Patient and Public Involvement in Healthcare Improvement

Antoine Boivin

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For reasons of consistency within this thesis, some terms have been standardized throughout the text. As a consequence the text may differ from the articles that have been published.

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Foreword

"Facts do not speak" (Henri Pointcaré, 1854-1912)

Authors of scientific publications often remain invisible in their writing, hiding behind rhetorical formulations like "our data demonstrates", or "evidence suggests", which support the construction of an Objective Science scenario. The research articles that form this thesis make no exception to these language conventions. This short foreword nonetheless aims to shed some light on the personal motivations and circumstances that led me to write a PhD thesis on patient and public involvement in healthcare improvement.

My interest in this topic is grounded in my personal clinical experience as a family physician. I was attracted to the medical profession because it offers a pretext for encounter with fellow human beings. During my medical training in Canada at the end of the 1990s, I was schooled under two dominant models on how to offer "good" medical care to my patients. Patient-Centered Medicine urged me to approach the patient as a person and to tailor my care to each individual. My training also coincided with the golden age of Evidence-Based Medicine, which offered the promise of anchoring my work in solid population-based research. As I progressed through my early clinical work, I became increasingly conscious of the tension between these two imperatives as I tried to apply evidence-based guidelines that did not always fit the needs of the people I cared for. Put simply, how could I offer meaningful choices to my patients when important options were not available on the "menu"?

With this question in mind, I was invited during my first year of practice to participate in a "strategic citizen forum" where members of the public, health professionals and researchers deliberated together on complex health policy issues. The level of dialogue and concrete proposals that emerged from these meetings between "ordinary people" and "experts" struck me. Attempting to involve patients and the public in reshaping the menu of health services available to them became the impetus for this thesis.

Chapter 1

Introduction

"Citizen participation is a little like eating spinach: no one is against it in principle because it is good for you" (Sherry Arnstein, 1969)

This doctoral thesis is about patient and public involvement in healthcare improvement. This thesis by articles is composed of eleven chapters. This first chapter introduces the background and research questions. The nine following chapters represent the body of original research conducted for the thesis. These nine research chapters are structured in three sections that aim to: 1) clarify the goals and expectations towards patient and public involvement; 2) describe current involvement practices and international experiences; and 3) develop and evaluate new and effective involvement methods. The last chapter discusses the core findings and their implications for research and practice. A summary of the whole thesis is also included in English, Dutch and French at the end of the book.

Background

The idea that patients should be "at the center" of healthcare is as old as medicine itself. While the emergence of scientific medicine was founded on a biomedical model of illness where diseases are at the center of care, Hippocrates in 5th century B.C. urged physicians to "investigate the entire patient" and to "first know the whole man".[1] At the end of the ninetieth century, William Osler also taught medical students to "care more particularly for the individual patient than for the special features of the disease".[2,3]

As the limits of scientific medicine became more obvious in the second half of the XXth century, so did the criticism of the biomedical model. "Patient-centered medicine" became increasingly contrasted to "disease-centered medicine" by authors like Balint, Engel, and Stewart who reemphasized the importance of the biopsychosocial dimensions of illness, and of understanding the patient as a whole person.[4-6] Socio-political critiques of medicine in the 1970s also challenged paternalistic physician-patient relationship and called for more egalitarian power-sharing within the clinical consultation.[7] Increasing concerns for patients' rights found echo in the regulation of medical practice and the requirement that physicians disclose information that a reasonable patient would want to know.[8,9] The 1990s saw the emergence of shared models of decision-making that placed more emphasis on patients as active agents, proposing that doctors and patients exchange information about available options and take steps together to agree on common health decisions.[10,11] The subsequent growth in the production of patient decision aids to support individual health choices contributed to the reframing of patients as "consumers" of care.[12,13] Recent developments have also focused on how patients can

manage their own health through education and self-management programs, as well as the role that professionals other than physicians can play in supporting individual patients' decisions.[14-18]

Major developments of the past fifty years in patient-centered care, shared decision-making and self-management have largely focused on the involvement of patients in their own individual care, at the micro-level of the clinical consultation. In contrast, patient and public involvement in collective decisions over healthcare improvement and policymaking has been historically slower to develop, in line with the vision of medicine as a self-regulated profession.[8] Although Donabedian started advocating in the 1970s for the inclusion of patients' perspective in the evaluation of medical care, it took 20 more years before performance measures based on patients' experience started being used more widely for healthcare improvement.[19,20] In the 1980s, quality improvement was primarily a professional activity developed through peer-evaluation and audits, licensing regulations by professional organizations, and continuing medical education. Such professional focus was reflected in authoritative definitions of quality of care, viewed as the degree to which health services "are consistent with current professional knowledge".[21] The emphasis shifted later towards managerial and organizational approaches such as continuous quality improvement and total quality management, which assumed that better care comes from changing the system rather than acting on individual professionals.[22]

Starting in the 1990s, patient and public perspectives became more important for quality improvement. We distinguish in the thesis the involvement of two main "publics" in healthcare improvement decisions: a) patients refer to people with personal experience of a health condition or health service, and b) the public is a more inclusive category that includes all members of society whose life may be affected directly or indirectly by healthcare improvement decisions, including caregivers, family members, and citizens. Research increasingly demonstrates that professionals often inaccurately presume of patients' expectations towards care, which leads to a growing recognition that care should be more responsive to patients' values and preferences.[23-25] As clinicians and policymakers struggle with competing clinical priorities and limited resources, a growing consensus is emerging towards active patient involvement in quality improvement to ensure that healthcare is geared towards their most pressing needs.[26-28] More specifically, the epidemic of

chronic disease is transforming the way health services are delivered and highlights the role that patients and communities can play as partners in healthcare.[14,29,30]

Patient and public involvement interventions include at least one formal method for involving patients or the public in healthcare improvement. We differentiate in the thesis between three main types of involvement interventions: 1) communication (where information is communicated to the public); 2) consultation (where information is collected from the public); and participation (where information is exchanged between professionals and the public).[31] Patient participation is slowly becoming the norm in clinical practice guideline development, health technology appraisal, health research, and other areas of health governance.[32-35] Public communication of education material, patient decision aids, performance data, and "league tables" is also playing a growing role in supporting patients' health choices.[36,37] Many forms of public consultation, such as patient satisfaction surveys and needs assessments, are also increasingly being used to inform healthcare improvement decisions.[38,39]

Finally, the move towards patient and public involvement also coincides with the deliberative turn in western democracies and the idea that citizens ought to be involved more actively in public policymaking.[40,41] In the 1990s, the British National Health Services implemented a number of policies aimed at increasing the responsiveness of health services to local community needs.[42,43] Health reforms in Canada and Australia in the late 1990s and early 2000 also created an impetus for involving members of the general public in healthcare improvement and policy decisions.[44-46]

Knowledge gaps addressed by the thesis

The growth of patient and public involvement is generally perceived as a "good thing" and is supported by a number of rhetorical claims about its potential benefits. For example, it has been argued that patients "logically and ethically should have a voice in both defining and judging the quality of care" and that it would be "absurd to assume otherwise".[38]

Moving from rhetoric to action in this area raises however a number of difficult questions. First, critical voices have questioned the actual impact of patient involvement and the risk that "token patients" are used to legitimize existing

decisions.[47,48] The evidence supporting patient and public involvement interventions is sparse and systematic reviews of the literature have documented "a huge gap in the evidence from comparative studies about desirable and adverse effects" of patient and public involvement in collective healthcare improvement decisions.[49] Concerns have also been raised regarding the feasibility to recruit participants who are representatives of "ordinary" patients and lay members of the public, yet have the competence to contribute to complex healthcare decisions.[50]

Taken together, these issues pose a major challenge for professionals and policymakers. On the one hand, healthcare organizations are increasingly required to involve patients and the public in one way or another in their decision-making process. On the other hand, policymakers can hardly find reliable guidance on the design of effective involvement interventions because, "at a policymaking level, [existing] literature does not help in the elaboration of productive and realistic participation policies".[44,47]

This thesis focuses on the involvement of patients and the public in improving the quality of healthcare. More specifically, it explores the role of patients and the public in the development and use of two important and related quality improvement tools: clinical practice guidelines and quality indicators. Clinical practice guidelines are systematically developed statements designed to support professionals' and patients' decisions about appropriate healthcare, while quality indicators are measurable elements of practice performance (often derived from guidelines' recommendations) that can be used to measure and report changes in quality of care.[51,52] Guidelines and quality indicators set standards on how healthcare should be organized and delivered to provide safe, effective, and appropriate care, to ultimately improve health outcomes.

Research questions

The thesis is structured around three main research questions:

1. What are the goals and expectations for patient and public involvement in healthcare improvement?
2. How are patients and the public currently involved in healthcare improvement?
3. How can effective patient and public involvement interventions be developed to foster healthcare improvement?

Each thesis chapter tackles these research questions (Table 1). The following section presents an overview of how each question will be addressed.

Table 1. Research questions addressed by each thesis chapter

Research question	Chapter title	Chapter
Section 1: Goals and expectations towards patient and public involvement		
What are professionals' experience and expectations towards patient and public involvement in healthcare improvement?	Competing norms: Canadian rural family physicians' perceptions of clinical practice guidelines and shared decision-making[53]	2
What are the different goals of patient and public involvement in healthcare improvement?	Why consider patients' preferences? A discourse analysis of clinical practice guideline developers[54]	3
What can patients and the public contribute to healthcare improvement?	Decision technologies as normative instruments: exposing the values within[55]	4
Section 2: Current involvement practices and international experiences		
How are patients and the public currently involved by healthcare improvement organizations?	Patient and public involvement in clinical guidelines: international experiences and future perspectives[56]	5
What is known of the barriers, facilitators, and impact of patient and public involvement in healthcare improvement?	Patient and public involvement in clinical practice guidelines: A knowledge synthesis of existing programs (study protocol and results)[57,58]	6-7
Section 3: Advancing methods for effective patient and public involvement		
Is it feasible to involve patients together with professionals in setting common clinical priorities for healthcare improvement?	Target for improvement: a cluster randomized trial of public involvement in quality indicator prioritization (intervention development and study protocol)[59]	8
What is the impact of patient involvement in setting clinical priorities for healthcare improvement?	Involving patients in setting clinical priorities for healthcare improvement: a cluster randomized trial[60]	9
What are the key components of effective patient and public involvement interventions?	What are the key ingredients for effective public involvement in healthcare improvement and policy decisions? A randomized trial process evaluation[61]	10

Section 1: Goals and expectations towards patient and public involvement

When asking how best to involve patients and the public, the first problem one stumbles across is how to define "successful" involvement. Many international organizations require that patients and the public be involved in healthcare improvement, but these recommendations have only partially been translated into practice because they provide little guidance on how this should be conducted and assessed.[32,33] Similarly, research on the impact of patient and public involvement has been hampered by a poor conceptualization of what is expected from patients and the public and what represents success in this area. Defining the goals and expectations towards patient and public involvement is critical for the design of structured interventions, by specifying the hypothesis to be tested and defining outcomes of interests. Section 1 seeks to clarify these questions by exploring professionals' and patients' expectations about public involvement in healthcare improvement.

Chapter 2 focuses on practicing physicians' experiences and expectations towards patient involvement in healthcare improvement. Because the quality of clinical care has traditionally been a professional stronghold, understanding clinicians' expectations is important to clarify what could realistically be expected from patient and public involvement. Some authors have argued that clinical practice guidelines, by providing a synthesis of the research literature, can inform clinical decision-making and enhance patients' autonomy. Many physicians have however expressed more critical views of these quality improvement tools and warned that guidelines, by standardizing clinical practice, promote a form of "cookbook medicine" that limits patients' involvement in clinical decision-making. In the focus group study of 17 Canadian primary care physicians described in this chapter, we seek to better understand professionals' experiences and expectations about patient and public involvement, as it relates to the use of guidelines in day-to-day clinical practice.

Much of the debate and controversy about patient and public involvement revolves around the unresolved issue of purpose: what is the goal of involving patients and the public in healthcare improvement? What criteria should be used to judge the effectiveness of different approaches? Chapter 3 seeks to describe the main rationales or "discourses" about what represents successful patient and public involvement in healthcare improvement, looking more specifically at why patients and the public should be involved in clinical practice guideline development and implementation.

This chapter draws from individual interviews carried out with 18 patients and health professionals from two guideline development groups in the United Kingdom, a country that has been a forerunner in the development of structured patient and public involvement programs in health research, quality improvement, and health policy.

Prominent authors within the evidence based medicine movement portray clinical practice guidelines and quality indicators as "knowledge tools" and "carriers of facts", providing clinicians and patients with a synthesis of the best available scientific evidence.[62] Under this framework, patients and the public are seen as contributing "soft" values and preferences, as opposed to "hard" knowledge and evidence about healthcare improvement.[63] Such technical conceptualization of quality improvement calls into question whether lay members of the public do have a role to play in strategic aspects of healthcare improvement, and whether their involvement risks "contaminating" the process of guideline and quality indicator development with unwelcomed biases. A number of critics have indeed opposed patient and public involvement in healthcare improvement to avoid politicizing what is seen as a scientific, value-neutral operation. Chapter 4 clarifies what can be expected from patients and the public to contribute to healthcare improvement by describing how implicit value judgments are embedded in healthcare improvement decisions. Based on qualitative interviews with guideline developers (n=18) and practicing clinicians (n=17), this chapter critically analyses whether norms and values can be seen as separate "ingredients" from evidence and knowledge. By making more explicit what quality improvement tools are made of, this chapter clarifies what can be expected from patients and the public.

Section 2: Current involvement practices and international experiences

Little is known about the extent to which patients and the public are currently involved in healthcare improvement, how they are involved, and what are the main barriers and facilitators for success. Previous systematic reviews indicate that the field is still at an early stage and that guidance is needed to strengthen the theory and practice of patient and public involvement in healthcare improvement.[44,49,64,65] Moreover, existing knowledge syntheses have left policymakers with little practical suggestions on how to move forward in the development of effective involvement interventions. Section 2 aims to strengthen the available knowledge base to develop

more effective patient and public involvement interventions, as well as to identify the most pressing gaps in empirical knowledge, by describing the landscape of existing practices of patient and public involvement in healthcare improvement.

Chapter 5 describes how patients and the public are currently involved by healthcare improvement organizations, based on an international consultation with 56 clinical guideline developers from 14 different countries. This consultation builds on the creation of the Guideline International Network Patient and Public Involvement Working Group, an international collaboration between researchers, guideline developers and patient representatives aimed at sharing experiences, fostering international collaboration, and developing new standards and methods of patient and public involvement. This chapter describes common practices used at the international level and proposes a common research and practice agenda on the topic.

In complement to this overview of international experiences, chapters 6 and 7 present the protocol (chapter 6) and results (chapter 7) of a systematic review of the published (n=31 peer-review articles) and gray literature (n=40 documents) on patient and public involvement in practice guidelines development and implementation. Our systematic review proposes to describe in details current public involvement interventions' component and activities (who is involved, how, at what stage, and for what purpose), as well as to identify the main perceived barriers and facilitators for successful involvement, in order to inform the design of more effective interventions.

Section 3: Advancing methods for effective patient and public involvement

Knowledge of the actual impact of patient and public involvement is limited and anecdotal. Not a single trial has been conducted to rigorously assess whether patient and public involvement makes any difference in healthcare improvement decisions at the population level.[44,49,64] Furthermore, although a number of practical "toolkits" have been developed to guide the development of involvement interventions, these are mainly based on expert opinions that are often poorly theorized and rarely anchored in empirical research. Section 3 aims to move forward towards the development of effective patient and public involvement interventions. Based on a structured framework for the design and evaluation of complex healthcare

interventions[66], we used a mixed-method design to develop a structured intervention where chronic disease patients where involved in setting clinical priorities for healthcare improvement. We test the impact of this intervention in a cluster randomized trial and use built-in process evaluation to help explain the trial's results. Too often, randomized trials fail because of poor intervention development and insufficient feasibility testing. In chapter 8, we build on knowledge generated in previous chapters to develop a structured patient involvement intervention and assess its feasibility in clinical practice. We first develop a 'menu' of healthcare improvement priorities, based on a systematic review of validated quality indicators for chronic disease in primary care. We then pilot test a mixed patient involvement intervention where 27 patients and health professionals are asked to agree on common clinical priorities to drive local healthcare improvement activities. We use knowledge generated from this pilot test to refine our patient involvement intervention and engage patients more effectively.

Lack of evidence from rigorous comparative studies has been identified as a major barrier for the implementation of effective patient involvement interventions. In chapter 9, we conduct the first cluster randomized trial of patient involvement in healthcare decisions at the population level. This trial formally assesses the impact of our patient involvement intervention. 172 participants from 6 local health authorities in Canada, including 83 chronic disease patients and 89 professionals, were asked to prioritize local healthcare improvement priorities from 37 validated chronic disease quality indicators. In intervention sites, patients: 1) received formal training; 2) were consulted by vote; and 3) participated in a deliberation meeting with professionals to agree on local healthcare improvement priorities. In control sites, professionals prioritized quality indicators among themselves, without patient involvement. The trial assesses whether structured patient involvement results in clinical improvement priorities that better agree with patients' priorities, and describes how patients and professionals influence one-another in the process of choice.

As clinicians and policymakers are seeking effective ways to involve patients and the public, there is a need to open the "black box" of public involvement to understand why and how these interventions work. Process evaluation of experimental studies can help explain why a particular intervention proved effective by focusing on its internal dynamics and actual operations.[7,68] In chapter 10, we mobilize qualitative data gathered alongside our trial to learn and reflect empirically and theoretically on

the key ingredients that influence both the process and outcomes of patient involvement in healthcare improvement. This process evaluation uses data collected during the trial through video recording and direct observations of 14 one-day meetings. By looking at what happens in real-life setting when mixing members the public with other experts, and by mobilizing a theory-informed understanding of the key processes at play, one could more fully grasp why certain outcomes are likely to be obtained and use this knowledge to strengthen existing involvement interventions.

Chapter 11 summarizes major research findings from this thesis in relation to the wider literature, discusses methodological considerations and directions for future research, and presents the main implications for practice and policy.

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Section I:

Goals and expectations towards patient and public involvement

Chapter 2

Competing norms: Canadian rural family physicians' perceptions of clinical practice guidelines and shared decision-making

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Abstract

Objectives: Implementation of clinical practice guidelines (CPGs) and shared decision-making are both advocated in primary care. Some authors argue that CPGs can enhance informed decisions by patients and physicians, while others warn that a standardized implementation of CPGs could hinder patients' involvement in decision-making. Our objective was to explore rural family physicians' perception of the interaction between clinical practice guidelines and shared decision-making in medical practice.

Methods: A qualitative study using a semi-structured focus group interview: with 17 family physicians and residents, in a Canadian rural town. Interviews were audio taped and transcribed verbatim. Thematic content analysis was performed and validated by the constant comparative method, member checking and group debriefing.

Results: Two distinct conceptions of how clinical practice guidelines should assist decision-making emerged. On the one hand, guidelines were seen as helping clinicians to make decisions on behalf of their patient about the best course of action. For interventions with uncertain benefit or that carried significant trade-off for patients, guidelines were seen as a tool that should inform decision-making between physicians and patients, providing them with details about risks, benefits, costs and alternative treatments. The pressure to apply guideline recommendations was perceived as a potential barrier to patient participation in decision-making.

Conclusion: In circumstances where physicians judge patient participation in decision-making to be important, physicians perceive a tension between the need to respect patients' preferences and the pressure to apply guidelines. CPGs should include information that supports shared decision-making, besides their current focus on influencing prescription patterns, costs and health outcomes.

Introduction

Clinical practice guidelines (CPG) are systematically developed statements to assist health professionals' and patients' decisions about appropriate healthcare for specific clinical circumstances and are playing an increasing role in developed countries.[1,2] Their stated goal is to improve patients' outcome by promoting effective care and warning health professionals against harmful practices.[2] From the perspective of health care organizations, they can also be used to promote a more cost-effective utilization of resources. However, implementation of CPGs remains a challenge.[3] It is also unclear how these tools foster the process by which primary care patients are engaged in expressing their preferences

Shared decision-making

Shared decision-making is a process by which a healthcare choice is made by health professionals together with the patient. Towle and Godolphin's informed and shared decision-making model emphasizes that clinical decisions must be 'informed by best evidence about risks and benefits but also [by information] on patient specific characteristics and values'.[5] Studies of family physicians have pointed out the importance of asserting patients' preferred role in decision-making and of communicating the uncertainty attached to a decision.[6]

Shared decision-making models recognize that well-informed patients, because of differing preferences and perceptions, might not choose what is recognized as appropriate care from a public health or professional perspective. In this approach, a 'good decision' could be defined as one that is informed, consistent with personal values, is acted on, and in which participants express satisfaction with the way a decision was made.[7] When compared to usual care, active participation of patients in decisions improves patients' knowledge about clinical options, realistic expectations and congruence between patient preferences and selected clinical options.[8]

Are clinical practice guidelines compatible with shared decision-making?

Some authors have argued that CPGs, by providing a synthesis of the research literature, can inform decision-making and enhance a patient's autonomy.[2] Others warn that CPGs standardize clinical practice and limit the patient's role in decision-making.[4,9]

A recent report from WHO has emphasized the need to consider patients' values in guideline development.[10] Studies exploring physicians' adherence to CPGs have

highlighted patients' preferences and attitude to treatment as an important barrier to implementing CPGs recommendations.[9,11,12]

There are no in-depth reports of physicians' views of the tension between CPGs and shared decision-making or descriptions of the circumstances in which interactions are perceived as being problematic. The aim of this study was to explore physicians' perceptions of the interaction between CPG and shared decision-making, and to assess in which circumstances CPG are perceived as either enhancing or obstructing patient participation in decision-making.

Method

Study setting

The study was conducted in Rouyn-Noranda, a remote town of 40 000 people, in the francophone Canadian province of Quebec. The study setting was selected for pragmatic reasons as one of the authors (AB) is a practicing family physician in the area.

CPGs are developed by a variety of professional and governmental organizations in Canada. They address both acute and chronic conditions and their diffusion is now an integral part of many family medicine residency training programs and professional development activities. CPGs are used as quality criteria in formative physicians' audits in Quebec; quality payment schemes based on physicians' adherence to CPGs had not been implemented in this province at the time of the study.

Study sample and recruitment of participants

We decided to use the opportunity of existing continuing medical education activities to conduct a focus group. Advertisements were posted in the local hospital and targeted at practicing family physicians. Personal reminders were given to individual physicians.

We assumed that participants' attitudes would be mainly influenced by four characteristics: whether physician's practice was focused on acute or chronic care; years of experience in practice or training; physicians' preferred role in decision-making;[13] and physician's gender. To ensure that recruited participants represented a wide variety of attitudes, a self-completed questionnaire assessing those dimensions was distributed to those participating. The questionnaire was anonymous, which prevented systematic analysis of transcript based on those characteristics.

Interview structure

A 30-minute presentation was developed by one of the authors (AB), after pilot presentations with two groups of urban academic family physicians. Basic concepts of shared decision-making were defined and potential contributions and conflicts between guidelines and shared decision-making were introduced.

The presentation was followed by a one-hour focus group discussion among participants to group norms in relation to the topic.[11] It was structured around three main issues:

- Should CPGs assist shared decision-making between physicians and patients, or should they mainly guide clinicians' decisions? Why?
- In your clinical practice, in what ways do CPGs facilitate or hinder patients' participation in decision-making?
- What elements should CPGs include to facilitate patient participation in decision-making?

Discussions were recorded and transcribed verbatim for analysis. Transcription was checked for accuracy and a copy of the original audio recording was kept available for reference during the analysis. Field notes were kept.

Data analysis

The interpretation was guided by thematic content analysis:[14] relevant quotes were identified and grouped under the three main themes that structured the interview, and under categories that emerged from a literature review done in preparation for this study. Comments that contradicted these predefined categories were explicitly sought and the classification was adapted to reflect discussions. The software OmniOutliner Pro was used to chart the coded quotes according to emerging themes and to organize these categories in a hierarchical way. An electronic copy of all documents was kept at each stage of the analysis to allow cross-checking by other researchers. A constant comparative method of analysis was used, with transcripts re-read to ensure that the emerging themes were reflected in the data. Analysis was done using the original French transcript; quotations used in the article were translated from French to English.

Initial analysis of transcripts was made by one of the authors (AB). Halfway through the analysis, all three researchers participated in a debriefing session to validate the interpretation of the data. To increase the validity of the analysis and translation, a draft of the final report, along with extended extracts of the original French

transcript, was sent back to participants for validation (member checking). Nine participants (50%) responded and all approved the interpretation.

Ethical approval

At the time this study was conducted, no research ethics committee existed within the hospital. The board of directors of the hospital, on which sits the Chair of the clinical ethics committee and medical director, approved the research protocol. Participants were free to attend the presentation without participating in the subsequent group discussion. All participants signed a consent form at the beginning of the session.

Results

Participants

The study raised a significant interest in the medical community: 50% of all family physicians practicing in Rouyn-Noranda attended the session. Physicians from different age groups, experience and gender were represented (Table 1).

Table 1. Demographic profile of participants

Profession	**n=18**	**% of participants**
Family physicians	14	78%
Specialists (excluded from analysis)	1	6%
Residents in family medicine	3	17%
Age group		
20 to 29 years	5	28%
30 to 39 years	5	28%
40 to 49 years	6	33%
50 to 59 years	2	11%
60 years or above	0	0%
Gender		
Male	8	44%
Female	10	56%
Years of practice		
Currently in training	3	17%
0-10 years	8	44%
11-20 years	2	11%
More than 20 years	5	28%
Percentage of long-term follow-up in participants' practice		
Less than 5%	1	6%
5-25%	5	28%
25-49%	4	22%
50-74%	3	17%
More than 75%	5	28%

The sample included physicians involved both in acute care and long-term follow-up of patients. One psychiatrist was also present in the discussion but his comments were excluded from the analysis. Participants' general attitude toward guidelines and preferred role in decision-making is presented in Table 2.

Guidelines help physicians to make decisions rather than to share them

Participants viewed current guidelines as tools that are potentially useful in improving health outcomes and assisting physicians to make better decisions on behalf of patients (Table 2).

Table 2. Participants' preferred role in decision-making and attitude toward CPG

"How do you usually prefer to take decisions with your patients?"	**n=18**	**%**
The patient takes the decision alone after being informed of the best scientific evidence	2	11%
The patient takes the decision but strongly considers my opinion	5	28%
We take the decision together	5	28%
I take the decision but strongly consider the patient's opinion	2	11%
I take the decision alone after considering the best scientific evidence	0	0%
Did not answer	*4*	*22%*
"Clinical practice guidelines help clinicians and patients to take better decisions"	**n=18**	**%**
Agree	13	72%
Disagree	5	28%

> *"There is no doubt in my mind that guidelines help to improve clinical practice because, although imperfect, they are currently the most rigorous tool we have to orient us." (Participant 9)*

Some felt that the standardization that CPGs bring to clinical practice could be beneficial to patients' health.

> *"When I speak about standardization, there was a time when every physician would do whatever he liked. At least now, we know what improves survival; for what patients and in what circumstances it is beneficial." (Participant 15)*

Patients' participation in decision-making was not felt to be a priority in urgent situations, when patients' competence may be impaired, or in cases where the risk/ benefit ratio clearly favours one option over another. Active patient involvement was instead felt to be more appropriate for interventions carrying important risks (e.g. thrombolysis for stroke patients), in chronic disease (e.g. diabetes) or around end-of-life issues:

> *"In the emergency room, I see a patient with a urinary tract infection, I don't need to inform him. I give him antibiotics, that's it! Most patients don't have any questions about this. [...] On the hospital ward, will we anticoagulate? Will we install a pacemaker? For those things that require more thinking, we will discuss more with patients." (Participant 12)*

If guidelines were considered to be helpful in guiding clinicians, their contribution to the process of involving patients in decision-making was generally seen as limited:

> *"Practice guidelines help me to decide what treatment is best for my patient. I don't think that they help the patient decide for himself. If I look for example at gestational diabetes, it will help me to say its better to treat but I will not have the necessary statistics [and] tools to [...] let the patient take his decisions. I am sure that if I had them and presented them to patients, many of them would not take insulin, in the face of weak evidence." (Participant 7)*

Several participants noted that guidelines could be detrimental to patient participation in decision-making. They mentioned that algorithms and prescriptive recommendations make it more difficult for physicians to adapt interventions to their patient's individual circumstances and preferences.

> *"The bad consequence of practice guidelines is that you treat only numbers. It happens that I call the internist to tell him "listen, the LDL cholesterol is at 2,3 [...] what should I do?" He tells me: "Restart a cholesterol-lowering drug, you are not optimal". So you misinform your patient and only see numbers: that is the drawback of guidelines [...] we somehow lose our vision of family physicians." (Participant 17)*

Participants perceived a tension between the pressure to apply guidelines and the wish to respect a patient's choice:

> *"Sometimes, I feel as if I do a bad job! [laugh] When I'm trying to sell a guideline that I feel is important to me, and my patient chooses not to follow it, I wonder if I used the right arguments." (Participant 7)*

This reported pressure to apply CPGs was felt to be mediated by a fear of litigation and peer pressure. This was reported to be particularly relevant in situations where several physicians were involved in the care of the same patient:

> *"I find that, especially in the hospital, we are often many physicians to go in the same patient file..." (Participant 6)*
> *"Yes, yes." (Researcher)*
> *"So [...] sometimes there is a pressure to look good [laugh] show our colleague that we know our clinical guidelines and that we apply them!" [Other participants laugh] (Participant 6)*
> *"Yes, that's it." (Other participant)*

One participant reported that this negative picture of CPGs was not reflected in what he observed in practice, noting that this could also be a reflection of the pressure to apply CPGs.

> *"I feel more resistance than I would have thought. People have very negative comments [about CPGs] but they apply them!*
> *Myself, I do less hospital work than others. I receive patients discharged from the hospital. Clinical practice guidelines are in your discharge summaries! [...] I think that the kind of obligation or fear is already there." (Participant 5)*

What elements should guidelines include to facilitate shared decision-making?

Synthesis of relevant information about risks, benefits and costs of interventions
One way in which CPGs were felt to assist physicians' and patients' decisions is by providing a short synthesis of the literature.

> *"Using guidelines is much quicker than reviewing all the literature on a topic." (Participant 15)*

However, some participants felt that such a digest of the literature lacks key elements to inform decision-making properly:

> *"I find that there's much information missing in guidelines for them to be useful [...] Guidelines are based a lot on validity and what makes a study valid is the size of the study, therefore, the pharmaceutical industry that financed it! [...]We don't see, in guidelines, the benefits and the risks. It often says that it's proven, that it will help your patient, but they won't tell you what are the actual numbers." (Participant 16)*

Participants mentioned that information about outcomes that are important to patients, like mortality and morbidity, is often not included in CPGs and that the costs of treatment options are also rarely included.

Discuss risks and benefits in a language that is easily understandable

To assist the communication of information to patients, participants stressed the importance of CPGs discussing risks and benefits in a language that is easily understandable by physicians and patients alike.

> *"[We need to present benefits] in a way that is understandable for patients. I would place physicians at the same level as patients: I am not so good in mathematics myself. [...] We need to always use the same language like numbers needed to treat." (Participant 5)*

They noted that statements like 'minor side effects' or 'significant benefits' are inadequate to inform decisions. A few participants suggested that a decision aid or information sheet, written specifically for patients, be included with guidelines to facilitate the discussion of treatment options.

Include information about the applicability of recommendations

Physicians noted that CPGs, if they are to facilitate the tailoring of treatment to individual patients' circumstances, should indicate the degree of uncertainty attached to each recommendation:

> *"What's missing in guidelines is details about which patients are recommendations most applicable to. Has it been studied on 90-year-old patients, on women? Who has been excluded from studies? Can we apply it to patients who take fifteen pills already?" (Participant 16)*

Discuss all possible alternatives, including the choice to 'do nothing'

Participants expressed the feeling that current guidelines are centred on pharmacological therapies and do not discuss non-pharmacological options of treatment:

> *"Practice guidelines are mainly pharmaceutical. They sometime include a "politically correct" statement on alternatives like exercise in diabetes, almost to be polite! So if recommendations always included the possibility of an alternative, we wouldn't feel so much medicolegal pressure in following them, if there was an alternative to the pharmacological option." (Participant 14)*

Physicians also mentioned that the choice to 'do nothing' is difficult to take in clinical practice and should be discussed more often as a legitimate alternative:

> *"We are compulsive prescribers! Like [Participant 16] said, it's much harder for us not to prescribe a pill and tell our patient "it's better this way", than to add one. And in this sense, clinical guidelines don't help us. None of them tell us "if your patient has already ten pills, maybe you should not add any other" or, "for this condition, this might not be the focus"." (Participant 17)*

Discussion

This exploratory study addresses some of the most pressing challenges that have been identified in the existing body of research on informed and shared decision-making.[15] It improves our knowledge of implementation of shared decision-making in clinical practice and shows that resistance to CPGs is partly motivated by competing norms of practice rather than only technical or organizational barriers.

Two distinct conceptions of how CPG should assist shared decision-making emerged. For urgent situations, or for interventions with clear benefits which most patients would accept, physicians expect CPGs to provide them with clear guidance and are less concerned with facilitating patient participation in the process. In contrast, decisions about chronic disease management, about interventions carrying an important risk or with uncertain benefit, were felt to be more appropriate for shared decision-making. This distinction between 'preference sensitive' and 'effective care' is consistent with the existing literature on shared decision-making and with previous studies which showed clinicians' tendency to judge, for themselves, when they considered patient involvement to be relevant to decision-making.[16]

Physicians feel a tension between what they perceive as two competing norms of good practice: the need to consider patients' preferences and the pressure to adhere to guidelines. To assist shared decision-making, participants felt that CPGs should aim to inform decisions instead of outlining what experts consider the best choice. Current guidelines are seen as not elaborating enough on patient relevant outcomes, rarely discuss costs and side-effects and do not provide enough details to allow treatments and investigations to be individualized, adapted to specific situations and discussed with patients. These concerns are consistent with the results of two recent studies on the information content of major Canadian CPGs.[17,18]

There is a demand for tools that will inform complex decisions[19] but this is not reflected in instruments currently used to assess the quality of CPGs.[20,21] Also, studies assessing the effectiveness of CPGs are mainly concerned with their impact on health outcome, physicians' adherence to recommendations, or cost, but not how they affect the involvement of patients in decision-making.[22]

Strengths and limitations of this study

The study did not focus on any specific CPG and caution is required in extrapolating its findings to other guideline programs and countries. Patient representatives are rarely involved in CPG development in Canada, unlike in the United Kingdom. Such involvement has been shown in other settings to improve the relevance of information available to patients.[24] The hypothesis that the presence of patient representatives reduces the tension between CPG recommendations and patients' involvement in decision-making should be tested empirically. Also, even if 'patient versions' of CPGs are sometimes published in Canada, no formal integration of guidelines and patient decision aids has been attempted so far in this country.[25]

Using an established continuing medical education event to recruit participants yielded a high participation rate. The generalizability of our findings might however be limited by the small number of participants and only one focus group. Residents and physicians in their first year of training were particularly quiet, which might have favoured criticisms of CPGs. Discussion with groups of urban family physicians after our pilot presentations yielded comments that were similar to those collected in rural practice.

Many comments made by participants referred to ways of improving the ability of CPGs' to guide physicians' decisions but it was more difficult to elicit comments on the relationship between CPG and shared decision-making. This might have been related to: the unfamiliarity of participants with the relatively new concept of shared

decision-making; the perception that CPG and shared decision-making might be incompatible; or the difficulty for the interviewer to keep participants focused on the topic.

We took a rather realist view of interview data, assuming that physicians' public accounts of how they perceived CPGs was a 'true' reflection of their opinion and was reflected in their clinical practice. This position entails specific limitations, including the possibility that respect for patients' preferences serves as a 'socially acceptable' argument to oppose guideline recommendations, instead of objecting to CPGs on the ground that they infringe professional autonomy.[23] Participants' opinions might have also been shaped by the group process or by the introductory presentation, although neither discouraged critical comments. Members of our research team also had diverging views at the start of the study, ranging from the view that CPGs could enhance shared decision-making to the position that the two concepts were inherently incompatible.

Directions for future research

This study has highlighted the need to recognize that physicians view CPGs as representing norms of practice (proposing a particular view of what is 'good care') instead of acting as 'knowledge translation' instruments (offering a neutral synthesis of the literature[26]). This perspective opens new avenues for understanding physicians' non-adherence to CPGs, including the possibility that such resistance emerges from competing norms of practice. It therefore calls for a better understanding of the professional culture and socio-political context of guideline development and implementation.[27–29]

If, for specific healthcare decisions, fostering patient autonomy and participation in decision-making are recognized as important components of quality care, CPGs will need to be adapted to include information to support decisions. The evaluation of quality improvement programs, like CPGs, should be broadened to measure its effect on the process of decision-making, in addition to the current focus on prescription patterns, costs, and health outcomes.

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Chapter 3

Why consider patients' preferences? A discourse analysis of clinical practice guideline developers

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Abstract

Background: Several organizations are advocating for patients' preferences to be considered in clinical practice guideline development and implementation. However, lack of agreement on the goal and meaning of this policy curtails evaluation and development of patient involvement programs.

Goal: To describe guideline developers' discourses on the goal of considering patients' preferences.

Method:

Design: Qualitative study using discourse analysis.

Subjects: 18 participants (patients, health professionals, and public health experts) from 2 groups of British guideline developers.

Data collection and analysis: Template analysis of semi-structured individual interviews was strengthened by active search for deviant cases, team debriefing, and member checking.

Results: All respondents supported the idea of taking account of patients' preferences in guidelines. Divergences with the goal and meaning of considering preferences were structured in 4 discourses: (1) The Governance discourse constructs guideline development as a rational process of synthesizing population data – including evidence on patients' preferences – to maximize public health within the constraints of available resources; (2) the Informed Decision discourse aims at fostering patients' choice by providing tailored information on the risks and benefits of interventions; (3) the Professional Care discourse insists on basing professionals' recommendations on the individual characteristics of patients; (4) The Consumer Advocacy discourse argues for greater political power and influence over guideline development and clinical decision making.

Conclusions: The identified discourses provide a set of hypothesis on how patient involvement programs are expected to work, which could help clarify the goals pursued by guideline organizations and anchor further evaluation efforts.

Introduction

Patient involvement has become an important component in healthcare, ranging from participation in clinical decision-making to priority setting and research funding.[1–5] More recently, consideration of patients' preferences and values has been advocated for the development and implementation of clinical practice guidelines (CPGs).[6–12]

However, recommendations regarding patients' role in CPG have only partly been translated into policy and practice, partly reflecting the lack of consensus and evidence on how patients' preferences should be considered.[8,13] A recent international survey found that only 53% of CPG organizations have a consumer involvement policy.[14] Most of these seek consumer feedback on draft CPG and one-third involve consumers on development panels.

Much of the debate concerns the unresolved issue of purpose: what is the goal of involving patients in CPG development and implementation? What criteria should be used to judge different approaches? Some frameworks have attempted to classify public involvement in healthcare,[15–21] distinguishing for example between the democratic (focused on principles of public accountability and active citizenship) and consumerist perspectives (promoting informed individual choice and "purchasing" of healthcare).[16] How such typologies can help framing the question of "effective patient involvement" in the context of CPG is unknown. This study aims to describe CPG developers' discourses on the goal of considering patients' preferences to inform further policy debate and evaluation on the preferred methods of patient involvement in CPG. We focus on chronic health problems as previous studies suggest that patients' preferences may be especially important to consider in this setting.[22,23]

Method

Design and theoretical approach

We conducted a qualitative study using discourse analysis of semi-structured individual interviews. Discourse analysis is particularly useful to analyze the rhetorical use of complex concepts such as "preferences" and "patient involvement".[20] Discourse is defined here as "socially accepted associations among ways of using language,"[24] which delineate the boundaries between what is considered real or false, and legitimate or illegitimate. Discourse analysis addresses socially patterned ways of thinking, and aims to uncover underlying assumptions encoded in language. Ethics approval for this study was obtained from the London School of Hygiene and Tropical Medicine ethical committee.

Sampling and recruitment

In England and Wales, most CPGs are commissioned by the National Institute for Health and Clinical Excellence (NICE), a publicly-funded institute that is part of the National Health Services.[25] Patient and carers are systematically represented in NICE guideline development groups, and patient organizations can comment on the scope and draft versions of CPGs.

We recruited study participants among a convenience sample of 2 groups of British CPG developers: 1 group developed a guideline for NICE addressing issues related to the diagnosis and treatment of patients with osteoarthritis[26]; the other group developed a guideline for the referral of patients with osteoarthritis of the knee to specialist services, carried out as part of the REFER project[27]. A purposive sampling strategy was used to include representatives of (1) health professionals, (2) patients and care-givers, and (3) public health experts (including health managers, economists, methodologists, or government representatives).

The sampling strategy aimed to achieve empirical rather than theoretical generalization,[28] seeking settings, and respondents that were qualitatively representative of the population of British guideline developers for chronic physical conditions, to describe typical discourses on the goal of considering patients' preferences. We recruited new participants until the emerging classification of discourses did not change with the new material collected.[29]

Data collection

The lead investigator (AB) carried out the interviews and attended 2 guideline development group meetings as nonparticipant observer. Access to minutes of meetings and preliminary reports was granted in preparation for the study. Individual interviews were conducted between March 2007 and February 2008 in person or over the telephone. They covered (1) respondent's experience in CPGs, (2) the perceived relevance of considering patients' preferences, and (3) views on methods for considering patients' preferences in CPG development and use. The interviewer introduced himself as a "graduate student" and acknowledged his role as a health professional when asked by interviewees. Interviews were recorded and transcribed verbatim. Analytical memos were generated throughout the study and detailed field notes were compiled after each interview – describing the interview setting and the difficulty in addressing certain topics – to support a reflexive approach to data analysis.

Data analysis and validation

We used thematic content analysis from categories generated inductively by detailed line-by-line open coding of the first interviews. The analysis, using the NVIVO software, focused on (1) the situated meaning of "patients' preferences," (2) rhetorical tools that were used to support or question the role of preferences in CPG development, and (3) implicit goals and assumptions supporting those views. Matrix coding[30] and concept mapping were used to explore relationships between participants' characteristics, their views on the role of preferences in guidelines, and preferred method of patient involvement.

The lead investigator did the initial coding and analysis, which was validated from the original transcript by another team member (JG). Active search for deviant cases was used to strengthen the analysis. A copy of the draft report was sent to respondents for member-checking, and did not lead to any significant change. One participant asked to have his/her quotes removed from the final article.

Results

Participants

Table 1 describes study participants. We contacted 23 people for the interviews: 3 did not answer, 2 refused, and 18 accepted to participate.

Table 1. Details of participants

	Participants (n=18)
Gender	
Male	11
Female	7
Role in guideline development	
Health professionals	8
Family physicians	3
Allied health professionals	3
Medical and surgical consultants	2
Patient representatives	4
Public health experts	6

All respondents emphasized the relevance of considering patients' preferences in CPG development and implementation as "obviously very important," or "forward looking." The notion of preference proved to be a powerful rhetorical tool used throughout the interviews. Its relevance was never questioned directly. Divergences were framed as disagreement with either the role of CPG, or with whose preferences should be considered, how, and for what purpose. We identified 4 main discourses: (1) governance, (2) informed decision, (3) professional care, and (4) consumer

advocacy. Each discourse is described below and is illustrated by quotes from respondents (Table 2).

Table 2. Illustrative quotes

Discourse	What are clinical practice guidelines?	Meaning of considering patients' preferences	Goal and expected benefits of considering preferences
Governance	*"We recommend a particular drug because on average it seems to be the best…on the basis of the evidence, on the basis of the economics" (public health expert)*	*"The patient's experiences need to really be collected in a similarly robust way as clinical evidence is. And the evidence that we use on benefit of intervention should use patient reported outcome measures. In which case we're then using a robust system to collect evidence, but we're using measures that are of value to the patient" (public health expert)*	*"For a publicly funded system there needs to be a discussion about the role of patient preferences (for intervention), and if they correlate poorly with benefit, then perhaps we shouldn't be using them." (public health expert) "Well, this treatment, even if it's really good, it's too expensive, so we can't recommend it" (public health expert)*
Informed Decision	*"When I see patients with osteoarthritis, the Guidelines are completely irrelevant to me. The problem being that they never seem to be relevant to the individual patient." (health professional)*	*"I favor a toolbox approach, which would say 'Look, these are the options that you have available to you; here are the pros and cons of some of these options, what do you want to choose?'" (health professional)*	*"If the preference is based on good information, then it can actually help with managing a demand for interventions ... We need to (consider patients' preferences), both for the benefit of the individual patient, but also for resource allocations, because I think if patients are truly informed, then they are likely to make rational choices" (public health expert)*
Professional Care	*"I used the Quick Reference Guidelines for certain medical conditions just to confirm that we were doing all the right things for the clients at all the right times" (health professional)*	*"I think that (guideline developers) are trying to tailor their advice ... to all sorts of things about the patient, some of which are fairly difficult and intangible, like you just look at them and you know just by their general demeanor, their apparent frailty, and other things that they would be a better candidate for surgery" (health professional)*	*"Interviewer: You're saying that these Guidelines are fairly patient centered, can you give me an idea in what way they are? Respondent: The assessment of the patient is key and we need to consider the wider issues relating to that patient (like) social issues, what job they do, the age they are, what factors worry them… to decide on their treatment and what they feel is appropriate, enable them to continue their normal activities and daily living." (health professional)*
Consumer Advocacy	*"the guideline – I mean, that may not be what it's there for at all, but to me, it's got to safeguard that minimum that you must never go below" (patient representative)*	*"Surveys...would improve guideline: in numbers there is strength, and unity...the Bigger Voice" (health professional) "I think (population surveys) would probably get over the hurdle of (patients' representatives) being intimidated by being in with professionals (but) the patients wouldn't be there (So) they wouldn't be really having active involvement." (health professional)*	*"Because I had private insurance, I can actually demand what I want… I felt that I was in charge of my own situation I had more control because I could demand to be seen, (by) a consultant of my choice" (patient representative)*

Governance: preferences as evidence collected from the population

The Governance discourse portrays CPG as embodying the best course of action on average for the population. It adopts a broad societal perspective to maximize population health within the constraints of available resources. CPG development is seen as a scientific process where experts translate research evidence on the effectiveness and efficiency of interventions into generic recommendations for health professionals and patients.

Preferences, in this context, are defined as evidence collected at the population level using scientifically robust methods. Data on preference may include information on patients' experience of illness, quality of life, utility, expectations, and satisfaction with care. Surveys or focus groups drawn from a statistically representative sample of patients with direct experience of the disease are seen as more reliable and less biased than the views of individual patients' representatives participating in CPG development:

> *"A specialist interest group ... will send you along one of their vocal articulate people ... so, you have this problem of then finding a genuine panel of lay people and that gets tricky ... You could find (instead a) truly random or representative sample of the population ... to take part in the study" (health professional).*

Overall, the Governance discourse shows a strong concern for the public good. The scientific process of CPG development is deemed to arbitrate the interests of different groups, including patient groups and professionals. It acknowledges the potential conflict between efficiency and individual patients' preferences, arguing that patients' requests for treatments are only legitimate when options of health professionals and patients are expected to comply with CPG recommendations:

> *"You have to try to make the patients aware that it really is the clinical evidence that's driving things, but ... if all other things being equal, there is an obvious preference of patients for one treatment over another, then that can really make a difference" (public health expert).*

Informed Decision: fostering individuals' rational and value based decisions

The Informed Decision discourse pivots on the assumption that patients are rational decision-makers who base their choices on preferences and available evidence. It

stresses the importance of adequately communicating clinical evidence to patients through structured decision methods.
The Informed Decision discourse constructs CPG development as a scientific process to translate knowledge or evidence into clinical practice. However, in contrast to the Governance discourse, it does not promote a single best average recommendation but expects CPG to present patients and health professionals with a menu of options and include tailored individual information on risks, benefits, and costs of each intervention. Patient involvement is therefore mainly located within the individual clinical encounter, rather than in the process of CPG development:

> *"I think what's important (to) get across that it's not a patient preference that sits on its own; it's a patient preference after (a) an assessment of the potential risks and benefits of intervention and (b) a communication around those risks and benefits and that may need (a) some tool and (b) it may need a particular professional with the skills to do that" (public health expert).*

This discourse holds two distinct perspectives on the outcome of informed, value-based choices. Firstly – assuming a linear relationship between knowledge, beliefs and behaviors – informing patients of the risks and benefits of interventions may form an important implementation strategy to ensure adherence with CPG recommendations and help maximize population health benefits and resource allocation. Another trend within this discourse saw the benefit of informed decision-making mainly in terms of improved decision-making process (e.g., greater knowledge and satisfaction with decision).

