

BMJ Open Clinical decision support tools for paediatric sepsis in resource-poor settings: an international qualitative study

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ABSTRACT

Objective New paediatric sepsis criteria are being developed by an international task force. However, it remains unknown what type of clinical decision support (CDS) tools will be most useful for dissemination of those criteria in resource-poor settings. We sought to design effective CDS tools by identifying the paediatric sepsis-related decisional needs of multidisciplinary clinicians and health system administrators in resource-poor settings.

Design Semistructured qualitative focus groups and interviews with 35 clinicians (8 nurses, 27 physicians) and 5 administrators at health systems that regularly provide care for children with sepsis, April–May 2022.

Setting Health systems in Africa, Asia and Latin America, where sepsis has a large impact on child health and healthcare resources may be limited.

Participants Participants had a mean age of 45 years, a mean of 15 years of experience, and were 45% female.

Results Emergent themes were related to the decisional needs of clinicians caring for children with sepsis and to the needs of health system administrators as they make decisions about which CDS tools to implement. Themes included variation across regions and institutions in infectious aetiologies of sepsis and available clinical resources, the need for CDS tools to be flexible and customisable in order for implementation to be successful, and proposed features and format of an ideal paediatric sepsis CDS tool.

Conclusion Findings from this study will directly contribute to the design and implementation of CDS tools to increase the uptake and impact of the new paediatric sepsis criteria in resource-poor settings.

INTRODUCTION

Paediatric sepsis is a major global public health problem. In 2017, an estimated 25 million cases of paediatric sepsis worldwide were associated with 3.3 million deaths.¹ Children in resource-poor settings suffer disproportionately from sepsis, but few tools exist to guide clinical decision-making in those

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Our multidisciplinary study team and the gold-standard iterative qualitative analytic process, which decreased the likelihood of injecting bias into the analysis because of the role separation between the qualitative and clinical study team members.
- ⇒ Multidisciplinary clinicians (both physicians and nurses) and health system administrators were largely aligned in their perspectives, which increases the likelihood of implementation and adoption of clinical decision support (CDS) tools and the forthcoming new paediatric sepsis criteria.
- ⇒ Although we conducted the study across the three major world regions where the impact of paediatric sepsis is most powerful, we did not capture perspectives from participants in every potentially important country or subregion.
- ⇒ Because the future sepsis CDS tools will be clinician-facing, we did not collect patient or caregiver perspectives, which will be important to obtain in future work.
- ⇒ Participant perspectives about paediatric sepsis decision-making may have been influenced by past experiences, raising the potential for social desirability bias because of the group format.

environments. There is an urgent need for generalisable and accurate clinical decision support (CDS) tools to improve sepsis recognition, treatment and risk stratification. This need was emphasised in the United Nations World Health Assembly 2017 resolution which recognised sepsis as a global health priority and proposed specific actions, including the development and implementation of CDS tools, to improve sepsis outcomes around the world.²

Well-designed decision support tools can improve the quality of medical

decision-making and can facilitate the uptake of new knowledge, guidelines and policies.^{3–5} However, to facilitate uptake of the new paediatric sepsis criteria, before a decision support tool can be developed, it is necessary to understand what information is most useful to decision-makers. Identifying these elements through a decisional needs assessment is typically performed using qualitative research techniques.⁶

We are developing new paediatric sepsis criteria with a group of over 40 international experts as part of the Paediatric Sepsis Definition Task Force,^{7–11} an effort sponsored by the Society of Critical Care Medicine and supported by the WHO, the World Federation of Pediatric Intensive and Critical Care Societies and the European Society of Pediatric and Neonatal Intensive Care, among others. Dissemination of the new sepsis criteria as ready-to-use CDS tools will increase the likelihood of impact on clinical outcomes, including in resource-poor settings. However, it is not known what type of sepsis CDS tools clinicians and administrators in resource-poor settings will find most useful (eg, on paper, mobile devices, web-based, or in electronic health records (EHRs)), particularly in low-income and middle-income countries (LMICs). Historically, most sepsis criteria and guidelines have been developed with limited engagement from clinicians and health systems in LMICs.

