



Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jped surg

Review Article

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

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ARTICLE INFO

Article history:

Received 27 April 2016

Received in revised form 12 August 2016

Accepted 18 September 2016

Available online xxxxx

Key words:

Patient safety

Quality improvement

Teamwork

Checklists

Handoff

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.

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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.

[☆] Conflicts of interest and source of funding: Sevdalis is the director of London Safety and Training Solutions Ltd, which provides team skills training and advice on a consultancy basis to hospitals and training programs in the UK and internationally. Sevdalis' research was supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. Sevdalis is a member of King's Improvement Science, which is part of the NIHR CLAHRC South London and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London, and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity, the Maudsley Charity, and the Health Foundation. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

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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.

Systematic search strategy

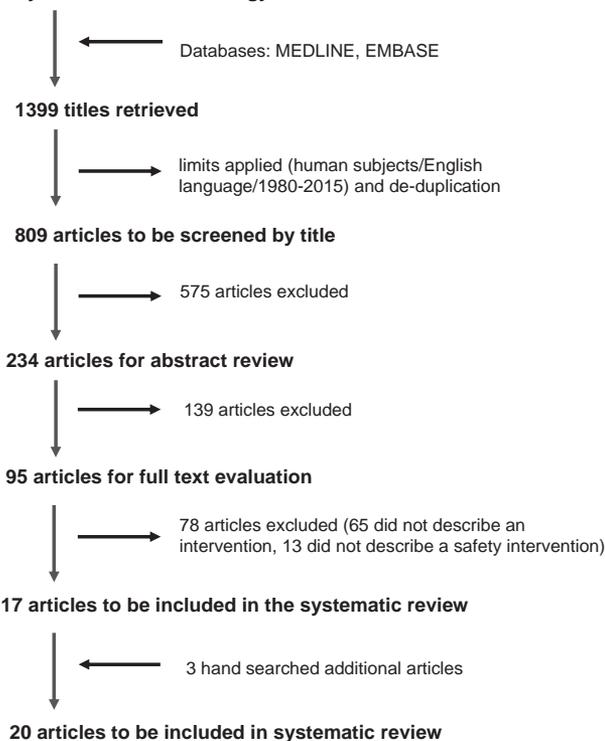


Fig. 1. Article selection flow diagram.

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

Table 1
Summary of included studies.

