


# BMJ Open Quality Severe illness getting noticed sooner – SIGNS-for-Kids: developing an illness recognition tool to connect home and hospital

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## ABSTRACT

**Background** Delays to definitive treatment for time-sensitive acute paediatric illnesses continue to be a cause of death and disability in the Canadian healthcare system. Our aim was to develop the SIGNS-for-Kids illness recognition tool to empower parents and other community caregivers to recognise the signs and symptoms of severe illness in infants and children. The goal of the tool is improved detection and reduced time to treatment of acute conditions that require emergent medical attention.

**Methods** A single-day consensus workshop consisting of a 17-member panel of parents and multidisciplinary healthcare experts with content expertise and/or experience managing children with severe acute illnesses was held. An a priori agreement of ≥85% was planned for the final iteration SIGNS-for-Kids tool elements by the end of the workshop.

**Results** One hundred percent consensus was achieved on a five-item tool distilled from 20 initial items at the beginning of the consensus workshop. The final items included four child-based items consisting of: (1) behaviour, (2) breathing, (3) skin, and (4) fluids, and one context-based item and (5) response to rescue treatments.

**Conclusions** Specific cues of urgent child illness were identified as part of this initial development phase. These cues were integrated into a comprehensive tool designed for parents and other lay caregivers to recognise the signs of serious acute illness and initiate medical attention in an undifferentiated population of infants and children. Future validation and optimisation of the tool are planned.

## BACKGROUND

Improving the outcomes of acute severe illness is contingent on the availability, timing and application of effective treatments. For our purposes, acute severe illness is any illness that could result in death or significant morbidity if not identified early or where treatment is significantly delayed. Fortunately, for many common acute severe illnesses (eg, sepsis), well-defined treatments are available

(eg, antibiotics, source control, circulatory and respiratory support).<sup>1</sup> Timing is a central element of acute care particularly for conditions like sepsis and trauma. Established literature and internationally accepted guidelines underscore the clinical importance of timely treatment.<sup>1 2</sup> The Society of Critical Care Medicine slogan ‘Right Care, Right Now’<sup>3</sup> further emphasises the relevance of these foundational principles of acute care.

Unfortunately, many recent studies of early protocolised goal-directed treatment for severe life-threatening illness such as septic shock have failed to demonstrate a mortality benefit in adult and paediatric populations.<sup>4 5</sup> This is likely in part due to widespread improvement in system and patient-level care resulting in overall in-hospital mortality that is now much lower for adult and paediatric populations compared with historical cohorts.<sup>6 7</sup> Further reductions in mortality may be achieved by understanding and shortening the duration from symptom onset to definitive treatment. In a series of infants with bacterial meningitis in the UK, 24% presented to the hospital >24 hours after symptom development<sup>8</sup>; this seemingly delayed presentation was associated with both increased mortality and neurologic morbidity.<sup>9</sup> Other severe illnesses including stroke,<sup>10 11</sup> malignancy<sup>12–14</sup> and kernicterus<sup>15 16</sup> can result in permanent injury and are also time-sensitive in terms of their need for definitive treatment. Furthermore, multiple jurisdictions in Canada, the USA and the UK have reported that children under 1 year of age are at greatest risk of death from medical conditions related to prematurity, congenital anomalies and infections with anywhere from 8% to 26% of deaths having



some degree of preventability.<sup>8 17–19</sup> Contributory themes to these deaths are multifactorial and include: (1) delays in seeking care, (2) delays in recognition of symptoms and abnormal vital signs at various levels of the health-care system, (3) poor team communication and (4) a lack of continuity of care particularly at transitions of care.<sup>8</sup>

The under-recognition of severe acute illness in hospital settings was the impetus for the development and implementation of medical emergency teams<sup>20 21</sup> and early warning scores.<sup>22 23</sup> When integrated with other system-level interventions, paediatric early warning scores reduce serious safety events<sup>24</sup> and significant clinical deterioration events.<sup>23</sup> Early identification of illness in a community setting prior to hospital admission is the next logical extension of this paradigm and necessarily relies on family members to recognise and act on the evolving features of severe acute illness in their child. Family triggered activation of medical emergency teams is integrated into many paediatric hospitals<sup>25 26</sup> and family assessment is acknowledged in the safety literature as paramount in illness recognition requiring urgent medical attention.<sup>13 27</sup> In outpatient settings, symptom checklists,<sup>28</sup> illness severity action plans<sup>29</sup> and parent early warning scores<sup>30</sup> have been described predominantly in selected populations with known disorders and more predictable symptoms. A parent early warning score for infants with complex congenital heart disease has demonstrated good acceptance and feasibility by parents but requires attention to parent preparation and confidence in the use of the instrument.<sup>30</sup> These examples demonstrate that an understanding of the signs and symptoms of severe acute illness progression and the populations at greatest risk are important. To our knowledge, a validated and accessible early warning tool designed to help parents and other members of the lay public identify often undifferentiated severe acute illness across the spectrum of childhood age and development does not currently exist.

