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Supplement to "Clinical Decision Support Tools for Pediatric Sepsis in Resource-Poor Settings: An International Qualitative Study"

1) Supplemental Methods
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4) Interview Guide

Supplemental Methods

We used the well-established RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework to maintain a focus on external validity.[1,2] We used the RE-AIM framework because a lack of attention to external validity in design, implementation, evaluation, and reporting is a known gap in clinical informatics research.[3–5] RE-AIM supports the design and dissemination of systems that generalize to other settings, have uptake, and are sustainable.[6,7] The reach of a CDS intervention includes both the audience intended to benefit (patients) and the audience exposed to the intervention (clinicians).[8] By eliciting perspectives from clinicians, we laid the groundwork for understanding the mechanisms of any effectiveness of pediatric sepsis CDS tools in resource-poor settings.[9]

The focus group and interview guides are appendices in this Supplement. Following professional transcription of the focus groups and interview recordings, we used the *coding reliability* approach of thematic analysis to create *a priori* codes based on the CDS tool guide and RE-AIM framework.[10] Two members of the research team (AJ-Z and CR) read the same two transcripts and through consensus agreed upon additional inductive codes. If consensus could not be reached, BDH read the same two transcripts to facilitate discussion and achieve consensus. To establish coding standards, sections of a third transcript

were double-coded to assess intercoder reliability. Once the codebook was finalized, the remaining transcripts were coded by the same two members of the research team. Next, the coded data was analyzed within and between participant types to identify the major themes, sub-themes, and illustrative quotes that captured the participants' perspectives.[11] Thematic saturation, where no new concepts or themes emerged, was recognized by both members of the coding team after analyzing two focus groups. Regular meetings with the larger study team maintained the perspective of clinical experts on the emergent categories and themes. Participants did not provide feedback on the findings.

Supplemental Methods References

1 Glasgow RE, Green LW, Klesges LM, *et al.* External validity: We need to do more. Annals of Behavioral Medicine. 2006; 31: 105–8.

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8 Bakken S, Ruland CM. Translating Clinical Informatics Interventions into Routine Clinical Care: How Can the RE-AIM Framework Help? Journal of the American Medical Informatics Association. 2009; 16: 889–97.

9 Bonafide CP, Roberts KE, Weirich CM, *et al.* Beyond statistical prediction: qualitative evaluation of the mechanisms by which pediatric early warning scores impact patient safety. *J Hosp Med* 2013; 8:

248–53.

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Clinical Decision Support Tool for New Pediatric Sepsis Criteria
Focus Group Guide for Clinicians

Introduction

Hello everyone! Welcome, and thank you for agreeing to be part of our focus group today/tonight. Let me introduce our team: I'm (name of facilitator) and I will be facilitating the discussion and this is (name of co-facilitator) and ___ will be taking notes this evening. We are working with the University of

Colorado, Northwestern University, and the University of British Columbia, among other centers around the world on a research project about the implementation of tools to guide clinical decision-making regarding new pediatric sepsis criteria, particularly related to tools to help care for children in low- and middle-income countries (LMICs). We know that children in these environments suffer disproportionately from sepsis. For the purposes of this focus group, we are defining sepsis as severe infectious illness connected to further organ dysfunction.

Today/tonight we want to get your ideas and opinions about your institutions' current decision-making processes, and about your perspectives on the important capabilities and characteristics of pediatric sepsis Clinical Decision Support tools and factors that would facilitate or obstruct tool implementation. For this study, a Clinical Decision Support tool is an electronic tool (phone, tablet, or computer) that may help facilitate diagnosis, prognosis, and treatment plans by providing a personalized risk assessment. We will refer to these as CDS tools for the remainder of the focus group. Our goal is to build CDS tools around new sepsis criteria that will be most impactful, readily implementable, and fit into clinicians' workflows. [Define any other terms here or interchangeable terms]

We really appreciate your time today. We value your opinions and want you to know that what you tell us during these discussions will help inform the design of tools that facilitate pediatric sepsis surveillance, early identification, and treatment plan development.

Ground Rules

Before we begin, let me mention a few things about how we usually conduct these groups:

1. I will be the facilitator for the group. My role is to ask the questions we have for the group, and to encourage everyone to participate. At times during our group discussion, I may need to move us ahead to my next question. If I do this, I do not intend to be rude. To be able to cover all the questions we have prepared for today, I may have to cut short some discussion.

2. There are no right or wrong answers. Each person's experiences and opinions are valid, and we want to hear a wide range of opinions on the questions we'll be asking. So, please speak up, whether you agree or disagree with what's being said, and let us know what you think.