Study	Sample	Intervention	Design	Findings	Quality score
Vergales et al. 2014 (US)	79 handoffs	Handoff tool	Prospective, pre/post interventional clinical study	Introduction of new handoff tool improved healthcare providers' subjective views of: <ul style="list-style-type: none"> - handoff efficiency ($p < 0.05$); - ease of asking questions (etc.); and - overall capability to improve patient care (etc.). 	Quantitative: 6/18 (33%) Qualitative: 2/18 (11%)
Joy et al. 2011 (US)	79 handoffs	Handoff tool	Prospective, pre/post interventional clinical study	Handoff intervention resulted in: <ul style="list-style-type: none"> - reduction in technical errors from 6.24 to 1.52 ($p < 0.0001$); - reduction in critical verbal handoff information omissions from 6.33 to 2.38 ($p < .0001$); and - improvement in teamwork and handoff content received. 	Quantitative: 11/18 (61%) Qualitative: 8/18 (44%)
Zavalkoff et al. 2011 (Canada)	31 handoffs	Handoff tool	Prospective, pre/post interventional clinical study	Implementation of the handoff tool resulted in: <ul style="list-style-type: none"> - significant improvement in total handoff score; - significant improvement in the medical and surgical intraoperative information subscores; - no prolongation of handoff duration ($p > 0.05$); and - more patients being free from high-risk events ($p = NS$). 	Quantitative: 15/18 (83%)
Catchpole et al. 2007 (UK)	50 handoffs	Handoff tool	Prospective, pre/post interventional clinical study	Handoff intervention resulted in: <ul style="list-style-type: none"> - reduction of mean number of technical errors from 5.42 to 3.15; - reduction of mean number of information omissions from 2.09 to 1.07; - reduction of duration of handoff from 10.8 min to 9.4 min; and - reduction of number of technical errors ($t = 3.63, p < 0.001$). 	Quantitative: 12/18 (66%)
Agarwal et al. 2012 (US)	175 staff	Handoff tool	Prospective, pre/post interventional clinical study	Implementation of the handoff tool resulted in: <ul style="list-style-type: none"> - reduction in loss of information for every category of patient clinical care ($p < 0.001$); - decrease for three of the four major complications studied ($p < 0.05$); and - increase in number of early extubations ($p < 0.04$). 	Quantitative: 16/18 (89%) Qualitative: 14/18 (78%)
Craig et al. 2012 (UK)	43 handoffs	Handoff tool	Prospective, pre/post interventional clinical study	Following implementation: <ul style="list-style-type: none"> - All three phases of the handoff were significantly improved. - Observer scores were significantly improved. - Staff perceptions were significantly improved. - There was no significant increase in the duration of the handoff. 	Quantitative: 13/18 (72%) Qualitative: 14/18 (56%)
*Carroll et al. 2013 (US)	205 handoffs	Handoff tool	Post-interventional clinical study	Following implementation: <ul style="list-style-type: none"> - Handoffs were performed 94% of the time. - Attendance by key providers ranged from 37% to 100%. - There was 100% compliance with critical steps. - Written positive comments were reported in 15% of handoffs. - There were no negative comments. 	N/A
Kim et al. 2012 (US)	93 patients	Multicomponent handoff tool	Prospective analyses	After implementation of the checklist and transfer protocol, prospective analysis showed no adverse events from miscommunication during transfer of care over the subsequent 11-month period.	Quantitative: 7/12 (58%) Qualitative: 3/18 (17%)
*Pappila et al. 2013 (Sweden)	N/S	Multicomponent handoff tool	Observational pilot study and post-intervention questionnaire survey	Benefits reported were: <ul style="list-style-type: none"> - clearer handoff structure; - coherent information; and - improved learning experience. 	N/A
Avansino et al. 2011 (US)	190 staff members	Checklist	Prospective audit and staff survey	Following checklist implementation: <ul style="list-style-type: none"> - Compliance at 12 months was significantly higher than that at inception (94% vs 88%, $p < 0.001$). - Surgeons had more positive perceptions of using the checklist compared with nurses and anesthesiologists ($p < 0.001$). 	Quantitative: 9/18 (50%) Qualitative: 9/20 (45%)
Nakayama et al. 2011 (US)	903 transfers	Checklist	Post-interventional clinical study	Following checklist implementation, problems with transfers: <ul style="list-style-type: none"> - fell to 3.5% (9/260) in Q2, 0.4% (1/243) in Q3, and 1.0% (2/209) in Q4 ($p < 0.001$). 	Quantitative: 8/16 (50%)

(continued on next page)

Table 1 (continued)

