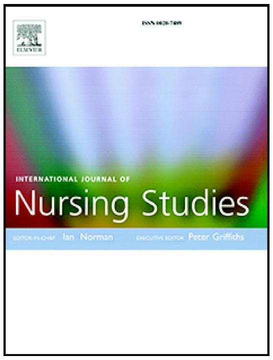

A child-centred research checklist to improve the design and reporting of paediatric research studies: A descriptive mixed methods study

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Abstract

Background: No internationally developed child-centred research checklist is currently available to enhance the quality and transparency of the development, reporting and evaluation of research undertaken with children.

Objective: To develop an internationally relevant, expert informed child-centred research checklist.

Design: A descriptive mixed methods study was undertaken in five sequential phases, including a Delphi component.

Setting(s): Academic/international context.

Methods: This study involved five sequential stages:

1. Literature review using four databases (CINAHL, MEDLINE, Scopus, PsycINFO) and analysis to identify key themes in child-centred research (January 2020)

2. Generate a questionnaire based on the key themes for international experts in child research to provide their opinions on what should be included in a child-centred research checklist (March 2020)

3. Inductive thematic analysis of the experts' responses to generate the initial draft checklist (June 2020)

4. The checklist progressed through three rounds of Delphi study for a wider range of experts to provide their consensus on what a child-centred research checklist should contain (August 2020-February 2021)

5. Refinement of the child-centred research checklist based on the Delphi study (March 2021- November 2022).

Results: A total of 160 articles met the inclusion criteria for review and were considered in the development of a 10-item open-ended questionnaire, adapted for four age-brackets (0-1yrs, 2-4yrs, 5-10yrs, >11yrs). Responses from 14 experts across 10 countries generated 205 generic statements and 76 examples to inform a child-centred research checklist. Following this, 158 experts from eleven disciplines across 18 countries participated in the three round Delphi study (38% retention rate over the three rounds). The final checklist includes 11 statements and 17 examples represented under three categories of "child-parent consent, assent and dissent", "code of conduct" and "child focused methods".

Conclusion: The child-centred research checklist was generated from a mixed methods study undertaken in five sequential phases, with input by 172 experts from 11 disciplines across 19 countries. The child-centred research checklist is the first international, expert informed tool to support good quality and transparent child-centred research. We call on researchers, clinicians, journal editors, organisations, and ethics committees to use this checklist for future research with children. The next phase of this project is engagement with children and their families to refine the checklist.

Tweetable abstract: New checklist to support good quality child research practices @IFNAorg

Keywords: Children; Checklist; Delphi Technique; Ethics; Interdisciplinary Research; Paediatric; Research

What is already known?

- A variety of reporting guidelines are available, however there are no specific guidelines for research undertaken with children.
- Researchers have various perceptions of what constitutes child centric, ethical processes when undertaking research activities with children.

What this paper adds

- The child-centred research checklist is the first international, expert informed tool to support good quality and transparent child-centred research.
- The child-centred research checklist can be used when designing proposals, writing manuscripts, and reporting on child research activities.

TITLE: A Child-Centred Research Checklist to Improve the Design and Reporting of Paediatric Studies: A Descriptive Mixed Methods Study

BACKGROUND

Significant emphasis is placed on the value, importance, and legitimacy of capturing the views and perspectives of children (0-18 years of age) as research participants (Foster et al., 2019). Over time there has been a paradigm shift from research being undertaken ‘on’ children to research being undertaken ‘with’ children, where children are positioned with a greater amount of inclusion, participation, ownership, and power (Mörelius et al., 2022, Water et al., 2017). The literature states that research undertaken with children is the most empowering type of research that honours and respects children’s rights at the highest level (Powell et al., 2012, Foster et al., 2023). Children’s input can also strengthen laws, policies and practices to advance children’s dignity, rights, and well-being (Clark and Moss, 2011, Foster et al., 2022). It is vital that the human dignity of children, their rights and well-being are honoured and respected in all research activities regardless of research context (Stafford et al., 2021). Currently, there is no collectively agreed upon child-centred research checklist available to enhance and guide research methods and reporting for research activities undertaken with children (Powell et al., 2012). Guidance in the form of a child-centred research checklist will promote and compliment good clinical practice, governance, and ethical standing as mandated in the United Nations Convention on the Rights of the Child and the Ethics on Research Involving Children philosophy (United

Nations International Children's Emergency Fund, 2019, Ethical Research Involving Children, 2019).

When undertaking research, utilisation of evidence-based, expert informed checklists for the planning, conduct, and reporting of the research can help ensure research quality and transparency (EQUATOR Network, n.d.). A research checklist, such as the STROBE or the PRISMA, act as a tool to generate critical thinking, engagement, reflective dialogue, and engagement in contemporary research practices (EQUATOR Network, n.d.). A child-centred research checklist should not be a prescriptive checklist but act as a tool to generate critical thinking, engagement, reflective dialogue, and engagement in contemporary research practices with children across multiple sectors. Considerations relating to research with children include the researcher critically reflecting, debating, discussing, and justifying how the core principles of respect, beneficence, and justice from a child and adult proxy lens are upheld (Abrar and Sidik, 2019).

We have searched the existing published peer reviewed literature from 1968 to May 2024 (articles, reviews, guidelines, theses, clinical pathways) and have not found any child research checklist for child researchers to use. A plethora of reporting guidelines are available for research undertaken with adults, but none developed by key international multidisciplinary experts on child centric concepts, challenges, dilemmas and risks (Ford et al., 2018b, Ford et al., 2018a). There are many child focused theoretical underpinnings used to guide research activities with children such as the United Nations Convention on the Rights of the Child (United Nations International Children's Emergency Fund, 2019); Child Centred Care (CCC) and participation (Foster et al., 2019, Foster and Shields, 2020, Kalverboer and Zijlstra, 2006); Family Centred Care (Coyne et al., 2018); Best Interests of the Child Model (Australian Paediatric Research Ethics & Governance Network, 2017); International Ethical Frameworks (World Medical Association, 2014), the World Medical Association (WMA) and World Health Organisation (Crane and Broome, 2017). Despite these recommendations, it is evident in the literature that researchers have various perceptions of what constitutes child centric ethical processes in undertaking research activities with children (Powell and Smith, 2009, Powell et al., 2012, Alderson, 2023). However, a practical tool to assist in optimising the research experience for children does not exist (Powell et al., 2012).