In 2016, the Healthcare Insurance Reciprocal of Canada (HIROC) determined that ‘failure to escalate medical treatment stemming from under-recognition of severe illness in hospitalised children’ in its top acute care risks leading to litigation for healthcare providers and organisations.<sup>31</sup> In conjunction with the Canadian Patient Safety Institute (CPSI) and HIROC, this project was initiated with a focus on the developing an early recognition tool for families and other community-based caregivers to detect the signs of severe acute illness and help to translate their concerns during the initial interactions with the healthcare system. This may lead to further reductions in preventable morbidity and mortality by (1) improving transitions to and within hospital settings and (2) earlier initiation of definitive medical treatment.

## METHODS

A panel of experts was selected from across Canada with a diverse spectrum of perspectives and disciplines who frequently manage children with severe acute illness

and/or have in-depth knowledge of the associated signs and symptoms in either a clinical or forensic capacity. The panel was limited to a maximum of three participants from any one group or perspective to maintain a manageable panel size and limit over-representation from any one key stakeholder group. A consensus development workshop<sup>32 33</sup> incorporating at least three stages of consensus-building was planned using elements of nominal group technique<sup>34 35</sup> to generate and distill signs of serious acute illness in children was planned with an a priori consensus of  $\geq 85\%$  on the final tool elements. An illness threshold to guide the tool development was selected whereby immediate escalation of care to an emergency department would be appropriate and the tool needed to have good applicability across all paediatric age categories ranging from term newborns to adolescents. Selected pre-reading material was distributed to panel members to provide context on the topic of symptom recognition in different scenarios by parents and lay care providers. The material included several published symptom checklists of severe illness designed for lay people and articles describing important signs and symptoms of severe infection in infants and the use of parental early warning scores in infants with complex congenital heart disease.<sup>28 30 36</sup> Initial evaluation of the construct validity of the SIGNS-for-Kids tool planned for an informal review of 10 randomly selected paediatric case files held by HIROC of delayed recognition of severe illness causing death or disability that resulted in legal claims. Selected cases were reviewed to determine the presence of one or more of the SIGNS criteria. It was hypothesised that most cases would have documentation indicating the presence of one or more of the SIGNS-for-Kids items.

## Patient and public involvement

The initial research question was identified by HIROC based on themes observed in medical-legal claims made on behalf of paediatric patients related to failure to escalate medical treatment in the Canadian healthcare setting. This finding was endorsed and championed by the CPSI, a not-for-profit organisation with a mission to advance a culture committed to sustained improvement for safer healthcare. At the inception of this project, the authors and the CPSI were committed to the inclusion of parents of paediatric patients with significant experience of the healthcare system throughout the consensus process, manuscript development and all future steps leading from this research. Various organizations including the Canadian Patient Safety Institute and Patients for Patient Safety Canada provided parent candidates from which the parent representatives were selected.

## RESULTS

A 17-member expert panel was formed (online supplementary appendix 1). Its members were representative of three Canadian provinces and included experience from the coroner’s office, two parents of children with

extensive healthcare system experience and multiple paediatric healthcare provider groups and specialties. The disciplines and specialties included inpatient paediatricians, paediatric and neonatal intensive care, emergency medicine, community paediatricians, a clinical nurse specialist, a respiratory therapist, primary care nurse practitioner and healthcare providers for remote Indigenous populations. The panel subsequently met in Toronto in May 2018 over 1 day. CPSI and HIROC provided financial support for travel and lodging for panel members to attend if they lived out of town.

An initial interactive facilitated discussion began the first stage of the consensus workshop. The group discussed and developed a comprehensive list of signs and symptoms of evolving severe acute illness that should prompt childcare givers to seek out urgent medical attention. The panel determined that the severity of illness indications to trigger an escalation in care should be independent of experience with the healthcare system or relationships with healthcare providers; be observable and detectable by lay members of the community; be inappropriate or unreasonable to ignore as they could represent the presence of a life-threatening condition; and be credible with frontline healthcare professionals who would interact with children whose parents were prompted to seek urgent medical attention.

