

Airway management in the paediatric difficult intubation registry: a propensity score matched analysis of outcomes over time



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Summary

Background The Paediatric Difficult Intubation Collaborative identified multiple attempts and persistence with direct laryngoscopy as risk factors for complications in children with difficult tracheal intubations and subsequently engaged in initiatives to reduce repeated attempts and persistence with direct laryngoscopy in children. We hypothesised these efforts would lead to fewer attempts, fewer direct laryngoscopy attempts and decrease complications.

Methods Paediatric patients less than 18 years of age with difficult direct laryngoscopy were enrolled in the Paediatric Difficult Intubation Registry. We define patients with difficult direct laryngoscopy as those in whom (1) an attending or consultant obtained a Cormack Lehane Grade 3 or 4 view on direct laryngoscopy, (2) limited mouth opening makes direct laryngoscopy impossible, (3) direct laryngoscopy failed in the preceding 6 months, and (4) direct laryngoscopy was deferred due to perceived risk of harm or poor chance of success. We used a 5:1 propensity score match to compare an early cohort from the initial Paediatric Difficult Intubation Registry analysis (August 6, 2012–January 31, 2015, 785 patients, 13 centres) and a current cohort from the Registry (March 4, 2017–March 31, 2023, 3925 patients, 43 centres). The primary outcome was first attempt success rate between cohorts. Success was defined as confirmed endotracheal intubation and assessed by the treating clinician. Secondary outcomes were eventual success rate, number of attempts at intubation, number of attempts with direct laryngoscopy, the incidence of persistence with direct laryngoscopy, use of supplemental oxygen, all complications, and severe complications.

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Findings First-attempt success rate was higher in the current cohort (42% vs 32%, OR 1.5 95% CI 1.3–1.8, $p < 0.001$). In the current cohort, there were fewer attempts (2.2 current vs 2.7 early, regression coefficient -0.5 95% CI -0.6 to -0.4 , $p < 0.001$), fewer attempts with direct laryngoscopy (0.6 current vs 1.0 early, regression coefficient -0.4 95% CI -0.4 to 0.3 , $p < 0.001$), and reduced persistence with direct laryngoscopy beyond two attempts (7.3% current vs 14.1% early, OR 0.5 95% CI 0.4–0.6, $p < 0.001$). Overall complication rates were similar between cohorts (19% current vs 20% early). Severe complications decreased to 1.8% in the current cohort from 3.2% in the early cohort (OR 0.55 95% CI 0.35–0.87, $p = 0.011$). Cardiac arrests decreased to 0.8% in the current cohort from 1.8% in the early cohort. We identified persistence with direct laryngoscopy as a potentially modifiable factor associated with severe complications.

Interpretation In the current cohort, children with difficult tracheal intubations underwent fewer intubation attempts, fewer attempts with direct laryngoscopy, and had a nearly 50% reduction in severe complications. As persistence with direct laryngoscopy continues to be associated with severe complications, efforts to limit direct laryngoscopy and promote rapid transition to advanced techniques may enhance patient safety.

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Research in context

Evidence before this study

Prior to this study, audits of paediatric anaesthesia practice revealed reliance on direct laryngoscopy for both routine and difficult airway management in neonates and children. Previous work from the Paediatric Difficult Intubation Collaborative identified that direct laryngoscopy has a poor chance of success and that multiple tracheal intubation attempts and repeated direct laryngoscopy are associated with complications in children with difficult tracheal intubations. Recent guidelines have emphasised the importance of limiting the number of attempts at tracheal intubation. The aim of this study was to evaluate if there have been changes in the management and outcomes of paediatric patients with difficult tracheal intubations in the context of these data and guidelines.

Added value of this study

We identified a decrease in the number of tracheal intubation attempts and number of attempts with direct laryngoscopy,

as well as a nearly 50% reduction in the incidence of severe complications in children with difficult tracheal intubations enrolled in the Paediatric Difficult Intubation Registry. Dissemination of the results of previous research have spurred quality improvement efforts over the last decade, leading to changes in both patient management and improved patient outcomes. Despite these improvements, children with difficult tracheal intubations still experience serious complications, including cardiac arrest, at higher rates than the general paediatric population. Persistence with direct laryngoscopy remains a modifiable risk factor associated with severe complications.

