

ORIGINAL ARTICLES

Clinical practice guidelines were adapted and implemented meeting country-specific requirements—the example of Kazakhstan

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Abstract

Objectives: In a twinning partnership between the Canadian Society for International Health and Kazakhstan's Ministry of Health, a project to build capacity and a process for the adaptation and implementation of international clinical practice guidelines (CPGs) was undertaken.

Study Design and Setting: A pragmatic CPG adaptation process was developed that took into consideration national and local contexts. A 15-step process ranging from topic prioritization to copyright clearance to final Ministry of Health approval was developed. An implementation strategy was developed and piloted in three local regions using a five-step approach.

Results: High-quality international CPG candidates were identified for all topics; forty-two CPGs were adapted locally by the clinical working groups. Three CPGs using 21 recommendations were implemented locally. Many challenges were identified including priority setting, obtaining permission to use and translate guidelines into Russian and producing high-quality translations, and organizational barriers during implementation. Facilitators included tools to guide the process and the creation of working groups.

Conclusion: We describe a process of large-scale adaptation of international CPGs with the pilot implementation of selected adapted CPGs and recommendations. Further evaluation and monitoring are required to ensure its integrity. © 2016 Elsevier Inc. All rights reserved.

Keywords: Evidence-based medicine; Practice guidelines as topic; Guideline adherence; Quality Assurance; Health care; Implementation research; Knowledge translation

1. Introduction

In a partnership between the Canadian Society for International Health and Kazakhstan's Ministry of Health, a project designed to result in the adaptation and implementation of international clinical practice guidelines (CPGs)

and build capacity for ongoing work was undertaken. Kazakhstan's Ministry of Health selected the Center for Standardization, a technical governmental agency in health care, to work directly with Canadian Society for International Health under the auspices of the World Bank. Together, they were tasked with introducing high-quality,

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Health; E.S. reports "project director" to author from Canadian Society for International Health for work on project described in the article, travel/accommodations expenses covered or reimbursed to author from Canadian Society for International Health; E.L. reports "Consultancy" to author from Canadian Society for International Health for work on project described in the article, travel/accommodations expenses covered or reimbursed to author from Canadian Society for International Health.

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What is new?**Key findings**

- Clinical practice guideline (CPG) adaptation was a preferred option to developing original guidelines in a country new to CPG development, and the process of CPG adaptation can be further customized to suit country-specific requirements.
- Adhering to copyright rules and obtaining permissions were variable and sometimes controversial and lengthy cumbersome process that needs to be taken into account.
- Translation issues related to language may place a significant barrier to CPG adaptation.

What this adds to what was known?

- The process of guideline adaptation was not straightforward and required the use of many different theoretical frameworks to suit the culture in Kazakhstan.
- Through the adapted CPGs, health care professionals in Kazakhstan now have access to high-quality evidence to apply in everyday practice.
- New capacity for Kazakhstan Ministry of Health and its affiliated institutions was developed and can be further built on with further CPG implementation across the country.
- Identified barriers such as lack of equipment or miscommunication between inpatient departments to CPG implementation brought to light important issues of care organization and administration.
- Detailed indicators developed for specific recommendations in the process of CPG implementation allowed reduction in the collection of additional or unimportant statistical data at the medical facility level.
- Detailed indicators developed for CPG implementation allowed reduction in the collection of additional or useless statistical data at the medical facility level.

What is the implication and what should change now?

- The in-country CPG regulatory framework should be updated.
- Patient confidentiality and copyright issues need to be reviewed and standards developed for in-country application.
- A formal system of continuous knowledge translation should be developed to include the updating/

revision of the CPG adaptation priority topic list, updating the adapted CPGs, implementation of CPGs recommendations into local clinical practice.

- Medical education with professional associations needs to play an important role at each step.
- Improved skills for specific indicators development are required to provide the opportunity to assess the process and results of the CPG implementation.

