

The development of guideline implementation tools: a qualitative study

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Abstract

Background: Research shows that guidelines featuring implementation tools (GItools) are more likely to be used than those without GItools, however few guidelines offer GItools and guidance on developing GItools is lacking. The objective of this study was to identify common processes and considerations for developing GItools.

Methods: Interviews were conducted with developers of 4 types of GItools (implementation, patient engagement, point-of-care decision-making and evaluation) accompanying guidelines on various topics created in 2008 or later identified in the National Guideline Clearinghouse. Participants were asked to describe the GItool development process and related considerations. A descriptive qualitative approach was used to collect and analyze data.

Results: Interviews were conducted with 26 GItool developers in 9 countries. Participants largely agreed on 11 broad steps, each with several tasks and considerations. Response variations identified issues lacking uniform approaches that may require further research including timing of GItool development relative to guideline development; decisions about GItool type, format and content; and whether and how to engage stakeholders. Although developers possessed few dedicated resources, they relied on partnerships to develop, implement and evaluate GItools.

Interpretation: GItool developers employed fairly uniform and rigorous processes for developing GItools. By supporting GItool development, the GItool methods identified here may improve guideline implementation and use.

Guidelines are recognized as the foundation of efforts to improve health care because they synthesize all of the available evidence on effective management of a given condition, offer recommendations to inform health care planning and delivery, and are the basis for measuring and improving performance and outcomes.^{1,2} Unfortunately, guideline use is less than ideal as shown by population-based studies from several countries.³⁻⁵ This is because of multiple, interacting contextual factors such as patient noncompliance, provider skepticism about guideline relevance for individual patients, lack of institutional infrastructure, and limited system-level resources and coordination.⁶ Even when interventions are used to implement guidelines, they have a small or inconsistent impact, perhaps because contextual challenges are not easily addressed.⁷ New approaches are urgently needed to support guideline implementation and use. Experts have referred to this as an evidence-based medicine crisis, and have called for developers to provide users with tools such as algorithms or decision-making aids with which to implement guidelines.^{8,9}

Incorporating implementation tools with guidelines may be a feasible approach for improving guideline implementa-

tion and use. Evaluations of guidelines showed that they were high in quality for scope and purpose, stakeholder involvement, rigor of development and clarity of presentation, but consistently lacking in applicability.¹⁰⁻¹⁴ This refers to guideline implementation tools (GItools) such as training material (e.g., workshop slides, self-directed learning kits), guideline summaries or algorithms, patient information, or guidance for evaluation (e.g., quality indicators, audit instructions). Focus groups found that health professionals were frustrated and uncertain about how to implement guidelines.¹⁵ GItools have been empirically associated with guideline use. Two trials and a systematic review of 23 studies based on 143 recommendations showed that compliance was greater for guidelines that offered implementation tools compared with guidelines that

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were not accompanied by implementation tools.^{16–18} We interviewed 30 guideline developers from 7 countries who said that their target users had requested GItools, but they required direction for developing GItools.¹⁹ Existing guideline development instructional manuals lack details on how to develop GItools.^{20,21} The purpose of this study was to identify common processes and considerations for developing GItools.

Methods

Approach

GItool developers were interviewed to learn how they developed GItools. Qualitative research is useful for revealing tacit knowledge.²² A descriptive qualitative approach was used along with various strategies to optimize rigor.^{23,24} Consolidated criteria for reporting qualitative research²⁵ guided the reporting of study findings. Conduct of this study was approved by the University Health Network Research Ethics Board (12-0091-AE). Participants gave informed consent before being interviewed.

Sampling and recruitment

The National Guideline Clearinghouse (US Department of Health and Human Services, Agency for Healthcare Research and Quality; www.guideline.gov) was searched for English-language guidelines published in 2008 or later on the management of prevalent conditions that affect both men and women (e.g., arthritis, asthma, cancer, depression, diabetes, heart failure, stroke) and topics relevant to guideline developers who were collaborators on this research (e.g., chiropractic, dermatology, neurology, nephrology). Clearinghouse records for individual guidelines indicate if they have implementation tools but do not specify type. For those guidelines with implementation tools, the guideline documents and the websites of corresponding developers were searched for GItools of the following 4 types: implementation (assessment of adoption barriers, selecting and tailoring implementation strategies), patient engagement (information for patients or the public, shared decision-making guides; self-management resources), point-of-care decision-making (paper or electronic templates or instruments that guide or document care delivery) and evaluation (performance measures or quality indicators, instructions for measurement). Our prior research showed that these were the most common types of GItools that accompanied guidelines.²⁶