Study	Sample	Intervention	Design	Findings	Quality score
Karakaya et al. 2013 (Belgium)	48 handoffs	Checklist	Prospective, pre/post interventional clinical study	<ul style="list-style-type: none"> - Patient care issues (14/31; 45%) were most common, followed by documentation (10, 32%) and process problems (7, 23%). Following checklist implementation: <ul style="list-style-type: none"> - Overall data transfer increased ($p < 0.001$). - Duration of data transfer decreased ($p < 0.04$). - Overall handoff assessment by staff improved significantly. 	Quantitative: 15/18 (83%) Qualitative: 11/18 (61%)
Norton et al. 2010 (US)	30 procedures	Checklist	Prospective, pre/post interventional clinical study	Implementation resulted in improvements in: <ul style="list-style-type: none"> - teamwork; - communication; and - adherence to process measure. 	Quantitative: 2/14 (14%) Qualitative: 4/20 (20%)
Low et al. 2012 (US)	29 staff	Checklist	Retrospective questionnaire survey	Post-implementation questionnaire demonstrated that staff valued the checklists and thought they contributed to patient safety.	Qualitative: 6/18 (33%)
Lander et al. 2010 (US)	50 patients	Trigger tool	Retrospective record review	Trigger tool interrater reliability ranged from poor to high for admission triggers, discharge triggers, medical records triggers, and medication triggers. Errors and adverse events were found in all admissions: of them, 3% were potentially harmful, and 93% were documentation related.	Quantitative: 8/10 (80%)
*Marquet et al. 2012 (Belgium)	N/S	HFMEA	Prospective analyses	HFMEA resulted in identification of 16 and 10 failure modes.	N/A
Norton et al. 2007 (US)	1210 procedures	Procedural safety protocol	Prospective analyses	N/S	Quantitative: 0/8 (0%)
*Levy et al. 2013 (US)	N/S	Reporting system	Prospective analyses	Median (interquartile range) of 34 (26–44) monthly reported variances. The most commonly reported variances involved policy/process. The variances included adverse events (1%), near misses/good catches (20%) and other patient care issues (79%). Post-intervention:	N/A
*Levy et al. 2013 (US)	510 cases	Multidimensional quality improvement initiative	Prospective, pre/post interventional clinical study	<ul style="list-style-type: none"> - Checkpoint adherence improved ($p < 0.0001$). - Median (interquartile range) checkpoint completion significantly improved ($p < 0.05$). 	N/A
*Mistry et al. 2006 (US)	171 patients	Multidimensional quality improvement initiative	Prospective, pre/post interventional clinical study	The intervention resulted in: <ul style="list-style-type: none"> - a reduction in turnaround time (15.3 to 9.6 min; $p < 0.001$); - a reduction in lab draw time (13.0 to 2.4 min; $p < 0.001$); - an increase in CXRs completed (60% vs 94%; $p < 0.01$); and - an increase in percent of patients placed on CR monitor (86 vs 99%; $p < 0.01$). 	N/A

N/S = not specified; N/A = not applicable.

* = published conference proceedings.

represented peer-reviewed conference proceedings (published abstracts of oral presentations $n = 4$ [22,30–32], posters $n = 2$ [24,29]).

The majority (70%) of studies originated from US institutions ($n = 14$ [16,17,20,22,23,25,27,28,30–35]), with the remainder from the UK ($n = 2$ [19,21]), Belgium ($n = 2$ [26,29]), Canada ($n = 1$ [18]) and Sweden ($n = 1$ [24]). The inclusion criteria allowed studies published after 1980, however, almost all (90%) were published within the last 5 years (2010–January 2015), with the remainder (10%) published in the period 2000–2009.

The reported safety intervention was deployed in a single clinical area in the majority (70%) of studies, with only 6 studies (30%) reporting interventions across multiple clinical areas. Critical care ($n = 9$ [17–22,24,32]) was the most common setting for intervention deployment, followed by the operating room ($n = 5$ [25,27,30,31,33]).

12 studies involved a single surgical specialty (CTS $n = 9$ [16–21,24,26,32]), ENT surgery $n = 3$ [23,28,29]), 6 studies involved multiple children's surgical specialties within an institution, and in 2 studies, the surgical subspecialties involved were not clearly specified.

2.2. Type of interventions

13 studies [16–23,26–28,30,35] (65%) described an entirely novel intervention, whereas 7 [24,25,29,31–34] (35%) described a

modification and/or local adaptation of an existing intervention imported from adult surgical services.

Interventions were targeted to a variety of safety issues, with the majority addressing postoperative handoff (55%, $n = 11$) and checklist adherence/perioperative patient safety (25%, $n = 5$). The remaining interventions sought to identify safety issues at the patient/process level ($n = 2$) and the service level ($n = 1$) and target intrahospital transfers ($n = 1$).

