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A QUALITY DRIVEN PROCESS FOR DEVELOPING SEPSIS PRACTICE GUIDELINE

KEYWORDS: clinical practice guideline, quality improvement, healthcare, AGREE II, PDSA

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ABSTRACT *The AGREE II instrument, initially developed for the appraisal of quality of practice guidelines, can also be used for the development of high quality guidelines or the improvement of existing guidelines. Using both the IHI improvement model and the AGREE II instrument, we adopted a systematic approach for improving British Columbia's Children Hospital sepsis guideline through iterative rapid improvement cycles in the context of an action research project. Descriptive statistics were used for analysis. The overall quality showed a 1 to 4 score improvement in a 7 point scale. Six domains of AGREE II showed improvement between 2% in domain 4 (Clarity of Presentation) to 78% in domains 6 (Clarity of Presentation and Editorial Independence), respectively. We report the successful use of a systematic approach to improve quality scores of a sepsis guideline. This process may be helpful for other clinicians involved in the development or the improvement of guidelines.*

INTRODUCTION

Infection and sepsis are among the leading causes of mortality in the world. In high-income countries, the annual burden of sepsis is around 2.8 million patients with mortality rate of around 30 - 40% . However, the largest portion of the global burden of sepsis is for middle-income and low-income countries. Around 70% of the 7- 9 million global deaths among neonates and infants are attributable to sepsis . Early recognition and treatment of sepsis using Clinical Practice Guidelines (CPGs) can improve sepsis survival . CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances" . Guidelines can reduce variation, improve quality and decrease cost of care, and be used as tools for medical education .

Many studies have shown the benefits of adherence to sepsis guidelines which include early recognition and treatment of sepsis, improvement in the quality of care patients receive, and a decrease in sepsis morbidity and mortality and lengths of stay in critical care and inpatient units . However, despite the benefits of compliance with CPGs, adherence to recommendations that require changing behavior is only 44% 6. Changing behavior is central to successful guideline implementation and thus low compliance with guidelines is a wide spread concern .

Among various factors that result in low compliance with guidelines , a suboptimal development process , resulting in a low quality CPG is a major contributor. Successful implementation of guidelines therefore, depends on rigorous planning and development including any revision and updates

Low quality guidelines and low adherence to these tools is also a challenge at British Columbia's Children Hospital (BCCH). Indeed, in 2006, BCCH developed and implemented a sepsis guideline with mixed results. A review revealed that the entire process of guideline development, implementation and evaluation was flawed and suffered from lack of a systematic approach and involvement of a multidisciplinary team at every stage of development, appraisal and implementation. Cognizant of the reasons for the failure, we initiated a systematic approach to adapt and re-develop a new sepsis guideline in context of an action research project. The purpose of this paper is to share our experience of using the Institute for Healthcare Improvement (IHI) framework and the AGREE (Appraisal of Guidelines for Research & Evaluation) II instrument to review and improve the quality of BCCH sepsis guideline. We report the detailed process of improving the guideline through iterative cycles and the final evaluation that compares the original guideline to the new version.

METHODS:

This project was conducted at BCCH, a tertiary center for healthcare, research and teaching located in Vancouver, Canada. This hospital treats infants, children and youth up to 17 years of age and is the only center for specialized healthcare services for children in the province of British Columbia with a population base of 4.667 million .

We adopted a systematic approach for quality improvement using the IHI model for improvement through iterative rapid improvement cycles in the context of an action research project . Through repeated PDSA (Plan, Do, Study and Act) cycles a new set of sepsis guidelines developed. We also used the AGREE II instrument to guide the development in each of the 6 AGREE domains. Ethics approval was not needed in our institution for this project.

Theoretical framework: IHI model for improvement

The IHI model for improvement is a simple and robust model for improvement with two parts: three fundamental questions and a PDSA (Plan, Do, Study, Act) cycle. The questions are: What are we trying to accomplish? How will we know that a change is an improvement? What changes can we make that will result in improvement? These three questions help in identifying the aim of improvement, the strategies for measuring changes and also the interventions that can lead to improving the situation

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and reaching the aim . Repeated PDSA cycles lead to a final stage of improvement. This model is one of the simplest quality improvement models that has been accepted and used by various healthcare organizations for improving quality of care 21.
Measurement tool: AGREE II instrument

During the entire process, the project teams used the AGREE II instrument to guide their work toward assessing the quality of the new CPG and improving it. The AGREE instrument was first published in 2003 for evaluating quality of guidelines; however, it can also guide the development of high quality guidelines or the improvement of existing guidelines .This instrument has been validated and has improved over time as reported in various studies and systematic reviews . The last version of this tool is AGREE II, which was re-launched in September 2013 in its 10th anniversary . As with the original AGREE Instrument, AGREE II has been well accepted and used significantly .

