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Title: Face and content validity, acceptability, feasibility and implementability of a novel outcome measure for children with life-limiting or life-threatening illness in three sub-Saharan African countries

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Abstract

Background: The Children's Palliative Care Outcome Scale (C-POS) is the first measure developed for children with life-limiting and -threatening illness. It is essential to determine whether the measure addresses what matters to children, and if they can comprehend and respond to its items.

Aim: To determine the face and content validity, comprehensiveness, comprehensibility, acceptability and feasibility and implementability of the C-POS.

Design: Mixed methods 1) *Content validation*: mapping C-POS items onto an evidence-based framework from prior evidence; 2) *Comprehensiveness, comprehensibility, acceptability feasibility and implementability*: qualitative in-depth and cognitive interviews with a purposive sample of children and young people (n=6), family caregivers (n=16) and health workers (n=12) recruited from tertiary facilities in Kenya, South Africa and Uganda.

Results: 1) C-POS content mapped on to palliative care domains for (a) children (i.e. *physical* [e.g. symptoms], *social* [e.g. play/socialise], *psychological* [e.g. happy]) and (b) families (i.e. *psychological* [e.g. worry], *social* [e.g. information] and *help and advice*. 2) C-POS items were well understood by children and their caregivers, acceptable and relevant. Completion time was a median of 10 minutes, patients/caregivers and health workers reported that using the C-POS improved their communication with children and young people. Methodological and content issues included: i) conceptual gap in the spiritual/existential domain; ii) further consideration of developmental, age-appropriate items in the social and psychological domains, and iii) linguistic complexity and difficulty in proxy rating.

Conclusion: C-POS items capture the core symptoms and concerns that matter to children and their families. C-POS is feasible, comprehensible, and acceptable for use in clinical settings; areas for further development and improvement are identified.

Key message

- Children, young people and families facing life-limiting and -threatening illness have complex needs and high service use. C-POS is the first outcome measure specifically developed and evaluated for this population.
- It is possible to measure and capture what matters to children and young people using C-POS. Measuring what matters is important in ensuring quality and outcomes-focused care.

What this paper adds

- C-POS has acceptable face and content validity properties.
- C-POS items are comprehensible and acceptable to children and young people and caregivers.
- Health workers endorse the relevance of C-POS items to paediatric palliative care.

Implications for practice

- The C-POS has acceptable content and is adequately brief and should be used in paediatric palliative care.

Key words: Paediatric palliative care, children, content validity, cognitive interviewing, C-POS, Africa, PROMs

Running title: Face and content validity of the C-POS

Background

Over 21 million children with life-limiting and -threatening conditions could benefit from palliative care.[1] Of these, over 97% reside in resource-limited settings where they face additional problems of late diagnosis, limited curative options and poor treatment access.[2] These children have high service utilisation and polypharmacy due to their complex symptoms and concerns spanning multiple domains: physical, existential or spiritual, psychological, social, health care goals and quality of care.[3, 4 5] Although research suggests paediatric palliative care can alleviate avoidable suffering,[6] improve treatment compliance, and reduce symptom-associated distress[7], the lack of validated patient-level, PPC outcome measures is a barrier to measurement of outcomes and service development.[8-10]

Outcome measures for adults in palliative care have transformed evidence and practice[11-14], particularly in Africa.[15-18] However, they cannot be directly extrapolated to children given the unique population and disease differences.[19] There are notable differences which span the holistic nature and include physical, social, spiritual and psychological may be explained by the socio-ecological structural differences which vary by developmental age. There are also measurement issues with children as one must take into consideration the communication difficulties and developmental delays due to illness. Currently, no person-centred outcome measure exists that is developed and validated for children and young people with life-limiting or -threatening illness.[19] To address this gap, a novel measure (the Children's Palliative care Outcome Scale [C-POS]) was developed.[20] This paper assesses C-POS in terms of its face and content validity, comprehensiveness, comprehensibility, acceptability, feasibility for use and implementability in clinical settings.[21]

Methods and study design

Design and measure construct

Initial development of the C-POS followed COSMIN guidance for the development and testing of health measures. This work focuses on aspects of the tool's validity (in terms of psychometric development) plus practical aspects of measure use (acceptability, feasibility, and implementability).[22] C-POS is a 12-item tool measuring the construct of symptoms and concerns in children and young people (0–17 years) and their families, living with life-limiting and -threatening conditions (figure 1), underpinned by the World Health Organization definition of paediatric palliative care.[23] The C-POS self- and caregiver-proxy report versions have seven child-focused items (completed by children who are able to self-report or by caregivers of children unable to self-report), and five items family-focused items. The C-POS was translated from English into the following African languages (Luganda, Runyakitara, Swahili, Luo and xhosa) for this study. Linguists and a clinical psychologist used the forward-and-backward method followed by a comparison of the two versions with reconciliation of inconsistencies through discussion by two members of the research team and the translators.[24]

(i) Face and content validation

The framework used to assess face and content in this study is derived from a systematic review on symptoms and concerns that matter to children living with life-threatening illnesses and their families [3] and a qualitative study on what matters to children living with life-limiting and -threatening conditions.[4] From the two sources, seven main themes were identified: *physical* (, e.g. pain, nausea, lack of appetite, and physical activities); *social* (family relationships, social functioning-attend school, play); *existential/spiritual* (worry about death, belonging); *psychological* (emotional-positive affects such as happiness, behavioural, [e.g. anger], cognitive [e.g. self-image]); *psycho-social* (perspectives of others, stigma); *life values* (normalcy, achieving life goals); and *quality of care* (information and communication, child-friendly services).