The value of including children’s voices into policy, practice, service delivery, education, and research is well referenced in the literature, but how researchers do this and report it is also important (Brady, 2020, Todd, 2020). A checklist would be helpful for researchers, organisations, clinicians, and journal editors from various disciplines to develop and evaluate research from a best practice, child centric perspective, in conjunction with existing ethical requirements.

METHODS

Aim: We aimed to develop an internationally relevant, expert informed child-centred research checklist that can be used to guide best practice in paediatric research and allow transparent reporting.

Research design: A descriptive mixed methods study was undertaken in five sequential phases (Figure 1).

Insert Figure 1

The research team included two professors, one associate professor, and one senior lecturer who each had greater than 30 years in paediatric practice, teaching and/or research across three countries and three disciplines (neonatal, paediatric and dietetics). The research assistant had greater than 10 years in dietetics and research including paediatrics. The research team were motivated to create a checklist that could be used to guide best practice in paediatric research and allow transparent reporting. This online study was undertaken during the first wave of the COVID-19 pandemic with paediatric research experts. The next phase of this project is engagement with children and their families to refine the checklist.

Procedure

Phase 1: Literature review and analysis (January 2020)

A literature review was undertaken to gain extant up to date (contemporary) evidence of research activities undertaken with children (neonates, infants, children, youth) to help generate a questionnaire. A search was undertaken across four databases (CINAHL, MEDLINE, Scopus and PsycINFO) using the medical subject headings ‘ethics OR ethical issue OR ethical concerns OR ethical dilemmas OR ethical considerations’ AND ‘children OR kids OR youth OR child OR neonates’ AND ‘research’. Inclusion criteria was full text peer reviewed published articles from 2015-2020 on ethical concepts in undertaking research with children. An inductive analysis was conducted where concepts to generate a questionnaire were identified and grouped into themes based on similarity of meaning (Thomas, 2006). The researchers moved between the manuscripts until no new concepts were evident. To ensure rigor themes were iteratively generated, retained, modified, and/or removed with a summary of the results circulated to the research team between meetings for discussion. Consensus occurred when members of the research team came together in face-to-face meetings to discuss the results with the aim of reaching an agreement (Thomas, 2006). The database search was updated in April 2024 (2015-2024) to ensure no checklist had been developed. In addition, websites (theses, guidelines, clinical pathways) were searched (2015-2024) to ensure no checklist had been developed.

Phase 2. Questionnaire developed to gain expert input into items for a checklist (March 2020)

Themes and concepts from the analysis were used to generate an online questionnaire using Qualtrics software (Qualtrics, Provo, UT) to identify which items experts felt would be important for a child-centred research checklist. International experts in the field of child research were invited to participate via email with a Qualtrics link. Eligibility criteria for experts included being a member of an international paediatric research network, organisation, or committee with peer reviewed publications in child health. Experts were identified through child health research networks, publications, colleagues, and organisations. Thirty-two experts were invited to participate in the open-ended questionnaire. Sampling was purposive to include representation of various countries, level of expertise, and research focus. This was captured with respondents reporting demographic data of gender, country, years of research experience, research focus and discipline.

Phase 3. Creation of the initial draft of the Child-Centred Research Checklist (June 2020)

Synthesis One

All qualitative responses to the open-ended questionnaire underwent inductive thematic analyses where the phenomena of undertaking research with children were identified (findings), coded (in vivo coding) and grouped into categories, and themes based on similarity of meaning (Thomas, 2006). The researchers moved between the data until no new themes or categories were evident. To ensure rigor themes were iteratively generated, retained, modified, and/or removed with a summary of the results circulated to the research team between meetings for discussion. Consensus occurred when members of the research team came together in face-to-face meetings to discuss the results with the aim of reaching an agreement (Thomas, 2006). The qualitative data analysis formed the basis for the first iteration of the questionnaire.

Synthesis Two and Three

The findings from the survey were consolidated by the research team to create a statement. Statements based on similarity of meaning were reduced to one generic statement across the various age brackets with some statements changed to examples to exemplify how that statement could be honoured. The researchers moved between the findings, statements, and examples for the various age brackets until no further statements or examples could be generated from the participants' responses.

Phase 4. Evolution of the Child-Centred Research Checklist through a three round Delphi study (August 2020-February 2021)

The Delphi design used in this study aligns with the approach described by Nasa et al. (2021). Invitation to 145 (round one), 227 (round two), and 80 (round three) experts in the field of child research were sent, asking for participation in the study via emails containing a Qualtrics survey link (Qualtrics, Provo, UT). Eligibility criteria for experts included being a member of an international paediatric research network, organisation, or committee with peer reviewed publications in child health. Further experts (n= 82) were invited in round two as the research team wanted a greater response rate and representation across countries and disciplines. Further experts were identified through child health research networks, publications, colleagues, organisations, and suggestions from the Delphi round one respondents to increase representedness across discipline, and country. Sampling was purposive to include representation of international child researchers from a range of health research backgrounds. The survey used a seven-point Likert scale where a higher number indicated greater importance for that statement to be included in the child-centred research checklist. All Delphi rounds were pilot tested with 10 academics experienced in Qualtrics Delphi surveys prior to sending out to experts. Descriptive statistical analysis at each round included summarization of the nominal data (highest and lowest score, average, median, percentage and frequency counts) for each statement/example. The threshold for inclusion into subsequent rounds required an importance score of 80% or greater. Nominal data were downloaded into Microsoft Excel and transferred to SPSS for data analysis. Qualitative results were analysed iteratively with the quantitative scores, and statements/examples were modified as required. To ensure rigor a summary of the retained, modified and/or removed statements/examples and corresponding scores were circulated to the research team between rounds for discussion. All statistical analyses were verified by a biostatistician. Consensus occurred when members of the research team came together in face-to-face meetings to discuss the results with the aim of reaching an agreement.