Purposive sampling was used to recruit developers of these GItools who represented, in nonmutually exclusive fashion, a variety of countries, types of organizations (e.g., specialty societies or associations, foundations, government agencies) and guideline topics. Eligible participants were those responsible for guideline development or implementation at those organizations. Contact information was identified on organization websites and each was invited by email to participate. A reminder email was sent to nonresponders at 2 and 4 weeks after the initial email was sent. We aimed to recruit a minimum of 5 GItool developers representing each of the 4 types of GItools. Detailed information from representative rather

than a large number of cases is needed in qualitative research. As is common in qualitative research, sampling was concurrent with data collection and analysis and proceeded until no further unique themes emerged from successive interviews (saturation). This was determined through discussion between 2 independent reviewers at various times during the iterative data analysis process until both deemed that the most recent interviews produced consistent information. Ultimately, 26 interviews were conducted.

Data collection

Interviews of about 1 hour were conducted via telephone by a trained research assistant who was coached by the principal investigator. A semistructured interview guide was developed to ask participants how GItools were planned, developed, evaluated and implemented; the resources required; challenges they experienced and suggestions for information or guidance that would support GItool development (Appendix 1, available at www.cmajopen.ca/content/3/1/E127/suppl/DC1). Discussion of the first 2 transcripts by the research assistant and principal investigator improved the wording and flow of questions. For example, initial responses revealed planning steps in advance of development and implementation after development, therefore, subsequent participants were asked specifically about planning and implementation. Interviews were audiorecorded and transcribed. Data were collected from June 4, 2013, to Sept. 27, 2013. The researchers had no relationships with the participants, or personal goals.

Data analysis

Themes were identified inductively and iteratively using constant comparative technique and NVivo9 (www.qsrinternational.com).^{27–29} Several transcripts were read independently by the research assistant and principal investigator to identify and define themes (first-level coding). They met to review the themes and their application, and to develop a refined coding scheme. This was applied independently by the research assistant and principal investigator to several more transcripts to add or merge thematic codes (second-level coding) and to generate a more developed version of the coding scheme (Appendix 2, available at www.cmajopen.ca/content/3/1/E127/suppl/DC1). Using this coding scheme, all remaining transcripts were analyzed independently by the research associate and principal investigator. They then met to achieve consensus on the final coding scheme by discussion. To enable interpretation, and identify similarities or differences in participant responses, all quotes were tabulated by theme and type of GItool. As is typical of qualitative research, themes with conflicting responses were identified and discussed because these themes provide insight on challenging issues that warrant interventions or ongoing research. Next, relational analysis was used to integrate data describing GItool development processes.³⁰ By using this technique, all data were perused and each unique finding was tallied. Each instance of a unique process or consideration of GItool development revealed by participants was tallied and compiled by GItool development phase.

Results

A total of 330 guidelines on relevant clinical topics were identified initially. Of these, 124 possessed GItools in the 4 categories of interest (point-of-care decision making [DM], implementation [IM], evaluation [EV], patient engagement [PE]). Of 124 GItool developers invited to participate, 95 either declined or did not respond, 29 consented and 26 were interviewed (Table 1). The GItools about which participants were interviewed addressed a wide range of conditions (Table 2). They were published between 2008 and 2013 and most (19 out of 26, [73.1%]) were supplemental to the guideline itself.

Participants described several phases of GItool development, multiple tasks in each phase (Box 1) and the different types of staff involved in the process (Box 2). They also articulated a number of resource considerations that highlight a lack of dedicated funding to support GItool development (Box 3). Despite the varied types of GItools for a range of

conditions, the phases, tasks and considerations were relatively similar across participants. For example, GItools were implemented most commonly by email distribution, on a website, at conferences and publication in journals (Box 4).

Table 1: Summary of participant characteristics, by type of organization and GItool

Type of organization	Type of GItool				Total
	IM	PE	DM	EV	
Professional society	1	5	1	3	10
Specialty foundation	4	2	3	3	12
Government agency	1	1	1	1	4
Total	6	8	5	7	26

Note: DM = point-of-care decision-making, EV = evaluation, IM = implementation, PE = patient engagement.

