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Patient safety improvement interventions in children's surgery: A systematic review☆

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ABSTRACT

Background: Adult surgical patient safety literature is plentiful; however, there is a disproportionate paucity of published safety work in the children's surgical literature. We sought to systematically evaluate the nature and quality of patient safety evidence pertaining to pediatric surgical practice.
Methods: Systematic search of MEDLINE and EMBASE databases and gray literature identified 1399 articles. Data pertaining to demographics, methodology, interventions, and outcomes were extracted. Study quality was assessed utilizing formal criteria.
Results: 20 studies were included. 14 (70%) comprised peer-reviewed articles. 18 (90%) were published in the last 4 years. 13 (65%) described a novel intervention, and 7 (35%) described a modification of an existing intervention. Median patient sample size was 79 (29–1210). A large number (n = 55) and variety (n = 35) of measures were employed to evaluate the effect of interventions on patient safety. 15 (75%) studies utilized a checklist tool as a component of their intervention. 9 (45%) studies [comprising handoff tools (n = 7); checklists (n = 1); and multidimensional quality improvement initiatives (n = 1)] reported a positive effect on patient safety. Quality assessment was undertaken on 14 studies. Quantitative studies had significantly higher quality scores than qualitative studies (61 [0–89] vs 44 [11–78], $p = 0.03$).
Conclusions: Pediatric surgical patient safety evidence is in its early stages. Successful interventions that we identified were typically handoff tools. There now ought to be an onus on pediatric surgeons to develop and apply bespoke pediatric surgical safety interventions and generate an evidence base to parallel the adult literature.
Level of Evidence: Level IV, Case series with no comparison group.

Over the past two decades, healthcare globally has awoken to the concept of patient safety both as a critical component of care quality that is to be strived for and as an outcome measure to be monitored and audited [1,2]. This awakening [3,4] and concurrent shift in policy agenda [5,6] have triggered a burgeoning science of clinical patient safety. This has been reflected by a proliferation of articles on patient safety interventions [7]. Along with anesthesiology, surgery can lay claim to spearheading this new safety paradigm with some of the most ambitious and high-profile studies such as the evaluation of the World Health Organization (WHO) Surgical Safety Checklist [8].

Within surgery, the above trend has resulted in a significant body of safety and quality improvement research within the adult surgical literature [9–13]. It remains unclear to date to what extent these developments have been mirrored in the pediatric surgical literature. The primary aim of this review was to provide a systematic overview of the evidence-based patient safety improvement interventions developed primarily for children's surgery and evaluate their clinical efficacy in improving patient outcomes, clinical processes, or both. Our secondary aim was to carry out a detailed methodological appraisal and critique of the evidence base – in order to provide meaningful direction for its future development.

1. Methods

1.1. Data sources

The MEDLINE and EMBASE databases were systematically searched. The gray literature was additionally searched utilizing Google and Google Scholar. The last set of searches was performed in January 2015.

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Given the heterogeneous nature of the subject matter, a deliberately broad three-dimensional search strategy was employed comprising three separate search strings of Medical subject heading (MeSH) terms and text words to define, in turn, the elements of 'children's surgery', 'safety interventions' and 'outcomes'.

Data triangulation (defined as validation through cross verification from two or more sources) was achieved by cross-referencing with the Agency for Healthcare Research and Quality's curated list of safety literature [14]. Data saturation (defined as satisfaction that no new information could be obtained) was achieved by hand-searching the reference lists of all selected full text articles for further relevant studies.

1.2. Study selection

Original articles in English describing a novel patient safety intervention (or a novel adaptation of an existing intervention specifically for pediatric surgical patients) pertaining to a pediatric population in the perioperative setting were included. For the purposes of this review, children's surgical practice was defined as encompassing the pediatric surgical subspecialties of pediatric surgery; neonatal surgery; pediatric urology; pediatric neurosurgery; pediatric cardiothoracic surgery (CTS); pediatric otolaryngology (ENT); pediatric oral and maxillofacial surgery; pediatric plastic surgery; and pediatric orthopedic surgery. Exclusion criteria comprised observational studies that did not report an intervention; studies focusing primarily on disease; studies primarily describing or evaluating aspects of medical education or training; studies primarily describing or validating patient safety and/or quality metrics/measures; and studies describing interventions not specifically developed for perioperative care in a pediatric population.

Article selection was conducted by a single reviewer with a background in pediatric surgery and patient safety (ALM). To test the reliability of the selection process, a block sample of the first 100 retrieved titles was independently reviewed by a second reviewer (ACM). Interreviewer agreement was determined by Cohen's Kappa to be very good (Kappa = 0.917, Standard Error = 0.058).