Phase 5. Development of the final Child-Centred Research Checklist (March 2021-November 2022)

The child-centred research checklist was developed based on the final consensus at the end of the third Delphi round. The aim of this phase was to ensure the checklist was user-friendly and practical for use by paediatric researchers. The research team formatted the checklist to make sure it was logically organised and contained clear items and examples that the experts had agreed upon.

Ethical Considerations

All invitations to experts included a letter of invitation explaining the rationale, purpose and objectives of the study, and an explanation on how to complete and return the questionnaire through Qualtrics. Informed consent was established by an “I agree” button that indicated that completion of the online questionnaire implied consent to participate in the study. The five sequential phase research project received approval from Edith Cowan University’s Human Research Ethics Committee (REMS 2020-01522-XXXXX), and adhered to the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research 2023 (National Health and Medical Research Council, 2023). To honour anonymity, confidentiality, and privacy, all expert responses were deidentified, data were stored on a password protected computer or locked filing cabinet, and only the research team had access to the data.

RESULTS

Phase 1: Literature review and analysis

The database search (2015-2020) resulted in 3718 hits, with 160 articles meeting inclusion for review (Supplementary File 1). The updated database and grey literature search using the same search terms (2015-2024) resulted in no child health research checklist.

Phase 2. Questionnaire developed to gain expert input into items for a checklist

Analysis of the articles generated three main themes of respect, beneficence, and justice. These informed the development of a 10-item open-ended questionnaire that experts in the field of child research could complete on how research activities with children across four age-brackets (0-1yrs, 2-4yrs, 5-10yrs and >11yrs) could incorporate these concepts (Supplementary File 2).

Phase 3. Creation of the initial draft of the child-centred research checklist

Out of 32 experts invited to participate, the open-ended questionnaire was completed by 14 participants (44% response rate) across 10 countries where research experience mean and SD ranged from (15.8 +/- 8.9) (Table 1).

Synthesis One

The initial responses from the experts resulted in 479 findings for the theme respect, 342 findings for the theme beneficence, and 208 findings for the theme justice. These were further synthesised based on similarity of meaning into three themes, 10 sub-themes and 29 categories (Supplementary File 3).

Syntheses Two and Three

The findings were further reduced by the research team where 638 findings across the various age brackets that were similar in meaning became either a generic statement (N=205) or an example (N=76) to exemplify how that statement could be honoured (Figure 2). The statements and examples were then placed into the four different age brackets (0-1yrs, 2-4yrs, 5-10yrs and >11yrs) as represented by the participants' responses under the themes informed consent, assent, and dissent; code of conduct; and child focused methods (Supplementary File 3).

Phase 4. Evolution of the child-centred research checklist through a three round Delphi study

Delphi Round One

Fifty-six of 145 (39% response rate) invited experts participated in the first round of the Delphi study. This included experts from five disciplines (dentistry, medical, nursing, physiotherapy, psychology) across 15 countries with the majority being female (n=49) (Table 1). Research experience mean and SD ranged from (14.6 +/- 9.9) years with experts being experienced in quantitative (n=32), qualitative (n=21), and mixed methods design (n=36). The greatest variance evident in the participants responses were in the 0-1 years informed consent, assent and dissent, 2-4 years child focused methods and 11+ child focused methods statements/examples. The greatest consensus on statements/examples being included in the child-centred research checklist was evident in the 2-4 years informed consent, assent and dissent and 5-10 years code of conduct statements/examples as represented in Table 2. Analysis from round one resulted in the child-centred research checklist being reduced to 75 statements with 32 examples for two age brackets (0-4yrs, 5-18yrs) under the themes informed consent, assent, and dissent; code of conduct; or child focused methods (Table 2).

Delphi Round Two

Participants from round one (N=145) and a further 82 experts were invited into round two to increase the response rate and representation across countries and disciplines, with 61 of 227 participating (27% response rate). This included experts from 11 disciplines (biostatistician, dentistry, dietetics, medical, nursing, occupational therapy, physiotherapy, psychology, public health, research, speech pathology) across 18 countries with the majority being female (n=49). Research experience mean and SD ranged from (14.1 +/- 8.9) years with experts being experienced in quantitative (n=30), qualitative (n=31) and mixed methods design (n=40) (Table 1). The highest level of consensus among experts on statements/examples to be included in the child-centred research checklist was noted for the 0-4 year age bracket on informed consent, assent and dissent and child focused methods statements/examples (Table 2). The greatest variance in participant responses were in the statements/examples related to code of conduct for the age brackets 0-4 and 5-18 years. Analysis from round two resulted in the child-centred research checklist being reduced to 26 statements with 20 examples for one age bracket (0-18yrs) under the themes informed consent, assent, and dissent; code of conduct; or child focused methods (Table 2).

Delphi Round Three

The participants that responded in round one and round two (N=80) were subsequently invited to participate in round three. Forty-one of 80 invited experts participated in round three (51% response rate). This included experts from seven disciplines (dentistry, dietetics, medical, nursing, physiotherapy, psychology, public health) across 13 countries with the majority being female (n=29). Research experience ranged mean, and SD ranged from (15.5 +/- 9.9) years with experts being experienced in quantitative (n=20), qualitative (n=21) and mixed methods design (n=21) (Table 1). The greatest consensus on statements/examples was the area of informed consent, assent, and dissent (Table 2). The greatest variance evident in the participants responses were in the code of conduct and child focused methods.

Analysis from round three resulted in the child-centred research checklist being reduced to 11 statements with 17 examples for the consolidated age bracket (0-18yrs) under the themes informed consent, assent, and dissent; code of conduct; or child focused methods (Table 2).

Insert Table 1

Insert Table 2

Insert Figure 2

Phase 5. Development of the final child-centred research checklist

The final child-centred research checklist includes 11 statements, 24 examples represented under three categories (informed consent, assent, dissent; code of conduct; and child focused methods) for children aged between 0-18 years as represented in Table 3.