Table 2: Characteristics of the GItools discussed by participants

ID	Type of GItool	Country	Type of organization	Condition	In or out of guideline	Year published
01	IM	Canada	Foundation	Mental health	Out	2011
02	PE	UK	Foundation	Diabetes	Out	2010
03	DM	Australia	Foundation	Congestive heart disease	Out	2008
04	IM	Australia	Government	Stroke	In	2009
05	DM	Canada	Foundation	Diabetes	Out	2013
06	EV	Canada	Foundation	Stroke	Out	2008
07	DM	Canada	Government	Hypertension	In	2008
08	PE	US	Professional	Head injury	Out	2013
09	EV	Germany	Foundation	Breast cancer	Out	2008
10	IM	Netherlands	Foundation	Generic	Out	2012
11	EV	Australia	Government	Neonatal health	Out	2011
12	EV	US	Professional	Prostate cancer	Out	2013
13	IM	Australia	Foundation	Stroke	Out	2012
14	EV	UK	Foundation	Stroke	In	2010
15	EV	UK	Professional	Skin disease	In	2012
16	EV	US	Professional	Head injury	In	2013
17	PE	Canada	Foundation	Depression	In	2010
18	PE	Netherlands	Professional	Physiotherapy	Out	2013
19	PE	Denmark	Professional	Urethral catheterization	In	2013
20	PE	Germany	Professional	Stroke	Out	2013
21	IM	Australia	Foundation	Stroke	Out	2011
22	PE	Finland	Professional	Osteoporosis	Out	2008
23	DM	US	Professional	Lung cancer	Out	2013
24	PE	Argentina	Government	Celiac disease	Out	2011
25	PE	US	Professional	Prostate cancer	Out	2012
26	DM	US	Foundation	Hypertension	Out	2008

Note: DM = point-of-care decision-making, EV = evaluation, IM = implementation, PE = patient engagement.

All unique tasks and considerations were tallied and organized by phase (Table 3).

Participants offered conflicting responses in 4 areas that are discussed here because they represent variations in practice that require ongoing investigation and resolution (see illustrative quotes in Box 5). Notably, these response variations did not appear to be associated with the type of GItool.

Participants discussed variable processes in terms of the timing of GItool development relative to guideline development. In this study, 1 GItool was pre-existing and integrated

Box 1: Participant descriptions of GItool development methods

- It's usually a subgroup of the guideline development group (09-EV)
- Three face-to-face meetings and the rest would be done over email (02-PE)
- We'll get a literature review to find out what the current evidence is (11-EV)
- They provided examples [of other GItools] that really helped us (12-EV)
- We did up a decision-matrix to decide on which elements should be included and why (04-IM)
- The staff may review the very first draft, they tweak it and then send it to the co-chairs who have to sign-off on it (025-PE)
- We got endorsement from [mentions several specialty societies] (04-IM)
- Then they go to our designer, someone to put in the layout with the colours and photo images and then they're proof-read once more and then published as PDF files to the website (08-PE)
- We begin a communication plan. Who are the stakeholders that need to be aware of this material? How are we going to reach them? (023-DM)

Box 2: Participant descriptions of contributors involved in the process of GItool development

- There are individuals that are experts in this area of neurology but weren't involved in the guideline development process (08-PE)
- We try and get a closely related medical specialty society on the panel (08-PE)
- Two senior implementation experts (10-IM)
- We include a methodologist who's capable of performance measure development (09-EV)
- We have a staff person that's dedicated to drafting the materials, liaising with others (08-PE)
- An information specialist (01-IM)
- We had two statisticians (10-IM)
- It's important also to have patient representatives on board (09-EV)
- We had strong secretarial support to organize the meetings and teleconferences (13-IM)
- We have a number of graphic designers...for the layout, colours, photo images (08-PE)
- We have a communications person to craft the messaging (023-DM)
- Those folks are experts in writing for right people (025-PE)

with the guideline. Others were developed concurrently with guideline development, but most were planned and developed following guideline development. However, several participants recognized the growing view that implementation planning, including GItools, must be considered early in the guideline development process to better accommodate the needs of target users (Box 5).