Implications of all the available evidence

This study reveals changes in patient management and associated improvements in patient outcomes over the past decade. Further improvements in patient outcomes may be possible with additional efforts to limit direct laryngoscopy in paediatric patients with difficult tracheal intubations.

Introduction

In the initial report from the Paediatric Difficult Intubation (PeDI) Registry, children with difficult direct laryngoscopy had a 3% incidence of severe complications, including a 2% incidence of cardiac arrest associated with airway management.¹ Analysis revealed that direct laryngoscopy had a very poor chance of success in these children and that multiple intubation attempts were associated with increased complications. Several follow-up studies have identified patient groups in whom different techniques are associated with improved success and reduced complication rates.^{2–5}

However, in many instances, children with difficult tracheal intubations are still routinely managed with direct laryngoscopy.^{6,7}

Following the initial PeDI Registry publication in 2016, the collaborative made efforts to increase awareness of the relationship between multiple attempts at direct laryngoscopy and the incidence of severe complications. Educational efforts included disseminating these results via lectures at national meetings, monthly reports to PeDI Registry members of benchmarked institutional data and aggregate data to change practice patterns and improve patient outcomes, and creating a

difficult airway bundle checklist for use prior to airway management (Supplemental Fig. S1).⁸ Concurrently, the American Society of Anesthesiologists (ASA), in collaboration with several partner societies, developed and published a paediatric-specific difficult airway algorithm and infographic that emphasises limiting the number of attempts.⁹

We conducted the present study to evaluate whether there has been a change in practice and outcomes in children enrolled in the PeDI Registry. Since the initial publication, 30 additional centres in North America, South America, Europe, India, and Australia have been added to the registry, along with more than 4000 additional patient encounters. We hypothesised that educational efforts targeting a reduction in the number of total airway attempts and the number of attempts with direct laryngoscopy in paediatric patients would result in changes in clinical practice, resulting in fewer attempts and fewer complications in the current cohort of patients.

Our primary aim was to determine if the first attempt success rate for tracheal intubation changed in the PeDI Registry following the publication of the initial cohort data. Key secondary aims were to determine if the number of attempts at intubation, number of attempts with direct laryngoscopy, incidence of persistence with direct laryngoscopy, all complications, and severe complications changed over time. Patients were entered into the registry based on four previously published criteria. We planned a subgroup analysis of patients entered into the registry due to a poor direct laryngoscopy view by the consultant or attending as this subgroup represents patients in whom the recommendations to minimise attempts with direct laryngoscopy may be most relevant. We performed a multivariable analysis to identify clinical factors associated with the incidence of severe complications in the current cohort of patients.

Methods

Study population

Patients younger than 18 years who received care under the direction of a consultant or attending anaesthetist in one of the participating centres entered into the PeDI Registry by meeting one of four criteria:¹

- 1) difficult laryngeal exposure with conventional direct laryngoscopy as assessed by the consultant or attending physician in anaesthesia or otolaryngology (Cormack and Lehane classification ≥ 3);¹⁰
- 2) conventional direct laryngoscopy is physically impossible because of anatomical reasons (e.g., severely limited mouth opening or other craniofacial anomalies);
- 3) history of failure of traditional direct laryngoscopy within the preceding six months;
- 4) the consultant or attending anaesthetist defers conventional direct laryngoscopy due to a known or

suspected poor chance of success and/or increased potential for harm.

Patients could meet multiple criteria for enrolment.