We, therefore, performed a qualitative decisional needs assessment study to fill this gap. The goals of the study were to understand (1) current decision-making processes, (2) current use of CDS tools or other decisional aids (eg, clinical guidelines) and (3) the essential features and format of a CDS tool for paediatric sepsis across three diverse regions (Asia, Africa and Latin America) which have the highest incidence of sepsis cases and deaths globally. We will use this information to design and build decisional needs-informed CDS tools to facilitate use of the new paediatric sepsis criteria in resource-poor settings.

METHODS

Study design

We based the study on the Ottawa Decision Support Framework,¹² which is based on the idea that designing decision support tools to meet identified decisional needs (eg, knowledge gaps, conflicts/uncertainty, values) will improve decision quality. Under this framework, a high-quality decision is both well-informed and reflective of the decider's values. In order to understand clinician and administrator value-informed perspectives about CDS tools for paediatric sepsis, we used a qualitative approach. We used the same approach in conducting clinician¹³ and parent¹⁴ decisional needs assessments related to the care of children with another acute paediatric condition, traumatic brain injury. In order to build tools with the potential for widespread adoption, particularly in LMICs, we must understand potential barriers to and facilitators of implementation. To gain that understanding, we asked clinicians, including physicians and nurses, and hospital

or health system administrators about their current paediatric sepsis management protocols and decision-making processes, their desired CDS tool capabilities, and barriers and facilitators for implementation of a CDS tool.

Sampling and recruitment

Research team members and members of the Paediatric Sepsis Definition Task Force identified potential clinician (nurse and physician) and health system administrator participants using purposive sampling from across three LMIC regions: Africa, Asia and Latin America. A list was generated from which study team members contacted participants and offered participation via email. Participants were purposefully recruited with a broad range of years of practice and a balance of men and women. Focus groups took place between April and May 2022. We included clinicians who are involved with decisions about how to treat paediatric sepsis but do not have primary decision-making responsibility (eg, nurses) to give us a greater breadth of understanding about the decision-making process. We also used purposeful recruitment to obtain perspectives from administrators involved in the implementation and dissemination of CDS tools and clinical information systems for their health systems. Verbal informed consent was obtained from all participants. Each participant was offered the equivalent of a US\$25 gift card in their preferred currency.

Data collection

We conducted three semistructured 120 min focus groups with clinicians including 8–14 participants per group (Africa n=8, Asia n=13, Latin America n=14) and five semistructured interviews with health system administrators (approximately 45 min each). All focus groups and interviews were conducted using Zoom, a video conferencing platform freely available to the study team (University of Colorado, HIPAA-compliant license). Clinical (TDB, LNS-P and MOW) and qualitative (BDH, AJ-Z and CR) experts collaboratively designed the focus group and interview guides based on the RE-AIM framework (see online supplemental material).¹⁵ The semistructured guides focused on exploring (1) current decision-making processes, (2) data required for decision-making, (3) desired data presentation and CDS tool capabilities and (4) barriers and facilitators for implementation of CDS tools.

Qualitative analysis

Audiorecordings were professionally transcribed verbatim in the language of the interview (English or Spanish) and Spanish-language interview transcripts were professionally translated into English. All translated transcripts were validated by the interviewer, who listened to the audio file and verified both the transcription and translation for accuracy. All interview transcripts were uploaded to ATLAS.ti (ATLAS.ti Scientific Software Development, Berlin, Germany) for data management, coding and analysis. Thematic analysis was the overall approach. For

additional details about the qualitative analysis, please see online supplemental methods.

Role of the funding source

The study sponsor had no role in study design, data collection, analysis, or interpretation, report writing, or decision to submit the paper for publication.

Patient and public involvement

We did not involve patients or the public in the design, conduct, reporting or dissemination plans of our research because the participants in this study were clinicians and because the CDS tools to be built in the future will be clinician-facing.

RESULTS

Participants

The three regional focus groups included 35 clinicians (eight nurses and 27 physicians). The settings in which participants worked varied. In the Africa focus group, these settings included teaching hospitals, public tertiary care hospitals, regional referral hospitals and district hospitals. Participants of the Asia focus group worked at institutions such as an international health research organisation; a large, private, for-profit hospital chain; a public hospital and medical school; an independent, non-profit paediatric hospital; a public tertiary care hospital and a public medical university. Those who participated in the Latin America focus group worked at settings that included public or private hospitals, teaching hospitals, university-affiliated hospitals, referral hospitals, multipurpose hospitals and social security hospitals. Participants reported working in paediatric intensive care units (ICUs), adult ICUs and emergency rooms, among other departments. Some institutions had ICUs and some did not. Five health system administrators (four practising physicians and one who no longer practices clinically) participated in individual interviews. Interview participants also worked in a variety of academic and clinical settings, including a large non-governmental organisation, a private university

hospital, a public university for health sciences and a paediatric hospital.

