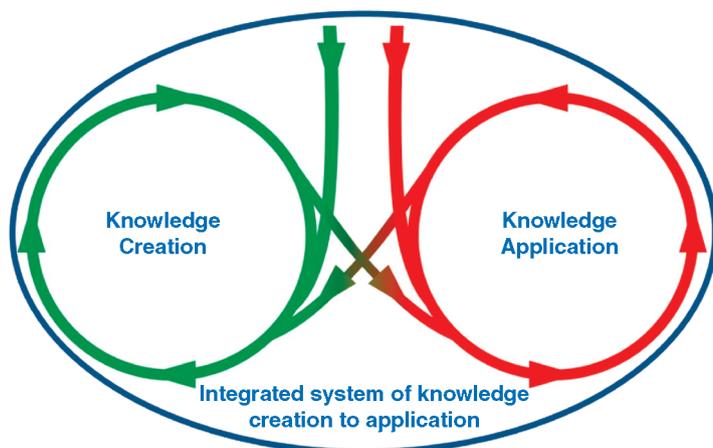
Figure 6.1.1 The KTA-E framework: enter the integrated system of knowledge creation and application by identifying a problem.

Table 6.1.1 Ethics considerations on entering the science lifecycle

Phase	Activity	Some potential ethics considerations
	Identify the problem: whether the focus is primarily one of research (knowledge creation) or application of research.	• Influence of disciplinary and epistemological lens • Influence of socio-political context • Priority-setting process • Agenda-setting process • Stakeholder engagement • Power and voice: whose concerns are addressed; who is (unintentionally) silenced? • Social responsibility of research
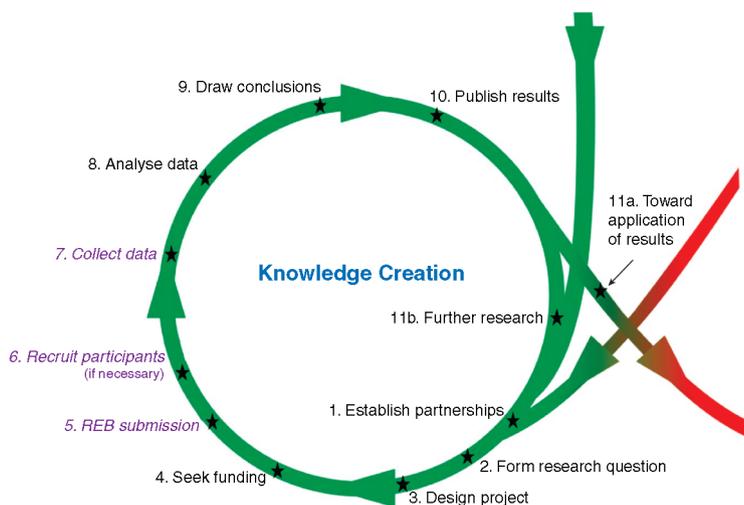
Figure 6.1.2 Phases of knowledge creation in the KTA-E framework.

Table 6.1.2 Ethics considerations in phases of knowledge creation (KC) as illustrated above

Phase	Knowledge creation activities	Some potential ethics considerations
1	Establish (or strengthen) partnerships	Choice of collaborators; concern for equity; power and voice (Whose concerns are addressed? How is the agenda set? Who participates; who is left out and why?)
2	Form research question	Stakeholder involvement; influence of context; framing; influence of theory; influence of previous research
3	Design research project	Resources and capacity available; theory used; methodology used; study population selected
4	Seek funding	Choice of funder; obligations to funder; public/private funding considerations
5	REB submission (if necessary)	Protection of human research participants; privacy concerns; informed consent; data stewardship; real, potential, or perceived conflict of interest
6	Recruit participants (if necessary)	Protection of human research participants; privacy concerns; informed consent; data stewardship; potential or perceived conflict of interest
7	Collect data	Protection of human research participants; privacy concerns; informed consent; data stewardship; real, potential, or perceived conflict of interest
8	Analyze data	Influence of methodological choices; role of collaborators; research integrity
9	Draw conclusions	What is taken to be evidence and why? Implications for individuals; groups and populations; real, potential, or perceived conflict of interest
10	Publish results	Authorship and attributions; choice of publication venue; publication bias; what to do with negative results
11a	Towards application of results	Selection of evidence to inform approaches for knowledge application (what is considered sufficient evidence?)
11b	Further research	Responsible stewardship of funds; justification of further research
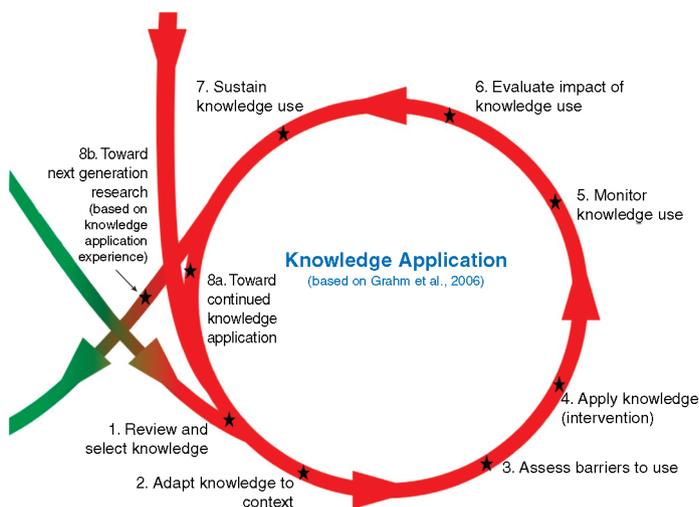
Figure 6.1.3 Phases of knowledge application in the KTA-E framework. Based on Graham, ID, Logan J, Harrison MB, Straus SE, Tetroe J, Casell W, *et al.* Lost in knowledge translation: time for a map? *J Contin Ed Health Prof* 2006; **26**(1): 13–24.