Clinicians caring for the patients completed a standardised data collection form (Appendix 1) which were then verified by the site's principal investigator. The standardised data collection forms were updated and expanded in March 2017, when the current cohort in this study began. Data were submitted by 44 institutions from August 2012 through March 2023. Cases from two institutions were excluded due to unreliable data entry discovered upon review for data quality audits. Some patients included in this analysis were also included in prior analyses published in studies from the PeDI Registry.^{1-5,11-13}

Ethics

The Boston Children's Hospital's Institutional Review Board granted approval with waiver of informed consent for this retrospective analysis of prospectively collected registry data (IRB P00005718 and P00040870). The study was also approved by the multi-institutional data-sharing agreement of the PeDI Registry and approved by the Executive Committee of the PeDI Registry. The PeDI Registry is a collaborative, multicentre, international registry created under the auspices of the Society for Paediatric Anaesthesia (SPA) to collect data about children with difficult tracheal intubation and has been previously described.¹ In April 2022, an email was sent to the members of the PeDI Collaborative soliciting interest in participating in the design and analysis for this study. In May 2022, we conducted a meeting to discuss and refine the analysis plan within the group prior to beginning the study. This study adheres to applicable STROBE guidelines.

Definitions

Successful tracheal intubation, complications, and video laryngoscopy blades were defined as in previous reports from the PeDI Registry.^{1-3,5,12,14} Severe complications included: death, cardiac arrest, severe airway trauma, oesophageal intubation with delayed recognition, aspiration, and pneumothorax. Non-severe complications included: hypoxemia (decrease in the pre-intubation SpO₂ of $\geq 10\%$ for >60 s), minor airway trauma (dental or lip), oesophageal intubation with immediate recognition, laryngospasm, bronchospasm, pharyngeal bleeding, epistaxis, arrhythmia without hemodynamic consequences, and emesis without aspiration. For video laryngoscopy, standard Macintosh and Miller type blade configurations allow the laryngoscopist to align the patient's oral, pharyngeal and laryngeal axes to facilitate direct visualisation while also providing video imaging of the glottic opening. Hyperangulated blade video laryngoscopes are defined as any video laryngoscope with a blade

design such that attempting direct visualisation of the glottic opening is impractical. Tracheal intubation with this blade type is intended to occur using only indirect video imaging.

For the purpose of classifying entry criteria, a patient could be enrolled as criteria 1 if a consultant or attending physician in anaesthesia attempted direct visualisation of the airway with a standard Macintosh or Miller blade video laryngoscope and reported a grade 3 or 4 view. For all other purposes, including the reporting of outcomes and complications, we report direct laryngoscopy separately from any type of video laryngoscopy.

We use the term “persistence with direct laryngoscopy” to refer to encounters in which three or more attempts were made with direct laryngoscopy.

Outcomes

The primary outcome was first attempt success rate. Secondary outcomes were eventual success rate, number of attempts at intubation, number of attempts with direct laryngoscopy, the incidence of persistence with direct laryngoscopy, use of supplemental oxygen, all complications, and severe complications.

Cohorts

The early cohort was defined by the initial report from the PeDI Registry (August 2012–January 2015).¹ The current cohort was defined from the initiation of an updated data collection form allowing for more granular description of intubation attempts and complications in March 2017 to March 2023. First attempt success rates and complications demonstrated a steady improvement over time ([Supplemental Figures S2](#)), comparisons were made using two cohorts rather than linear trends given the practical aspects of data collection (i.e., change in data forms). Additionally, these periods allow us to assess the impact of recommendations based on the analysis of the original cohort in the current practice in the PeDI Registry.

Statistics

We performed five-to-one propensity score matching to account for differences between the early PeDI Registry cohort (August 2012–January 2015) and a current cohort of patients (March 2017–March 2023) using absolute standardised mean differences. In addition to the above inclusion criteria, we required complete data for matching characteristics and primary outcome (first attempt success) for study inclusion. Patients with missing data for secondary outcomes were excluded from those analyses with sample size indicated in text and tables. We matched for age, weight, sex, ASA physical status, PeDI Registry entry criterion, the presence or absence of abnormal physical exam findings on the treating clinician’s preanaesthetic assessment ([Appendix 2](#)), the presence of one or more medical diagnoses or syndromes commonly associated with airway