Professional Care: treating the person rather than the target

The Professional Care discourse puts the personal interaction between patients and professionals at the heart of what represents good care: health professionals' decisions should be based on evidence of clinical effectiveness as well as on personal knowledge of the patient as a person (individual clinical characteristics, socio-economic situation, cultural background, etc). Within this discourse, the responsibility for clinical decision-making is predominantly that of the competent health professional. Patients' preference is considered a legitimate component of decision-making only after it has been informed and guided by professionals towards what is clinically indicated.

The role of CPG in clinical decision-making is ambivalent. On the one hand, CPGs are seen as embodying professional norms of practice and summaries of clinical research that can strengthen the expert status of professionals and guide trainees. On the other hand, the Professional discourse argues that CPG based on population data can never account for the subtle individual characteristics of patients, which can only be known by the health professional interacting with the patient. Attempts at imposing population-based CPG recommendations and targets are opposed, as such recommendations are perceived as undermining patient-clinician interaction or aiming at cost reduction. Consequently, considering patients' preferences in guidelines implies giving clinicians more autonomy when deciding (not) to use CPG recommendations:

> *"They've brought all these targets in now, so that the targets are far more important than the person, which I think is very sad .... If you start saying, look I've got a target, but I've got to consider the patient's preference, you are therefore beginning to consider the patient again and you might actually say, well, I'm not bothered about the target for this person" (health professional).*

Consumer Advocacy: preferences as political power

In contrast to the above discourses, which tend to emphasize the scientific and technical aspects of CPG, the Consumer Advocacy discourse sees guideline development as a political arena in which the competing interests of government, health professionals and patients are negotiated. CPG recommendations are primarily seen as a safety net, representing a minimum set of health services to which patients are entitled as consumers of care.

Considering patients' preferences is interpreted in terms of active involvement and influence over CPG development and clinical decision-making. Fostering greater patient influence is seen as a goal in itself, justified by the role of patients as beneficiaries of care. Active methods of patient involvement (e.g., patient representation in CPG development group), are favored over passive consultation methods. These involvement strategies should address power imbalances between consumers, health professionals and experts. Mastery of the technical language of science, and representation by a sufficient number of skilled representatives, were seen as bringing strategic influence to consumers within the CPG development process. The Consumer Advocacy discourse frames the issue of patients' legitimacy in terms of political representation, rather than statistical representativity or expertise.

Patient representatives are primarily seen as spokespersons of consumers' views and interests:

> *"I was there to shout for us ... you have to be really confident and strong, and when you have 2 people representing 8 million, it's a big task and responsibility" (patient representative).*

Ultimately, genuine consumer involvement in CPG development is assumed to lead to greater empowerment of individual consumers, greater access to beneficial treatments, and better self-management.

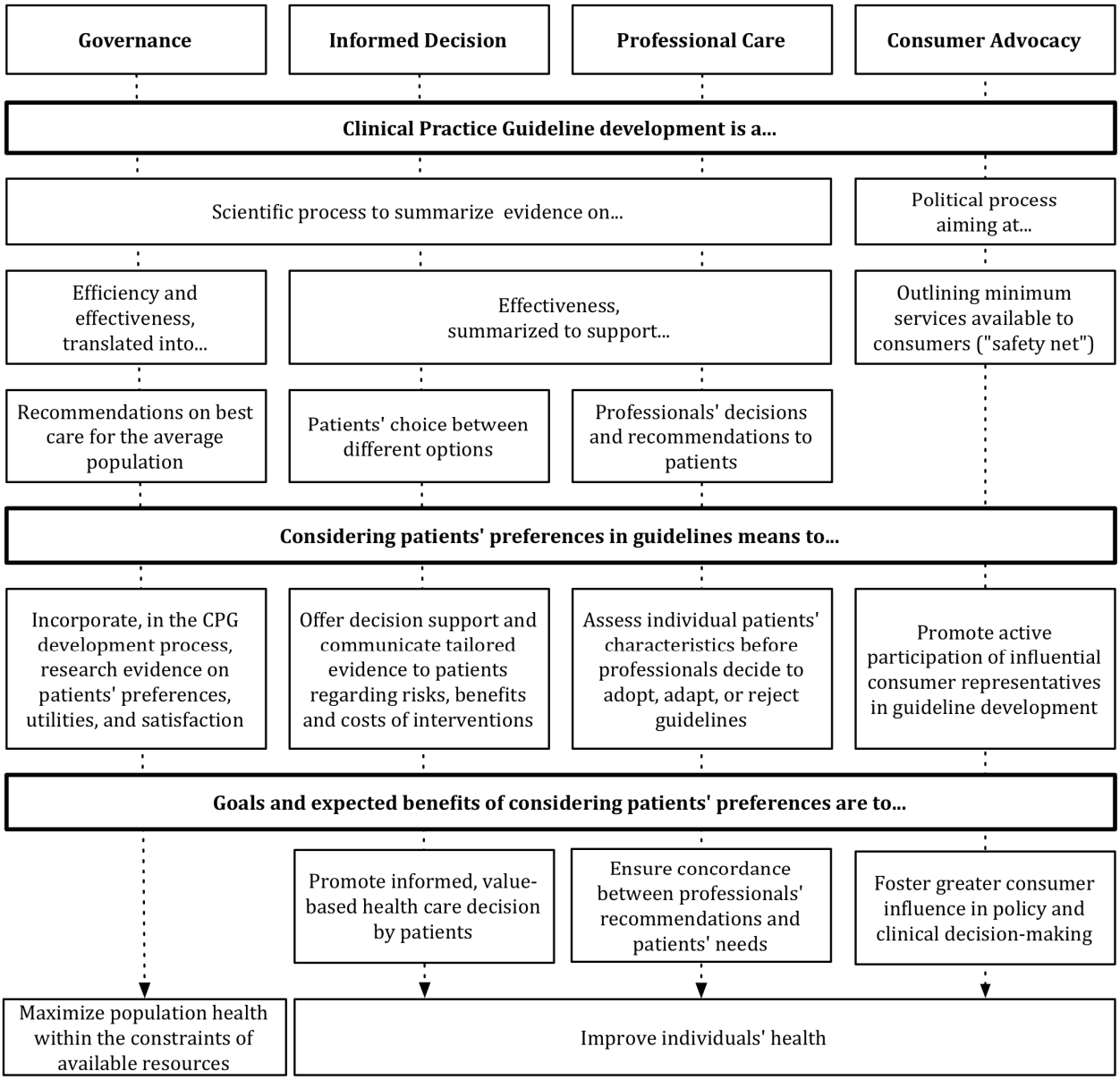
Who said what?

Individual interviewees' response patterns tended to fall into one discursive framework, although overlaps occurred. Healthcare managers and public health experts favored the Governance discourse, while physicians were most closely aligned with the Professional discourse. Patients' representatives and allied health professionals tended to use the Consumer Advocacy discourse, although their responses also incorporated some elements from the Informed Decision discourse. Public health experts with a health professional background sometimes switched between the Informed and Governance discourse and saw the provision of individualized risk information as a way to reconcile public health goals with the respect of patients' preferences.

Physicians and public health experts appeared skeptical of the assumptions underpinning the Consumer Advocacy discourse, and questioned the legitimacy and competence of patients' representatives. Conversely, patients' representatives tended to reflect on the fact that their perspectives had shifted during their participation in the CPG development process, with research evidence and medical expertise becoming more important for them. This suggests that the register of their preferred discourses might change over time to be aligned with those perceived as more dominant.

Figure 1 summarizes the key components and relationships between each discourse.

Figure 1. Four discourses on the meaning and goals of considering patients' preferences in CPG



The dotted lines summarize the 4 main discourses identified. Each discourse is structured around key statements regarding: (a) the nature of CPG, (b) the meaning of considering patients' preferences, and (c) the expected benefit of considering preferences.

Discussion

To the best of our knowledge, this study is one of the firsts to describe CPG developers' discourses on the relevance of considering patients' preferences in CPG. The findings highlight the rhetorical power that patient involvement has reached in health policy debate. "Considering preferences" is being used as an intrinsic good that cannot be legitimately opposed other than on methodological ground. However,

beyond this apparent consensus, there are profound differences in the meaning of considering preference and the underlying rationales to support such policy. The analysis uncovered 4 discourses, in which considering preferences may refer in turn to: scientific methods of collecting population evidence on patient preferences, preferred treatment choices and valuation of health outcomes (Governance); active consumer representation and influence over the guideline development process (Consumer Advocacy); health professionals' assessment of patients' characteristics and personalized care (Professional Care); and informed patient participation in clinical decision-making and guideline implementation (Informed Decision).

These discourses may be related to existing models of patient involvement in health care. The Governance discourse, with its emphasis on the synthesis of research evidence to guide resource allocation and clinical decision-making, appears aligned with certain public health approaches informed by evidence-based medicine and economic theory.[31,32] The Informed Decision discourse may find echo in the shared decision-making and risk communication literature,[21] although its emphasis on patient's adherence places this discourse at odds with some models of decision-making that argue that a quality decision is one that is informed by the best evidence in line with what the patient value, and thus may not necessarily lead to greater adherence to professional or population-based standards.[33] The Professional Care discourse resonates with models of patient-centered care, especially those that emphasize the role of autonomous health professionals in understanding patients' needs as unique human beings.[34] Finally, the Consumer Advocacy discourse, with its concern over power imbalance and informed "purchasing" of health care, has much in common with consumerist models of participation.[16,35]

Elucidating these discourses helps understand the broader interests around patient and public involvement initiatives in the context of difficult guideline implementation and common criticisms that CPG promote a form of cookbook medicine.[36,37] The rising interest by CPG developers for shared decision-making and patient involvement has been read as a sign that the CPG community is moving away from a "one size fit all approach". However, findings from this study suggest that, within the Governance and Informed discourses, patient involvement in clinical decision-making is seen as a strategy for implementing CPG recommendations established from a population perspective, rather than a radical shift of perspective regarding who should define what represents "good care". Similarly, by interpreting the call for considering patients' preferences in CPG as strengthening professionals' role in validating and helping patients to "make" their preference, the Professional discourse does not

support a shift of power towards patients but instead offers a new set of arguments to resist government's perceived attempts at restricting professional autonomy.

Limitations of the study

Involvement policies are highly contextualized and findings from this study are therefore difficult to generalize.[15] Characteristics of the UK context that may have shaped the content of the identified discourses include: (1) a strong democratic and consumerist tradition; (2) a largely government-funded health care system; (3) a CPG development process centralized around a major organization (NICE) in which patient and public involvement has now become a routine component. These factors may have contributed to the apparent consensus on the relevance of involving patients, and the omnipresence of the "public payer" in the Governance discourse.

Although we made a conscious attempt to not explicate the health professional status of the lead investigator, the influence of this role was noted on a few occasions. Health professionals in particular tended to assume a common perspective, which helped establish rapport: "I think the reason that you're in this field and the reason I am is ..." (health professional). Conversely, patients' representatives sometimes expressed opinions in line with professionals' views on the topic, which might partly explain the apparent convergence between the discourses given by those 2 groups.

Finally, we did not explore the role of the public at large (beyond patients) and thus cannot extrapolate from these findings. With those limitations in mind, the identified discourses might still be relevant to other contexts of health care policy, such as the involvement of patient representatives in health technology assessment, where similar questions on the purpose of patient involvement are being raised.[38]

Research and policy implications

This study highlights the diversity of views on the goal of considering patients' preferences in CPG development, and has profound implications for the development and evaluation of patient involvement programs. It may be argued that the strategies proposed in each discourse are somewhat complementary and that comprehensive patient and public involvement programs could combine – in the development stage – (a) the collection of evidence on patients' preferences and utilities with (b) the involvement of patients' representatives on guideline development groups; while promoting a tailored implementation of CPG based on (c) the use of patient information material and (d) the careful consideration of individual patients' characteristics by health professionals.

However, there appear to be more fundamental differences with regards to the goal and expectations for involving patients in CPG. A central division lies between discourses that adopt a social perspective and seek to maximize health benefits for the total population (e.g., Governance discourse), from those that promote individual interests. A further core tension divides the Consumer Advocacy discourse, which sees CPG development as a policy arena and promotes patient involvement on grounds of political legitimacy, from the other 3 discourses that depict CPG development as a technical process and justify involvement on the basis of scientific standards of expertise and validity. The attraction of all categories of respondents for the Informed Decision discourse comes at the price of an internal tension, within this discourse, regarding the desirable outcome of patients' active participation in decision-making: for some, it is a strategy for consumer empowerment, while others see it as a means to guide patients towards more effective and efficient interventions.

These differences are fundamental for clarifying the meaning and operationalizations of "effective patient involvement in guidelines". For example, an evaluation grounded in the Informed Decision discourse would tend to use measures of patient knowledge as an outcome of successful involvement, while the Consumer Advocacy discourse would focus on the influence of patient representatives on CPG content and recommendations. The hypothesis embedded within each discourse could therefore serve as the basic architecture of future research projects, including knowledge syntheses, by mapping the possible meanings of effective involvement. This classification could also be further developed to guide dialogue, networking, and exchange across organizations and groups anchored in different discourses. Emerging international forums on this topic are highlighting the need for frameworks that help to make sense of the complexity and variety of approaches and rationales underpinning patient involvement programs in CPG.[25,39–41]

The growing consensus on the need to consider patients' preferences in CPG has seemed to align the interests of policymakers, patient organizations, clinicians, and researchers in the field of evidence-based medicine and shared decision-making.[6,8,12,22,41] Developers of patient involvement programs should, however, be cautious of this apparent consensus and the risk of reducing policy debates on preferred methods of involvement to questions on "what works best". Although efforts to develop more effective involvement programs are laudable and should be pursued, the findings of this study clearly suggest that any such effort needs to first be anchored in a defined and explicit perspective on what is expected of such programs and what represents effective patient involvement in CPG.

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Chapter 4

Decision technologies as normative instruments: Exposing the values within

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Abstract

Objective: Describe some of the implicit normative and value judgments made in decision technologies development and use.

Methods: Using conceptual analysis of published models, we first outline some of the background assumptions of the knowledge translation/evidence-based medicine view of decision technologies. We then describe how normative judgments are embedded in decision technology development and use, drawing from empirical normative analysis of qualitative interviews with clinical practice guidelines developers (n=18) and users (n=17) in Canada and the UK.

Results: Normative judgments are made in at least three stages of decision technologies' "life cycle": (1) in the identification of contexts where decisions are seen as requiring support; (2) in determining what type of information and options should be part of the content of decision technologies; (3) in the negotiation between different actors regarding how effectiveness of decision technologies should be judged. These findings contrast with the knowledge translation/evidence-based medicine picture of decision technologies as neutral carriers of facts, or 'pure' synthesis of research evidence.

Conclusion: Normative judgments are at play throughout the life cycle of decision technology development and use. References to scientific notions of truth and validity in the knowledge translation/evidence-based medicine model tend to overlook the socio–political dimension of decision technology development and implementation, as well as the contested nature of what "good decision" these technologies aim to support.

Practice implications: Empirical normative analysis is an important research tool to better understand the values, interests and power relationships embedded in decision technologies. Such lines of inquiry could foster a more open debate among stakeholders – including patients and members of the public – regarding the norms promoted by practice guidelines and patient decision aids. It also offers new insights in understanding the problem of implementing decision technologies in clinical practice.

Introduction

The development and use of clinical decision technologies – from computer prompts and reminders to paper-based algorithms and patient information material – is advocated as a critical component of many quality improvement programs.[1] Following the spectacular development of clinical practice guidelines (CPGs) in the 1990s, patient decision aids (PtDA) have now become another important decision technology used in healthcare delivery, hence recognizing an increased role for patients and their families in clinical decision-making.[2]

CPG and PtDA are increasingly portrayed as knowledge translation tools, whose purpose is to "bridge the gap" between research evidence and clinical practice. Decision technology development thus becomes a logical extension of knowledge synthesis, a rational "attempt to distillate a large body of medical expertise into a convenient, readily usable format".[3] Although several groups within the evidence-based medicine community are now aware of the value judgments and contextual factors that may underlie the development of decision technologies – and some are also seeking concrete ways to involve patients in the process[4–7] – such initiatives could prove misleading if they get off the ground without first being properly theorized. The goal of this article is to describe some of the implicit normative and value judgments embedded in decision technology development and use.

Methods

In the first section of the article, we use conceptual analysis of published knowledge translation/evidence-based medicine (KT/EBM) theoretical models to expose some of its underlying assumptions. In the second section, we introduce the notion of 'implicit normativity' used in science and technologies studies. This theoretical construct supports empirical normative analysis, a research approach that can expose the implicit normative and value judgments embedded in the development and use of decision technologies. To illustrate the relevance of empirical normative analysis, we use examples from two qualitative studies that used individual interviews of CPG developers in the United Kingdom (n=18) and focus group of Canadian CPG users (n=17). The methodology of those studies is described in detail elsewhere.[8,9] Both studies outline where normative judgments are being made throughout the "life cycle" of decision technology development and use, from the identification of contexts where decision are seen as insufficiently informed, to negotiations between stakeholders regarding the content of those technologies, and how their effectiveness will be judged. Finally, we draw some practice, research and policy implications of

adopting a normative perspective on decision technologies. We describe how empirical normative analysis might fruitfully be applied beyond CPG to understand the socio–political context of PtDA development.

The illusion of neutrality in decision technologies

The development and implementation of decision technologies are grounded in a variety of different theoretical models, each with its own assumptions regarding the nature of innovation and the conditions under which clinical decisions can be enhanced.[1,10] Of particular importance is the rise of knowledge translation, a "contemporary cross-cutting theme in many professions and academic disciplines".[10] Knowledge translation can hardly be thought of as a unified body of theoretical work: our focus here is on the evidence-based medicine "strand" of knowledge translation (KT/EBM).[11,12]

Guidelines and decision aids as neutral knowledge

Under KT/EBM, decision technologies are conceptualized as a form of knowledge. Decision technologies therefore serve the purpose of "bridging the gap" between evidence and practice. For example, Graham et al. describe clinical practice CPG and PtDA as "third generation knowledge", summarizing and tailoring research findings "in clear, concise, and user friendly formats and ideally (providing) explicit recommendations with the intent of influencing what stakeholders do".[11] Most KT/EBM models are grounded in rationalist models of human behaviors where it is assumed that providing patients and clinicians with quality information will influence health behaviors and, ultimately, result in better population health outcomes.[12] KT/EBM is a dominant framework for the development of CPG and PtDA and its language is increasingly embraced by research funders.[13]

KT/EBM assumes that, if based on sound research and rigorously developed, CPG and PtDA can act as neutral information carriers between research and clinical decision making, "cleaned" from bias, as well as from political, professional or commercial influences.[13] KT/EBM brings about the metaphors and language of research and measurement to describe the ideal CPG, hence described as a "valid" document containing recommendations and/or information that are "unbiased".[14] A comparable ideal of neutrality is expressed in the requirement that PtDA presents "balanced" information on the risks and benefits of options presented to patients.[5,15,16] The notion of validity implies the existence of a true recommendation and information, which could serve as a reference to judge the quality of decision technologies. In line

with this vision, Watine et al. have attempted to measure the validity of CPG recommendations based on the assumption that recommendations from properly developed CPGs should match the conclusions of systematic reviews.[17]

In support of this scientific quest for valid decision technologies, most of the academic debate within the KT/EBM community has focused on strengthening the technical quality of CPG and decision aid development (how to effectively and rigorously synthesize existing knowledge in a way that is valid, reliable and practical) and implementation strategies (how can knowledge uptake be fostered by scientifically documenting and overcoming cultural, social and political barriers to implementation). These concerns are reflected in international quality standards like the AGREE and IPDAS instruments, which require that CPG and PtDA be developed in accordance with the best available evidence and that their implementation be rigorously planned.[4,5] Furthermore, the involvement of consumers in the process of decision technology development is justified on the basis that patients and members of the public can act as "experts" in their own right, thus reinforcing the scientific credibility of CPG and PtDA development.[16]

Like oil and water: purifying knowledge from values

KT/EBM marks a clear distinction between knowledge and values. Both are seen as fundamentally distinct ingredients of decision-making to be integrated either when recommendations are developed, or when decision technologies are used and interpreted in clinical practice. Rational models of decision technology development clearly distinguish the (value-free) process of knowledge synthesis from the (value-laden) process of clinical decision-making. Clinicians are therefore summoned to consider patients' preferences and values when applying CPGs to individual clinical circumstances, while patients are to ponder the "best evidence" contained in decision aids in light of their own values.[16]

Although values are seen as having a role to play in how decision technologies are implemented or interpreted in practice, they are perceived as a potential source of bias to be excluded from the process of CPG and PtDA development. Any political, cultural, or subjective influences on decision technology development are viewed with suspicion as they could lead to "biased" recommendations or "unbalanced" decision aids.[18] Decision analysis attempts only to integrate values in CPG development by transforming it into measurable health utilities.[19]

Orthodox KT/EBM thus holds the ideal that rigorously developed decision technologies can act as neutral carriers of fact. Experts who contribute in their

development can purify decision technologies from the biased influence of normative and value judgments, or transform 'values' themselves into a scientifically measurable form of knowledge.

Decision technologies as normative instruments

KT/EBM view of decision technologies rests on the questionable assumption that knowledge and information can be produced in a social vacuum. It also leaves the unaddressed question of how the notions of "best practice", "appropriate care" and "good decisions" are constructed and shaped by the development and use of decision technologies. In contrast with this approach, science and technology studies (STS) posit that the development and use of decision technologies embody specific normative assumptions.[20] "Normative assumptions" refer to sets of norms, principles and values that are tacitly understood within certain professional, policy or disciplinary communities as the right way of interpreting the world in which a technology is being designed and introduced.[20] STS would reject any rigid distinction between facts and values, arguing that descriptive statements (e.g. a quantitative description of the outcome of an intervention) are interwoven with discipline-specific values. Berg argues that normative, political and ethical judgments are embedded in decision technologies as "every such tool passes judgment on the acceptability of risk, the meaningfulness of treatment for a specific group of patients, (and) the value of life".[21] Molewijk et al. use the concept of "implicit normativity" to describe the various presupposition and normative assumptions that are incorporated in decision technologies.[22]

Empirical normative analysis is a method of inquiry that can help making explicit the normative assumptions driving the development and use of technologies like CPG and PtDA.[23] To illustrate the relevance of empirical normative analysis for the study of decision technologies development and implementation, we use results from two qualitative studies of CPG users and developers.[8,9] These studies exemplify where normative judgments are being made throughout the "life cycle" of decision technology development and use: (1) in the recognition of contexts where decisions are seen as requiring support; (2) in determining what type of information and options are included as part of the content of decision technologies; (3) in the negotiation between different actors regarding how the effectiveness of decision technologies should be judged.

Contexts in which decisions are seen as requiring support

Decision technologies do not serve uniform purposes. The development of new decision support tools and its introduction in clinical practice results from the judgment that current decisions are inadequate and require support, either because of a perceived 'gap' between evidence and practice, of assumed under or overutilization of services, or because decisions are not seen as 'patient-oriented'. This gap between research and practice results from negotiations between actors who expect different things from decision technologies, as illustrated from this interview of a health professional with extensive experience in CPG development:

> *"Respondent: We know that doctors, by and large, including myself, don't really use [CPG], so I'm pretty sceptical about them. [However, government-sponsored] CPG have a slightly bigger role than that because they, sort of, will influence not just individual physicians, they will potentially influence what [healthcare managers] will be willing to purchase in terms of services, so I was quite keen to be involved in these guidelines 'cause I think they have a wider influence as, sort of, you know, Government edict in a sense... "* [9]

The apparent contradiction between this physician's motivation to actively contribute to CPG development and his lack of belief in the effectiveness of these instruments in changing health professionals' behaviors explained by his interest in influencing healthcare managers' resource allocation decisions. This professional's view contrasted with government and patient representatives reported motivations to be involved in CPG development, which revolved more around their hope to influence physicians' clinical decisions and behaviors.[9] Competing views about whose decisions require 'support' and why will impact on participants' view of the information that should be included and excluded from decision technologies.

Information content and the construction of agency

Studies of the impact of risk communication have highlighted how the way information and risks are "framed" (for example, by presenting survival instead of mortality rates, or by presenting risks numerically or verbally) impacts on the perception of risk and the choices made by clinicians and patients.[24] The implication of these findings is that information is not a neutral ingredient and the way it is presented reveals choices regarding the purpose and expectations of decision support designers and users.

For example, choosing whether to present a single best recommendation or to describe different intervention options represents an important judgment made by CPG and PtDA developers. Deciding which options should be on the patients' and clinicians' "menu" is revealing the perspective and interests at stake regarding who should have the responsibility to decide and whether a good decision is judged from the perspective of the average or the individual patient:

> *"[In our CPG] we recommend a particular drug because on average it seems to be the best. [But if] the concerns from the patients are so strong about a particular drug [because it] doesn't suit their lifestyle, their job or whatever, then, even though on the basis of the evidence – on the basis of the economics – it's the best, you're going to actually temper that. [...] So rather than saying 'This is the first choice' [...], we're actually going to say 'There are two or three different first choices and you need to stop, sit down with the patient and discuss it, and then choose which one you go with'."* [9]

Decision technologies, therefore, do not simply provide decision makers with "facts" about the pros and cons of a decision. Because they frame information in a particular way and pre-select a given number of acceptable options, decision technologies structure the decision-making environment and the conditions under which patient and professional autonomy and agency role may or may not be realized.[22]

The politics of effectiveness

The variety of different outcomes that are used to assess the effectiveness of CPG and decision aids is also symptomatic of the different norms, interests, and competing goals at stake. Most CPG impact studies are focused on physicians and patients' behavior change, adherence to recommendations, resource use and health outcome, while effectiveness studies of PtDA tend to pay greater attention to the effect of those decision technologies on the process of decision-making (patient satisfaction with the decision process, decisional conflict, patients' knowledge).[2,25] Various authors have highlighted the potential contradiction between those different goals and outcome measures.[2,26–28] For example, a "good decision" as judged from the patient's perspective might not be aligned with guideline recommendations that rank interventions on the basis of their population effectiveness or efficiency.

What counts as an effective decision technology is also likely to differ whether seen from the perspective of developers (the "embedded script" of how designers intend

technologies to be used) or users (the "effective script" of technology used in practice[20]). Thus, the question of who gets to decide what represents an effective decision technology is important. Interviews of CPG use in primary care practice are illustrative of the potential gap between embedded and effective scripts of decision technology use. Two of us (AB and FL) carried out a study on primary care physicians' perceptions of CPG and patient involvement in decision-making.[8] Based on the shared decision-making literature[29], we assumed that modifying CPGs to include more information on the risks and benefits of interventions could bring about less paternalistic CPGs and would offer greater room for individual health decisions to "deviate" from population-based recommendations. Physicians met the proposition with enthusiasm. However, for some of them, the rationale for developing patient information material was markedly different from our design intentions:

> *"I fully agree with the idea of information to give to patients because often time, when I propose a good treatment to a patient, they usually say yes, but will they take it? [...] So if I have a little sheet then, it doesn't take me much more time – because explaining can be very long – [...] and it increases trust."*

In this case, while effective decisions support might be judged by designers in terms of the instrument's ability to promote a more active role of patients in decision-making, it might be judged by users (clinicians in this case) on the basis of the instrument's ability to speed-up the clinical encounter and increase compliance with professional recommendations.

Discussion and conclusion

Discussion

This article is important for the field of evidence-based medicine and shared decision-making as it reframes the debate on bias in decision technology development and use. We show, through empirical normative analysis of qualitative interviews with decision technology developers and users, that normative judgments cannot be isolated from scientific judgments, and are an intrinsic component of 'knowledge translation' tools like CPG and PtDA.

The most important limitation of this analysis is that most of our empirical examples are drawn from the context of CPG development and use. One could wonder whether normative considerations are equally present in PtDA, as these technologies usually

do not contain explicit recommendations on appropriate care and appear to present 'only facts', leaving the final decision for patients to decide in collaboration with their health professional.[16] However, framing the purpose of PtDA in such a way already presupposes a number of normative a-priori (e.g., a good decision is informed and consistent with patients' values; patients are experts for judging values; options should be presented to patients when faced with a 'preference sensitive' decision). Current debates within the shared decision-making community regarding how a good decision should be defined, what risks and information should be incorporated in PtDA, or what decisions should be considered 'preference sensitive', show that these normative issues are far from being unproblematic.[26,28]

The study of Molewijk et al. on PtDA developers offers an example of the normative assumptions implied in the choice of PtDA information content.[22] In this study, decisions regarding the number of options to present, the source of evidence used, and the way information is framed reveal the range of normative assumptions made by PtDA developers. For example, quoting a specific mortality rate associated with the choice of undergoing surgery for aortic aneurism is not simply a matter of finding an accurate prediction, but of choosing the reference group on which this measure will be based (whether this is at the country, region, local or even surgeon level). Presenting the national mortality level – which might be lower than mortality rates in university hospitals – is likely to influence the choice being made by the clinician–patient dyad and the "effectiveness" of the instrument (whether the initial problem is thought to be an under or an over-utilization of services).

Another recent example illustrates the 'politics of effectiveness' that surrounds PtDA development. In 2007, the state of Washington endorsed the principles of shared decision-making and introduced a legislation that promotes the use of patient decision aids in the clinical encounter. It did so in response to recommendations of a state commission set-up a year earlier with the goal of offering solutions for substantially improving access to affordable health care. Policy documents in support of the legislation highlighted research evidence showing that the use of patient decision aids could reduce the rate of invasive interventions, such as hysterectomy[2], and therefore had the potential to:

> *"Improve healthcare while at the same time manag[e] fiscal resources by encouraging collaboration and using nationally developed and approved patient decision aids."* [30]

Such preoccupation with cost-effectiveness may not have the same importance for consumer advocacy groups who may see shared decision-making primarily as a way to correct power imbalance in the medical encounter or to foster empowerment of patients.

Conclusion

References to scientific notions of truth and validity in the KT/EBM model tend to overlook the socio–political dimension of decision technology development and implementation, as well as the contested nature of what "good decision" these technologies aim to support. Empirical normative analysis can expose the normative judgments that are at play throughout the life cycle of decision technology development and implementation, and may thus be an important research tool to better understand the socio–political context of both PtDA and CPG development. It is also a promising avenue of inquiry for scholars in the field of shared decision-making and evidence-based medicine to address the following questions: How are norms of practice evolving in health care? What norms are embodied in decision technologies? Who sets the agenda and defines which evidence 'gaps' need to be corrected? So far, these questions have tended to been put aside by researchers, arguing that interests, power and politics are sources of bias that should be neutralized. Their study could rather be seen as opportunities for exposing the normative and value judgment inherent to decision technology development.

Practice implications

Exposing the normative role that decision technologies play in daily clinical practice has important practical implications. First, it reframes the debate on what 'effective implementation' means for the different actors involved, and offers explanatory insights as to why target user groups may be resisting implementation because of different normative frame of reference.[21] Some of those insights have been formally incorporated in theories of normalization and can help to explain how complex interventions like CPG and PtDA come to be part or not of the taken-for-granted elements of clinical practice.[31]

The reframing of the problem of decision technologies development and implementation also has important policy implications. Normative dilemmas are hardly amenable to technical fixes: addressing them thus broadens the competence required to develop those instruments. Because interests, values and norms are inextricably tied to the very notion of decision technology, their development and

implementation calls not only for technical expertise but also for social legitimacy. A rigorous and scientifically sound development and implementation process is necessary but not sufficient to develop decision technologies that will lead to "better" decisions. Empirical normative analysis can help to expose the competing values and perspectives regarding the "good" that decision technologies are promoting. Recognizing the normative assumption embedded in those instruments should therefore be seen as an opportunity to debate those influences more transparently. It also opens room for a more explicit acknowledgment of the role of patients and members of the public in decision technology development and implementation.

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Section II:

Current involvement practices and international experiences

Chapter 5

Patient and public involvement in clinical guidelines: international experiences and future perspectives

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Abstract

Background: Clinical practice guidelines (CPG) are important tools for improving patient care. Patient and public involvement is recognized as an essential component of CPG development and implementation. The Guideline International Network Patient and Public Involvement Working Group (G-I-N PUBLIC) aims to support the development, implementation and evaluation of guideline-oriented patient and public involvement programs (PPIPs).

Objective: To develop an international practice and research agenda on patient and public involvement in CPG.

Method: 56 CPG developers, researchers, and patient/public representatives from 14 different countries, were consulted in an international workshop. Recommendations were validated with G-I-N PUBLIC steering committee members.

Results: Many CPG organizations have set up PPIPs that use a range of participation, consultation and communication methods. Current PPIPs aim to improve the quality and responsiveness of CPGs to public expectations and needs, or to foster individual healthcare decisions. Some organizations use structured involvement methods, including providing training for patient and public representatives. A number of financial, organizational and sociopolitical barriers limit patient and public involvement. The paucity of process and impact evaluations limits our current understanding of the conditions under which patient and public involvement is most likely to be effective.

Conclusion: More international collaboration and research are needed to strengthen existing knowledge, development and evaluation of patient and public involvement in CPG.

Introduction

Clinical practice guidelines (CPGs) are important tools for improving patient care.[1,2] Many national organizations and experts recommend involving patients, consumers and the public in CPG development and implementation.[3-6] In recent years, patient and public involvement programs (PPIPs) have been developed with wide variations between countries. This partly reflects the thin evidence guiding the development of PPIPs[4,7] but also highlights how cultural, organizational context, and stakeholders' perspectives influence these programs.[8]

In 2007, the Guideline International Network[9] created its Patient and Public Involvement Working Group (G-I-N PUBLIC, http://www.ginpublic.net). G-I-N PUBLIC aims to support effective patient and public involvement in specific contexts of CPG development and implementation through: the sharing of experiences and evidence, international research collaboration, and the development of standards and methods of involvement. To date, no structured consultation process has been used to establish priorities in the field. This paper presents current international experiences, and a research and practice agenda for the development of effective patient and public involvement in CPG, based on the results of an international workshop organized by G-I-N PUBLIC.

Methods

Definitions and scope

Different labels are used internationally to describe involvement methods and their participants (consumers, users, citizens, patients and the public).[10] For the purpose of the workshop, PPIP refers to at least one formal method of involving patients and the public in CPG development and/or implementation. Involvement methods may include: communication (information is communicated to patients/the public); consultation (information is collected from patients/the public); or participation (patients/the public exchange information with other stakeholders).[11] PPIPs can be used at different stages, from the macro-level of CPG development (e.g., topic selection, evidence review, recommendation, and development of ancillary products), its meso-level of implementation to specific target groups, or its use at the micro-level of the clinical consultation.

International consultation and validation

G-I-N PUBLIC members organized a 3 hours interactive workshop[12,13] using structured and facilitated discussion at the 5th Guidelines International Network conference in Helsinki (Finland), in November 2008. Participants were divided into subgroups to foster active participation and to address specific questions, including (1) expectations and goals of PPIP; (2) participation and consultation in CPG development; (3) the integration of patient decision support technologies; (4) priorities for research and international collaboration. In each subgroup, a facilitator introduced the topic and chaired discussions, while a different person took notes. An oral summary of discussions was fed back to all participants at the end of the workshop, and facilitators produced a written report of discussions.[14] We distributed the original data to G-I-N PUBLIC Steering Committee members and solicited written comments to validate findings, before discussing recommendations with them in two teleconferences.

Results

A total of 56 people from 14 countries participated in the workshop and subsequent discussions (table 1). Results are reported as per the main themes of discussion presented above.

Table 1. Details of participants

	Participants (n=56)
Role in relation with guidelines	
Guideline developers	35
Researchers	16
Patient and public representatives	5
Countries (n=14)	**Participants (n=56)**
Australia	3
Belgium	2
Canada	5
Czech Republic	3
Finland	5
France	6
Germany	3
Japan	4
Netherlands	8
New Zealand	2
Norway	5
Spain	4
United Kingdom	3
United States	3

Expectations and goals of PPIP

Workshop participants agreed on the importance of patient and public involvement in CPG. However, they reported that patient and public involvement goals are often largely implicit or articulated in vague terms by their organizations, which makes it difficult to assess success or failure. Tension also exists between collective and individual perspectives. From a collective perspective, PPIP can be seen as a way to develop recommendations that will improve the quality of healthcare and its responsiveness to population needs and expectations. Patient and public involvement can also be seen as an accountability mechanism that fosters CPG social legitimacy and its ability to be implemented in clinical practice. At the individual level, patient and public involvement can be geared towards the promotion of individuals' rights and the protection of patients' autonomy and freedom of choice. For some, the position of patients as consumers and users of healthcare justified their participation in CPG development. Other PPIP goals discussed by participants were focused on promoting informed choice to ensure that patient/provider interaction was patient-centered and responsive to individual needs, values and priorities. Participants considered that differences in perspectives can have a profound impact on the choice of methods for involving patients and the public, as well as on the criteria used to assess PPIP effectiveness.

Participation and consultation in CPG development

Participants agreed that participation methods, where patient or public representatives exchange information and deliberate with other CPG developers, are present in many existing PPIPs. CPG organizations often include patient members in guideline development groups to provide consumer perspectives in the interpreting of the evidence and develop recommendations that are relevant to patients. The National Institute for Health and Clinical Excellence (NICE) citizens' council uses deliberative participation methods to involve members of the general public to discuss social values related with CPG development.

Participants pointed towards the importance of recruitment, support and training as key conditions for meaningful involvement of patient and public representatives. Training may cover the fundamentals of guideline development and approaches for reporting back to consumer constituencies, or offer mentoring opportunities from other patient/public representatives. Participants concluded that training and support may facilitate understanding of the technical aspects of CPG development,

address financial and organizational barriers to participation, and enhance mutual understanding regarding the role of PPIP.

Participants highlighted the importance of recruiting patient/public members early in the process, with consideration given to a balanced socio-demographic representation, because many CPGs disproportionately impact certain subgroups. A key recruitment question is whether patient/public members should be expected to represent a constituency or to bring their personal experience to the table: job descriptions are used by some participants' organizations and may assist in clarifying expectations. Concerns were raised about the dependence of some consumer organizations on pharmaceutical or biomedical industry funding and its potential impact on CPG validity: some participants reported that their organization required declarations of interests from all CPG developers, including patients/public members. On the other hand, patient representatives argued that some patients' and consumers' organizations have became quite sophisticated in their understanding of the evidence, as exemplified by the Cochrane Consumer Network, and that their involvement could strengthen the quality of CPGs by expanding the range of evidence being considered and by questioning certain experts' assumptions.

Participants regarded open consultation and written submissions by patient organizations as particularly useful in defining CPG topics and comments on draft CPGs. Participants reported that the use of a focus group has been useful at the beginning of the CPG development process, when little evidence on patients' preferences is available, or at the end of the process to test recommendations and improve its potential for implementation. Participants also noted that little is done currently to synthesize existing published evidence on patient and public views and preferences, and suggested that the range of consultation methods currently used in PPIP could be expanded to include satisfaction surveys, or web-based consultations.

Integration of patient decision support technologies

According to workshop participants, many PPIPs focus on communication methods to promote more active and informed health decisions by patients and consumers at the micro-level of the clinical consultations. Some organizations (e.g., German Agency for Quality in Medicine, New-Zealand Guideline Group and NICE) have developed large online repositories and short summaries of patient versions of CPGs. Others have attempted to disseminate CPGs through collaboration with patient organizations.[15] Participants agreed that the development of patient oriented material may assist understanding of CPG recommendations and could foster informed and shared

decision-making between patients and clinicians. For example, the Dutch Institute for Healthcare Improvement (CBO) has produced patient decision aids presenting options, individualized risk assessment, and the probabilities of benefits and downsides to support choices regarding 'preference sensitive decisions' (such as prostate cancer screening),[16] which are characterized either by evidence that points to a balance between harms and benefits or by scientific uncertainty.[17]

Participants suggested that professional versions of CPGs could also be adapted to foster shared decision-making. For example, methods could be developed to search and analyze preference-related evidence and present it in the CPGs. Some guideline organizations also convey information about the relative importance of interventions for patients in their grading of recommendations. It was also felt that professional versions of CPGs could signal decisions and recommendations that are most likely to require discussion with patients, decision-support tools, or specific preference-eliciting and communication strategies. With the growth of increasingly sophisticated health information technology, guidelines and decision tools can be disseminated in concert (e.g., by hypertext links in electronic guideline documents), rather than as stand-alone products.

Participants identified priorities for research and international collaboration (table 2). They indicated the lack of evaluation of PPIP as a barrier to the wider acceptance and development of PPIP. Participants identified diverging roles for evaluation: for some, research should help to assess the added value of PPIP in CPG development and implementation, while others see involvement as having intrinsic value, and evaluation efforts are expected to help develop and identify the most effective involvement methods.

There was a high demand among participants for stronger international collaboration on patient and public involvement within and outside the CPG community. Participants saw the international community as a pool of ideas and experiences, and expressed the need to share both 'success' and 'failure' stories.

The heterogeneous level of expertise and capacity, as well as cultural and health system variations, was seen as both a motivator and a barrier for greater international collaboration.

Table 2. Priorities for patient and public involvement in guidelines identified by participants

Research priorities
1. To synthesize existing knowledge and experience in order to provide CPG developers with an overview of existing methods for involving patient and the public. Such synthesis should draw from the practical experience accumulated in other areas of healthcare (e.g. research, health technology assessment, health policy, performance measurement).
2. To expand primary research on the pros and cons of different methods of involvement, including their impact on CPG development and implementation, as well as on CPG perceived validity, acceptability and legitimacy for health professionals, patients and the public. There is a need to study in greater detail the contextual and process factors that influence PPIP effectiveness.
3. To assess whether patient versions of CPGs and information material foster informed and shared decision-making and impact on decisions. There is a need to understand how and in which situations patient decision aids and/or evidence on patient preferences and values should be integrated in existing CPGs.
4. To adapt or expand the AGREE criteria[5] to better evaluate the quality of patient and public involvement in existing CPGs.
International collaboration priorities
1. To develop recruitment methods, training and support strategies, information material and tools, and glossaries of technical terms used in CPGs.
2. To develop common international standards and frameworks for PPIP development and evaluation that allow for adaptation to local context.
3. To support the development and exchange of information on alternative methods of patient and public involvement (e.g. systematic reviews of evidence on patients' views and preferences and the integration of decision support tools).
4. To contribute to the enhancement of skills and expertise in countries with identified capacity needs.
5. To foster comparative research and evaluation of PPIP methods and impact on guideline development and implementation.

Discussion

To our knowledge, this paper reports the first international consultation to develop priorities for research and collaboration on patient and public involvement in CPGs, based on international experience. The involvement of patients and the public is motivated by attempts to improve CPG quality and implementation, and its responsiveness to population expectations and needs, and to foster individual healthcare choices.[8,18,19]

Current approaches favor involvement of patient members on guideline development groups, consultation of draft CPGs and the development of patient versions of CPGs, an observation that is in line with previous surveys of CPG organizations.[20-22] The range of reported methods to involve patients and the public appears to make little use of alternative methods proposed in the literature, such as systematic reviews of published evidence on patients' views and preferences, the integration of patient decision aids, the use of decision analysis to integrate patients' utilities in CPG recommendations and their involvement in strategic aspects of CPG development, including CPG evaluation.[4,16,23-30]

Previous reviews have found few empirical studies of PPIP in the context of CPG development or implementation.[7,31-34] The evidence supporting when and how PPIP should be developed needs to be strengthened.[35] These efforts should recognize the specific challenges of evaluating patient and public involvement, including: (1) the absence of consensus over what constitutes 'effective involvement'; (2) the lack of agreed-upon evaluation tools; and (3) the value-laden and context-sensitive nature of PPIP.[36,37]

The strength of this study rests on the broad reach of the consultation process, with direct participation of 56 representatives from 14 countries, including most of the CPG organizations active in the published and grey literature on patient and public involvement.[4,23,35] Validation of findings against original data reported by an international group of guideline developers and consumer representatives brings robustness to the findings. On the other hand, practical constrains kept us from recording discussions, which would have strengthened data collection and analysis. Using the G-I-N conference workshop participants for convenience sampling also limits the consulted audience to persons likely to be supportive of both CPG and PPIP. Participants from developing regions and patient representatives were under-represented, partly because of financial barriers to attend.

Previous studies found that patients can have a different view of their role in CPG,[8] and in our study, patient and public representatives highlighted the need for early and active involvement, as well as the potential that PPIP may improve the quality of guidelines. Other participants voiced concerns that PPIP may introduce controversy, bias, and resistance from professional groups, thus illustrating the delicate balance between the search for legitimacy and credibility among the different 'publics' involved in CPG development and use (health professionals, researchers, patients, policymakers, and the wider public).[38-42]

Conclusion

In recent years, CPG organizations have set up PPIPs that use a range of participation, consultation, and communication methods. A number of financial, organizational, and socio-political barriers limit patient and public involvement in CPG. The lack of process and impact evaluations limits our current understanding of the conditions under which PPIP are most likely to be effective. More international collaboration is needed to strengthen existing knowledge, exchange experiences and expertise, and address barriers to effective involvement.

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Chapter 6

A knowledge synthesis of patient and public involvement in clinical practice guidelines: study protocol

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Abstract

Background: Failure to reconcile patient preferences and values as well as social norms with clinical practice guidelines (CPGs) recommendations may hamper their implementation in clinical practice. However, little is known about patients and public involvement programs (PPIPs) in CPG development and implementation. This study aims at identifying what it is about PPIPs that works, in which contexts are PPIPs most likely to be effective, and how are PPIPs assumed to lead to better CPG development and implementation.

Methods and design: A knowledge synthesis will be conducted in four phases. In phase one, literature on PPIPs in CPG development will be searched through bibliographic databases. A call for bibliographic references and unpublished reports will also be sent via the mailing lists of relevant organizations. Eligible publications will include original qualitative, quantitative, or mixed methods study designs reporting on a PPIP pertaining to CPG development or implementation. They will also include documents produced by CPG organizations to describe their PPIPs. In phase two, grounded in the program's logic model, two independent reviewers will extract data to collect information on the principal components and activities of PPIPs, the resources needed, the contexts in which PPIPs were developed and tested, and the assumptions underlying PPIPs. Quality assessment will be made for all retained publications. Our literature search will be complemented with interviews of key informants drawn from a purposive sample of CPG developers and patient/public representatives. In phase three, we will synthesize evidence from both the publications and interviews data using template content analysis to organize the identified components in a meaningful framework of PPIP theories. During a face-to-face workshop, findings will be validated with different stakeholders and a final toolkit for CPG developers will be refined.

Discussion: The proposed research project will be among the first to explore the PPIPs in CPG development and implementation based on a wide range of publications and key informants interviews. It is anticipated that the results generated by the proposed study will significantly contribute to the improvement of the reconciliation of CPGs with patient preferences and values as well as with social norms.

Background

The challenge of clinical practice guidelines implementation

Clinical practice guidelines (CPGs) are described as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'.[1] Within the knowledge to action framework, CPGs are understood as the product of a knowledge tailoring strategy, translating primary and secondary research into specific recommendations for action.[2] Their application in clinical practice is expected to improve patient outcomes by promoting an effective, equitable, and rational utilization of resources.[3] However, despite the vast amount of resources invested in developing CPGs, their implementation in clinical practice remains a major challenge.[4] As a result, appropriate evidence-based care is not offered to patients, while unnecessary or harmful care often is.[5-9] An important barrier to the implementation of CPG recommendations is their inability to reconcile patient preferences and values as well as social norms.[10,11] CPGs have also been criticized for not being responsive to increased demands from patients to share decisions with health professionals and play an active role in their care.[12-14] Furthermore, current CPGs are leaving unaddressed some of the critical challenges posed by the rising burden of chronic disease and its impact on the context of decision-making. Therefore, the role that patients and public involvement programs (PPIPs) could play in CPG development and implementation is increasingly attracting the attention of policymakers, health professionals, patients, and the public.