The prompt for developing GItools and, by association, the reason for choosing to develop a particular type of GItool, varied across participants. The type of GItool was sometimes informed by a perceived or measured health care problem (Box 5). Other organizations developed GItools for every guideline but tended to develop the same type for all guidelines (Box 5). Therefore, it may not be clear if GItools are warranted for all guidelines and which types of GItools best support the implementation of different types of guidelines. The format of GItools and views about ideal GItool format varied widely across participants. Most GItools were supplemental products rather than information included in the body or appendices of the guidelines (Box 5). The GItools discussed by participants were paper-based, electronic or available in both formats, and content was organized in a variety of ways including bullets, tables, and flow charts or algorithms. Overall, participants recommended that GItools be simple and concise, offered in multiple formats to suit different users and include graphics. However, the variation in GItool formats and recommendations to issue GItools in all possible formats suggest that the format most conducive to the use and effectiveness of different types of GItools is unknown.

Processes for assembling and reviewing GItool content also

Box 3: Participant views on resource considerations

- We don't have extra resources to create these tools. We hand it off to the region (026-DM)
- We didn't have any budget for it apart from the printing budget (04-IM)
- The office of the guideline and the members of the specialty societies work on a voluntary basis (09-EV)
- We have one staff person that works full-time on this (08-PE)
- We would reimburse them for travel to come to a meeting (12-EV)
- Practices received \$200 for participating in a pilot (03-DM)
- The organization that funded it disseminated the tools (10-IM)

Box 4: Participant descriptions of GItool dissemination and implementation strategies

- The societies will publish our tools in their newsletters (08-PE)
- We have a big email group that we notify (11-EV)
- It will be on our website (12-EV)
- If we go to conferences we also bring print versions (022-PE)
- We have an official launch (02-PE)
- It's under review in the [journal name] (10-IM)
- We are going to actively recruit site champions (13-IM)
- Now these indicators are incorporated into accreditation (06-EV)

varied across participants; in particular, the degree to which target users were engaged. Content was often drawn from existing guidelines or by reviewing published research. Decisions about content were often made by committee members through solicited feedback or structured means such as decision matrix, rating or consensus technique. Although these decision-making techniques appear robust, few participants said that target users were consulted about content or engaged in the decision-making process. Several participants recognized the mounting consensus that target users must be meaningfully involved in the development of guidelines and associated products to ensure that they are relevant and useful (Box 5).

Box 5: Participant views about GItool development processes or considerations that were conflicting

- You need to think about new tools and how you're going to do it before you start writing the guideline (11-EV)
- We conducted a national needs assessment of healthcare providers (05-DM).
- We produce a patient version for every guideline now (02-PE)
- It is helpful for any user if these documents can easily be found in one document (09-EV)
- Don't make these decisions and try to get them [target users] to agree to the decisions that you've made (04-IM)

Table 3: Steps and considerations in GItool development

Step	Considerations or tasks
Prepare	<ul style="list-style-type: none"> • Commence planning in conjunction with guideline development* • Identify need by consulting with stakeholders, or collecting or analyzing data • Select GItool that best addresses identified problem* • Schedule and budget for 6 mo to 2 yr • Partner with professional groups or researchers, or acquire research funding • Resources required include staff (coordinator, graphic designer, editor, implementation expert) and operations (printing, communication, dissemination, travel reimbursement, conduct of systematic reviews, licenses) • Establish a multidisciplinary Steering Committee of 10–15 individuals along with an administrative and clinical lead, plus relevant target users • Specify expectations; ask individuals to declare conflicts of interest • Others may be involved on Steering Committee or as needed (e.g., patients or advocacy groups, professional societies, informatics experts, public relations or marketing, technical writers)
Plan	<ul style="list-style-type: none"> • Steering Committee launch meeting • Make decisions about format (i.e., paper or electronic, stand-alone or in guideline) and content (i.e., sources, length, graphics)* • Use voting, rating or other consensus techniques for decision-making
Collect data	<ul style="list-style-type: none"> • Identify existing GItools that could be adapted • Collect data from various sources (i.e., guideline, review of published research)
Develop a draft	<ul style="list-style-type: none"> • Organize, synthesize and format collected data • Refer to existing GItools as exemplars and to GItool Framework¹⁴ to describe objectives, methods, evidence, evaluation and instructions
Engage target users	<ul style="list-style-type: none"> • Consult with target users e.g., interviews, focus groups, survey) • Incorporate target user feedback • Steering Committee review meeting • Incorporate Steering Committee feedback
Pilot-test with target users	<ul style="list-style-type: none"> • Consult with target users e.g., interviews, focus groups, observation, survey) • Gather and summarize feedback on use and impact • Incorporate target user feedback
Final review and approval	<ul style="list-style-type: none"> • Steering committee review meeting • Incorporate Steering Committee feedback • Final approval by Steering Committee, or other internal or external groups
Editorial	<ul style="list-style-type: none"> • Proof, edit, translate to lay language, add graphics, refine layout
Endorsement	<ul style="list-style-type: none"> • Acquire endorsement by one or more professional bodies
Implementation	<ul style="list-style-type: none"> • Options include: dissemination by others (health regions, funders, professional societies; presentation at conferences or webinars; membership newsletters or email; websites or social media; distribute print material; mention of GItools in published guidelines; journal publications; local champions; incentives such as compensation, credits for continuing professional development or accreditation
Evaluate use and impact	<ul style="list-style-type: none"> • Conduct interviews, focus groups, observation, survey • Build survey into GItool or website for prospective evaluation • Engage others to more rigorously evaluate GItool use and impact