For the purposes of comparison, interventions were synthesized and classified according to type. The predominant type of intervention was a single-component handoff tool, which accounted for 35% ($n = 7$) of studied interventions. This was followed by a standalone checklist ($n = 5$), a multicomponent handoff tool ($n = 2$) and a multidimensional quality improvement initiative ($n = 2$). The remaining interventions were classed as incident reporting systems ($n = 1$), trigger tools ($n = 1$), HFMEA ($n = 1$) and procedural safety protocols ($n = 1$).

The majority (75%) of studies included a checklist as a component of their intervention or the sole intervention.

2.3. Study designs and efficacy measures

10 studies [16–21,23,26,31,32] were described as prospective pre/post-interventional clinical studies, 4 [29,33–35] were described as prospective analyses, 2 [22,35] were described as a post-interventional

clinical study and the remainder was described as prospective audit and staff survey [25] (n = 1); retrospective questionnaire survey [27] (n = 1); retrospective record review [28] (n = 1), and observational pilot study and post-intervention questionnaire survey [24] (n = 1). No studies included an element of randomization.

In total, 75% of reviewed studies (n = 15 [16–21,23,25,26,29,31–35]) had a prospective design. The median sample size was 79 (range 29–1210). The nature of the study population varied and comprised handoff episodes (n = 7 studies [16–19,21,22,26]); patients (n = 3 studies [23,28,32]); procedures (n = 3 studies [31,33,34]); staff members (n = 3 studies [20,25,27]); and patient transfers (n = 1 study [35]). In 3 studies [24,29,30], the nature and composition of the study population were not clearly specified.

Across the 20 studies reviewed, a large number (n = 55) and variety (n = 35) of measures were employed to evaluate the efficacy of the study intervention (Table 2). Those studies in which the intervention considered safety issues around postoperative handoff employed a total of 30 discrete measures, the majority of which were quantitative (87%, n = 26). Examples of these are duration of handoff; number of interruptions during handoff; number of technical errors; and number of omissions during handoff.

5 studies [25,27,31,33,34] considered checklist adherence and perioperative patient safety. These studies used a considerably smaller subset of efficacy measures with a total of 3 discrete measures of which 2

were quantitative. These measures comprised checklist compliance (n = 5); staff perceptions/attitudes to the intervention (n = 3); and incidence of 'near miss' events (n = 1).

3 studies [28–30] described an intervention, which addressed identifying safety issues at either the service or the patient or process level. These studies only utilized two efficacy measures (the number of variances and type of variance, and the incidence of errors and adverse events), both of which were quantitative in nature.

Finally, 1 study [35] described an intervention addressing intrahospital transfers and utilized 'incidence and type of problems with intra-hospital transfers' as a measure of intervention efficacy.

2.4. Efficacy of interventions to improve children's surgical safety: Synthesis of findings

8 (40%) studies reported a statistically significant positive result (i.e. an improvement in their safety measure/s) as a result of the described intervention. 5 (25%) studies reported an effect size even if it was a rudimentary measure (e.g. confidence intervals).

9 (45%) studies [17–21,23,24,26,32] were successful and concluded that their intervention had a positive effect on patient safety. These studies comprised checklists (n = 1); handoff tools (n = 7); and multi-dimensional quality improvement initiatives (n = 1). The positive effects reported were concluded from significant improvements in clinical effectiveness (n = 9) and efficiency (n = 3).

Only 1 study [20] reported a measurable decrease in morbidity attributed to the study intervention, which was a structured multidisciplinary postoperative handoff process for pediatric cardiothoracic cases.

Some studies addressed the question whether the intended interventions were successfully implemented (as part of their evaluation of intervention efficacy). 9 (45%) studies [16,22,25,27–29,31,34,35] concluded that the implementation of the intervention was successful but found no associated improvement in patient safety as a result. 1 study [30] reported neither a successfully implemented intervention nor an improvement in patient safety.