The grey zone of decision-making

Clinical decisions largely occur in contexts of scientific uncertainty. These grey zone (or preference sensitive) decisions are characterized either by scientific evidence that points to a balance between harms and benefits within or between options, or by the absence or insufficiency of scientific evidence.[15-17] Moreover, probabilities of risks and benefits in a population cannot be directly attributed at the individual level. Consequently, both clinicians and patients need help in resolving uncertainty when facing clinical decisions.[18] However, current CPGs are insufficiently adapted to grey zone decisions, and thus cannot help providers and their patients make informed decisions in these highly prevalent decision-making contexts.

CPGs are still largely conceived as tools that should foster adherence to a best decision defined by the 'expert health professional', rather than instruments that should support the best decision for a specific patient in a specific context. Health

professionals have criticized CPGs for lacking relevant information to assist shared decision-making with patients.[12,19] In Canada, a large proportion of CPGs development is undertaken by expert panels and, most of the time, patient and public organizations have a limited role to play or are at best asked to comment on draft versions of CPGs.[20,21] This is surprising because evidence suggests that patient involvement might be beneficial at different levels of health care. At the clinical level, it is associated with the quality of the decision-making process[22], reduction in unwarranted surgical interventions[23], and patients' quality of life at three years.[24] At the level of the population, patient involvement fostered by patient decision aids has been found to reduce overuse of options not clearly associated with benefits for all (e.g., prostate cancer screening)[25] and to enhance use of options clearly associated with benefits for the vast majority (e.g., cardiovascular risk factor management).[26] The most recent systematic review of the effectiveness of patient involvement in decision-making (or shared decision-making) found this approach to be particularly effective in fostering adherence to the treatment choice that was made in the context of chronic disease, more specifically in the context of mental health diseases.[27] Thus, engaging patients as decision-makers, experts, and co-producers of health is particularly important in this context, as productive interactions between active and informed patients and health care providers are understood as key components to effective chronic disease management.[28,29] As decision-makers in Canada are increasingly focusing their efforts to tackle the rise of chronic diseases, the relevance for involving patients in CPGs development is thus becoming more pressing.

Beyond their role in assisting individual clinical decisions, CPGs have also a broader impact on health policy, funding decisions, and service organization.[30,31] However, social norms and economic judgments are largely implicit and poorly articulated in current CPGs, which leads to potential conflicts of interests, contradictions in CPG recommendations, and confusion among health professionals, patients, and the public.[12,32-34] For example, the Canadian Diabetes Association recommended in 2003 that insulin glargine could be used as an alternative to generic long-acting insulin for the treatment of diabetes.[20] After reviewing virtually the same evidence, the Common Drug Review, a national advisory panel, recommended that the drug should not be listed in provincial formularies on the basis of questionable added clinical benefit and a five-fold increase in price.[21] Such controversies illustrate the grey zones of decision-making and the importance that CPG developer should be accountable not only to patients but also to the general public, which implies to consider cost effectiveness

and cost impact.[33,35-37] The McDonnell Norms Group suggests that response to public demand and social norms be regarded as a key ingredient for the successful implementation of research evidence in clinical practice.[38] Considering the perspectives of patients and members of the public is thus a logical approach for conceptualizing the development and effective implementation of CPGs.

International consensus on the importance of patient and public involvement in CPGs

International experience of patient and public involvement in CPGs has been accumulating in the past ten years.[39] For example, the British National Institute for Health and Clinical Excellence (NICE) has adopted a comprehensive approach to involving patients and the public in all stages of CPG development, from the scope of CPG topics to patient representation on CPG development groups.[40] A citizen council also ensures that members of the public can openly and transparently debate CPG social and economic value judgments.[41] The Dutch Institute for Healthcare Improvement (CBO) has also innovated by producing patient decision aids to support grey zone decisions in existing CPGs (e.g., prostate cancer screening).[42] In 2007, the Guideline International Network (GIN), an international network of 85 CPG organizations, announced the creation of the GIN Patient and Public Involvement working group, thus reflecting the increasing recognition of this issue among CPG developers.[43] In light of these initiatives, major organizations in Canada have started to call for a CPG development process that will engage patients and the public in a more meaningful and effective way. The Canadian Medical Association, in its 2007 handbook on clinical practice guidelines, notes that patient and public involvement is 'increasingly common (and desirable) to gain input from non-health professionals and groups who are affected by the CPGs'.[44] In 2008, inspired by the British NICE, the Quebec government announced the creation of a single provincial organization that would oversee the development of all CPGs in the province to foster a more transparent and accessible platform for public and patient involvement throughout the CPG development process.[45] Such developments could spearhead the development of structured PPIPs among Canadian and international CPG organizations, as long as decision-makers are equipped with practical knowledge to support those initiatives.

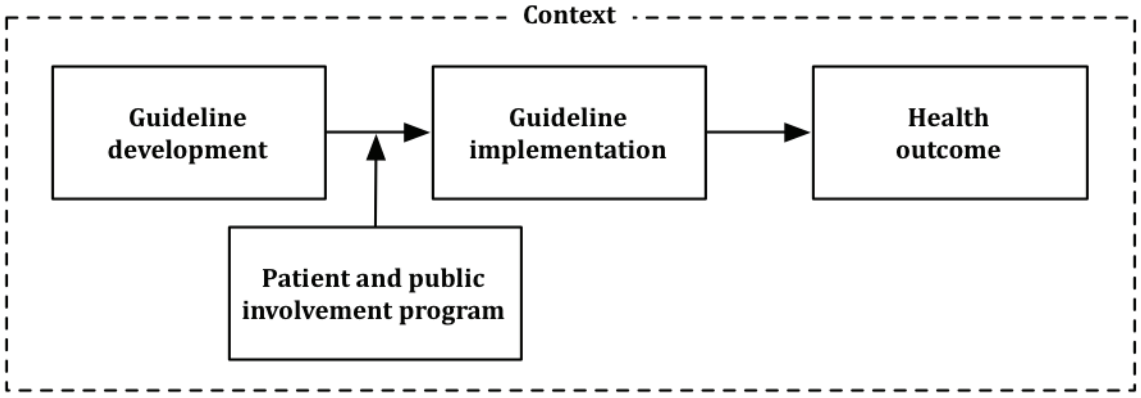
What knowledge gaps does this study address?

Despite this growth in interest and experience, previous knowledge syntheses have left decision-makers with little practical guidance on the design of effective PPIPs in CPG development. Two recent reviews produced for the World Health Organization (WHO) and the Cochrane collaboration found no comparative intervention study of PPIPs in CPGs.[46,47] These findings indicate that the development and evaluation of PPIPs are still in an early stage, and that guidance is needed to strengthen PPIP theory and effective development. However, by simply asking 'what works' and restricting their synthesis to comparative intervention studies, these reviews do not allow CPG developers to build on the experience of other organizations and identify where efforts should be put in priority to develop effective PPIPs. Furthermore, these syntheses used approaches that account neither for the high level of complexity of PPIPs, the competing rationales that underpin those interventions, nor for the contextual factors that promote or impede success. Research efforts in the field of patient and public involvement must therefore move into the development of effective PPIP by focusing on more encompassing research questions.[48] Consequently, the overarching goal of this study is to strengthen the knowledge base that will support the elaboration of effective PPIPs in CPG development and implementation by undertaking a knowledge synthesis of the literature that will explore not only what works but also, how and in which context effective PPIPs are developed. This in turn has the potential to foster better implementation of CPGs in clinical practice, a key need of the decision-maker partners.

Conceptual underpinnings of this knowledge synthesis

We conceptualize a patient and public involvement program as an intervention that influences CPG development and, indirectly, its implementation in clinical practice and health outcomes (Figure 1). Grounded in the logic model, our framework recognizes that PPIPs contain a set of activities that are put forward in order to answer the needs of clients in relation to expected outcomes.[49] In turn, these activities require specific resources (e.g., human and material). Furthermore, our framework recognizes that the design and effectiveness of PPIP are influenced by the context in which they are developed.

Figure 1. Conceptual framework: Patients and public involvement programs in clinical practice guideline development and implementation



Research questions

This knowledge synthesis aims at identifying and refining the underlying PPIP theories by conducting a systematic literature review inspired by 'realist' methods.[50] Realist inquiries are based on a generative model of potential causality where outcome is linked to the assumed underlying mechanisms of the intervention, implemented within a specific context that will provide answers to the following research questions:

1. WHAT are the principal components and activities of PPIP that have been used to date in CPG development? Who is involved, how are they involved, at what stage of CPG development, and for what purpose? Which components of PPIP are perceived as important and/or effective in improving CPG development, implementation, and/or health outcomes? What types of resources are needed to run the PPIP?
2. IN WHICH CONTEXTS have PPIPs been developed and tested? What are the individual, interpersonal, institutional, and social contexts in which PPIPs appear to be most effective? What factors are perceived as barriers and facilitators for the development and implementation of effective PPIPs?
3. HOW are PPIPs assumed to improve CPG development, implementation, and/or quality of health care? What are the expected outcomes?

We argue that PPIPs rest on a set of expectations and assumptions that are held by their sponsors, participants, and those who judge their effectiveness.[51] These expectations constitute the underlying theory of PPIPs, which provides a model of how PPIPs are assumed to work.[52] PPIP theory logically links together PPIP methods, context, and outcome in a hypothesis chain, whose generic format is: 'if a specific patient and public involvement program is implemented within a given context, it will

then impact on the CPG development process, implementation, and/or health outcome'. In other words, this knowledge synthesis will take into account context as an essential element for improving our understanding of PPIPs in CPG development and implementation.

Methods and design

The proposed knowledge synthesis is comprised of four main phases.

Phase one: Search for evidence

Search strategy

With the help of an information specialist, English and French publications up to January 2009 will be identified through: bibliographic databases (e.g., Cochrane Consumers and Communication Review Group's Specialized Register, the Cochrane Controlled Trials Register, MEDLINE, EMBASE, CINAHL, PsycINFO, Sociological Abstracts, G-I-N database)[53]; manual search of key journals and of the G-I-N conference proceedings; personal contact with key authors and experts in CPG development using the network of G-I-N; and reference lists of included studies and systematic reviews. A call for bibliographic references and unpublished reports will also be sent via the mailing lists of the G-I-N Patient and Public Involvement Working Group. Our decision-maker partners will be consulted to help in this search for evidence. A list of publications considered eligible by the research team will be used to devise the search strategy and compute the precision of our search[54].

Inclusion and exclusion criteria

Types of studies

Eligible publications will include original qualitative, quantitative or mixed methods study designs (i.e., case study, observational, and intervention studies). They will also include documents produced by national/governmental supported/non-profit CPG organizations to describe their PPIPs. Studies focused on PPIPs in other areas of healthcare (e.g., health technology assessment, health research, planning and delivery of health services, development of health information material) will be excluded.

One team member is currently involved in two other knowledge syntheses that share a similar focus. One deals with patients' perspective on electronic health record[55], the other deals with patients and public involvement in health technology assessment.[56] Also, another team member is involved with the International Patient Decision Aids

Standards (IPDAS) Collaboration, a group dedicated to patients' involvement in healthcare decisions.[57]

Participants

Patients refer to people with personal experience of the disease, health interventions or services discussed in CPGs (including family members and carers). The public refers to members of society interested in health care services and whose life may be affected directly or indirectly by a specific CPG.[58]

Intervention

PPIP refers, at the minimum, to one formal method of involving patients and/or the public in CPG development. Formal involvement methods may include: communication (information is communicated to patients or the public); consultation (information is collected from patients or the public); or participation (patients or the public participate in an exchange of information and deliberation with other CPG developers).[59] CPG development is defined as the systematic process leading to the production of statements to assist health professional and patient decisions about appropriate healthcare for specific clinical circumstances.[1] Our definition of CPG development is purposefully broad as to include CPG implementation strategies dealing with patient-mediated interventions (e.g., communication of information to patients and the public about CPGs, production of patient/public versions of CPGs and the integration of patient decision aids in existing CPGs). We excluded other CPG implementation strategies (e.g., audit and feedback, education, organizational change) because of our decision-maker partners priorities and of the practical challenge of concurrently addressing PPIP in CPG development and all possible strategies of implementation.[4,5]

Phase two: Appraise and extract data from identified primary studies

Study identification and data extraction

A research assistant will screen all references. Potentially eligible references will be reviewed by the two co-PIs independently. Any discrepancies between the two reviewers on study inclusion will be resolved by discussion with other team members, including at least one of our decision-maker partners. All eligible references will then be extracted by pairs of research team members using a data extraction form that was developed from previous work in this field.[58,60-62] Pilot testing of the standardized form will be conducted and its results discussed by team

members to finalize the form. Pairs of reviewers will compare abstracted information and disagreements will be resolved through consensus. Information will be collected on:

1. Bibliographic reference, type of publication, and study design.
2. Principal components of PPIPs, including: planned activities, who is involved, how they are involved, how they are trained or guided, their level of decision-making power, at what stage of CPG development, and for what purpose; components that seem the most important and effective; and resources needed (research question one).
3. Context in which PPIPs are developed and tested, including individual, interpersonal, institutional, and social context factors; factors perceived as barriers and facilitators for the development and implementation of effective PPIPs (research question two).
4. PPIP theory: explicit and implicit assumptions regarding how PPIPs are deemed to lead to improved CPG development, implementation, and/or health outcomes (research question three).[60,63]

Quality assessment

Study quality will be assessed by two independent reviewers and based on two main criteria: relevance (whether the authors of the included publication are explicit about the principal components of PPIPs that have been used in CPG development), and rigor (whether the study can make a credible contribution in terms of validity and reliability). Quality criteria developed for mixed methods review will be used.[64]

Data validation

Key informants will be drawn from a purposive sample of six to ten CPG developers and patient/public representatives working with organizations with a PPIP. Individual phone interviews with key informants will serve as a method for complementing and validating data extraction from publications. Examples of questions in the interview guide include: descriptive information on existing PPIPs and their context of development, components of PPIPs that seem the most important and effective; perceived barriers and facilitators for the development and implementation of effective PPIPs; examples of best (and 'bad') practices. Interviews will be recorded and transcribed verbatim. The appropriate software will be used for qualitative analyses to support data collection, organization, and analysis.

Phase three: Synthesize evidence and draw conclusions

Both publication and interview data will be analyzed. A research assistant will enter findings into a data matrix to facilitate comparison of how each publication performs on principal components of each PPIP. For each publication and interview, template content analysis will be used to organize its identified set of principal components into a meaningful framework of PPIP theories.[65] Thus, based on a taxonomy of PPIP theories, we will identify and classify existing PPIP theories based on the principal components that will have been extracted from each study. This taxonomy was previously developed by one of the author based on qualitative interviews with CPG developers.[14] For example, the 'health care governance' PPIP theory holds that consultation with a statistically representative group of patients in the summary of evidence stage of CPG development should result in improved patient adherence with cost-effective interventions. In the context of this synthesis, the taxonomy of PPIP theories will be refined and expanded to include contextual factors that are seen as influencing PPIP effectiveness.

Phase four: Achieve consensus with our decision-maker partners on a proposed toolkit on PPIP that could be tested in a subsequent study

In consultation with our decision-maker partners, we will engage in a consensus process for developing a toolkit on effective PPIP in CPG development that could be tested in a subsequent study with the potential target users. We will use the PPIP theories resulting from this knowledge synthesis as background evidence to inform an international consensus on best practices in PPIP. In line with our concern with contextual factors, we will not aim at developing a monolithic set of recommendations on 'what works' but rather provide decision-makers with a toolkit of key issues to consider when designing, implementing, and evaluating PPIP in specific contexts of CPG development.

The consensus process will involve: the production of a background evidence document and draft quality criteria based on the knowledge synthesis; recruitment of participant stakeholder groups (including patient/public representatives, CPG developers, health professionals, and government representatives); and refinement of the toolkit in a face-to-face workshop held at one of the stakeholders' conference meeting. Topics addressed in the workshop will include: reaction of participants to the findings from the knowledge synthesis, proposed changes to the toolkit, barriers and facilitators to implementing this toolkit in CPG development, and recommendations for future research. We will also collect information on the

demographic characteristics of the participants and additional information on their organizations.

Strategies to ensure methodological rigor

To minimize bias, a standard checklist of inclusion/exclusion criteria and a data extraction sheet will be piloted and refined by two team members. One reviewer will apply the inclusion/exclusion criteria to the result of the searches. Two reviewers will independently perform data extraction, classification, and analysis of the included studies and interviews. Any contentious results will be referred to the research team. With the aim of verifying credibility of the findings, a summary of the data extraction of the identified publication will be sent to the concerned authors (member checking)[66] who will be invited to make additional comments or corrections. A log book and audit trail will be kept and be made available for an external assessor. Findings and recommendations from the review will be validated through group debriefing within the research team and research advisory committee during the synthesis, and our consensus procedure with CPGs developers and patient/public organizations to develop final recommendations.

Ethical considerations

All documents collected for the knowledge synthesis will be obtained from publicly available sources. Participants in the individual interviews will be asked to complete a consent form presenting research objectives and information about research implications. Participants to the Delphi web-based exercise study will be informed that they consent to participate when creating their electronic account. Ethics approval for the project has been received from the Research Ethics Board of the Centre Hospitalier Universitaire de Québec (approved 18 December 2008; ethics number 5-08-12-07).

Discussion

The main decision-makers and stakeholders of this knowledge synthesis are patients, public, government, and health professional organizations in Canada and abroad that are interested in, or affected by, CPG development. Knowledge translation researchers will also be interested in our results given their potential to advance a new paradigm in knowledge science: one that acknowledges the contribution of patients and the public in the creation and application of knowledge. This knowledge synthesis will provide decision-makers with the essential knowledge that is needed

for elaborating effective PPIPs in CPG development and implementation, notably through the creation of an evidence-based toolkit. CPG developers will then better be able to understand the conditions where PPIPs are likely to be most effective and which resources need to be prioritized when designing such programs. Furthermore, insights into the inner mechanisms of involvement strategies will lay the foundation for a consensus on how to involve patients and the public within specific contexts of CPG development and implementation. Also, our research team will be in a unique position to perform a comparative analysis of patients and public involvement in a number of key areas of healthcare services and systems: electronic health records[55], health technology assessment[56], patients' decision aids[67], and CPGs, the focus of this knowledge synthesis. This proposal is directly linked with policymaking priorities at the Canadian Institute of Health Research (CIHR), the funding agency for this research initiative. Its Partnerships and Citizen Engagement Branch is committed to ensure the effective management of public engagement activities and foster research in knowledge management, values-based decision-making, and public engagement.[68] Production of the synthesis could lead to greater public legitimacy, acceptability, and effectiveness of CPG implementation.

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Chapter 7

Patient and public involvement in clinical practice guidelines: a knowledge synthesis of existing programs

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Abstract

Background: The role of patient and public involvement programs (PPIPs) in developing and implementing clinical practice guidelines (CPGs) has generated great interest.

Purpose: The authors sought to identify key components of PPIPs used in developing and implementing CPGs.

Data sources: The authors searched bibliographic databases and contacted relevant organizations.

Study selection: In total, 2161 articles and reports were retrieved on PPIPs in the development and implementation of CPGs. Of these, 71 qualified for inclusion in the review.

Data extraction: Reviewers independently extracted data on key components of PPIPs and barriers and facilitators to their operation.

Data synthesis: Over half of the studies were published after 2002, and more than half originated from the United States, the United Kingdom, Australia, and Germany. CPGs that involved patients and the public addressed a variety of health problems, especially mental health and cancer. The most frequently cited objective for using PPIPs in developing CPGs was to incorporate patients' values or perspectives in CPG recommendations. Patients and their families and caregivers were the parties most often involved. Methods used to recruit PPIP participants included soliciting through patient/public organizations, sending invitations, and receiving referrals and recruits from clinicians. Patients and the public most often participated by taking part in a CPG working group, workshop, meeting, seminar, literature review, or consultation such as a focus group, individual interview, or survey. Patients and the public principally helped formulate recommendations and revise drafts.

Limitations: The authors did not contact the authors of the studies.

Conclusion: This literature review provides an extensive knowledge base for making PPIPs more effective when developing and implementing CPGs. More research is needed to assess the impact of PPIPs and resources they require.

Introduction

Clinical practice guidelines (CPGs) are systematically developed statements designed to help practitioners and patients decide on health care for specific clinical circumstances.[1] The implementation of CPGs in clinical practice is expected to improve patient outcomes by promoting interventions of proven benefits and discouraging ineffective ones.[2] Also, CPGs accompanied by consumers' versions may empower patients to make more informed health care choices.[2] Productive interactions – such as shared decision-making – between active and informed patients and their health care providers have been shown to be a key component of good care.[3] Involving patients in decisions also produces a better decision-making process, more personal comfort with the decision,[4] a reduction in the overuse of options that are not beneficial for the vast majority, an increase in the options known to be beneficial,[5] and better patient quality of life.[6] Nonetheless, implementing CPGs has been a major challenge.[7] CPGs often fail to reconcile patients' preferences and social norms with best evidence[8,9] and do not always account for patients' increased demands to play a more active role in their own care.[10–12]

Based on a typology proposed by Rowe and Frewer,[13] patient and public involvement methods may include direct participation (e.g., patient representatives as members of the CPG development group), consultation (e.g., information is collected from patients and the public through surveys), or communication (e.g., information is communicated to patients/consumers and the public through plain-language versions of guidelines). This typology has been used successfully in the past by team members in related work.[14,15]

Involving patients and the public when developing and implementing CPGs is therefore attractive because of its potential to address the gaps between patient preferences and best evidence.[10,12,16] Yet there is little guidance as to the design of patient and public involvement programs (PPIPs) in the context of CPGs.[17] Consequently, we reviewed and synthesized the existing knowledge (published and unpublished) to identify and appraise the key components of PPIPs in the development and implementation of CPGs.[18]

Methods

Data sources

A detailed description of our search methods can be found elsewhere.[18] Briefly, with the help of an information specialist, we searched bibliographic databases and the reference lists of relevant articles for English and French documentation on PPIPs in

the development and implementation of CPGs published before January 2009. With help from the Guidelines International Network Public Working Group (G-I-N PUBLIC), we searched for gray literature by writing to the e-mail lists of relevant organizations and by contacting provincial and national institutions involved in the production and implementation of CPGs.

Selection criteria

To be included, the document had to 1) refer to the development or implementation of a CPG, 2) refer to patients (people with a personal experience of the disease, the health intervention, or the service discussed in the CPG, as well as their family members and caregivers) and/or members of the public (members of society interested in health care services, whose life could be directly or indirectly affected by the CPG), and 3) refer to a PPIP (at a minimum, refer to a formal method of involving patients and/or the public in the development or implementation of a CPG). Eligible documents included original qualitative, quantitative, or mixed-method studies and reports produced by academics or by national, governmental, for-profit, or nonprofit organizations.

Two research assistants screened all the documents thus retrieved to determine which were relevant. Any disagreements were resolved in discussions with the co–principal investigators (FL and AB).

Data extraction

The data from all relevant documents were independently extracted by pairs of research assistants who used a data extraction form employed in previous work in this field.[19–22] The data collected consisted of 1) characteristics of the documents, 2) key components of the PPIP (who was involved, how and for what purpose were they involved, and at what stage of the CPG's development and implementation were they involved), 3) involvement methods based on the typology proposed by Rowe and Frewer,[13] and 4) the context in which the PPIP was developed and tested –namely, perceived barriers and facilitators and the impact of the PPIP on involvement and other outcomes. Pairs of reviewers compared abstracted information. Any disagreements were resolved in research team meetings.

Data analysis

A research assistant entered the abstracted information into a data matrix to facilitate comparison of how PPIPs performed on each principal component. Template content

analysis was used to organize the principal components into a meaningful framework.[23] We computed the frequency of mention of each principal component extracted.

This study was funded by a knowledge synthesis grant from the Canadian Institutes of Health Research (CIHR). CIHR had no role in the study.

Results

Included documents

Of the 2104 articles identified in bibliographic databases, 38 were eligible for our review. In addition, we obtained 57 reports from relevant organizations: of these, we included 33 reports in our review. After reviewing the material, we concluded that 7 of the 38 studies were more akin to gray literature reports than to studies. Our review thus consisted of 71 documents[24–94]: 31 studies from peer-reviewed publications and 40 reports from the gray literature. Figure 1 shows the flow of the data synthesis.

Characteristics of the documents

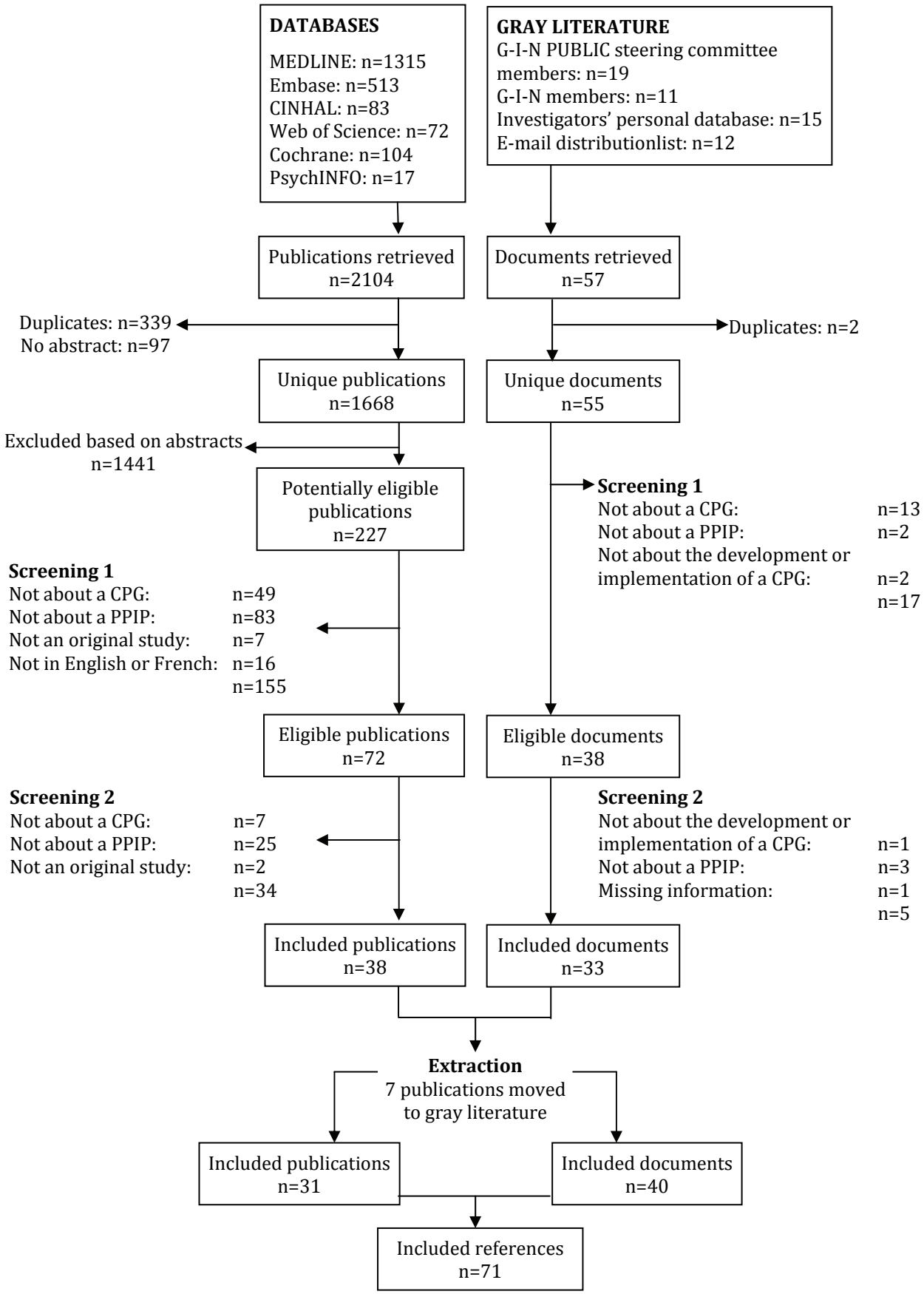
More than half (49/71)[24–72] were produced after 2002; the rest (22/71)[73–94] were produced before 2002. The appendix summarizes the characteristics of PPIPs in the context of clinical practice guidelines in all the papers included in our review. Most originated from the United States (22/71), the United Kingdom (15/71), Australia (8/71), and Germany (5/71). Most of the published studies were descriptive (21/31) and used qualitative methods (23/31) (Table 1).

CPGs that had involved a PPIP addressed a variety of health problems. Mental health (13/71) and cancer (9/71) were overly represented. The CPGs mainly targeted users: patients (13/71), physicians (13/71), other health professionals (11/71), and the public (8/71) (Table 1).

Patient and public involvement programs in CPGs

The patient and public involvement programs and interventions discussed in the documentation are described in the appendix. In general, the studies and reports provided a superficial description of the process of developing the CPG and the components of the PPIP involved. Only one study, from Australia, assessed the PPIP's impact on participants.[91] Reports from organizations made more detailed presentations of the components of the PPIP and the practicalities of involving patients and the public in CPG development and implementation activities.

Figure 1. Flow of data synthesis



The most frequently cited objective of using PPIPs to develop CPGs was to incorporate patients' values, preferences, knowledge, or perspectives in CPG recommendations (23/71) (Table 1). Other objectives were to improve the implementation of the CPG (7/71), increase the comprehensiveness of the CPG (7/71), promote patients' or the public's influence over the CPG development process (7/71), and adapt CPGs to the target population (5/71).

Table 1. Characteristics of studies

Characteristics	Subcategory	Number of studies	References
Country of origin	United States	22	24, 34, 42, 43, 45, 46, 57, 65, 67, 72–84
	United Kingdom	15	26, 27, 33, 36, 39, 51, 53, 54, 63, 66, 71, 85–88
	Australia	8	37, 40, 41, 59, 64, 89–91
	Germany	5	48, 50, 60–62
Design	Descriptive	21	26, 28, 35, 43, 47–49, 51, 52, 59, 65, 67, 71, 72, 74, 75, 80, 82, 83, 85, 90
	Qualitative methods	23	26, 28, 35, 38, 40, 41, 43, 47-49, 51, 52, 65, 67, 71–74, 78, 82, 83, 85, 91
Health problem	Mental health	13	27, 30, 40, 41, 44, 55, 59, 65–67, 72, 75, 81
	Cancer	9	31, 33, 43, 45, 48, 78, 87, 90, 92
Targeted users	Patients	13	25, 29, 31, 44, 48, 51, 57, 63, 74, 78, 79, 87, 91
	Physicians	13	28, 38, 43, 48, 57, 63, 72, 74, 78, 90–93
	Other health professionals	11	29, 31, 34, 44, 45, 57, 67, 78, 80, 81, 90
	The public	8	25, 40, 41, 47, 52, 73, 89, 92
Objective of using PPIPs	Incorporate patients' values, preferences, knowledge, or perspectives in CPG recommendations	23	24, 28, 31, 33, 36, 40–42, 44, 50, 53, 54, 57, 60, 63, 64, 67, 70, 80, 84, 86, 88, 90
	Improve implementation of the CPG	7	29, 42, 53, 58, 62, 68, 69
	Increase the comprehensiveness of the CPG	7	52, 61, 75, 79, 88, 89, 92
	Promote patients' or the public's influence over the CPG development process	7	25, 28, 46, 59, 85, 88, 91
	Adapt CPGs to the target population	5	35, 49, 73, 82, 83
Involved parties	Individual patients	45	27–36, 38–42, 44, 49, 51, 53–56, 58–60, 63, 65–70, 72–76, 79, 80, 83, 85, 86, 88, 90, 94
	Patient representatives (family, caregivers)	32	26, 28, 31, 33, 35–37, 39–44, 46, 53, 54, 56, 57, 62–66, 68, 69, 72, 73, 79, 86, 88, 91, 94
	Other (e.g., community leaders and individuals without health problems but who might use the CPG in future)	14	42, 47, 50, 52, 53, 63, 71, 73, 77, 81, 82, 84, 89, 92

Characteristics	Subcategory	Number of studies	References
Recruitment method	Recruiting through patient/public organizations	12	31, 33, 36, 40, 41, 44, 52–54, 63, 73, 86
	Sending invitations	8	36, 48, 53, 85, 87, 88, 90, 93
	Receiving referrals and/or recruits by clinicians	6	28, 35, 40, 41, 80, 91
Participation format	CPG working group	28	25, 26, 30–33, 36, 37, 42, 45, 46, 48, 50, 53, 54, 56, 57, 60, 63, 64, 68–70, 74, 78, 81, 88, 92
	Workshop, meeting, or seminar	10	26, 36, 42, 46, 51, 64, 74, 78, 85, 88
	Literature review	7	26, 38, 43, 45, 46, 48, 81
	Focus group	24	28, 30, 31, 33, 35, 36, 42, 44, 47, 50–52, 58, 64, 68, 72, 73, 75, 82, 83, 87, 89, 91, 92
	Individual interview	11	27, 28, 35, 39, 42, 44, 47, 49, 67, 84, 90
	Public poll or survey	9	36, 50, 55, 64, 66, 68, 71, 76, 80
Stage of involvement	Formulating recommendations	29	25, 28, 31, 33, 37, 38, 42, 43, 49, 51, 53, 54, 57-59, 60, 63–65, 67, 70–73, 80–83, 91
	Synthesizing the knowledge	25	26, 30, 31, 33, 35–38, 42–46, 48, 54, 57, 60, 62, 63, 65, 71, 74, 81, 87, 92
	Revising drafts	23	28, 33, 35, 36, 42, 44–46, 52–54, 57, 59, 60, 62, 70, 75, 77, 87–90, 93
Focus of decisions made	CPG development process	15	31, 33, 36, 37, 42, 44, 53, 58, 62–64, 70, 85, 88, 94
	Development of products for patients or the public	13	31, 33, 36, 37, 44, 45, 53, 60, 61, 63, 68, 79, 92
Material resources required	Written documentation	15	29, 31, 34, 36, 39, 43, 46–48, 50, 57, 63, 74, 80, 84
	Draft or existing CPGs	14	26, 35, 36, 43, 45, 46, 48, 52, 59, 74, 75, 88, 90, 93
	Questionnaires	12	35, 40, 41, 47, 48, 51, 73, 75, 80, 82, 83, 85
	Recording material	9	28, 31, 47, 49, 51, 52, 82, 88, 93
	Financial resources	4	63, 73, 88, 94
Human resources required	Facilitator or chairperson	6	33, 51, 67, 82, 85, 93
	Project coordinator	4	31, 33, 36, 63
	Translator	1	52
	Trained interviewer	1	47
	Trained moderator	1	47

Individual patients (45/71) and patient representatives (family, caregivers) (32/71) were the parties most frequently involved in PPIPs, followed by a more diverse group of individuals (e.g., community leaders and individuals without health problems but who might use the CPG in the future) (14/71). Methods used to recruit patients or the public in the CPG development process were rarely described, but recruiting through patient/public organizations (12/71), sending invitations (8/71), and receiving referrals and/or recruits by clinicians (6/71) were mentioned.

Most often, patients and the public helped develop CPGs by participating in a CPG working group (28/71); a workshop, meeting, or seminar (10/71); a literature review (7/71); or a consultation such as a focus group (24/71), an individual interview (11/71), or a public poll or survey (9/71). Accordingly, based on the typology proposed by Rowe and Frewer,13 the involvement method that was the most frequently identified by data extractors was participation (n=40).

Patients and the public were mainly involved at the stage of formulating recommendations (29/71), synthesizing the knowledge (25/71), and revising drafts (23/71). In some reports, patients and the public helped make strategic decisions about the CPG development process (e.g., the scope, what actors to involve) (15/40) or the development of products for patients or the public (e.g., information material, decision aids) (13/40).

The studies and reports indicated that PPIPs require the following material resources: written documentation (publications, reports, reminders, booklets, handbooks) (15/71), draft or existing CPGs (14/71), questionnaires (e.g., validated, self-administered questionnaires or interview guides) (12/71), recording material (tape recorders and video cameras) (9/71), and financial resources (4/71). The human resources required by PPIPs were a facilitator or chairperson (6/71), a project coordinator (4/71), a translator, a trained interviewer, and a trained moderator.

Lessons learned by CPG development organizations

Few documents reported detailed lessons learned by CPG development organizations that had employed a PPIP. Some organizations held a positive opinion of their experience with the PPIP, feeling that the PPIP had helped formulate extra key questions, had changed existing questions,[33] or had encouraged patients to join health care practitioners in making decisions.[50,61] For example, for one organization, patients' input helped ensure that the complex medical terminology used in the CPG would be widely understood. This was felt to be necessary for enhancing the community's understanding of current health and disability issues and increasing community access to the most appropriate health services.[94]

Another organization reported extensively on its experience with the PPIP.[88] This organization felt that patients experienced difficulty with the technical language and contributed infrequently to the discussion. The organization therefore developed a series of workshops in which it explained the technical elements of CPG development to patients, who then made relevant suggestions. However, this process was resource intensive. This organization also felt that involving an "expert" patient was helpful but

acknowledged that this "expert patient may not be representative." The organization concluded that a range of methods for involving patients and the public was ideal[88] and suggested that involving consumers both in CPG development groups and in other structures, such as focus groups or surveys that informed the CPG development groups, should be considered. Two organizations opined that it was necessary to involve patients or the public at every stage of the CPG development process and at individuals' desired level of involvement.[69,88] Other organizations suggested that it was better to involve patients before the process officially began.[58,68,70] The organizations also pointed out that participation in a CPG development group requires abilities or skills necessary for effective group processes, such as communication skills,[33,44,53,63] teamwork skills,[36,53,63] and the ability to represent the views of a wider group.[33,53,63]

Feedback by PPIP participants

One organization reported that patients felt that they had little or no influence on finance, group composition, literature searches, and the measurement of the effects of the CPG.[58] However, patients considered they had some influence on defining key questions for the CPG, writing questions used to search the literature, selecting and reviewing the literature, writing text, implementing the CPG, and developing information for patients. Patients believed their greatest influence was defining key problems for CPGs to address, writing recommendations, and reviewing draft guidelines.[58] This feedback is congruent with what other organizations have reported: the impact of patients' involvement is felt to be small (e.g., patients help choose the words used to formulate recommendations), and their influence on debates is rarely measured.[31] Some experts expressed reserve toward PPIPs because of what they felt was patients' inability to act on highly technical documents.[31]

Few organizations formally assessed patients' and the public's satisfaction following their participation in a CPG development process. Overall, and despite the variability of the experiences reported, the respondents were generally satisfied with having been part of a CPG development group. For example, 72% of participants in CPG development groups led by the National Institute for Health and Clinical Excellence (NICE) rated their overall experiences as excellent or very good. These participants were generally positive about the methodology adopted and the final CPG. Lay members were enthusiastic about the version for patients and caregivers and its intended use, and they valued the personal development opportunities that involvement in the guideline development group had afforded them.[66] In a study by

Wilson and others,[91] 90% of parents felt that participating in a CPG development group was an informative process, and nearly 67% said that they gained valuable knowledge and felt more confident in caring for their sick children.

The New Zealand Guidelines Group (NZGG) conducted an evaluation survey of consumers involved in the development of their CPGs.[55] Although respondents were generally satisfied with the final guideline, some had experienced resistance to their input and had felt isolated, whereas others had felt accepted and valued. Interestingly, 11 of 12 respondents said that they would be willing to participate in a CPG development group again.[55] In contrast, some participants mentioned that they were often concerned that the hard work that had gone into developing the recommendations had not translated into actual changes in practice.[66] Some parents involved in focus groups in the Wilson study mentioned that more information at the outset would have been useful and felt that the discussions had been one-sided.91 Other patients reported having had great difficulty in understanding the complexity and technicality of the subject and having felt maladjusted to the procedure. These feelings were compensated by a strong sense of belonging to the working group.[31]

Barriers and facilitators to PPIPs

Table 2 details barriers and Table 3 describes facilitators to PPIPs in the development of CPGs, based on excerpts from the publications included in our review.

Table 2. Barriers to patient and public involvement programs

Barriers (total frequency)	Organizations' reports (n)	Empirical studies (n)	Excerpts
Discrepancies between experts' and patients'/the public's perspectives (n=7)	References: 31, 58, 60, 68, 69, 94 (n=6)	Reference: 41 (n=1)	Main topics from patients' point of view differed from topics in the guideline[69] There may not be shared agreement about the most important issues[94] Experience v. evidence[58] Difficulty of integrating patients' views into professionals' recommendations[69] An evidence-based atmosphere[68] Difficult for the patient to judge whether his or her comment regarding "evidence-based" information was relevant[31] Apparent marginalization of the evidence from patients' and caregivers' experiences (insufficient worth afforded to published qualitative studies)[66] Patients and health professionals can weigh health care issues differently[60]
Recruitment difficulties (n=7)	References: 30, 31, 42, 50, 69, 70 (n=6)	Reference: 40 (n=1)	Hard to find/recruit patients capable of and interested in participating[69] Difficulty of identifying patients and caregivers

Barriers (total frequency)	Organizations' reports (n)	Empirical studies (n)	Excerpts
			who are willing and able to contribute directly to guideline development[42]
			Lack of a suitable consumer group[70]
			Caregivers were difficult to recruit for this study and, after the first round of the questionnaire, only one remained involved[40]
Representativity of patients/the public (n=6)	References: 55, 68		*"As one person with a large group of medical people ... I felt the weight of being the only person specifically representing consumers"*[55]
	31, 42, 58, 69 (n=6)		A small number of patients does not guarantee representativity in terms of sex, ages, social background, stage of disease, etc.[31]
			Patient advocates may be perceived as particularly unrepresentative[42]
			Variability of patients' values and preferences at different stages of the disease, at different levels of the disease's severity, and with respect to different issues. Values and preferences may also differ by age, sex, socioeconomic status, ethnicity, and culture. This poses a challenge to integrating consumers' values into guideline recommendations.[42]
Lack of familiarity with complex scientific and medical language (patients/the public found the material difficult to understand) (n=5)	References: 30, 31, 70, 94 (n=4)	Reference: 88 (n=1)	Technicality and complexity of the subject does not encourage patients' participation[31]
			It was not possible to meaningfully discuss any of the scientific content of the guideline[88]
Significant work commitment (n=3)	References: 31, 36, 55 (n=3)		Very hard work and exhausting[55]
			Duration of project[31]
Time constraints (n=3)	References: 55, 68, 70 (n=3)		Training is not practical for consumers with other employment responsibilities – they would have to take time off work without pay[55]
			No time[68]
Professionals' resistance to patients' participation (n=2)	References: 42, 60 (n=2)		Professionals' resistance to patient membership[42]
Feeling isolated (n=2)	References: 50, 55 (n=2)		Consumers can feel isolated and uneasy at guideline meetings[50]
Financial issues (n=1)	Reference: 68 (n=1)		No money[68]
Resource intensive (n=1)	Reference: 42 (n=1)		Patient involvement can be resource intensive[42]
Feeling little affected by the problem (n=1)	Reference: 31 (n=1)		Feeling little affected by the problem[31]
Patients' contributions are sometimes limited (n=1)	Reference: 42 (n=1)		Patients' contributions are sometimes limited[42]
Patients underestimate their capabilities (n=1)	Reference: 30 (n=1)		Patients underestimate their capabilities[30]
Large documents sent by e-mail not practical for consumers (too expensive to print at home) (n=1)	Reference: 55 (n=1)		Sending large documents by e-mail as an alternative to face-to-face meetings makes it difficult to negotiate and reach consensus[55]

The two most frequently reported facilitators were training (14/71) and support (12/71). For example, some organizations offered training days and seminars to assist PPIP participants with technical matters and critical appraisal skills. Support took the form of telephone and e-mail assistance, mentoring, a supportive chair of the guideline development group, an analysis grid for knowledge synthesis, or a "welcome pack" for selected patients. Providing assistance with complex scientific and technical issues was another valuable way to optimize the participation of patients and public, as was offering participants opportunities to interact with other patients who had participated in the development of CPGs. Other facilitators included clear expectations about the process (e.g., who was involved and what role they were expected to fill, disclosure of the funds available, and specification of the time commitment expected) (9/71) and involving a group of patients rather than a single patient (8/71).

Table 3. Facilitators to patient and public involvement programs

Facilitators (total frequency)	Organizations' reports (n)	Empirical studies (n)	Excerpts
Training (n=14)	References: 31, 33, 36, 39, 42, 53–56, 63, 66, 68–70 (n=14)		Training in technical aspects of the guidelines[55] Training day[53 33] Training seminars[33] Critical appraisal training and seminars[36,63] SIGN ensure opportunities to attend training events[36]
Support (n=12)	References: 30, 31, 33, 36, 39, 42, 53, 56, 63, 66, 68 (n=11)	Reference: 88 (n=1)	Telephone support[31] Telephone and e-mail support[33,36]
Supporting staff (mainly chair of the guideline development group) (n=8)	References: 36, 50, 53, 56, 58, 66, 68, 69 (n=8)		Select a supportive chair to lead the guideline group[58] Availability of a mentor/coach[58, 69] Chair of each guideline development group is asked to support patient representatives by ensuring they are fully engaged with the group, addressing the group if their contributions are not acknowledged appropriately, and welcoming and encouraging their contributions[36] Mentoring[56] Need to take special care to ensure that consumers have a voice at meetings and to feed back to constituencies[50]
Help with complex scientific and technical issues (to increase participants' understanding) (n=5)	References: 39, 55, 56, 68, 94 (n=5)		Provide extra assistance, explanations, and background information, particularly if the matter under consideration is technical[94] More time on practical statistics would have been helpful[55] Explain evidence-based process[68]

Facilitators (total frequency)	Organizations' reports (n)	Empirical studies (n)	Excerpts
			Develop competencies in the design and development of information for consumers, including the use of plain language for all consumer-oriented documents and, where possible, the use of formats that are accessible to the visually impaired[56]
Supporting documents/ material (n=5)	References: 31, 53, 56, 58, 69 (n=5)		Clear analysis grid for knowledge synthesis[31] NICE's "welcome pack" for selected patients[53] Templates and processes for the preparation of evidence-based consumer information[56]
Contact and interactions with other consumers (n=3)	References: 31, 55, 63 (n=3)		They can explain and listen[31] They can offer one-off or ongoing support[63]
Support from organizations (n=1)	Reference: 56 (n=1)		Work collaboratively with other organizations to develop strong partnerships with government and nongovernment organizations, and agencies supportive of initiatives to strengthen consumers' voice[56]
Clear expectations (details about the process, who is involved, roles, etc.) (n=9)	References: 36, 39, 53–55, 58, 94 68, 69 (n=9)		Disclose the funds available for the service or matter under discussion[94] Information about the time frame and expected time commitment[55] Why the patient is invited, who he or she represents, what is expected – tasks and level of participation – whether time and costs are reimbursed[69] Ensure that everyone recruited to the guideline development group is fully aware of the scope of the guideline and agrees to work within it[39] Well-defined goal[68] A member of the patient and public involvement program contacts patients and caregivers to give them background information about what they might expect at the first meeting[53] The NICE PPIP gives a short presentation to all members, at the first meeting, on the role of patient and caregiver members[54] SIGN provides clear guidance on patients' roles and responsibilities within the group[36]
More than one patient (n=8)	References: 44, 50, 54-56, 58, 68, 70 (n=8)		Need to involve more than one consumer[50] Recruitment of a minimum of 2 representatives, following a transparent selection process and a well-established protocol[44]
Representation of different patients' perspectives (n=3)	References: 50, 58, 68 (n=3)		Participants should be as representative as possible of the whole population[68]
Gender representation and balance (n=1)	Reference: 70 (n=1)		Gender representation and balance should be considered in selecting group members[70]
Development group committed to and in favor of patient involvement (n=4)	References: 55, 66, 68, 69 (n=4)		Sensitivity of other group members to consumers' nonprofessional status (recognition that consumers should feel that they are listened to and that their opinions are valued)[55]

Facilitators (total frequency)	Organizations' reports (n)	Empirical studies (n)	Excerpts
			A belief, especially on the part of the chair and opinion leaders, that it works[68]
			Members of the guideline development group – mainly medical doctors – put the professionals and the laypeople on an equal footing[66]
			The health professionals in the group seemed open to the view that consumers can contribute a valid and valuable perspective[55]
Good preparation (n=4)	References: 31, 42, 44, 68 (n=4)		Working group meetings preceded by preparatory meetings and training[31]
Reimbursement/sufficient financial assistance (n=4)	References: 55, 63, 68, 94 (n=4)		Ensure there is sufficient funding to pay consumers and to cover additional expenses, such as child care and transportation[94]
			Cover certain expenses (transportation, child care, loss of earnings)[63]
Keeping patients/the public informed and maintaining dialogue (n=3)	References: 55, 68, 94 (n=3)		E-mail is a good way to keep in touch and keep up-to-date on progress[55]
			Organization gives feedback and information and acknowledges results[55]
Involving patients from the start (n=3)	References: 58, 68, 70 (n=3)		Participation from (before) the start[58, 68]
			Consumer involvement should be considered and encouraged from the start70
Past experiences (n=1)	Reference: 55 (n=1)		Past experience with other groups helps[55]
Smaller subgroups (n=1)	Reference: 55 (n=1)		Smaller subgroups definitely helped progress[55]
Sense of belonging (n=1)	Reference: 31 (n=1)		Sense of belonging[31]
Actively involving patients at every stage of the process and at patients' desired level of involvement (n=1)	Reference: 69 (n=1)		Actively involving patients at every stage of the process and at patients' desired level of involvement[69]
Combining methods of involving patients (n=1)	Reference: 69 (n=1)		Combining methods of involving patients[69]
Atmosphere of mutual respect and positive working relationships with other members of the group (n=1)	Reference:66 (n=1)		Leads to constructive debate and agreement[66]

NICE, National Institute for Health and Clinical Excellence; SIGN, Scottish Intercollegiate Guidelines Network

Discussion

We identified 71 documents that reported on PPIPs in the context of the development and implementation of CPGs. Only a few of these documents contained substantial information about the key components of PPIP and the resources needed, including financial resources. Very few documents provided information on the impact of PPIPs on the development and implementation of CPGs in clinical practice, and none discussed health outcomes. Although reports were more likely than studies to

provide information on participants' perceptions of their experience, very little quantitative impact assessment took place. Nonetheless, this knowledge synthesis is among the first to provide decision-makers with several elements of practical guidance.