The AGREE II instrument has 23 three items that assess six domains in each guideline, namely: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability and editorial independence. It also has two global rating items that assess the guidelines overall quality and help the appraiser decide if the guideline can be recommended for use in practice . The AGREE II items are rated on a 7-point scale (1– strongly disagree to 7–strongly agree). For each of six AGREE II domains a quality score is calculated. This score is calculated by summing up all the scores of the specific items in each domain and by scaling the total as a percentage of the maximum possible score for that domain (Supplemental file 1). The quality-scores of these six domains are independent and cannot be aggregated into a single quality score.

Assessment of Guideline Quality
We used the "AGREE II rater concordance calculator" developed for appraising guidelines quality . This tool is an electronic version of AGREE II instrument that calculates quality scores (overall and in each of the six domains) assessed by more than one rater. It also calculates the degree of concordance between the raters that determines the number of raters needed for appraising the guideline under study. A minimum of 2 and at most 4 raters are recommended for the appraising process .

After entering the scores of the 3 appraisers into the electronic tool, the concordance between raters' scores and then the scores of various domains of AGREE II were calculated for both the old and the new guidelines. As recommended by the AGREE II user manual, the overall quality of the guideline was assessed based on two global rating items. Descriptive statistics were used to compare the scores of various domains of the two guidelines as indicators of quality.

RESULTS:
A. DEVELOPING THE NEW GUIDELINE
Step 1: Forming the teams
For developing the new sepsis guideline, three teams were formed and worked in close collaboration simultaneously: (1) a multidisciplinary improvement team composed of pediatricians, pediatric critical care specialists, epidemiologist, nurses and quality improvement specialists worked on the content and structure of the guideline. (2) A guideline methodology team was formed with expertise in guideline development and appraisal. This team was responsible for standardizing and supervising the process, assessing the validity of the guideline content and providing feedbacks to the first team. (3) An external guideline evaluation team was composed of three individuals who worked independently of the previous two teams and conducted an external evaluation of the guidelines throughout the different phases of the project.

Step 2: Using the IHI model

Step 2, stage 1: using the first part of IHI model: answering three fundamental questions

The three teams worked on the first part of IHI model and answered three fundamental questions as follow: (1) What are we trying to accomplish: improving quality of first generation of BCCH sepsis guideline considering six domains addressed in AGREE II instrument; How will we know that a change is an improvement: using AGREE II tool scoring system for measurement; what changes can we make that will result in improvement: standardizing process of developing/improving guideline based on continuous evaluation of the AGREE II 6 domains; A graphical illustration of this part can be found in Figure 1(Supplemental file 2).

Step 2, stage 2: Using the second part of IHI model for improvement: PDSA cycles

First series of PDSA cycles: standardizing process of developing/improving guideline

To standardize the process, the guideline methodology team in collaboration with the content and structure team (teams 2 and 1, respectively) developed a general guide for reviewing and improving guidelines, a user manual and a standard guideline layout specifically for sepsis guideline (Supplemental file 3) all based on the AGREE II instrument. The standard guideline layout included all sections for a guideline recommended in AGREE II instrument. The entire process of standardization went through iterative PDSA cycles using IHI PDSA cycle worksheets (Supplemental file 4).

Second series of PDSA cycles: improving various domains of the first generation sepsis guideline:

Using the above mentioned documents, team 1 (content and structure team) developed the first draft of the new guideline. This draft was appraised by team 2, and modifications were suggested and agreed up on by both teams. Team 1 did the modifications suggested by team 2 and this process continued through iterative PDSA cycles in the context of an action research (Supplemental file 4) until the two teams confirmed that guideline had reached a satisfactory level in accordance with AGREE II standards.

Step 3: External evaluation of two generations of BCCH sepsis guidelines

After finalizing the second iteration of BCCH sepsis guideline, using the AGREE II instrument the external evaluation team of three individuals evaluated the quality of the two generations of sepsis guideline, using the approach and tools described before. As per original description one additional appraiser was needed in specific situations: (a) when the individual item scores of one appraiser was ≥ 1.5 standard deviation (SD) away from the mean, in 3 of 5 domains or (b) the individual scores of one appraiser was ≥ 2 SD away from the mean in 1 of the 5 domains.

