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journal homepage: [www.elsevier.com/locate/jped surg](http://www.elsevier.com/locate/jped surg)Trial registration in pediatric surgery trials<sup>☆,☆☆</sup>Sana Rokhsafat<sup>a</sup>, Deanna E. Morra<sup>a</sup>, Martin Offringa<sup>a,b</sup>, Lisa M. Askie<sup>c,d</sup>, Lauren E. Kelly<sup>a,e,\*</sup><sup>a</sup> Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Canada<sup>b</sup> University of Toronto, Faculty of Medicine, Toronto, Canada<sup>c</sup> University of Sydney, Sydney Medical School, Sydney, Australia<sup>d</sup> University of Sydney, NHMRC Clinical Trials Centre, Sydney, Australia<sup>e</sup> Seneca, School of Biological Sciences and Applied Chemistry, Toronto, Canada

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## ABSTRACT

**Background:** Prospective clinical trial registration serves to increase transparency and to mitigate selective reporting bias. An assessment of adult surgical trials revealed poor trial registration practice with incomplete provision of information in registries and inconsistent information in the corresponding publication. The extent and completeness of pediatric surgical trial registration are unknown. We aimed to determine the proportion and adequacy of clinical trial registration in pediatric surgery trials published in 2014.

**Methods:** Using sensitive search strategies in MEDLINE, abstracts and full-texts of prospective pediatric intervention studies published in 2014 were screened in duplicate. Pediatric surgical trials were included. Clinical trial registration numbers obtained from publications were searched in trial registries. Data were extracted based on WHO 20-item minimum data set to determine the completeness of registration data. The proportion of registered trials was recorded and registration data were compared to reported data in the corresponding publication.

**Results:** Our search and abstract screening identified 3375 articles for full text review. Following coding, a total of 54 pediatric surgical trials were included and analyzed; 28% (15/54) of which published a registration number. In trials which reported a registration number, 40% (6/15) were retrospectively registered and 40% (6/15) had made changes to their registered primary and/or secondary outcome measures. One included published trial reported an incorrect registration number.

**Conclusions:** Analysis of pediatric surgery trials published in 2014 revealed a poor prospective trial registration rate and incomplete registration data. Our study supports future initiatives for improved registration behaviors in pediatric surgery trials to ensure high-quality, transparent, reproducible evidence is generated.

**Study type:** Therapeutic (clinical trials), level II.

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Pediatric surgical practice must be guided by a reliable evidence-base including randomized, comparative effectiveness trials. Reporting bias in clinical trials, including publication bias (preferential publication of positive studies) and selective reporting bias, can distort the validity of medical literature and undermine clinical decision-making [1,2]. Prospective trial registries emerged as a strategy to deter selective reporting by increasing transparency and promoting accountability

through public cataloguing of clinical trials [3] prior to their commencement. The International Committee of Medical Journal Editors (ICMJE) implemented a policy in 2005, mandating registration of clinical trials as a prerequisite for publication in their respective journals which was adopted by eleven peer-reviewed scientific journals [3]. Their intent was to reduce reporting bias, prevent unnecessary duplication and provide an information portal for patients and the public [4,5].

The effectiveness of prospective trial registration, particularly in its role in increasing transparency and accountability, relies on the provision of complete and accurate information [6,7]. In the past, the completeness of information provided in prospective trial registries has been variable [6] and reporting bias remains an ongoing challenge [8]. The assessment of information provided in trial registries has been predominantly focused on adult trials and the completeness of pediatric surgical trial registration has yet to be investigated. The purpose of this paper is to investigate the proportion of pediatric surgical trials that have been registered and to compare information recorded in

**Abbreviations:** ICMJE, International Committee of Medical Journal Editors; StaR Child Health, Standards for Research in Child Health; WHO, World Health Organization.

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clinical trial registries with the information reported in corresponding publications. The objectives of this study are to: (1) assess the proportion of registered pediatric surgical trials and the completeness of information provided in trial registries based on the WHO 20-Item Minimum Data Set; and (2) determine if information reported in clinical trial registries matches the information presented in the corresponding publication.

## 1. Methods

### 1.1. Study selection and search strategy

A MEDLINE search was conducted using a sensitive and specific search strategy (Appendix 1) restricted to 2014 publications (Fig. 1). The search strategy employed MeSH and non-MeSH terms that are relevant to pediatrics, clinical trials and study protocols. Publications of abstracts and titles were retrieved and screened independently by two reviewers in Endnote. Abstracts pertaining to prospective, interventional trials in children were selected for full-text assessment, and relevant full-text publications were reviewed. Studies without an intervention, without patients younger than 18 or with a mean age greater

than 21 years were excluded. Data from each published full-text article were collected and managed using REDCap a secure, web-based application designed to support data capture, hosted at The Hospital for Sick Children [9]. Data were collected by six independent reviewers, with a sample completed in duplicate to assess consistency of data collection. Random spot checks for consistency between reviewers were completed weekly by the Senior Project Manager.