First, there is a perception that it is difficult to reconcile the preferences of patients and the public with the views of experts (health professionals). Also, patients find it difficult to affirm their views and experiences in the presence of evidence-based information and complex scientific and medical terminology.[31,58,68] Several CPG organizations have developed structured training and support to address these issues. Therefore, it is possible to adapt PPIPs so as to deepen patients' and the public's understanding of and confidence in scientific information.

Second, many fear that patients or members of the public who participate in a PPIP may not be representative.[31] The World Health Organization has reviewed NICE's experience of involving patients and the public in CPGs and concluded that it is uncertain whether the right stakeholders were involved and whether their input was as efficient as it could have been. However, prevalent participation methods (such as involving patients in CPG development groups) dictate small numbers of participants,[95] and it may be inappropriate to expect 1 or 2 patients to represent the views of large segments of the population. Other authors have challenged PPIP sponsors to clarify their understanding of representativeness and adapt their involvement methods and recruitment strategies accordingly.[96] Some organizations have responded by using structured open recruitment strategies and by complementing their participation methods with larger consultations such as surveys and online comment options.[54]

Third, and related to the above, better evaluations of the methods used to involve patients and members of the public are essential. A Cochrane systematic review on methods of involving consumers in developing health care policy and research, CPGs, and patient information material found 6 eligible trials.[17] None focused on CPGs.

Fourth, training and supporting patients and members of the public who are participating in a PPIP should focus not only on critical appraisal skills but also on the skills needed to participate in a group process. Attention should also be paid to the role that chairs and other guideline developers can play in supporting PPIP participants.

Fifth, our review shows that among guideline developers, there seems to be a clear distinction between technical, knowledge-based aspects of guideline development (in which patients are assumed not to be competent) and value/preferences issues in

which patients and the public would be experts.[97] This may explain why patients are less often involved in literature reviews and other "technical" aspects of guideline development. However, this strict distinction between knowledge and values has been criticized.[98,99] This "demarcationist view" assumes that clinicians, managers, and methodologists only bring "hard evidence" and do not make value judgments and that patients, on the contrary, only make claims that are based on "soft" preferences. However, this distinction does not always hold in actual CPG development activities.[100]

Notwithstanding its interesting results, this knowledge synthesis has limitations. First, the significant proportion of gray literature in our source material (33/71) is evidence of the extensiveness of our search for eligible documents. However, we cannot exclude that we may have overlooked important documents. Second, we did not contact the authors of the studies or reports for elaboration on their findings. More research is needed to identify the key components of successful PPIPs and the resources they need and to assess their impact on the quality of care.

Nonetheless, our knowledge syntheses provide an extensive knowledge base for elaborating effective PPIPs in the context of developing and implementing CPGs in the future. This could also help standardize PPIP reporting. The review provides 3 main lessons. First, there are many ways to involve patients in developing CPGs and patient information material. Second, patients' involvement tends to produce material that is more relevant, readable, understandable, and less likely to make the reader anxious. However, future research will need to assess the impact of PPIPs in the context of CPGs on the quality of care and health outcomes.

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Appendix. Characteristics of included patient and public involvement programs (PPIPs) in the context of clinical practice guidelines

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
McConnell, 1994	Report by organization	US Department of Health and Human Services	Benign prostatic hyperplasia (BPH)	To evaluate the preferences of actual patients in regard to the simplified version of the CPG	Consultation/ public polls or surveys	Individual patients	Unclear
Duff, 1996	Published study; descriptive study; qualitative	Royal College of Nursing	Not mentioned	To promote patient/ public influence over the process	Participation/ seminar	Individual patients	Strategic decisions
Rischer, 1996	Published study; intervention study (before/ after); qualitative	HealthInsight, Utah, Nevada	Cancer	Not mentioned	Participation/ member of the CPG working group; meetings	Representatives of patients' group(s)	Dissemination/ implementation
Schofield, 1996	Published study; descriptive study; mixed	Cancer Education Research Program, University of Newcastle	Cancer	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation/ individual interviews	Individual patients	Review of draft
Collège des Médecins du Québec, 1998	Report by organization	Collège des Médecins du Québec	Prostate cancer	To validate the clarity and acceptability of an information leaflet designed for the public	Consultation and participation/ focus groups; member of the CPG working group	Individual citizens	Knowledge synthesis, evaluation of specific products for patients/ public
Friedman, 1998	Published study; descriptive study; qualitative	Lovelace Health System	Diabetes	Not mentioned	Communication and participation/ patient information material; member	Individual patients	Knowledge synthesis, dissemination/ implementation
Schulberg, 1998	Published study; review of literature; mixed	The Agency for Health Care Policy and Research (AHCPR)	Depression	Not mentioned	Participation/ member of the CPG working group; literature review	Individual citizens; representatives of citizens' group(s)	Knowledge synthesis, formulation of recommendations

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Steward, 1998	Report by organization	Clinical Decision Making Group, Massachusetts Institute of Technology	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation/ individual interviews	Individual citizens	Unclear
Rymer, 1999	Report by organization	Saint Luke's Hospital Stroke Center, Kansas City, Missouri	Stroke	To increase the general population's understanding of the CPG	Communication/ patient version of guideline	Individual patients and patients' representatives	Development of patient products
Lanza, 2000	Published study; descriptive study; mixed	Nurse Manager Veterans Center for Addiction Treatment; Edith Nourse Rogers Memorial Veterans Hospital, Bedford, Massachusetts	Assaultive behavior	To increase the general population's understanding of the CPG	Consultation/ focus groups; written consultations	Individual patients	Review of draft
Shoultz, 2000	Published study; descriptive study; qualitative	Frances A. Matsuda Foundation; Hawaii Community Liaisons Nurse's Association; Sigma Theta Tau	Alcohol, smoking, and drug use	To adapt CPGs to the population's characteristics	Consultation/ focus groups	Individual patients	Formulation of recommendations
van Wersch, 2001	Report by organization	North of England Evidence Based Guideline Development Programme	Asthma, angina, myocardial infarction	To promote patients'/ the public's influence over the process; to incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations; to increase the general population's understanding of the CPG	Participation/ meetings; workshops; member of the CPG working group	Individual patients; patients' representatives	Strategic decisions, review of draft

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Wilson, 2000	Published study; randomized controlled trial; qualitative	Information not available	Acute respiratory infection	To promote patient/ public influence over the process	Consultation/ focus groups	Patients' representatives	Formulation of recommendations
Women's Health Action, 2000	Report by organization	Women's Health Action	Not mentioned	To ensure that the rights of consumers are upheld and consumers' input is valued	Unclear	Individual patients, patients' representatives, representatives of citizens' groups	Strategic decisions
Egger, 2001	Report by organization	Department of Health and Aged Care	Excessive weight and obesity	To increase the general population's understanding of the CPG	Consultation/ focus groups	Individual citizens	Review of draft
Southern African Hypertension Society, 2001	Report by organization	Southern African Hypertension Society	Hypertension	Not mentioned	Participation/ consensus meeting	Representatives of citizens' group	Review of draft
Braun, 2002	Published study; intervention study (before/after); qualitative	The Pacific Diabetes Today Resources Center (PDTRC)	Diabetes	To adapt the CPG to the population's characteristics	Consultation and participation/ training of community members to lead discussion groups; focus groups	Individual citizens and representatives of citizens' groups; individual patients and patients' representatives	Formulation of recommendations
Kelson, 2002	Report by organization	National Guidelines and Audit Patient Involvement Unit in collaboration with National Institute for Clinical Excellence	Not mentioned	To develop fair, transparent, and defensible methods for patient/caregiver involvement; to ensure that patient issues and	Unclear	Individual patients and patients' representatives	Unclear

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
		(NICE)		perspectives are directly addressed and presented in ways that are meaningful and acceptable to patients			
National Kidney Foundation, 2002	Report by organization	National Kidney Foundation	Chronic kidney disease	To review National Kidney Foundation clinical practice guidelines	Unclear	Individual, citizens	Review of draft
Pell, 2002	Published study; intervention study (before/ after); mixed	Information not available	Prophylactic oophorectomy	To use patient-specific information on risks and preferences to provide guidance	Consultation/focus groups	Representatives of citizens' group	Formulation of recommendations, review of draft
Scherer, 2002	Published study; descriptive study; mixed	The Institute for Matching Person & Technology, Inc.	Rehabilitation	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation and participation/ survey; nominal group technique	Individual patients	Formulation of recommendations
Shoultz, 2002	Published study; descriptive study; qualitative	University of Hawaii School of Nursing and Dental Hygiene, Kauai Community College	Violence against women	To adapt CPG to the population's characteristics	Consultation/focus groups	Individual citizens	Formulation of recommendations
Behets, 2003	Published study; intervention study (before/after); mixed	The nongovern-mental "67 Ha Clinic" in Antananarivo; the public dispensary in Tamatave	Sexually transmitted infections	To promote patients'/ the public's influence over the process	Participation/CPG working group	Representatives of citizens' group (sex workers)	Determining what intervention options, recommendations, and information to include in the CPG

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Bond, 2003	Published study; descriptive study; qualitative	Grampian Evidence Based Community Pharmacy Guidelines Group	Vulvovaginal candidiasis	Not mentioned	Participation/ meetings; literature review; nominal group technique; member of the CPG working group	Patients' representatives	Knowledge synthesis, development of a draft, revision of the final CPG
World Health Organization; Global Programme on Evidence for Health Policy, 2003	Report by organization	World Health Organization	Not mentioned	Not mentioned	Participation/ member of the CPG working group	Individual patients	Unclear
Hadjistavropoulos, 2003	Published study; descriptive study; qualitative	Regina Qu'Appelle Health Region	Community case management for elderly clients	To adapt the CPG to the population's characteristics	Consultation/ individual interviews; focus groups	Individual patients; patients' representatives	Evaluation of case management time, review of draft
NZGG, 2003	Report by organization	New Zealand Guidelines Group, Inc. (NZGG)	Atrial fibrillation, elders' health, women's health (caesarean), mental health (depression, suicide prevention), hormone replacement therapy, diabetes	To better advocate for an approach to participation that meets consumers' needs and expectations	Consultation/ public polls and surveys	Individual patients	Evaluation survey of consumers involved in CPGs
Pijnenborg, 2003	Report by organization	Dutch College of General Practitioners; Dutch Institute for Healthcare Improvement	Low back pain, eczema, rheumatoid arthritis, psoriasis	To improve CPG implementation and quality	Consultation/ focus groups	Individual patients	Strategic decisions, formulation of recommendations

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines Team for Panic Disorder and Agoraphobia, 2003	Published study; descriptive study; mixed	The Royal Australian and New Zealand College of Psychiatrists	Panic disorder, agoraphobia	To promote patients'/ the public's influence over the process	Consultation/Not mentioned	Individual patients	Review of draft, formulation of recommendations
Guihan, 2004	Report by organization	The Veterans Health Administration, Department of Veterans Affairs	Spinal cord injury	To foster patients' adherence to recommendations	Communication/Patient information, material	Individual patients	Dissemination/ implementation
Jarett, 2004	Report by organization	National Institute for Health and Clinical Excellence (NICE)	Not mentioned	To explore the experiences of patients/caregivers involved in CPG development groups; to identify good practices, highlight problems, and improve the process for future groups	Consultation and participation/individual interviews; member of the CPG development group	Individual patients and patients' representatives	Unclear
Landier, 2004	Report by organization	Children's Oncology Group (National Cancer Institute)	Children's cancer aftermath	Not mentioned	Participation/ member of the CPG working group; literature review	Representatives of patients' group(s)	Knowledge synthesis, development of a draft, review of draft; development of patient products

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Luboldt, 2004	Published study; descriptive study; qualitative	The German Urology Association, European Randomised Screening for Prostate Cancer (ERSPC), German Association of the Scientific Medical Societies or AWMF	Prostate cancer	Not mentioned	Participation/ member of the CPG working group; literature review; nominal group technique	Representatives of patients' group(s)	Literature review, final revision
Phelan, 2004	Report by organization	Cincinnati Children's Hospital Medical Center	Children's health	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ member of the CPG working group	Patient representatives (parents of affected children)	Knowledge synthesis, formulation of recommendations, review of draft
van Vuuren, 2004	Report by organization	Dutch Institute for Healthcare Improvement	Not mentioned	To improve CPG implementation	Participation/ member of the CPG working group	Individual patients, patients' representatives	Unclear
Marshall, 2005	Report by organization	German Agency for Quality in Medicine and New Zealand Guideline Group (NZGG)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/member of the stakeholders' groups; member of the CPG working group; focus groups; public polls or surveys	Stakeholders, Individual citizens	Unclear
Sänger, 2005	Report by organization	German Agency for Quality in Medicine	Not mentioned	To better adapt CPGs to patients' needs; to address patients' most important problems; to encourage patient autonomy; to foster acceptance of patients' version of CPGs; to	Unclear	Representatives of patients and representatives of patients' groups (6 patient representatives are involved in each CPG	Strategic decisions, Knowledge synthesis, development of a draft, review of the draft, final revision

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
				improve implementation by supporting the implementation process		process	
Suppes, 2005	Published study; descriptive study; qualitative	The Texas Department of State Health Services (TDSHS), formerly the Texas Department of Mental Health and Mental Retardation	Bipolar 1 disorder	To review the newest available evidence to guide the selection of treatments, maintenance treatment, and issues regarding safety and adverse effects in the treatment of bipolar disorder	Participation/ consensus conference	Individual patients and patients' representatives	Knowledge synthesis, formulation of recommendations
van Veenendaal, 2005	Report by organization	Dutch Institute for Healthcare Improvement	Not mentioned	To improve CPGs and their implementation	Consultation and participation/ focus groups; public polls or surveys; member of the CPG working group	Individual patient, patients' representatives	Development of products for patients/the public and dissemination/ implementation
de Joncheere, 2006	Report by organization	National Institute for Health and Clinical Excellence (NICE)	Nutrition, tuberculosis, anxiety, obsessive-compulsive disorder, contraception, pressure ulcers	Not mentioned	Consultation/ Individual interviews	Individual patients, representatives of patients' group (stakeholders' representatives)	Unclear
Deschepper, 2006	Published study; descriptive study; qualitative	Information not available	End-of-life (heterogeneity regarding disease)	To promote patients'/ the public's influence over the process; to incorporate patients' values/preferences, knowledge, and perspectives in CPG recommendations	Consultation/ focus groups; quality circle (consecutive discussion sessions) with various caregivers; individual interviews	Individual patients and patients' representatives	Review of draft, formulation of recommendations

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Dijkstra, 2006	Published study; Randomized controlled trial; quantitative	Centre for Quality of Care Research	Type 2 diabetes	To improve implementation of CPG	Communication/ Patient information material; educational meetings	Individual patients	Development of products for patients; dissemination/ implementation
Landsman, 2006	Report by organization	New York State Department of Health	Cerebral palsy and motor delay	To promote patients'/ the public's influence over the process	Participation/ member of the CPG working group; meetings; literature review	Patients' representatives	Knowledge synthesis, development of a draft, review of a draft
Maputle, 2006	Published study; descriptive study; qualitative	University of Limpopo; Level III hospital in Limpopo Province	Childbirth	To adapt CPG to the population's characteristics	Consultation/ participant observation; individual interviews; unstructured conversations	Individual patients	Formulation of recommendations
Murie, 2006	Published study; descriptive study; qualitative	Royal College of General Practitioners	Coronary heart disease	To promote informed, value-based health care decisions by individual patients; to foster patients' adherence to recommendations	Consultation and participation/ workshops; focus groups	Individual patients	Formulation of recommendations; development of patient products
NICE, 2006	Report by organization	National Institute for Health and Clinical Excellence (NICE)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations; to improve implementation	Communication, consultation, and participation; patient version of CPG; written consultation; member of the CPG working group	Individual patients, patients' representatives, individual citizens	Strategic decisions, formulation of recommendations review of draft, and development of products for patients/the public; dissemination/ implementation

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Tunner, 2006	Published study; descriptive study; qualitative	Two large mental health agencies in Philadelphia, Pennsylvania	Schizophrenia	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation/ individual interviews	Individual patients	Formulation of recommendations
Baunmann, 2007	Report by organization	American College of Chest Physicians (ACCP)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Unclear	Unclear	Unclear
Fervers, 2007	Report by organization	Fédération Nationale des Centres de lutte contre le cancer	Cancer	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation and participation/ focus groups; member of the CPG working group	Individual patients, patients' representatives, representatives of patients' group	Strategic decisions, knowledge synthesis, formulation of recommendations development of a draft, final revision, development of products for patients/the public; dissemination/ implementation
Hoes, 2007	Published study; review of literature; qualitative	European League Against Rheumatism (EULAR)	Rheumatic diseases	Not mentioned	Participation/ Delphi process; literature review; generate and validate recommendations	Individual patients	Knowledge synthesis, formulation of recommendations

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Kelson, 2007	Report by organization	American Thoracic Society and European Respiratory Society	Chronic obstructive pulmonary disease	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations; to improve implementation	Consultation and participation/ workshops; focus groups; interviews; consultation on guideline products; member of the CPG working group, separate consumer panels	Individual patients, patients' representatives, representatives of patients' group, individual citizens, community organizations	Strategic decisions, knowledge synthesis, formulation of recommendations review of draft
NICE, 2007	Report by organization	National Institute for Health and Clinical Excellence (NICE)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ member of the CPG working group	Individual patients, patients' representatives	Knowledge synthesis, formulation of recommendations review of draft
Yardley, 2007	Published study; descriptive study; qualitative	ProFaNE Thematic Network	Falls	To foster patients' adherence with recommendations	Consultation/ surveys of older people's views on falls prevention	Individual citizens	Formulate evidence-based recommendations
Zuckerbrot, 2007	Published study; descriptive study; qualitative	Center for the Advancement of Children's Mental Health at Columbia University	Adolescent depression	To understand the problems and obstacles faced by primary care clinicians regarding the management of adolescent depression	Consultation/ focus groups	Individual patients, patients' representatives	Formulation of recommendations
Domus Medica, 2008	Report by organization	Domus Medica	Chronic illnesses, diabetes, depression	Not mentioned	Consultation and participation/ focus group; member of the CPG working group and consensus conference	Individual patients, representatives of patients' group	Knowledge synthesis

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Harbour, 2008	Report by organization	Scottish Intercollegiate Guidelines Network (SIGN)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation and participation/ written consultation; public meetings; public polls or surveys; focus groups; member of the CPG working group	Individual patients, patients' representatives, representatives of citizens' group	Strategic decisions, knowledge synthesis, development of a draft, review of the draft, development of products for patients/the public; dissemination/ implementation
Harris, 2008	Report by organization	Health for Kids in the South East (HFK)	Children's health (asthma, croup, gastroenteritis, bronchiolitis, diarrhea)	Not mentioned	Participation/ member of the CPG working group	Patients' representatives	Strategic decisions, knowledge synthesis, formulation of recommendations development of products for patients/the public
Kelly, 2008(a)	Published study; Delphi study; qualitative	ORYGEN Research Centre	Deliberate nonsuicidal self-injury	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ Delphi process	Individual patients, patients' representatives	Development of a draft
Kelly, 2008(b)	Published study; Delphi study; qualitative	ORYGEN Research Centre	Suicidal behavior	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ Delphi process	Individual patients, patients' representatives	Development of a draft

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Konety, 2008	Published study; descriptive study; qualitative	Iowa Prostate Cancer Consensus Project	Prostate cancer	Not mentioned	Participation/ attending a 1-day conference; evaluating the available literature	Patients' representatives	Knowledge synthesis, formulation of CPGs
Kotzeva, 2008	Report by organization	Catalan Agency for Health Technology Assessment and Research (CAHTA)	Stroke prevention and treatment of obesity in children and adolescents, tuberculosis, safety of the surgical patient, dementias, eating disorders, schizophrenia, osteoporosis, bronchiolitis of the nursing infant, hyperactivity and attention deficit syndrome, pathological gambling, behavioral addictions, borderline personality disorders	Incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation/ focus groups; individual interviews	Individual patients, patients' representatives, representatives of citizens' group	Strategic decisions, Knowledge synthesis, development of a draft, draft review, development of products for patients/the public, dissemination/ implementation

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Love, 2008	Published study; descriptive study; qualitative	South Africa food-Nutrition based dietary guidelines work group	Nutrition	To foster patients' adherence to recommendations	Consultation/ focus groups; individual interviews	Individual citizens	Dissemination/ implementation
Murray, 2008	Published study; descriptive study; qualitative	South Africa food-Nutrition based dietary guidelines work group	Pediatric diet	To increase the general public's understanding of CPGs	Consultation/ focus groups	Mothers with infants younger than 6 months	Review of draft
SIGN, 2008	Report by organization	Scottish Intercollegiate Guidelines Network (SIGN)	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ member of the CPG working group	Individual patients, representatives of patients, individual citizens	Strategic decisions, knowledge synthesis, formulation of recommendations, development of a draft, final revision, development of products for patients/the public, dissemination/ implementation
Southern Health, 2008	Report by organization	Southern Health	Children's health	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation and participation/ public meetings; public polls or surveys; focus groups; member of the CPG working group	Patients' representatives	Strategic decisions, formulation of recommendations

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Thomas, 2008	Report by organization	National Institute for Health and Clinical Excellence (NICE)	Mental health, maternity, chronic and acute conditions	To evaluate lay members' experiences of being surveys part of a CPG development group	Consultation/ public polls or surveys	Individual patients, patients' representatives	Evaluation of participants' experience of being part of the development of the CPG
WHO, 2008	Report by organization	World Health Organization	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Participation/ member of the CPG working group	Individual patients	Strategic decisions, formulation of recommendations, review of draft, dissemination/ implementation
NZGG, 2009	Report by organization	New Zealand Guidelines Group, Inc. (NZGG)	Not mentioned	To encourage greater involvement by consumers of health and disability services in the activities of NZGG and to ensure a consumer-centered approach to the development and implementation of NZGG guidelines	Participation/ member of the CPG working group	Individual patients, patients' representatives	Unclear

First author, year	Source, study design, methodological approach	Author's institution or organization	Disease/health problem addressed by the CPG	Objective of the PPIP	Involvement method/description of activity or activities	Who was involved	Participation at what stage of CPG development
Graham, 2006	Report by organization	Scottish Intercollegiate Guidelines Network (SIGN)	Cancer, bronchiolitis in children, peripheral arterial disease, epilepsy in children, autism spectrum disorders, dementia, coronary heart disease, chronic hearth failure	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Consultation and participation/ focus groups; member of the CPG working group	Individual patients, patients' representatives	Strategic decisions, knowledge synthesis, formulation of recommendations review of draft, development of products for patients/the public
Sänger, 2008	Report by organization	German Agency for Quality in Medicine	Not mentioned	To incorporate patients' values, preferences, knowledge, and perspectives in CPG recommendations	Communication and participation/ patient version of guideline; member of the CPG working group	Individual patients, representatives of patients' group	Knowledge synthesis, formulation of recommendations development of the draft, review the draft, development of products for patients/the public; dissemination/ implementation
Sänger, 2004	Report by organization	German Agency for Quality in Medicine	Not mentioned	To establish a program whereby laypeople can evaluate and improve health information posted online	Participation/ establishment of an Internet network for critical appraisal	Unclear: The German Patient Forum	Development of products for patients/the public

Section III:

Advancing methods for effective patient and public involvement

Chapter 8

Target for improvement: a cluster randomized trial of public involvement in quality-indicator prioritization (intervention development and study protocol)

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Abstract

Background: Public priorities for improvement often differ from those of clinicians and managers. Public involvement has been proposed as a way to bridge the gap between professional and public clinical care priorities but has not been studied in the context of quality-indicator choice. Our objective is to assess the feasibility and impact of public involvement on quality-indicator choice and agreement with public priorities.

Methods: We will conduct a cluster randomized controlled trial comparing quality-indicator prioritization with and without public involvement. In preparation for the trial, we developed a 'menu' of quality indicators, based on a systematic review of existing validated indicator sets. Participants (public representatives, clinicians, and managers) will be recruited from six participating sites. In intervention sites, public representatives will be involved through direct participation (public representatives, clinicians, and managers will deliberate together to agree on quality-indicator choice and use) and consultation (individual public recommendations for improvement will be collected and presented to decision-makers). In control sites, only clinicians and managers will take part in the prioritization process. Data on quality-indicator choice and intended use will be collected. Our primary outcome will compare quality-indicator choice and agreement with public priorities between intervention and control groups. A process evaluation based on direct observation, video recording, and participants' assessment will be conducted to help explain the study's results. The marginal costs of public involvement will also be assessed.

Discussion: We identified 801 quality indicators that met our inclusion criteria. An expert panel agreed on a final set of 37 items containing validated quality indicators relevant for chronic disease prevention and management in primary care. We pilot tested our public-involvement intervention with 27 participants (11 public representatives and 16 clinicians and managers) and our study instruments with an additional 21 participants, which demonstrated the feasibility of the intervention and generated important insights and adaptations to engage public representatives more effectively. To our knowledge, this study is the first trial of public involvement in quality-indicator prioritization, and its results could foster more effective upstream engagement of patients and the public in clinical practice improvement.

Background

Quality indicators can be used for setting measurable targets for improvement and ensure that quality improvement activities tackle the most pressing areas for change.[1] Public priorities on quality improvement[1] often markedly differ from those of clinicians and managers.[2-4] Several authors have recommended that public representatives, including patients and carers, should be involved in quality-improvement activities to ensure that these efforts target their needs and expectations.[5-9] With the aging population and the growing epidemic of chronic disease, transforming the way health services are delivered for chronic disease patients is a critical focus of quality-improvement initiatives here and abroad. These changes highlight the expert and proactive role that patients, carers, and communities can play in healthcare delivery and quality improvement.[10,11] In recent years, a growing body of literature has explored the use of different methods to involve patients and the public, along with other experts, in complex healthcare policy and delivery decisions, including priority setting, health research, technology assessment, and clinical practice guideline development.[12-19]

Public-involvement interventions can be classified in three broad categories: communication methods (where information is communicated to the public), consultation (information is collected from the public), and participation (information is exchanged between participants).[20] To date, most of the work on patients' roles in quality improvement falls under communication and consultation methods, including public reporting of performance results[21-23]; the development of patient education material and decision aids[24]; the collection of data on patients' expectations, experience of care, and satisfaction[25-31]; or the use of open consultations in the development of quality indicators and clinical practice guidelines.[4,12]

Although these involvement strategies allow patients and the public to contribute to the quality agenda, they leave several gaps unaddressed. First, the prioritization of indicators that will be used as targets for improvement and will drive change at the clinical and management level is still largely left to panels of experts and professionals. Quality indicators can help to identify priority areas for improvement, monitor change, and report on the performance and quality of care.[1] Quality-indicator development and selection is usually based on a combination of literature review and consensus methods in which public representatives are seldom involved, despite their critical strategic importance.[1] A few examples of large-scale consensus

[1] In chapters 8, 9, and 10, the labels "patients" and "public representatives" are used to refer to trial participants, depending of the journal where these articles were published. Similarly, we use the labels "clinicians and managers", "professionals", or "decision-makers" interchangeably in these chapters.

conferences aiming at prioritizing quality indicators at the national or international level have included patient and public representatives, but these initiatives have never been formally evaluated.[32-34]

A second gap in current involvement strategies is that consultations on patients' experience of care and satisfaction often focus on those dimensions of care that are easier to be appraised by patients, such as interpersonal communication and access, as opposed to other clinical and organizational aspects of care.[4] Also, patients involved through communication and consultation methods tend to appraise and judge quality in relation to their own individual care, without consideration of existing research evidence, the competing needs of different users in the community, and the constraints of available resources and services. As a result, health professionals, policy makers, and the public often operate in different and separate worlds in relation to quality improvement.[35,36]

In response to those limitations, there is a growing call for public-involvement methods that allow for active participation and deliberation between stakeholders with different expertises and knowledge.[37] Public deliberation is a 'means by which the public can influence the generation of data and the derivation of the policy options as well as discussing acceptable decisions, thus, taking account of public as well as expert knowledge[38]'. Deliberation is expected to result in (a) mutual learning between participants; (b) the generation of options that are formed on the basis of broader perspectives, interests, and information; and (c) the formation of solutions that most people involved in the deliberative process can find acceptable.[17,39]

Consultation, participation, and communication methods rest on different theoretical assumptions and methods. In the academic literature, a methodological and paradigmatic divide tends to separate proponents of consultation strategies (based on the collection of data from population surveys and other epidemiological methods) and proponents of participation methods that rest on deliberative theory and political sciences.[39,40] Similarly, communication experts tend to focus their work on methods to present information and evidence to individual patients and public members in order to support healthcare choices, behavior change, and public accountability.[24,41] As a result, mixed public involvement strategies have rarely been tested, although a number of quality-improvement organizations do combine these different strategies in practice.[12]

Many doubts remain regarding the feasibility and impact of public involvement in quality improvement.[14,42-44] To date, most empirical research on public involvement in healthcare has studied the process of involvement and its perception by

participants (e.g., whether public representatives are satisfied with the experience and feel that deliberations were fair); no study has assessed the impact of public involvement in quality-indicator prioritization.[14] A recent knowledge synthesis identified many barriers to the development of effective involvement programs, including the following: the lack of evidence on public-involvement effectiveness, concerns that public involvement may often be tokenistic and is unlikely to influence group decision making, the technical complexity of the task, the difficulty in identifying and recruiting public members who are competent and representative, the gap between professional and public perspectives, and the feasibility of public-involvement interventions in terms of time constraints and cost.[45]

Our goal is to assess the feasibility and impact of public involvement on quality-indicator prioritization. Our specific aims are the following:

1. Evaluate the impact of public involvement on:
   a. quality-indicator choices and agreement with public priorities (primary outcome);
   b. decision-makers' intention to use the indicators for quality improvement.
2. Identify factors that explain the effectiveness of the public-involvement program.
3. Estimate the costs of involving the public in quality-indicator prioritization.

Our main hypothesis is that public involvement will result in quality-indicator choices that better agree with public priorities.

Methodology

Project overview and design

We will conduct a cluster randomized controlled trial that will assess the impact of public involvement on quality-indicator choice and intended use (Figure 1). A cluster design is warranted because of our interest in group decision making. In preparation for the trial, we have developed a 'menu' of validated quality indicators based on a systematic review of the literature and expert consultation. We also pilot tested our intervention and instruments. Participants (public representatives, clinicians, and managers) will be recruited from six participating sites, which will be randomized in intervention (quality-indicator prioritization with public involvement) and control sites (without public involvement).

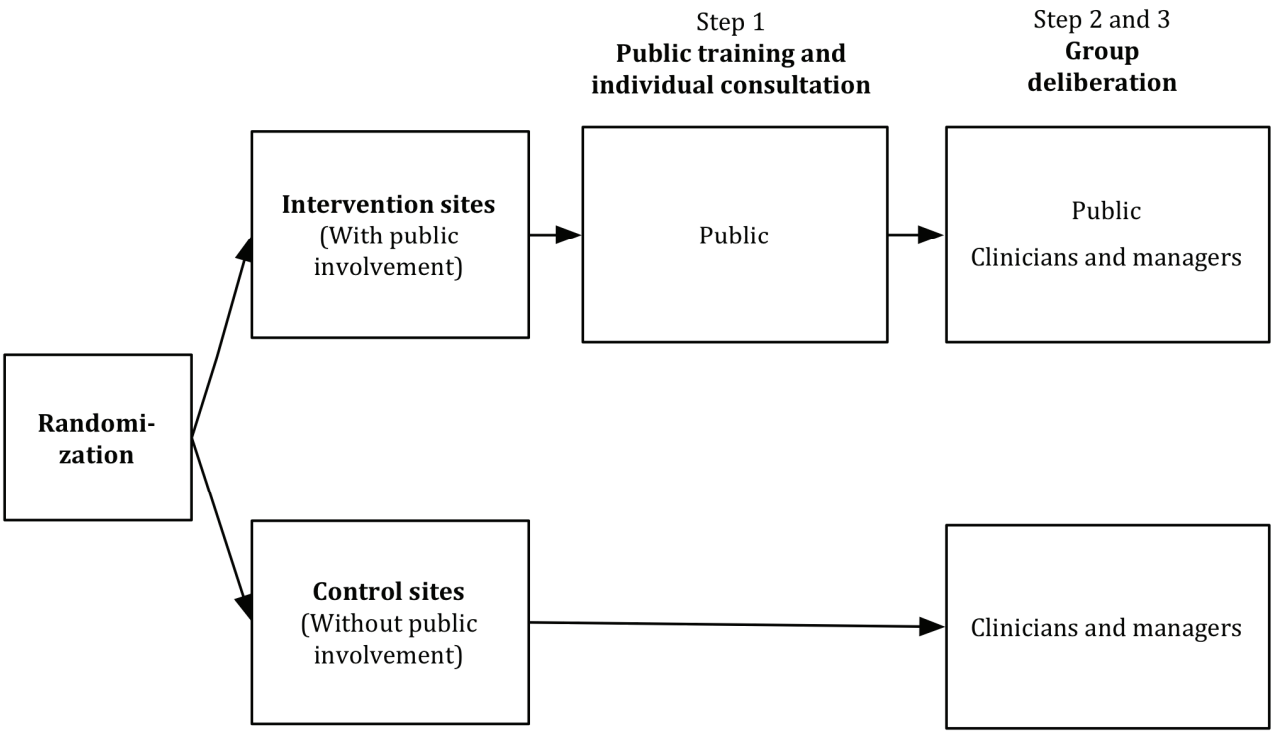
Quality-indicator prioritization will be conducted in three steps. In step 1, public representatives will have a one-day training session to familiarize themselves with the proposed indicators and will be asked to make individual recommendations on indicator choice. In step 2, public representatives will participate in a one-day

deliberative meeting with clinicians and managers to agree on five group recommendations. In step 3, individual and group recommendations will be fed back to decision-makers, who will choose the indicators to be selected as local targets for improvement and discuss actions to support their use in clinical and management practices.

Public-involvement methods in intervention sites will combine participation (deliberation between public representatives, clinicians, and management) and consultation methods (public priorities collected at the training meeting will be fed back to decision-makers). Quality-indicator prioritization in control sites will only involve clinicians and managers.

Data on quality-indicator priorities will be collected from participants at each meeting. Decision-makers' intentions to use the selected indicators for quality improvement purposes will also be collected at the end of the step 3 meeting. This study was approved by the Université du Québec en Abitibi-Témiscamingue ethics committee. The following section will describe in detail the process of intervention development and pilot testing, as well as the protocol of the trial that will be used to assess the intervention's impact.

Figure 1. Trial overview



In intervention sites, quality-indicator prioritization is done by clinicians, managers and public representatives, while prioritization in control sites is done by clinicians and managers only, without public involvement.

Study setting

Abitibi-Témiscamingue is one of the largest administrative regions of Québec, Canada, with a population of 145 886 people, including 6 500 people (4,5%) from First Nations communities. The economy of the region is centered around the mining and wood industry. Most of the population is francophone and 4% have English as their first language.[46] The Regional Health Authority of Abitibi-Témiscamingue (Agence de la santé et des services sociaux de l'Abitibi-Témiscaminge [ASSSAT]) is responsible for coordinating the services in the region. The region is divided into six local service networks, each one under the responsibility of a local health authority (Centre de santé et de services sociaux [CSSS]). The six local health authorities cover rural territories of a few thousand people with basic community care and medium-size towns of approximately 40 000 people with specialized hospital care. Local Health Authorities are responsible for ensuring access to health and social services for the population in their territory through direct service delivery and agreements with partner organizations in their local services network (medical clinics, community organizations, specialist services and hospitals, etc.).[47] Most family physicians providing primary care services in the region are organized in family medicine groups (Groupes de Médecine Familiale [GMFs]), a group of family physicians working in close collaboration with nurses in an environment that fosters providing family medicine to registered individuals. Family physicians in the region cover many secondary care services (e.g., emergency room, hospital care, obstetrical care, intensive care unit). Each local health authority is more than 100 km from another local health authority and serves a rather captive population that receives most of its care within its own community.

Since 2005, the ASSSAT has been implementing a regional chronic disease prevention and management program based on the integration of public health approaches and clinical services for chronic disease prevention and management, the promotion of interdisciplinary work, collaboration with community organizations, self-care support, and case management.[48] Modeled on the Expanded Chronic Care Model[49], this regional program targets the prevention and management of four chronic conditions (diabetes, chronic obstructive lung disease, ischemic heart disease, and heart failure) but also supports broader structural changes and integration within local health authorities and their local services network partners. Adaptation of the regional program to local priorities and context has been encouraged since the beginning of the program. An implementation evaluation of the program conducted in 2008-2009 concluded that the development and use of quality indicators could help

support change and quality improvement at the local level.[50] The trial was developed and integrated within the overall implementation strategy of the ASSSAT regional chronic disease prevention and management program. The study will be conducted among the six local health authorities of the region.

Identification of quality indicators

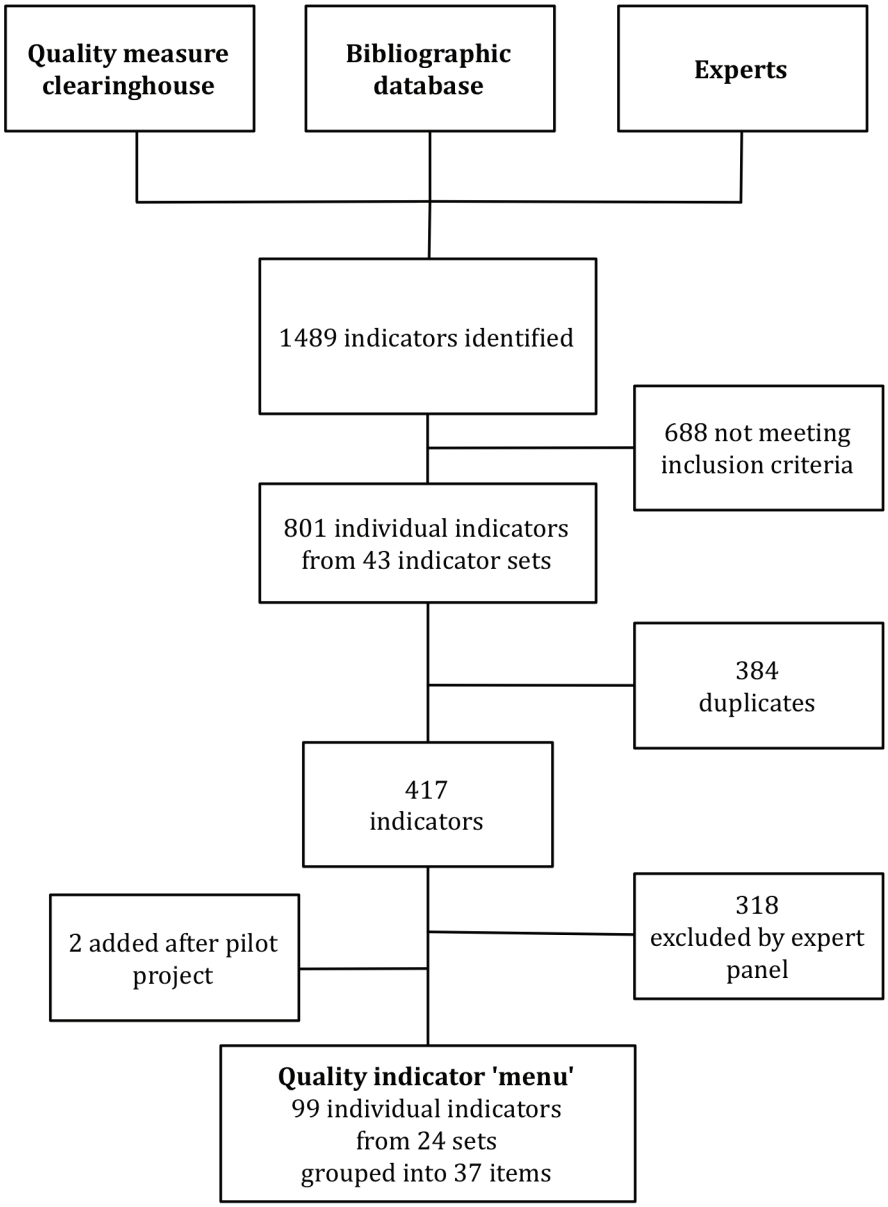
We used a systematic process to develop a menu of quality indicators on chronic disease prevention and management that would be valid, relevant within the context of primary care in Canada, and measurable using existing information systems. To be included, the identified indicator had to:

1. relate to the prevention or management of chronic diseases, defined as health conditions requiring ongoing management over a period of years or decades.[51] We included generic indicators applicable to any chronic disease and disease-specific indicators related to the prevention and management of type 2 diabetes, chronic obstructive pulmonary disease, coronary heart disease, or heart failure;
2. measure an element of practice structure, process, or outcome for which there is evidence or consensus that it can be used to assess the quality, and hence effect change, in the quality of care provided[1];
3. be cited in a peer-review publication that either described its development process, assessed its psychometric properties, or used it for research and evaluation.

We grouped our indicators into five quality domains: access, integration, technical quality of prevention and clinical management, interpersonal care, and outcomes. Our classification was developed from a concept analysis of existing quality-domain frameworks.[2,3,33,34,52-59] and rested on operational definitions of primary care attributes developed by Canadian experts.[59]

Figure 2 summarizes the indicator identification and selection process. We first conducted a systematic search for quality indicators from the National Quality Measure Clearinghouse[57] [a] and bibliographic databases (MEDLINE, PsycINFO, HTA Database, NHS Economic Evaluation Database, EconLit, Business Source Premier, Health and Psychosocial Instruments)[b], as well as through contact with experts and key informants and hand-searching of references from relevant papers.

Figure 2. Systematic review of quality indicators flowchart



We identified a total of 1489 individual indicators. 801 indicators met our inclusion criteria. We extracted each included individual indicator and built a quality-indicator database. Two independent researchers, including the principal investigator, identified and removed duplicates. When multiple related clinical care indicators were present, we chose indicators that were developed in Canada or that were most closely aligned with current Canadian clinical practice guidelines.[60-65] We presented the remaining list of individual indicators to a panel of five experts (two physicians, two health managers, and an information specialist) who shared collective expertise in the clinical and organizational aspects of chronic disease management and

knowledge of the clinical context and the available information systems. Expert panel members independently rated each indicator based on relevance and measurability. Expert panel members met twice to agree on the final list of indicators.

Primary care delivery in Canada is largely provided by family physicians, but allied health professionals, such as primary care nurses and nurse practitioners, are playing an increasing role in this area. To reflect these system characteristics, we adapted the wording of some indicators by changing 'regular doctor' to 'family doctor' or 'regular primary healthcare provider', in accordance with current Canadian indicators.[66] We translated the selected indicators in French and wrote a plain language description of each. Our expert panel validated the indicator translation and description. Subscales of individual questionnaires (e.g., the Primary Care Assessment Survey continuity domain[67]) and disease-specific clinical indicators (e.g., clinical management of type 2 diabetes) were grouped together as individual menu items.

The proposed indicator menu was tested for comprehensiveness and relevance with a group of public representatives and professionals in our pilot project (described below). The final menu of indicators is composed of 37 menu items (Table 1).

Table 1. Menu of quality indicators

Access	
1. Perceived difficulty to obtain an appointment	2. Primary health care organization's opening hours
3. Access for disabled people	4. Family physicians accepting new patients
5. Medication and treatment cost	6. Language barriers
7. Phone access to a primary care provider	
Integration	
8. Coordination among health care organizations	9. Electronic communications
10. Primary care registries for chronic conditions	11. Perceived continuity of care
12. Team work and interdisciplinary care	13. Links with community organizations
Technical quality of prevention and clinical management	
14. Physical activity counselling	15. Healthy eating counselling
16. Tobacco counselling	17. Influenza vaccination
18. Hypertension screening	19. Perceived technical quality of care
20. Clinical management of type 2 diabetes	21. Clinical management of coronary heart disease
22. Clinical management of chronic obstructive pulmonary disease (COPD)	23. Clinical management of heart failure
Interpersonal care	
24. Self-care support	25. Patient participation in clinical decision-making
26. Respect and empathy	27. Time available during the consultation
28. Trust towards primary care provider	29. Stress and responsibilities at work and at home
Outcomes	
30. Fruit and vegetable consumption rate	31. Smoking rate
32. Physical activity rate	33. Blood pressure control
34. Perceived self-efficacy	35. Hospitalization for ambulatory-care sensitive conditions
36. Emergency room visit for ambulatory-care sensitive conditions	37. Quality of life

The complete description of each indicator and a reference to the original indicator set is included in the Appendix.

Development of the intervention and pilot testing

The development, pilot testing, and refinement of the intervention followed a structured framework for the design and evaluation of complex interventions in health.[68] Our public-involvement intervention development is based on best-practice recommendations for public involvement in healthcare[5,12,13,69-72] and quality-indicator development.[33,73-75] We sought to use a public-involvement strategy that combined consultation and participation methods. The consultative component aims at collecting public recommendations from a broad and diverse group of public representatives. The participation component aims at supporting deliberation among clinicians, managers, and public representatives to foster mutual learning, respectful disagreement, consensus building, and the emergence of a collective perspective on quality improvement.[20,39] Our quality-indicator prioritization process is based on the RAND appropriateness method, which combines a systematic review of existing indicators, an individual rating of indicators by a Delphi procedure, and a face-to-face deliberation and rerating of indicators using nominal group technique.[76]

Research questionnaires were pretested with 21 people before being used in our three pilot meetings. We pilot tested the format of step 1 and step 2 meetings in the region of Lanaudière (Québec), 500 km away from the participating sites. The northern part of this region has sociodemographic and health system characteristics that are similar to those of the region of Abitibi-Témiscamingue, thus allowing us to test the feasibility of the intervention without contaminating our study sites. Nineteen participants (ten public representatives, nine clinicians and managers) participated in the step 1 and step 2 pilot meetings in January and February 2010. We pilot tested our decision-makers' meeting (step 3) with 10 participants (two public representatives, eight managers and clinicians) from the Regional Health Authority of Abitibi-Témiscamingue at the end of September 2010. Two researchers were present during each pilot meeting and took observation notes. A structured debriefing session was held with participants at the end of each pilot meeting to identify what worked and what did not and to collect suggestions for improvement. We held debriefing meetings with our team to adjust the intervention format and data collection instruments based on participants' comments and observations.