Mapping Procedures

Two study authors mapped the C-POS items (the C-POS was previously developed [25]) to an evidence-based framework of symptoms and concerns derived from narrative synthesis systematic review[3] and thematic analysis of a qualitative interview study conducted with children and their caregivers in Kenya, Uganda and South Africa[4] between September 2014 to December 2018.

Content validation drew on the methodology proposed by Engler,[26] i.e.: breadth and depth, where breadth is representation of top-level framework themes, and depth is representation of sub-themes.[26] The latter enables a balanced representation of the themes that underpin a given construct. For breadth, C-POS domains were mapped on the evidence-based content framework derived from the review and primary data. For depth, C-POS items were mapped onto content at the sub-theme level. The team used a visual display to examine whether each C-POS item fell into a content column, and whether each major theme was represented by at least one sub-theme item.[27] Evidence for face and content validity was demonstrated if the C-POS items addressed domains previously identified as important for this population.[28]

(ii) Comprehensiveness, comprehensibility, acceptability and feasibility

Cognitive interviews with children and family caregivers

Cognitive interviews were conducted with children and young people living with life-limiting and -threatening conditions, and their family caregivers (the caregivers were related to patients or known guardians/legal guardians). Children and family caregivers could participate independently or as dyads. If a child was of self-reporting age (7-17) but could not self-report due to developmental age or advanced disease, the family caregiver was interviewed alone. In the case that a family caregiver accompanying the child did not meet inclusion criteria, their consent was sought to interview the child alone as long as they were aged 7-17 and were willing to give assent.

Inclusion criteria for children: aged between 7 - 17 years, receiving palliative care and able to communicate verbally in a study language.

Inclusion criteria for family caregivers: aged 18 years and above, caring for a child living with life-limiting or -threatening illnesses at least 50% of the time, and able to communicate verbally in a study language. Family caregivers were recruited irrespective of the child's age (although they were purposively selected to ensure participation by caregivers of children who could and could not self-report). Dyads of children and family caregivers were excluded in instances where both were too ill to participate.

Interview procedures: Study participants were identified by clinical teams at out-patient clinics of eight facilities, including tertiary hospitals and hospices, in Kenya, South Africa and Uganda. Facility staff introduced the children and their family caregivers to the data collection team.

Written informed consent was obtained from study participants, for younger than seven (7) years, consent was obtained from their caregiver and these children provided assent for participation.

Cognitive interviews were conducted by five experienced qualitative interviewers (four clinicians, a social scientist and a child clinical psychologist), all of whom were female and trained for this study. Two of the interviewers were staff at the recruitment site; the others were not known to participants. All interviews were conducted at health facility premises in the local languages or English. Cognitive interviews assessed the tool in terms of comprehensibility, comprehensiveness, item relevance, appropriateness of the response scale, recall timeframe, the instructions given to complete it, and how well the items translated into the local languages and environments. Interviews involved completion of the C-POS (C-POS completion time was measured) with verbal probing to gather data on how they developed responses to each item, whether C-POS items were clear or unclear, and whether any content was irrelevant or had been missed.[29,30] (see supplementary material 1 for the topic guide).

During cognitive interviewing, three response formats were explored: faces, the numerical scale, and a hand scale[31] (figure 2). Children, family caregivers and health workers were asked to explain their response format preference. All interviews were audio recorded, although respondents had an option to accept or refuse audio recording (in which case the protocol allowed for note taking).

In-depth interviews with health workers

In-depth interviews were conducted with health workers who participated in pre-testing of the C-POS, exploring their experiences using the outcome measure, clarity of the items, types of scale most commonly used, and relevance of content (see supplementary material 1).

Inclusion criteria for the health professionals: working with children with life-limiting or -threatening illnesses for more than twelve months as part of the clinical team, and had previously participated in the C-POS field-testing phase.

Interview procedures

Health workers were interviewed by two members of the research team (MA and EN). Informed consent was obtained prior to the interviews.

Data management and analysis

Comprehensiveness, comprehensibility, and acceptability

All interviews were transcribed verbatim, translated into English and reviewed with the audio recording by a bilingual member of the data collection team. Inconsistencies were resolved through discussion, and transcripts anonymised. All interview transcripts were imported into NVIVO version 12 for analysis.

Two members of the study team (EN and MA) randomly selected and read six cognitive interview transcripts multiple times to identify emergent themes. Subsequently, they developed an analysis guide and draft codebook and coded the remaining transcripts. EN and MA then used a content data analysis approach and index using Tourangeau's model of the response process (comprehension of questions, retrieval from memory, decision process, and response process).[32] All quotes were anonymised and included by type of respondent and unique identifying number (for example, child 05).