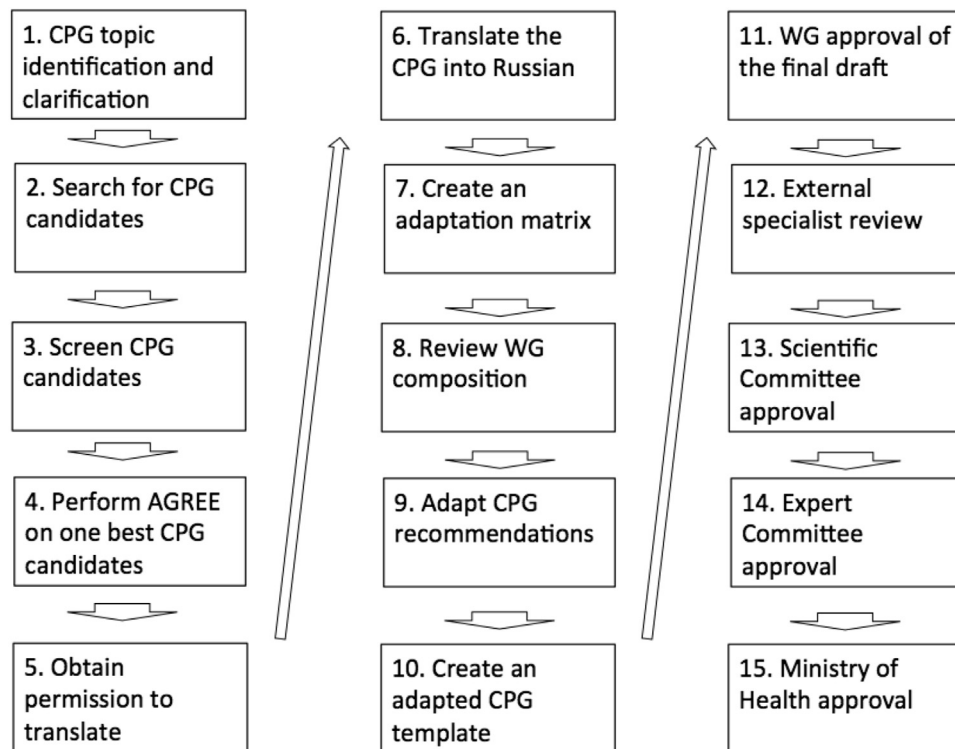
evidence-based CPGs into the Republic of Kazakhstan. Several attempts have been made to develop CPG tools for health professionals in Kazakhstan within the past decade. CPGs were among them too, but use of a CPG quality development process was not developed.

CPGs are documents that have been developed systematically and include recommendations to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options [1]. Internationally, the use of CPGs has impact at four levels, including the patient level, the health provider level, the organizational level, and the political level [2]. Incorporating CPGs (or CPG methodology?) into medical education provides the basis for future excellence in clinical decision making. If CPGs are carefully developed and well implemented, they result in improved quality of care [3]. Implementing guidance can help clinicians and decision makers in Kazakhstan ensure that patients receive clinically and cost-effective care. This article describes general principles relevant to guideline adaptation and implementation in settings that are only recently emerging into evidence-based health care models.

2. Methods

The aim of this initiative was to develop a process to select, adapt, and implement one hundred CPGs in Kazakhstan over a two and a half year period. Initially, the original request included the development of new CPGs. However, the country level experience for using, developing, and implementing CPGs was at the beginning stages. It was decided that the best approach would be to adapt high-quality international CPGs so that capacity and familiarity around the use of CPGs could be built on and a product for adaptation could be developed more quickly for implementation. The focus was to develop a process that was pragmatic and practical because of our short timelines. The approach took into consideration national contexts and needs.

At the beginning of the project, key CPG methodology and guidance publications were reviewed and used to inform project methods [4–13]. However, none of these

Table 1. Pragmatic adaptation steps

documents were inclusive enough to be readily usable in their current formats as they did not include enough detail were too complex in their language and much information was missing.

Therefore, it was necessary to develop a unique methodology, guided by the research evidence where possible. A 15-step pragmatic process for the adaptation process was developed with clear assignment of tasks and roles between the twinning partners emphasizing accountability for various components of the adaptation process (see Table 1). The approach to each of these steps included writing detailed documentation on the methods that we would use, including work plans and timelines. We provided many in-country training sessions to our partners to help build capacity in each of these areas, and our partners were included in the teaching of the sessions, where possible. The topics of training sessions included detailed information on not only our process but the tools that we used, including AGREE II, ADAPTE, CAN-IMPLEMENT, GRADE, and GLIA [4,5,12–14]. The methods used by guidelines organizations were reviewed [6,15,16]. Training sessions also included learning about evidence-based medicine (EBM), systematic review development, and developing implementation indicators and monitoring as these areas were not well understood. These sessions included didactic learning but focused on group and individual exercises and feedback sessions.