As a result of our pilot testing, we adapted our intervention and instruments and decided to:

1. clarify participants' responsibilities, by developing a detailed written task description;
2. introduce the menu of indicators to public representatives during the training session;
3. develop structured recruitment documents with explicit representation criteria to facilitate the identification of public representatives from different socioeconomic backgrounds;
4. invite more public representatives and physicians in step 2 meetings to deal with potential attrition;
5. prepare a seating plan to facilitate interactions between public representatives, clinicians, and managers;
6. develop structured prompts and suggestions to support the group deliberation process and enable participants to complete the task more effectively;
7. add two new items to the indicator menu on stress and collaboration with community organizations, in response to public representatives' and professionals' suggestions;
8. use video recording rather than audio recording to better capture social interactions among participants;
9. use color coding and ranking of step 1 and step 2 reported recommendations, to facilitate their communication to decision-makers in step 3 meetings;
10. clarify the regional health authority's expectations towards indicator use.

Recruitment and randomization of the participating sites

The local health authorities' Chief Executive Officers (CEOs) and GMF medical directors from all six territories of Abitibi-Témiscamingue agreed to participate in the study (response rate = 100%). Site randomization will be done after the recruitment process of individual participants is completed, using a random allocation software.[77] Randomization will be carried out by one of the researchers, with two independent observers present, and will be concealed to the professionals in charge of recruitment, the group facilitator, and participants until the end of the step 1 meeting (see Control section below).

Individual participants' recruitment

Within each local health authority participating in the study, we created recruitment teams who are responsible for identifying public representatives, clinicians, and managers interested in participating in the study. Each local recruitment team includes a member of the CSSS user committee, the manager in charge of the chronic disease program, and the medical director of the family medicine group. Local health authorities' CEOs will also be solicited to identify the managers and clinicians who will act as decision-makers. Local recruitment teams will identify potential participants by purposive sampling and the snowballing technique, using our inclusion and representation criteria described in Table 2.[78] We seek to recruit clinicians and managers who are closer to healthcare delivery to participate in the step 2 meeting (group recommendations) and senior-level managers and professional council representatives for step 3 (decision-makers' meeting), allowing for overlap between both meetings.

Table 2. Inclusion and representation criteria

Category of participant	Inclusion criteria	Representation criteria
Public representatives Steps 1-2-3 meetings (Target: 90 participants)	1) Adult with or without a chronic condition; 2) Be competent to share opinions with others; 3) Not be currently or previously working as a clinician or healthcare manager.	Age, gender, employment, and health status (healthy adults without chronic disease; patients with uncomplicated chronic disease; patients with complex chronic conditions)
Clinicians and managers Step 2-3 meeting (Target: 72 participants)	1) Work as a clinician or manager in relation with the prevention or management of chronic diseases; 2) Work within the catchment area of a participating health authority; 3) Be competent tor share opinions with others.	Include a minimum of two familye physicians, one manager familiar with the chronic disease program and existing information systems, and a balanced mix of clinicians and managers involved in chronic disease prevention and management.
Clinicians and managers Step 3 decision-makers' meeting (Target: 60 participants)	1) Be identified by the local health authority's CEO to advise him/her on the choice of quality indicator 2) Be a member of the board or professional council of the local health authority or family medicine group	Include the CEO or his/her representative, as well as one physician; the identification of other key decision-makers is left to the CEO's discretion

CEO: Chief executive officer

For the purpose of our study, a public representative can include any adult targeted by the regional chronic disease prevention and management program who is not a healthcare professional or employee. This includes healthy adults, carers, and patients with chronic conditions. Interested individuals will be given a written description of the project and a 'job profile', explicitly stating that we are looking for

people who represent a broad range of backgrounds and personal experiences and who are willing to work collaboratively with other public representatives, clinicians, and managers (Table 2). Identification of public representatives through local recruitment teams allows us to reach public members who have perceived legitimacy within their own community and who are interested in the issues discussed.[79] A research assistant will contact potential participants, confirm their eligibility criteria and interest/availability for participating in the study, and collect basic sociodemographic characteristics. The research team will select participants based on the representation criteria described in Table 2.

Description of the intervention

The intervention is composed of three one-day meetings (step 1, step 2, and step 3) that aim at prioritizing local quality indicators. The Regional Health Authority expects that the selected indicators will be used to support continuous quality improvement of chronic disease prevention and management (rather than for external control or benchmarking), and each local health authority will be allowed to select its own indicators. The selected indicators will be integrated in the regional accountability contracts signed with each local health authority. Table 3 summarizes the topics addressed in each intervention meeting, and their content is described in detail below.

Table 3. Intervention meetings' content

Meetings	Participants	Content
Step 1: Public representatives' training and recommendations	Public representatives (target : 15/site)	• Participants' discussion on positive and negative experience in relation with quality of care • Information on chronic disease and local prevention and management services • Explanation of the indicator menu and data collection on baseline public recommendations
Step 2: Group recommendation	Clinicians and managers (target: 9/site) and public representatives (target: 6/site)	• Individual baseline prioritization • Deliberation on indicator choice – Block 1 (Structure: access and integration) – Block 2 (Process: technical quality and interpersonal care) – Block 3 (Outcome indicators) • Final group recommendation and individual recommendations
Step 3: Decision-makers' meeting	Clinicians and managers (target : 10/site) and public representatives (target: 2/site)	• Expectations from the Regional Health Authority on quality-indicator choice and use • Presentation of recommendations issued in step 1 and step 2 meetings • Deliberation on indicators choice and implementation • CEOs summarize decisions and foreseen actions for each Local Health Authority

CEO: Chief executive officer

Step 1: public representatives' training and recommendations

The step 1 meeting aims to train public representatives and to collect their individual recommendations for local quality improvement. Public representatives (target: 15 per site) will meet with the moderator for a one-day meeting. Participants will be asked in turn to reflect and share their experiences with and expectations towards quality of care, will receive background information on chronic disease and on existing prevention and management services in their community, and will receive explanations on the proposed quality indicators. At the end of the meeting, public representatives will individually prioritize the quality indicators and identify five indicators that they recommend as local targets for improvement (public baseline recommendations).

Step 2: group recommendations

In the step 2 meeting, public representatives, clinicians, and managers will deliberate together to agree on five local group recommendations. We will aim to recruit a total of 15 participants in each group (nine clinicians and managers and six public representatives). We will recruit public representatives from step 1 participants, based on their availability, interest, and natural attrition. If more people volunteer, the research team will select candidates based on our representation criteria to ensure a balanced representation of age, gender, employment, and health status (Table 2).

Group rating and deliberation on quality-indicator prioritization will be done in four steps: (1) participants prioritize indicators individually at the beginning of the day; (2) feedback on individual responses is given to the whole group; (3) participants deliberate as a group on the indicators' pros and cons; (4) if consensus on group recommendations cannot be reached, the moderator asks participants to vote. At the end of the day, participants will be asked to agree on five indicators that they recommend using as targets for improvement in their territory (group recommendation). They will also be asked to record five indicators that they recommend individually. We will explain to the participants that it is not necessary for everybody to agree with the final group recommendations, as long as everyone can 'live with' the compromise or consensus reached by the group.

Step 3: decision-makers' meeting

In the step 3 meeting, decision-makers identified by the local health authority's CEO will choose which indicators to use as local targets for improvement and identify actions to implement these indicators in clinical practice and management. While step 1 and step 2 meetings will be held locally within each participating site, we will hold one semiregional step 3 meeting that will bring together decision-makers from all intervention sites, and another semiregional meeting with all control sites. A semiregional format will allow us to involve senior directors from the Regional Health Authority and send consistent messages across all sites regarding the Regional Health Authority's expectations.

Local and regional recommendations developed in steps 1 and 2 meetings will be presented to decision-makers. Individual recommendations will be communicated to decision-makers by reporting the rank of each indicator, calculated from the proportion of participants who recommended each indicator. Group recommendations and individual recommendations will be color-coded to facilitate their identification by decision-makers. Recommendations will be discussed in small-group deliberation sessions within each site. At the end of the meeting, each local health authority's CEO will summarize the decisions and actions proposed within his/her own territory. A Regional Health Authority representative (RL) will be present to explain the quality indicator expected use, describe the professional and technical resources that will be available to support quality-indicator implementation, and answer questions.

Public involvement in the step 3 meeting will combine consultation and deliberation methods. Decision-makers will receive written feedback about individual recommendations made by public representatives in step 1 meetings (consultative component). Public representatives who participated in step 1 and step 2 meetings will also be invited to attend the meeting (target: two participants/site) to answer decision-makers' questions and assist them in their choice (participation component).

Moderator

A professional moderator (JL) with previous experience in communication and group facilitation will moderate all step 1 and step 2 meetings and will also facilitate the step 3 plenary sessions. In the step 3 meeting, two additional moderators will facilitate small-group deliberation among decision-makers from each site. All moderators attended our pilot meetings and participated in a preparation session to develop an animation grid, agree on solutions to potential pitfalls, and develop

prompts to guide discussions. The moderators will be responsible for welcoming participants, establishing ground rules with them, ensure fair participation, and facilitate deliberation and agreement on the proposed indicators and actions. A member of the research team (AB) will attend all meetings, present the project and the proposed indicators, and answer technical questions.

Control

In control sites, quality-indicators prioritization will be done by clinicians and managers only, following the format described for the above step 2 and step 3 meetings. Public representatives will not be involved in quality-indicator prioritization.

For research purposes, we will also conduct step 1 meetings in all control sites to collect data on local public recommendations (see the Data Collection and Analysis sections below). The format and content of the step 1 meeting will be identical in control and intervention sites. The moderator and participants will be blinded to their allocation until the end of the meeting. We will present the results of this public consultation to control sites' decision-makers after we collect all trial outcome data on quality-indicator choice and intended use, during the post-randomization phase of the project.

The six participating sites are more than 100 km apart from one another, clinicians and managers have rare contact among themselves, and they serve rather captive populations who receive most of their care within their community, thus minimizing the potential for contamination across intervention and control groups. We will ask all participants to respect the confidentiality of discussions and not to share any information between meetings. We will assess for potential contamination among participants in all meetings.

Data collection

Table 4 describes the questionnaires that will be used for data collection. Specific data collection instruments are described in detail below. Research questionnaires were pretested with 21 persons, before being used in our three pilot meetings (described above).

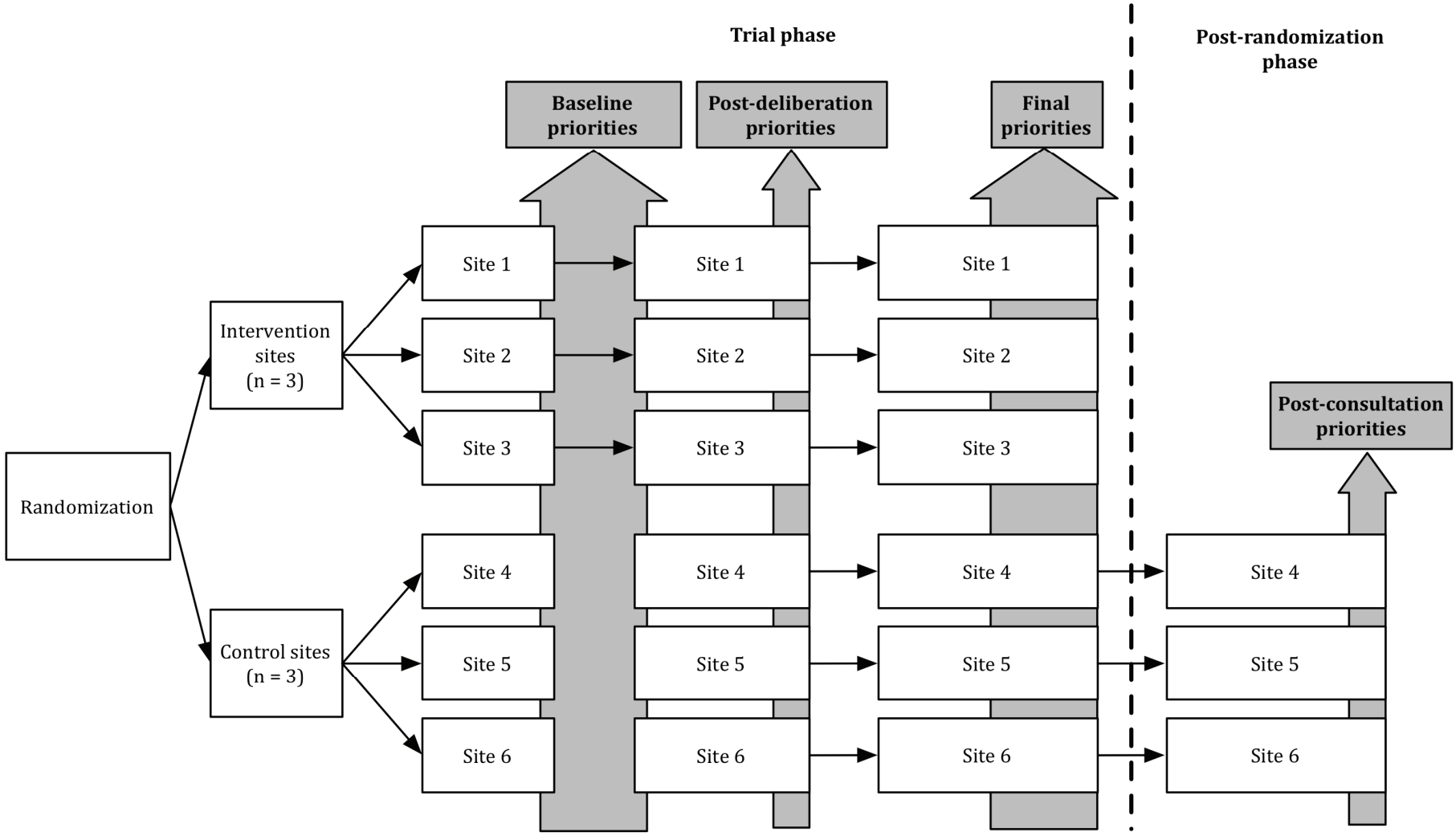
Table 4. List of questionnaires

#	Timing	Respondents	Data collected
Q1	Beginning of step 1	Public	Public representatives' sociodemographic data (age, gender, ethnic group, language, education, socioeconomic status, health status, health services use, prior attitude towards public involvement)
Q2	End of step 1	Public	Quality-indicator prioritization (public baseline priorities)
Q3	End of step 1	Public	Participants' evaluation of the step 1 meeting
Q4	Step 2 and step 3 meetings	Clinicians and managers	Clinicians' and managers' sociodemographic data (age, gender, ethnic group, language, education, socioeconomic status, professional role, prior attitude towards public involvement)
Q5	Beginning of step 2	Clinicians and managers	Quality-indicator prioritization (clinicians' and managers' baseline priorities)
Q6	End of step 2	Clinicians, managers, and public representatives	Quality-indicator prioritization (post-deliberation priorities)
Q7	End of step 2	Clinicians, managers, and public representatives	Participants' evaluation of the step 2 meeting
Q8	End of step 3	Clinicians, managers, and public representatives	Quality-indicator prioritization, attitude and intention to use the selected indicators for quality improvement (decision-makers' choice and intention to use).
Q9	Post-randomization phase	Clinicians and managers (control sites only)	Quality-indicator prioritization (post-consultation priorities). This questionnaire is completed after we collect data on decision-makers' choice and intention to use, during the post-randomization phase of the project.
Q10	End of step 3	Clinicians, managers, and public representatives	Participants' evaluation of the step 3 meeting.

Quality-indicator prioritization

Our primary outcome is the comparison of indicator choice and agreement with public priorities between intervention and control groups. Data on quality-indicator prioritization will be collected at baseline and at the end of each meeting (Figure 3). In order to collect public baseline priorities from all participating sites, we will hold step 1 meetings with public representatives from the six participating sites. Clinicians and managers' baseline priorities will be collected at the beginning of the step 2 meeting. Post-deliberation priorities will be collected at the end of the step 2 meeting. Decision-makers' choice and final priorities will be collected at the end of the step 3 meeting. We will also collect post-consultation priorities from control site participants during the post-randomization phase of the project. Post-deliberation and post-consultation priorities will be used for process evaluation purposes to assess the contribution of each component of the intervention.

Figure 3. Data collection on quality-indicator prioritization



Participants' priorities will be collected from each site at baseline and after each meeting.

The questionnaire on quality-indicator prioritization includes the menu item title, a description of the indicator under each item (e.g., 'percent of family physicians who accept new patients'), as well as the source of information (patients' charts, administrative data, or survey) and original reference (Appendix). At the end of each questionnaire, participants are asked to prioritize five quality indicators ('indicate the five indicators that you believe are the most important to improve chronic disease prevention and management in your territory') and to rank these five indicators in order of importance.[80]

In step 1 and step 2 meetings, a research team member (AB) will read each item individually and answer questions. Participants in these two meetings will be asked to rate each indicator according to its perceived importance and feasibility, using a Likert scale from 1 to 9.[2] In step 3, participants will be sent the indicator by mail before the meeting. Decision-makers will be asked to prioritize their five most important indicators after they receive feedback on individual and group recommendations.

Decision-makers' intention to use the selected indicators

The questionnaire on decision-makers' attitude and intention towards indicator use will be completed by all participants in the step 3 decision-makers' meeting, after decision-makers agree on which indicators they will select as targets for improvement for their territory. We have developed this questionnaire from known predictors and instruments used to measure the likely adoption of quality indicators and health innovations.[75,81-85] The questionnaire consists of 11 items covering decision-makers' attitude towards selected quality indicators (importance, feasibility, credibility, group consensus) and their intention to use and report on the selected indicators for quality-improvement purposes. Each item is scored on a 7-point Likert scale.

Cost analysis

In order to estimate the financial costs of public involvement in quality-indicator prioritization, a cost analysis will be conducted. In this type of analysis, the costs of an intervention are presented in a disaggregated form.[86] We will adopt the perspective of the intervention sponsor and report on the marginal financial costs of public involvement, including the costs of public representatives' recruitment, training, financial compensation, group facilitation, administrative support, meals, and didactic

material. The average costs per site will be estimated based on actual project expenses.

Process evaluation

In the context of trials, process evaluation can be used to explain the study's results.[87,88] Our process evaluation will focus on understanding the effects of the intervention and the mechanisms that underlie change. A multiple case study will be used for this analysis, capitalizing on natural intersite variations. Our analysis will be guided by group process and deliberative theory to explore how public involvement influences the content of deliberation and the social interactions among participants.[39,89-91] Data collection will be carried out using standardized questionnaires, direct observation of all meetings by two independent nonparticipant observers, and video recording of all meetings. A group debriefing session will be held with participants at the end of each meeting. A standardized self-administered evaluation questionnaire will also be distributed at the end of each meeting, based on an existing deliberation assessment questionnaire.[92] The evaluation questionnaire is composed of 22 items divided into five domains covering (1) roles, procedures, and objectives; (2) meeting facilitation and support; (3) information received; (4) participants' interaction; and (5) overall satisfaction. Each item is scored on a 7-point Likert scale. The observers and moderators will hold a debriefing session among themselves immediately after each meeting to share observations.

Statistical analysis

Descriptive statistics will be used to summarize the characteristics of the study population and assess the comparability of intervention and control groups, as well as to summarize data on quality-indicator choice, intended use, and on the marginal costs of the intervention.

We will descriptively report which quality indicators are selected as targets for improvement within each site at the end of the trial and calculate the proportions that are in agreement with local public baseline priorities (ranks 1 to 5). Individual quality-indicator priorities will be analyzed as a dichotomous measure by reporting the proportion of participants who selected each indicator as part of their five priorities and by calculating its rank (rank 1 = indicator selected by the greatest proportion of participants). Agreement with public priorities will be analyzed by calculating the correlation between professionals (clinicians and managers) and public priorities at baseline and at the end of the trial (primary outcome). Cluster

randomization leads to a reduction of effective sample size and can give spurious statistical results if it is not accounted for properly.[93,94] We will check the data to assess the level of clusterization within study sites and use appropriate cluster-level analysis (e.g., multilevel modeling) if necessary. We will also compare decision-makers' intention to use the selected indicators and participants' satisfaction between intervention and control sites. Statistical significance will be assumed at $p < 0.05$ (two-tailed test) for all tests.

Sample size

Our sample size calculation is based on pragmatic considerations and takes into consideration the maximum number of available sites/clusters in the region (n=6 sites) and the maximum number of recommended participants in small-group deliberation meetings (n=15 participants per meeting). We aim to recruit a total of n=90 public representatives, n=72 clinicians and managers for the step 2 meeting, and n=60 senior managers and professional council representatives for the step 3 meeting. We will allow for overlap between clinicians and managers participating in step 2 and step 3 meetings.

Abelson and colleagues note that small sample sizes are hard to overcome in studies of public participation in healthcare as 'deliberation decision-making dictates small groups'.[13] We expect that the power of our study will be further decreased by the cluster nature of the trial, although we are currently unable to estimate the magnitude of this effect due to the absence of prior trials of public involvement in quality-indicator prioritization and unknown intra-cluster coefficients for our outcome of interest.[93]

Integrated knowledge translation and post-randomization follow-up

We are following an integrated knowledge-translation plan throughout the trial preparation and implementation, where knowledge users are directly involved in strategic aspects of research and knowledge production.[95] This study is embedded in a larger implementation strategy of the regional integrated chronic disease prevention and management program.[50] Our team is pursuing two core objectives in this project: (1) to support chronic disease prevention and management through the selection and use of quality indicators that will be used as local targets for improvement (practice component) and (2) to assess the impact of public involvement on quality-indicator prioritization and intended use (research component). Within this project, partnership between decision-makers and

researchers will be an ongoing process throughout the cycle of knowledge production and use. At each stage of the intervention, we will collaboratively (a) plan the initial 'blueprint' of the intervention; (b) pilot test it; (c) 'lock in' the final format of the intervention for its implementation in the trial; and (d) collect, analyze, and communicate knowledge to researchers and decision-makers.

Our target knowledge users include clinicians, managers, and public representatives from local health authorities and the Regional Health Authority, as well as provincial and national organizations involved in indicator use and quality improvement. The principal investigator (AB) will act both as a researcher (IQ healthcare) and as a medical advisor for the Regional Health Authority (ASSSAT) and will be responsible for facilitating the interaction between decision-makers and researchers on the project. A member of the Regional Health Authority's board of directors (RL) has been included in all aspects of the study design and research. Key aspects of the study protocol were presented and discussed with the CEOs of all participating local health authorities, medical directors of family medicine groups, the Regional Health Authority's board of directors, as well as with local and regional users' committees and population forums. The project was also presented to the Québec provincial government in February 2010.[96] Representatives from AETMIS, a provincial organization that has received the mandate from the provincial Ministry of Health to develop quality indicators for primary care improvement, have also partnered with us on the project.

Gibbons argues that research conducted in the context of application has the potential to increase the relevance and impact of the knowledge produced and to foster its use and implementation in practice.[97] The Regional Health Authority of Abitibi-Témiscamingue is committed to supporting indicator implementation and use after the completion of the study to support the improvement of chronic disease prevention and management. Professional and technical resources will be made available regionally to support indicator use. Follow-up on quality-indicator use will be integrated in the regional director-generals meeting, as part of a statutory point on chronic disease prevention and management.

Discussion

To the best of our knowledge, this study is the first trial of public involvement in quality-indicator prioritization.[14] It tackles important knowledge gaps on how members of the public, including patients and carers, can be effectively involved in strategic aspects of quality improvement. A strength of the study is the systematic

approach that was used to develop and refine the public-involvement intervention, based on existing frameworks for the development and testing of complex health interventions. Our pilot project provided important insights on how to engage public representatives more effectively. The testing of this intervention in a real-world prioritization context has the potential to increase the external validity of findings and test the feasibility of the intervention in practice. A limitation of the study is our small effective sample size, given the cluster nature of the trial and restrictions regarding the maximum number of sites and individual participants that can be recruited for a deliberative intervention. We nonetheless expect that this trial will provide important knowledge into the feasibility, process, and effectiveness of public involvement in quality-indicator prioritization, thus fostering upstream engagement of patients and the public in clinical practice improvement.

a. We carried out two searches in the National Quality Measure Clearinghouse for indicators published between 2005 and 2010. The first search looked at all quality indicators listed under the domains 'Access' and 'Structure'. The second used the MeSH terms 'cardiovascular disease', 'diabetes mellitus', and 'lung diseases, obstructive' with the filter terms (Care setting: Ambulatory care OR Community health care) AND (IOM care needs: Living with illness OR Staying healthy).
b. The search strategy was developed by two information specialists from the Québec Agence d'Évaluation des Technologies et des modes d'intervention en santé (AETMIS) for literature published between 2007 and 2010, using the keywords quality indicators/measures, performance indicators/measures, chronic diseases, diabetes, ischeamic heart disease, and heart failure. References without an abstract were excluded.

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Appendix. Description of the quality indicators used in the trial

ACCESS

Nº	Quality indicator	Source	Reference
1	**Perceived difficulty to obtain an appointment:** • Perceived delay to obtain an appointment with a primary care provider for minor problems and routine care • Perceived difficulty to obtain an appointment with a primary care provider[a]	Patient reported questionnaire	Canadian Institute for Health Information [1] Primary Care Assessment Survey [2]
2	**Primary health care organization's opening hours:** Average primary care organizations' opening hours in the evening (after 17h) and weekends	Administrative data	Canadian Institute for Health Information [1]
3	**Access for disabled people:** Primary care services are physically accessible for disabled people	Administrative data	Quality indicators for general practice [3]
4	**Family physicians accepting new patients:** % of family physicians accepting new patients	Administrative data	Canadian Institute for Health Information [1]
5	**Medication and treatment cost:** • Do you ever skip medication or treatments because they are too expensive? • How would you rate the amount of money you pay for medication & other prescribed treatments?	Patient reported questionnaire	Primary Care Assessment Survey [2]
6	**Language barriers:** % of patients/clients who experienced language barriers when communicating with their regular primary care provider, over the past 12 months	Patient reported questionnaire	Canadian Institute for Health Information [1]
7	**Phone access to a primary care provider:** Possibility to obtain information and advices over the phone with a primary care professional when a visit is not necessary or difficult[b]	Administrative data	Quality indicators for general practice [3]

a. The PCAS survey is framed around the perceived difficulty to obtain an appointment at the doctor's office. This item has been adapted to refer to primary health care providers, including family physicians and primary care nurses.
b. Excluding access to "Info-Santé", a provincial government service providing generic health advices over the phone.

INTEGRATION

Nº	Quality indicator	Source	Reference
8	**Coordination among health care organizations:** % of primary health care organizations who currently coordinate client/patient care with other health care organizations (e.g. hospital, specialized clinics) using standardized clinical protocols or assessment tools	Administrative data	Canadian Institute for Health Information [1]
9	**Electronic communications:** % of primary care organizations that have electronic communication links (other than fax and telephone) with other health services organizations (e.g. hospitals, specialized clinic, emergency room, etc).	Administrative data	Canadian Institute for Health Information [1]
10	**Primary care registries for chronic conditions:** % of primary care organizations that can produce a list of all patients with diabetes, chronic obstructive pulmonary disease, and cardiovascular disease	Administrative data	Quality and Outcome Framework [4-7]
11	**Perceived continuity of care [c]:** • Family physicians' knowledge of your entire medical history • Other primary care professionals' knowledge about your medical history and your health • Family physicians' knowledge about the care you receive from other physicians and professionals (for example: visits that you make, treatments recommended)?	Patient reported questionnaire	Primary Care Assessment Survey [2]
12	**Team work and interdisciplinary care:** • Perceived effectiveness of primary care professionals' team effectiveness, leadership and communication • Diversity of professionals within the team • Shared goals, team's decision and conflict resolution	Clinician or manager reported questionnaire	Team Climate Inventory [8] Canadian Institute for Health Information [1]
13	**Links with community organizations:** Partnerships with community organizations are actively sought to develop formal supportive programs and policies across the entire system	Clinician or manager reported questionnaire	Assessment of Chronic Illness Care [9]

c. "Regular doctor" was changed to "family physician".

TECHNICAL QUALITY OF PREVENTIVE AND CLINICAL CARE

Nº	Quality indicator	Source	Reference
14	**Physical activity counseling:** % of inactive clients/patients who received specific help or information on regular physical activity from their primary care provider, over the past 12 months	Patient reported questionnaire	Canadian Institute for Health Information [1]
15	**Healthy eating counseling:** % of clients/patients with unhealthy eating habits who received specific help or information on healthy dietary practices from their primary care provider, over the past 12 months	Patient reported questionnaire	Canadian Institute for Health Information [1]
16	**Tobacco counseling :** % of smokers who have received advices or were referred for smoking cessation services	Medical file	Canadian Cardiovascular Outcomes Research Team [10]
17	**Influenza vaccination:** % of patients at high risk who are offered influenza vaccination in the last year	Administrative data	European Practice Assessment [11]
18	**Hypertension screening:** % of adults whose blood pressure was checked in the last 24 months	Medical file	Canadian Institute for Health Information [1]
19	**Perceived technical quality of care:** • Thoroughness of your doctor's questions about your symptoms and how you are feeling • Thoroughness of doctor's physical examination to check a health problem you have? • How often do you question whether your doctor's diagnosis of your health problem is right?	Patient reported questionnaire	Primary Care Assessment Survey [2]
20	**Clinical management of type 2 diabetes [d]:** • % of patients with Type 2 diabetes who have had in the past 15 months: – Their smoking status checked – A measure of their blood pressure – HA1C testing – Microalbuminuria screening – Body mass index measure – A referral for a visual assessment (in the past 24 months) – Foot examination (documented at least once) • % of Type 2 diabetes patients with obesity who have been prescribed metformin or have documented counter-indication or intolerance to metformin	Medical file	Canadian Diabetes Association [12] Canadian Task Force on Preventive Health Care [13] Canadian Cardiovascular Outcomes Research Team [10] Quality Outcome Framework [5] Canadian Institute of Health Information [1] National Diabetes Quality Improvement Alliance [14]
21	**Clinical management of coronary heart disease [d]:** • % of adult patients who have: – Their smoking status documented – Their body mass index measured – Their blood pressure recorded on the chart in the past three years – Lipid testing at least every five years recorded on the chart for men 40 to 80 years of age, or women 50 to 80 years of age • % de patients with ischeamic heart disease who were prescribed, or have documented counter-indication or side-effects to: – A beta-blocker – An acetylsalicylic acid – An angiotensin-converting enzyme inhibitors	Medical file	Canadian Cardiovascular Outcomes Research Team [10] Canadian Institute of Health Information [1] Canadian Hypertension Education Program [15]

Nº	Quality indicator	Source	Reference
22	**Clinical management of chronic obstructive pulmonary disease [d]:** % of patients with chronic obstructive pulmonary disease who have: – An annual evaluation of their smoking status – An annual evaluation of their respiratory symptoms – Received vaccination against pneumonia – Been prescribed a rapid-acting bronchodilator (stage 1 or more) – Been prescribed a long-action bronchodilator if symptoms are not relieved by as-needed bronchodilator (stage 2 or more) – Received teaching on how to use their inhaler device – Been prescribed long-term oxygen if their PaO2 is less than 55mmHg	Medical file	Canadian Cardiovascular Outcomes Research Team [10] Health Effectiveness Data and Information Set (HEDIS) [16] Assessing Care of Vulnerable Elders [17] American Heart Association [18] Canadian Thoracic Society [19]
23	**Clinical management of heart failure [d]:** • % of patients with heart failure who have: – Their smoking status recorded in the chart – Their weight and cardiac symptoms recorded at each visit – Their blood pressure checked at each visit – Their left ventricular function assessed • % of patients with systolic heart failure who were prescribed, or have documented counter-indication or side-effects to: – A beta-blocker – An angiotensin-converting enzyme inhibitors • % of patients with systolic heart failure who were prescribed warfarin, or have documented counter-indication or side-effects to warfarin.	Medical file	Canadian Cardiovascular Outcomes Research Team [10] Canadian Cardiovascular Society [20] American Heart Association [21]

d. Participants were informed that they would be allowed to narrow down the specific indicators measured within each disease-specific clinical indicator item, should they choose it as target for improvement.

INTERPERSONAL RELATIONSHIP

Nº	Quality indicator	Source	Reference
24	**Self-care support** [e] **:** In the past 6 months, chronic disease patients report that they: • Received a written list of things they should do to improve their health • Were shown how what they did to take care of themselves influenced their condition • Were encouraged to go to a specific group or class to help them cope with their chronic condition • Were helped to plan ahead so that they could take care of their condition even in hard times	Patient reported questionnaire	Patient Assessment of Chronic Illness Care [22]
25	**Patient participation in clinical decision-making** [e] **:** In the past 6 months, chronic disease patients report that they were: • Asked to talk about their goals in caring for their condition • Given choices about treatment to think about • Asked about their ideas when making a treatment plan	Patient reported questionnaire	Patient Assessment of Chronic Illness Care [22]
26	**Respect and empathy** [e]**:** Chronic disease patients' satisfaction with the level of attention, empathy, and respect of private life that is demonstrated by their primary care provider	Patient reported questionnaire	Primary Care Assessment Survey [2] European Task Force on Patient Evaluations of General Practice Care (EUROPEP) [23] Canadian Institute of Health Information [1]
27	**Time available during the consultation** [e]**:** Chronic disease patients' satisfaction with : • Time available during the consultation • Patience of primary care providers regarding to address their questions and preoccupations	Patient reported questionnaire	Primary Care Assessment Survey [2]
28	**Trust towards primary care provider** [e]**:** Chronic disease patients report that they have trust in: • Their primary care provider and hi/her judgment • The fact their primary care provider always tells them the truth • The fact their primary care provider truly cares about their health	Patient reported questionnaire	Primary Care Assessment Survey [2]
29	**Stress and responsibilities at work and at home** [e]**:** Primary care providers have discussed chronic disease patients' stress, preoccupations, and responsibilities at work and at home	Patient reported questionnaire	Primary Care Assessment Survey [2] General Practice Assessment Survey [24] Agency for Healthcare Research and Quality [25]

e. "Doctor" in the original indicator set has been changed for "primary care provider".

OUTCOMES

Nº	Quality indicator	Source	Reference
30	**Fruit and vegetable consumption rate:** % of population, 12 years and over, who currently consume five or more servings of fruits and vegetables daily	Population Survey	Canadian Institute of Health Information [1]
31	**Smoking rate:** % of population, 12 years and over, who are current smokers	Population Survey	Canadian Institute of Health Information [1]
32	**Physical activity rate:** % of population, 12 years and over, who currently engage in regular physical activity	Population survey	Canadian Institute of Health Information [1]
33	**Blood pressure control:** % of patients identified as hypertensive for longer than 12 months whose most recent blood pressure was at target: • Below 140/90 for nondiabetics • Below 130/80 for diabetics or patients with renal disease • Below 125/75 for patients with proteinuria	Medical file	Canadian Cardiovascular Outcomes Research Team [10]
34	**Perceived self-efficacy:** Chronic disease patients trust in their ability to: • Limit the impact of fatigue, pain, and emotional distress caused by their disease on their daily life • Do the different activities needed to manage their health condition and reduce their need to see a doctor • Do things other than taking medication to reduce the impact of illness on their daily life	Patient reported questionnaire	Standford Self-Efficacy 6-item Scale [26]
35	**Hospitalization for ambulatory care sensitive conditions:** Age standardized acute care hospitalization rate for conditions where appropriate ambulatory care prevents or reduces the need for admission to hospital in population 75 years and under: • diabetes • angina • chronic obstructive pulmonary disease • heart failure (Excluding cases where inter-hospital transfer or death occurs during admission)	Administrative data	Canadian Institute of Health Information [1]
36	**Emergency room visits for ambulatory care sensitive conditions:** % of primary care patients, ages 20 to 75 years, with congestive heart failure, diabetes, COPD, or angina who visited the emergency department for a decompensation/exacerbation of their condition in the past 12 months	Administrative data	Canadian Institute of Health Information [1]
37	**Quality of life:** Chronic disease patients' perception of the impact of their chronic condition on their quality of life	Patient reported questionnaire	Minnesota Living with Heart Failure Questionnaire [27] Chronic respiratory Disease Questionnaire [28] Audit of Diabetes-Dependent Quality of Life [29] The Medical Outcomes Study Short Form 36 (SF-36) [30]

Original indicator sets

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Chapter 9

Involving patients in setting clinical priorities for healthcare improvement: a cluster randomized trial

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Submitted.

Abstract

***Background**:* There is growing consensus that patients should be involved in healthcare improvement. While a large body of research supports shared decision-making at the individual clinical level, no trial of patient involvement in health decisions at the population level has been conducted. We assessed the impact of patient involvement in setting clinical priorities for healthcare improvement.

Method: We conducted a cluster randomized controlled trial involving 172 participants (83 chronic disease patients and 89 health professionals) from 6 local health authorities in Canada. In the intervention group, patients and professionals selected clinical priorities from a list of 37 validated quality indicators. Patients: 1) received formal training; 2) were consulted by vote; and 3) participated in a two-day deliberation meeting with health professionals. Local health authorities included the selected priorities in their accountability contract. In the control group, health professionals selected priorities among themselves, without patient involvement. The primary outcome was the agreement between patients' and professionals' final priorities.

***Results**:* Agreement between patients' and professionals' priorities was significantly stronger in intervention sites (correlation coefficient 0,69 vs. 0,19, $p<0.001$). Patient involvement fostered mutual influence between patients' and professionals' choices. Priorities in intervention sites focused on self-care support and access, as opposed to the technical quality of disease management. Health professionals perceived the selected priorities as realistic and actionable. The marginal costs of public involvement represented 17% of total project costs.

***Interpretation**:* Structured patient involvement increases agreement between patients' and professionals' priorities, is affordable, and can be implemented locally to drive change at the clinical level.

Introduction

There is a growing consensus towards the need to actively involve patients in health services delivery to improve responsiveness to individuals and communities.[1] More specifically, the epidemic of chronic disease highlights patients' role as partners in healthcare improvement.[2,3] A number of interventions have been found effective to strengthen patient involvement and support more productive interactions with health professionals.[4-12]

While a significant body of research supports patient involvement and shared decision-making at the individual clinical level, extending patient-professional partnership to healthcare improvement and policy decisions at the population level poses a number of challenges.[13-18] First, the feasibility of involving patients in complex healthcare improvement decisions is of concern. Lack of understanding of scientific literature or resource implications could lead to unrealistic expectations. Recruiting participants who are representative of "ordinary patients" and disadvantaged socio-economic groups is also a barrier to meaningful involvement.[17] Finally, while patient involvement is widely advocated, claims of benefits are not grounded in solid research. To date, no trial has documented the impact of patient involvement on healthcare improvement and policy decisions and there is "a huge gap in the evidence from comparative studies about desirable and adverse effects of consumer involvement in healthcare decisions at the population level".[14-18]

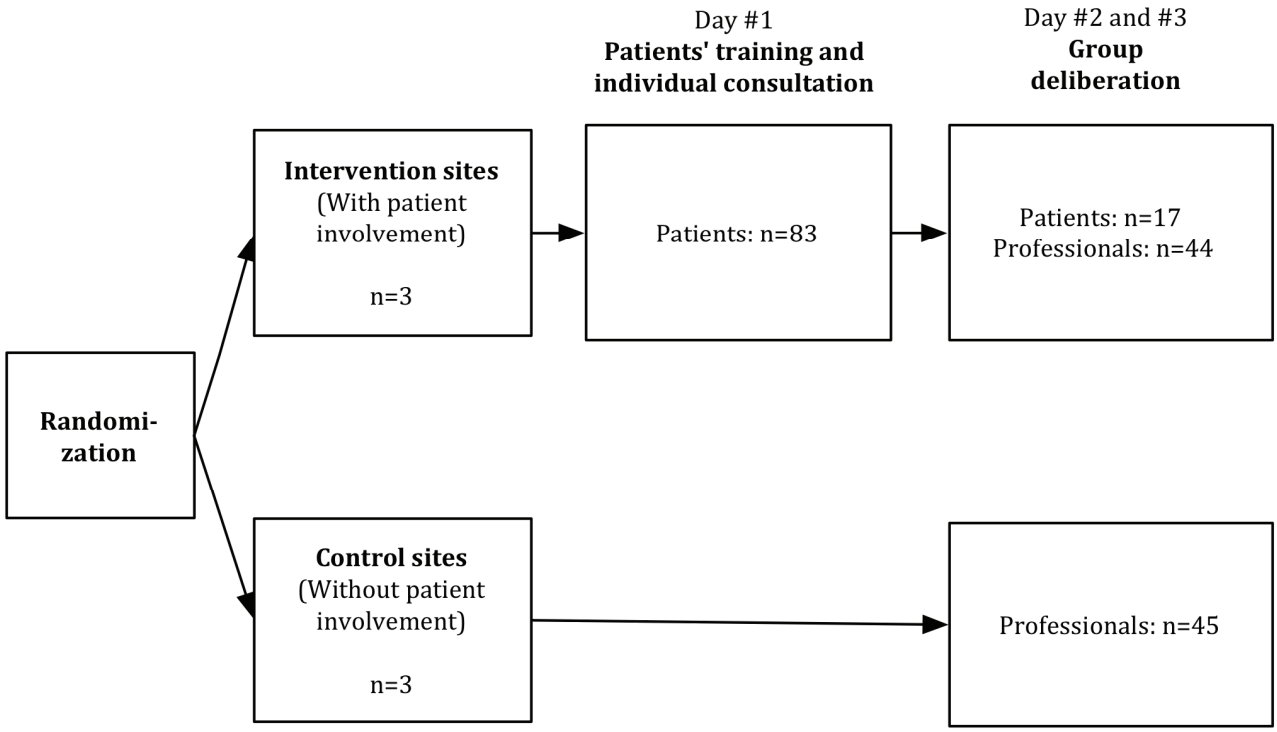
Our study thus sought to fill a pressing knowledge gap by assessing the impact of patient involvement in setting clinical priorities for healthcare improvement, and describe how patients and professionals influence one another in the process of choice. Our main hypothesis was that structured patient involvement would result in clinical priorities that better agreed with patients' priorities.

Methods

Design and study setting

We conducted a cluster randomized controlled trial comparing clinical priority-setting with and without patient involvement. Local health authorities in the region of Abitibi-Témiscamingue, Quebec, Canada, were used as our unit of randomization (Figure 1). Local health authorities assume responsibility for supporting health services delivery on their territory, and direct primary care services for chronic disease patients are mostly provided by family physicians, nurses and allied health professionals. Our detailed study protocol has been published elsewhere.[19]

Figure 1. Trial overview



In intervention sites, clinical priorities are selected by patients and professionals, while prioritization in control sites is done by professionals only.

Identification of quality indicators used as clinical priorities

Trial participants were required to select clinical improvement priorities from a "menu" of quality indicators, which are defined as measurable elements of clinical practice structure, process, or outcome for which there is evidence or consensus that they can be used to assess quality of care.[20] We conducted a systematic review of validated quality indicators for chronic disease prevention and management in primary care[19], including diabetes, chronic obstructive pulmonary disease, and cardiovascular disease.

We identified a total of 1489 individual quality indicators, 801 of which met our inclusion criteria. An expert panel agreed on a preliminary set of indicators that was measurable with existing information systems and relevant for primary care. This preliminary indicator set was tested for comprehensiveness with a group of 9 patients and 11 professionals. The final "menu" of indicators is composed of 37 items grouped into 5 quality domains: access, integration, technical quality, interpersonal care, and outcomes (www.implementationscience.com/content/6/1/45/additional).[19]

Intervention

Patient involvement interventions can be classified in three categories: communication (where information is communicated *to* patients), consultation (information is collected *from* patients), and participation (information is exchanged *between* patients and experts).[21] We tested a mixed involvement intervention where: 1) all patients received formal training; 2) they were individually consulted by vote on their priorities; and 3) a subgroup of available patients participated in a two-day deliberation meeting with professionals to agree on common clinical improvement priorities through feedback of individual public consultation, group deliberation, and voting.[22] Each Local Health Authority was allowed to select their own clinical improvement priorities, which were integrated in their financial accountability contract with the Regional Health Authority and communicated to all participants after the trial was completed.

An expert moderator facilitated all meetings with two co-moderators. Between January and September 2010, we pilot tested our intervention with 27 patients and professionals and tested our study instruments with an additional 21 people.[19] The study was completed in May 2011.

Control

In control sites, clinical prioritization was done as in intervention sites, but was done by health professionals only, without patient involvement. We found no evidence of contamination between the intervention and control sites, which are more than 100 km apart from one another.

Recruitment and randomization

We sought to recruit adult patients targeted by chronic disease prevention and management, including: 1) patients without chronic disease; 2) patients with uncomplicated chronic disease (diabetes, chronic obstructive pulmonary disease, or cardiovascular disease); 3) patients with complex chronic conditions (hospitalized in the previous year). Patients who trained or worked as a health professional were excluded.

Within each site, we created recruitment teams composed of the medical director, the local chief executive officer, a manager in charge of chronic disease services, and a patient sitting on the local health authority's user committee. Recruitment teams were responsible for identifying a diversified pool of potential participants through purposive sampling and snowballing techniques.[23] A blinded research assistant

contacted potential participants, collected socio-demographic characteristics, confirmed their eligibility criteria, and selected participant based on pre-defined criteria to ensure a balanced representation of age, gender, socio-economic background, and health status.

Professionals were identified by our local recruitment teams and selected by a blinded research assistant to include a balanced group of clinicians and managers involved in chronic disease prevention and management, including: 1) primary care physicians, 2) allied health professionals directly involved in patient care, 3) managers responsible for chronic disease services and existing information systems, and 4) the chief executive officer of each Local Health Authority.

We sought to recruit the whole population of available study sites in the region (Target=6 Local Health Authorities) and a maximum number of participants per meeting (Target=15 participants/meeting). Blocked randomization of study sites was done after recruitment of all individual participants.[24] The random allocation sequence was generated with an independent expert, through randomization software.[25] It was impossible to mask study site allocation after randomization was performed, and participants were thereafter unblinded to their assignment.

Data collection and analysis

The primary outcome was the agreement between patients' and professionals' final clinical improvement priorities. Secondary outcomes included changes in patients and professionals' priorities, final group priorities, professionals' intentions to use the selected priorities for healthcare improvement, and the marginal cost of patient involvement. At baseline and at the end of the trial, each participant was asked to identify five priorities for clinical improvement from the quality indicator menu. Individual priorities were analyzed as a dichotomous measure by calculating the proportion of participants who selected each indicator. Descriptive statistics were used to compare individual priorities in intervention and control sites, and to calculate their rank (rank #1=indicator selected by the greatest proportion of participants). Agreement between patients' and professionals' priorities was calculated using Spearman correlation coefficient. We used multi-level analysis to account for clustering of correlation scores.[26] Statistical differences in correlation coefficients between intervention and control sites were tested using Fisher r-to-z transformation and were assumed to be significant at $p<0.05$ (two-tailed test).[27] Group priorities were analyzed descriptively.

Professionals' intentions to use the selected priorities for healthcare improvement were collected at the end of the trial from an 11-item questionnaire measuring their perception of the credibility, feasibility, and importance of the selected group priorities, as well as their intention to use them for healthcare improvement. Each item was scored on a 7-point Likert scale and analyzed descriptively. We calculated the marginal costs of patient involvement (recruitment, training, and compensation of patients' representatives) in relation with total project costs (costs of patient involvement, health professionals' salary, quality indicator menu development, moderation of meetings, and project coordination). All costs were calculated from the sponsoring organization's perspective and assumed an average of 15 patient representatives per training meeting and 5 patient representatives per deliberation meeting. All statistical analyses were conducted with SPSS version 19.