In-depth interviews with health workers were managed as described for cognitive interviews. However, for analysis, all themes and suggestions for improvement identified via the interviews were collated in a matrix alongside findings from the C-POS item mapping.

Feasibility assessment

Feasibility was assessed by completion time, and feedback from health workers regarding ability to use the C-POS in clinical settings, as well as the clarity and usefulness of questions. Existing guidance suggests a median completion time of 10 minutes in adult patients.[33] This estimate was adopted given the lack of evidence in paediatric palliative care.[9]

Ethics

Ethical approval was granted in participating countries: Kenya refs: KEMRI/RES/7/3/1 and ERC/B/VOL1374; Uganda ref: UNCST SS2366; South Africa ref: HPCA 004/09; King's College London (LRS-15/16-3524).

Results

(i) Face and content validation

Table 1 provides the visual results of the C-POS content validation against the content framework. Three of the four domains of palliative care (physical, social, and psychological) mapped on to the thematic content framework's seven themes. For the child sub-scale, the following domain-level conceptual gaps were identified: spirituality/existential, and normalcy.

[insert table 1]

(ii) Comprehensiveness, comprehensibility, acceptability and feasibility and other concerns

Cognitive interviews

Twelve health workers provided in-depth interview data on the comprehensiveness, comprehensibility, acceptability and feasibility of the C-POS. Six children and young people participated in the cognitive interviews, with ages ranging from 10-17 years (see table 2). Sixteen family caregivers (n=16) participated in the cognitive interviews. No potential participants refused. Interview duration was a median of 45 minutes for the children; 60 minutes for the family caregiver and 60 minutes for the health workers.

[insert table 2]

(a) Comprehensiveness

Children and family caregivers felt all questions were useful and suggested additional content for consideration, including the impact of illness on school attendance and relationships with teachers.

> *"I want to be asked about the effect of this diseases on my schooling. I miss the lessons because I am ill, I do not get promoted, my performance is poor. Will I even achieve my education dream?" (*CYP 5 aged 15 years)

> *"Ask me about education, how illness impacts my education or stress."* (CYP 6 aged 16 years)

The children, their caregivers and staff also noted the need to ask about the quality of child/family relationships. Some children were concerned about whether their family still loved them, and others were concerned about the quality of family relationships and abuse.

> *"I worry if my family loves me. Ask about how well are you communicating with your family. Are you feeling heard by your family?"* (CYP 6 aged 16 years)

> *"Ask me about the family-child relationships. There are some things such as child abuse."* (CYP 2 aged 15 years)

> *"Relationships with the father. Sometimes you know they have negative relationships and then they decide to keep off from giving the care ... If someone is leading a polygamous life and it happens like this child falls sick and is dumped in the hospital, it has a very big impact on the child and on this very mother who is taking care of the child."* (Health worker 11)

Caregivers and children were equally interested in knowing about whether children were able to voice concerns, fears or other problems.

> *"Maybe some questions relating to the caregiver-child relationship would be helpful. For example, how often does the child voice fears, concerns and problems related to the illness?"* (Family carer 4)

Additionally, caregivers requested consideration of items around finances and social grants:

> *"We [have] financial concerns; caring for such children is financially draining. Social grants would help. It is important to learn about how the child and the family are coping with all this, including the stigma and changes in activities of daily living." (*Family carer 14)

(b) Comprehensibility

Children and caregivers noted most questions were clear, but children could not understand some words describing symptoms.

> *"Most questions were okay, but I do not know what [the] word nausea means. The words should be easier to understand - some are difficult. The hard words I said before made it difficult for me to give an answer, because I did not understand. Yes, the words should all be easier in the questions."* (CYP 1 aged 17 years)

Moreover, there were challenges differentiating between questions that seemed similar:

> *" Advice' and information' are quite closer in meaning and I had to give examples of what advice entails for ease of understanding."* (Health worker 3)

Feedback on each question is presented in Table 3.

[Insert table 3]

Although English is recognised as a national or second language in the study countries, health workers consistently expressed a preference for questions in their local languages and valued the translations from English.

> *"Yes it [the C-POS's standard operating procedure] was useful in practice, especially the one translated into the local language. It makes everything very easy and things flow so well."* (Health worker 14)

Concerns existed around differentiating some response categories and options. Some health workers who administered the C-POS also noted that respondents struggled to differentiate between scale categories 4/5 and 2/3:

> *"Response options 1 and 5 were easy to explain but 2 and 3 were difficult to explain, especially when using the verbal rating scale. Suggest that these should be narrowed to say 3 possible responses but for hand and linear scales the options can remain at 5."* (Health worker 1)

> *"A bit confusing when it came to grade the responses [using the scale response options]. Should be narrowed down to four options. For example, question I. Could*

> *we merge some of the response options, for example, response options 1&2, then 4&5, can be combined?"* (Health worker 2)

In one instance, a caregiver was concerned about the biased use of scale anchors when reading out options, which may influence respondents' answers. For example, one respondent noted the interviewer consistently read out the anchors of the response options (0 and 5) and that if the full-scale options were not read out, one may be compelled to just choose an answer from the two options offered.