In the second stage, each participant was asked to individually rank the top three signs or symptoms according to the participant's perceptions of importance in detecting severe acute illness in infants and children. The ranked list of signs and symptoms was then re-presented to the group and were sub-categorised via group consensus into child-based cues and context-based cues. This resulted in 10 child-based cues and 2 context-based cues.

In the third stage, the panel was asked to examine the ranked items for shared themes that would allow them to be distilled into overarching individual tool components. This resulted in the identification of four stand-alone items into which other ranked items were integrated and used as descriptors. A fourth stage was added for the group to reflect on the included items and ensure that the a priori consensus threshold and reach agreement on the final product (figure 1). In this final review, 100% of the members reached agreement after the addition of a category describing lack of response to either prescribed or over-the-counter treatment that may have been initiated prior to seeking medical attention. The wording and definitions of the items were discussed, refined for lay language and accessibility to a wide range of end-users. Phrasing, presentation and design elements were discussed to facilitate the rapid interpretation and utilisation by parents or other non-healthcare professional caregivers in both English and French. This resulted in the articulation of the five SIGNS items:

1. Behaviour: (a) reduced interaction with surroundings; (b) reduced independent actions; (c) persisting uncontrolled movements or lack of movement.

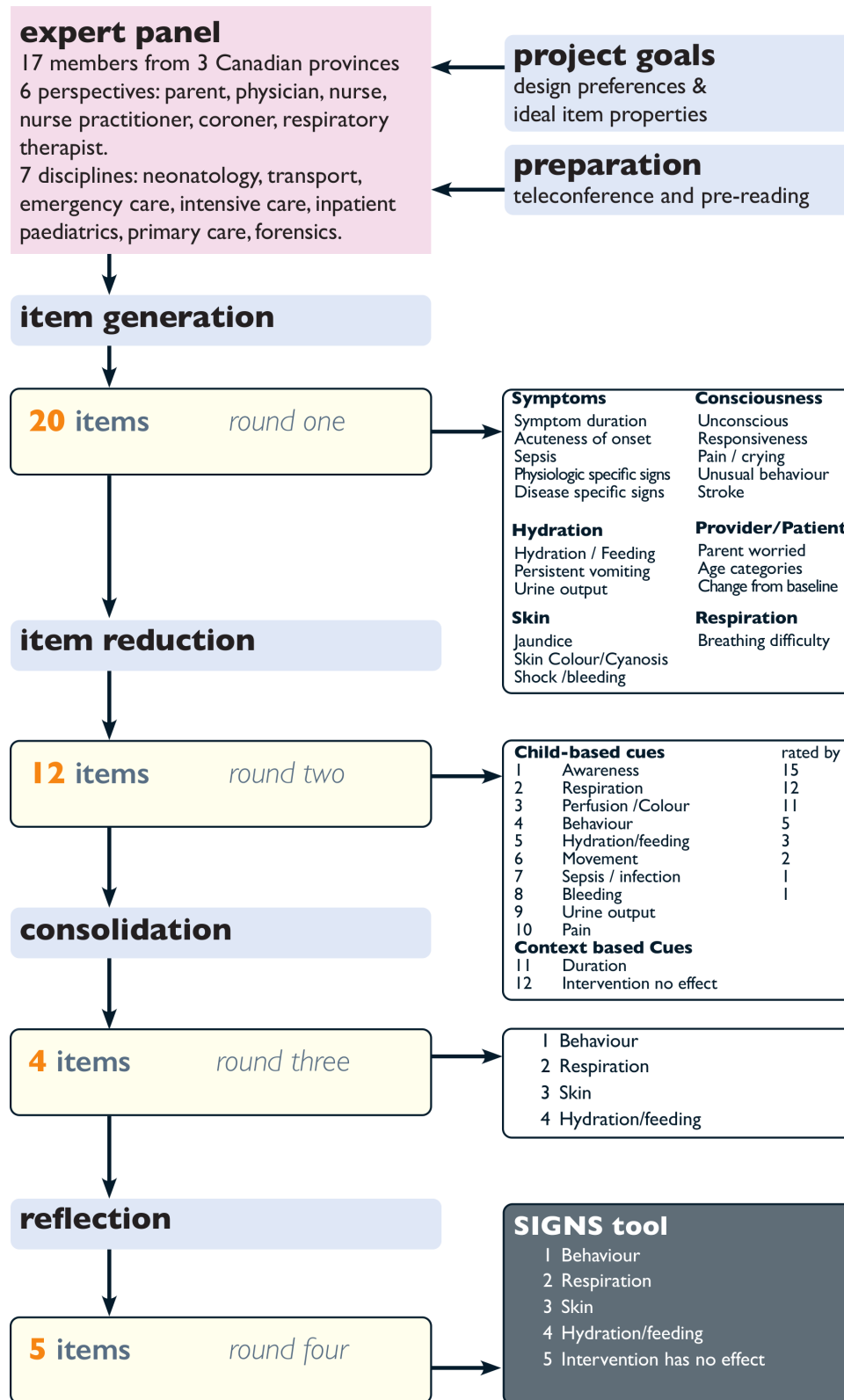
2. Breathing: (a) noticeable breathing; (b) long pauses between breaths.  
 3. Skin: (a) jaundice in the first month of life; (b) mottled and cold skin (with other concerns); (c) blue (ish) skin and tongue; (d) purple rash.  
 4. Fluids: (a) persistent vomiting; (b) colourful vomiting (red or green); (c) minimal fluid intake; (d) No urine.  
 5. Response to rescue treatments: (a) known health issue getting worse despite the use of usually effective treatment.