3. Whatever is discussed during this group and everyone who is here today is private. Would everyone agree to keeping this group's content and participants private?

4. We would like to record the group discussion to help us accurately capture and analyze what we learn from you all today. As a result, please speak one at a time so the recording will clearly pick up what is said. We use first names only in the transcript, and when we put together the results from all the groups, we don't include any names. All recordings and records will be on a password protected computer that only members of the research team have access to.
    a. Is everyone okay with being recorded? *(Wait for affirmative responses from everyone.)*

5. We plan to be finished with our discussion by (time). You do not have to be part of this discussion group if you don't want to. If you do choose to be in the group, a $25 gift card will be offered to you as compensation. By continuing to participate in this focus group, you are consenting to the collection of your perspectives used for our research project. Are there questions about any of this? [provide contact information].

6. Please turn off or at least silence your phones, watches, and pagers during this group.

Turn on recorders

Read: "Consent for Providers"

Focus Group Questions

Let's start by introducing ourselves with 1) your name, 2) your clinical or non-clinical role, and 3) the institution at which you practice/work.

General Information

1) Describe your clinical practice/role at _____________

- What is your specialty? (only for providers)
- What is your role?
- How many years have you been in your current role?

Current decision-making processes and general CDS tool characteristics

1. What clinical decision support tools are currently being used by your institutions? *[Question to gauge the landscape of tools available; If everyone starts describing their current tools and there is overlap, ask if anyone has used anything different]*
    a. If yes:
        i. What works well with these tools?
        ii. What are some limitations with this tool?
        iii. Who led the effort to develop/implement the tool?
            1. Can you describe the process?
        iv. What were some facilitators to this process?
            1. Were there any champions or early adopters of the tool?
        v. Tell me about any barriers to the development/implementation of the CDS tools.

    b. If no:
        i. Why do you think these types of tools are not available at your institution?
        ii. What do you think would be the benefit of having CDS tools available for use at your institution?
        iii. How would you suggest a CDS tool is created?
            1. By whom? Administrators or clinicians? Both?

2. What information/features should a good CDS tool have? *[Could prompt about functions for risk stratification and identification]*
    a. Probes: recognizing infection, recognizing a child who is sick or deteriorating, and recognizing a child with sepsis
    b. What would be the features/format (e.g. digital vs paper) of your ideal CDS tool?

3. Describe your current processes for assessing, diagnosing, and treating a pediatric sepsis patient?
    a. What works well?

b. What issues do you see with this process? (Probe: policy, institutional, departmental or personal)
c. What are some limitations?

Data required for decision-making

1. What critical information do you need to feel comfortable/confident when making a pediatric sepsis diagnosis and developing a treatment plan? (Probe: Tell me more about the reasons those are important)
    a. Is that information consistently available/accessible/usable? If not, why not?

2. Is there any additional information that is not necessary, but could be helpful in making a pediatric sepsis diagnosis and developing a treatment plan?

3. How do you discuss this diagnosis and treatment plan with your team members?
    a. How are they a part of the decision?

Desired data presentation and Sepsis Clinical Decision Support (CDS) tool capabilities
Now, let's talk about how a CDS tool will influence your decision-making process.

1. What are some advantages of having access to a Clinical Decision Support tool based on the new criteria?

2. What are some disadvantages of having access to a Clinical Decision Support tool based on the new criteria?

Barriers and facilitators to implementation of CDS tool

1. What do you anticipate could pose as a potential barrier of CDS tool implementation for pediatric sepsis diagnosis, prognosis and treatment at your institution? (Probe: Do you anticipate any pushback to implementing this type of CDS tool at your institution?)

2. What do you anticipate could pose as a potential facilitator of CDS tool implementation for pediatric sepsis diagnosis, prognosis, and treatment at your institution? (Probe: What do you think your institution requires, specifically, for successful CDS tool implementation?)

3. Who do you think is in charge of making decisions related to new CDS tools or diagnostic, prognostic, and treatment plan development processes at your institution?
    a. What is your role in this process?

4. What are some suggestions for the "successful implementation" of a CDS tool in your current [hospital/clinic/university]?

That is all I have for you, is there anything else you would like to discuss or say in regards to this topic?

https://redcap.ucdenver.edu/surveys/?s=3WTE8AWEY9A8PDMT

Closing

Thank you so much for being here tonight and for sharing your ideas with us!

Do you have any more questions/comments for us? As I mentioned earlier, we will be transcribing tonight's session but no names or proper nouns will be included. Also, if any of you are interested in the results of our work, we would be happy to notify you about the results of this and similar focus groups carried out by our research team.