Table 1 shows demographic and other characteristics of the participants. The 40 participants had a mean age of 44.5 years (range 28–70 years), mean experience of 14.6 years (range 1–30 years), and 45% were female.

Themes

Overall, three central themes emerged from our qualitative analysis. Those three themes were: (1) variation across regions and institutions in clinical decision-making processes, (2) necessity of flexibility for successful CDS tool implementation and (3) proposed features and format of an ideal paediatric sepsis CDS tool. Clinician and administrator perspectives were largely aligned and provided insight into current decision-making processes, tools and guidelines related to paediatric sepsis in resource-poor settings, and essential features and format of future CDS tools.

Theme 1: variation across regions and institutions in clinical decision-making processes

Four subthemes emerged related to variation in clinical decision-making processes for paediatric sepsis: (a) institutions' reliance on guidelines or criteria, (b) challenges in paediatric sepsis diagnosis and treatment related to infectious aetiologies that are prevalent in these regions (and many low-resource environments), (c) prevalence of offline, often paper-based, formats for guidelines, criteria and tools and (d) limitations in paediatric sepsis recognition and treatment related to knowledge gaps, challenges educating rotation trainees, and a lack of laboratory and other resources (table 2). First, across all three regions many clinicians and administrators reported not using established CDS tools, but rather basing their approach on guidelines and subjective clinical knowledge and decision-making. A variety of guidelines are used, even within the same region. Some existing criteria, protocols and guidelines that are used include the 2005 International Pediatric Sepsis Consensus Conference criteria,¹⁶ the adult Sepsis-3 criteria,¹⁷ the 'Sepsis 6' bundle,¹⁸ the

Table 1 Characteristics of participants in the focus groups and interviews

	Participants (n)	Sex (n)		Age (years) overall mean 44.5	N of role (physician, nurse, admin)			Years of experience overall mean 14.6
		Male	Female		Some participants have >1 role			
				Range, mean	Phys	Nurse	Admin	Range, mean
Africa	11	7	4	34–70, 46	8	3	7	1–27, 10.8
Asia	14	6	8	28–63, 45	10	4	1	3–28, 16.4
Latin America	15	9	6	35–59, 43	14	1	1	4–30, 14.2
Total	40	22	18		32	8	9*	

*Four clinician focus group participants reported to us that they served as part-time health system administrators, making the administrator total n=9 rather than just the n=5 who participated in individual interviews.
Admin, administrator; Phys, physician.

**Table 2** Illustrative quotes related to variation across region and institution in clinical decision-making processes

Subthemes	Participant quote
Current CDS tool versus guideline/criteria use	<i>'We're a district hospital that—we don't have a pediatric ICU. We do not even have an ICU per se, but we manage our patients in general wards. We actually do not have specific guidelines or protocols for pediatric sepsis...Most of the decisions are subjective. Our clinicians or our physicians make subjective decisions. In our wards, we typically base our decisions on children presenting with fever. Sometimes our diagnosis is confirmed at discharge. If you go through our records, we discovered that most of our sepsis diagnoses are confirmed at discharge based on the clinician's treatment that has been followed throughout the time of admission...that is how we approach our patients, but we are working on developing some protocols to be used.'</i> (Clinician, Africa)
Challenges in paediatric sepsis diagnosis related to infectious aetiologies	<i>'Many of the tropical diseases that many of our colleagues have highlighted, malaria, dengue, maybe scrub typhus and all, which often do not find a mention in the sepsis guidelines which come from the developed world because they don't see this particular spectrum. I think we would need to focus on that as well in terms of the non-bacterial illnesses and all where the supportive care is important, but antibiotics may not be all that important.'</i> (Clinician, Asia)
Prevalence of offline, often paper-based formats, for guidelines, criteria and tools	<i>'The big advantage, in our context, is the availability of paperwork makes it easier for people in areas where there's not technology. Also, because in order for us to open an app [digital application], some of the apps require us to have internet, and internet's very expensive in these parts of the world...It's cost-prohibitive to you to use. If you are to make it usable is to have it written in a way that is open offline. Having an offline version means the same thing—that we're just writing on paper—but it's digital. Whereas having it in a way that's already online, if you have update, then it comes automatically.'</i> (Administrator, Africa)
Limitations in paediatric sepsis recognition and treatment	<i>'One of the things I find difficult is the variability in the age of children. In children, we have—we assist from neonates to adolescents. Variability in vital signs makes it difficult for the system to recognize them. The other thing is that we can't just base only on vital signs, but there are other things in the child's general appearance that the system can't see. For example, alterations in the child's perfusion...The general appearance of the child is a very important thing and we can't leave it all to the system. Then, I think that what makes it possible for us to capture these patients well is the mix between a system and software that enable us to somewhat stabilize the decision making a little; but also the staff training to be able to recognize those children who don't look good.'</i> (Clinician, Latin America)