*Steps or considerations that varied among participants and may require further research.

Interpretation

Main findings

This study compiled GIt tool development methods based on the experiences of GIt tool developers. They articulated fairly uniform methods despite representing different countries, types of organizations, guideline topics and types of GIt tools. Processes used by participants to develop GIt tools appeared to be rigorous because they reflected GIt tool Framework elements considered important by the international guideline community, such as searching for evidence, engaging stakeholders, pilot-testing and evaluation.³¹ Variations were identified in the timing of GIt tool development relative to guideline development; decisions about GIt tool type, format and content; and whether and how to engage target users.

Explanation and comparison with other studies

In this study, GIt tool developers had few dedicated resources; instead, they relied on partnerships with professional organizations or researchers to develop or evaluate GIt tools. This approach also addresses the need to meaningfully engage stakeholders. The principles and practices of action research or integrated knowledge translation could be used by others to establish partnerships for the purpose of planning, developing, implementing and evaluating GIt tools.^{32,33} Still, an overall conundrum remains to be resolved. Target users require support to adopt and apply guideline recommendations.¹⁵⁻¹⁸ Implementation is not considered the responsibility of guideline developers but of target users.² Most guideline developers are already challenged by resources and time-to-issue guidelines without the additional burden of concurrently having to work with partners and stakeholders to generate GIt tools that support user implementation of guidelines. Perhaps the answer lies in resources offered by knowledge-sharing networks. Both the Guidelines International Network (www.g-i-n.net) and the Agency for Health Care Research and Quality (www.guideline.gov) provide access to GIt tools in guideline repositories. Although not all guidelines have GIt tools, existing GIt tools could be tailored to suit different guidelines or contexts by either developers or users. In previous research, we engaged international guideline developers in identifying the ideal characteristics of GIt tools, defined as any information within or accompanying guidelines that helps users to implement the recommendations.³¹ This resulted in a 12-item GIt tool Framework that could be used to assess the merits of existing GIt tools, and GIt tool development methods identified here would enable adaptation.

Schünemann and colleagues reviewed the content of guideline development manuals to generate a guideline development planning framework. Although the framework included considerations for dissemination and implementation, this was restricted to only 4 points, one of which was to develop or adapt implementation tools. The limited detail on guideline implementation was noted by Schünemann and colleagues as a gap. This work addresses that gap by providing more detailed guidance for the development of GIt tools.²¹

Limitations

These findings may be limited by transferability. We attempted to mitigate this through purposive sampling of participants who varied on several characteristics that may have influenced their views. Although we achieved thematic saturation, and there were no trends by sampling characteristics, participant responses reflected the GIt tools they described. Further research may confirm if these findings are true of developers in other settings or of different types of GIt tools.

Conclusion and implications for practice and future research

The process of GIt tool development appeared to be similar across different types of GIt tools. The methods identified here may provide a starting point for the development of GIt tools. However, the application of the findings may be limited because most guideline developers have few resources by which to disseminate or implement guidelines, which may restrict their capacity to develop GIt tools.

Further research is needed to investigate how to optimize the development process and the type, format and content of GIt tools. It is hoped that these findings may support the development of more, high-quality GIt tools to facilitate the implementation of clinical guidelines into practice.

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