Results

172 individuals from the 6 eligible sites participated in the study, including health professionals (n=89) and patients (n=83). Study sites and professionals' characteristics were similar in intervention and control groups (Table 1). Patients involved in intervention groups were statistically representatives of chronic disease adults in Canada in terms of age, gender, education, and income.[28] 58% of the patients had primary or high school education, 56% had an annual household income of less than 40 000$, 81% was diagnosed with at least one chronic condition, and 24% had been hospitalized at least once in the past year. All 83 patients participated in the training and individual consultation and 17 of them participated in group deliberation with health professionals. All patients completed the study, one professional did not.

Table 1. Study sites' and individual participants' characteristics

Sites' characteristics	**Intervention (n=3)**		**Control (n=3)**	
Average population size	25 002		23 610	
Family physician/population ratio	1 / 771		1 / 789	
% population 65 years or above	15,6%		13,4%	
% population with low income	12,3%		11,3%	
% population with diabetes	6,5%		6,5%	
Professionals' characteristics	**Intervention**		**Control**	
	n=44	**(%)**	**n=45**	**(%)**
Age				
20 to 44 years	21	(47,7)	19	(48,7)
45 to 64 years	20	(45,5)	20	(51,3)
65 years or above	3	(6,8)	0	(0,0)

Professionals' characteristics	**Intervention**		**Control**	
	n=44	**(%)**	**n=45**	**(%)**
Gender				
Male	9	(20,5)	10	(23,3)
Female	35	(79,5)	33	(76,7)
Type of work				
Primary care physician	6	(13,6)	6	(13,3)
Nurse	11	(25,0)	10	(22,2)
Allied health professional	11	(25,0)	14	(31,1)
Manager	16	(36,4)	15	(33,3)
Patients' characteristics	**Intervention**			
	n=83	**(%)**		
Age				
20 to 44 years	12	(14,6)		
45 to 64 years	44	(53,7)		
65 years or above	26	(31,7)		
Gender				
Male	36	(43,4)		
Female	47	(56,6)		
Family income				
Less than 20 000 $	16	(20,0)		
From 20 000 $ up to 39 999 $	29	(36,3)		
From 40 000 $ up to 59 999 $	13	(16,2)		
60 000 $ or more	22	(27,5)		
Education level				
Primary school	12	(14,8)		
High school	35	(43,2)		
College or University	34	(42,0)		
Diagnosed with chronic condition(s)				
Arthritis	13	(15,7)		
Cardiovascular disease	24	(28,9)		
Chronic pain	11	(13,3)		
Diabetes	30	(36,1)		
Dyslipidemia	22	(26,5)		
Hypertension	30	(36,1)		
Mood disorder	9	(10,8)		
Pulmonary disease	17	(20,5)		
Other	24	(28,9)		
Hospitalizations in the past 12 months				
0	62	(76,5)		
1	10	(12,4)		
2 or more	9	(11,1)		

Agreement between patients' and professionals' priorities

We found a statistically significant difference in agreement between patients' and professionals' final priorities, with an absolute difference of 50% favoring intervention sites (correlation coefficient 0,69 vs. 0,19, $p<0.001$) (Table 2).

Table 2. Agreement between patients' and professionals' priorities

		Baseline priorities	Final priorities
Intervention	Mutual agreement between patients and professionals	0,27	0,69***
	Professionals' influence on patients' final priorities		0,50
	Patients' influence on professionals' final priorities		0,36
Control	Mutual agreement between patients and professionals	0,18	0,19
p value		0,62	<0.001

Agreement between patients' and professionals' priorities, calculated using Spearman's correlation coefficients (0=no correlation, 1=perfect correlation). p value for the difference between agreement in intervention and control group is calculated using Fisher r-to-z transformation (two-tailed test), with correction for clustering. ***p<0.001.

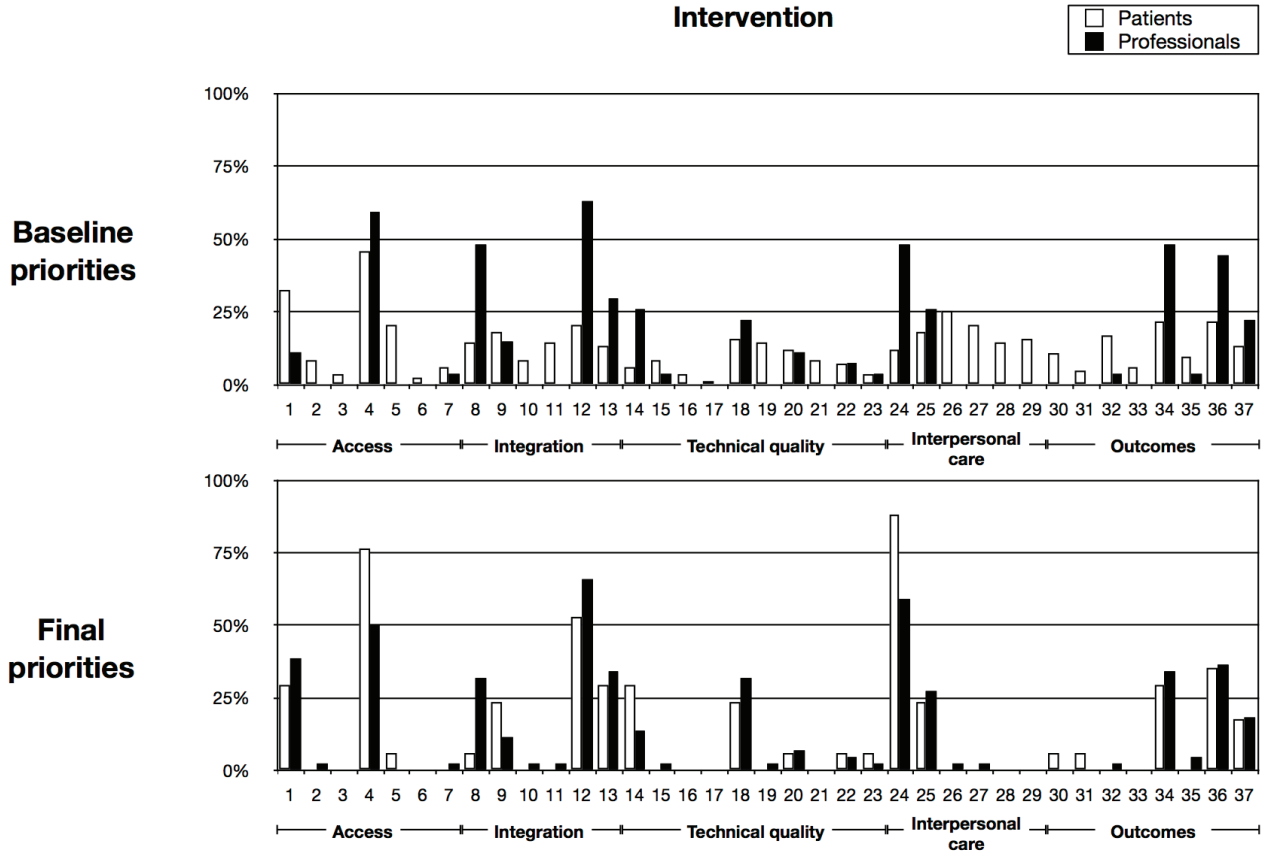
In intervention sites, increased agreement was explained by mutual influence between patients' and professionals' priorities (Figure 2). As the intervention progressed, patients' priorities moved towards indicators of high priority for professionals. For example, as a result of their interaction with professionals, the proportion of patients who prioritized self-care support rose from 12% (rank #20) to 88% (rank #1). Similarly, deliberation with patients led to increasing professional support for patients' clinical priorities. For example, "difficulty to obtain an appointment with a primary care provider" was one of patients' top two priorities at baseline and its support among intervention sites professionals rose from 16% (rank #10) to 36% (rank #4) between baseline and the end of the trial. In control sites, we did not observe any change or convergence in professionals' priorities.

Final priorities in intervention and control sites

Common priorities identified by professionals and patients in intervention sites focused on generic aspects of chronic disease prevention and management, such as self-care support, access to a primary care professional, interdisciplinary teams, and partnership with community organizations (Table 3). Priorities selected in control sites by professionals alone placed more emphasis on emergency room visits, collaboration between healthcare organizations, and the technical quality of disease management.

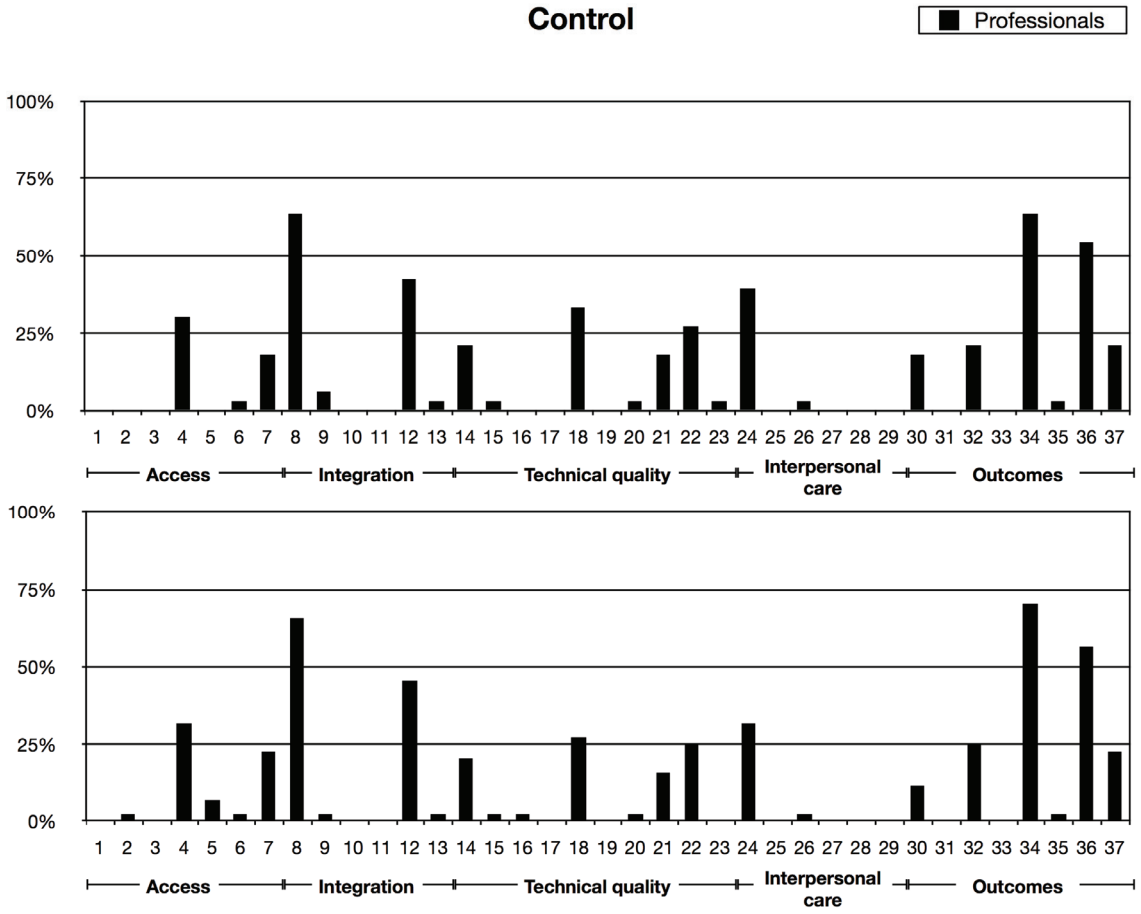
At the end of the trial, all intervention sites selected one of patients' top two priorities on access to a primary care professional for inclusion in their financial accountability contract, while none of the control sites did.

Figure 2. Change in patients' and professionals' baseline and final priorities



	Quality Indicators
	Access
1	Difficulty to obtain an appointment with a primary care provider
2	Primary care organization's opening hours
3	Access for disabled people
4	Family physicians accepting new patients
5	Medication and treatment cost
6	Language barriers
7	Phone access to a primary care provider
	Integration
8	Collaborative care with other health organizations
9	Electronic communications
10	Primary care registries for chronic conditions
11	Perceived continuity of care
12	Team work and interdisciplinary care
13	Partnerships with community organizations
	Technical quality of prevention and clinical management
14	Physical activity counseling
15	Healthy eating counseling
16	Tobacco counseling
17	Influenza vaccination for high-risk groups

Proportion of patients (white) and professionals (black) who selected each priority at baseline and at the end of the trial.



	Quality Indicators
18	Blood pressure screening
19	Perception of the technical quality of care received
20	Clinical management of type 2 diabetes
21	Clinical management of coronary heart disease
22	Clinical management of chronic obstructive pulmonary disease
23	Clinical management of heart failure
	Interpersonal care
24	Self-care support
25	Participation in clinical decision-making
26	Respect
27	Time available during the consultation
28	Trust toward primary care provider
29	Primary care provider consideration of stress and responsibilities
	Outcomes
30	Fruit and vegetable consumption rate
31	Smoking rate
32	Physical activity rate
33	Blood pressure control
34	Perceived self-efficacy
35	Hospitalization rate for diabetes, angina, COPD, or heart failure
36	Emergency room visit for diabetes, angina, COPD, or heart failure
37	Quality of life

Table 3. Final clinical care priorities in intervention and control sites

Quality Indicators	Intervention (n=61)		Control (n=45)	
	Rank	(%)	Rank	(%)
Access				
Difficulty to obtain an appointment with a primary care provider	4	(36,1)	14	(0,0)
Primary care organization's opening hours	14	(1,6)	13	(2,3)
Access for disabled people	15	(0,0)	14	(0,0)
Family physicians accepting new patients	3	(57,4)	5	(31,8)
Medication and treatment cost	14	(1,6)	12	(6,8)
Language barriers	15	(0,0)	13	(2,3)
Phone access to a primary care provider	14	(1,6)	8	(22,7)
Integration				
Collaborative care with other health organizations	8	(24,6)	2	(65,9)
Electronic communications	10	(14,8)	13	(2,3)
Primary care registries for chronic conditions	14	(1,6)	14	(0,0)
Perceived continuity of care	14	(1,6)	14	(0,0)
Team work and interdisciplinary care	2	(62,3)	4	(45,5)
Partnerships with community organizations	5	(32,8)	13	(2,3)
Technical quality of prevention and clinical management				
Physical activity counseling	9	(18,0)	9	(20,5)
Healthy eating counseling	14	(1,6)	13	(2,3)
Tobacco counseling	15	(0,0)	13	(2,3)
Influenza vaccination for high-risk groups	15	(0,0)	14	(0,0)
Blood pressure screening	6	(29,5)	6	(27,3)
Perception of the technical quality of care received	14	(1,6)	14	(0,0)
Clinical management of type 2 diabetes	11	(6,6)	13	(2,3)
Clinical management of coronary heart disease	15	(0,0)	10	(15,9)
Clinical management of chronic obstructive pulmonary disease	12	(4,9)	7	(25,0)
Clinical management of heart failure	13	(3,3)	14	(0,0)
Interpersonal care				
Self-care support	1	(67,2)	5	(31,8)
Participation in clinical decision-making	7	(26,2)	14	(0,0)
Respect	14	(1,6)	13	(2,3)
Time available during the consultation	14	(1,6)	14	(0,0)
Trust toward primary care provider	15	(0,0)	14	(0,0)
Primary care provider consideration of stress and responsibilities	15	(0,0)	14	(0,0)
Outcomes				
Fruit and vegetable consumption rate	14	(1,6)	11	(11,4)
Smoking rate	14	(1,6)	14	(0,0)
Physical activity rate	14	(1,6)	7	(25,0)
Blood pressure control	15	(0,0)	14	(0,0)
Perceived self-efficacy	5	(32,8)	1	(70,5)
Hospitalization rate for diabetes, angina, COPD, or heart failure	13	(3,3)	13	(2,3)
Emergency room visit for diabetes, angina, COPD, or heart failure	4	(36,1)	3	(56,8)
Quality of life	9	(18,0)	8	(22,7)

Final clinical improvement priorities in intervention and control sites. Ranks are calculated from the proportions (%) of participants who selected each priority (rank #1=prioritized by the highest proportion of participants).

Professionals' intention to use the selected priorities

We found no evidence of a negative impact of patient involvement on professionals' intention to use the selected priorities for healthcare improvement. Professionals' perception of the credibility, feasibility, and importance of the clinical priorities, as well as their intention to use them for healthcare improvement, scored high in both intervention and control groups (average scores between 1,15 and 1,94 on a 7-point Likert scale).

Costs of prioritization

The direct costs of patient involvement were on average 9 427$ per site. Most of these costs were incurred by coordination of patient recruitment (29%), as well as by patient training and consultation (44%). The marginal costs of patient involvement represented 17% of the total project costs.

Interpretation

This is the first trial documenting the impact of patient involvement in healthcare decisions at the population level.[14-16] We have found that structured patient involvement increases agreement between patients and professionals, is affordable, and can be implemented locally to drive change at the clinical level. Our results show how professionals and patients can extend their partnership beyond the consultation room, and engage together in shared decision-making over healthcare improvement and policymaking. Our study tackles important knowledge gaps on how patients can effectively be involved in setting concrete and measurable priorities to improve clinical care for major chronic diseases.

This study is important as it addresses several concerns expressed by physicians and policymakers who are seeking effective ways to engage with patients in healthcare improvement and policy decisions.[14-17] We have found that a structured involvement intervention fosters mutual influence and changes both patients' and professionals' clinical priorities. Our findings suggest that deliberation offers a learning opportunity for patients and professionals, resulting in priorities that are perceived as realistic and actionable. We have also found that it is possible for patients to have a real impact on group decision-making and influence professionals' opinion in strategic aspects of clinical care. Shared priorities identified by patients together with professionals focused on generic aspects of chronic disease management as opposed to the technical quality of disease management (e.g., HbA1C testing for diabetes patients), an interesting aspect of findings given the fact that clinical practice

guidelines and healthcare improvement activities tend to focus on these technical dimensions of quality. The fact that all intervention sites selected final priorities related to access with a primary care professional, while none of the control site did, is significant as this aspect of care scored highest among patients' concerns and is a well recognized target for healthcare improvement in Canada.[28] Patients have also changed their view and showed a more positive attitude toward self-care support as a result of their interaction with professionals. Overall, these findings suggest that involving patients together with health professionals in clinical priority setting could increase healthcare responsiveness to patients' most pressing needs and foster more productive patient-professional partnership at the individual clinical level.

Successful testing of this intervention in real-world priority setting and our ability to recruit a balanced group of patients – including people with complex chronic conditions and from lower socioeconomic groups – strongly supports the feasibility of involving patients in complex healthcare improvement and policy decisions. Conversely, the disconnect we observed between professionals' and patients' priorities in control sites illustrates documented difficulties for professionals alone to presume and address issues that are most important for patients.[29-31]

Small sample sizes are hard to overcome in studies of patient and public involvement in healthcare decisions at the population level, given the maximum number of participants who can meaningfully participate in small-group deliberation meetings.[18] While the study was sufficiently powered to test our primary hypothesis, it is limited in its ability to explore secondary research questions. Also, patient involvement is a context-sensitive intervention influenced by socio-political and organizational factors.[32] Our intervention benefited from high-level policy support and was implemented within relatively small communities with moderate health services integration. It is unknown whether the observed impact can be generalized to other settings, although our study sites shared many features of primary care organizations and chronic disease management programs elsewhere in Canada and in other developed countries.[33]

Conclusion

Structured patient involvement increases agreement between professionals' and patients' priorities, is affordable, and can be implemented locally to drive change at the clinical level. Involving patients together with health professionals in clinical priority setting could increase healthcare responsiveness to patients' most pressing needs and foster more productive patient-professional partnership.

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Chapter 10

What are the key ingredients for effective public involvement in healthcare improvement and policy decisions? A randomized trial process evaluation

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Submitted.

Abstract

Context: Individual patient involvement at the clinical consultation level has received considerable attention in the past fifty years. More recently, policymakers have become increasingly interested in involving patients and the public in collective decisions on healthcare improvement and policymaking. However, rigorous evaluation is lacking to guide the development of effective involvement interventions. This article seeks to describe the key ingredients of a successful public involvement intervention by explaining why and how it proved effective.

Method: We conducted the process evaluation of a cluster randomized trial of public involvement in setting clinical priorities for healthcare improvement. 172 participants (including 83 public representatives and 89 decision-makers) from 6 local health authorities in Canada participated in the trial. 14 one-day meetings were video recorded while two non-participant observers gathered structured notes. Qualitative analysis sought to elucidate the effects of the intervention's components and their dynamic relationships.

Findings: Public representatives' legitimacy, credibility, and influence on group decisions was supported by recruitment of a balanced group of participants, structured training fostering public representatives' identity-building and ability to draw from others' experience; a moderation style that facilitated the expression of dissenting voices; as well as the combination of direct public participation in small group deliberation, wider public consultation, and public communication of group decisions. Engagement of key stakeholders in negotiations as to how patient involvement would be operationalized in practice helped build local policy support for public involvement.

Conclusions: Public involvement interventions incorporate a number of interacting active ingredients that frame and foster the public's legitimacy, credibility and influence on collective decisions. More attention to these key ingredients can support more effective public involvement interventions, and increase agreement between decision-makers and the public over healthcare improvement and policy decisions.

Introduction

In the past fifty years, patient involvement at the individual clinical consultation level has received considerable attention through the development of patient-centred medicine, self-care, and shared decision-making.[1-6] The growing epidemic of chronic diseases has also led to the recognition that patients make day-to-day decisions about the management of their own health and can be engaged as active partners in clinical care.[7] More recently, policymakers have become increasingly interested in extending this partnership to collective decisions about healthcare improvement and policymaking.[8] For example, patient and public involvement is now considered the norm in clinical practice guideline development and quality improvement by many national and international organizations, and is increasingly being seen as an important component of clinical priority setting, health technology assessment, comparative effectiveness research, and health governance.[9-20]

How to effectively involve patients in health decisions at the population level remains however a major challenge.[5,6,17,21-23] First, concerns have been raised regarding the recruitment of participants who are representative of "ordinary" patients, and about the difficulty to reach people from lower socio-economic backgrounds.[24,25] A second problem is the feasibility of involving patients in complex healthcare decisions and the risk that participants may not understand the available scientific literature or may be unaware of clinical and resource implications. Considerable uncertainty also exists regarding the actual influence that patients can have on group decision-making. Systematic reviews have consistently highlighted "a huge gap in the evidence from comparative studies about desirable and adverse effects of consumer involvement in healthcare decisions at the population level".[22] Many critics have thus argued that patient involvement, despite rhetorical claims about its benefits, often remains merely tokenistic.

Taken together, these issues pose a major challenge for decision-makers. On the one hand, healthcare organizations are increasingly required to involve patients in key aspects of their operations. On the other hand, policymakers cannot find reliable guidance on the design of effective involvement interventions from the literature.[26-29] As a result of their extensive review of the available evidence, Abelson and colleagues note that "the literature is still mainly characterized by a combination of practice stories that are heavy on contextual learning but light on causal mechanisms, and experimental studies that are implemented in a theoretical vacuum".[30] These authors recommended to address current knowledge gaps by: 1) defining public participation mechanisms more consistently; 2) linking empirical research with theory and pre-

specified hypothesis; 3) using multidisciplinary perspectives and mixed research methods in evaluation designs; and 4) conducting research on real-world involvement interventions.[31] Process evaluation of experimental studies offers an appropriate study design to address such gaps, generating a better understanding of why a particular public involvement intervention may prove effective by focusing on its internal dynamics and actual operations.[32,33] By reporting the findings of such a process evaluation, the aim of this paper is to provide guidance for policymakers on the design of effective involvement interventions.

We recently conducted the first trial of public involvement in healthcare improvement and policymaking.[17,21-23,30,34] This trial demonstrated that structured public involvement increased agreement between patients and decision-makers, resulting in clinical priorities that are seen as realistic and actionable.[35] Participants' perception of the quality of the involvement process also scored high. We therefore concluded that our involvement intervention was successful, both in terms of the quality of the involvement process and of its impact on collective decisions on healthcare improvement. In this paper, we mobilise process evaluation data gathered alongside this trial to learn and reflect empirically and theoretically on the key ingredients that influence both the process and outcomes of public involvement in healthcare improvement and policymaking.

The paper is divided in three sections. We first provide an overview of the literature on public involvement interventions' components and internal dynamic. Using the empirical material collected from our trial's process evaluation (e.g., video recordings and direct observation), we then describe how decision-makers and the public engaged in a complex public involvement intervention. This qualitative analysis focuses on the "active ingredients" of public involvement and their relationships, in order to explain why and how the intervention proved effective. We finally discuss our results in relation to the existing literature to reflect on how the public's credibility, legitimacy, and influence can be fostered by structured involvement interventions. For the purpose of the article, we use the term "public" to refer to patients, caregivers, family members and other people affected by healthcare services and policies. Our focus is on public involvement in "collective" decisions on healthcare improvement and policymaking, as opposed to individual patient involvement in clinical decision-making.[8]

Components and internal dynamics of public involvement interventions

Existing typologies of public involvement embody certain assumptions and hypotheses about what public involvement interventions are "made of" (their principal components) and "how they are expected to work" (their internal dynamic).[36-40] Arguments supporting public involvement can be grouped in technocratic justifications – which emphasize the importance of the public's knowledge and their credibility as "experts" – and democratic justifications, which focuses on the public's legitimacy to speak on behalf of a wider constituency.[24]

Technocratic arguments justify public involvement on the basis of the public's ability to demonstrate credible expertise to contribute to collective decision-making. Rowe and Frewer contend that information sharing is the core process underlying public involvement and classifies those interventions according to the flow of information: communication methods (where information is communicated to the public), consultation (information is collected from the public), and participation (information is exchanged between the public and decision-makers).[41] Table 1 presents selected examples of public involvement methods used in healthcare improvement and policy, based on this typology.

Table 1. Examples of public involvement in healthcare improvement and policymaking

Involvement strategy	Methods used in healthcare improvement and policymaking
Communication (information is communicated *to* the public)	• Public reporting of quality indicators and performance measures • Dissemination of patient education material, lay version of policy documents
Consultation (information is collected *from* the public)	• Satisfaction surveys and complaint systems • Questionnaires on patients' experience of care • Open consultation and comments on draft clinical practice guidelines, health technology appraisal reports, or other policy documents
Participation (information is exchanged *between* the public and decision-makers)	• Public representation in expert committees and advisory boards • Consensus conference • Citizen jury • Town hall meetings

Such "information flow" perspective is particularly developed in deliberative theories, which anchor democratic concerns about public policymaking around the careful weighing of reasons for and against some proposition.[42] The core underlying hypothesis of deliberative theories is that the exchange of reasonable arguments between members of the public and other experts should result in mutual learning between participants and the generation of solutions that can be rationally justified to those affected by it.[43-46] From this perspective, participants' adherence to fair procedural rules and access to the best available evidence through training and

preparation are seen as critical factors for successful deliberation, ensuring that valid and relevant information are collected and exchanged between competent participants.[41,47]

Collins and Evans contend that members of the general public are "experience-based experts" whose knowledge is based on their personal experiences (e.g. as patient with a specific health condition and experience with healthcare services) rather than based on degrees and professional qualifications.[48] *Contributory expertise* refers to the public's ability to bring credible and relevant knowledge that can contribute to the decision at hand. Conversely, public members displaying *interactional expertise* would be able to interact with other forms of expertise held by health professionals and decision-makers (e.g. to understand the language of critical literature appraisal or health economics) without necessarily contributing to this specific aspect of deliberation. From a technocratic perspective, a core question underlying the design of effective public involvement interventions would then be to identify what specific knowledge and experience public members are expected to contribute to collective decisions, and what forms of expertise they require to interact meaningfully with other decision-makers.

While technocratic justifications of public involvement focus on the public's ability to contribute credible and relevant expertise, democratic justifications focus on the *legitimacy* of the public to represent people affected by collective healthcare decisions. The construction of the public's ability to speak on behalf of others is recognized as a critical factor influencing the impact of the public on policy decisions.[26,45,49-52] Judging the public's legitimacy requires paying close attention to the social practice of public involvement and the political and organizational context in which "divergent notions of representativeness are deployed in pursuit of differing roles for public participation".[49] Observations of real-life involvement interventions have indeed suggested that different criteria are used by decision-makers to support (or question) the public's legitimacy, such as the statistical representativeness of participants, the use of delegation and accountability mechanisms (such as formal nomination and elections), as well as participants' personal connections to other members of the public.[49,50,52]

In summary, the current literature points towards the need to look in more details at how public involvement interventions frame and foster the public's legitimacy and credibility, which are in turn seen as critical determinants of their influence on collective decisions. This requires clarifying whom are public representatives speaking for and what specific expertise are they expected to contribute to collective

decision-making. Several authors suggest that issues over the public's credibility and legitimacy are subject of ongoing negotiations among different stakeholders whose interests may be fostered or challenged by public involvement.[19,50,51] A potential tension can exist between conceptions of legitimacy that emphasize the need to involve "ordinary" or "lay" public members, and the competence required for the public to meaningfully contribute to complex healthcare improvement and policy decisions.[24] Exploring these tensions requires opening the "black box" of public involvement to understand why and how these interventions work. By looking at what happens in real-life settings wherein members of the public interact with other experts, and by mobilizing a theory-informed understanding of the key processes at play, one could more fully grasp why certain outcomes are likely to be obtained.

Methods

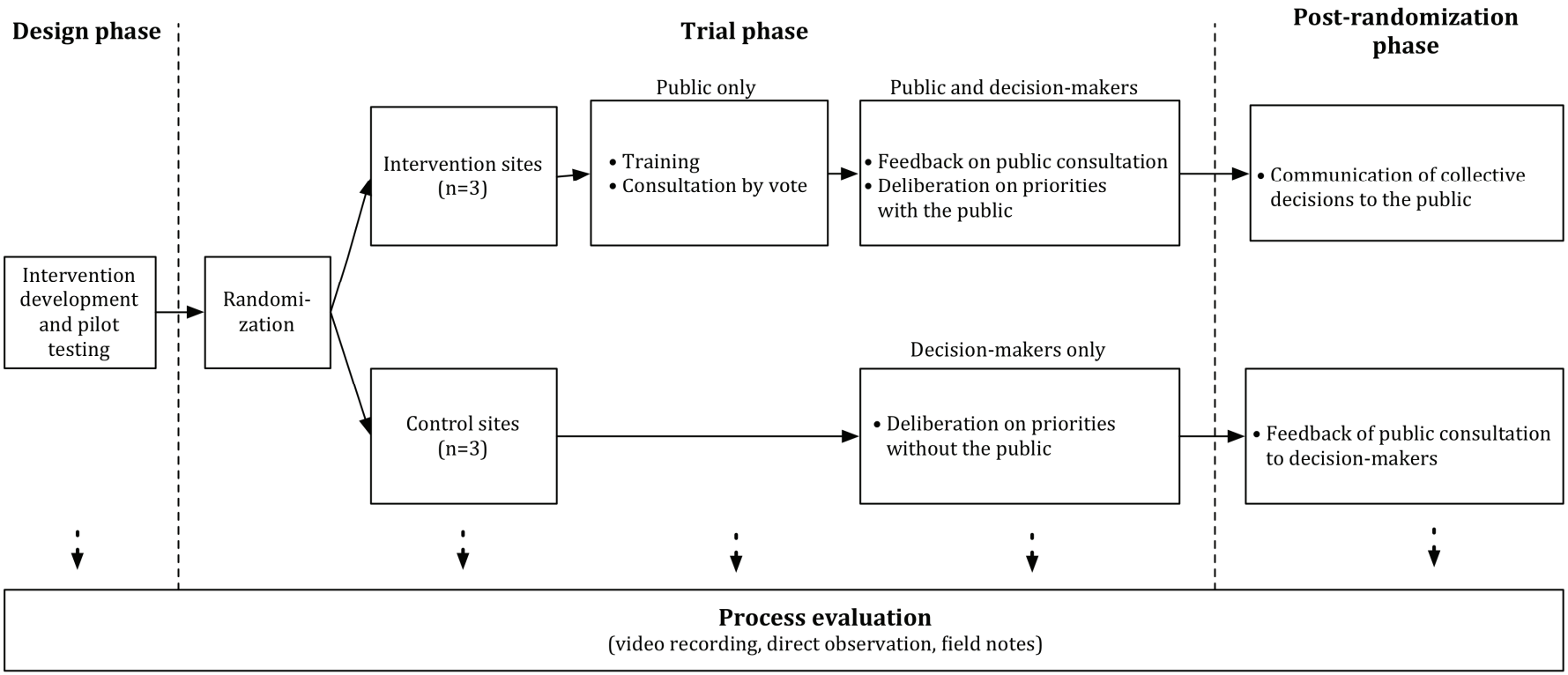
We conducted a qualitative process evaluation of a public involvement cluster randomized trial. Six local health authorities in Canada were randomized in intervention and control sites. 172 participants, including 83 chronic disease patients ("public representatives") and 89 clinicians and managers ("decision-makers"), were asked to select local clinical care priorities from 37 validated chronic disease quality indicators. In intervention sites, public representatives: 1) received formal training; 2) were consulted by vote; and 3) participated in a two-day meeting with decision-makers to agree on local healthcare improvement priorities, through feedback of individual public consultation, group deliberation, and voting. Public representatives were recruited by local recruitment teams through snowballing technique and purposive sampling, to ensure a balanced representation in terms of age, gender, socio-economic background, and health status. In control sites, decision-makers prioritized quality indicators among themselves, without public involvement. After the trial was completed, control sites participants were given feedback about the public consultation. Details of the development and testing of our public involvement intervention have been published elsewhere.[35,53] Box 1 summarizes the trial's results.

Box 1. Overview of the trial's results

172 individuals from 6 local health authorities participated in the study, including 83 public representatives and 89 decision-makers. All 83 public representatives participated in the training session and individual consultation, and 17 of them volunteered to participate in deliberation meetings with decision-makers. Public participants were representative of chronic disease patients in Canada: 58% had primary or high-school education, 56% had an annual household income of less than 40 000$, and 23% had been hospitalized in the previous year. Our primary outcome was agreement between the final priorities of professionals and patients.
Agreement between public and decision-makers' priorities was significantly stronger in intervention than in control sites (correlation coefficient=0,69 vs. 0,19, p<0.001). Intervention sites' priorities placed more emphasis on self-care support, access to a primary care professional, interdisciplinary teams, and partnership with community organizations, and were more responsive to patients' priorities than in control sites. The intervention fostered mutual influence between patients and decision-makers priorities. While decision-makers' choices moved towards indicators prioritized by the public (e.g. access to a primary care professional), public representatives' choices also moved towards indicators prioritized by decision-makers (e.g. self-care support). Decision-makers perceived the selected priorities as realistic and actionable. Participants' perception of the quality of the deliberation process also scored high in all domains (quality of the information received, procedures and moderation, interaction between participants, and overall satisfaction). The marginal costs of public involvement represented 17% of total project costs.
Post-randomization follow-up
All six local health authorities included the selected quality indicators in their financial accountability contract with the regional health authority. Local health authorities' final choices were made public and communicated to all participants. Decision-makers from control site received feedback from the public consultation after the trial was completed.

The trial's process evaluation aimed at explaining the trial's results by looking at how the intervention operated in practice. Qualitative data were collected at different phases of the study, including the design and pilot testing of the public involvement intervention, direct observations during the intervention arm of the trial, and control site participants' reactions to feedback about public priorities after the trial was completed (Figure 1). Davies and colleagues have shown the value of combining video recording and direct observations in studies of public involvement.[45] Accordingly, 14 one-day meetings were video recorded while two independent non-participant observers used structured observation charts describing the deliberation content, the types of arguments used, and the social interactions between participants. Field notes were taken during all phases of the project to record informal interactions that were not captured on video. Structured debriefing sessions were held immediately after each meeting between the observers and moderators. Key interactive moments were flagged and all observations were linked to the video transcript using time codes to allow later validation against the original recording.

Figure 1. Overview of the study



Observation and field notes were used as our primary analysis material, along with a full verbatim transcription of video recording from a sample meeting in each intervention site. Key moments flagged from all meetings were also transcribed from the original recording. All videos were analyzed, seeking to complement the observations. Given our applied policy research focus, we used framework analysis[54] to chart all transcribed material and notes and graphically map the key aspects of the public involvement process and their relationships to outcomes. The principal investigator (AB) attended all meetings with a research assistant, transcribed recordings and conducted the initial analysis. The co-principal investigator (PL) attended a subset of meetings and validated the initial analysis against the original transcript, before we discussed and refined our analysis with the rest of our research team.

Our analysis was structured around the main public involvement intervention components[32], including: 1) negotiations over the goals, methods, and design of the public involvement intervention; 2) participants' recruitment and training; 3) group moderation; 4) participation of public representatives in deliberations with decision-makers; 5) individual public consultation; and 6) public communication of group decisions.

Results

Negotiating the boundaries and support for concrete public involvement

During the design and pilot phase of the project, stakeholders generally supported the idea of involving the public in clinical priority setting. However, stakeholders' endorsement was motivated by different reasons and was shaped by the surrounding organizational context. For example, the regional health authority (which co-sponsored the trial), saw public involvement as a lever for influencing local health authorities' priorities and better align them with population needs. In contrast, local managers saw public involvement as an opportunity to "educate" the public and legitimize their own organization's priorities: *"I think this will help the population to better understand our priorities and action (Manager, Site C[1])".* Clinicians saw the intervention as a way to promote patients' responsibility in their own individual care: *"It is winning to involve people in taking care of themselves, that is why it is important that they be present when big decisions are made" (Clinician, Site B).* Public representatives' motivation to participate in the study was either to improve local

[1] Quotes are from intervention sites, unless otherwise mentioned. Pseudonyms are used throughout the text.

services or to learn about health and healthcare: *"I am curious to see what we will learn", "I want to bring my experience to improve services" (Public, Site A).*

These competing expectations about goals and methods were negotiated among stakeholders as the intervention unfolded and the abstract idea of "involving patients" became more concrete. For example, as the group's task became clearer, public representatives questioned how they were expected to contribute to clinical priority-setting and what rules would be put in place to address power imbalance: *"[I'm wondering] not in a pejorative sense, but with the level of the debate, will the population's comments have a similar weight than those of a chief executive officer?" (Public, Site A).* Public representatives also negotiated the boundaries of their role to ensure that they could bring a credible contribution. For example, public representatives were initially asked to rate the feasibility of using each quality indicator, a task they did not feel sufficiently competent to carry and that was eventually dropped. Creating space to negotiate these competing expectations and tailor patient involvement to local context was thus necessary to build mutual support and agreement among stakeholders as to how patient involvement would be operationalized in practice.

Recruitment and training: becoming a legitimate and credible public representative

Our recruitment strategy sought to identify members of the public who would be seen as credible and legitimate in the eyes of local decision-makers and the public themselves. We thus delegated the identification of potential candidates to local recruitment teams composed of a senior manager, a physician, and one patient representative sitting on the Local Health Authority's users committee. We assumed that descriptive representation of different sociodemographic groups would further increase the public's perceived legitimacy.[52] A member of the research team therefore selected members of the public from the local lists of proposed candidates to ensure a balanced representation in terms of age, gender, health, and socio-economic status. Such recruitment strategy proved effective in reaching public members from low socio-economic groups and building a sample that was statistically representative of chronic disease patients in Canada. Interestingly, we observed that decision-makers were more sensitive to the priorities expressed by people from their own local territory (although these were drawn from small samples of 12 to 15 public members) than from the pooled regional priorities collected from the total sample of 83 members of the public involved in the trial. This suggests that decision-makers'

judgments about the public's legitimacy may be guided by the recruitment of people representing *relevant* perspectives, rather than by strict statistical representativeness criteria based on demographic characteristics.

Perceived public legitimacy and credibility evolved over time. Public training contributed to the intervention's impact by building participants' sense of credibility and their ability to contribute to the prioritization task. Introducing the prioritization exercise in this public-only meeting allowed participants to ask questions of clarification in a non-threatening environment and put the public in a favourable position when they later met with professionals: *"I am part of those who had a warm-up!" (Public, Site A).* The public also felt more competent to contribute to the group's task as they progressed through the intervention: *"I knew the topic because we had a [training] day. This was really helpful. Without it, it would have been painful." (Public, Site B).* The training session also contributed to the construction of participants' sense of legitimacy as patient representatives, which was critical in their ability to later influence the group's decisions. As members of the public discussed their personal experiences in relation to quality of care during the training day, we observed a broadening of participants' perspective and growing sense of a collective "public representative" identity. One participant noted that hearing the experience of others made her more aware of the needs of different people in her community: *"I have a family physician myself but I have become more conscious of the difficulties for people who don't. In the end, I voted to help Paul and to help Clare [pointing at these participants]" (Patient, Site A).* This change in perspective was also reflected in participants' sense of identity as public representative: while at the beginning of training they mainly introduced themselves by referring to where they lived or what disease they had, many of them presented themselves in subsequent meeting as "population", "public", or "patient representatives". The ability to refer back to experiences voiced by other participants in the training session supported this ability to legitimately claim that they spoke on behalf of a wider constituency when they later deliberated with decision-makers (e.g., *"I am still speaking on behalf of the public" [Patient, Site A]).*

These observations suggest that participants *become* 'public representatives' as they progress into their understanding of their *representation role*. It also suggests that their legitimacy and credibility evolves over time and is partly framed by how they are recruited and selected, who they interact with, and what kind of training they receive.

Moderation: legitimizing dissenting opinions

Participants' task and ground rules presented at the beginning of each meeting emphasized the value of expressing diverging views. High-level policymakers and intervention sponsors also highlighted the importance of the public's view. Expressing dissenting views in group deliberation was nonetheless difficult for many participants and we observed a number of instances where professionals would "lecture" patients rather than deliberate with them.

The moderators used a number of strategies to facilitate the expression of dissenting opinions, including sitting plans that aimed at levelling-down existing power differences (e.g., by avoiding to sit lead physicians alongside chief executive officers, and by sitting public representatives in pairs). During deliberations, moderators also played a pivotal role in ensuring that public representatives engaged actively in debates, actively seeking the expression of dissenting views:

> *Physician: "[For all these reasons], I have a lot of difficulty with [the indicator measured from] patients' perception. Perceptions are not reality."*
>
> *Moderator: "So for you, this would not be a valid indicator. I would be interested to hear someone who has an opposite opinion?"*
>
> *Manager: "I disagree with Dr Smith on the uselessness of patients' perception. If we measure it as a general tendency, it is important."*
>
> *Public: "I agree with Dr Smith. However, when we have a global statistic, it can help. Perceptions require us to dig deeper."*

A moderation style that actively sought the expression of dissenting voices therefore facilitated the active involvement of patients in small group deliberations with professionals.

The expression of different perspectives did come at a cost in terms of time and effort to reach consensus. We observed that debates were more dynamic and lively in groups where the public was involved, but that group deliberation lasted on average 9% longer. A delicate balancing act was therefore needed to ensure that moderators kept participants focused on the task (e.g., *"when you say that, what indicator are you arguing for?"*), that they "closed" debates when acceptable compromises and consensus were emerging (e.g., "*ok, it seems that we will definitely keep this*

indicator"), and "stored away" persistent disagreements and unresolved issues (e.g., "*for your action plan, it is clear that there will be discussions to pursue among yourselves"*).

Public participation: rational deliberation and social interactions

In our mixed public involvement intervention, the different involvement methods (public consultation through voting, public participation in small group deliberation, and public communication of group decisions) were introduced sequentially, which allowed us to explore their respective contribution to the intervention's impact on group decision-making (Figure 1).

In the participation component, observation of deliberation content revealed specific areas where public representatives were seen as credible "experts" by decision-makers. This included issues such as their personal experience of care, their expectations and needs, as well as their knowledge of existing community organizations and services. Decision-makers actively sought validation from public representatives when they discussed issues such as the quality of interpersonal relationships and communication: *"Our final group priority is 'patient participation in clinical decision-making', where one of our healthcare user said a key sentence: working in team with the patient... Do user representatives around the table agree with all that?" (Manager, Site B)*. In other areas of deliberation, such as the psychometric properties of the proposed quality indicators, the clinical value of different treatment options, or the resource implications of the proposed changes, public representatives increasingly displayed interactional expertise as they became more familiar with the issues, but most contributions in these areas were made by clinicians or managers.

The public participation component of the intervention shaped the content of deliberation and changed the type of arguments that were put forward. As the intervention progressed, we observed a process of mutual influence between the public and decision-makers. For example, public representatives increasingly supported self-care and slowly shifted their priorities from access to a physician to access to a team of professionals, while professionals' views increasingly recognized the need to improve access.

Finally, the impact of the public participation component of the intervention also appeared to be mediated by informal social interactions between decision-makers and the public, which fostered greater mutual understanding. We observed that informal interactions during breaks and lunch time supported this change in perspective*:"we see that they are like us, fathers and mothers", "when we hear health*

professionals through their union's representatives [on TV], it is not very positive and we gain from meeting them", "I had some ideas and, by hearing others, my opinions have changed. [Interacting with these] professionals allowed us to see the other side of the coin because we are on one side, in the waiting room, and they are on the other side, waiting for us" (Public, Site B). As a consequence of this face-to-face interaction, dissent rarely opposed professionals and patients in a "us and them" pattern, but triggered instead shifting alliances between participants.

In sum, direct public participation – including deliberation and informal social interactions – supported the recognition of respective domains of expertise, trust-building, strategic alliances and mutual influence between public representatives and decision-makers, each contributing to the public's influence on group decisions.

Public consultation: bringing the population's view

Although public participation alone brought some change in professionals' priorities, we observed that it was somewhat ineffective in challenging more entrenched opinions. Part of the difficulty for public representatives was to legitimize their claim of speaking on behalf of the wider population rather than bringing anecdotal personal experiences:

> *Clinician #1: "The only thing I would have liked to know is: what does our population wants? I know you told us that we will know it later [with statistical summary of the public consultation], but this could have influenced our choices today. We still had the participation of those people here [pointing at public representatives], but maybe [with earlier feedback on the public consultation] we would have been more conscious of our clinician and manager's point of view." (Site B)*

Statistical summaries of the public consultation introduced in a subsequent meeting made visible the gap between decision-makers and public priorities. Results of the consultation also added weight to public representatives' claims of speaking on behalf of "the population" and opened the door for exploring differences of opinions:

> *Public #1: "I will tell you frankly, I am surprised that there are three indicators on which we agreed [in the participation-only meeting] and the rest…for me as a member of the public…"*

Public #2: "There are important things that have been left aside."

Public #1: "Yes."

Public #2: "We have some difficulty to subscribe to the group's decision" (Site C)

In contradiction with control sites where these differences of opinions were not discussed, early feedback of the public consultation in intervention sites prompted participants to negotiate these differences of opinions further. As a result, in two of the three intervention sites, statistical feedback of the public consultation shifted decision-makers' opinions in favour of the public's priorities on access to a primary care professional.

In the post-randomization follow-up, we provided decision-makers with feedback of the public consultation to control site decision-makers after they made their group decisions and we collected all data from the trial (Figure 1). We observed that the public consultation alone was limited in its ability to influence decision-makers' opinion because these results could easily be dismissed on the ground that the public did not express credible opinions: *"I am not sure that they knew the percentage of people who have a family physician, while decision-makers and managers know this information"; "I don't know what the public is expecting, we offer enough already" (Control sites D, E, and F respectively).*

In intervention sites, results of the public consultation were not so easily dismissed because of public representatives presence in those meetings. The participation of public representatives in intervention sites shaped the interpretation of the credibility and legitimacy of the public consultation statistical summaries. In some instances, public representatives took their distance from the public consultation findings *("self-care support, in reality, I participated in this consultation […] maybe we did not understand the question and did not put enough importance on this" [Public, Site B]*), while in other cases, public representatives' presence supported the credibility and legitimacy of these findings and ensured that they were not simply tossed aside by decision-makers.

Public: "There is an enormous gap between public and professionals' priorities."
Moderator: "Do you think this is a [public] misunderstanding problem?"

Public: "Not at all. This would imply that you question the population's intellectual capacities [laughs]" (Site A)

Therefore, the public consultation component of the intervention added "weight" to public representatives' legitimacy as it strengthened their claims of speaking on behalf of the "population". We also observed that the combination of public consultation and direct public participation acted in synergy and was more influential on group decision making than when consultation and participation were conducted in isolation.