Insert Table 3

DISCUSSION

The participants in this study stated researchers working with children need to respect and value each child as an individual, with their own unique thoughts and feelings. Respect was linked closely with a child’s rights and implied valuing children within the context of their lives with recognition of dignity and capability to express views in matters that affect them. The participants relayed that the consent, assent, and dissent processes required a critical reflexive approach considering the topic and included the child’s chronological and developmental age, competence, capacity, and understanding the child’s social, political, and cultural context. However, despite evidence in the literature of researchers undertaking a thorough peer-reviewed process in creating transparent child friendly age-appropriate information and consent forms, variance in understanding, competence, and/or motivation related to consent to participate in a research project is reported (Boyd et al., 2021, Hein et al., 2015, Gertsman et al., 2020). This has been attributed to a lack of comprehension of the potential value of the project, a lack of understanding in the consent/assent and dissent process, age of the child and parent, context of care, cultural values, ethnicity, psychological state of the child, trust in the researcher, altruism and competing factors (Boyd et al., 2021, Hein et al., 2015, Gertsman et al., 2020, Mustanski et al., 2018). Areas of importance to consider in the consent process are the caregivers/parents and children's developmental and health literacy level; capabilities; experiences; their right to self-determination; socio-economic, political, and cultural background; perspectives and how the research is placed within their local ecosystem. These are especially important to consider when the researcher brings an outsider perspective to the local context; motivational factors; burden; benefits; the ethnicity and viewpoint of the researcher (Hein et al., 2015, Gertsman et al., 2020, Alderson and Morrow, 2020).

It is an ethical requirement that children and parents are fully informed of the purpose of the study, level of risk, treatment offered for adverse events, benefits, incentives, data collection techniques, how confidentiality and anonymity will be honoured, data storage/sovereignty and sharing, feedback channels, dissemination plan, ethics approval and complaints pathways (Chou and Frazier, 2020). This is aligned to good ethical practices by honouring the principles of beneficence; fidelity and responsibility; integrity; justice; and respect for children and parents' rights and dignity (Russell and Barley, 2022). The participants in this study relayed that researchers working with children need to honour the aforementioned concepts of good ethical practice and also reflect on their practice beyond ethical review requirements with the assumptions, values, beliefs, social etiquette and practices that influence the research process.

The respondents referred to beneficence when researchers mitigate any harm or injury to children and ensure their safety during and after participation. The evidence suggests that to avoid harm, researchers need to be appropriately qualified and have a research design that is methodologically and ethically sound, rigorous and contextually relevant to children (Chou and Frazier, 2020, Korkiamäki and Kaukko, 2023). The literature reports that harm can emanate from decisions related to inclusion or exclusion at all stages of the research process, or on study completion and includes consideration of coercion, bias, physical harm, retribution/reprisal, stigmatisation, bullying, punishment, distress, discomfort, re-traumatisation, burden, unmet expectations, anxiety, distrust, unrealistic perceptions of beneficial outcomes and/or loss of self-esteem (Powell et al., 2012, Korkiamäki and Kaukko, 2023). All these concerns were similarly reported as important areas to consider by the participants in this study especially in relation to the child's age, capacity, competency, and agency in society.

The experts in this study referred to justice in relation to how researchers treat children fairly and equitably including attention to power imbalances between researchers, children, adults and communities and the distribution of benefits and burden. The literature reports that researchers must consider how the participation of children as advisors or consumers contribute to the project with justification for inclusion and exclusion criteria including under and over researched populations and ease of access to participate for disadvantaged groups; accurate representative of results and transparent reporting of reimbursement, compensation and/or appreciation payments to participants (Mörelius et al., 2022, Chou and Frazier, 2020, Freire et al., 2022). The participants relayed beneficence as the obligation to improve the status, rights and/or well-being of all children not only through acts of kindness or tokenism but that the research process and outcomes include positive benefits in policy, practice, research, and knowledge for children as a social group. Some of the participants recommendations were that children felt heard, validated, respected and/or received compensation or access to resources, programs, policies, and further opportunities to be involved in research. Similarly, children have self-reported on the justification and importance of being offered incentives such as being compensated for their time, discomfort experienced, and effort (Boyd et al., 2021).

The use of child friendly focused and age-appropriate research designs/methods/strategies were vital components that needed to be embedded throughout the project from conception to post-completion. Similarly, it has been reported in the literature that data collection methods need to be aligned to a culturally responsive child centric approach that takes into consideration the child's developmental age, capacity and competency (Ericsson and Boyd, 2017, Qiu et al., 2021). Some of the child friendly focused methods used in prior studies have included therapeutic play, stories, the draw and write technique, a yarning style, the use of comics and cartoons, a participatory art-based approach and animated videos (Water et al., 2017, United Nations International Children's Emergency Fund, 2019, Foster and Whitehead, 2019).

Strengths and limitations

All the members of the research team followed a systematic rigorous process at every stage of the study to generate the child-centred research checklist as guided by the literature (Holmbeck and Devine, 2009, Nasa et al., 2021). This included establishing the scientific need for a child-centred research checklist, a review and definition of concepts to generate an interview guide, experts' opinion on what was important to include in a child-centred research checklist, and three separate stages of analysing experts' responses with attention to content being representative of the participants' recommendations in guiding the three-round-Delphi-study. This approach has provided rigor and credibility in the development of the child-centred research checklist that can be used as an adjunct with other ethics review processes for researchers, clinicians, journal reviewers and editors to use to evaluate how research activities undertaken with children have honoured good clinical practice from a child centric perspective (EQUATOR Network, n.d., Holmbeck and Devine, 2009, Adler et al., 2019).

A further strength of this study is that it allowed data to be collected electronically from experts that were geographically diverse, provided anonymity within the group and reduced the likelihood of group pressure from more assertive or expert participants. Respondents were able to submit further feedback generated from prior rounds which provided objectivity and rigour.

A significant limitation of this research was the lack of public and patient (child and parent) involvement from the onset of this study. Some further limitations of this study included the low response rate, attrition, and the project taking a relatively long time to complete (due to the need to follow up and wait for responses after each round). In hindsight, greater utilisation of social media (tweets, LinkedIn), organisations, Universities, and child health research networks/websites to increase the visibility of the project may have resulted in increased participant recruitment, response rate and global involvement.