2.5. Study quality assessment

Quality assessment was feasible and undertaken on 14 (70%) studies [16–21,23,25–28,33–35]. The remaining 6 represented conference proceedings (posters, oral presentations), wherein formal structured quality appraisal was not feasible. Quality assessment scores can be found in Table 1.

13 (92%) studies [16–19,21–23,25–28,34,35] utilized a quantitative methodology (either entirely or as part of a mixed methodology) and the average quality score was 61% (range 0–89%). 9 studies [20,21,23,27,28,34] utilized a qualitative methodology and the average score was 44% (range 11–78%). Across all studies, quantitative studies achieved higher scores than qualitative (Mann–Whitney U = 25, p = 0.03). 8 (57%) studies [16,17,20,21,23,25,26,34] utilized a mixed methodology. In these studies, the quantitative component quality scores were not significantly higher than those for the qualitative component (Mann–Whitney U = 19.50, p = 0.20). We did not observe any association between type of safety intervention (handoff tool, checklist or trigger tool) and study quality score (Kruskal–Wallis = 1.50, p = 0.50).

3. Discussion

While the adult surgical safety literature has been extensively reviewed [2,9,11,12,36–38], this review represents, to the best of our knowledge, the first synthesis of the literature pertaining to patient safety interventions in children's surgery.

The children's surgical patient safety literature is in its early stages, and its growth is reflected in the distribution of studies by year of publication, with the majority published in the last few years. This is an encouraging trend and, if sustained, can lead to a rich evidence base accumulating within a few years. The US, through a number of early

Table 2
Measures of efficacy across reviewed studies.

	Studies utilizing measure (n)
<i>Safety problem/area: handoff</i>	
Duration of handoff	7
Staff experience/attitudes	3
Number of interruptions	2
Rate of technical errors	2
Information omissions	2
Adherence/compliance with handoff tool items/steps	2
Handoff score	2
Coherence of information	2
Handoff cost	1
Realized errors	1
Clinical characteristics and outcomes of the patients	1
Incidence of complications	1
Incidence of adverse events from miscommunication	1
Handoff structure	1
Number of irrelevant handoff data points	1
Quality of learning experience	1
Patient safety	1
Staff perception of teamwork	1
Staff perception of information received	1
Incidence of high-risk events	1
Team performance	1
Staff assessment of handoff quality	1
Patient safety culture	1
RACHS score	1
Time to transition patient to monitoring modalities	1
Time to obtain postoperative XR	1
Time to secure ET tube	1
Time to obtaining vital lab results (lab draw time)	1
% of CXRs taken within 15 min of arrival	1
% of patients placed on monitoring within 3 min	1
<i>Safety problem/area: checklist adherence/perioperative patient safety</i>	
Checklist compliance	5
Staff perceptions/attitudes	3
Incidence of 'near miss' events	1
<i>Safety problem/area: identifying safety issues</i>	
Number of variances and type of variance	1
Incidence of errors and adverse events	1
<i>Safety problem/area: intrahospital transfers</i>	
'Incidence and type of problems with intra-hospital transfers'	1

landmark papers [8,39], could be considered to have spearheaded the global surgical patient safety movement, and this continuing influence is reflected in the large proportion of studies in this review originating from US institutions. However, it is encouraging to see that studies are currently reported across a number of other countries and institutions.