(c) Acceptability

Children and caregivers noted all C-POS questions were appropriate and clear. However, some caregivers also made observations about the difficulty they faced providing caregiver-proxy reports on non-observable constructs, such as feelings, and caregiver proxies felt they had insufficient information to respond on behalf of their children. This concern related to item 7 ("How much have questions about your illness been answered"):

> *"Information about my child's illness – I feel I do not have enough information.* (Family carer 2)

> *"I felt it was difficult in answering how happy he was."* (Family carer 5)

Caregivers preferred to be asked about function-based or observable phenomena to avoid assumptions:

> *"Maybe practical questions about the child's concerns and condition. Often, I find myself assuming things rather than verifying them with the child in my care."* (Family carer 12)

Participants were asked about their preferences in regard to the three scales and their options (Figure 1). According to staff that administered the C-POS, children and family carers preferred the hand scales to linear and face scales given it was easier to understand and use. Some children noted their dislike of looking at sad faces and hence had a dislike for the face scales, while staff noted difficulty in their use as the face scales proved difficult to interpret:

> *"Hand scale was easier to use and understand. Faces were harder for me to give an answer.* (CYP 4 aged 13 years)

> *"Hand scale, it was easier to understand to show how I was feeling. I don't like looking at sad faces."* (Family carer 5)

Additional appropriateness issues identified by health workers included child boredom at being asked the questions during each visit. Other children preferred to be asked about 'the now' and not the 'since yesterday':

> *"Yes, I need to tell you what is happening now and not yesterday."* (CYP 3 aged 16 years)

Whilst other staff noted children found the time frame short:

> *“The children also found the days in between the interviews to be too few.”* (Health worker 3)

(d) Feasibility

Health workers found it feasible to administer the C-POS in clinical settings, noting better communication with patients and family, better symptom identification and management. The C-POS was completed in a median of 10 minutes (interquartile range 10-20).

> *“The carers were comfortable with most questions and the tool was seen as good, as it encouraged children to open up and express themselves without necessarily relying on carers.”* (Health worker 1)

> *“The tool helped to improve the relationship between the healthcare workers and the children/caregivers. For example, one respondent came later to complain that the drugs the child had been given were not working and thus needed them changed. Their participation in the pilot got them thinking and to be freer with the healthcare workers.”* (Health worker 11)

Equally, the children reported positive experiences associated with the use of the C-POS:

> *“I think this is a good tool. It helps to see how you are feeling and I enjoyed being asked these questions.”* (CYP 2 aged 15 years)

(e) Other concerns

According to interviewers, some children were introverted and not forthcoming in answering questions:

> *"Some children are shy, making them not able to explain how much pain they have. They can choose to remain quiet."* (Health worker 4)

Furthermore, self-reporting children were concerned about confidentiality issues and needed reassurance from caregivers that whatever they were sharing would be kept confidential:

> *"The fear of disclosure, but the healthcare workers stressed the confidential nature of the engagement."* (Health worker 1)

Health workers reported they believed at times family caregivers gave 'false' information about the child to achieve their desired goals. For example, some expected to receive social support, or to have analgesia for their children:

> *"Yes, sometimes the caregivers could not express what really the child was feeling or could give a false statement so that the child could be given pain killers [other] than as required."* (Health worker 6)

Health workers also noted that item 10 (*Have you been able to share how you are feeling about your child's illness with others when you have wanted to?*) was problematic for respondents who had not disclosed the illness of their child to anyone. Caregivers also noted it might be useful to qualify who 'others' mean:

> *"This question was difficult, especially so for those who had not disclosed the child's illness to anyone. Needs to be specific who information is being shared with when talking freely."* (Health worker 1)

> *"Who are we referring to, when we say 'other' for the question on for sharing information? Does it mean family or anyone on the street?"* (Family carer 1)

Discussion

This study determined the face and content validity, feasibility acceptability and implementability in clinical settings of the first outcome measure for children and families facing life-limiting or -threatening illness.

Acceptable face and content validity of C-POS was demonstrated as it maps on to evidence-based themes and sub-themes from the framework of symptoms and concerns that matter to children living with life-limiting and -threatening conditions and their families.[34] However, we noted conceptual gaps (e.g., spiritual/existential wellbeing aspects, life values/normalcy), which mirror important areas under-researched in paediatric palliative care.[35] An earlier version of the C-POS included an item on spiritual/existential wellbeing, which was removed in the earlier developmental stage due to incomprehensibility, especially for young children (below 12 years). Addressing developmental age variation in content alignment will help resolve such issues. The concern of life values/normalcy has received increasing attention in paediatric palliative care, with children expressing a pressing need to be just like other children.[36] It highlights the need to pay attention to the values of the children, and supporting them to live as normal a life as possible.

Children and caregivers suggested additional content on the child subscale should be considered, including illness impact on school, quality of child-family relations, care costs and mechanisms for family coping (raised by caregivers). These have been cited as critical concerns for children with life-limiting or -threatening conditions, but are largely missing in the few existing paediatric outcome measures.[37]

Lastly, content on family coping was also considered appropriate for inclusion in the C-POS. Families that cope positively remain functional and can support the child with serious illness. Without adaptive coping support for caregivers,[38] these children may be exposed to severe vulnerability, which may worsen their outcomes.