Implications for practice and research

The child-centred research checklist provides a tool to guide researchers in designing proposals, writing manuscripts, and reporting on child research activities with children from 0 to 18 years. The child-centred research checklist can be used in addition to existing ethical requirements and study design checklists. Guidance in the form of a child-centred research checklist will promote good research practice, governance, and ethical standing as mandated in the United Nations Convention on the Rights of the Child.

We call on the researchers, journal editors, organisations, and ethics committees in the following ways to progress future research with children:

- Researchers and student supervisors – to utilise the child-centred research checklist as a framework in the design of research studies to ensure important aspects have been considered and included.
- Journal editors – to include a requirement for authors to submit the completed child-centred research checklist with journal submissions, for transparent reporting.
- Organisations – to request the child-centred research checklist be completed in the planning and development of quality improvement and research projects.
- Ethics committees – to request the child-centred research checklist is submitted with their research proposal for review.

The authors will be undertaking further research with international collaborators through our leadership roles on international committees to ensure global representation of key stakeholders (children/parents) to further develop/refine the tool. In addition, evaluation on the utilisation of the child-centred research checklist is required within different clinical settings, designs, age-groups, and countries.

CONCLUSION

The child-centred research checklist is the first international, expert informed tool to support good quality and transparent research for children 0-18 years. The child-centred research checklist was generated from a mixed methods study undertaken in five sequential phases, with input by 172 experts from 11 disciplines across 19 countries. This approach has provided development of a credible Child Centred Research Checklist that can be used as an adjunct with ethics review and other study checklists to evaluate how research activities undertaken with children have honoured good research practice from a child centric perspective (Russell and Barley, 2022, EQUATOR Network, n.d.). The final 11-item child-centred research checklist will be registered on the EQUATOR Network as a reporting guideline once published and modified after the Consumer Engagement Study (EQUATOR Network, n.d.).

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Conflict of interest

The authors do not have any conflicts of interest to declare.

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Figure 1: Sequential phases of the study
CRCC Child-Centered Research Checklist

Figure 2: Inductive Thematic Analyses

Table 1: Demographical Characteristics of Expert Child Health Researchers

Country	Questionnaire Development N=14 n (%)	Delphi Round 1 N=56 n (%)	Delphi Round 2 N=61 n (%)	Delphi Round 3 N=41 n (%)
Australia	2 (14.4)	15 (26.8)	20 (32.9)	11 (26.9)
Brazil		1 (1.8)	1 (1.7)	
Canada			1 (1.7)	1 (2.4)
Denmark	1 (7.1)	2 (3.6)	2 (3.3)	2 (4.9)
Estonia		1 (1.8)	1 (1.7)	1 (2.4)
Finland		2 (3.6)	2 (3.3)	1 (2.4)
Ghana	1 (7.1)	2 (3.6)	1 (1.7)	1 (2.4)
Iceland		1 (1.8)		
Indonesia	1 (7.1)		1 (1.7)	
Ireland		4 (7.1)	5 (8.1)	4 (9.8)
Jordan	1 (7.1)		1 (1.7)	
Malaysia	1 (7.1)	1 (1.8)	1 (1.7)	
Malawi	1 (7.1)	3 (5.3)	2 (3.3)	2 (4.9)
New Zealand		3 (5.3)	3 (4.8)	2 (4.9)
Singapore			3 (4.8)	3 (7.3)
Sweden	4 (28.7)	9 (16.1)	8 (12.9)	7 (17.1)
Turkey	1 (7.1)	2 (3.6)	1 (1.7)	
United Kingdom	1 (7.1)	4 (7.1)	4 (6.5)	3 (7.3)
United States of America		6 (10.7)	4 (6.5)	3 (7.3)
Gender	n (%)	n (%)	n (%)	n (%)
Female	9 (64.3)	49 (87.5)	49 (80.3)	29 (70.7)
Male	5 (35.7)	7 (12.5)	12 (19.7)	12 (29.3)
Years of Research Experience: Mean, SD (range)	15.8 ± 8.9 (8-35)	14.6 ± 9.9 (2-35)	14.05 ± 8.93 (1-30)	15.48 ± 9.90 (1-40)

Table 2: Exemplar Delphi Round Statements and Examples, Likert Scores, Total Mean and Standard Deviation for the Themes Informed Consent, Assent, and Dissent; Code of Conduct; and Child Focused Methods

Delphi Round One Statement 0-1 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent Total Statements (n=4); Examples (n=5)	1	2	3	4	5	6	7
The study reported how the rights	1 (3.0)	1	1	3	3 (9.1)	4	20

of the infant were honoured. Example: Evidence that parents were well informed and calm so that the infant felt safe prior to participation.		(3.0)	(3.0)	(9.1)		(12.1)	(60.6)
Researchers demonstrated consideration on whether the infant would want to be in the research project if they had a choice.	2 (6.1)	2 (6.1)	3 (9.1)	6 (18.2)	2 (6.1)	9 (27.3)	9 (27.3)
Total Mean 80 (Standard Deviation 19.83)							
Code of Conduct Total Statements (n=15); Examples (n=0)	1	2	3	4	5	6	7
The research team demonstrated and described appropriate qualifications, credentials, knowledge, and understanding in conducting research with infants.	1 (3.0)	-	-	2 (6.1)	10 (10.3)	4 (12.1)	16 (48.5)
The study stated how a diverse population of infants were given the opportunity to participate (such as including marginalised, vulnerable communities or deprived settings).	1 (3.1)	-	1 (3.1)	3 (9.4)	4 (12.5)	15 (46.9)	8 (25.0)
Total Mean 62 (Standard Deviation 14.05)							
Child Focused Methods Total Statements (n=8); Examples (n=0)	1	2	3	4	5	6	7
The methodology demonstrated or described an infant friendly approach including: the infant could play with anything that interested them during data collection (such as toys or their parents/guardian/sibling).	-	-	1 (3.1)	5 (15.6)	4 (12.5)	9 (28.1)	13 (40.6)
The methodology demonstrated or described an infant friendly approach including: the infant's behavioural cues were observed for signs of discomfort and responded to as required.	-	-	-	1 (3.0)	3 (9.1)	6 (18.2)	23 (69.7)
Total Mean 82 (Standard Deviation 11.38)							
Delphi Round One Statement 2-4 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent	1	2	3	4	5	6	7