B. ASSESSING THE QUALITY OF THE GUIDELINES
Concordance between scores from the three external appraisers

In both iterations of guidelines, only two domains showed one appraiser's score > 1.5 SD; however, none were higher than 2 (Table 1). Therefore, an additional appraiser was not necessary.

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Table 1: Concordance of the scores of three appraisers before and after revision

Domain	Standard Deviation	Discrepancy Level		
	Before revision	After revision	Before revision	After revision
1	1.86	0.38	Medium	Medium
2	0.89	1.07	Low	Low
3	1.12	1.99	Low	Low
4	1.28	0.89	Low	Low
5	1.15	1.91	Low	Low
Overall Guideline Assessment	1.73	0.58	Medium	Medium
Result:	No action required			

Overall quality

The overall quality of the new sepsis guideline was rated as improved by all three appraisers: a 1 to 4 improvement in a 7-point scale. Before revision, the appraisers recommended that the guideline not be used (one appraiser) or be used with modifications (two appraisers). After revision, two of the appraisers recommended the guideline for use and one appraiser believed that it required some further modifications before its use (Table 2).

Domain quality scores

The scores in each domain of the new sepsis guideline improved compared to the old version. The maximum improvement was observed in domain 6 (editorial independence) that improved by 78% while the minimum improvement was seen in domain 4 (clarity of presentation) that improved from 85% to 87% (Table 3). The second largest improvement was seen in domain 1 (scope and purpose) increasing from 20% to 96 %.

Table 2: Overall guideline assessment scores before and after revision

Overall Guideline Assessment item		Appraisers		
		1	2	3
Rate the overall quality of this guideline (Scoring: 1=Least Quality and 7=Highest Quality)	First generation of guideline (before revision)	2	2	5
	Second generation of guideline (after revision)	6	5	6
I would recommend this guideline for use (Scoring: "Yes", "Yes, with modifications", "No")	First generation of guideline (before revision)	No	Yes, with modifi cations	Yes, with modifi cations
	Second generation of guideline (after revision)	Yes	Yes, with modifi cations	Yes

Before revision, the lowest domain score was 0% for domain 6 (editorial independence), and the highest score was 85% for domain 4 (clarity of presentation). After revision, the lowest domain scores were those of domains 3 (rigor of development) and 5 (applicability) both with 69% while the highest domain score was given to domain 1 (scope and purpose) with 96%.

AGREE II item scores

Table 4 (Supplemental file 5) compares scores of all three appraisers before and after revision for all items of AGREE II instrument. As can be seen in this table, after revision all three appraisers rated most items higher, with few exceptions (such as items 15 and 17).

Table 3: Standardized scores of domains of AGREE II in two generations of sepsis guidelines at BCCH

AGREE II Indicator (Domain, Score for 3 Appraisers)	Assessment of the Guideline Domains		Amount of improvement in domain score
	First generation of guidelines (domain score before revision)	Second generation of guidelines (domain score after revision)	
Domain 1 - Scope and Purpose	20%	96%	76%
Domain 2 - Stakeholder Involvement	17%	80%	63%
Domain 3 - Rigor of Development	12%	69%	57%
Domain 4 - Clarity of Presentation	85%	87%	2%
Domain 5 - Applicability	7%	69%	62%
Domain 6 - Editorial Independence	0%	78%	78%

DISCUSSION:

Application of clinical practice guidelines can improve quality of care and lead to better outcomes . Compliance with a sepsis guideline in Boston led into a decrease of 57% in length of stay (LOS) in the Pediatric Intensive Care Unit (PICU). Using Guidelines of American College of Critical Care Medicine (ACCM) for children correlated with a 30% drop in mortality rate in community hospitals if the recommendations were applied for initial resuscitation . However, due to various barriers at guideline, care provider, institution and health system levels, the application of these tools for clinical decision making is not as good as expected . Poor guidelines quality is a serious barrier for their use in practice, therefore, improving CPG's quality can play an important role in enhancing their application and improving care quality

Our project showed guideline improvement in each of the 6 AGREE II domains and also for the "overall guideline assessment". Overall, the domains-specific scores of the new sepsis guideline not only were higher than the corresponding scores of the first generation, but they were also higher than their cor-

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responding mean domain scores of CPGs over the last two decades as reported in a systematic review in 2010 (96, 80, 69, 87, 69 and 78% respectively for domains 1 to 6 of new sepsis guideline vs. 64, 35, 43, 60, 22 and 30% for corresponding mean domain scores in the last two decades) . The external assessment of guideline quality was a very important aspect of the overall process; it also served as a reward to the two teams that worked synergistically to improve the guideline. Overall, there was a good concordance between the scores given by the three appraisers in assessing both sets of guidelines; the discrepancies were minor and did not require any change .