physical exam findings that often result in difficult direct laryngoscopy ([Appendix 3](#)), anticipated difficulty with tracheal intubation as determined by the treating clinician, and training status of the initial clinician managing the airway. Sex was reported by the treating clinicians as a biological factor. Gender was not recorded in the PeDI Registry. We performed matching using nearest neighbour greedy matching with a calliper width of 0.2 times the standard deviation of the logit of the propensity score.¹⁵ An absolute standardised mean difference <0.1 indicates a good balance between propensity-matched groups. Propensity scores were calculated using multivariable general estimating equation (GEE) modelling to account for clustering of patients within centres. The assumption of linearity of continuous variables against the logit function was assessed using the Box–Tidwell test. We performed logistic regression and report odds ratios or regression coefficients as well as 95% confidence intervals and p-values to compare outcomes between matched cohorts. We calculated regressions using GEE modelling to account for the clustering of patients within matched sets. We performed multivariable analysis of factors associated with the occurrence of severe complications in the full unmatched current cohort. Incidence of any severe complication (one or more) was analysed on a per encounter basis. Factors associated with severe complications at a level of $p < 0.1$ in univariate analysis were included in the multivariable model. We set statistical significance at a two-tailed p-value <0.05. We stored data in a REDCap database (Vanderbilt University, Nashville, Tennessee, USA) hosted at the Children’s Hospital of Philadelphia and audited monthly for accuracy and completeness. We performed statistical analyses using Stata (version 16, StataCorp LLC., College Station, Texas, USA).

Role of the funding source

This study was supported by departmental funds from the participating institutions with no external funding source, as such funders had no role in the design of the study, data collection, data analyses, interpretation, or writing of this report.

Results

We compared an early cohort of patients enrolled in the PeDI Registry from its inception in August 2012 through January 2015 and a current cohort enrolled from March 2017 through March 2023. The early cohort included 1049 cases contributed by 13 centres. The current cohort included 5224 cases contributed by 44 centres: 12 of the centres in the early cohort along with 32 new ones ([Supplemental Table S1, Appendix 4](#)). Data from two centres were excluded for data quality issues.

We performed propensity score matching to compare similar groups of patients from the early and

current cohorts (Table 1). Prior to matching, the cohorts differed with respect to ASA physical status, the criterion for registry entry, the presence of abnormalities on physical examination, anticipated difficulty, and initial clinician managing the airway. After 5 to 1 matching, the cohorts were similar on all variables with a standardised mean difference (SMD) less than 0.1, indicating good balance. There were 785 patients in the early matched cohort and 3925 patients in the current matched cohort.

The current cohort had a significantly higher first-attempt success than the early cohort (41.7% (1635/3925) vs 32% (251/785) (OR 1.5, 95% CI 1.3–1.9, $p < 0.001$, Table 2). Eventual success rates did not differ between cohorts (98.6% (3871/3925) current and 98.2% (771/785) early, OR 1.3, 95% CI 0.72–2.35, $p = 0.4$). On average, the current cohort had fewer attempts at tracheal intubation than the early cohort (2.2 attempts current vs 2.7 attempts early, regression coefficient -0.48 , 95% CI -0.58 to -0.37 , $p < 0.001$).

The current cohort had fewer attempts with direct laryngoscopy (0.6 current vs 1.0 early, regression coefficient -0.36 , 95% CI -0.44 to -0.28 , $p < 0.001$). There was less persistence with direct laryngoscopy in the current cohort compared with the early cohort (7.3% (287/3925) current vs 14.1% (111/785) early, OR 0.5, 95% CI 0.4–0.6, $p < 0.001$).