CDS, clinical decision support.

Surviving Sepsis Campaign guidelines,¹⁹ the American College of Critical Care Medicine guidelines²⁰ and the Smart triage platform.²¹ Both clinicians and administrators reported that these guidelines defined a 'standard approach' to sepsis care, but they also noted being unclear which standard approach should be used. In addition, many clinicians and administrators reported the difficulty of making a paediatric sepsis diagnosis while simultaneously diagnosing and treating other conditions (eg, malnutrition, dengue, malaria, etc). Most of these guidelines were implemented using paper versions, as many of the clinicians and administrators in all three regions reported not having access to EHRs or other clinical information systems in their healthcare environment. A few participants reported mobile/digital capabilities at their current institutions. In addition, some participants mentioned the limitation of paediatric sepsis recognition due to the lack of laboratory capabilities, general lack of sepsis knowledge in their environment, difficulty with educating rotating trainees and resource limitations.

Theme 2: necessity of flexibility in format, customisation and support for successful CDS tool implementation

Participants emphasised that in order for implementation to be successful, any future CDS tool needed to be flexible and customisable to local realities. In addition, four subthemes emerged related to suggestions for

successful paediatric CDS sepsis tool implementation: (a) adaptation to user level of training, (b) context-specific constraints, (c) language translation and cultural tailoring and (d) leadership buy-in and support (table 3). Clinicians and administrators communicated that it is imperative for a paediatric sepsis CDS tool to be adapted to different users with varying levels of clinical training (ie, nurses, medical trainees, community health workers). Most participants emphasised that context-specific barriers should be considered when developing a paediatric sepsis CDS tool, specifically considering the lack of confirmatory laboratory tests, access to EHRs, as well as the lack of general awareness of paediatric sepsis. Participants emphasised the diversity within their own environments and recognised the importance of accurate and specific language translation and cultural tailoring for each country and each region where it will be implemented. Clinicians and administrators recognised the importance of having supportive leadership within hospital systems and local health authorities. This type of leadership buy-in and support would enable the necessary stakeholder engagement and CDS tool piloting and local validation. Although most participants discussed the necessary components for successful CDS tool implementation, some clinicians expressed concern about whether

Table 3 Illustrative quotes related to necessity of flexibility for successful CDS tool implementation