Improvement in domain 1 (scope and purpose) indicates that the new guideline had addressed a clear purpose and focused on most important issues for clinicians and targeted patients as recommended in the literature . Clearly informing the CPG's users of the purposes may enhance the attention, facilitate emphasis of important points and improve the recommendations' uptake . In addition, having clear purposes outlined in the guideline facilitates the design of the validation studies .

Improvement in domain 2 (stakeholder involvement) implies that the lack of multidisciplinary work for the development of the first version has been properly addressed for developing the new version. In our project we included professionals from a variety of related disciplines (pediatricians, pediatric critical care specialists, nurses, respiratory therapists, pharmacists, anesthesiologist, epidemiologist, as well as quality improvement and guideline specialists from various departments of the hospital such as Emergency Department, Pediatric Intensive Care Unit, and Respiratory Therapist) and clearly reported this in the new guideline. Although involvement of all stakeholders in the guideline development process is challenging logistically, it is a critical step to ensure that each participant has personal stake and takes ownership for the new guidelines and its future use . Involving various stakeholders is also useful for identifying and overcoming other factors that may affect adherence to the guideline, such as contextual factors of the clinical environment in which they will be adopted . It is still possible to improve item #5 related to the involvement of the guideline target population (patients, public, etc.). Contact with patients' organizations in the beginning stages of developing the guideline, including a representative from these organizations, as well as considering findings of qualitative or mixed method researches that seek patient and public views, values and preferences would be helpful in this regard However, this aspect may be less important for the sepsis guideline, which is developed for clinicians working in a tertiary hospital, with a content that is largely technical.

The small improvement in domain 3 (rigor of development) can be explained by the fact that both old and new sepsis guidelines were based on the same rigorous systematic literature review. A lower score would reflect that a systematic literature review was not undertaken The score of domain 4 (clarity of presentation) did not improve much. This is related to the inclusion in the guideline of detailed information regarding the development methodology, which led to the production of a lengthy document with less visibility of its key recommendations. One solution for this would be to publish the methodological information in a separate document .

Improvement in domain 5 (applicability) is important because directly related to the likelihood of adopting the guideline . It would be helpful to include in the guideline facilitators and barriers, as well as required resources to its application. According to classic behavior models and frameworks such as Health belief Model (HBM), PRECEDE/ PROCEEDD TDF (Theoretical Domain Framework) '' and also sociocultural theories of practice , these factors are essential to facilitate the adoption of suggested recommendations.

Low score in domain 6 (editorial independence) has been reported by other researchers as a persistent issue unlike improvements that reported in other domains' scores . Lack of improvement in editorial independence during the last two decades might be related to the lack of information regarding the source of funding and possible conflicts of interests . In our project this issue was solved and clearly reported in the second guideline so that this domain showed the largest improvement among all domains.

These improvements in sepsis guideline quality will remove or reduce guideline-related barriers, which are integral for adoption in practice, and will likely affect positively the adoption and use in the next phases .

CONCLUSIONS:

Adopting a systematic approach based on IHI improvement model and using AGREE II instrument in the context an action research project led to improvement in the quality of various domains of the BCCH sepsis guideline and production of new version of the guideline that is consistent with AGREE II standards. The IHI model helped us identify our aim for improvement and various interventions for improving BCCH sepsis guideline and the AGREE II instrument was used to appraise if the changes we made led into any improvement. Using PDSA cycles to implement changes we had identified, and evaluate these changes using AGREE II standards to detect improvements in quality scores of various domains of the guideline enabled us to produce a high quality sepsis guideline. This systematic approach for improving the quality of our sepsis guideline might be helpful to others.

Funding and conflicts of interest:
This project did not receive any funding and the authors declare that they did not have any conflict of interest.