The breakdown of studies by surgical specialty highlights significant disparities, and of note, one of the smallest (by surgeons) specialties – pediatric CTS – accounts for the majority of the children's safety literature. CTS's leading position in the safety research output is perhaps a reflection of the specialty's focus on safety, which may be explained by several factors. Firstly, the nature of congenital cardiac disease is such that the surgical caseload is predominantly high risk, high complexity, and low volume, making active safety management critical [40]. Secondly, CTS is closely associated with critical care, a discipline with considerable history in producing safety interventions. Safety research in CTS is thus invariably interlinked with safety research in cardiac critical care, as is highlighted by the high proportion of studies principally set in the intensive care unit. It should be noted, however, that both of these conditions (a high-risk caseload and a close association with critical care) could arguably equally be attributed to other children's surgical specialties such as pediatric neurosurgery and the neonatal work of pediatric general surgery, yet neither of these has yet to establish a significant body of safety literature. Pediatric CTS has a strong culture of outcome data reporting, driven by extensive work on clinical scoring and risk stratification [41–43]. Along with such scrutiny of outcome data invariably comes consideration of the full range of factors beyond the pathophysiological that influence outcomes, resulting in attention to patient safety and any interventions that might enhance it. Furthermore, pediatric CTS finds itself under considerable scrutiny in both the lay press and the medical literature, further driving attention to safety interventions within the specialty [44–46].

3.1. Interventions

Handoff was the most commonly addressed patient safety issue. Handoff is an attractive area of practice to target, as it represents a safety concern [47] with universal appeal relevant to all children's surgical specialties and applicable to several aspects of their practice. Further, checklists were widely used as an interventional tool, either in the context of a standalone intervention or as part of a multicomponent intervention. This was not an unexpected finding, as checklists are one of the original safety interventions [48] with considerable pedigree outside of healthcare [49] and a relatively high degree of acceptability [38,50,51]. The prevalence of checklists is encouraging, as they represent a standardized intervention; and the use of a common interventional tool across several studies adds to our wider understanding of their efficacy and what determines it. Overall, it was encouraging to observe that a significant number of studies described novel interventions and did not simply replicate existing adult interventions. Indeed, almost all interventions were either entirely novel or a bespoke modification of an existing intervention.

3.2. Methodological critique

3.2.1. Study designs

While authors utilized a variety of study designs, reflecting the heterogeneity of the studies themselves, the significant majority of studies were prospective. None of the included studies were randomized, which may have been the result of relatively small-scale studies without the scope and required support (e.g. by a trials unit) for a randomized intervention. A further consideration is that certain interventions within the surgical safety arena are not easily amenable to randomization. For example, there cannot be a randomized trial of a perioperative checklist in the UK, as national guidance requires the application of the WHO Surgical Safety Checklist across all surgical procedures [52]. With the emergent body of quality improvement techniques applicable to surgery

[53–58], we anticipate quality improvement study designs and methods to appear in the children's surgical literature in the coming years.

Sample sizes varied considerably in quantity and composition. Very few studies sought to formally establish if their sample size was statistically sufficient via formal power analysis and sample size calculations; this is certainly an area for future methodological improvement. The low prevalence of certain safety problems and the typically small patient populations inherent to the highly specialized nature of children's surgical practice render this a real problem for well-designed intervention studies. The solution we envisage is multicenter studies across multiple institutions. Our colleagues with an interest in this area should be encouraged to work with other institutions and establish research collaboratives to deliver suitable study populations and produce interventions with a robust evidence base.

3.2.2. Measures of efficacy

We found multiple and inconsistent measures of efficacy across studies (Table 2). Only a single study reported a decrease in patient morbidity and/or mortality that could be directly attributed to the study intervention. In addition to the variety of measures, a significant proportion was not readily generalizable (i.e. unlikely that they could be satisfactorily applied to the undertaking of a separate study on the same type of intervention in a different setting). This presents a problem for the reproducibility and comparability of studies. If the studies identified in this review are to stimulate the dissemination and widespread adoption of the safety interventions that they describe, then it is necessary that their effects be applicable to other contexts. Equally, if a meaningful synthesis of broadly similar interventions (such as handoff tools) is to be undertaken, it is critical that the measures of effect are comparable. Future studies should aim to utilize standardized and comparable measures of clinical efficacy and patient outcomes. Alongside these, as per the state-of-the-art guidance for the evaluation of clinical interventions [59], measures of process and intervention implementation need to be collected – these include metrics on how well interventions are being delivered (intervention fidelity), to how many of the eligible patients (intervention reach or coverage), and whether they are subjected to any adaptation. Further metrics relating to surgical safety may include rates of (well-defined, clinically appropriate) errors. A suite of metrics is thus required for methodologically sound evaluation of interventions such as those we reviewed here – to allow reproducibility as well as understanding of how to best implement interventions that show promise or clinical efficacy.