Public communication: pressing for action and accountability

Decision-makers were informed at the onset that final decisions would be made public through a letter sent to all participants at the end of the project, including all 83 public representatives (Figure 1). We observed that public involvement raised expectations regarding the need to communicate information back to the community. For public members, communicating the selected clinical priorities was necessary to ensure that results of their involvement would bring tangible results: "*regarding all this work, my worry is that our study ends-up on the shelves"; "other people could be informed about what happened this afternoon" (Public, Site B and C)*. Public communication of results also created an accountability link between public members and the people they represented. Decision-makers in intervention sites showed a more positive attitude than in control sites towards public reporting of quality indicator. After the trial was completed, two of the three intervention sites took the initiative to involve lay board members and public representatives in follow-up activities on quality indicator use and reporting. It therefore appears that the public communication component of the intervention was important to support follow-up on actions taken.

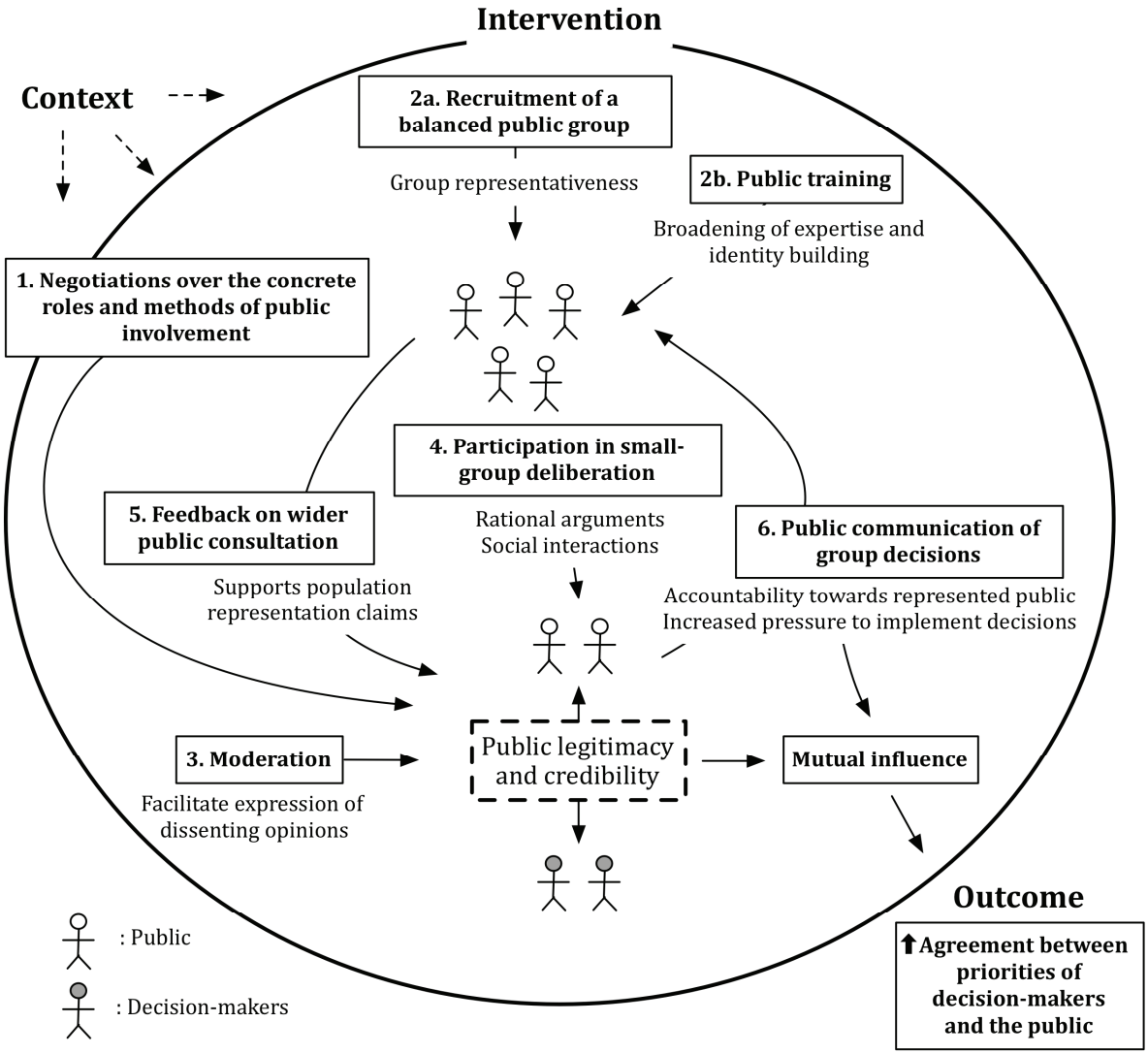
Discussion

Key findings and contribution to the existing literature

Results from this study are important as they unpacked some of the "active ingredients" that contribute to the success of public involvement. Although a number of expert opinions have been published on the topic, this is the first study to tackle the design of effective public involvement using process evaluation data collected from a successful randomized trial of public involvement in healthcare improvement and policymaking. While previous studies have highlighted the importance of clarifying

whom are public representatives expected to speak for and what kind of expertise they can contribute to collective decision-making[45,49,50], our findings point at how specific components of involvement interventions foster the public's legitimacy and credibility, both in their own eyes and in those of decision-makers (Figure 2). Our study shows that both technocratic and democratic processes are at play throughout the unfolding of a complex public involvement intervention and shape its impact on collective healthcare improvement and policy decisions.

Figure 2. Key components of a public involvement intervention



In the literature, technocratic discussions about public expertise largely focus on the notion of technical competence and assumes that "lay" members of the public suffer from a knowledge deficit in their understanding of scientific and technical

information, which needs to be corrected through appropriate training.[55,56] Our findings point more specifically towards the importance of credibility as a condition for successful involvement, that is, the perception that decision-makers and public members themselves have of their own contributory expertise in key areas of deliberation. This means that public involvement interventions not only need to provide public participants with sufficient information to understand technical issues and interact with other experts, but also need to support their ability to become a credible source of knowledge for other participants in relevant aspects of the decision-making process. It is interesting to observe empirically that such expertise comes partly from public members' previous individual experiences, as well as from their ongoing interaction with other public representatives and decision-makers. In our trial, recruiting participants with direct personal experience of chronic disease and giving them the opportunity to broaden their knowledge-base through interaction with other public members fostered the development of a specific contributory public expertise.[48]

From a democratic perspective, our findings point towards the need to better distinguish group representativeness from individuals' representation role.[52] Statistical representativeness, the correspondence between the descriptive characteristics of a group and those of the population from which they are drawn, is only one aspect of the public's legitimacy and is most applicable to public consultation strategies, where large groups of participants can be recruited. In contrast, the logic of direct public participation in small group decision-making is mainly one of *representation*, where individual participants are expected to speak on behalf of a wider constituency. Our findings highlight the need to look more closely at how involvement interventions support participants' ability to legitimately speak on behalf of others by drawing clearer links with the wider public that they are asked to represent.

Finally, it is important to note that supporting the development of a credible and legitimate public contribution is compatible with deliberation and did not result in clashes with decision-makers, as is often feared. As they became more solidly grounded in their roles, public members and decision-makers became more aware of the limits of their own expertise and actively engaged in a process of mutual learning and influence, as postulated by deliberation theory.[34,46,57-61]

Policy implications

Two main policy implications can be drawn from this study. First, questions over the design of public involvement interventions have often be reduced to identifying the "right" participants, sufficiently competent to understand the conversation, while still being seen as representative of "ordinary" or "lay" public members. As a result, much emphasis is put on "sampling strategy" and less on other intervention components such as who identifies public members and what opportunities they have to interact with the people they are asked to represent. Our results point towards the importance of training that go beyond a basic understanding of technical terms to foster the development of a task-specific contributory public expertise. It also supports the development of more comprehensive public involvement interventions that better integrate consultation, participation and communication. Reducing public involvement to offering "a seat at the table" to one or two people without appropriate support (as may often be the case) is unlikely to bring about change if public representatives cannot draw on evidence collected from wider public consultations, or if no form of communication is put in place to ensure public accountability and follow-up on actions taken.

Defining on what basis can one legitimately claim to represent the public, and what experience and knowledge is necessary for them to bring a credible contribution to healthcare improvement and policy decisions is highly context-sensitive. As we observed in our study, the goals and actual process of involvement was subject of ongoing negotiations throughout the design *and* implementation of the intervention. Because the rhetoric of public involvement commands such widespread support, it is tempting to gloss over tensions about the competing goals and the different roles that the public can be expected to play. However, without appropriate space to negotiate such tensions and come to some form of context-bound agreement, the search for effective involvement interventions will likely remain elusive. As such, decision-makers should remain critical in their search for the "best involvement method" and rather seek more generalizable principles that could guide the development of effective involvement interventions tailored for specific contexts.

Strengths and limitations of the study

The strength of this study lies in the detailed process evaluation data collected from a real-world experimental study. This multi-method approach, informed by theory and anchored in empirical observations of a successful intervention wherein both productive disagreements and mutual learning took place, offers a concrete example

of integration between quantitative outcome results and qualitative process analysis of a public involvement trial, and helps explain its impact on collective decisions.
The generalizability of our findings is limited by the heterogeneity of public involvement interventions and the influence of the socio-political context in which they are implemented. However, by breaking the process analysis of our complex intervention into its different components, one can more easily assess the potential generalizability of our findings to similar public involvement interventions.[32]
Also, seeking the active ingredients of public involvement, rather than simply describing how the intervention is unfolding in practice, implies certain normative judgments about the desirable outcomes of public involvement interventions. In our study, it was assumed that interventions fostering the public's influence on collective decisions are valuable. We however recognize that other normative models of what constitutes successful involvement exist (e.g., considering public involvement as an intrinsic good, independently of its impact on collective decisions) and could have resulted in different interpretations.[62]

Conclusion

Public involvement are complex interventions that incorporate a number of interacting active ingredients. In this study, the public's credibility, legitimacy, and influence on group decisions was framed and fostered by recruitment of a balanced group of participants, structured training supporting public representatives' identity-building and ability to draw from others' experience; a moderation style that facilitated the expression of dissenting voices; as well as the combination of direct public participation in small group deliberation, wider public consultation, and public communication of group decisions. Engagement of key stakeholders in negotiations over the design and implementation of the intervention helped build political support and align the goals and methods of involvement with the local context. There is a need to better distinguish statistical representativeness from representation roles in discussions about the public's legitimacy. It is also necessary to expand our notion of the public's competence beyond the understanding of technical terms, in order to support the development of a task-specific contributory public expertise. Greater attention to these key ingredients can support more effective public involvement interventions, and increase agreement between decision-makers and the public over healthcare improvement and policy decisions.

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Chapter 11

Discussion

The nine previous chapters presented original research on patient and public involvement in healthcare improvement. These chapters were structured around three core research questions concerning the goals, current practices, and effective methods of involvement. This final chapter summarizes major research findings, discusses methodological considerations, and draws the main research and policy implications from this thesis.

Major research findings

Goals and expectations towards patient and public involvement

Using qualitative interview studies with patients and health professionals, we first clarified the different goals and expectations for patient and public involvement in healthcare improvement. A striking finding from these studies is the wide consensus around the general idea of involving patients and the public, which is seen as "obviously very important" and has strong rhetorical appeal for all stakeholder groups. Detailed analysis revealed however important disagreements as to why patient and public involvement is necessary and how it should be operationalized in the context of healthcare improvement. These divergences find echo in current academic and policy debates.

For many, patients' role is first and foremost located within the individual clinical encounter. In the context of healthcare improvement, this means that health professionals recognize the need to personalize their care based on careful assessment of individual patients' preferences and needs rather than apply rigid rules for everyone. This view is attuned with the patient-centered medicine literature and with health professionals' critiques of clinical practice guidelines, population-based standards, and quality indicators.[1-4] As paternalistic decision models are increasingly being questioned, patient involvement is also being equated with active partnership in clinical decision-making, shared decision-making, and self-management support.[5-11] A core tension within these clinical models of involvement lies between approaches considering that informed patients' choice between alternative healthcare options is an intrinsic good, and those that look at patient involvement as a mean to influence individual patients towards a single "best" course of action.[11-13]

In parallel with this reframing of the individual clinical interaction, we documented a growing interest towards more collective forms of involvement in "upstream" healthcare improvement and policy decisions at the population level. Such proposals

are however met with ambivalence. Some fear that patient involvement in strategic healthcare decisions may result in clashes between different interest groups or in the "politicization" of guideline development and other healthcare improvement activities. These fears are most acute towards involvement models that seek to promote the influence of certain advocacy groups (e.g. "weak" patient groups against "powerful" professional organizations).[14,15] Others propose instead to keep patient involvement within the hands of experts charged with collecting evidence on individual patients' needs and expectations through different research methods. This view is dominant in the evidence-based medicine literature and resonates with methods developed in epidemiology and health economics such as need assessment surveys, quantification of health utilities, decision-analysis, and systematic reviews of primary research on patients' views and expectations.[16-22] Deliberation models of group decision-making are also becoming increasingly popular, partly because they seek to resolve the tension between informed collective healthcare improvement decisions and active patient participation. These deliberative models also appear attractive because they seek to move beyond interest group struggles to work towards group decisions that are more acceptable for all parties involved.[23-28]

In line with these different views on the goals of involvement, we also uncovered important differences about what patients and the public are expected to contribute to healthcare improvement. A common assumption among health professionals is that patients and the public can bring "values" and "preferences" to healthcare improvement decisions, as opposed to evidence and knowledge.[22,29-34] In line with recent research, we have shown that such distinction is misleading and obscures implicit value judgments made by health professionals themselves when they contribute to guideline development and other healthcare improvement decisions.[26,35-37] Recognizing that values and knowledge are interrelated ways of reasoning is important to inform the development of structured patient and public involvement interventions. These findings reframe discussions around the recruitment and training of "lay" patients, as well as concerns about the risk that patient involvement may "contaminate" the scientific, "value-neutral" process of healthcare improvement.[26] These results also highlight the importance of making more explicit the values underpinning professionals' and patients' judgments about collective healthcare improvement decisions.

In sum, patient and public involvement in healthcare improvement has come to be taken as an obvious, taken for granted "good idea", generating wide consensus among healthcare organizations, professionals, and patients. For many, the question is no longer why patients and the public should be involved, but how this should be done. Studies in Section 1 point however towards the need for a more critical analysis of this apparent consensus and shows that "patient and public involvement" means many different things for different people. We have highlighted the importance of clarifying what exactly is expected from patients and the public before examining how they should be involved. Our findings also call for involvement methods that increase the credibility and legitimacy of knowledge claims and value judgments made by professionals and patients about healthcare improvement.

Current involvement practices and international experiences

In Section 2, we described how patients and the public are currently involved in healthcare improvement, and identified the main perceived barriers and facilitators for effective involvement. Chapter 5 described current involvement methods used by healthcare improvement organizations at the international level, while chapters 6 and 7 complemented this information with a systematic review of the published and gray literature.

These studies suggest that a wide variety of participation, consultation and communication methods are currently used to involve patients and the public. Patients and the public are often involved as individual healthcare users and "consumers". Accordingly, current involvement strategies are often framed as ways to support their individual health decisions. Communication of information about health conditions and recommended treatments are commonly used to increase patients' adherence to treatments. New trends are also visible at the international level as healthcare organizations are increasingly seeking to support a broader range of patient choices.[11] Large-scale public consultation through surveys, focus groups, and other primary research methods are also used.[19-22] Finally, participation of patient and the public in collective decisions over healthcare improvement is becoming more common, as exemplified by frequent patient representation on guideline development groups. These collective forms of involvement appear to be more common in publicly-oriented healthcare systems such as the United Kingdom, which go as far as involving citizen representatives in guideline development to address the broader social and ethical implications of healthcare improvement decisions, while

countries like the United States seem to be more oriented towards supporting individual patient choices.[38,39] Patient and public involvement also appears to be generally more developed in relation with chronic diseases, in line with the Chronic Care model emphasizing ongoing patient partnership in the management of long-term conditions.[8,40]

We also documented many shortcomings in current involvement practices. Key components of involvement intervention are rarely mentioned and official descriptions often account to little more than offering patients "a seat at the table". Our systematic review identified no study rigorously assessing the impact of patient and public involvement on collective healthcare improvement decisions, a pressing knowledge gap identified also in other areas of healthcare.[22,24,41-43] Common concerns also include difficulties to reconcile professionals' and patients' perspectives, representativeness, understanding of technical terms and scientific evidence, and fears that patient organizations may serve special interest groups.[22,24,41,44-46]

Studies in section 2, as well as the growing literature on the issue, show that healthcare organizations are increasingly taking concrete steps to involve patients and the public in a number of healthcare improvement decisions. While patient and public involvement is becoming institutionalized in many countries, such initiatives are often unstructured and rarely evaluated, which can fuel criticisms of tokenism.[47,48] Furthermore, a number of barriers limit the effectiveness of patient and public involvement and point towards the need for developing more effective involvement interventions.

Advancing methods for effective patient and public involvement

We conducted the first trial assessing the impact of patient involvement in collective healthcare decisions. This trial tested a new method of involvement where patients worked in partnership with professionals to agree on common healthcare improvement priorities. Described in Chapters 8, 9 and 10, this trial addresses a pressing knowledge gap identified in the literature more than a decade ago.[24,41-43,49] We have found that structured patient involvement increases agreement between professionals and patients, is affordable, and can be implemented locally to drive change at the clinical level. Our findings suggest that structured involvement offers a learning opportunity for patients and professionals alike, who mutually influenced each other and became more aware of their respective knowledge and expectations.

Results from this trial are important as they address several concerns expressed by professionals who are seeking effective ways to engage with patients and agree with them on concrete and measurable healthcare improvement goals.[41,43,49,50] The fact that patient involvement did not result in interest group clashes is important and is congruent with deliberative theories that posit that such processes may serve as "collective learning devices", thus fostering decisions that are more acceptable for all parties involved.[23,24,26,28,51-53] Professionals perceived the priorities established together with patients are credible, realistic and actionable, which is also clinically important given fears that patient involvement may lead to unrealistic or inappropriate decisions. Our ability to recruit a balanced group of participants – including patients with complex chronic conditions and low socioeconomic groups – strongly supports the feasibility of actively involving a diverse group of patients in complex healthcare improvement and policy decisions.[54] Conversely, the disconnect we observed between professionals' and patients' priorities in control sites, where patients were not involved, illustrates documented difficulties for professionals alone to presume and address issues that are most important for patients.[55-57]

Our built-in process evaluation unpacked some of the "active ingredients" that explains the impact of patient involvement. We observed that patients' influence is associated with their perceived legitimacy and credibility by professionals. Patients' legitimacy and credibility is in turn fostered by the recruitment of a balanced group of participants and the opportunity for these participants to interact together and familiarize themselves with the proposed task through training and preparation. A moderation style that facilitates the expression of dissenting opinions facilitates patients' influence on group decision-making. The impact of patient involvement is also supported by the combination of small group deliberation between patients and professionals, wider patient consultation, and public communication of group decisions. Another key to success was the tailoring of our patient involvement intervention to the local implementation context through early engagement with stakeholders, pilot testing, and refinement of the intervention. The importance of adapting patient involvement methods to local context is congruent with theories proposing to tailor healthcare improvement interventions to identified barriers and needs.[58,59]

Methodological considerations and directions for future research

From a methodological perspective, a strength of this thesis is the use of a wide range of research methods to build solid evidence on a complex and challenging field of inquiry. Qualitative methods were used to build our intervention from the ground-up and helped reframe some of the assumptions that have dominated the field so far. We have used a systematic process to map current involvement practices, develop a taxonomy of involvement methods, and develop more structured interventions. Finally, we documented the impact of patient involvement using a robust trial design and built-in process evaluation. We believe that the successful completion of the first randomized trial of patient involvement in health decisions at the population level represents an important landmark for the field of public involvement in healthcare. Testing of this intervention in a real-world setting increased the external validity of findings and strongly supports the feasibility of the intervention in clinical practice. Nonetheless, a number of methodological limitations should be noted to put our findings in perspective and orient future research.

Are results reproducible?

Policy interventions in general, and patient involvement interventions in particular, are difficult to test in large-scale studies because of the nature of the intervention and the maximum number of people who can meaningfully be involved in small-group decision-making. Furthermore, cluster randomization (which is necessary to test population-based interventions) increases the required sample size and the costs of designing appropriately powered trials. Our trial's sample size was rather large compared to existing studies of public involvement, but may appear small for medical audiences used to large-scale clinical trials with tens of thousands of patients. From a research perspective however, our trial had sufficient power to test our primary hypothesis and demonstrate a statistically significant increase in the level of agreement between professionals' and patients' priorities, which means that its size was appropriate to address our primary research question. Our sample size was nonetheless limited to test secondary research questions such as the relative influence of patients and professionals on group decisions, or the impact of patient involvement on more distal outcomes such as changes in healthcare delivery and health outcomes. The strength of evidence supporting the benefit of patient involvement would be increased from reproducing our trial at a larger scale, especially now that a validated intervention and research instruments exist and that we know that rigorous trials can successfully be conducted in this area. However,

given the absence of documented adverse effects and the benefits on clinically relevant intermediate outcomes demonstrated in our trial, we believe that the research priority should not be so much around "reproducing" our results at a larger scale, but testing whether the observed effects of patient and public involvement can be observed in different contexts.

What works in what context?

The strength of randomized trials is their ability for generating causal inference, but it does so at the expense of "controlling" for contextual variables that influence outcome. As a result, context has remained in the background of this thesis and is a key area for future research. More specifically, there is a need to better understand the social, political and organizational factors that are likely to influence positively and negatively the process and outcome of patient and public involvement. For example, our patient involvement intervention benefited from high-level policy support and was implemented in communities that have a high degree of social cohesion. It is unclear whether such intervention would be similarly effective in other contexts, in more urban or fragmented settings, or around decisions that are more controversial or polarized. We agree with others who argued that the field of patient and public involvement not only needs studies exploring "what works" (what this thesis sought to contribute by testing the effectiveness of a structured patient involvement intervention in real-world setting), but also document "what works when" (i.e. the contextual conditions under which public involvement interventions are more or less likely to be effective).[25,60,61] We have shown the potential of process evaluations built-in alongside comparative studies to shed light on some of the factors explaining the (lack of) success of patient and public involvement interventions, which could guide future studies and help shed light on contextual factors influencing the effectiveness of these interventions.

Who wants what from patients and the public?

This thesis has focused on formal patient and public involvement practices, conceptualizing public involvement as an intervention designed and implemented by policymakers and health professionals working within the healthcare system. This approach has obvious strengths in that it helped clarify the different goals and expected benefits, refine a clear typology of involvement interventions, test the effectiveness of such interventions in the context of healthcare improvement, and

identify a number of "key ingredients" that policymakers and health professionals can use to support successful patient and public involvement.

A limit of this approach is that it tends to look at patient and public involvement as a simple means to an end. Such assumption is visible in researchers' and professionals' quest for the "best" involvement method. The problem is that this tends to overlook the social and political dynamics that shape patient and public involvement. For example, "patients and the public" have remained relatively disembodied participants in our studies, described through socio-demographic statistics that leave aside their individual motivations to engage in such process.[62] This thesis has also largely ignored more spontaneous forms of involvement where patients and the public take the initiative, or even sometimes force their way into the collective decision-making process through social movements and associations.[63] As our findings suggest, patient and public involvement can be harnessed to achieve different (often largely implicit) goals. Support and challenges by traditional interest groups such as consumer groups, medical organizations, and industry lobbies can however remain unacknowledged when patient and public involvement is framed as a "value-free", scientific intervention.[23,46]

From a research perspective, all these issues point towards the policy aspects of patient and public involvement and the need to better understand "who wants what" from patients and the public. A more naturalistic research approach could yield important insights regarding the social factors and power struggles that shape patient and public involvement interventions. Understanding how different involvement interventions are constructed as "successful" and by whom would therefore be a logical next step in the science of patient and public involvement in healthcare improvement.

Practice and policy implications

As patients and the public are increasingly being involved in healthcare improvement, findings from this thesis have several practice and policy implications.

Tailoring involvement interventions to specific contexts

As highlighted by this thesis, different people hold different expectations about patient and public involvement. Existing practices are often clouded by rhetorical claims, which obscure the actors' actual goals and the concrete actions being put in place to support effective involvement. Because patient and public involvement is likely to challenge existing power arrangements, it is necessary to create opportunities for negotiating proposed goals and methods and to generate "buy-in" from key stakeholders. We have also shown that the ability to adapt involvement interventions to the local organizational and socio-political context is key to success. As such, professionals and policymakers should remain critical in their search for a "one-size-fit-all involvement recipe", and aim instead at tailoring involvement interventions for specific contexts.

A core task of organizations charged with actualizing patient and public involvement policies is therefore to understand the context of implementation and negotiate the different expectations towards patient and public involvement. Basic questions about the "when, why, who, and what" of patient and public involvement are useful to clarify expectations and ground subsequent choices of an appropriate involvement method:

- Context (when): What specific decisions and aspects of healthcare improvement are at stake? What stakeholders groups and organizations are interested in, or can be affected by patient and public involvement?
- Goals (why): What are the different goals and expectations for patient and public involvement? What would "successful" involvement represent for different stakeholders?
- Targeted group (who): Which groups of patients or members of the public are targeted? On behalf of whom are they expected to speak?
- Task (what): What concrete role are patients and the public expected to play? What specific knowledge and values are they expected to contribute to this task? What type of information will be collected from them, communicated to them, or exchanged with them?
- Output (then what): What will be done with the recommendations and decisions made by or together with patients? Who will be accountable for the implementation of these recommendations or decisions? How will these decisions be communicated to patients?

Ensuring coherence between involvement aims and methods

Equipped with clearer expectations about patient and public involvement, healthcare organizations can explore which involvement methods are most appropriate to reach these goals. The framework of involvement interventions that we have adapted from Rowe and Frewer and presented in the introduction chapter can be used as a heuristic device to support greater coherence between proposed involvement aims and methods.[25] We have found this framework to be useful in fostering international collaboration by organizing the dozen of different involvement methods into a simple and meaningful typology[21,64]:

- Communication methods involve the transmission of information *to* patients and the public, including the production of plain language versions of clinical practice guidelines, the development of patient education material and decision aids, and the public reporting of performance indicators and measures. Communication methods are most appropriate to support individual patients' health choices or to increase public accountability of collective healthcare improvement decisions.
- Consultation methods involve the collection of information *from* patients and the public through surveys, focus groups, interviews, or literature reviews of primary research on patients' needs, experience, and expectations. Consultation methods are useful to gather the views of a large number of individuals, and this is where statistical representativeness is a relevant consideration. Consultation methods add to the evidence base being considered to inform individual and collective healthcare improvement decisions.
- Participation methods involve the exchange of information *between* the public and other experts, most often through deliberation in small group meetings. Because of the small numbers of people involved, these methods proceed from a logic of representation rather than statistical representativeness, which means that individual participants are often expected to represent the views of a larger group of people. Deliberation methods are useful to foster mutual learning and influence between participants with different expertise, and to agree on collective healthcare improvement decisions that are more acceptable for all parties involved.

These different involvement methods are complementary and, as we have shown in our trial, can usefully be combined together. For example, research on patient expectations (consultation) can inform deliberation between patients and professionals (participation) and the development of patient decision aids (communication).

It should be noted also that this typology is precise enough to distinguish between different "families" of involvement interventions, yet broad enough to accommodate a number of new involvement methods. An important avenue for practical development of involvement intervention is indeed offered by new information technologies such as interactive web applications, online survey tools, downloadable information material, social media, patient portals, and electronic personal health records. These technologies create new opportunities for increasing the reach of involvement interventions, address geographical barriers at low cost, and facilitate more rapid information exchange between patients and professionals. They also create new challenges for patient and public involvement related to computer litteracy, equity in computer access, information credibility and overload, and loss of informal face-to-face interaction. [65-68]

Beyond "ordinary patients": fostering legitimacy and credibility

Although the above typology is helpful in distinguishing different involvement methods, we have also shown that patient and public involvement is more than the exchange of information and "facts". Questions over the design of public involvement interventions are often reduced to the communication and collection of "valid information" and the identification of the "right" participants, sufficiently competent to understand the conversation, while still being seen as representative of "ordinary patients" or "lay" public members. As a result, much emphasis is put on recruitment strategies and on information content, and less on other involvement interventions' components.

We have found that patient and public involvement should be regarded as complex interventions composed of a number of interacting active components fostering participants' legitimacy, credibility, and influence on healthcare improvement decisions. Our findings suggest that patient training should go beyond basic understanding of technical terms to foster the development of a task-specific contributory public expertise. A critical question is therefore to clarify what specific expertise is required from patient and public representatives to bring a *credible* contribution to healthcare improvement decisions, and what kind of training and support will be put in place to ensure that participants can develop relevant expertise. There is also a need to reframe the debate about the recruitment of "real patients", and explore instead how these participants can be expected to *legitimately* represent the voice of patients and the public, both in their own eyes and in those of health professionals. The recruitment of a balanced group of participants in

collaboration with key local stakeholders, a moderation style that facilitated the expression of dissenting voices, and structured training and interactions among patients have been found in our thesis to increase patients' legitimacy, credibility, and influence on healthcare improvement decisions.

Building bridges across involvement methods

Another important observation from our trial is the synergy between participation, consultation, and communication methods. In the academic literature, a theoretical divide tends to separate proponents of participation methods (based on deliberative theory and political sciences), consultation methods (based epidemiological methods and health economics) and communication methods (focused on risk communication, behavior change theories, and clinical decision-making).[11,13,18,32,69]

This academic fragmentation has so far supported a piecemeal approach that may have hampered the value and practical effectiveness of patient involvement. For example, public reporting of physicians and hospital performance data often operates with little or no patient participation in the selection of indicators that will be used to measure and report on quality. As a result, despite the fact that enormous resources are being invested in the collection, analysis and public reporting of quality data, many consumers find little relevance in this information and do not use it.[39,70-72] Similarly, offering patients "a seat at the table" on advisory boards is unlikely to bring about change if patient representatives cannot draw on evidence collected from wider public consultations, or if no form of communication is put in place to ensure public accountability and follow-up on decisions taken.

Another frequent dichotomy in the academic literature lies between individual patient involvement in clinical decision-making ("choice") and more collective forms of involvement in health services delivery and policy decisions ("voice").[73-75] In our trial, patient involvement in healthcare decisions at the community level resulted in clinical improvement priorities focusing on individual patient involvement, patient participation in clinical decision-making, and self-management support. This means that patient and public involvement at the collective level could foster more meaningful and effective individual patient participation in clinical decision-making.

Overall, these observations thus support the need for building bridges across different involvement methods and the development of more comprehensive patient and public involvement interventions.

Conclusion

In conclusion, this thesis has brought greater clarity and more solid evidence about the goals, current practices, and effective methods of patient and public involvement in healthcare improvement. We have found that patient and public involvement has strong appeal for a wide range of stakeholders and is increasingly being used internationally for healthcare improvement. We developed a new method of involvement, supporting patient-professional partnership in collective healthcare improvement decisions. We conducted the first trial of patient involvement in healthcare decisions at the population level, which demonstrated that structured patient involvement increases agreement between professionals and patients, is affordable, and can be implemented locally to drive change at the clinical level. We have identified a number of practical implications from these findings, which could guide the development of more effective involvement interventions.

Fifty years after the expression "patient-centered medicine" was coined, rigorous research increasingly supports the development of structured and effective patient and public involvement interventions to improve clinical care. This growing evidence can help extend patient-professional partnership beyond the clinical consultation. It also opens new models of shared decisions at the collective and policy level. Results from this thesis could bring greater coherence between proposed involvement aims and methods, foster participants' influence on healthcare improvement decisions, and help build bridges between different involvement interventions. Effective patient involvement in collective healthcare decisions could foster more meaningful partnership in clinical care by reshaping the menu of choices available to patients, bringing concrete and tangible meaning to the call for a more patient centered healthcare system.

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Summary

This doctoral thesis is about patient and public involvement in healthcare improvement. This thesis by articles is composed of eleven chapters. The first chapter introduces the background and research questions addressed by the thesis. The nine following chapters represent the body of original research conducted for the thesis. These nine research chapters are structured in three sections that aim to: 1) clarify the goals and expectations towards patient and public involvement; 2) describe current involvement practices and international experiences; and 3) develop and evaluate new and effective involvement methods. The last chapter discusses the core findings and their implications for research and practice. This summary provides a general overview of the thesis content.

Introduction and research questions

Chapter 1 presents the background and introduces the questions addressed in subsequent research chapters. The idea that patients should be "at the center" of healthcare is as old as medicine itself and grew stronger in the second half of the XXth century. Major developments over the past fifty years in patient-centered medicine, shared decision-making, and self-management have largely focused on the involvement of patients in their own individual care, at the micro-level of the clinical consultation. Accordingly, a number of programs supporting active patient involvement in their own health are being implemented internationally.

In contrast, patient and public involvement in collective healthcare improvement and policy decisions has been much slower to develop. As a result, collective choices about health services organization and delivery are still largely done by professionals only, despite research showing that professionals often inaccurately presume of patients' expectations towards care. In recent years, a growing consensus has emerged towards active patient involvement in healthcare improvement to ensure that healthcare is geared towards their most pressing needs. More specifically, the epidemic of chronic disease is transforming the way health services are delivered and highlights the role that patients can play as partners in healthcare. Finally, the move towards patient and public involvement also coincides with the deliberative turn in western democracies and the idea that citizens ought to be involved more actively in health services delivery and policymaking.

The growth of patient and public involvement is generally perceived as a "good thing" and is supported by a number of rhetorical claims about its potential benefits. However, moving from rhetoric to action raises a number of difficult questions. First, critical voices have questioned the actual goals and impact of involvement interventions and the risk that "token patients" be used to legitimize existing policy decisions. Systematic reviews have documented a lack of evidence from comparative studies about desirable and adverse effects of patient and public involvement at the population level. Concerns have also been raised regarding the feasibility to recruit participants who are representative of "ordinary" patients and "lay" members of the public, yet have the competence to contribute to complex healthcare improvement decisions.

This thesis focuses on the involvement of patients and the public in healthcare improvement. Our focus is on the involvement of patients and the public in collective decisions about healthcare affecting more than one patient. More specifically, it explores the role of patients and the public in the development and implementation of two important and related quality improvement tools – clinical practice guidelines and quality indicators – which set standards on how healthcare should be organized and delivered to provide safe, effective, and appropriate care. The thesis is structured around three core research questions:

1. What are the goals and expectations for patient and public involvement in healthcare improvement?
2. How are patients and the public currently involved in healthcare improvement?
3. How can effective patient and public involvement interventions be developed to foster healthcare improvement?

Section 1: Goals and expectations towards patient and public involvement

When asking how best to involve patients and the public in healthcare improvement, the first problem one stumbles across is how to define success. Clarifying the goals and expectations towards patient and public involvement, and defining key outcomes of interests, is critical for the design of effective interventions.

Because healthcare improvement has traditionally been a professional stronghold, understanding clinicians' experiences and expectations is important to clarify what could realistically be expected from patients and the public. In ***Chapter 2*** we

conducted a focus group study among 17 Canadian primary care physicians to explore their expectations towards patient involvement, as it relates to the use of practice guidelines in day-to-day clinical practice. Interviews were audio taped, transcribed verbatim, and analyzed using template content analysis. We found that clinicians experience a tension between two competing norms of good practice: to comply with practice guidelines and to involve patients in clinical decision-making. Practice guidelines are seen as useful to help physicians make decisions on behalf of their patients and influence their choice when a single best course of action is clear. For interventions with uncertain benefit or with significant trade-offs, clinicians are seeking tools that will allow them to share decisions with patients and provide them with information about the pros and cons of alternative options. According to physicians, current guidelines and other quality improvement tools fail to meet these needs and require adaptations to support active patient involvement in clinical decision-making. These findings suggest that lack of patient involvement in collective decisions about guideline development and healthcare improvement can constrain individual patient-professional partnership in clinical care.

Chapter 3 describes the main goals or "discourses" about what represents successful patient involvement in healthcare improvement. Individual semi-structured interviews were carried out with 18 patients and health professionals participating in two guideline development groups in the United Kingdom. Discourse analysis of transcribed interviews was strengthened by an active search for deviant cases, team debriefing, and member checking. All respondents supported the general idea of patient involvement in healthcare improvement as "obvious" and "vitally important", but disagreed as to why such involvement is necessary. Divergences were structured in 4 discourses: 1) the Governance discourse constructs healthcare improvement as a scientific process and proposes to complement clinical research evidence with data on patients' preferences and needs in order to maximize population benefits of health interventions within the constraints of available resources; 2) the Informed Decision discourse aims at fostering patients' individual choices by communicating information on the risks and benefits of different health interventions; 3) the Professional Care discourse insists on tailoring professional care based on individualized assessment of patients' medical and psychosocial condition; 4) the Consumer Advocacy discourse argues for greater political power and influence of patient and public representatives in strategic aspects of healthcare improvement and policymaking. We conclude that although patient and public involvement in

healthcare improvement generates wide consensus and support from health professionals and patients, important differences exist as to why such involvement is seen as necessary and how it should be operationalized in practice. Although these views are not necessarily incompatible with one another, these findings call for greater transparency and clarity about the actual goals of patient and public involvement.

Chapter 4 seeks to clarify what patients and the public can contribute to collective healthcare improvement decisions, by examining more closely how and when value judgments get embedded in the development and use of clinical practice guidelines. Using empirical data from the above two chapters, this study shows that value judgments are made in at least three stages of quality improvement: 1) in the identification of contexts where health professionals' and patients' individual decisions are seen as inappropriate and needing improvement; 2) in determining what type of information and options should be presented to professionals and patients; 3) in negotiations regarding how the effectiveness of quality improvement should be measured and by whom. In contrast with the evidence-based medicine picture of guidelines as neutral "carriers of facts", these results suggest that value judgments are made by patients and health professionals throughout the cycle of healthcare improvement. References to scientific notions of truth and validity in evidence-based medicine tends to overlook the socio–political dimension of quality improvement. These findings call for involvement methods that make more explicit, credible, and legitimate the knowledge and values made by professionals and patients about healthcare improvement.

Section 2: Current involvement practices and international experiences

Little is known about the extent to which patients and the public are currently involved in healthcare improvement, how they are involved, and what are the main barriers and facilitators for success. Section 2 aims to strengthen the available knowledge base and to identify the most pressing gaps in empirical knowledge, by describing the landscape of existing involvement practices at the international level. This section builds on the creation of the Guideline International Network Patient and Public Involvement Working Group, an international collaboration between guideline developers, patient representatives, and researchers aimed at sharing experiences,

fostering international collaboration, and developing new standards and methods of involvement.

Chapter 5 describes how patients and the public are currently involved by healthcare improvement organizations. We conducted a consultation with 56 guideline developers, researchers and patient/public representatives from 14 different countries as part of an international face-to-face workshop. Participants were divided into subgroups to foster active participation and address specific questions on current involvement practices and on priorities for research and international collaboration. A summary of discussions was communicated to participants, and written reports were discussed in team meetings. We found that many healthcare improvement organizations involve patients and members of the public through a range of consultation methods (where information is collected from patients and the public), communication methods (where information is communicated to patients and the public), and participation methods (where information is exchanged between patients/public and other experts). Study participants highlighted the lack of process and impact evaluations as a major barrier to develop more effective patient and public involvement interventions.

Chapters 6 and 7 present the protocol (chapter 6) and results (chapter 7) of a systematic review of the published and gray literature on patient and public involvement in guideline development and implementation. Bibliographic references and unpublished reports were retrieved from electronic databases and from international mailing lists and networks. 2161 articles and reports were retrieved and 71 met our inclusion criteria. Over half of the studies were published after 2002, and more than half originated from the United States, the United Kingdom, Australia, and Germany. Chronic disease patients and caregivers were most often involved and tended to be recruited through patient organizations, personal invitations, and referrals from clinicians. Patients and the public principally helped formulate recommendations and revise drafts through participation on guideline development groups, consultation through individual interviews and surveys, and communication of patient information material and decision aids. Facilitators for effective involvement included structured training and support, opportunities to interact with other patients, and having clear expectations about patients' role and responsibilities. Common barriers included discrepancies between professionals' and patients' perspectives, recruitment difficulties, participants' representativeness, and lack of

familiarity with the scientific and medical terminology. These findings point towards the need to develop new involvement interventions that address these documented barriers.

Section 3: Advancing methods for effective patient and public involvement

Knowledge of the actual impact of patient and public involvement is limited and anecdotal. Evidence is lacking from controlled trials to rigorously assess whether patient and public involvement makes any difference on collective healthcare decisions. Building on the knowledge established in the previous chapters, Section 3 aims to move forward towards the development of effective patient and public involvement interventions.

In ***Chapter 8***, we develop, pilot test, and refine a new method of involvement, supporting patient-professional partnership in selecting common priorities for healthcare improvement. We first developed a 'menu' of healthcare improvement priorities, based on a systematic review of validated quality indicators for chronic disease in primary care. We identified a total of 1489 individual quality indicators, 801 of which met our inclusion criteria. An expert panel agreed on a preliminary set of indicators that were measurable with existing information systems and relevant for primary care. This indicator set was tested for comprehensiveness with a group of 9 patients and 11 professionals. The final "menu" of indicators was composed of 37 items grouped into 5 quality domains: access, integration, technical quality, interpersonal care, and health outcomes. We pilot tested a mixed patient involvement intervention that combined patient consultation and participation: 1) all patients received formal training to familiarize themselves with the proposed indicators and discuss their personal experience in relation to the quality of chronic disease prevention and management; 2) they were then all consulted by vote on their individual priorities; and 3) a subgroup of patients participated in a two-day deliberation meeting with professionals to agree on common healthcare improvement priorities. We pilot tested our intervention with 27 patients and professionals and tested our study instruments with an additional 21 patients and professionals, which demonstrated the feasibility of the intervention and generated important adaptations to engage patients more effectively.

Lack of evidence from rigorous comparative studies has been identified as a major barrier for the implementation of effective patient involvement interventions. ***Chapter 9*** assesses the impact of the patient involvement intervention described above, as tested in the first cluster randomized trial of patient involvement in collective healthcare improvement decisions. Our primary hypothesis was that structured patient involvement would result in clinical improvement priorities that better agreed with patients' priorities. In intervention sites, patients were involved together with health professionals in setting local clinical improvement priorities. In control sites, professionals selected priorities among themselves without patient involvement. Each local health authority included the selected priorities in its financial accountability contract. 6 local health authorities were randomized in intervention and control sites. 172 individuals participated in the trial, including chronic disease patients (n=83) and health professionals (n=89). Our primary outcome was the agreement between the final priorities of professionals' and patients. Agreement between professionals' and patients' priorities was significantly stronger in intervention sites (correlation coefficient = 0,69 vs. 0,19, $p<0.001$). Patient involvement fostered mutual influence between patients and professionals' choices. Clinical priorities in intervention sites placed more emphasis on self-care support, access to a primary care professional, interdisciplinary teams, and partnership with community organizations. Health professionals perceived the selected priorities as credible, realistic and actionable. The marginal costs of public involvement represented 17% of the total project costs. We conclude that structured patient involvement increases agreement between professionals and patients, is affordable, and can be implemented locally to drive change at the clinical level.

As professionals and policymakers are seeking effective ways to involve patients and the public in healthcare improvement, there is a need to open the "black box" of public involvement to understand why and how these interventions work. In ***Chapter 10***, we mobilize qualitative process evaluation data gathered alongside our trial to reflect empirically and theoretically on the key ingredients that influence the process and outcomes of public involvement in healthcare improvement. 14 one-day meetings were video recorded while two non-participant observers gathered structured notes. Qualitative analysis sought to elucidate the effects of the intervention's components and their dynamic relationships. We observed that patients' influence is associated with their perceived legitimacy and credibility by professionals. Patients' legitimacy and credibility is fostered by the recruitment of a

balanced group of participants and the opportunity for these participants to interact together and familiarize themselves with the proposed task through training and preparation. A moderation style that facilitates the expression of dissenting opinions facilitates patients' influence on group decision-making. The impact of patient involvement is also supported by the combination of small group deliberation between patients and professionals, wider patient consultation, and public communication of group decisions. Another key to success was the tailoring of our patient involvement intervention to the local implementation context through early engagement with stakeholders, pilot testing, and refinement of the intervention. We conclude that patient involvement interventions incorporate a number of interacting active ingredients that frame and foster the public's legitimacy, credibility and influence on healthcare improvement. Greater attention to these key components has the potential to increase the effectiveness of patient and public involvement.

Implications for policy, practice and research

Chapter 11 discusses the main research and practice implications of our findings in relation with the wider literature on public involvement and quality improvement. A strength of this thesis is the use of a wide range of research methods to build solid evidence on a complex and challenging field of inquiry. The successful completion of the first randomized trial of patient involvement in collective healthcare decisions represents an important landmark for the field of public involvement in healthcare. However, context has remained somewhat in the background of this thesis and is a key area for future research. More attention should be paid to contextual factors that influence the success of patient and public involvement in different settings. The growth of information technology offers new opportunities and challenges for patient and public involvement and is another area for future development. A refined analysis of the power struggle around "who wants what" from patients and the public, and how different involvement interventions are constructed as "successful" and by whom, is a next step in the science of patient and public involvement in healthcare improvement.

From a practice and policy perspective, the findings from this thesis can strengthen patient and public involvement effectiveness and address existing shortcomings. Current involvement interventions are often limited by glossy rhetorical claims, unclear goals, and unstructured methods. This thesis shows that simply "offering a seat at the table" to unprepared "ordinary" patients is unlikely to impact on

healthcare improvement. Professionals and policymakers should also remain critical in their search for a "one-size-fit-all involvement recipe", and rather seek to tailor the development of effective involvement interventions for specific contexts. This chapter describes a framework of patient and public involvement interventions which can be used as a heuristic device to support greater coherence between proposed involvement aims and methods. Patient training should go beyond the understanding of technical terms and aim at fostering the development of a task-specific patient expertise, allowing credible patient influence on healthcare improvement decisions. Rather than focusing exclusively on statistical representativeness considerations, recruitment and training should also support participants' legitimacy. Finally, there is a need for building bridges between different involvement methods and for the development of more comprehensive patient and public involvement interventions incorporating consultation, participation, and communication components.

In conclusion, this thesis has brought greater clarity and more solid evidence about the goals, current practices, and effective methods of patient and public involvement in healthcare improvement. Fifty years after the expression "patient-centered medicine" was coined, rigorous research increasingly supports the development of structured and effective patient and public involvement interventions to improve clinical care. This growing evidence can help extend patient-professional partnership beyond the clinical consultation and opens new models of shared decisions at the collective level. Effective patient involvement could foster more meaningful partnership in clinical care by reshaping the menu of choices available to patients, bringing concrete and tangible meaning to the call for a more patient centered healthcare system.

Samenvatting

Dit proefschrift gaat over het betrekken van patiënten en burgers bij de verbetering van de gezondheidszorg. Het bestaat uit elf hoofdstukken, die gegroepeerd zijn rondom drie hoofdthema's. Deze betreffen de doelen, bestaande praktijken en effectieve methodes van het betrekken van patiënten en burgers bij de verbetering van de gezondheidszorg. Deze samenvatting geeft een algemeen overzicht van het proefschrift.

Introductie en onderzoeksvragen

Hoofdstuk 1 begint met een beschrijving van de achtergronden en introduceert vervolgens de vragen die behandeld worden in de verdere hoofdstukken. De opvatting dat de patiënt "centraal" staat in de gezondheidszorg is zo oud als de geneeskunde zelf; een opvatting die bovendien steeds sterker werd vanaf de tweede helft van de twintigste eeuw. Belangrijke ontwikkelingen in de afgelopen vijftig jaar in de patiëntgerichte geneeskunde, methoden van gezamenlijke besluitvorming en zelfmanagement waren voornamelijk gericht op de deelname van patiënten aan hun eigen individuele zorg, op het microniveau van het klinische consult. Het betrekken van patiënten bij individuele klinische besluitvorming wordt tegenwoordig ondersteund door een grote hoeveelheid onderzoek, en in een aantal landen worden gestructureerd zelfmanagement en programma's die de besluitvorming ondersteunen inmiddels geïmplementeerd.