The C-POS questions were mostly relevant, clear and acceptable to participants, and included aspects important for the successful implementation of person-centred outcome measures in clinical care.[39] Regarding the reference time period, some respondents felt ‘the now’ was more important than ‘since yesterday’, and some felt ‘since yesterday’ was too monotonous for repeated measures. The study did not explore the preferences for recall time period by developmental age, and it is recommended that future studies investigate this. A recent systematic review looking at recall period, response scale format, and administration modality of self-reported health outcome measurement for children and young people, recommended that recall periods of 24-28 hours are appropriate for children under eight years and 7–14 days for those above the age of 8.[40] The study findings have implications for the practical implementation of the C-POS, including the importance of translating measures into local languages.

Concerns around shy/introverted children being less forthcoming to self-report their symptoms and concerns highlights a need for the training of health workers to build their skills in communicating with children.[41] Using staff such children are familiar with may help them "open-up" better, indeed this was a useful strategy in this study. That said, this may preclude children from being critical of care and therefore reporting "good" scores only. Furthermore, there was a concern over provision of potentially misleading responses. This is an implementation concern and could be addressed by allowing a joint completion of the measure for verbal children as recommended in the literature.[42] Such a mismatch between self- and caregiver-proxy reports has been noted in the literature.[43, 44] Consequently, self-reports should be prioritised whenever possible.

Limitations

Although the development of the C-POS included primary interview data from with children and caregivers, there were sample limitations in terms of age (adolescents were less well represented as the sample included (n=6 caregivers of children aged 0-6 years; n=6 for self-reporting children and n=10 caregivers of children aged 7-17 years) , diagnostic groups (HIV and cancer were the main diagnoses) and phase of illness was mainly advanced. As such, some important aspects relevant to the construct of symptoms and concerns could have been omitted. Minor amendments to address these conceptual gaps and tailored instructions for users will be undertaken in further development of the measure. This is in line with best practices for developing outcome measures.[45] Although our inclusion criteria for self-reporting children was seven years, our youngest respondent was ten years. Further research on engaging younger children in cognitive interviews is thus warranted. Moreover, the data collection team consisted of females only and this could have introduced some bias from participants.

Conclusion

C-POS items capture the core symptoms and concerns that matter to children and their families. C-POS is feasible, comprehensible, and acceptable for use in clinical settings; areas for further development and improvement are identified.

What this study adds

While there are many adult, person-centred outcome measures appropriate to palliative care, this is the first children's version. This study provides evidence for the face and content validity of the C-POS and identifies areas for improvement and best practices for using it in clinical settings. Next steps in the validation will focus on further revisions and a psychometric evaluation of the C-POS to determine its construct validity, cross cultural validity, measurement invariance, reliability, acceptability, responsiveness, and minimum important difference.

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Table 1: Mapping of C-POS items from themes from qualitative interviews and the evidence-based checklist – for content and comparative validity assessment

	Source			
Framework themes and subthemes	**Systematic review**	**Qualitative interviews**	**Covered by C-POS**	**C-POS items**
Physical	*	*	⩚	
Physical symptoms	x	x	֍	Can you tell me how much pain you have had since yesterday?
Symptom-related distress	x	x	֍	How much have other problems with your body been troubling you since yesterday? (Prompt only if needed: e.g., being sick, going to the toilet a lot.)
Physical function/daily activities	x	x		
Treatment-related concerns	x	x		
Physical needs Feeding Have parent/caretaker nearby Hunger	x	X +	֍	Can you tell me how much you have been feeding since yesterday?
Spiritual /existential				
Worry about death	x	x		
Existential loss and worry	x	x		
Transcendence concerns	x	x		
Search for meaning of illness or life	x	x		
Feel at peace or calm		+		
Religious-related concerns	x	x		
Connectedness/feel close to God		x		
Loss of control	**x**			
Hope		x		
Coping and resilience	x	x		
Demoralisation		+		
Psychological	*	*	⩚	
Emotional				
Positive effect Happiness feeling of contentment	x	x	֍	Can you tell me how often you have felt happy since yesterday? * Can you tell me how much you have cried since yesterday?
Negative effect Sadness, anger, moodiness, anxiety, nervousness, worry, depression, mood swings	x	x	֍	How much have you been feeling worried about your child’s illness?
Behavioural				
Adherence/non-adherence to treatment	x	x		
Unruly behaviour	x	x		
Suicidal behaviour	x	x		
Cognitive				
Low self-esteem	x	x		
Self-image concerns	x	x		
Concentration concerns	x	x		
Decline in performance at school	x	x		
Reduced mental capacity	x	x		
Psycho-social	*	*		
Perspectives of others	x	x		
Disclosure	x	x		
Confidentiality of diagnosis	x	x		
Stigma and discrimination	x	x		
Bullying	x	x		
Being denied name-lack of family belonging		+		
Social			⩚	
Relationships with others	x	x		
Family relationships	x	x	֍	How much have you been feeling worried about your child’s illness? Have you been able to share how you are feeling about your child’s illness with others when you have wanted to?
Social function	x	x	֍	How much have you felt like playing since yesterday? *
Growing closer or more distant during the crisis	x	x		
Financial burden of treatment and care				
Includes financial costs associated with care	x	x		
Financial burden of care borne by adolescents		+		
Lost financial opportunities for caregivers	x	x		
Loss of leisure	x	x		
Life values /normalcy				