2.1. Steps 1: CPG topic identification and clarification

Taking into account what may be feasible in the Republic of Kazakhstan, the following list of prioritization criteria was put forward for discussion with the Center of Standardization based on the criteria developed by Reviez et al. [17]: disease burden as measured in terms of mortality and morbidity, high-quality evidence of effectiveness, economic impact on the health system, clinical practice variation suggesting opportunities for standardization and increased uniformity, feasibility of development and implementation and information needs within the health sector. It was hoped that a full prioritization exercise would be conducted, but the process proved too difficult to manage. Documentation was provided on the process itself and how it could be done. This process was tested in one information priority setting exercise at a conference, but this step was not completed formally, and this was a weakness in the process. The Kazakhstani partners simply identified the key CPG topics for us, which were driven by policy priorities. In the future, we hope to have opportunities to discuss this process again.

2.2. Steps 2, 3, and 4: search for CPG candidates, screen CPG candidates, perform AGREE on one best CPG candidates

CPGs candidates were searched for, screened, and selected using systematic methods as guided by The

Table 2. Adaptation matrix

Original recommendation	Strength of the recommendation / level of the evidence	Decision made: Accept/Reject/Modify	KZ version of the recommendation (incl adjustment to the strength and level)	Decision confirmation	Next steps needed	Levels of care

Cochrane Handbook [18]. Each CPG candidate was assessed by two Canadian Society for International Health experts for quality and applicability using AGREE II [4]. A four-item global rating scale was developed as alternative to AGREE II by the AGREE II authors, but it was the preference of our partners to use the full AGREE II tool [19]. We found the Web version of the AGREE II tool easy to use, and disagreement was resolved between the two experts before the assessment was finalized. The tool itself did not address issue of equity and the fact that some recommendations may just not work in all settings; this was also noted in an appraisal of AGREE II [20].

2.3. Steps 5 and 6: obtain permission to translate and translate the CPG into Russian

There is no one process to receive permission to translate CPGs from publishers and guideline producers. ADAPTE and CAN-IMPLEMENT both recommend consulting with the source developers, but actual process guidance is not included in any of these tools [5,12]. The process is time consuming (up to 5 months), and sometimes, there are fees involved, although many publishers waved fees when contacted directly about the nature of the project. In addition to permission for translation, the authors tried to request permission to “adapt” the CPG. It was found that most publishers and producers did not know how to deal with the request. Technically, one can view adaptation as an academic activity and follow correct citation rules to include text from the original CPG. If large parts of the CPG are being reprinted, then it is necessary to seek permission. However, what does “large parts of content” mean and how does “fair dealing” work in other countries. Articles published under an open-access license are not only free to read, but all reuse is permitted provided only that the original article is properly cited. However, the vast majority of CPGs that the project dealt with were not available through an open-access license.

2.4. Step 7: create an adaptation matrix

An adaptation matrix was developed for each selected CPG to facilitate adaptation decision making (see Table 2). Across several columns, the table lists original recommendations with strength and level of evidence, an

adaptation decision followed by a Kazakhstani version of the recommendation, and possible next steps, if any needed.

2.5. Step 8: review working group composition

Working groups that comprised Kazakhstan clinical experts and health policy makers were established in the four major Kazakhstan medical specialties (pediatrics, internal medicine, surgery, and obstetrics). Each of the working groups had a primary care physician to aid with recommendations on outpatient management. Members were selected by the Center for Standardization based on the national database of clinical specialists who had gone through training in EBM and CPG development and implementation.