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Supplemental file 1, Appendix 1: AGREE II tool domains and related items		
AGREE II Domains	Domain Items	Scores: 1 – 7 (1= Strongly Disagree; 7= Strongly Agree)
Domain 1. Scope and Purpose	1. The overall objective(s) of the guideline is (are) specifically described.	Scores: 1 – 7
	2. The health question(s) covered by the guideline is (are) specifically described.	Scores: 1 – 7
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	Scores: 1 – 7
Domain 2. Stakeholder Involvement	4. The guideline development group includes individuals from all relevant professional groups.	Scores: 1 – 7
	5. The views and preferences of the target population (patients, public, etc.) have been sought.	Scores: 1 – 7
	6. The target users of the guideline are clearly defined.	Scores: 1 – 7
Domain 3. Rigour of Development	7. Systematic methods were used to search for evidence.	Scores: 1 – 7
	8. The criteria for selecting the evidence are clearly described.	Scores: 1 – 7
	9. The strengths and limitations of the body of evidence are clearly described.	Scores: 1 – 7
	10. The methods for formulating the recommendations are clearly described.	Scores: 1 – 7
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	Scores: 1 – 7
	12. There is an explicit link between the recommendations and the supporting evidence.	Scores: 1 – 7
	13. The guideline has been externally reviewed by experts prior to its publication.	Scores: 1 – 7
	14. A procedure for updating the guideline is provided.	Scores: 1 – 7
Domain 4. Clarity of Presentation	15. The recommendations are specific and unambiguous.	Scores: 1 – 7
	16. The different options for management of the condition or health issue are clearly presented.	Scores: 1 – 7
	17. Key recommendations are easily identifiable.	Scores: 1 – 7
Domain 5. Applicability	18. The guideline describes facilitators and barriers to its application.	Scores: 1 – 7
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	Scores: 1 – 7
	20. The potential resource implications of applying the recommendations have been considered.	Scores: 1 – 7
	21. The guideline presents monitoring and/or auditing criteria.	Scores: 1 – 7
Domain 6. Editorial Independence	22. The views of the funding body have not influenced the content of the guideline.	Scores: 1 – 7
	23. Competing interests of guideline development group members have been recorded and addressed.	Scores: 1 – 7
Overall Guideline Assessment	1. Rate the overall quality of this guideline	Scores: 1 – 7 (1= Lowest possible quality; 7= Highest possible quality)
	2. I would recommend this guideline for use.	Yes; Yes, with modifications; No

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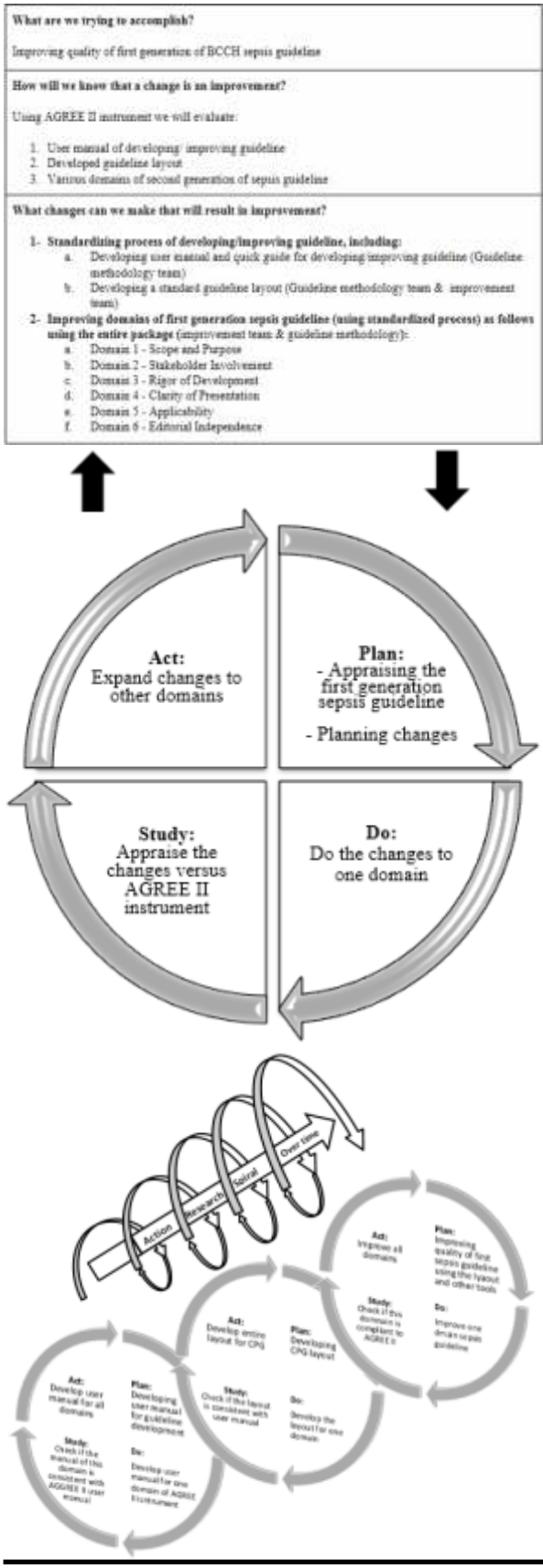
Supplemental file 2, Appendix 2:
Figure 1: Systematic approach for improving quality of sepsis guideline based on IHI model for improvement and using AGREE II instrument