3.2.3. Quality assessment

Overall, the quality of studies was not satisfactory. We take the view that high quality reporting of surgical safety studies is a priority. Regardless of the positive or negative study findings, high quality study design and reporting will allow this rapidly expanding field to build up a sufficiently robust evidence base via reviews and meta-analyses in the future. This will in turn allow us to direct our efforts toward interventions of proven efficacy and focus our resources in scaling them up and implementing them across different settings to achieve maximum positive effect on children's surgical patient safety.

3.3. Limitations of this review

This review has a number of limitations, many of which are intrinsic to the evidence base that we covered [60–63]. Firstly, the taxonomy and nomenclature in patient safety research are heterogeneous. While a broad and comprehensive search strategy was undertaken, it is possible that owing to the diversity of study terminology, some studies were overlooked. To counteract this, the search strategy was reviewed by a senior surgical safety academic (NS). Secondly, a number of types of study that could potentially be considered as constituting patient safety intervention research were deliberately excluded from this review. Studies pertaining to medication errors, regional or national reconfiguration of

services and aspects of medical education were excluded. This decision was taken, as it was felt that such studies are invariably either broad quality improvement undertakings lacking a single salient safety intervention or broad pan-institution undertakings not necessarily unique to children's surgery. Studies describing novel or modified clinical and/or operative techniques were also excluded, although it is acknowledged that these are often developed with the aim of improving the safety of a surgical procedure. Nevertheless, such work was excluded from this review, as the subject matter was considered outside the remit of the review. Finally, it was not possible to undertake a meta-analysis of the included studies. The subject matter and methodology of the included studies were too diverse and the outcome measures too varied for comparison to be possible.

3.4. Implications for surgical practice and further research

This review has identified that while the evidence base is overall small, it offers a promising foundation for future development, evaluation and application of evidence-based children's surgical safety interventions. Furthermore, a number of these studies can be seen to be demonstrably efficacious. The question is: Which interventions should children's surgeons aspiring to increase patient safety deploy in their own institutions? In this review, interventions comprising handoff tools offered the most clearly demonstrable improvements in patient safety. Safe handoff is integral to the practice of all pediatric specialties regardless of the nature of the clinical work and thus represents a common ground with regard to risk. Thus, those looking for a starting point for incorporating safety interventions into their practice should consider adopting one of the handoff interventions identified in this review as a first step.

Moving forward, there remains a need to broaden the range of children's surgical safety interventions. We urge our colleagues to seek collaborative multicenter multidisciplinary studies to achieve sufficient patient populations to evaluate definitively intervention efficacy. In addition to research, effective clinical implementation is also critical. This review lays a first foundation for our colleagues to evaluate the range of interventions reported and their effectiveness, and to consider what could readily be applied to routine children's surgical practice. By producing high-quality safety evidence and also by closing the gap between evidence and practice, we can aspire to improve the safety of care routinely offered to our patients and ultimately improve their postoperative outcomes.

4. Conclusions

The nature of surgical practice in the pediatric population is in many ways distinct from that in the adult population. The delivery of safe children's surgical care requires development and application of bespoke evidence-based pediatric surgical safety interventions. The onus is now on children's surgeons to develop an evidence base to rival that of the adult literature and to implement proven interventions into their routine practice.

Acknowledgments

Contributors: Andrew C Macdonald: independent review of articles and quality assessment.

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