Table 6.1.3 Ethics considerations in phases of knowledge application (KA) as illustrated

Phase	Knowledge application activities	Some potential ethics considerations
1	Review and select knowledge	Choice of KA theory; publication bias; data access; intellectual property considerations; what to do with negative results
2	Adapt knowledge to context	Honoring local knowledge; voice; agency
3	Assess, barriers to use	Concern for equity; access issues
4	Knowledge translation interventions	Resource allocation; equity; opportunity costs; intellectual property
5	Monitor knowledge use	Potential real or perceived conflict of interest with respect to roles and responsibilities (if investigators have interest in applications of results)
6	Evaluate impact of knowledge use	Criteria-setting; potential, real, or perceived conflict of interest (if investigators have interest in applications of results); disparities inadvertently created by knowledge use

(*continued*)

Table 6.1.3 (*continued*)

Phase	Knowledge application activities	Some potential ethics considerations
7	Sustain knowledge use	Ethics of sustainability concerns (capacity-building to maintain momentum for application of knowledge); opportunity costs (application of new knowledge could imply trade-offs for policy and budget allocation)
8a	Toward next generation research	Selection of evidence; responsible stewardship of funds (is further research in this area justified? Based on what?)
8b	Toward continued quality improvement in the application of knowledge (i.e.: through this side of the cycle again)	Selection of evidence; responsible stewardship of funds (is continued application of this knowledge justified? Based on what?)

Applying the KTA-E Framework: Sample case scenarios and analyses

To exemplify how the critical analysis of relations of power and context can highlight the ethicality of an activity, and to help situate and understand the ethics problematic of knowledge creation and knowledge application, some scenarios are presented below. Each phase in the cycle will, under analysis, present its own ethics considerations. As a starting point for each of these scenarios, it is useful to bear in mind a few common considerations:

• How do the intent, design and methodology of a knowledge creation or application activity affect its ethicality?
• Are participants and researchers on level ground? Is there an unfair gain or advantage (or disadvantage) in the activity?
• Are public resources being used fairly? How are public and private resources used?

Scenario 1

A group of researchers from various universities decide to create a web-based information sharing site where they will exchange information freely and openly. The site uses strong security protocols and only the original research group (all members of which know each other personally) will be able to participate. The type of information to be shared includes personal identifiers of research participants and details of their health charts.

Scenario 1 is of particular relevance to knowledge translation and how it impacts the next iteration of knowledge creation. Some of the ethics considerations related to this case include:

- Do researchers have the right to treat data they collect or are given access to as a personal property?
- With privacy and confidentiality concerns protected, isn't the free sharing of information by experts an important element of knowledge creation?

These questions relate to the KTA-E cycle at phases 3 (access, barriers to use) and 7 (sustain knowledge use) of knowledge application. The case is interesting because the lens of ethics scrutiny can be aimed in two opposing directions. One analyst might see the primacy of protecting participant privacy while another might champion the ethical imperative to freely share data that could lead to important scientific advances with great public benefit.