Supplemental file 3, Appendix 3:
BCCH- Agree II Guideline Layout for Clinical Practice Guideline

1. Title of the guideline
2. Date
3. Table of contents
4. Executive summary:
a. Different options for management (of the condition or health issue)
b. Key recommendations: quick reference guide

5. Introduction: Screening, prevention, diagnosis and treatment options
a. Epidemiological data of the clinical condition in question
b. Management of the disease/condition:
I. Usual practice
ii. Issues regarding standard practice
iii. Rational for CPG

6. Purpose and scope:
a. Overall objective(s) of the guideline
b. Question(s) covered by the guideline
c. Population (patients, public, etc.) to whom the guideline is meant to apply

7. Target users:
a. Target/ intended users of the guideline

8. Guideline
a. Recommendations
b. Symptom management
c. Complication management
d. Community-based management
e. Follow up/review
9. Appendices and other guideline-related material

Appendix 1: Guideline development methods: description and material
1.1-Generating evidence process:
- Literature search strategy
- Inclusion/exclusion criteria
- Grading System for selecting evidence
- Strengths and limitations of the body of evidence
- Cost utility, cost effectiveness and implications for acquisition costs

1.2-Guideline development process
- Methods for formulating the recommendations
- Explicit link between the recommendations and the supporting evidence

1.3-Guideline management process:
➢ Development:
- Original guideline development group
- Guideline date

➢ Update procedure:
- Guideline revision group
- Dates

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➢ Acknowledgements

1.4-Target population (patients, public, etc.): views and preferences

Appendix 2: Budget: Funding used in the development of the document

Appendix 3: Disclaimer and conflicts of interest:

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- Conflicts of interest
- Disclaimer and funding source

Appendix 4: Glossary/definitions and acronyms

Appendix 5: Other material for guideline development and implementation:
- Tools and resources necessary for implementation
- Barriers, guideline utilization, and quality indicators
- Audit criteria: guideline monitoring and/or auditing criteria
- Documents implying guideline externally reviewed by experts prior to its publication
- Etc.

Appendix 6: References and more readings:
- References
- More readings:
  Handbooks
  Manuals

Supplemental file 4, Appendix 4: PDSA (Plan-Do-Study-Act) Worksheet

TOOL: Sepsis CPG STEP: Developing CPG development manual CYCLE: 1st Try: DOMAIN 1. SCOPE AND PURPOSE

PLAN
I plan to:
We are going to develop a guideline development/ improvement manual using AGREE II user manual focusing on one domain (scope and purpose).

I hope this produces:
We hope to get at 100% of the "DOMAIN 1. SCOPE AND PURPOSE" consistent with AGREE II user manual

Steps to execute:
- We will read "DOMAIN 1. SCOPE AND PURPOSE" section of user manual of AGREE II
- We will find all the guidance inside this section and compile them
- We will change the language to action verb and recommendation format
- We will do this in/ for one week

DO
What did you observe?
- We noticed that the developed manual is 100% consistent with the original AGREE II tool.
- We noticed that we need some edits.

STUDY
What did you learn? Did you meet your measurement goal?
- We had 100% compliance to AGREE II user manual.