2.6. Steps 10 and 11: adapt CPG recommendations and create an adapted CPG template

Working group members attended a 1-day meeting to conduct CPG adaptation. The working groups reviewed the selected CPGs on a recommendation-by-recommendation basis and adopted, rejected, or modified each recommendation with justification provided. The GRADE approach was used to help understand the balance of desired and undesired outcomes on our population in combination with the evidence that was found [21]. The process also included a discussion of values and preference of patients. The partners found it very difficult when they were faced with weak recommendations. Our team worked through the issues in the local context with our partners to try to determine if or how a weak recommendation could be accepted.

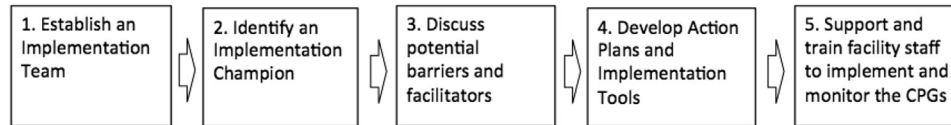
Working groups also developed sample indicators for implementation monitoring. Background sections of a CPG template for Kazakhstan were then completed based on the chosen CPG.

2.7. Step 11: Working group approval of the final draft

The approval was granted based on consensus. No voting system was used.

2.8. Step 12: external specialist review

Two external specialists reviewed the approved final draft for information accuracy, clarity, and adequateness

Table 3. Implementation steps

of recommendations in the Kazakhstani context, style, and professional language use.

2.9. Steps 13, 14, and 15: Scientific Committee approval, Expert Committee approval, and Ministry of Health approval

Before the draft received final approval from the Ministry of Health, it had to pass several ministerial committees. At later stages of the project, to improve overall project governance, streamline decision making, and ensure participation of all relevant Ministry's departments, the Ministry of Health decided to set up a Coordination Committee chaired by the Vice-Minister of the Ministry of Health.

2.10. CPG implementation

CPG implementation is a complex process that requires the engagement of multiple stakeholders and the understanding that desired outcomes may not be achieved. It often implies change and meets resistance from end users. We applied CPG implementation strategies that were drawn from international experience and executed with consideration of the Kazakhstani context in general and the context of the three local implementation sites in particular [22]. Five steps were used to pilot the implementation activities (see Table 3).

The Ministry of Health selected three medical facilities as pilot sites. Each site used a different topic for CPG implementation. Astana Perinatal Center #1 is a new maternal hospital for 150 beds with an outpatient department that services up to 250 visits a day (hypertension in pregnancy). Almaty City Children's Hospital #2 is a general hospital for 270 beds with 11 departments (community-acquired pneumonia). Karaganda Regional Hospital for adults is a general hospital for 490 beds with 16 departments (management of diabetes).

3. Results

3.1. CPG adaptation

High-quality international CPG candidates were identified for all 100 topics and the clinical working groups at the end of the project adapted 42 CPGs. Three CPGs were chosen for implementation locally over a 3-month pilot period seeing 21 recommendations incorporated into

practice. The adaptation process was a task undertaken by each of the working groups and involved reviewing all the recommendations included in the relevant international CPGs. Each recommendation was reviewed, and the working group completed a matrix for how each was addressed. In addition to confirming the intended local target audience for each recommendation (including internists, surgeons, nurses and patients), the working groups categorized each recommendation in one of the three following ways: accept as is with no significant modifications, reject outright, or modify for adaptation into one or more Kazakhstani settings. No recommendation was accepted "as is" with no significant modification. All required a mandatory justification based generally on feasibility concerns. We were very cautious about any recommendation modification that working group members would suggest. We advised against any modifications that would change the entire meaning of a recommendation unless the working group members were ready to undertake a properly designed systematic review to answer the clinical question.

3.2. CPG implementation

Three separate site visits were held at each of the implementation sites with teams made up of international experts, staff from the Center for Standardization, and local experts. The first visit included an introduction to the CPG integration process to introduce the goals of the project, explain the CPGs and the evidence base, as well as exercises to determine priority recommendations for implementation and review site-specific barriers and facilitators. The number of priority recommendations varied per each CPG: from 4 to 12 recommendations were to be implemented. The recommendations implemented included 4 for diabetes, 5 for pneumonia, and 12 for hypertension in pregnancy. Action plans, indicators, and a monitoring process were developed at each site. The second visit continued work on indicators and the monitoring process and allowed for time to discuss the process and answer questions. During the final visit, wrap-up meetings were held each of the implementation sites where a presentation was given on preliminary results of implementation monitoring and a summary of other work to date (e.g., implementation tools, case studies, and so forth).