Thank you again!

[Information about distribution of compensation]

Clinical Decision Support Tool for New Pediatric Sepsis Criteria
Interview Guide for Policymakers and Administrators

Introduction

Welcome, and thank you for agreeing to participate in an interview. Let me introduce our team: I'm (name of facilitator) and I will be conducting the interview and this is (name of co-facilitator) and ___ will be taking notes today. We are working with the University of Colorado, Northwestern University, and the University of British Columbia, among other centers around the world on a research project about the implementation of tools to guide clinical decision-making regarding new pediatric sepsis criteria, particularly when caring for children in low- and middle-income countries (LMICs). We know that children in these environments suffer disproportionately from sepsis. For the purposes of this interview, we are defining sepsis as severe infectious illness connected to further organ dysfunction.

Today/tonight we want to get your ideas and opinions about your institutions' current decision-making processes, and about your perspectives on the important capabilities and characteristics of pediatric sepsis Clinical Decision Support tools and factors that would facilitate or obstruct tool implementation. For this

study, a Clinical Decision Support tool is an electronic tool (phone, tablet, or computer) that may help facilitate diagnosis, prognosis, and treatment plans by providing a personalized risk assessment. We will refer to these as CDS tools for the remainder of the focus group. Our goal is to build CDS tools around new sepsis criteria that will be most impactful, readily implementable, and fit into institutional workflows. [Define any other terms here or interchangeable terms]

We really appreciate your time today. We value your opinions and want you to know that what you tell us during these discussions will help inform the design of tools that facilitate pediatric sepsis surveillance, early identification, and treatment plan development.

Before we get started, I would like to outline a few important points from the consent form that I sent to you before our interview:

- There are no right or wrong answers to any of the questions I ask you today.
- This interview is voluntary. You may choose to answer or not answer any questions, and you can stop participating at any time without losing any benefits or rights.
- All responses will be kept private. The information you share with us will be combined with responses from other participants and summarized without identifying information.
- The principal investigators for this study are Drs. Tell Bennett and Nelson Sanchez-Pinto. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may contact Dr. Bennett at 303-724-8661. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

[TURN ON Digital RECORDER]
State date, location, and interview ID number into digital recorder.

General Information

1. Describe your role at _____ institution.
    a. How many years have you been in your current role?

Current decision-making processes and general characteristics of CDS tools

1. What do you know about your institution's existing process for assessing, diagnosing, and treating a pediatric sepsis patient?
    a. What works well?
    b. What issues do you see with this process? (Probe: policy, institutional, departmental or personal)
    c. What are some limitations?

2. Does your institution currently have any existing CDS tools?
    a. If yes:
        i. What works well with these tools?
        ii. What are some limitations with this tool?
        iii. Who led the effort to develop/implement the tool?
            1. Can you describe the process?
        iv. What were some facilitators to this process?
            1. Were there any champions or early adopters of the tool?
        v. Tell me about any barriers to the development/implementation of the CDS tools.

b. If no:
   i. Why do you think these types of tools are not available at your institution?
   ii. Do you think your institution would benefit from having CDS tools available for use?
   iii. How would you suggest a CDS tool is created?
      1. By whom? Administrators or clinicians? Both?

3. What information/features should a good CDS tool have?
   a. Probes: recognizing infection, recognizing a child who is sick or deteriorating, and recognizing a child with sepsis

4. How does your institution make decisions about choosing whether or not to implement or use a CDS tool? Who are the key stakeholders? What does the process look like?

5. Who do you think is in charge of making decisions related to new CDS tools or diagnostic processes at your institution?
   a. What is your role in this process?

Barriers and facilitators to implementation of CDS tool

1. What do you anticipate could pose as a potential barrier of CDS tool implementation for pediatric sepsis diagnosis, prognosis, and treatment plan at your institution? (Probe: Do you anticipate any pushback to implementing this type of CDS tool at your institution?)

2. What do you anticipate could pose as a potential facilitator of CDS tool implementation for pediatric sepsis diagnosis, prognosis, and treatment plan at your institution? (Probe: What do you think your institution requires, specifically, for successful CDS tool implementation?)

3. What are some suggestions for the “successful implementation” of a CDS tool in your current [hospital/clinic/university]?

Final Reflections

1. Thank you for sharing these experiences with us. Before we wrap up, do you have any final reflections? Anything we missed? Things that pop out to you? General reactions?

[Information about distribution of compensation]

Thank you again for taking the time to speak with me.