ACT
What did you conclude from this cycle?
- We can use this method to develop a user manual for developing/ improving guidelines encompassing all six domains of AGREE II instrument.PDSA (plan-do-study-act) worksheet

TOOL: Sepsis CPG STEP:Developing CPG development manual CYCLE: 2nd Try: entire user manual

PLAN
I plan to:
We are going to develop a full guideline development/ improvement manual using AGREE II user manual focusing on entire AGREE II instrument.

I hope this produces:
We hope to get at 100% of all section of our manual to be consistent with AGREE II user manual

Steps to execute:
- We will read all sections related to user manual of AGREE II
- We will find all the guidance inside all sections and compile them according to each section
- We will change the language to action verb and recommendation format
- We will develop a quick user guide using this user manual
- We will do this in/for three months

DO
What did you observe?
- We noticed that all sections of the developed user manual and quick user guide are 100% consistent with the original AGREE II tool.
- We noticed that we needed some edits.
- We noticed that in order to have a user manual fully consistent with the original one, it is better to keep the design and location of our manual the same as the original one user manual.

STUDY
What did you learn? Did you meet your measurement goal?
- We had 100% compliance to AGREE II user manual in our manual and related quick user guide.

ACT
What did you conclude from this cycle?
- We can use the developed manual and its quick user guide for developing new guidelines
- We can use the developed manual and its quick user guide for improving quality of existing guidelinesPDSA (plan-do-study-act) worksheet

TOOL: Sepsis CPG STEP: Developing CPG layout CYCLE: 3rd Try

PLAN
I plan to:
We are planning to use the guideline development/ improvement manual and its quick user guide developed in previous PDSA cycles for developing a CPG layout that is consistent with AGREE II instrument. We will focus on one domain, (scope and purpose).

I hope this produces:
We hope to develop a layout that is 100% consistent with AGREE II instrument.

Steps to execute:
- We will use the first development manual and its quick user guide to develop a CPG layout
- We will modify the layout according to our need to sepsis guideline
- We will modify it based on the opinion of the content specialists in sepsis management

DO
What did you observe?
- We observed that we needed to add some elements to the layout that were not addressed in AGREE II explicitly.

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STUDY
What did you learn? Did you meet your measurement goal?
- We had a clear CPG layout for domain 1 that was 100% concordant with the AGREE II.

ACT
What did you conclude from this cycle?
- The GPG layout for domain 1 is consistent with the AGREE II instrument.
- We can move ahead and develop the layout for all sections of AGREE II instrument.

PDSA (plan-do-study-act) worksheet

TOOL: Sepsis CPG STEP:Developing CPG layout CYCLE: 4th Try

PLAN
I plan to:
We are planning to use the guideline development/ improvement manual and its quick user guide developed in previous PDSA cycles for developing a full CPG layout that includes all sections of AGREE II instrument and is consistent with this instrument.

I hope this produces:
We hope to develop a full layout that is 100% consistent with AGREE II instrument.

Steps to execute:
- We will use the first development manual and its quick user guide to develop a CPG layout
- We will modify the layout according to our need to sepsis guideline
- We will modify it based on the opinion of the content specialists in sepsis management

DO
What did you observe?
- W observed that we needed to add some elements to the layout that are not addressed in AGREE II instrument explicitly

STUDY
What did you learn? Did you meet your measurement goal?
- We had a clear CPG layout that was 100% consistent with the AGREE II instrument and included all sections recommended in AGREE II instrument.

ACT
What did you conclude from this cycle?
- The GPG layout is consistent with the AGREE II instrument.
- The layout can be used for improving existing CPGs or developing new guideline.
- We need to add some elements to the AGREE II elements in order to have a more practical layout for producing improved or new clinical guideline.

PDSA (plan-do-study-act) worksheet

TOOL: Sepsis CPG STEP: Developing second generation of sepsis CPG CYCLE: 5th Try

PLAN
I plan to:
We are planning to improve quality of the first sepsis guideline in one domain and develop second generation of sepsis guideline consistent with AGREE II instrument using the CPG layout, guideline development manual and its quick developed in previous PDSA cycles.

I hope this produces:
We hope to improve quality of one domain (domain 1: scope and purpose) of the existing sepsis guideline and produce new sepsis guideline that is 75% consistent with our CPG layout in this domain.

Steps to execute:
- We will work on one domain (domain 1) of the guideline
- We will compare this domain with the CPG layout and original AGREE II instrument
- We will modify it according to the opinions of the team for more improvement

DO
What did you observe?
- Using AGREE II instrument, we observed that first domain (scope and purpose) had a good improvement.

