Updated clinical trial reporting guidelines include patient voices to improve trial utility and transparency

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In a global study of outcome reporting in clinical trials, a research team at The Hospital for Sick Children (SickKids) has issued updated guidelines on what should be included in all trial protocols and published clinical trial reports, with the goal to improve their transparency and utility.

Clinical trials are an important stage in translating research from labs to real-world care, but when outcomes are poorly defined and reported, it can be difficult for clinicians and scientists to apply learnings from a trial to a new population. This is especially true for children and youth, who make up only 25 percent of the population and rely on clear, consistent child health outcome reporting to make trials relevant to their needs.

"The outcomes currently reported in clinical trials often lack transparency and are highly variable," says first author Dr. Nancy Butcher, who led the study as a Senior Research Associate in the Child Health Evaluative Sciences (CHES) program. "Our research is helping to change the world of clinical trials by providing clear guidelines for defining, measuring and analyzing trial outcomes. By using this guidance, the scientific community can make research findings more widely interpretable and usable for as many children as possible."

Currently, the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement, and the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement, provide checklists for the development of clinical trial protocols and reporting of

randomized controlled trials, respectively.

Today's publications in a *JAMA Special Communication* include SPIRIT-Outcomes 2022, an extension to the SPIRIT 2013 Statement and CONSORT-Outcomes 2022, an extension to the CONSORT 2010 Statement, with detailed outcome-specific requirements.

"As the science on outcome reporting advances, our extensions will help support a global community of clinicians and researchers working to provide children with the latest evidence-based advancements in pediatric medicine," says Butcher, who is a Cundill Scholar at the Cundill Centre for Child and Youth Depression at the Centre for Addiction and Mental Health (CAMH) and leads the Toronto Outcomes Research in Child Health (TORCH) Initiative.

Including patient voices in defining trial outcomes

This multi-year project identified nine new outcome-specific items that should be defined in all trial protocols, in addition to 17 outcome-specific items that should be addressed in all published clinical trial reports.

These updates are the first to highlight the importance of reporting how outcomes are chosen and defined, to ensure that the measured outcomes are useful to patients and clinicians.

For the first time patient and public panelists, as well as contributors such as journal editors, were engaged in the development of both extensions, alongside researchers, clinicians and the developers of SPIRIT 2013 and CONSORT 2010.

Consensus on the recommendations was achieved through a three-round voting process completed by 124 panelists with expertise in clinical trials

from 22 countries, followed by a global consensus meeting with patient and public partners hosted at SickKids in 2019. Together, their input determined which recommendations would be included to improve how clinical trials are planned and their results are shared.

"By defining outcomes and involving patient and non-scientific voices from the trial protocol stage, we can help ensure the outcomes used in studies and, as a consequence, the research itself are relevant to patients," says Dr. Martin Offringa, Senior Scientist in CHES and neonatologist who co-chaired the study.

Setting the stage for individualized care

Beyond advancing research integrity, standardizing transparent outcome selection, measurement and analysis in clinical trials is an important component in the development of individualized medicine. Achieving SickKids' vision for Precision Child Health, a movement to deliver individualized care for every patient, relies on clear data to inform novel care approaches tailored to each child, notes Offringa.

"When we think about achieving unprecedented outcomes through Precision Child Health, it's vital to define those outcomes with input from patients and families, from the very beginning of every study," says Offringa, who also leads the EnRICH Research Group and Network. "What clinicians define as a relevant study outcome may differ from a patient's perspective. Ensuring patient partners are involved when clinical trial outcomes are being planned can help provide a foundation for the provision of truly tailored care."

While these guidelines represent the minimal set of reporting elements, the research team continues to work with a variety of researchers and institutions to support the development of transparent clinical trials and identify where more reporting measures are needed, such as in mental

health and rare disease research where outcome reporting is highly variable.

More information: Nancy J. Butcher et al, Guidelines for Reporting Outcomes in Trial Protocols The SPIRIT-Outcomes 2022 Extension, *JAMA Special Communication* (2022). DOI: 10.1001/jama.2022.21243

Nancy J. Butcher et al, Guidelines for Reporting Outcomes in Trial Reports The CONSORT-Outcomes 2022 Extension, *JAMA Special Communication* (2022). DOI: 10.1001/jama.2022.21022

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