Use of supplemental oxygen during intubation attempts increased from 8% (63/785) in the early cohort to 21.8% (856/3925) in the current cohort (OR 3.2 95% CI 2.4–4.2, $p < 0.001$). Maintenance of spontaneous ventilation during intubation decreased from a rate of 30% (234/780) in the early cohort to 19.2% (753/3919) in the current cohort (OR 0.55 95% CI [0.47–0.66], $p < 0.001$). Induction and intubation performed with controlled ventilation with a neuromuscular blocking agent increased between cohorts (44% (346/780) early vs 56% (2173/3919) current, OR 1.56 95% CI 1.34–1.82, $p < 0.001$). The incidence of impossible ventilation decreased between cohorts, although absolute incidence

	Before Matching			After Propensity Score Matching (5-1)		
	Early cohort	Current cohort	SMD	Matched early cohort	Matched current cohort	SMD
Number of patients	1049	5224		785	3925	
Age (years)	5 (0.7, 12)	5.7 (0.9, 12.7)	0.07	5.9 (0.7, 12.3)	5.5 (0.8, 12.6)	<0.01
Weight (kilograms)	16.3 (6.6, 33.7)	17.3 (7.5, 36.2)	0.08	18 (6.7, 34)	16.9 (7, 36)	0.02
Sex						
Male	611 (58.3%)	2927 (56%)	0.04	438 (55.8%)	2235 (56.9%)	0.02
Female	438 (41.7%)	2297 (44%)		347 (44.2%)	1690 (43.1%)	
ASA-PS						
I/II	227 (21.6%)	1249 (23.9%)	0.1	174 (22.2%)	932 (23.8%)	0.05
III	695 (66.3%)	3269 (62.6%)		511 (65.1%)	2489 (63.4%)	
IV	126 (12%)	682 (13.1%)		99 (12.6%)	494 (12.6%)	
V	1 (0.1%)	24 (0.5%)		1 (0.1%)	10 (0.3%)	
Emergency status	58 (5.5%)	468 (9%)	0.13	50 (6.4%)	303 (7.7%)	0.05
Abnormal physical exam?	912 (86.9%)	4201 (80.4%)	0.18	672 (85.6%)	3260 (83.1%)	0.07
Airway associated syndrome?	728 (69.4%)	3356 (64.2%)	0.1	538 (68.5%)	2568 (65.4%)	0.07
Anticipated difficulty?	839 (80%)	4477 (85.7%)	0.15	647 (82.4%)	3289 (83.8%)	0.04
Initial clinician managing the airway						
Trainee	603 (57.5%)	2992 (57.3%)	0.16	450 (57.3%)	2213 (56.4%)	0.07
CRNA	174 (16.6%)	665 (12.7%)		124 (15.8%)	550 (14%)	
Attending anaesthesiologist	236 (22.5%)	1281 (24.5%)		179 (22.8%)	980 (25%)	
Otolaryngologist	29 (2.8%)	185 (3.5%)		25 (3.2%)	136 (3.5%)	
Other	7 (0.7%)	101 (1.9%)		7 (0.9%)	46 (1.2%)	
Criteria for registry entry?						
1—Poor DL view by attending	382 (36.4%)	1237 (23.7%)	0.28	232 (29.6%)	1137 (29%)	0.01
2—Limited mouth opening	211 (20.1%)	625 (12%)	0.22	136 (17.3%)	595 (15.2%)	0.06
3—Failed DL in last 6 months	152 (14.5%)	433 (8.3%)	0.2	89 (11.3%)	407 (10.4%)	0.03
4—Anticipated difficulty, attending DL deferred	390 (37.2%)	3173 (60.7%)	0.48	378 (48.2%)	1996 (50.9%)	0.05

Findings meeting the criteria for the presence or absence of abnormal physical exam findings on the treating clinician's preanaesthetic assessment and the presence or absence of a syndrome associated with airway involvement are listed in the appendices. Patients could meet multiple criteria for Registry entry. Continuous data are presented as median (interquartile range) and categorical data are presented as n (%). Standardised mean difference (SMD) values less than 0.1 are considered as indicating good balance between the two groups. Propensity scores were calculated using multivariable GEE modelling to account for clustering of patients within centres. ASA-PS—American Society of Anesthesiologists Physical Status, CRNA—certified registered nurse anaesthetist, DL—direct laryngoscopy.

Table 1: Patient characteristics and matching.