Total Statements (n=9); Examples (n=8)							
How children's responses (artwork or results) were anonymised or not, in consideration with children's wishes were reported.	-	-	1 (5.0)	-	-	6 (25.0)	7 (70.0)
The study reported how the rights of the child were honoured. Example: The child information documents included the importance of the child's participation.	-	-	1 (5.0)	-	2 (10.0)	3 (15.0)	14 (70.0)
Total Mean 82 (Standard Deviation 9.05)							
Code of Conduct Total Statements (n=27); Examples (n=2)	1	2	3	4	5	6	7
Evidence that only non-invasive methods were used.	3 (15.0)	-	-	-	3 (15.0)	6 (30.0)	7 (40.0)
Evidence that appropriate pain relief was provided if required.	1 (5.0)	-	-	-	1 (5.0)	1 (5.0)	17 (85.0)
Total Mean 76 (Standard Deviation 12.83)							
Child Focused Methods Total Statements (n=15); Examples (n=6)	1	2	3	4	5	6	7
The methodology reported on developmentally appropriate and safe data collection methods (such as the use of drawing, conversations, open-ended questions, computer technology, laboratory tests and/or diagnostics).	-	-	-	-	2 (10.0)	3 (15.0)	15 (75.0)
The methodology demonstrated or described a child friendly approach including a. researchers were patient and allowed children time to respond.	-	-	-	-	1 (5.0)	5 (25.0)	14 (70.0)
Total Mean 75 (Standard Deviation 17.87)							
Delphi Round One Statement 5-10 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent Total Statements (n=9); Examples (n=15)	1	2	3	4	5	6	7
Ongoing child informed voluntary assent/dissent was evident throughout the research trajectory. Example: The study demonstrated	-	-	-	-	1 (4.0)	6 (24.0)	18 (72.0)

how child friendly tools such as green, amber and red cards or stickers were used by children to let the researcher know yes, they understand or no, they don't understand, or they wish to continue, take a break or stop participation.							
The study described that parents could explain the project to their child.	-	2 (8.0)	-	-	5 (20.0)	9 (36.0)	9 (36.0)
Total Mean 91 (Standard Deviation 9.17)							
Code of Conduct Total Statements (n=28); Examples (n=3)	1	2	3	4	5	6	7
Documentation that a small token or gift were given to the child and parent for any costs associated with being in the study (such as time, travel, accommodation, food and drinks).	-	-	-	1 (4.2)	1 (4.2)	7 (29.2)	15 (62.5)
Documentation that parents were notified if their child was negatively affected by the study.	1 (4.2)	-	-	1 (4.2)	1 (4.2)	2 (8.3)	19 (79.2)
Total Mean 76 (Standard Deviation 10.35)							
Child Focused Methods Total Statements (n=25); Examples (n=7)	1	2	3	4	5	6	7
Researchers considered how the child felt. Example: Researchers asked if they were comfortable before and during data collection.	-	-	-	1 (4.2)	-	4 (16.7)	19 (79.2)
Researchers responded to any possible concerns the child expressed. Example: Researchers asked the child if they felt safe.	-	-	-	2 (8.3)	1 (4.2)	2 (8.3)	19 (79.2)
Total Mean 79 (Standard Deviation 14.89)							
Delphi Round One Statement 11-18 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent Total Statements (n=9); Examples (n=18)	1	2	3	4	5	6	7
It was demonstrated that the child was addressed in the first instance and parents were included through	-	-	-	1 (4.5)	-	6 (27.3)	15 (68.2)

discussions with the child.							
Child explanations on withdrawal from the study without consequence to care or treatment was reported.	-	-	-	-	1 (4.5)	1 (4.5)	20 (90.9)
Total Mean 91 (Standard Deviation 11.35)							
Code of Conduct Total Statements (n=27); Examples (n=3)	1	2	3	4	5	6	7
The study demonstrated how closure of the researcher-child relationship was managed.	-	-	-	-	3 (13.6)	5 (22.7)	14 (63.6)
The study described how children could provide participant experience feedback.	-	-	-	1 (4.5)	3 (13.6)	2 (9.1)	16 (72.7)
Total Mean 83 (Standard Deviation 11.30)							
Child Focused Methods Total Statements (n=26); Examples (n=9)	1	2	3	4	5	6	7
Researchers let children, if possible, choose the place, time and people present during data collection.	-	-	-	1 (4.5)	2 (9.1)	6 (27.3)	13 (59.1)
Researchers shared the results of the study with child participants.	-	-	-	2 (9.1)	3 (13.6)	2 (9.1)	15 (68.2)
Total Mean 84 (Standard Deviation 17.10)							
Delphi Round Two Statement 0-4 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent Total Statements (n=7); Examples (n=7)	1	2	3	4	5	6	7
The research team demonstrated or described age and developmentally appropriate consent/assent methods for the child greater than two years of age. Example: The use of pictures or signs so the child could stipulate yes, no, unsure or stop. The child information document was read, and project explained to the child through the use of illustrations, visual and written and/or phonic aids that were colourful, creative and informative (such as cartoons, pictures, activity booklets, stories, games, play, comics and/or	-	4 (9.8)	2 (4.9)	3 (7.3)	4 (9.8)	12 (29.3)	16 (39.0)