Scenario 2

Researchers call a meeting of the members of an HIV/AIDS community-based treatment center to discuss the design of the clinical trial phase III protocol of a new drug. The participants proposed a series of modifications to the original design. These changes included expanding the responsibility of the clinical researchers regarding their duty of care, and expanding the trial sponsors' duties to include not only drug access after the closure of trial but also remuneration of the participants for a more extended period of time.

Scenario 2 exemplifies the continuous and iterative nature of the knowledge-to-action process. Participants want the knowledge and are willing to participate in the activity but only at a price. Both researchers and the trial sponsor are being asked to negotiate terms that have no tangible benefit for them. The scenario leads us to question:

- Who defines and controls the benefits of research.
- What implications would different definitions of "benefits" have?

The case reflects some of the questions at phases 1–4 on the knowledge creation side of the cycle and phase 4 on the knowledge application side.

Scenario 3

A researcher who is funded through a federal grant from emergency funds aiming at the control of epidemics, and through a grant from industry, comments with colleagues on a public online forum that he stumbled across an important finding that may change forever a key vaccination protocol. However, he will not share the results before signing a contract ensuring that he will receive part of the profits the company will get due to the changed protocol.

In other career tracks, professional advancement and personal gain are often viewed as a positive measure of success, but in health research, these same goals are often be interpreted negatively as ego-driven. One might pause to consider:

- Whose interests should be foremost in knowledge creation activity: The researcher? Society? The granting agency representing society? The employer? The government of the day?
- Do researchers have a duty to serve social ends? Does it matter where their funding is from?

Scenario 3 focuses on issues related to the use and application of research and some of the potential barriers to that use. Some of the barriers may be so significant that a subsequent iteration of the knowledge to action cycle may not occur. This scenario demonstrates that the personal choices of the researcher may impact all phases of the knowledge to action cycle.

Scenario 4

A group of social workers want to develop a protocol to study health interventions aimed at the improvement of health conditions in a suburban setting. The target population is engaged, interested, wealthy, and intellectually sophisticated. The Clinical Ethics Board of the institution wants the social workers instead to apply the research resources to a disadvantaged population. The social workers reasoned that there is still a lot to learn from the population they chose to study.

Conducting social work research with a disadvantaged, underserved, or vulnerable population is quite common, but the same cannot be said for a more affluent population. At first sight, it may be interpreted as a waste of resources. Working through the KTA-E analysis framework, questions might arise such as:

- Who defines the research agenda and therefore the study population? Are there populations that do not "need" to be studied, while other populations "merit" research?
- Who defines where resources should and should not be to be used?

In Scenario 4, because it is intervention research, knowledge is being created with the specific objective of translating it to a service aimed at a particular population group. If this were an underprivileged urban population, there would be many justifications for undertaking research, most of them from a social justice perspective. With an affluent population group, however, is there a "right" to research? Can research even be framed as a "right"?

Although many of the considerations along the KTA-E cycle should be addressed, this scenario in particular raises issues at phase 5 of the

knowledge creation side. Would a research ethics board view this protocol differently from a clinical ethics board (to which it was submitted)? Would the researchers have to justify their choice of study population in any case? Would either board consider elements of the proposal differently if a more disadvantaged population were chosen for research?

Scenario 5

A researcher has developed a participatory project in a rural community, addressing issues related to mental health in young adults. Her studies, using an appreciative inquiry methodology, demonstrated the importance of resilience in this group. Because positive research results may reduce the mental health care funding allocation for this community by the regional health board, there is some pressure from community members to withhold important data from publication in an effort to maintain the current health care funding allocation for mental health services.

Scenario 5 exemplifies the unexpected consequences of research. A very simple proposal, to evaluate the results of a public health intervention, demonstrates the benefits of the intervention. Consequently, the community is faced with the prospect of seeing its funding allocation reduced.

- Does the researcher have an obligation to publish her results?
- Does the researcher have any obligation to the participant community? Do this particular community's interests come before the interests of society, which stands to learn from the published research?
- Is omitting or misrepresent the results justifiable on the grounds that it would protect the participant population?

Scenario 5 highlights the external factors that may influence the knowledge application without impinging on its creation.