	Source			
Framework themes and subthemes	**Systematic review**	**Qualitative interviews**	**Covered by C-POS**	**C-POS items**
Be normal and be treated like normal children	x	x		
Achieve goals	x	x		
Keep living	**x**			
Quality of care	x	x		
Physical environment				
Strange hospital environment	x	x		
Having an appropriate place to play in hospital	x	x		
Sharing wards with adult patients		**+**		
others				
Help advice and support	x	x	֍	Have you had enough help and advice for your family to plan with regard to your child's illness? How confident does the family feel caring for the child?
Communication and access to information	x	x	֍	How much have your questions about your sickness been answered since yesterday?
Continuity of care/continuity of health worker	x			
Negative/positive experiences of care	x	x		
Proximity to service access		x		
Child‑adult transitioning care needs	x	x		
Decision making	x	x		
Breadth coverage				
In-depth coverage				

+These themes were unique to sub-Saharan Africa

x source of sub-theme (systematic review or qualitative I interview); ⩚ C-POS coverage at breadth level (umbrella theme);

֍ C-POS coverage at depth level (sub-theme)

Table 2: Socio-demographic characteristics for child cognitive interview participants

Variable	(*n*=6)
Age range	10‑17 years
Sex	
Male	3
Female	3
Care setting	
Inpatient	4
Outpatient	2
Diagnosis	
HIV	3
HIV and TB	1
Cancer	2
Relationship for caregivers interviewed with children	
Mother	5
Sibling	1

Table 3: Findings from cognitive interviews

	C-POS items		**Question clear**		**Question important**		**comments**
	Child version	**Proxy version**	**Yes**	**No**	**Yes**	**No**	
1	Can you tell me how much pain you have had since yesterday?	Can you tell me how much pain your child has had since yesterday?	**34**	**0**	**34**	**0**	
2	How much have other symptoms been troubling you since yesterday? (*Prompt only if needed:* e.g., being sick, going to the toilet a lot.)	How much have other symptoms been troubling your child since yesterday (*Prompt only if needed:* e.g., vomiting, diarrhoea, skin problems etc.)	**34**	**0**	**34**	**0**	We should use the term other problems and prompt to be used only if needed. This should allow children/caregivers to talk about their physical concerns. Expert panel recommendation
3	Can you tell me how much you have been feeding since yesterday?	Since yesterday, how much your child has been feeding?	**34**	**0**	**34**	**0**	*We should use the term feeding because it accommodates children who are taking non-solid foods and children who are being fed artificially*. Expert panel recommendation
4	Can you tell me how much you have cried since yesterday?	Since yesterday, how much your child has cried?	**29**	**5**	**29**	**5**	*Crying was not reported as a prevalent problem, rendering a ceiling effect. Health worker 10* *since crying is generally accepted as a sign of distress or discomfort in a child, it can be used as an outcome measure*. Expert panel recommendation
5	Can you tell me how often you have felt happy since yesterday?	Since yesterday, how much your child has felt happy?	**30**	**4**	**34**	**0**	About feeling happy – seems not very easy to apply to children, you may not know their feelings. Caregiver 05
6	How much have you felt like playing since yesterday?	Since yesterday, how much your child has felt like playing?	**30**	**4**	**34**	**0**	The children often looked puzzled about being asked if they *felt like playing* – they would just say, "I played"! 'I think children have a simplistic view of play – they either do or they do not, and so I am not sure that trying to quantify this is easy or helpful.' Health worker 03
7	How much have your questions about your sickness been answered since yesterday?	How much have questions about your child's sickness been answered since yesterday?	**29**	**5**	**29**	**5**	*Non-verbal children may not have questions making the question redundant*. Health worker 01
֍	Can you tell me how much you have been sleeping since yesterday?	Since yesterday, how much your child has been sleeping?	**2**	**32**	**5**	**29**	*The scores on sleeping could be interpreted differently. For example, a child sleeping a great deal could be good or bad depending on their normal routine and prevailing condition (i.e. too much sleeping may not always be a positive thing and could be due to the severity of an illness).* Health worker 11
֍	Have you been feeling worried about your sickness since yesterday? If so, how worried have you been?	Since yesterday, how much have you been feeling worried about your child's illness?	**4**	**30**	**12**	**22**	*Some wording of the questions were not meant to be directed to a child who 12 years is below. question 8 because a child who 12 years is below cannot know how he/she is worried about his/her sickness since yesterday*. Health worker 06
	Family Items						
8	How much have you been feeling worried about your child's illness?		**34**	**0**	**34**	**0**	
9	Have you been able to share how you are feeling about your child's illness with others when you have wanted to?		**34**	**0**	**34**	**0**	
10	How much information have you and your family been given about your child's illness?		**34**	**0**	**34**	**0**	
11	Have you had enough help and advice for your family to plan with regard to your child's illness?		**34**	**0**	**34**	**0**	
12	How confident does the family feel caring for the child?		**34**	**0**	**34**	**0**	

Note: There were in-depth Interviews with health worker (*n*=12), caregivers (*n*=16) and children (*n*=6).