question time on what will happen during data collection).							
How children's responses (artwork or results) were anonymised or not, in consideration with children's wishes were reported.	2 (4.9)	3 (7.3)	1 (2.4)	2 (4.9)	7 (17.1)	16 (39.0)	10 (24.4)
Total Mean 70 (Standard Deviation 7.23)							
Code of Conduct Total Statements (n=11); Examples (n=1)	1	2	3	4	5	6	7
The study demonstrated or described the appropriateness and safety of data collection tools used by taking into consideration: the environment (at home, community or hospital setting and whether other children such as siblings were present). Example: The use of Lego, playdoh, crayons, smelly pens, glitter and photos.	1 (2.4)	1 (2.4)	1 (2.4)	2 (4.9)	10 (24.4)	9 (22.0)	17 (41.5)
The study described how cultural sensitivity was integrated into the project.	1 (2.4)	-	-	4 (9.8)	6 (14.6)	15 (36.6)	15 (36.6)
Total Mean 77 (Standard Deviation 12.18)							
Child Focused Methods Total Statements (n=13); Examples (n=1)	1	2	3	4	5	6	7
The methodology demonstrated an infant or child friendly approach including: privacy and breaks were provided so parents could comfort their infant or child (such as nutrition, diaper change, medication, cuddles or play).	-	1 (2.4)	-	1 (2.4)	4 (9.8)	13 (31.7)	22 (53.7)
The methodology demonstrated an infant or child friendly approach including: researchers did not edit or correct children's writing or speech if applicable.	-	-	-	3 (7.3)	4 (9.8)	13 (31.7)	21 (51.2)
Total Mean 87 (Standard Deviation 4.51)							
Delphi Round Two Statement 5-18 years	Likert Scores n (%)						
Informed Consent, Assent and Dissent Total Statements (n=8); Examples (n=10)	1	2	3	4	5	6	7

Informed voluntary signed and/or verbal consent/assent/dissent from the child was reported. Examples: Children were informed that both parent and child consent was required. Increased opportunity to participate through the use of an interpreter, if the researcher did not speak the language of the child or parent.	-	1 (2.7)	-	-	4 (10.8)	3 (8.1)	29 (78.4)
It was demonstrated that the child was addressed in the first instance and parents were included through discussions with the child.	-	-	2 (5.4)	4 (10.8)	4 (10.8)	13 (35.1)	14 (37.8)
Total Mean 85 (Standard Deviation 8.56)							
Code of Conduct Total Statements (n=18); Examples (n=6)	1	2	3	4	5	6	7
The study reported adaptations to data collection methods to enable children with a disability or developmental delay the ability to participate.	1 (2.7)	1 (2.7)	-	1 (2.7)	4 (10.8)	13 (35.1)	17 (45.9)
Evidence that only non-invasive methods were used.	1 (2.9)	-	2 (5.7)	9 (25.7)	4 (11.4)	9 (25.7)	10 (28.6)
Total Mean 73 (Standard Deviation 11.71)							
Child Focused Methods Total Statements (n=18); Examples (n=7)	1	2	3	4	5	6	7
Researchers included children's opinions in the project design and dissemination pathways. Examples: Active consultation with children to ensure data collection methods were child friendly. Children participated in working groups, community consultations or as co-producers with illustrators. Children trialled interventions to provide feedback on the feasibility of the study.	-	1 (2.7)	-	4 (10.8)	6 (16.2)	14 (37.8)	12 (32.4)
Researchers provided positive feedback to children to limit response bias.	-	1 (2.9)	-	4 (11.8)	5 (32.4)	10 (29.4)	8 (23.5)
Total Mean 79 (Standard Deviation 10.42)							
Delphi Round Three Statement 0-18 years	Likert Scores n (%)						

Informed Consent, Assent and Dissent Total Statements (n=6); Examples (n=13)	1	2	3	4	5	6	7
Informed voluntary signed and verbal consent/assent/dissent from parents/legal guardians and the child were gained. Examples 0-4 years: Signed voluntary informed consent from the parents or legal guardian was gained prior to participation. Evidence that the child's assent was gained at a time or over several times when the child was able to comprehend the information and understand what they had consented to. Increased opportunity to participate through the use of an interpreter, if the researcher did not speak the language of the parent and child. Examples 5-18 years: Children were informed that both parental consent and child assent was required.	1 (2.5)	-	-	1 (2.5)	2 (5.0)	8 (20.0)	28 (70.0)
Parental consent/assent was gained at a time or over several times when the parent was able to comprehend the information and understand what they had consented their infant or child to take part in. Examples 0-4 years: Evidence that parents and/or guardians were given adequate time to consider participation and ask questions prior to consent. Parent or legal guardian's questions on agreeing to their infant or child's participation were addressed.	-	1 (2.6)	-	1 (2.6)	3 (7.7)	12 (30.8)	22 (56.4)
Total Mean 80 (Standard Deviation 7.36)							
Code of Conduct Total Statements (n=9); Examples (n=5)	1	2	3	4	5	6	7
The study described appropriate safe data collection processes by taking into consideration the infant or child's chronological and	-	-	1 (2.6)	1 (2.6)	3 (7.9)	11 (28.9)	22 (57.9)

developmental age. Examples 0-4 years: The researchers used developmentally appropriate and safe data collection methods (such as the use of Lego, playdoh, crayons, smelly pens, glitter, photos, open-ended questions, computer technology, drawings, conversations, open-ended questions, computer technology, laboratory tests, radiology, imaging and/or diagnostics). Examples 5-18 years: The use of photos with descriptions or videos to inform the child of the data collection approach. The use of GIS/GPS devices. Photography and how children could include photos.							
The study described appropriate safe data collection processes by taking into consideration the infant or child's capacity and competency. Examples as above.	1 (2.7)	-	1 (2.7)	2 (5.4)	6 (16.2)	13 (35.1)	14 (37.8)
Total Mean 82 (Standard Deviation 13.26)							
Child Focused Methods Total Statements (n=11); Examples (n=2)	1	2	3	4	5	6	7
The methodology described an infant or child friendly approach: Researchers acknowledged the infant or child's responses as valuable and meaningful. Examples 0-4 years: The infant or child's behavioural cues were observed for signs of discomfort and responded to as required. Examples 5-18 years: Researchers asked the child if they felt safe in their current environment.	-	1 (2.5)	2 (5.0)	1 (2.5)	3 (7.5)	15 (37.5)	18 (45.0)
The methodology demonstrated an infant or child friendly approach: Researchers responded to any possible concerns the infant or child expressed. Examples as above.	-	-	1 (2.5)	-	3 (7.5)	11 (27.5)	25 (62.5)
Total Mean 80 (Standard Deviation 10.31)							

Table 3: Child Centred Research Checklist

The Child Centred Research Checklist was generated from a Three Round Delphi Study in 2021: 172 international child research experts from 11 disciplines across 19 countries scored statements on a level of importance. An 80% or above consensus score was required for inclusion into subsequent rounds.