Scenario 6

A group of researchers have finished the *in vitro* phase of the study of an experimental anti-convulsive agent. In preparing to study the pharmacological effects of the agent *in vivo,* they are selecting potential animal models. The literature suggests that primates would be an appropriate model for the trial but the researchers feel uneasy about using higher order animals. The researchers have to decide between using the best available animal model – a primate – or using a mouse model which may not yield data of equivalent quality, but the use of which generally does not carry the same ethical sensitivities as research with primates

Personal feelings or beliefs may interfere in study design. In some cases, the interference may compromise the scientific validity of the experiment while in others it may open new avenues of knowledge creation. Whether scientists acknowledge it or not, such beliefs underpin all phases of the KTA-E cycle. It is when they influence key factors in study design or in the selection and use of evidence that they can have the most significant impact on outcomes. This scenario leads to "big picture" questions in the philosophy of science such as:

- What influences are at work as data become information and information becomes evidence?
- Is all evidence equal?
- Who decides what will and will not be "taken as evidence?" What are the implications of this choice when health interventions are at stake?

Scenario 6 reflects considerations particular to phase 2 of the knowledge creation side of the KTA-E cycle. However, the outcome of this phase will set up a chain of influences that affect phases along the entire cycle. In fact, the impact of research design decisions on knowledge application should not be underestimated.

Summary and future directions

As this chapter attempts to illustrate, the social and ethical responsibilities of researchers, research administrators, research institutions, and funders are not limited to the ethics review process. At its most fundamental, the review process assesses compliance with policies and regulations and mitigates identified risks – most often to individuals. But being compliant should not be equated with being ethical, nor does it imply a specific regard for potential unintended consequences from a science *lifecycle* perspective, which includes the application of knowledge generated.

In the quickly changing landscape of health research, where research is more expensive, more collaborative, more international and more interdisciplinary than ever before, there is a pressing need for a better understanding of what it means to be ethical in the practice of science. This understanding must take into account the diverse perspectives of the multiple agents in the scientific enterprise – from funders and funding partners to administrators, institutions, investigators, trainees, health professionals, and patients. In the knowledge-to-action process, ideas about professional integrity, fairness of process, and protection of participants and privacy, for instance, do not account sufficiently for the exceptional place of science in society.

The framework presented in this chapter offers some signposts that help to structure critical thinking for (presumably) non-ethicist health researchers, but it is also an invitation to ethicists to consider in greater detail all of the phases along the KTA-E lifecycle. More empirical ethics research would be welcome in areas that critically analyze the "how" and the "so what" of, for instance: setting the research agenda; selecting a study population; applying a particular methodology; attributing authorship; and, of course, moving from "data" to "evidence" to "action," among many others.

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Chapter 6.2 Ethical issues in cluster-randomized trials in knowledge translation

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Key learning points

- Human research is governed by four ethical principles that are reflected in national and international regulations: respect for persons, beneficence, justice, and respect for communities.
- The choice of cluster (as opposed to individual) randomization in knowledge translation (KT) research must be carefully justified.
- Cluster randomized trials (CRTs) evaluating KT interventions are research and must be submitted to and approved by a research ethics board (REB).
- Professionals who are intervened upon in KT CRTs are research participants, but their patients may not be research participants.
- As is the case with any study design, if seeking informed consent would make a KT CRT infeasible, researchers may apply to an REB for a waiver of consent, provided that the study poses no more than minimal risk.

> • Cluster gatekeepers may be approached for permission to enroll a cluster in a KT trial when they possess the legitimate authority to provide such permission, but gatekeeper permission is not a substitute for the informed consent of individual research participants.

Chapter 5.1 presented study designs for evaluating effectiveness of knowledge translation (KT) interventions. A randomized controlled trial is often considered the ideal choice for evaluating KT intervention effectiveness because, when properly executed, it can guarantee internal validity of the study. In a cluster randomized trial (CRT), the unit of allocation may be a health professional, medical practice, hospital, or similar unit, and outcomes collected from individual patients are nested within the unit of allocation. Cluster randomization has methodological [1, 2] as well as ethical implications [3–9]. Although national and international research ethics guidelines (such as the Tri-Council Policy Statement [10], Declaration of Helsinki [11], and CIOMS [12]) apply to CRTs in KT research, their interpretation is more complicated because, for example, the units of allocation, intervention, and outcome measurement may be different in a single study.

The Ottawa Statement on the Ethical Design and Conduct of CRTs [13] presents explicit recommendations for the ethical design and conduct of CRTs (see Box 6.2.1 for the list of recommendations). The Ottawa Statement is the product of a five-year mixed methods research project [14] that included a series of empirical studies of the ethical challenges in CRTs, an extensive ethical analysis, and a consensus process. A 19-member multi-disciplinary expert panel, appointed by the research team, met during closed sessions to develop guidelines. Draft guidelines were posted on the project website and input was invited from conference delegates and the broader research community before final publication. Further details of the consensus process are provided elsewhere [13]. In this chapter, we interpret recommendations in the Ottawa Statement with respect to CRTs of KT interventions using three case examples. The case examples are summarized in Box 6.2.2.

