Information sheet:
Development of SPIRIT-Children and CONSORT-Children

What are reporting guidelines? What is a clinical trial protocol and report?

Reporting guidelines are tools that come in the form of a checklist, a flow diagram, or text. They list what information researchers should include when writing a publication that reports on their study. When researchers use reporting guidelines, it helps them know what important information ("items") to include in their papers. This way, readers of the publication will have all the information to fully understand what the study was about, how it was designed, how it was conducted, and what was found.

There are reporting guidelines for specific types of studies. For example, SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) is a reporting guideline for clinical trial protocols. A trial protocol is a document that outlines why the trial is being done and details - step-by-step - how it will be done. Related but slightly different, CONSORT (Consolidated Standards for Reporting Trials) is a reporting guideline for clinical trial reports. A trial report is a document with detailed information on what was done in a completed trial, what was found, and what the findings mean.

Why are these reporting guidelines called SPIRIT-Children and CONSORT-Children?

• Reporting guidelines for trials in adults have been around for some time:
o SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) is for clinical trial protocols
o CONSORT (Consolidated Standards for Reporting Trials) is for clinical trial reports
• However, they are often missing information that is important for research that involves children.
• The two new reporting guidelines we are developing will be called SPIRIT-Children and CONSORT-Children, so people know that these guidelines are for clinical trials with children.

Why do we need SPIRIT-Children and CONSORT-Children?

Pediatric clinical trials have unique challenges that are not seen in other clinical trials. Some of these challenges are getting the right dose of a drug that needs to be studied in participants between 0 and 17 years old, picking the most relevant health outcome to study, monitoring long-term growth and development effects of study interventions, to name a few. Because of challenges with pediatric clinical trials, there are relatively few trials that include children and youth. This also means that there is less pediatric-specific information and evidence that can inform the choice of treatments for children and youth.

To make sure that information from pediatric clinical trial protocols and reports are reported properly and no key information is left out, a reporting guideline that considers the unique challenges seen in pediatric trials is needed. This will help researchers report important information in their pediatric clinical trial protocols and reports, ensuring that the information and evidence can be used to help develop treatment options for children and youth is there.

Who is involved in developing SPIRIT-Children and CONSORT-Children?

The development of SPIRIT-Children and CONSORT-Children is led by the core project team, including Ami Baba (project coordinator), Maureen Smith (patient engagement expert), and professors Beth Potter, An-Wen Chan, David Moher, and Martin Offringa. The team is based at The Hospital for Sick Children in Toronto, Ontario, Canada.
This project also involves:

- An international group of researchers; healthcare professionals; journal editors;
- Young people (ages 12-24) with lived experience of participating in a pediatric clinical trial; or who read research and use trial results to inform healthcare decision making; or have experience collaborating with researchers on a research team;
- Family caregivers (e.g., parents) of children who have participate(d) in a pediatric clinical trial, or are interested in pediatric trial results.

SPIRIT | CONSORT CHILDREN
Reporting Guidelines for Child Health Trials

What does the Delphi study involve?

To decide which items should be in SPIRIT-Children and CONSORT-Children, it is important to get everyone's opinion and try to reach agreement, or "consensus", on what the most important items are. We will do a "Delphi study", where people involved with pediatric clinical trials, such as researchers, healthcare professionals, journal editors, young people (ages 19-24) and family caregivers vote and give their opinion on which items are the most important ones. The Delphi study is an anonymous "voting process" that is used to reach group consensus and makes sure that everyone's opinion is heard. There are usually multiple rounds of the Delphi study. For this project, we will do up to three rounds. Delphi panelists will receive email links to complete the Delphi questionnaires.