The Child Centred Research Checklist can be used in addition to existing ethical requirements and study design checklists. Some of the statements are broad to ensure relevance to multiple study designs and settings, with examples represented for each section on a statement's application in research projects.

Child Centred Research Checklist

Study Title _______________________________ Age Range of Children_____________ (circle: months or years)

Date of Completion_____________________ Completed by (name) _______________________________________

Please score each statement as: Yes, No, Unclear or Not Applicable

Please provide evidence (eg. page number) for each statement scored Yes or a short statement to explain how this statement was met or why it was not addressed.

May be more applicable for children aged between 0-4 years of age. * May be more applicable for children aged between 5-18 years of age

Statements and Examples	Yes	No	Unclear	N/A	Comment
Informed Consent, Assent and Dissent					
1. Was informed voluntary signed and verbal consent/assent/dissent from parents/legal guardians and the child gained?					
The authors should provide clear evidence on who in the project were required to provide voluntary consent, assent and dissent and whether this was signed or not signed. **Examples 0-4 years #** ❖ Signed voluntary informed consent from the parent or legal guardian was gained prior to participation. ❖ Evidence that the child's assent was gained at a time or over several times when the child was able to comprehend the information and understand what they had consented to. ❖ Increased opportunity to participate through the use of an interpreter, if the researcher did not speak the language of the parent and child. **Example 5-18 years *** ❖ Children were informed that both parental consent and child assent was required.					
2. Was parental consent/assent gained at a time or over several times when the parent was able to comprehend the information and understand what they had consented their infant or child to take part in?					
The authors should provide clear evidence on how informed voluntary consent, assent and dissent were obtained from the child and parent.					

Statements and Examples	Yes	No	Unclear	N/A	Comment
Examples ❖ Evidence that parents and/or guardians were given adequate time to consider participation and ask questions prior to consent. ❖ Parents' or legal guardian's questions on agreeing to their infant or child's participation were addressed.					
3. Did the research team demonstrate or describe age and developmentally appropriate consent/assent and dissent? *					
The authors should provide clear evidence on how informed voluntary consent, assent and dissent were age and developmentally appropriate for their sample. **Examples 0-4 years #** ❖ The use of pictures, play or videos to help explain and prepare the child for what the study would involve, and potentially (depending on age) have the opportunity to ask questions or stipulate yes, no, unsure or stop. **Examples 5-18 years *** ❖ The child information document was read and project explained to the child through the use of illustrations, visual, written and/or phonic aids that were colourful, creative and informative (such as cartoons, pictures, activity booklets, stories, games, play, detailed comics, graphics, videos, animations and/or question time on what will happen during data collection). ❖ Children were provided with time and opportunity to ask questions and could sign the child adjusted consent form as they deemed fit (such as their name, a picture or sign). ❖ Children were encouraged to explain the study to you or as if to a friend to reveal their understanding. ❖ Prior to assessments, using pictures or signs so the child could stipulate yes, no, unsure or stop.					
Code of Conduct	**Yes**	**No**	**Unclear**	**N/A**	**Comment**
4. Did the study describe appropriate and safe data collection processes by taking into consideration: a. the infant or child's chronological and developmental age? b. the infant or child's capacity and competency?					
The authors should provide clear evidence on their data collection processes taking into consideration the infant/child's chronological and developmental age and their capacity and competency. **Example 0-4 years #**					

Statements and Examples	Yes	No	Unclear	N/A	Comment
❖ Researchers used developmentally appropriate and safe data collection methods (such as the use of Lego, playdoh, crayons, smelly pens, glitter, photos, drawings, conversations, open ended questions, computer technology, laboratory tests, radiology, imaging and/or diagnostics). **Examples 5-18 years** * ❖ The use of photos with descriptions or videos to inform the child of the data collection approach. ❖ The use of geographic information system/global positioning system devices. ❖ The use of photography and how children could include photos.					
5. Was appropriate pain relief offered, according to current evidence?					
The authors should state that appropriate pain relief was provided, if required.					
6. Were the potential benefits and risks of participation in the study for the infant or child disclosed? **#**					
Example The authors should state how the benefits and risks of participation in the study were disclosed to the participants.					
7. Were parents allowed to be present with their infant or child? **#**					
Example ❖ The authors should state whether parents were allowed to be present with their infant or child during data collection.					
8. Did the research team seek out appropriate guidance from a paediatric expert if they lacked the qualifications, credentials, knowledge and understanding in conducting research with children? *					
The authors should state that appropriate guidance from a paediatric expert was sought, if required.					
9. Were parents notified if their child was negatively affected in the study? *					
The authors should state that parents were notified if their child was negatively affected during the study. **Example** If the child appears distressed, parents need to be notified.					
Child Focused Methods	**Yes**	**No**	**Unclear**	**N/A**	**Comment**
10. Did the methodology describe an infant or child friendly approach including: a. the researchers acknowledged the infant or child's responses as valuable and meaningful? b. the researchers listened carefully to what the infant or child said? c. the researchers responded to any possible					

Statements and Examples	**Yes**	**No**	**Unclear**	**N/A**	**Comment**
concerns the infant or child expressed? d. the researchers acknowledged the child as a competent and active participant? e. the researchers asked the child for more detail, if they were unsure of a response?					
The authors should provide clear evidence on how their methodology was child friendly taking into consideration the areas above (a-e). **Example 0-4 years #** ❖ The infant or child's behavioural cues were observed for signs of discomfort and responded to appropriately. **Examples 5-18 years *** ❖ Time was taken to get to know the child as an individual and develop a respectful relationship ❖ Researchers asked the child if they felt safe in their current environment.					
11. Did the methodology demonstrate or describe a child friendly approach, including age appropriate language that children were comfortable with? *					
The authors should provide clear evidence on the language used being age appropriate and safe for their sample. **Examples** ❖ Using everyday language rather than technical terms ❖ Provision of concrete examples of concepts ❖ Use of a warm, friendly tone with reassurance that there are no wrong answers and children can speak freely					
Overall Appraisal: Child Friendly, Provide Recommendations, Seek Further Information **Comments:** ____					

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.