General ethical principles

All research involving human participants should be conducted in accordance with four fundamental ethical principles [11, 12, 15]: respect for persons, beneficence, justice, and respect for communities. These principles are grounded in moral theories, the research ethics literature, and convention.

Box 6.2.1 Summary of recommendations in the Ottawa
Consensus statement [13]

Justifying the cluster randomized design
1 Researchers should provide a clear rationale for the use of the cluster ran-
domized design and adopt statistical methods appropriate for this design.

Reb review
2 Researchers must submit a CRT involving human research participants for
approval by a REB before commencing.

Identifying research participants
3 Researchers should clearly identify the research participants in CRTs. A
research participant can be identified as an individual whose interests may
be affected as a result of study interventions or data collection procedures,
that is, an individual:
   (a) who is the intended recipient of an experimental (or control) inter-
   vention; or
   (b) who is the direct target of an experimental (or control) manipulation
   of his/her environment; or
   (c) with whom an investigator interacts for the purpose of collecting data
   about that individual; or
   (d) about whom an investigator obtains identifiable private information
   for the purpose of collecting data about that individual.
   Unless one or more of these criteria is met, an individual is not a research
participant.

Obtaining informed consent
4 Researchers must obtain informed consent from human research partici-
pants in a CRT, unless a waiver of consent is granted by a REB under spe-
cific circumstances.
5 When participants' informed consent is required, but recruitment of par-
ticipants is not possible *before* randomization of clusters, researchers must
seek participants' consent for trial enrolment as soon as possible after clus-
ter randomization—that is, as soon as the potential participant has been
identified, but before the participant has undergone any study interven-
tions or data collection procedures.
6 A REB may approve a waiver or alteration of consent requirements when
(1) the research is not feasible without a waiver or alteration of consent,
and (2) the study interventions and data collection procedures pose no
more than minimal risk.
7 Researchers must obtain informed consent from professionals or other ser-
vice providers who are research participants unless conditions for a waiver
or alteration of consent are met.

Gatekeepers
8 Gatekeepers should not provide proxy consent on behalf of individuals in
their cluster.

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9   When a CRT may substantially affect cluster or organizational interests, and a gatekeeper possesses the legitimate authority to make decisions on the cluster or organization's behalf, the researcher should obtain the gatekeeper's permission to enroll the cluster or organization in the trial. Such permission does not replace the need for the informed consent of research participants.

10   When CRT interventions may substantially affect cluster interests, researchers should seek to protect cluster interests through cluster consultation to inform study design, conduct, and reporting. Where relevant, gatekeepers can often facilitate such a consultation.

Assessing benefits and harms

11   The researcher must ensure that the study intervention is adequately justified. The benefits and harms of the study intervention must be consistent with competent practice in the field of study relevant to the CRT.

12   Researchers must adequately justify the choice of the control condition. When the control arm is usual practice or no treatment, individuals in the control arm must not be deprived of effective care or programs to which they would have access, were there no trial.

13   Researchers must ensure that data collection procedures are adequately justified. The risks of data collection procedures must (1) be minimized consistent with sound design and (2) stand in reasonable relation to the knowledge to be gained.

Protecting vulnerable participants

14   Clusters may contain vulnerable participants. In these circumstances, researchers and REBs must consider whether additional protections are needed.

15   When individual informed consent is required, and there are individuals who may be less able to choose participation freely because of their position in a cluster or organizational hierarchy, REBs should pay special attention to recruitment, privacy, and consent procedures for those participants.

Box 6.2.2 Case examples

Case example 1: Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer [29]
Objective: To evaluate a decision aid to inform early breast cancer patients about their treatment options.
Unit of randomization: General surgeons practicing in community hospitals.
Intervention: Patient level. Intervention was a decision aid (audiotape and workbook) versus a standard educational pamphlet distributed to patients during the surgical consultation.
Data collection: Patient scores on a decisional conflict scale, and breast cancer knowledge, anxiety, and decisional regret obtained from patient questionnaires; data on pathology and actual treatment received extracted from patient charts by research nurses.
Results: No significant differences in knowledge, anxiety or regret; non-significant trend toward lower decisional conflict in the decision aid group.

Case example 2: A behavioral intervention to improve obstetrical Care [30]

Objective: To evaluate a behavioral intervention to improve obstetrical care in Argentina and Uruguay.

Unit of randomization: Hospitals randomized to the behavioral intervention or no-intervention control.