Subthemes	Participant quote
Need for flexibility in CDS tool implementation in order to adapt to diverse contexts	<i>'I definitely agree that it [a CDS tool] needs to be flexible or customizable, 'cause one size is not gonna fit all. I think that rather than necessarily pre specifying specific outcomes or actions that should come from a scoring system it might be better to try and provide a risk or a probability of how likely it is that the child has sepsis or is gonna deteriorate and with that probability, decision-makers, hospital managers, service providers, can contextualize that probability to their own setting. If you're working in the rainy season and the hospital is extremely busy, then you're gonna have a different threshold for making your decision than if you're working in the dry season and there's more capacity. I think trying to say that one decision is the correct one at all times of year or in different places is not likely to succeed.'</i> (Clinician, Asia)
Adaption to user level of training	<i>'Something like this [a CDS tool for pediatric sepsis] would be desirable, there's no doubt, particularly in a setting where a large—people with different levels of resources and training are looking after children. Certainly, that kind of a tool is what I understand should be the endpoint of what we are discussing or what the SCCM task force is trying to develop the criteria which are specific to children.'</i> (Clinician, Asia)
Context-specific constraints	<i>'Then, as I said, lack of other supporting systems, like internet, electricity, even, sometimes, water and soap—you produce guidelines that, when you are dealing with sepsis, this is how to prevent sepsis—the infection prevention and control—but the equipment to use or the supplies are not there. I think, briefly, those may be some of the barriers.'</i> (Administrator, Africa)
Language translation and cultural tailoring	<i>'Language [can be a big barrier] in this sense. Maybe a lot of software—if it's developed in a platform, an app, or something—translates from English; and there are many Anglicisms that remain... So, it would have to be, or maybe they understand it that way, closer to central America, where there's a different lexicon, a lot more mixed with Anglicisms than in South America. I think language is something we have to pay serious attention to, if we want to develop the tool. To make it as international as possible.'</i> (Clinician, Latin America)
Leadership buy-in and support	<i>'The other bit is that the management—the hospital, the facilities, the management plays a very key role in having these tools being used. The staff are more likely going to use the tools, if at all, the administration, if at all, their supervisors really appreciate and promote it or, yeah, love the tool and promote it among the staff.'</i> (Clinician, Africa)

CDS, clinical decision support.

CDS tools would improve clinical outcomes in their institutions.

Theme 3: proposed features and format of an ideal paediatric sepsis CDS tool

Three subthemes emerged related to the ideal features and content of a CDS tool for the new paediatric sepsis criteria: (a) ease of use and affordability of the tool, (b) risk stratification functionality and focus on sensitivity vs specificity and (c) focus on clinical assessment rather than laboratory data (table 4). First, participants, both clinicians and administrators, agreed that a potential paediatric sepsis CDS tool should be simple and easy to use so that a diverse group of providers can use it, including general practitioners, specialists, trainees, nurses and community health workers. They also emphasised that the tool would need to be affordable and inexpensive to maintain. An ideal tool should be able to differentiate between lower risk and higher risk forms of sepsis, as well as include clear criteria for sepsis. Participants shared the reality of diversity within regions, countries and hospital systems, compounded by local resource constraints which would impact how a paediatric sepsis CDS tool would be used in different locations. Therefore, they suggested that an ideal CDS tool (and the criteria on which it is based) should be primarily based on clinical assessment, with laboratory diagnostic data as an optional component, but not an essential part of the tool. It was re-emphasised

in theme 3 that the desired format of a paediatric sepsis CDS tool may vary based on local context. Participants highlighted the need for this CDS tool to be available in different formats (paper, mobile phone or EHR) appropriate for both low and high resource settings within LMICs. Having this flexibility would allow the tool to fit within each local context and work within its restraints. Clinicians in the Asia and the Latin America focus groups recognised that overdiagnosis of paediatric sepsis is an issue. Among participants there were mixed opinions on whether sensitivity or specificity should be prioritised when designing a paediatric sepsis CDS tool (even within the same region), however, overall there was a greater preference for a more specific and accurate tool.

DISCUSSION

We conducted a qualitative study of multidisciplinary clinicians who care for children with sepsis and health system administrators from LMICs in three regions of the world to understand what type of CDS tools will be most useful for dissemination of forthcoming new paediatric sepsis criteria in resource-poor settings. Incorporating multidisciplinary clinician input during the needs assessment will increase the likelihood that a future CDS tool will meet the needs of clinicians and have uptake and impact. We identified three main themes, namely:

**Table 4** Illustrative quotes related to proposed features and format of an ideal paediatric sepsis CDS tool

Subthemes	Participant quote
Ease of use and affordability of the tool	<i>'It [a CDS tool] has to be an easy tool, affordable, low cost, in order for it to be implemented in the great periphery units, where, as I told you before, there aren't many resources. Another thing is that all staff, both technical and—because sometimes triage is done by a technician in the nurse station. It's true, we may know a lot about scores, about early detection, but many of them don't know anything about it, about the alarm signs in those patients. I think that's the heart of the matter. To be able to implement all these tools, but tools that are affordable and understandable for them; as well as to the periphery.'</i> (Clinician, Latin America)
Risk stratification functionality: sensitivity vs specificity	<i>'I think the tools should do both. There's risk stratification, as well as management of the patient, because risk stratification helps us to make some bigger decisions, including referral in situations where you think the facility's not able to manage in this case. I know this patient is going to require a tube inside the throat to survive later down the road. I don't have the capacity to ventilate this child here, so I might as well as give this medicine and refer the patient. You can only make that decision if you risk stratify the patient. It might be too late if you don't do the risk stratification for the patients to require that tube and you don't have the tube. I think you should do both.'</i> (Administrator, Africa)
Focus on clinical assessment rather than laboratory data	<i>'I think if we are looking at the things that should be in any tool for sepsis identification and management, and again based on my experience, I think it has to be huge or large on clinical presentations. Our colleagues, at least, in Nigeria, and I would also imagine in other states, have very good solid clinical methods. They take excellent histories and do very good physical exams. Any management of sepsis, so identification of sepsis, that would have to be based on what the search criteria says might not suffice much if you want to base them on labs. One is that these—some of these patients do not have the money to pay, the labs are delayed for you to get your results. If you focus most of the tools on what people could just do right at the point of seeing this patient and starting them on treatment, I think that we're gonna go a long way in identifying these kids and starting prompt treatment.'</i> (Clinician, Africa)

CDS, clinical decision support.

(1) variation across regions and institutions in clinical decision-making processes; (2) a need for flexibility for successful CDS tool implementation and (3) proposed features and format for an ideal paediatric sepsis CDS tool. These themes were directly related to the decisional needs of clinicians as they care for children with sepsis and of health system administrators as they make decisions about which CDS tools to implement in LMICs.

One overarching theme that was present throughout the focus group and interview discussions was a need for CDS tools to be customisable to the respective local context. This customisability was mentioned at several levels: context-specific versions of the new paediatric sepsis criteria, local adaptation to language, culture, and training, and dissemination format (digital vs paper, etc). Because of resource constraints related to availability of internet access, water and other hygiene supplies, clinical information systems and laboratory testing, as well as variation in personnel awareness of paediatric sepsis, CDS tools and the criteria they are designed to disseminate may need to be built (and validated) in several different formats adapted to local realities. Those formats could be paper based, mobile device based or embedded into an EHR or clinical information system, depending on local resources. Each has different implications for feasibility, affordability and accessibility in different contexts for different users that will need to be tested with prototype versions of the CDS tools. Similarly, whether the tools include laboratory values will depend on local availability and the validated criteria being used. The CDS tools

will need to be adapted to both local language and local cultural context. Participants highlighted the unique challenges in their regions compared with the regions where many paediatric sepsis guidelines and protocols originate. Different infectious aetiologies of paediatric sepsis in different regions require that paediatric sepsis criteria and CDS tools be developed and calibrated using data from those regions to accurately capture baseline risk and better incorporate specific risk factors observed and measured in those contexts. Some participants suggested that CDS tools should be customisable over time as available local resources varied with, for example, dry versus wet seasons and associated burden of disease. In peripheral and field care locations, rotating clinicians may provide most of the care. Because of varying educational backgrounds and experience, their needs for paediatric sepsis CDS tools may be different than experienced clinicians at paediatric centres in urban settings. A balancing measure may be that message inconsistency in CDS tools could be perceived by clinicians in remote locations as demeaning. If, for example, they developed a care plan based on the new CDS tools and that plan was changed immediately after transfer, overall CDS tool perception may worsen.

A need for multiple versions of paediatric criteria (eg, including laboratory assessments or not) and customisability of CDS tools will pose unique challenges to criteria and tool developers. Criteria are easier to evaluate, disseminate and reinforce when they are simple and consistent, instead of in multiple forms. Multiple forms

of CDS tools (eg, paper based, mobile device based and EHR based) will be more costly to implement, maintain and update. However, overcoming these challenges may improve dissemination and implementation of paediatric sepsis criteria and ultimately have a greater impact on paediatric sepsis outcomes. Similarly, other investigators have suggested that the current guidelines for the treatment of paediatric sepsis may not be equally useful in the different regions where sepsis is frequent and that their recommendations should be adjusted to these realities.²²