The implementation pilot phase resulted into the development of many supporting tools. These included a manual

for CPG implementation with detailed information about the CPG implementation processes. Clinical case studies were developed to help the understanding of the specific CPG recommendations. Detailed plans were developed after each visit, and a CPG implementation strategy tool has been used in the process of CPG implementation in the pilot regions. A job aid for the CPG for community-acquired pneumonia, a diabetes checklist for use in primary care, and a patient leaflet for hypertension in pregnancy were also created.

4. Discussion

The 15-step process developed did enable the adaptation and implementation of CPGs. We drew heavily on the CAN-IMPLEMENT structure [12]. The process was a simplified version of this tool because of many constraints. For example, it was not possible to conduct a full prioritization exercise or identify specific health questions for our 100 topics. In other instances, the international consultants did tasks that should be done in future locally for International Health experts (such as critical appraisal steps). The process of external review was not established but is hope to be included in the future.

An early internal review shows that the process of implementation was successful at each of the three pilot sites. The piloted approach to CPG implementation has already been used for further implementation at other sites across Kazakhstan. All the CPG implementation steps were followed, and implementation action plans and agreement on concrete steps and dates for the completion of activities were established. Detailed discussions of each CPG recommendation and identification of barriers and facilitators were seen as innovation at the pilot sites. Plans are being developed to adopt this approach nationally and use it systematically. The process of CPG implementation that was performed in collaboration with the Canadian Society for International Health consultants showed that the CPG implementation at medical facilities should be done with training and detailed discussion of the CPG recommendations with all stakeholders and specialists of different levels of health care. Such a process has never taken place in practice in Kazakhstan; the developed CPGs have been directly sent to medical facilities and were discussed by end users/providers of medical services.

The monitoring process was a useful experience for all stakeholders. Most indicators demonstrated meaningful changes, positive or negative, and indicated areas needing

Table 4. Overview of challenges and solutions

Issue	Challenges	Solutions
Project scope	The original scope of the project was extremely broad and included developing 100 CPGs. Delivering results was difficult within a short timeline.	High-quality CPGs were adapted rather than developed following a 15-step process.
Priority setting	A full prioritization exercise that the consultants could observe did not take place.	After documentation on the process was provided, the process was tested in one information priority setting exercise at a conference.
Adhering to copyright rules and obtaining permissions	The process of obtaining permission to use and translate CPGs for adaptation was time consuming and inconsistent as no clear description of the process exists in this regard.	Issues were addressed directly with publishers and developers.
Translation of CPGs into Russian	Insufficient English language skills proved to be a major barrier to producing high-quality translations for working group members.	Professional translators were used; however, the skill and quality of translators were still limited.
Data collection	Data available from health facility databases were not useful for monitoring purposes.	A system for manual data collection was developed.
Capacity	Issues included little previous experience in quality CPG adaptation and implementation and lack of skills related to clinical epidemiology and biostatistics.	Documentation and limited training were provided. Worked in teams with our partners for all the implementation activities facilitated knowledge transfer.
Privacy and informed consent	Rules around privacy and informed consent should be reviewed; compliance with the rules should be reinforced.	Training was recommended to protect patient privacy and confidentiality.
Organizational barriers during implementation	Issues included a lack of equipment, intradepartmental miscommunication (e.g., within hospitals), or interdepartmental disagreements (e.g., between health facilities and quality control agency).	Issues were addressed on individual basis in collaboration with local facility staff and higher health authorities.
Legislative issues	CPG implementation was hindered by discrepancies in or a total lack of regulatory base that guided the use of CPGs.	All barriers were successfully overcome by the Ministry of Health issuing ad hoc regulatory acts. The need to review the regulatory base was reinforced at meeting with authorities.

Abbreviation: CPGs, clinical practice guidelines.

attention. The detailed indicators developed in the process of CPG implementation allowed reducing the collection of additional or useless statistical data at the medical facility level. During site visits, our partners had many opportunities to participate in data collection and interpretation and to deal with emerging problems (e.g., canceling some proposed indicators and arranging procurement of new equipment).