Intervention: Health professional level. Teams of birth attendants (physicians, residents, and midwives) were identified as opinion leaders and participated in a workshop to develop and disseminate clinical guidelines. Teams returned to their respective hospitals, disseminated guidelines, trained other birth attendants, and implemented a system of reminders.

Data collection: Rates of episiotomy and prophylactic use of oxytocin in the third stage of labor were collected using a standard clinical record form. No information identifying individual patients was transmitted from the hospitals. Birth attendants completed self-administered questionnaires measuring their readiness to change.

Results: Rates of prophylactic oxytocin use increased significantly; rates of episiotomy use decreased significantly in intervention versus control hospitals.

Case example 3: Effect of computerized evidence based guidelines on management of asthma and angina in adults in primary care [31]

Objective: To evaluate the use of a computerized system to support evidence based clinical decision making for the management of asthma and angina in primary care.

Unit of randomization: 60 general practices in England.

Intervention: Practice level. Computerized decision support system for physicians integrated into practice computer software. Each practice was invited to send two members to a training workshop. Each doctor or practice nurse in the study received a paper copy of the summary of both guidelines, and each practice received a paper copy of the full version of both guidelines.

Data collection: Patients were identified from a computerized search of practice records. Prescribing data were abstracted electronically from computerized clinical records. Trained data collectors manually abstracted non-prescribing data from paper and electronic patient records. Patients completed quality of life questionnaires in a postal survey.

Results: The intervention had no impact on either the process or outcomes of care.

Respect for persons implies the need to seek valid informed consent from research participants for study participation. The principle of beneficence obliges researchers not to inflict unnecessary harm and, where possible, to promote the welfare of research participants. The principle of justice may be defined as the ethical obligation to distribute the benefits and burdens of research fairly. Respect for communities implies that researchers have an obligation to respect communal values, protect and empower communities, and, where applicable, abide by the decisions of legitimate communal authorities.

Justification for the CRT design

An important decision in designing a trial in KT research is the unit of allocation. This decision must be carefully justified [16]. It depends, in part, on the "level" at which the KT intervention is administered. In the case of a professional level or cluster level intervention, cluster randomization may be the only feasible choice. In case example 2 (a behavioral intervention targeted at birth attendants) and case example 3 (the introduction of an electronic decision-support system in general practices) it would not have been practical to randomize individual patients. In contrast, in case example 1 (a patient level intervention), the patient could have been the unit of allocation, but the surgeon was selected as the unit of allocation to avoid experimental contamination.

Is research ethics review required?

National and international research ethics guidelines stipulate that all human research must be submitted to and approved by a research ethics board (REB). Research may be defined as a systematic investigation designed to produce generalizable knowledge. CRTs of KT interventions meet the definition of research and must be reviewed by an REB. REBs ought to take a proportional approach to the review of study protocols; thus, protocols not involving vulnerable participants and posing only low risk to research participants may be eligible to undergo expedited or delegated review.

How should research participants be identified?

Clusters in a KT CRT are usually composed of members at multiple levels (e.g., patients, health professionals)—but not all cluster members are necessarily *research participants*. The identification of human research participants is an ethical requirement before consent procedures and harm-benefit issues can even be considered. A defining feature of research participants is that their interests are affected by study interventions or data collection procedures [17]. Based on this definition, the Ottawa Statement provides four criteria for identifying research participants in a CRT (see Box 6.2.1, recommendation 3).

In case example 1, patients are research participants as they were the recipients of an experimental intervention (the decision aid) (a), completed study questionnaires (c), and contributed identifiable medical information through review of their medical records (d). Surgeons were not targeted by any interventions, did not otherwise interact with researchers to provide

Table 6.2.1 Identification of research participants in the three case examples

Criterion	Case example 1		Case example 2		Case example 3	
	Surgeons	Patients	Birth attendants	Patients	Doctors and nurses	Patients
(a) Recipient of intervention?	No	Yes	Yes	No	Yes	No
(b) Direct target of environmental manipulation?	No	—	—	No	Yes	No
(c) Interacts with researcher for purpose of data collection?	No	Yes	Yes	No	No	Yes
(d) Their identifiable private information obtained for data collection?	No	Yes	—	No	No	Yes
Research participant?	**No**	**Yes**	**Yes**	**No**	**Yes**	**Yes**

data, and did not provide identifiable private information; thus, surgeons are not research participants. Birth attendants in case example 2 are research participants as they were the recipients of a behavioral intervention (a) and completed questionnaires (c). Patients are not research participants: they were not directly intervened upon by an investigator, nor were they deliberately intervened upon via manipulation of their environment; investigators did not interact with them for the purpose of collecting data, and no identifying patient information was transmitted beyond the hospital. Doctors and nurses in case example 3 are research participants as they were directly intervened upon (a, b). Patients who were contacted for completion of quality of life surveys (c) and those whose medical records were reviewed (d) are also research participants. Table 6.2.1 summarizes the identification of research participants in the three case examples.