֍ these items were part of the 14-item version and were dropped following feedback from the pilot.

Figure 1: The C-POS _version 2 (12 items)

Child items					
	Self-report			Proxy report	
Q1.	Can you tell me how much pain you have had since yesterday?	0 (No pain) – 5 (The worst pain you can imagine)		Can you tell me how much pain your child has had since yesterday?	
Q2.	How much have other problems with your body been troubling you since yesterday? *(Prompt only if needed: e.g.* being sick, going to the toilet a lot)?	0 (No other problems with my body have been troubling me) – 5 (Other problems with my body have been troubling me very much)		How much have other problems with their body been troubling your child since yesterday (*Prompt only if needed:* e.g. vomiting, diarrhoea, skin problems etc)	
Q3.	Can you tell me how much you have been feeding since yesterday?	0 (Not feeding at all) – 5 (Feeding enough)		Since yesterday, how much has your child been feeding?	
Q4.	Can you tell me how much you have cried since yesterday?	0 (Not cried at all) – 5 (Cried all the time)		Since yesterday, how much has your child cried?	
Q5.	Can you tell me how often you have felt happy since yesterday?	0 Happy all the time) 5 (Not happy at all)		Since yesterday, how much your child has felt happy?	
Q6.	How much have you felt like playing since yesterday?	0 (Felt like playing all the time) 5 (Have not felt like playing at all)		Since yesterday, how much has your child felt like playing?	
Q7.	How much have your questions about your sickness been answered since yesterday?	0 (As much as I wanted) 5 (Have not been answered at all)		How much have your questions about your child's sickness been answered since yesterday?	

Child items					
	Self-report			Proxy report	
	Can you tell me how much you have been sleeping since yesterday?	0 (Not sleeping at all) – 5 (Sleeping as much as I need to)		Since yesterday, how much has your child been sleeping?	
	Have you been feeling worried about your sickness since yesterday? If so, how worried have you been?	0 (Not worried) – 5 (Worried all the time)			
Family items					
Q8.	How much have you been feeling worried about your child's illness?			0 (Not at all worried) – 5 (Worried all the time)	
Q9.	Have you been able to share how you are feeling about your child's illness with others when you have wanted to?			0 (Not at all) – 5 (Talked freely)	
Q10.	How much information have you and your family been given about your child's illness?			0 (None) – 5 (As much as wanted)	
Q11.	Have you had enough help and advice for your family to plan with regards to your child's illness?			0 (None) – 5 (As much as wanted)	
Q12.	How confident does the family feel caring for the child?			0 (Not at all) – 5 (Very confident)	

Supplementary material 1 -Topic guides

Topic guide used for the C-POS user post-survey interviews

Following completion of the data collection the Lead Researcher for each site will conduct semi-structured interviews with the health professionals. This will help to ascertain issues of utility, acceptability and feasibility of the tool. Questions for the interviews will include:

1. Which of the scales did the children tend to use? Why do you think this was?
2. Which of the scales did the adults tend to use? Why do you think this was?
3. What challenges did you face when asking the children and adults to rate the questions?
4. How did you find the wording of the questions and the answers?
5. Did you translate the questions from English?
6. Did you find any of the questions did not translate easily, was it hard to find words that meant the same thing?
7. Did you have to explain any of the questions, and if so, which ones?
8. Did the respondents seem to have any difficulty with any questions, and if so, which ones?
9. Do you think we should change any of the questions, and if so, which ones?
10. Was it possible to speak to the same caregiver each time?
11. Any other thoughts about the questions?
12. When asking the children about the time frame i.e. ‘yesterday’ did they have any challenges in this? Do you think this was an appropriate time frame?
13. Do you have any other comments/ questions about the tool?

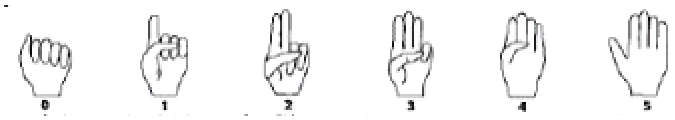
Where possible, the interviews will be recorded and transcribed. However, if there is no recording equipment at the site, notes will be taken throughout the interview.

Topic guide for cognitive interviews

- What did you think of the wording of the questions?
- What did you think of the wording of the answers/ response options?
- Which of the scales did you use to answer the questions? Why do you think this was?
- What challenges did you face to rate the questions?
- Did you find any of the questions did not translate easily, was it hard to find words that meant the same thing? Please describe your experience
- Did you need explanation to any of the questions, and if so, which ones?
- Did you have any difficulty with any questions, and if so, which ones?
- Do you think we should change any of the questions, and if so, which ones, how and why?
- Do you think we should add some questions, and if so, which ones, how and why?
- Do you have any other comments/ questions about the tool?