STUDY
What did you learn? Did you meet your measurement goal?
- First domain (scope and purpose) was around 95% consistent with AGREEE II instrument.

ACT
What did you conclude from this cycle?
- The CPG layout, guideline development manual and its quick guide developed in previous PDSA cycles is working and leads to improvement in sepsis guideline.
- These tools can be used for improving other domains of the guideline.

PDSA (plan-do-study-act) worksheet

TOOL: Sepsis CPG STEP: Developing second generation of sepsis CPG CYCLE: 6th Try

PLAN
I plan to:
We are planning to improve quality of all domains of the first sepsis guideline and develop full version of second generation of sepsis guideline consistent with AGREE II instrument.

I hope this produces:
We hope to improve quality of the existing sepsis guideline in all domains recommended in AGREE II tool and produce new sepsis guideline that is 75% consistent with our CPG layout.

Steps to execute:
- We will improve all domains of the guideline
- We will compare each section of new sepsis guideline against the CPG layout and the original AGREE II instrument
- We will modify it according to the opinions of the team for more improvement

DO
What did you observe?
- Using AGREE II instrument, we observed that all domains had a good improvement.

STUDY
What did you learn? Did you meet your measurement goal?
- Our changes led to improvements in all domains of sepsis guideline.
- Some domains showed more improvement than the others.
- Domains that showed less improvement had good baseline quality.

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ACT

What did you conclude from this cycle?

- The CPG layout, guideline development manual and its quick guide developed in previous PDSA cycles is working and leads to improvement in sepsis guideline. This can be used for developing or improving other guidelines.

Supplemental file 5, Appendix 5

Table 4: Comparing the items of AGREE II in first and new set of BCCH guidelines

AGREE II Domains	AGREE II item	Score					
		Before revision	After revision				
		Appraiser 1	Appraiser 2	Appraiser 3	Appraiser 1	Appraiser 2	Appraiser 3
Domain 1 (Scope and Purpose)	Q1 - The overall objective(s) of the guideline is (are) specifically described.	1	2	1	7	7	7
	Q2 - The health question(s) covered by the guideline is (are) specifically described.	1	1	7	7	6	7
	Q3 - The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	1	2	4	6	7	7
Domain 2 (Stakeholder Involvement)	Q4 - The guideline development group includes individuals from all relevant professional groups.	2	3	5	6	6	7
	Q5 - The views and preferences of the target population (patients, public, etc.) have been sought.	1	1	2	2	3	7
	Q6 - The target users of the guideline are clearly defined.	1	1	2	7	7	7
Domain 3 (Rigour of Development)	Q7 - Systematic methods were used to search for evidence.	1	2	6	2	6	7
	Q8 - The criteria for selecting the evidence are clearly described.	1	2	1	3	6	7
	Q9 - The strengths and limitations of the body of evidence are clearly described.	1	1	1	7	2	7
	Q10 - The methods for formulating the recommendations are clearly described.	1	1	1	7	6	7
	Q11 - The health benefits, side effects, and risks have been considered in formulating the recommendations.	1	1	5	3	4	6
	Q12 - There is an explicit link between the recommendations and the supporting evidence.	1	1	1	2	3	7
	Q13 - The guideline has been externally reviewed by experts prior to its publication.	1	1	7	4	1	7
	Q14 - A procedure for updating the guideline is provided.	1	1	1	7	6	7
Domain 4 (Clarity of Presentation)	Q15 - The recommendations are specific and unambiguous.	4	7	7	7	6	7
	Q16 - The different options for management of the condition or health issue are clearly presented.	4	6	7	6	6	7
	Q17 - Key recommendations are easily identifiable	7	6	7	7	6	4
Domain 5 (Applicability)	Q18 - The guideline describes facilitators and barriers to its application.	1	1	1	5	5	7
	Q19 - The guideline provides advice and/or tools on how the recommendations can be put into practice.	3	3	6	4	5	7
	Q20 - The potential resource implications of applying the recommendations have been considered.	1	1	1	3	2	7
	Q21 - The guideline presents monitoring and/or auditing criteria.	6	1	1	7	3	7
Domain 6 (Editorial Independence)	Q22 - The views of the funding body have not influenced the content of the guideline.	1	1	1	4	6	7
	Q23 - Competing interests of guideline development group members have been recorded and addressed.	1	1	1	7	3	7

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