### 1.2. Data extraction and analysis

The proportion of registered trials, and the completeness of registered data versus reported data in a corresponding publication were determined. Using the WHO Trial Registration Data Set (Appendix 2) [10], two investigators (SR, DM) independently manually extracted all data into an Excel (Microsoft, Redmond, United States of America) database. The WHO Trial Registration Data Set was chosen as it is the internationally agreed standard for the minimum information required for a trial to be considered fully registered [10]. Completeness of WHO Trial Registration Data Set was classified as a) did not meet criteria, b) partially met criteria or c) fully met criteria. “Did not meet criteria” was defined as registered information that did not match reported published

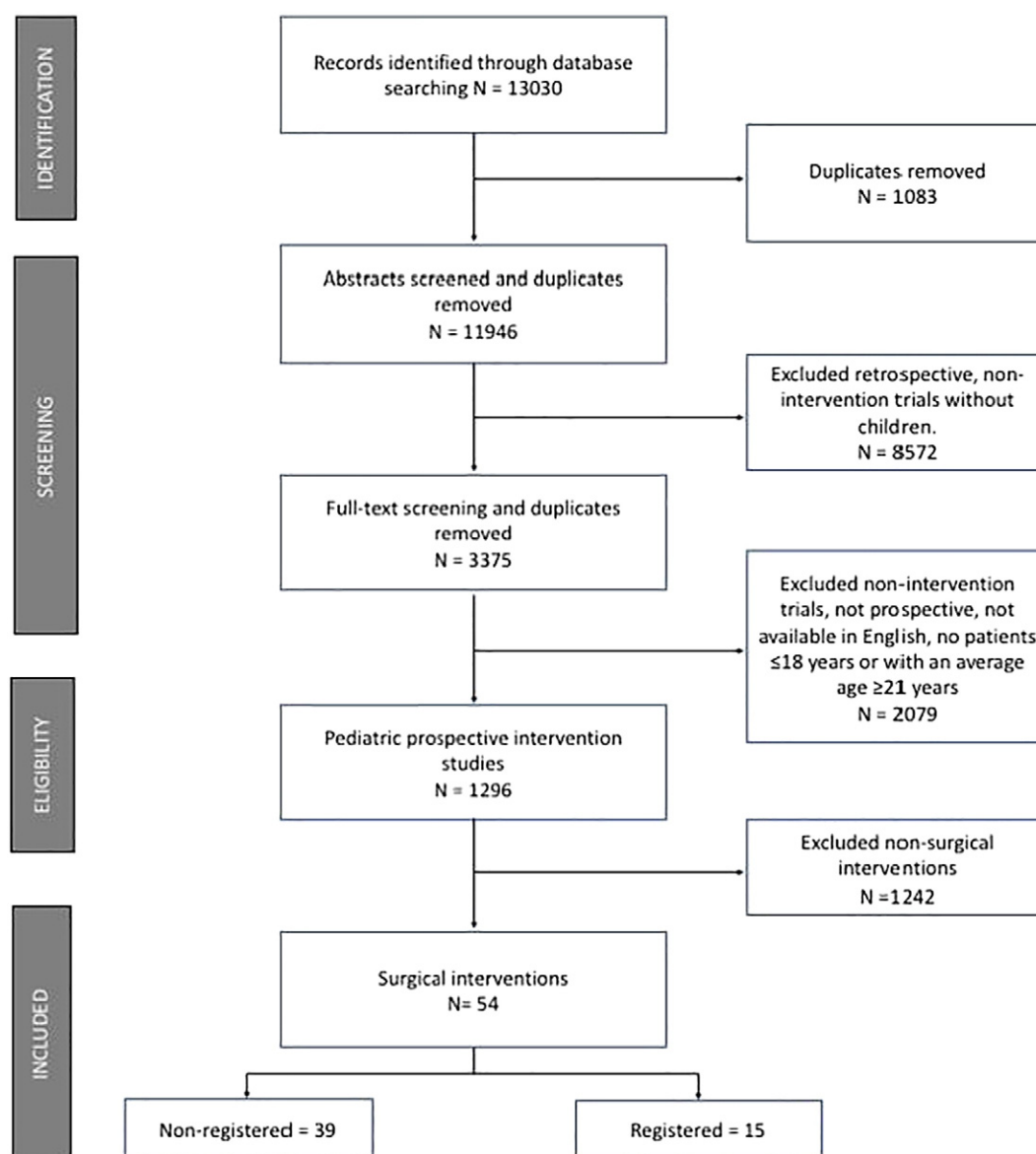


Fig. 1. Modified PRISMA [23] flow diagram of prospective pediatric surgical trials published in 2014.

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