Figure 2: Response scale options

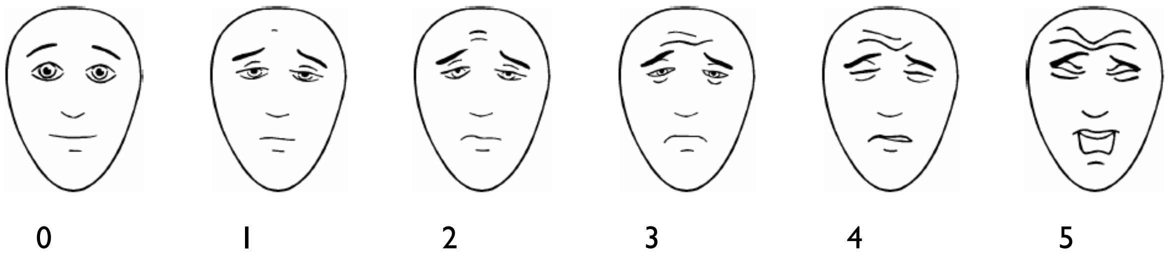
1: Hands Scale



2: Numeric Scale

|-------------|-------------|-------------|-------------|-----------|
0 1 2 3 4 5

3: Faces Scale



Supplementary material 1: Process of the Development and Validation of the APCA African C-POS

May 2009

Meeting of Multi-disciplinary experts from across Africa in Kampala
(Kenya, Malawi, South Africa, Swaziland, Uganda, Zambia, Zimbabwe)

Development of Tool – Verbal and non-Verbal

Piloting of Tool – longitudinal mixed-methods approach
Aim: Initial testing of the tool, looking at feasibility, ease of administration and utility of the tool
4 sites – Nyahururu Hospice (Kenya), Isibani Sethemba and Soweto Hospice (SA), HAU (Uganda)

Quantitative Data Collection
19 verbal tools completed
21 non-verbal tools completed

Qualitative Data Collection
11 Staff - semi-structured interviews re feasibility, ease of administration and utility of the tool

March 2010

Meeting of Multi-disciplinary experts from across Africa in Nairobi to review results
(Kenya, Malawi, South Africa, Uganda, Zambia, Zimbabwe)

Revision of Tool (Combined into one tool, changed time frame)

Piloting of Tool – Repeated measures mixed method approach
Aim: To assess the utility of the tool, it's acceptability in practice, feasibility and gathering initial data on face validity
8 sites - Nyahururu Hospice and Nyanza Provincial General Hospital through Kisumu Hospice (Kenya), Isibani Sethemba and Soweto Hospice (SA), HAU, Mildmay and MPCU (Uganda), Island Hospice (Zimbabwe)

Quantitative Data Collection
198 children recruited (85 Ug, 50 Ken, 44 South Africa and 19 Zimbabwe)
15 languages utilised
185 children completed 4 time points
Time taken: T1 x=23 – T4 x=15 mins

Qualitative Data Collection
In-depth and cognitive interviews
There were challenges with completing some of these, so some interviews completed during the validation of the tool. Initial results used to review the tool but full analysis during validation

Jan 2012

Review of results (by tele-conf.) by multi-disciplinary experts from across Africa
(Kenya, South Africa, Uganda, Zimbabwe and the UK)

Revision of Tool (Faces scale removed, only verbal anchors for 0 and 5, N/A responses removed, since yesterday inserted, some wordings changed e.g. feeding not eating, removed sleep from the tool, moved question on worry from the child to the carer)

Sept 2014-
December 2018

Validation of Tool – Repeated measures mixed method approach
Aim: To assess the validity of the tool, establishing face, content and construct validity, reliability and acceptability of the APCA African C-POS
3 sites - Nyanza Provincial General Hospital through Kisumu Hospice (Kenya), The Red Cross Children's Hospital (SA), Mildmay Uganda Hospital – 6 translations used Swahili, Luo, Runyakitara, Luganda, Afrikaans and isiXhose

Quantitative Data Collection
434 children recruited (233 Ug, 99 Ken, 102 SA) and 429 family carers
302 Completed C-POS and PedsQL for construct validity

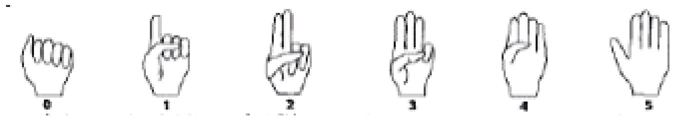
Qualitative Data Collection
In-depth and cognitive interviews
In-depth interviews (n=120): 59 carers, 61 children
Cognitive interviews: 12 staff, 16 carers, 6 children

January 2019 -
December 2020

Finalisation of the APCA African Children's POS (APCA African C-POS)

Supplementary material 1: Response scale options

1: Hands Scale



2: Numeric Scale

|-------------|-------------|-------------|-------------|-----------|
0 1 2 3 4 5

3: Faces Scale

0 1 2 3 4 5