4.1. Challenges in adaptation and implementation

Table 4 includes an overview of challenges and solutions. Adhering to copyright rules and obtaining permission to use translated versions of the CPGs for adaptation were problematic adding complexity and limiting the progress. Although recommendations as to how to resolve problems were provided to our Kazakhstani partners, additional issues of copyright and permission may persist.

Most internationally developed CPGs are published in English. CPG adaptation to the context of Kazakhstan required producing high-quality translations into Russian for WG members to work with and then to introduce nationally. Insufficient English language skills proved to be a major barrier in this regard. We also encountered limited capacity in key areas such as clinical epidemiology, biostatistics, and so forth that put certain limits to the depth of understanding evidence base behind recommendations. The issue must be addressed nationally, but any solutions need long-term planning and were beyond our contract.

Challenges were also encountered working with the Ministry of Health. The desire of officials to adapt too many CPGs within a short timeline was difficult. The CPG process would benefit from more flexibility on the part of the Ministry, but it was prohibited by the complexities of the local bureaucratic system. Appointing a ministerial official/delegate early on to oversee the CPG processes is important. CPGs become out dated as evidence evolves. An official process for updating adapted CPGs is necessary to ensure ongoing relevance and accuracy. Professional associations may play an important role in updating CPGs.

Challenges specific to the CPG implementation process were identified. For instance, all data collection for monitoring purposes was done manually. It was not possible to pull useful data from the facility health record databases. Some significant organizational barriers were brought to light at the start of CPG implementation such as lack of required equipment, miscommunication between inpatient departments, and so forth. Resolving the issues caused delay in implementation process.

Issues around privacy and informed consent should be reviewed for the audit and monitoring of patient records. Training is recommended to protect patient privacy and confidentiality. It is recommended to consult a Kazakhstan University Research Ethics Board to develop policies around use of patient records.

There is currently no Kazakhstan health legislation that guides the use of CPGs; their implementation and full use are limited until this happens. Currently, clinical protocols are governed under the law as the primary guide to clinical practice. There exist also medicoeconomical protocols (MEPs) as a legacy of previous health reforms. The current system of using clinical protocols, MEPs, and CPGs overlaps. Although the Kazakhstan health system can incorporate different types of guidance, the roles of various types should be reviewed to ensure their coexistence. CPGs provide overarching guidance, from which protocols, checklists, and other guiding documents can be developed. One option, if clinical protocols continue to be mandated by law, will be to ensure that protocols are updated to reflect the CPG recommendations that have been implemented in the pilot sites.

Synergies should be developed between the clinical audit processes and the CPG implementation monitoring processes. The role of clinical audits needs to be revised and brought in line with international practices. Although disciplinary (e.g., financial or otherwise) methods may be required on some occasions, the educational aspects of auditing should be introduced and eventually prevail. Approaches that emphasize high standards of personal responsibility for patient care, continuous self-education, peer-to-peer practice review, teamwork in supportive environment must replace the current punitive mentality and fear of sanctions. Such practices will create a positive milieu for CPG implementation. The challenges we encountered and solutions devised in this collaborative model have implications well beyond this country and may serve as a model for operationalizing evidence-based health care in middle-income countries whose health care delivery models may have not yet embraced the approach.

5. Conclusion

Translating research results into practice in a local setting is yet a challenge, particularly in a non-English country with lower resources. CPGs play an adjunct/supplementary role building on/fine tuning medical knowledge taught at universities, but implementation is more difficult when local clinical practices are significantly different.

The Canadian Society for International Health has started to set into motion a process to select, adapt, and implement CPGs. Although adhering to a pragmatic model of guideline adaptation made the project feasible, evaluation and monitoring are required to ensure its integrity.

A number of challenges were faced throughout the project but were able to manage issues at hand and provided recommendations to the Kazakhstan government's Ministry of Health on further resolution. To make the process easier, the government would need to update its regulatory base to institute the notion of CPGs. The government could encourage stricter adherence to internationally recognized

copyright regulations and review confidentiality and informed consent practices. The limited capacity in some areas requires further planning.

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