Several subthemes that emerged in our study can also directly inform future CDS tool design and implementation. Participants emphasised the value of careful clinical assessments that include not only vital signs, but also metrics like perfusion/capillary refill and mental status. These metrics may be less standardised than quantitative vital signs. Supporting personnel and systems to reliably capture and record these metrics will be of high value. One potential secondary benefit of paediatric sepsis CDS tools in resource-poor settings is that they can also serve as data collection tools.²³ This will increase the availability of digitised data from LMICs and allow future calibration and improvement of sepsis and organ dysfunction criteria based on more extensive data over time.²⁴ In areas with and without laboratory capabilities, increased capture, standardisation, and digitisation and standardisation of clinical assessments will add tremendous value.

Participants indicated a desire for CDS tools to contribute to both paediatric sepsis identification and risk stratification. This result is consistent with the findings of a recent international survey that asked clinicians to state needs in relation to new paediatric sepsis criteria.⁷ One related subtheme that emerged is the balance of sensitivity vs specificity of a CDS tool's diagnostic threshold. Participants from two regions (Asia, Latin America) described that overdiagnosis was an unintended consequence of some paediatric sepsis initiatives. Even in resource-rich settings, there is a tension between sepsis quality improvement initiatives encouraging early antibiotic therapy (more early/emergency department focused) and antibiotic stewardship initiatives to reduce antimicrobial resistance (more inpatient/intensive care focused). This tension is the reason that some infectious disease organisations did not endorse the adult 2017 Surviving Sepsis Campaign.²⁵ Furthermore, in some settings, sufficient resources may not be available to treat or transport every patient identified by a highly sensitive tool. Customisability to local context (eg, of the diagnostic threshold) has the potential to alleviate some of these tensions, but will need to be carefully evaluated by both criteria developers and local implementation teams. In the future, multiple CDS tools (or a single CDS system with multiple modules) will be needed, as the necessary support for early recognition and treatment decisions will likely be different than support for later escalation/de-escalation decisions based on risk stratification.

One key strength of the findings of this study is that multidisciplinary clinicians (both physicians and nurses)

and health system administrators were largely aligned in their perspectives. Alignment between these key groups of stakeholders will increase the likelihood of implementation and adoption of CDS tools and the new paediatric sepsis criteria. For example, if clinicians valued CDS tools of a type or format that was not readily implementable by health systems, the tools would be less likely to have uptake. Conversely, if administrators preferred CDS tools of a type or format not perceived as useful by clinicians, then the tools might not be used after implementation. Another strength of the study is the multidisciplinary study team and the gold-standard iterative process. Injection of pre-existing bias was less likely because of the role separation between the qualitative and clinical study team members.

This study has several potential limitations. First, while we conducted the study across the three major world regions where the impact of paediatric sepsis is most powerful, we did not capture perspectives from participants in every potentially important country or subregion. The themes and perspectives identified may not generalise to all clinicians and health system administrators. Second, we chose to focus on clinician perspectives in this study because the future CDS tools will be clinician-facing. Because of that choice, we did not collect patient or caregiver perspectives, which will be important to obtain in future work. Third, all of the health system administrators we interviewed either previously or currently practice clinically as physicians. The perspectives of non-clinician administrators may differ. Fourth, participant perspectives about paediatric sepsis decision-making may have been influenced by past experiences. There is the potential for social desirability bias because of the group format. Focus group facilitators were aware of that potential and attempted to minimise it by reviewing discussion guidelines and ground rules with the participants prior to the focus group. These guidelines and ground rules instruct participants to equally contribute to the discussion, describe viewpoints in first or third person, respect all viewpoints and keep information provided during the focus group confidential. In addition, participants were told by the focus group facilitators that the purpose of the focus group is to obtain their perspectives, therefore it's most important they provide honest information and there is no right or wrong way to respond.

Conclusion

Dissemination of the forthcoming new paediatric sepsis criteria as customisable and ready-to-use CDS tools will increase their uptake and impact in resource-poor settings. The findings from this study will directly contribute to the design and implementation of decisional-needs informed multidisciplinary CDS tools to disseminate and support use of the new paediatric sepsis criteria in LMICs and resource-poor settings.

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

- 1) Supplemental Methods
- 2) Supplemental Methods References
- 3) Focus Group Guide
- 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.

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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.