An article flow summary through the review procedure is shown in Fig. 1.

1.3. Data extraction and synthesis

Data were extracted and abstracted using a standardized proforma. The proforma included article title; article type; authors; country of origin; year of publication; aims; setting; author's own description of intervention; sample population; methodology; measures of effect; results; limitations; areas identified for further research; and conclusions.

Data were qualitatively synthesized to identify the safety problem the intervention addressed; type of intervention; checklist involvement; intervention originality; study design; surgical specialty; and whether a safety improvement was achieved and/or if the intervention was successfully implemented.

Safety problems addressed by the interventions were synthesized and classified into the following categories: postoperative handoff; identifying safety issues (at patient and/or process level); checklist adherence; perioperative patient safety; and intrahospital transfers.

Intervention type was synthesized and classified into the following categories: checklists; reporting systems; multidimensional quality improvement initiatives; trigger tools; healthcare failure modes and effects analysis (HFMEA); safety protocols; and handoff tools. Handoff tools were further subclassified as multi- or single-component tools. Multicomponent tools were defined as those comprising more than one interventional component (e.g. a handoff protocol and a checklist jointly applied).

Quantitative data synthesis (including meta-analysis) was not feasible owing to the heterogeneity of the included study designs and their reported outcome measures.

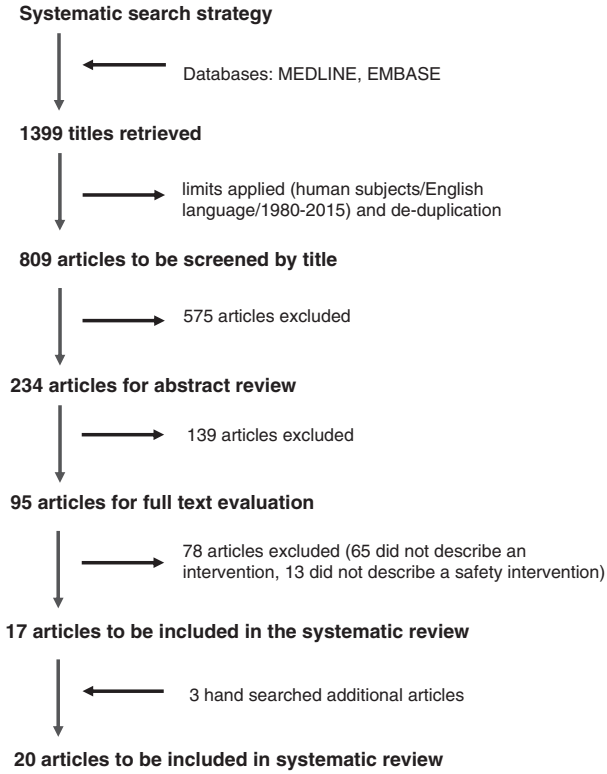

Fig. 1. Article selection flow diagram.

1.4. Quality assessment

Two independent reviewers (ALM, ACM) undertook quality assessment on all full text articles. Interreviewer agreement was determined by Cohen's Kappa to be good (Kappa = 0.773, Standard Error = 0.216).

Quality assessment comprised a structured critical appraisal of each paper conducted with the aid of quantitative and qualitative criteria checklists previously employed in similar reviews [15]. For each assessment criterion, articles were scored on a 3 point scale based on the extent to which they met the criteria (0 = criteria not met, 1 = criteria partially met, 2 = criteria definitely met). The quantitative checklist had 9 criteria and hence a total possible score ranging between 0 and 27. The qualitative checklist had 12 criteria and hence a total possible score ranging between 0 and 36. Each paper's quality score was expressed as a percentage (%) of the maximum possible score that could be achieved – to allow cross-study comparison. Where studies were of a mixed methodology, two separate quality assessments were undertaken and two separate quality scores were calculated.

Statistical analysis of quality data was undertaken using GraphPad PRISM 6. Data were deemed non-parametric and Mann–Whitney and Kruskal–Wallis tests were used. Statistical significance was set at $p \leq 0.05$.

2. Results

2.1. Included studies

The systematic search of the MEDLINE and EMBASE databases combined with the search of the gray literature yielded an initial 1399 articles. These articles were screened first by title and then by abstract and full text, resulting in 17 studies deemed suitable for inclusion (Fig. 1). Triangulation against the AHRQ's curated collection and hand-searching of reference lists yielded a further 3 studies for inclusion. Following the last search in January 2015, 20 studies [16–35] were identified for inclusion in the review (Table 1).

The majority (70%) of included studies comprised peer-reviewed journal articles (n = 14 [16–21,23,25–28,33–35]) and the remainder