From whom must informed consent be obtained?

The ethical principle of respect for persons generally requires that researchers seek the informed consent of prospective research participants. The consent process allows potential participants to adopt the ends of the study as their own instead of being treated merely as a means to an end. In KT

CRTs, consent is required only from those cluster members who are research participants [18].

In case example 1, informed consent is required from patients (research participants), but not from surgeons; in case example 2, informed consent is required from birth attendants (research participants), but not from patients. Doctors and nurses in case example 3, as well as patients who completed survey questionnaires and those whose medical records were being reviewed, are research participants and their informed consent is therefore required.

Consent for what?

National and international research ethics guidelines provide detailed disclosure requirements for consent processes, including information about the purpose of the study, study interventions and data collection procedures, the potential benefits and risks of study participation, and alternatives to participation. In standard randomized controlled trials, patients usually consent to randomization, intervention, and data collection prior to study enrolment. In KT CRTs however, the units of allocation, intervention, and data collection are usually different, which implies that consent for these three aspects of the trial may need to be sought separately. In case example 1, patients are required to consent to study interventions and data collection procedures; in case example 2, birth attendants are required to consent to study interventions and completion of questionnaires; in case example 3, doctors and nurses are required to consent to study interventions, whereas patients are required to consent to data collection.

What if informed consent is not feasible?

In some KT CRTs, seeking individual informed consent may be logistically impossible (e.g., due to the sheer size of a cluster which could be a practice, city, or region). In such cases, a waiver of consent may apply, provided the risk to study participants is minimal. A waiver of consent means that the REB removes the requirement to obtain informed consent. Minimal risk refers to the risks of daily life of the study population. A variety of study procedures, including physical examination, non-invasive medical monitoring, ultrasound, and review of medical records, are commonly regarded as presenting only minimal risk to research participants. The researcher is responsible for adequately justifying to the REB that obtaining informed consent is infeasible and that study participation poses only minimal risk. In case example 3, as long as appropriate confidentiality protections were

in place, an REB may approve a waiver of consent for the review of patient medical records.

In some KT CRTs, interventions are administered at the cluster level. An example of a cluster level KT intervention is the introduction of posters and videos in hospital waiting rooms targeting patients with educational messages about antibiotic treatments. In trials with cluster level interventions, individual informed consent is usually not feasible because there is no way for an individual to opt out or avoid the intervention and, as a result, refusals of consent are not meaningful. In such cases, researchers may apply for a waiver of consent for the study intervention, provided it presents no more than minimal risk to research participants. However, a waiver of consent may not extend to all study procedures. For example, if a waiver of consent is granted for the study intervention, researchers may still be required to seek informed consent for data collection procedures.

In some KT CRTs, researchers may be concerned that information disclosed during the informed consent process may lead to either selection or response bias [19, 20]. It is up to the REB to determine whether these concerns constitute sufficient grounds for a waiver or alteration of consent. An alteration of consent means that the REB permits changes to or removal of some of the standard elements of disclosure in the informed consent, for example, by allowing incomplete disclosure of the nature of a behavioral intervention. Alterations of consent procedures must be approved by the REB and are subject to the same restrictions as waivers, i.e., the risk of bias must make the study infeasible and study interventions must pose no more than minimal risk. To minimize the risk of participation or response bias in case example 1, the REB may have approved an alteration of informed consent by allowing researchers to provide identical informed consent sheets to patients in intervention and control arms that do not disclose the exact nature of the intervention. In other cases, the risk of bias may be mitigated by adopting certain design features. In case example 3, researchers adopted an incomplete block design [21, 22]: one arm received guidelines for the management of angina, the other for the management of asthma. This design was used to equalize any possible Hawthorne effects arising from health professionals being aware of the guidelines being studied.

When should informed consent be sought?

Researchers should strive to identify participants and seek their consent *before* cluster allocation. However, in some KT CRTs, it is not possible to approach or even identify eligible participants before cluster randomization. In such cases, researchers should seek potential participants' consent

as soon as possible after the participant has been identified, and before administering any study interventions or data collection procedures. Researchers should be aware of the risks of bias associated with post-randomization consent and should avoid differential consent procedures in the intervention and control arms of the study [23, 24].