Vanuit de geschiedenis echter kent het betrekken van patiënten en burgers bij collectieve verbetering van de gezondheidszorg en bij beleidsbesluiten een trager verloop, overeenkomstig de gedachte dat de geneeskunde een zelfregulerend beroep is. Alhoewel discussies over het opnemen van het patiëntenperspectief in de evaluatie en de verbetering van de gezondheidszorg al in de jaren zeventig plaatshadden, duurde het toch nog twintig jaar voordat prestatie-indicatoren gebaseerd op patiëntenervaringen vaker gebruikt gingen worden voor kwaliteitsverbeteringen. Onderzoek laat in toenemende mate zien dat professionals vaak onjuiste vooronderstellingen hebben van de verwachtingen van patiënten met betrekking tot de zorg. Terwijl artsen en beleidsmakers worstelen met het stellen van klinische prioriteiten en beperkte middelen, ontstaat er een toenemende consensus in de richting van het actief betrekken van patiënten, om ervoor te zorgen dat de gezondheidszorg aangepast wordt aan de behoeften die voor hen het meest dringend

zijn. Door de epidemische omvang van chronische ziekten verandert vooral de manier waarop gezondheidszorg wordt geleverd, waarbij ook de rol die patiënten kunnen hebben als deelnemers aan de gezondheidszorg wordt benadrukt. Ten slotte valt de stap naar het meer betrekken van patiënten en burgers samen met de doelbewuste veranderingen in de westerse samenleving en met de opvatting dat burgers meer actief betrokken zouden moeten worden in de gezondheidszorg en in beleidsvorming.

De groeiende deelname van patiënten en burgers wordt algemeen gezien als een "goede zaak" en wordt bovendien ondersteund door een aantal retorische claims over de potentiële voordelen ervan. De stap van retoriek naar actie werpt echter wel een aantal vragen op. Ten eerste hebben critici de feitelijke doelen en de impact van interventies met betrekking tot patiëntenparticipatie betwijfeld, en gewezen op het risico dat slechts "symbolische patiënten" gebruikt worden om bestaande beleidsbesluiten te erkennen. Systematische literatuuroverzichten laten een gebrek aan wetenschappelijk bewijs zien op grond van vergelijkende studies over de gewenste en de onbedoelde effecten van het betrekken van patiënten en burgers op bevolkingsniveau. Er werd ook bezorgdheid geuit over de uitvoerbaarheid van het rekruteren van deelnemers die representatief zijn voor de "gewone" patiënt en het lekenpubliek, maar die tegelijkertijd ook de vaardigheden bezitten om bij te dragen aan complexe besluiten rondom gezondheidszorgverbetering.

Dit proefschrift richt zich op het betrekken van patiënten en burgers bij het verbeteren van de gezondheidszorg. Meer specifiek onderzoekt het de rol van patiënten en burgers in de ontwikkeling en implementatie van twee belangrijke en gerelateerde kwaliteitsverbeterende instrumenten – richtlijnen voor de klinische praktijk en kwaliteitsindicatoren – die bepalen hoe de gezondheidszorg georganiseerd en geleverd zou moeten worden om zo veilige, effectieve en geschikte zorg te geven. Het proefschrift is opgezet rondom drie onderzoeksvragen:

1. Wat zijn de doelen en verwachtingen van het betrekken van patiënten en burgers bij het verbeteren van de gezondheidszorg?
2. Hoe worden patiënten en burgers momenteel betrokken bij het verbeteren van de gezondheidszorg?
3. Hoe kunnen effectieve interventies worden ontwikkeld om het betrekken van patiënten en burgers bij gezondheidszorgverbetering te stimuleren?

Sectie 1: Doelen en verwachtingen met betrekking tot het betrekken van patiënten en burgers

Het antwoord op de vraag hoe patiënten en burgers het beste kunnen worden betrokken bij gezondheidszorgverbetering, hangt af van de definitie van een succesvol resultaat. Zowel het verhelderen van de doelen en verwachtingen van het betrekken van patiënten en burgers als het definiëren van de belangrijkste uitkomstmaten is doorslaggevend bij het opzetten van effectieve interventies.

Omdat gezondheidszorgverbetering vanouds een bolwerk was van zorgprofessionals is het belangrijk om de ervaringen en verwachtingen van clinici in kaart te brengen, om te verhelderen wat realistisch gezien verwacht kan worden van interventies met betrekking tot het betrekken van patiënten en burgers. In ***Hoofdstuk 2*** hebben we een focusgroep onderzoek uitgevoerd onder 17 Canadese huisartsen naar hun verwachtingen omtrent patiëntenparticipatie, in relatie tot het gebruik van richtlijnen in de dagelijkse praktijk. Interviews werden opgenomen, op papier gezet en geanalyseerd met gebruikmaking van sjablonen voor inhoudsanalyse. Hieruit bleek dat artsen een spanningsveld ervaren tussen twee normen voor goede praktijkvoering: voldoen aan de richtlijnen en het betrekken van patiënten in de klinische besluitvorming. Richtlijnen worden als nuttig beschouwd omdat ze artsen helpen in hun besluitvorming in het belang van hun patiënten en om te bepalen wat de beste beleidsoptie is. Als dit onduidelijk is of als er een afweging moet worden gemaakt tussen voor- en nadelen van de verschillende beleidsopties, zoeken artsen naar hulpmiddelen waarmee ze hun overwegingen kunnen delen met patiënten en informatie kunnen geven over de voor- en nadelen van de beleidsopties. Deze informatie ontbreekt veelal in de huidige richtlijnen en andere kwaliteitsverbeterende instrumenten. Aanpassingen van deze instrumenten zijn nodig om patiënten actief te betrekken bij de klinische besluitvorming.

Hoofdstuk 3 beschrijft de belangrijkste doelen en het “discours” van succesvolle patiëntenparticipatie bij de verbetering van de gezondheidszorg. Er werden individuele semigestructureerde interviews gehouden met 18 patiënten en zorgprofessionals die deelnamen aan twee richtlijnwerkgroepen in het Verenigd Koninkrijk. De analyse van de uitgewerkte interviews werd ondersteund door actief te zoeken naar afwijkende uitspraken, teamondervraging en controle van individuele leden. Alle ondervraagden ondersteunden de algemene gedachte achter

patiëntenparticipatie en vonden het “voor de hand liggend” of “zeer belangrijk”, maar ze verschilden wel van mening over waarom dit nodig zou zijn. De verschillen werden onderverdeeld in 4 discoursen: 1) het bestuursdiscours construeert gezondheidszorgverbetering als een wetenschappelijk proces en geeft als suggestie om wetenschappelijk bewijs uit klinisch onderzoek aan te vullen met gegevens over de voorkeuren en behoeften van patiënten, om zodoende de voordelen van gezondheidsinterventies maximaal te benutten op populatieniveau, rekening houdend met de beperkte middelen; 2) het geïnformeerde besluitvormingsdiscours richt zich op het stimuleren van individuele keuzes door patiënten door het geven van informatie over de voor- en nadelen van de verschillende beleidsopties; 3) het professionele zorgdiscours pleit voor het individueel afstemmen van de zorg op basis van een individuele beoordeling van de medische en psychosociale toestand van de patiënt; 4) het consumentendiscours pleit voor meer politieke macht en invloed van vertegenwoordigers van patiënten en burgers op strategische aspecten van de gezondheidszorgverbetering en beleidsvorming. We concluderen dat er brede consensus en steun bestaat onder professionals en patiënten voor het betrekken van patiënten en burgers in het verbeteren van de gezondheidszorg, maar dat er ook belangrijke verschillende gezichtspunten zijn over waarom zulke betrokkenheid noodzakelijk is en hoe het geoperationaliseerd zou moeten worden in de praktijk. Ondanks het feit dat deze gezichtspunten niet noodzakelijkerwijs onverenigbaar zijn, vragen deze bevindingen om meer transparantie en duidelijkheid over de doelen van het betrekken van patiënten en burgers.

Hoofdstuk 4 probeert te verhelderen wat we kunnen verwachten van patiënten en burgers wanneer ze bijdragen aan de verbetering van de gezondheidszorg, door nauwkeurig te onderzoeken hoe en wanneer waardeoordelen ingebed worden in de ontwikkeling en het gebruik van klinische richtlijnen. Door empirische gegevens te gebruiken uit de bovenstaande twee hoofdstukken laat dit onderzoek zien dat waardeoordelen gevormd worden in tenminste drie stadia van kwaliteitsverbetering: 1) bij het identificeren van de context waarin individuele beslissingen van professionals en patiënten beschouwd worden als ongeschikt en verbeterd zouden moeten worden; 2) bij het bepalen van wat voor soort informatie en welke opties gepresenteerd zouden moeten worden aan professionals en patiënten; 3) bij onderhandelingen over hoe de effectiviteit van kwaliteitsverbeterende maatregelen gemeten zouden moeten worden en door wie. In tegenstelling tot het beeld van richtlijnen als neutrale “dragers van feiten” op basis van evidence-based medicine,

suggereren deze bevindingen dat waardeoordelen gemaakt worden door patiënten en professionals in de gehele cyclus van gezondheidszorgverbetering. Bij verwijzingen naar de wetenschappelijke opvattingen van waarheid en validiteit in de context van evidence-based medicine, wordt vaak de sociaal-politieke dimensie van kwaliteitsverbetering over het hoofd gezien. Deze bevindingen geven de noodzaak aan van methodes die de kennis en waarden van professionals en patiënten over gezondheidszorgverbetering expliciteren en meer geloofwaardig maken en legitimeren.

Sectie 2: Bestaande praktijken en internationale ervaringen met betrekking tot het betrekken van patiënten en burgers

Er is niet veel bekend over de mate waarin patiënten en burgers tegenwoordig deelnemen aan de verbetering van de gezondheidszorg, noch hoe ze erin deelnemen en wat de belangrijkste bevorderende en belemmerende factoren voor succes zijn. Sectie 2 heeft als doel de beschikbare kennis in kaart te brengen en de meest urgente kennislacunes te identificeren door een beschrijving te geven van de bestaande praktijken op internationaal niveau. Deze sectie bouwt voort op de oprichting van de zogenoemde Guideline International Network Patient and Public Involvement Working Group, een internationale samenwerking van ontwikkelaars van richtlijnen, vertegenwoordigers van patiënten en onderzoekers, gericht op het uitwisselen van ervaringen, het stimuleren van internationale samenwerking en het ontwikkelen van nieuwe standaarden en methodes voor participatie van patiënten en burgers.

In ***Hoofdstuk 5*** wordt beschreven hoe patiënten en burgers momenteel worden betrokken door organisaties gericht op gezondheidszorgverbetering. We organiseerden een bijeenkomst met 56 richtlijnontwikkelaars, onderzoekers en vertegenwoordigers van patiënten en burgers uit 14 verschillende landen, als onderdeel van een internationale workshop over patiënt- en burgerparticipatie. Patiënten werden in subgroepen ingedeeld om een actieve bijdrage te bevorderen en om specifieke vragen te beantwoorden over de huidige praktijken, prioriteiten voor onderzoek en internationale samenwerking. De deelnemers ontvingen een samenvatting van de discussies, en in groepsbijeenkomsten werden de verslagen bediscussieerd. Hieruit bleek dat veel organisaties patiënten en burgers betrekken bij het verbeteren van de gezondheidszorg door middel van een reeks van consultatiemethodes (waarin informatie verzameld wordt van patiënten en burgers),

communicatiemethodes (waarin informatie gecommuniceerd wordt naar patiënten en burgers) en participatiemethodes (waarin informatie uitgewisseld wordt tussen patiënten, burgers en andere experts). Het gebrek aan proces- en impactevaluaties werd door de deelnemers aan het onderzoek als een belangrijke belemmerende factor gezien bij de ontwikkeling van effectieve interventies gericht op participatie van patiënten en burgers.

In ***Hoofdstukken 6 en 7*** worden het protocol (hoofdstuk 6) en de resultaten (hoofdstuk 7) gepresenteerd van een systematisch overzicht van de gepubliceerde en de 'grijze' literatuur over patiënt- en burgerparticipatie aan de ontwikkeling en implementatie van richtlijnen. Uit elektronische databases en via internationale mailinglijsten en netwerken werden referenties en ongepubliceerde rapporten verzameld. Van de 2161 artikelen en rapporten die we vonden waren er 71 die voldeden aan onze inclusiecriteria. Meer dan de helft van de onderzoeken werd na 2002 gepubliceerd, en meer dan de helft kwam uit de Verenigde Staten, het Verenigd Koninkrijk, Australië en Duitsland. Chronisch zieke patiënten en diens mantelzorgers namen het meest deel en werden vaak gerekruteerd via patiëntenorganisaties, persoonlijke uitnodigingen en verwijzingen door artsen. Patiënten en burgers hielpen voornamelijk bij het formuleren van aanbevelingen en bij het herzien van concepten door middel van participatie aan richtlijnwerkgroepen, consultatie via interviews en vragenlijstonderzoeken, en communicatie van informatiemateriaal voor patiënten en keuzehulpen. Bevorderende factoren voor een effectieve deelname waren onder andere gestructureerde training en ondersteuning, mogelijkheden voor interactie met lotgenoten, en het hebben van duidelijke verwachtingen van de rol en de verantwoordelijkheden van patiënten. Belemmerende factoren waren onder andere verschillen in perspectieven tussen professionals en patiënten, problemen met de werving en vertegenwoordiging van deelnemers en het onbekend zijn met de wetenschappelijke en medische terminologie. Deze resultaten wijzen op de noodzaak om nieuwe interventies te ontwikkelen, die op deze barrières ingaan.

Sectie 3: Methodes die een effectieve participatie van patiënten en burgers bevorderen

De bestaande kennis over de daadwerkelijke impact van participatie van patiënten en burgers is beperkt en anekdotisch. Er is geen wetenschappelijk bewijs vanuit gecontroleerde onderzoeken beschikbaar dat participatie van patiënten en burgers invloed heeft op gezondheidszorgbeslissingen op populatieniveau. Op grond van de kennis in de voorgaande hoofdstukken, richt sectie 3 zich op het ontwikkelen van effectieve interventies voor participatie van patiënten en burgers.

In ***Hoofdstuk 8*** beschrijven we een onderzoek met een interventie voor patiëntenparticipatie in een gezondheidszorgomgeving die duidelijk verbetering behoeft. De interventie werd ontwikkeld, getest in de praktijk en aangepast door middel van een gestructureerde methodologische benadering voor complexe interventies. Als eerste stap ontwikkelden we een 'menu' met onderwerpen in de gezondheidszorg die mogelijk verbetering behoeven, gebaseerd op een systematisch overzicht van gevalideerde kwaliteitsindicatoren voor chronische ziekten in de eerstelijnsgeneeskunde. Daarbij identificeerden we in totaal 1489 kwaliteits-indicatoren, waarvan er 801 voldeden aan onze inclusiecriteria. Vervolgens kwam een panel met experts tot overeenstemming over een set van indicatoren over zorgaspecten die meetbaar waren met de bestaande informatiesystemen en relevant voor de eerste lijn. Met een groep van 9 patiënten en 11 zorgprofessionals werd getest of deze indicatorenset toereikend was. Het uiteindelijke 'menu' met indicatoren bestond uit 37 items, gegroepeerd in 5 kwaliteitsdomeinen: toegankelijkheid, integratie, technische kwaliteit, intermenselijke zorg en zorguitkomsten. We testten een gemengde interventie voor het betrekken van patiënten, namelijk een combinatie van consultatie en participatie van patiënten: 1) alle patiënten kregen een formele training om kennis te nemen van de voorgestelde indicatoren en om hun persoonlijke ervaringen met betrekking tot de kwaliteit van de preventie en behandeling van chronische ziekten te bespreken; 2) ze werden allemaal gevraagd naar hun individuele voorkeuren door middel van stemming; en 3) in een tweedaagse bijeenkomst probeerde een subgroep van patiënten tot overeenstemming te komen met zorgprofessionals over de zorgaspecten die prioriteit zouden moeten krijgen. De interventie werd in de praktijk getest op 27 patiënten en zorgprofessionals en onze onderzoeksinstrumenten op aanvullend 21 (in totaal 48) patiënten en professionals. Hieruit kwam naar voren dat de interventie geschikt werd

bevonden, waarbij er belangrijke aanpassingen werden gedaan om patiënten op een effectievere manier te betrekken.

Gebrek aan wetenschappelijk bewijs vanuit degelijk opgezette, vergelijkende studies wordt gezien als een belangrijke barrière voor de implementatie van effectieve patiëntenparticipatie interventies. In ***Hoofdstuk 9*** beschrijven we de impact van de hierboven beschreven interventie in een cluster- gerandomiseerd onderzoek naar het effect van patiëntenparticipatie in gezondheidszorgbesluiten op populatieniveau. Een dergelijk onderzoek is nog nooit eerder uitgevoerd. Onze primaire hypothese was dat gestructureerde patiëntenparticipatie zou resulteren in klinische verbeterpunten, die beter overeenstemmen met de voorkeuren van patiënten. In de interventiegroepen werden patiënten samen met zorgprofessionals op lokaal niveau betrokken bij het opstellen van een lijst van klinische verbeterpunten. In de controlegroepen stelden professionals de voorkeurslijst op zonder patiënten erbij te betrekken. De geselecteerde verbeterpunten werden in de contracten van alle lokale zorgautoriteiten opgenomen. Zes lokale zorgautoriteiten werden 'at random' ingedeeld in interventie- en controlegroepen; 172 personen namen deel aan het onderzoek, waaronder 83 chronisch zieke patiënten en 89 zorgprofessionals. Onze primaire uitkomstmaat was de overeenstemming tussen de uiteindelijke voorkeuren van professionals en patiënten. In de interventiegroepen was de overeenstemming tussen de voorkeuren van professionals en patiënten beduidend sterker (correlatiecoëfficiënt = 0,69 vs. 0,19, $p<0,001$). Patiëntenparticipatie bleek een stimulerende werking te hebben op de wederzijdse beïnvloeding van de keuzes van patiënten en professionals. In de lijst van geprioriteerde verbeterpunten in de interventiegroepen werd meer de nadruk gelegd op ondersteuning bij zelfzorg, toegang tot een eerstelijns zorgprofessional, interdisciplinaire teams, en samenwerking met gemeentelijke organisaties. Zorgprofessionals beschouwden de geselecteerde prioriteiten als geloofwaardig, realistisch en uitvoerbaar. De marginale kosten van patiëntenparticipatie bedroegen 17% van de totale projectkosten. We concluderen dat gestructureerde patiëntenparticipatie leidt tot meer overeenstemming tussen professionals en patiënten, betaalbaar is, en lokaal geïmplementeerd kan worden om veranderingen in de zorg in gang te zetten.

Professionals en beleidsmakers zoeken naar effectieve manieren om patiënten en burgers te betrekken bij de verbetering van de gezondheidszorg. Hierdoor is de noodzaak ontstaan om de "black box" van patiënten- en burgerparticipatie te openen

en om te begrijpen waarom en hoe deze interventies werken. In ***Hoofdstuk 10*** gebruiken we data voor kwalitatieve procesevaluaties, die we verzameld hebben in ons clustergerandomiseerd onderzoek om empirisch en theoretisch te reflecteren op de hoofdingrediënten die het proces en de resultaten van patiënt- en burgerparticipatie aan gezondheidszorgverbetering beïnvloeden. Veertien eendaagse bijeenkomsten werden op video opgenomen, terwijl twee toehoorders gestructureerde aantekeningen maakten. Door middel van een kwalitatieve analyse probeerden we de effecten van de verschillende componenten van de interventie te verduidelijken, alsmede hun onderlinge relatie. Op grond van deze analyse merkten we op dat de authenticiteit, overtuiging en invloed van patiënten op besluiten over gezondheidszorgverbetering ondersteund werden door het werven van een gebalanceerde groep deelnemers, gestructureerde training die de eigen identiteit van patiënten benadrukt en de mogelijkheid om van de ervaringen van anderen te leren, door een stijl van modereren die het uiten van afwijkende meningen mogelijk maakt, en door de combinatie van directe patiëntenparticipatie aan kleine groepsbijeenkomsten, consultatie van patiënten op grotere schaal, en communicatie met patiënten over groepsbeslissingen. Het betrekken van stakeholders in de onderhandelingen over het operationaliseren van patiëntenparticipatie in de praktijk droeg bij aan de beleidsondersteuning en aan het aanpassen van de interventie aan de lokale context. We concluderen dat interventies gericht op patiëntenparticipatie een aantal actieve, interacterende ingrediënten bevatten die de authenticiteit, overtuiging en invloed van burgers op gezondheidszorgverbeteringen vormgeven en stimuleren. Meer aandacht hiervoor kan leiden tot een grotere effectiviteit van interventies gericht op het betrekken van patiënten en burgers.

Implicaties voor beleid, praktijk en onderzoek

In ***Hoofdstuk 11*** worden de belangrijkste implicaties van onze bevindingen voor onderzoek en praktijk besproken in relatie tot de omvangrijke literatuur over patiënten- en burgerparticipatie en kwaliteitsverbetering. Een van de sterke punten van dit proefschrift is het gebruik van een uitgebreid arsenaal aan onderzoeksmethodes om solide wetenschappelijk bewijs te creëren in een moeilijk en uitdagend onderzoeksgebied. De succesvolle afronding van het eerste gerandomiseerde onderzoek naar patiëntenparticipatie in gezondheidszorgbesluiten op populatieniveau is een belangrijke mijlpaal in dit onderzoeksgebied. In dit proefschrift is de context echter wat op de achtergrond gebleven. In toekomstig

onderzoek zou meer aandacht besteed moeten worden aan contextuele factoren die van invloed zijn op een succesvolle deelname van patiënten en burgers in verschillende settings. De toenemende informatietechnologie biedt nieuwe mogelijkheden en uitdagingen voor het betrekken van patiënten en burgers hetgeen ook een gebied is waarin nieuwe ontwikkelingen zullen plaatsvinden. Een volgende stap in het wetenschappelijk onderzoek naar patiënten- en burgerparticipatie bij de verbetering van de gezondheidszorg is een verfijnde analyse van de machtsstrijd over "wie wil wat" van patiënten en burgers, en hoe interventies succesvol samengesteld worden en door wie.

Vanuit het perspectief van praktijk en beleid kunnen de resultaten van dit proefschrift de effectiviteit van patiënten- en burgerparticipatie versterken en bestaande tekortkomingen aan de orde stellen. De huidige interventies worden vaak beperkt door 'glossy' retorische claims, onduidelijke doelen en ongestructureerde methodes. Dit proefschrift laat zien dat het niet waarschijnlijk is dat het simpelweg aanbieden van een plaats aan de overlegtafel aan onvoorbereide "gewone" patiënten invloed zal hebben op gezondheidszorgverbetering. Ook zullen professionals en beleidsmakers zich kritisch moeten blijven opstellen in hun zoektocht naar een "one-size-fit-all recept"; beter zou het zijn als ze zich zouden richten op het op maat maken van effectieve interventies voor specifieke contexten. We stellen voor om een kader te maken van interventies voor het betrekken van patiënten en burgers, dat gebruikt kan worden als heuristisch hulpmiddel om een grotere samenhang tussen de voorgestelde doelen en methodes te ondersteunen. Training van patiënten zou verder moeten gaan dan alleen het begrijpen van technische termen; het zou gericht moeten zijn op het stimuleren van de ontwikkeling van een taakspecifieke expertise van patiënten, waardoor een overtuigende invloed van patiënten op besluitvorming met betrekking tot gezondheidszorgverbetering mogelijk gemaakt kan worden. In plaats van zich exclusief te richten op beschouwingen over statistische vertegenwoordiging, zouden werving en training ook de authenticiteit van de deelnemers moeten ondersteunen als het gaat om hun rol als vertegenwoordiger. Ten slotte is er behoefte aan het slaan van bruggen tussen de verschillende methodes, en aan het ontwikkelen van meer omvattende interventiemethodes voor het betrekken van patiënten en burgers, met inbegrip van componenten als overleg, deelname en communicatie.

Concluderend kunnen we stellen dat dit proefschrift heeft geleid tot meer duidelijkheid en meer solide wetenschappelijk bewijs over de doelen, huidige praktijken en effectieve methodes van het betrekken van patiënten en burgers bij verbetering van de gezondheidszorg. Vijftig jaar nadat de term patient-centred medicine werd bedacht, wordt in toenemende mate de ontwikkeling van gestructureerde en effectieve interventies gericht op het betrekken van patiënten en burgers ondersteund door nauwgezet onderzoek, met als doel de verbetering van de zorg. Dit wetenschappelijk bewijs kan professionals en beleidsmakers stimuleren om van retoriek tot actie over te gaan. Effectieve deelname aan strategische besluitvorming rondom gezondheidszorgverbetering op populatieniveau kan de samenwerking tussen individuele professionals en patiënten bevorderen in de dagelijkse praktijk, door de beschikbare beleidsopties in een nieuwe vorm aan te bieden. Hierdoor wordt een concrete betekenis gegeven aan de roep om een meer patiëntgericht gezondheidszorgsysteem.

Résumé

Cette thèse de doctorat traite de la participation des patients et du public à l'amélioration des soins de santé. Cette thèse par articles est composée de onze chapitres distincts. Après un premier chapitre d'introduction, neuf articles de recherche sont présentés dans chacun des chapitres subséquents. Ces neuf chapitres sont structurés en trois sections distinctes concernant: 1) les buts et bénéfices attendus; 2) les pratiques actuelles à l'échelle internationale; 3) les méthodes efficaces de participation des patients et du public. Le dernier chapitre discute des principales conclusions et recommandations. Ce résumé présente un survol du contenu de l'ensemble de la thèse.

Introduction et questions de recherche

Le ***Chapitre 1*** présente l'introduction et les questions traitées dans les chapitres subséquents. L'idée que les patients devraient être "au centre" des soins de santé trouve ses origines dans la fondation même de la profession médicale est s'est imposée à partir de la deuxième moitié du XXe siècle. Au cours des cinquante dernières années, des développements importants ont eu lieu dans les domaines de la médecine centrée sur le patient, de la prise de décision partagée, et de l'autogestion des soins. Ainsi, de nombreux programmes visant à favoriser une participation plus active des patients dans leurs propres soins de santé sont mis en place à l'échelle internationale.

La participation des patients et du public aux choix collectifs par rapport à la façon dont les soins de santé sont organisés s'est développée beaucoup plus lentement. Ainsi, l'amélioration des soins demeure largement guidée par les priorités des professionnels. Bien que les discussions sur l'intégration de la perspective du patient dans l'amélioration des soins aient commencé dans les années 1970, plus de vingt ans ont été nécessaires avant que l'évaluation des soins par les patients commence à être plus largement utilisée. Afin de s'assurer que les services disponibles répondent à leurs besoins les plus pressants, un consensus émerge quant à la nécessité de faire participer activement les patients à l'amélioration des soins. Plus spécifiquement, l'épidémie croissante des maladies chroniques transforme la façon dont les soins sont offerts et souligne le rôle de partenaire que peuvent jouer les patients. Finalement, l'intérêt vers la participation des patients et du public coïncide avec l'idée que les

citoyens doivent participer plus activement à l'élaboration des politiques publiques et à l'organisation des soins de santé.

L'émergence de la participation des patients et du public est généralement perçue comme une "bonne chose". Par contre, passer de la rhétorique à l'action pose plusieurs difficultés. Premièrement, certains critiques remettent en question les buts et l'impact concret des interventions participatives et soulignent le risque que des patients soient utilisés pour légitimer des décisions prises par d'autres. Plusieurs revues systématiques de la littérature ont documenté l'absence d'études comparatives sur les effets positifs et négatifs de la participation des patients et du public aux choix collectifs de santé. Des préoccupations ont également été soulevées quant à la faisabilité de recruter des participants représentatifs de la population ayant la compétence de contribuer à des décisions complexes.

Cette thèse explore comment les patients et les professionnels peuvent travailler ensemble à améliorer les soins de santé. Plus spécifiquement, elle explore le rôle des patients et du public dans la conception et l'implantation de deux outils importants d'amélioration de la qualité - les guides de pratique clinique et les indicateurs de qualité - lesquels définissent des normes de bonne pratique sur la façon dont les soins de santé devraient être organisés et offerts. Cette thèse est structurée autour de trois questions de recherche principales:

1. Quels sont les buts et les bénéfices attendus par rapport à la participation des patients et du public à l'amélioration des soins de santé?
2. Comment les patients et le public participent-ils actuellement à l'amélioration de soins de santé à l'échelle internationale?
3. Quelles méthodes permettent aux patients et au public de participer efficacement à l'amélioration des soins de santé?

Section 1: Buts et bénéfices attendus de la participation des patients et du public

Le premier problème posé par la participation des patients est la définition même du succès. Clarifier les buts et les bénéfices attendus est une étape essentielle à l'élaboration d'interventions efficaces.

Puisque l'amélioration des soins de santé a traditionnellement été une question relevant des professionnels de la santé, il est nécessaire de comprendre les attentes des cliniciens par rapport à la participation des patients et du public. Dans le ***Chapitre 2***, nous avons mené une recherche auprès de 17 médecins de famille canadiens. Un groupe de discussion a été organisé afin d'explorer les attentes et expériences des médecins par rapport à la participation des patients et à l'utilisation des guides de pratique clinique. Les entrevues audio ont été enregistrées, transcrites de façon verbatim, avant d'être soumises à une analyse de contenu. Les entrevues démontrent que les médecins ressentent une tension entre deux normes distinctes de bonne pratique médicale: se conformer aux recommandations des guides de pratique clinique et considérer la perspective du patient. Les guides de pratique cliniques sont perçus comme utiles pour aider les médecins à prendre des décisions au nom de leurs patients et pour influencer leur choix lorsqu'une option semble manifestement favorable. Devant des interventions aux avantages incertains ou comportant des risques importants, les médecins cherchent des outils leur permettant de partager le processus décisionnel avec leurs patients en communiquant les avantages et inconvénients des différentes options disponibles. Selon les médecins, les guides de pratiques actuels sont limités et doivent être adaptés pour permettre une participation plus active des patients à la prise de décision clinique.

Le ***Chapitre 3*** décrit les principaux buts sur ce que représente une participation efficace des patients à l'amélioration des soins de santé aux yeux des concepteurs de guides de pratique clinique. Des entrevues individuelles semi-structurées ont été menées auprès de 18 patients et professionnels de la santé au Royaume-Uni. Une analyse de discours a été menée à partir d'une transcription des entrevues et a été validée par une recherche active de cas divergents, par des discussions d'équipe, et par triangulation auprès des participants. Tous les participants se disaient en accord avec la participation des patients à l'amélioration des soins de santé et jugeaient cette idée comme "évidente" et d'une "importance vitale". Ils étaient par contre en désaccord sur les buts et bénéfices attendus d'une telle participation. Ces différentes visions de la participation des patients ont été structurées en 4 "discours" différents: 1) le discours de la Gouvernance construit l'amélioration des soins de santé comme un processus scientifique visant à accroître la valeur des services financés collectivement. Selon ce discours, le rôle des patients se résume à participer à des sondages ou enquêtes permettant de recueillir des données objectives sur les préférences et besoins de la population; 2) le discours des Choix Santé conçoit le

patient comme acteur dans la prise de décision clinique. Il propose de soutenir les choix individuels de chaque patient en lui communiquant des informations sur les risques et bénéfices des interventions disponibles. Ce discours présume qu'une meilleure information permettra l'adoption de comportements sains par le patient; 3) le discours de l'Autonomie Professionnelle insiste sur l'individualisation des soins offerts à chaque personne. Ce discours n'implique pas nécessairement un rôle actif du patient dans la prise de décision clinique, mais souligne l'importance de préserver l'autonomie clinique permettant d'appliquer de manière flexible les recommandations professionnelles issues des guides de pratique clinique; 4) le discours du Consommateur Militant argumente en faveur d'un plus grand pouvoir d'influence collective des patients dans des aspects stratégiques de l'organisation des soins. Ce discours conçoit la participation des patients comme un processus essentiellement politique. Il propose que des représentants de patients jouent un rôle actif au sein d'instances responsables de l'amélioration des soins de santé. Nous concluons que malgré le fait que la participation des patients génère un large consensus, des visions très différentes existent quant à la signification et aux buts d'une telle participation. C'est donc dire que la "meilleure" façon de faire participer les patients dépend étroitement des buts et bénéfices attendus par les différents acteurs. Le choix d'une façon concrète de faire participer les patients demande donc d'abord de clarifier les objectifs visés.

Dans le domaine de la médecine basée sur les données probantes, les outils d'amélioration de la qualité comme les guides de pratique clinique sont souvent vus comme des outils d'information porteurs de "faits objectifs" et de données de recherche brutes. Une telle conception peut limiter le rôle des patients dans la conception des guides de pratique clinique par crainte que ceux-ci viendraient biaiser l'interprétation des données scientifiques. À partir de données empiriques issues des deux chapitres précédents, le ***Chapitre 4*** examine comment et quand des jugements de valeur sont posés dans la conception et l'utilisation des guides de pratique clinique. Cette étude démontre que des jugements de valeur implicites sont posés dans au moins trois étapes du processus d'amélioration de la qualité des soins: 1) dans l'identification des décisions perçues comme inappropriées et nécessitant une meilleure information; 2) dans l'identification des options disponibles et du type d'information présentés aux patients et aux professionnels; 3) dans les négociations sur la façon dont l'efficacité des activités d'amélioration de la qualité sont mesurées et par qui. En contraste avec le portrait tracé par les promoteurs de la médecine basée

sur les données probantes, ces résultats suggèrent que le développement des guides de pratique clinique repose sur plusieurs jugements de valeur posés à la fois par les professionnels et les patients. Les notions de vérité et de validité scientifique utilisées dans la médecine fondée sur les données probantes tendent à passer sous silence les dimensions sociopolitiques de l'amélioration des soins. Ces résultats soulignent l'importance de rendre plus explicites, crédibles et légitimes les connaissances et les valeurs des professionnels et des patients participants aux choix collectifs d'amélioration des soins de santé.

Section 2: Pratiques actuelles de participation des patients et du public

Peu de choses sont connues sur la façon dont les patients et le public participent à l'amélioration des soins de santé et quelles sont les principaux facteurs de succès. La Section 2 vise à cartographier les pratiques actuelles à l'échelle internationale dans le but de favoriser une participation plus efficace. Cette section prend appui sur la création du Guideline International Network Patient and Public Involvement Working Group, un groupe de travail international regroupant des concepteurs de guides de pratique cliniques, des chercheurs et des représentants de patients et du public visant à développer des méthodes efficaces de participation.

Le ***Chapitre 5*** décrit comment les patients et le public participent actuellement à la conception et à l'implantation des guides de pratique cliniques utilisés dans l'amélioration des soins de santé. Nous avons mené une consultation auprès de 56 concepteurs de guides de pratique clinique, chercheurs et représentants de patients de 14 pays différents, lors d'une conférence internationale d'une journée. Les participants étaient divisés en sous-groupe pour débattre de questions spécifiques sur les pratiques actuelles ainsi que les priorités de recherche à l'échelle internationale. Un résumé des discussions a été validé auprès des participants, et le rapport écrit a été discuté en réunions d'équipe. Nous avons trouvé que plusieurs organisations de santé font participer les patients et le public à travers un large éventail de méthodes. Ces approches peuvent être regroupées en méthodes consultatives (où des informations sont colligées auprès des patients et du public), en méthodes de communication (où des informations sont transmises aux patients et au public), et en méthodes délibératives (où des informations sont échangées entre les patients et les professionnels de la santé). Les participants à l'étude ont souligné le

besoin d'études rigoureuses évaluant l'efficacité de ces différentes méthodes participatives.

Les ***Chapitres 6 et 7*** présentent le protocole (chapitre 6) et les résultats (chapitre 7) d'une revue systématique de la littérature sur la participation des patients et du public dans la conception et l'implantation des guides de pratique clinique. Les études publiées ainsi que les rapports issus de la littérature grise ont été recensés à partir de bases de données électroniques et de listes de diffusions internationales. 2161 articles et rapports ont été recensés, dont 71 répondaient à nos critères d'inclusion. Plus de la moitié des études étaient publiées après 2002, et plus de la moitié venaient des États-Unis, du Royaume-Uni, de l'Australie et de l'Allemagne. Les patients atteints de maladies chroniques et leurs proches sont les plus souvent impliqués, par opposition aux représentants du public en général. Les participants tendent à être recrutés à partir d'organisations de patients, d'invitations personnelles, et de références par les cliniciens. Les patients et le public participent de différentes façons: 1) à travers la participation à des comités délibératifs chargés de la formulation des recommandations des guides de pratiques cliniques, 2) en étant consultés par entrevue individuelle ou par sondages; 3) à travers la communication d'informations de santé, de matériel éducatif, et d'outils d'aide à la décision. Les facteurs favorisant une participation efficace incluent une formation structurée des participants, l'opportunité d'interagir avec d'autres patients, et l'identification d'attentes claires par rapport aux rôles et responsabilités des patients et du public. Les barrières communes incluent la difficulté de réconcilier les perspectives des professionnels et des patients, le recrutement et l'identification de participants représentatifs, et la familiarité avec le vocabulaire scientifique et médical. Aucune étude n'a évalué l'impact de la participation des patients sur l'amélioration des soins.

Les études de la Section 2 indiquent que les patients et le public participent de plus en plus à l'amélioration des soins de santé, mais soulignent la nécessité de développer des interventions plus efficaces permettant de répondre aux principales barrières identifiées.

Section 3: Accroître l'efficacité de la participation des patients et du public

Les connaissances sur l'impact réel de la participation des patients et du public sont limitées et anecdotiques. Il n'existe aucun essai randomisé sur les conséquences de la participation des patients aux choix collectifs par rapport à l'amélioration des soins de santé. À partir des connaissances développées dans les chapitres précédents, la Section 3 vise à favoriser une participation plus efficace.

Le ***Chapitre 8*** décrit le développement d'une intervention structurée visant à faire participer des patients au choix de priorités collectives d'amélioration des soins de santé. Nous avons d'abord développé un "menu" de priorités concrètes et mesurables d'amélioration. Pour ce faire, nous avons mené une revue systématique d'indicateurs de qualités permettant de mesurer l'amélioration de la prévention et du suivi des maladies chroniques. Nous avons identifié un total de 1489 indicateurs de qualité, dont 801 répondaient à nos critères d'inclusion. Un groupe d'experts a identifié un ensemble préliminaire d'indicateurs mesurables et pertinents au contexte de la première ligne. Ces indicateurs préliminaires ont été présentés à 9 patients et 11 professionnels afin de s'assurer qu'ils mesuraient les dimensions importantes de l'amélioration des soins. Le "menu" final comprend 37 indicateurs regroupés en 5 dimensions de la qualité: l'accessibilité, l'intégration des soins, la qualité technique, la qualité relationnelle, et les résultats de santé. Nous avons ensuite développé une intervention où patients et professionnels de la santé ont eu à choisir parmi ces priorités d'amélioration des soins. L'intervention combine des méthodes consultatives et délibératives: 1) tous les patients ont d'abord reçu une formation leur permettant de se familiariser avec les priorités proposées en lien avec leurs expériences personnelles; 2) ils ont tous été consultés par vote sur leurs priorités d'amélioration des soins de santé pour leur communauté; et 3) un sous-groupe de patients a ensuite participé à une rencontre délibérative de deux jours avec des professionnels de la santé afin de s'entendre sur des priorités communes d'amélioration des soins de santé. Nous avons mené notre projet pilote auprès de 27 patients et professionnels et raffiné nos instruments de mesure auprès d'un groupe additionnel de 21 patients et professionnels. Ce projet pilote a permis de démontrer la faisabilité de l'intervention et d'en adapter certains aspects importants dans le but d'en accroître l'efficacité.

Le ***Chapitre 9*** évalue l'impact de l'intervention décrite plus haut, à l'aide du premier essai randomisé sur la participation des patients aux choix collectifs de santé. 172 personnes ont participé à l'étude, incluant des patients atteints de maladies chroniques (n=83) et des professionnels de la santé (n=89). Six centres de santé au Canada ont été répartis au hasard en sites d'intervention et sites contrôles. Dans les sites d'intervention, les patients ont participé avec les professionnels de la santé au choix de priorités d'amélioration des soins. Dans les sites contrôles, les professionnels ont choisi ces priorités entre eux, sans la participation des patients. Chaque centre de santé s'est engagé par contrat à mettre en action et mesurer l'atteinte des priorités choisies. Notre hypothèse primaire était que la participation des patients améliorerait l'accord entre les priorités des patients et des professionnels.

L'accord entre les priorités des patients et des professionnels était significativement plus élevé dans les sites d'intervention (coefficient de corrélation = 0.69 vs. 0.19; $p<0.001$; différence absolue = 50%). L'intervention a favorisé une influence mutuelle entre les priorités des patients et des professionnels: les patients ont influencé les professionnels et les professionnels ont également influencé les patients. Les priorités choisies dans les sites d'intervention ont mis davantage l'accent sur l'accessibilité à un professionnel de première ligne, les activités d'autosoin, le travail en équipe interdisciplinaire et la collaboration avec les organisations communautaires, par opposition à la qualité technique du suivi de maladies chroniques. Les professionnels ont perçu les priorités choisies comme réalistes et ont exprimé l'intention de mettre ces priorités en action. La participation des patients a représenté 17% de l'ensemble des coûts liés au choix de priorités par les centres de santé. Nous concluons qu'une intervention participative structurée améliore l'accord entre les priorités des professionnels et des patients, est abordable, et peut être implantée localement pour guider l'amélioration des pratiques cliniques.

Dans le but de développer des interventions plus efficaces, il est nécessaire d'ouvrir la "boîte noire" de la participation du public afin de comprendre pourquoi et comment ces interventions fonctionnent. Dans le ***Chapitre 10***, nous mobilisons des données qualitatives issues de notre essai randomisé pour identifier les ingrédients clés de la participation du public dans l'amélioration des soins. Cette évaluation de processus repose sur l'enregistrement vidéo de 14 rencontres d'une journée et de notes d'observations colligées par deux chercheurs à différentes phases de l'étude. L'analyse qualitative des données a porté sur les différentes composantes de

l'intervention et leur relation dynamique aux résultats observés. Nous avons observé que l'influence des patients est liée à leur légitimité comme représentants des patients et à la perception de leur crédibilité à contribuer aux choix collectifs d'amélioration des soins. La légitimité et la crédibilité des patients sont favorisées par le recrutement d'un groupe équilibré de participants et par une formation structurée permettant un échange d'expériences et d'expertises. Une animation facilitant l'expression d'opinions divergentes facilite l'influence des patients. La combinaison de méthodes consultatives, délibératives et de communication supporte également l'influence des patients sur les choix collectifs de santé. Finalement, permettre aux acteurs clés de s'entendre sur le rôle attendu des patients accroît la légitimité de leur participation. Nous concluons que plusieurs ingrédients facilitent la légitimité, la crédibilité et l'influence des patients aux choix collectifs de santé. Une attention plus grande à ces ingrédients clés pourrait permettre une participation plus efficace des patients et du public.

Implications pour les politiques, la pratique clinique et la recherche

Le ***Chapitre 11*** discute des principales conclusions et de la portée des résultats pour la pratique clinique, les politiques de santé et la recherche. Les recherches présentées dans cette thèse utilisent une variété d'approches méthodologiques permettant de construire une base empirique solide sur une thématique de recherche complexe. La réalisation du premier essai randomisé sur la participation des patients aux choix collectifs de santé représente une avancée importante. Une avenue prioritaire de recherche future consisterait à clarifier quel type d'intervention fonctionne dans différents contextes. Une analyse plus fine des joutes de pouvoir sur "qui attend quoi" des patients et du public, et pourquoi différentes interventions sont jugées "efficace" et par qui, est également une prochaine étape dans la science de la participation des patients et du public à l'amélioration des soins.

Sur le plan de la pratique clinique et des politiques publiques, les résultats de cette thèse permettent de développer des interventions plus efficaces. Les pratiques actuelles sont souvent caractérisées par des objectifs vagues et des méthodes peu structurées. Cette thèse démontre qu'offrir simplement "un siège à la table" à des patients "ordinaires" ne bénéficiant d'aucune préparation a peu de chance de mener à des changements concrets sur les soins de santé. Par ailleurs, les professionnels et les décideurs publics devraient demeurer critiques dans leur quête d'une "recette"

unique de participation des patients et chercher plutôt à adapter les méthodes existantes au contexte spécifique d'application.

Nous proposons dans ce dernier chapitre un cadre de référence permettant une plus grande cohérence entre les buts et les méthodes de participation des patients et du public. Nous proposons que la formation des patients doive aller plus loin que de viser la compréhension de termes techniques et doive servir à développer une expertise spécifique permettant aux patients de contribuer de façon crédible aux choix collectifs. Plutôt que de mettre l'accent uniquement sur des considérations de représentativité statistique, les stratégies de recrutement et de formation devraient favoriser la légitimité des participants dans leur rôle de représentants des patients et du public. Finalement, il est nécessaire de bâtir des ponts entre les différentes méthodes consultatives, délibératives et de communication afin de développer des interventions plus efficaces jetant les bases d'un partenariat à long terme entre les patients et les professionnels.

En conclusion, cette thèse a apporté une plus grande clarté et des données plus solides sur les buts, les pratiques actuelles, et les méthodes efficaces de participation des patients et du public aux choix collectifs de santé. Cinquante ans après la création de l'expression "médecine centrée sur le patient", des recherches rigoureuses soutiennent le développement d'interventions efficaces permettant aux patients et au public de participer à l'amélioration des soins. La participation des patients et du public aux choix collectifs de santé pourrait favoriser un meilleur partenariat entre les patients et les professionnels, concrétisant ainsi l'appel vers un système de santé centré sur les besoins des patients.

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At this point in his young life, my son Loris has no clue what patient and public involvement in healthcare improvement means, but he sure knows the meaning of having his dad type on a computer when he wants to play outside. While Julia and I waited to welcome Loris into our family, I have found in the gestation of this PhD thesis the patience to wait for our parenthood project to come to life, and have found in Julia and Loris the inspiration of nurturing both projects as a work of love. This thesis is dedicated to them.

Curriculum Vitae

Antoine Boivin was born in Canada and grew-up on île d'Orléans, near Quebec City. Nurturing eclectic interests between philosophy, science, sociology, history, and humanitarian work during his college education, he started his medical training as an experience in "applied ethics with a human touch".

During his medical education at Université de Montréal, Antoine hitchhiked for a year in Europe, worked in a community hospital in Haitï, as a camp counselor with young cancer patients and their families, and was involved in student policy issues. He completed his postdoctoral training in family medicine at Dalhousie University, and was introduced to primary care research by Dr Fred Burge.

Upon completion of his medical training, Antoine worked for a year as a physician in a primary care and methadone replacement clinic in Montreal, before moving with his wife to Rouyn-Noranda, a 40 000 people rural town located seven hours north of Montreal. Between 2005 and 2012, he worked in this community as a clinician in an acute care hospital – caring mainly for elderly patients – while teaching research and critical literature appraisal. He was also appointed as medical advisor for chronic disease management and primary care delivery within the regional department of public health of Abitibi-Témiscamingue.

In 2006-2007, Antoine graduated with distinction from an MSc degree in health services research from the London School of Hygiene and Tropical Medicine (United Kingdom). Between 2008 and 2012, he completed his PhD thesis on patient and public involvement in healthcare improvement at IQ healthcare (The Netherlands), while doing his empirical work from Rouyn-Noranda (Canada). Antoine is one of the first family physicians in Canada to have been awarded a clinician-scientist training award from the Canadian Institutes of Health Research.

Antoine's interest for public involvement extends from healthcare to music, and he is a proud member of the sing-along traditional music band "Les Vieux Borlots".

Antoine is married to Julia Sohi and is the happy father of Loris Boivin.

Patient and Public Involvement in Healthcare Improvement

Patient-professional partnership is considered an essential element of good clinical care. However, collective choices about health services' organization and delivery are still largely driven by professionals' priorities.

This doctoral thesis explores how patients and professionals can work together to improve healthcare. Based on the first randomized trial on the topic, it argues that effective patient involvement increases agreement between patients' and professionals' priorities and could help reshape healthcare services around patients' most pressing needs.

Antoine Boivin is a practicing family physician in Canada and a doctoral candidate at the Scientific Institute for Quality of Healthcare in the Netherlands.