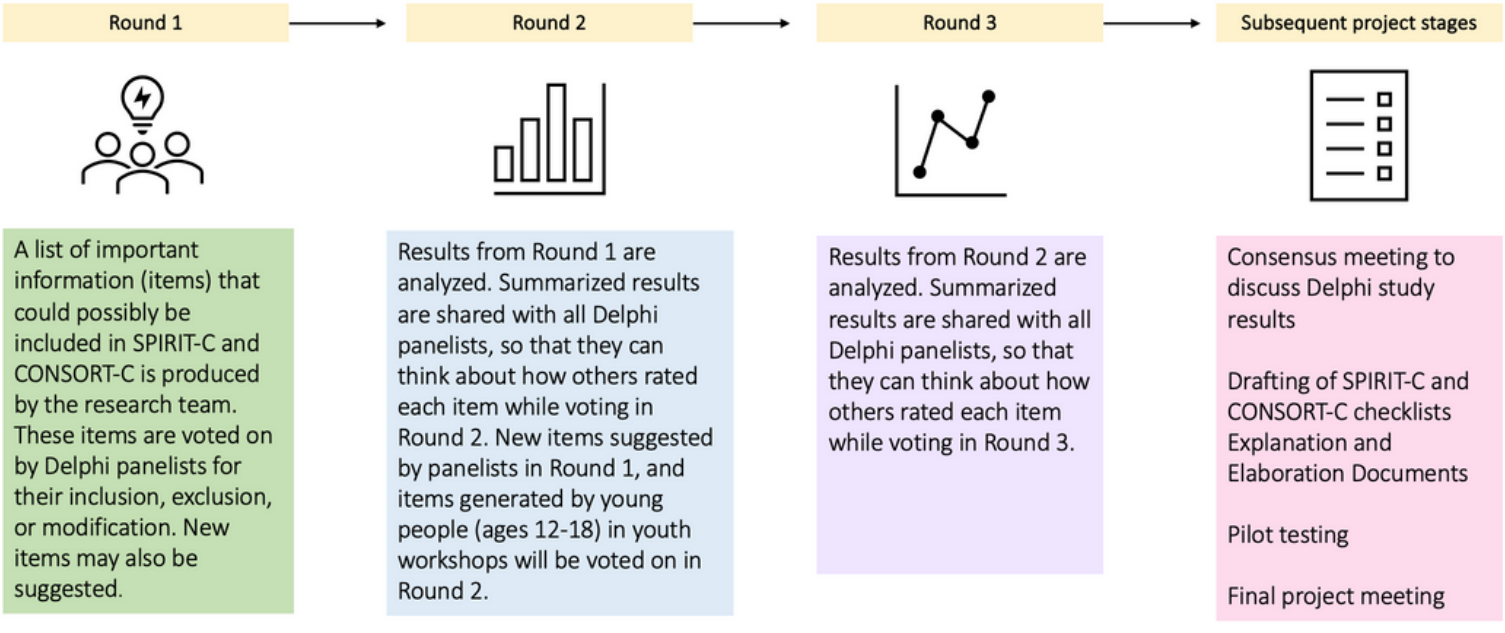
Before the Delphi study begins, there will be a training session with those who signed up to be a part of the Delphi study ("panelists"). We will go over how to complete the Delphi study, provide examples, and answer any questions.

In Round 1, all panelists will receive an e-mail survey with the list of items for inclusion in the final checklist (known as candidate items) and will be asked to score the importance of each item. If they wish, panelists are invited to explain why they scored an item a certain way. If panelists think an item is not easy to understand, they are encouraged to make suggestions. Panelists also are invited to add items that they think are still missing from the list. If a panelist thinks they don't have enough knowledge on how to score a particular item, maybe because it involves a very technical or statistical topic, they can choose the option "not my expertise".

After the first round, the results are summarized and sent back to each panelist. No one can see the scores of other panelists, only the overall results for the group. You will have the opportunity to see how other groups (e.g., researchers and health care providers) scored each item. Using this information, in Round 2, all panelists will be asked to score the importance of the items again. Round 2 results are then summarized and sent back, like what was done after Round 1. If there are still items that have not reached consensus for inclusion or exclusion, they will be scored again in final third round by the panelists. The third round will be similar to the second round.

We expect that each round will take about an hour to complete. After the Delphi study, there will be a debrief session to talk about the Delphi study experience, what worked, what didn't, and how it can be improved.

Delphi process summary



Questions? Please feel free to reach out to Ami Baba at enrich.network@sickkids.ca