In case example 1, pre-randomization consent was not feasible as breast cancer patients needed to be prospectively identified after allocation of surgeons. However, patients provided informed consent before receiving the decision aid and completing questionnaires. Researchers may have considered possible selection biases arising from the fact that surgeons, who were aware of their own allocation status and familiar with characteristics of patients, were required to identify and enroll patients.

Considerations in health professional consent procedures

Health professionals are commonly research participants in KT CRTs; in such cases, their informed consent is required unless conditions for a waiver of consent obtain. Recruitment of health professionals in KT CRTs should be free of coercive influence from supervisors, hospital administrators, or organization leaders. Health professional consent procedures should include discussions about career-related risks (e.g., due to detection of negligence or incompetence). Data about health professional performance should be kept confidential within the research team, unless circumstances arise, such as gross negligence or incompetence that mandate disclosure to a professional certifying or licensing body.

What is the role of cluster gatekeepers?

KT CRTs may have one or more "gatekeepers" associated with study clusters. Examples of gatekeepers in KT CRTs include hospital administrators, senior practice partners, or practice managers. Gatekeepers have an important role with respect to the protection of group or organizational interests affected by a KT CRT [25]. As long as a gatekeeper's role within the cluster or organization endows them with the authority to make decisions on behalf of the cluster, and as long as cluster members recognize this authority, researchers may approach a gatekeeper for permission to enroll a cluster in a trial. However, gatekeeper permission is not a substitute for the informed consent of individual research participants in a KT CRT. In case example 2, there is an obligation to seek the permission of hospital authorities to conduct the study in their facility

(but not to enroll birth attendants in the trial). In case example 3, there is an obligation to seek the permission of practice managers to include practices and to install the computer software (but not to enroll individual doctors and nurses in the trial).

Gatekeepers may also facilitate consultation between researchers and cluster members about the goals, design, and implementation of the study, as well as dissemination of research findings. In case examples 2 and 3, hospital authorities and practice managers, respectively, may facilitate consultation with birth attendants, and doctors and nurses about specific aspects of the trial.

Gatekeepers may also have the authority to withdraw a cluster from an ongoing KT CRT. As cluster withdrawals can have serious consequences for participants as well as the scientific validity of a CRT, researchers should make every reasonable effort to retain all enrolled clusters in the trial. In case example 2, researchers offered the control hospitals aspects of the intervention at the end of the study to help secure the cooperation of the hospitals and prevent hospital attrition.

Future research

Prior to publication of the Ottawa Statement, there were no comprehensive ethics guidelines specific to CRTs; as a result, researchers and REBs had to rely on ambiguous interpretation of standard research ethics guidelines. This process contributed to considerable uncertainty and variability in the conduct and ethics review of CRTs within and among different jurisdictions [26], including CRTs in KT research. Future research may focus on evaluating the uptake of the Ottawa Statement amongst researchers and REBs, and determining to what extent it has contributed to improvements in the research ethics review process of KT CRTs. As a first step, the development of translational materials for KT researchers and REBs is an important requirement to its uptake.

In this chapter we interpreted recommendations in the Ottawa Statement with respect to KT applications in health care. There is now increasing interest in implementation science among researchers in public health, education, welfare, and crime prevention [27], as well as economic development, engineering, and business [28]. Future research may focus on the application of the Ottawa Statement to KT CRTs in these areas. Finally, given the rapidly expanding nature of the field, the authors of the Ottawa Statement anticipate the need for significant revisions and additions to the guidelines over the next few years.

Summary

This chapter focused on specific recommendations in the Ottawa Statement pertaining to justification of the CRT design, the need for REB review, the identification of research participants, obtaining informed consent, and the role of gatekeepers in KT CRTs. Cluster randomization is an ideal study design for evaluating KT interventions, but the choice of cluster (as opposed to individual) randomization must be carefully justified. KT CRTs should be submitted to and approved by a REB. In designing informed consent procedures, researchers should first identify who the research participants are; unless an individual is a research participant, their informed consent is not required. Waivers of consent may apply in many KT CRTs that pose minimal risk. Cluster gatekeepers who have legitimate authority may be approached for permission to enroll a cluster in a KT CRT, but gatekeeper permission is not a substitute for the informed consent of individual research participants. Other recommendations in the Ottawa Statement, not discussed here, provide guidance on the assessment of benefits and harms, and the protection of vulnerable participants.

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