Ten randomly selected cases of delayed recognition of severe illness leading to death or disability that resulted in medical-legal claims were subsequently reviewed from the HIROC database and confirmed the presence of at least one SIGNS-for-Kids criteria in each case.

## DISCUSSION

We describe the first phase of development of the SIGNS-for-Kids (SIGNES Enfant) tool—a five-item public health tool to; (1) help parents and other lay-caregivers identify acute severe illness in children, and (2) support the articulation and efficient communication of parental and lay concerns to healthcare professionals and (3) to facilitate timely escalation of care. The selected signs, criteria and cues align with other tools listing symptoms described in case series of severe infection in infants,<sup>9 36</sup> the criteria of the Advanced Paediatric Life Support assessment triangle,<sup>37</sup> the lived experience of a diverse group of paediatric clinicians, the perspectives of parental representatives and selected cases of delayed recognition of severe illness resulting in medical-legal action. The panel's selection of severe acute illness as a threshold was a balancing principle to prevent adversely increasing attendance at emergency departments for children who did not require urgent medical attention as this could have counterproductive service delivery effects at the system level. Ultimately, the panel envisioned a tool to help prevent community cases of failure-to-rescue leading to death or disability that occur despite the presence of abnormal signs and symptoms warranting immediate medical attention.

This is the first tool created using an established development methodology that addresses the undifferentiated populations of children. Other tools have been created for patients with specific diseases (asthma management plan)<sup>29</sup> or broader populations of high-risk patients (cyanotic heart disease).<sup>30</sup> The SIGNS-for-kids tool is intended to provide a comprehensive set of items describing severe illness in children with and without comorbidities across the spectrum of age and development anticipated in the paediatric population. Short semi-technical descriptions have been created for each element of the tool that will provide important clinical anchors to develop visual and language aids. Further development is required.



**Figure 1** Consensus workshop flow diagram showing item generation and refinement

### Limitations

There are three main limitations of this work. First, tool development included a limited number of healthcare professionals. The inclusion of more representatives from each discipline may have increased the diversity of

items during item generation and increased the depth of consideration during item reduction phases. Second, the development panel included two parent representatives. Biased representation linked to direct experiences of the parents is acknowledged as a possibility. For this

reason, we chose experienced parent representatives who had been pre-screened and recommended as having both personal and broader experience as patient/parent representatives. Observations from within the panel discussion confirmed the parents were able to bracket their experiences and provide a broader perspective. Third, limited evidence of validity is provided. Overlap of the SIGNS items with tools used for triage by healthcare professionals provides face validity, however more direct measures of validity are lacking. The use of 10 cases provides evidence of initial criterion validity only as it is a small sample and does not ensure generalisability to a larger more diverse population. Further evidence is needed and is a focus of our future work.

### Future directions

The development of the SIGNS-for-kids tool is the first step towards the objective of an early warning/recognition tool for use in the community by lay child caregivers. Parents and caregivers will be a key part of the future development and evaluations of the usability of the SIGN-for-Kids materials, validity of and in the evaluations of effectiveness evaluations of the SIGNS for Kids tool. Required future work will include the development and refinement of communication materials to represent the SIGNS to parents and other caregivers, demonstration of that parents and other carers can understand the items, the validation of the SIGNS items as useful markers of severe illness when applied by parents or other caregivers, and in evaluations of clinical effectiveness.

### CONCLUSIONS

The SIGNS-for-kids tool addresses a previously unexplored gap in the acute severe illness recognition process for children. We think this initiative will help inform and support families and other community-based care providers to recognise the signs of severe illness, support the deployment of healthcare resources and has great potential to reduce preventable death and disability in children.

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