	Matched early cohort	Matched current cohort	Odds Ratio or Regression Coefficient (95% CI)	p-value
Number of patients	785	3925		
First attempt success	251 (32%)	1635 (41.7%)	1.52 (1.29, 1.78)	<0.001 ^a
Eventual success	771 (98.2%)	3871 (98.6%)	1.3 (0.72, 2.35)	0.383
Number of attempts	2.7 ± 1.9	2.2 ± 1.4	-0.48 (-0.59, -0.37)	<0.001 ^a
Number of attempts with DL	1.0 ± 1.3	0.6 ± 1.0	-0.36 (-0.44, -0.28)	<0.001 ^a
DL persistence (more than 2 attempts with DL)	111 (14.1%)	287 (7.3%)	0.48 (0.38, 0.6)	<0.001 ^a
Supplemental O ₂	63 (8%)	856 (21.8%)	3.2 (2.44, 4.18)	<0.001 ^a
Ventilation technique				
Spontaneous ventilation	234/780 (30%)	753/3919 (19.2%)	0.55 (0.47, 0.66)	<0.001 ^a
Controlled ventilation without muscle relaxant	194/780 (24.9%)	985/3919 (25.1%)	1.01 (0.85, 1.21)	0.877
Controlled ventilation with muscle relaxant	346/780 (44.4%)	2173/3919 (55.5%)	1.56 (1.34, 1.82)	<0.001 ^a
Impossible ventilation	6/780 (0.8%)	8/3919 (0.2%)	0.26 (0.09, 0.76)	0.014 ^a
Successful device	n = 783	n = 3922		
Direct laryngoscope	93 (11.9%)	324 (8.3%)	0.67 (0.52, 0.85)	0.001 ^a
Standard blade VL	39 (5%)	1224 (31.2%)	8.66 (6.24, 12)	<0.001 ^a
Hyperangulated blade VL	282 (36%)	1061 (27.1%)	0.66 (0.56, 0.77)	<0.001 ^a
Flexible intubation scope	203 (25.9%)	643 (16.4%)	0.56 (0.47, 0.67)	<0.001 ^a
Combination technique	135 (17.2%)	502 (12.8%)	0.7 (0.57, 0.87)	0.001 ^a
Other	14 (1.8%)	86 (2.2%)	1.23 (0.69, 2.18)	0.475
Surgical airway	3 (0.4%)	28 (0.7%)	1.87 (0.56, 6.19)	0.306
Failed intubation, alternative airway management (SGA, mask, awaken patient)	14 (1.8%)	54 (1.4%)	0.77 (0.42, 1.39)	0.38

Data are presented as n (%) or mean ± SD. Odds ratios or regression coefficients, 95% confidence intervals, and p values were calculated using GEE modelling to account for clustering of patients within matched sets. Fisher's exact test was implemented for categorical data. DL—direct laryngoscopy, VL—video laryngoscopy, SGA—supraglottic airway. ^aStatistically significant at p < 0.05.

Table 2: Airway management outcomes.

was low (0.8% (6/780) early vs to 0.2% (8/3919) current, OR 0.26 95% CI 0.09–0.76, p = 0.014).

The successful use of standard Macintosh or Miller blade video laryngoscopes increased significantly from 5% of cases (39/783) in the early cohort to 31.2% of cases (1224/3922) in the current cohort (OR 8.66 95% CI 6.24–12, p < 0.001, Fig. 1, Table 2). Concomitantly, the successful use of direct laryngoscopes, hyperangulated blade video laryngoscopes, flexible intubation scopes, and combination techniques decreased from the early cohort to the current cohort.

Complications

The matched cohorts had similar incidence of complications (19.4% (762/3925) current vs 20.2% (158/785) early, OR 0.95 95% CI 0.8–1.2, p = 0.6, Table 3). The incidence of severe complications (death, cardiac arrest, severe airway trauma, oesophageal intubation with delayed recognition, aspiration, and pneumothorax) was significantly lower in the current cohort (1.8% (70/3925) current vs 3.2% (25/785) early, OR 0.55 95% CI 0.35–0.9, p = 0.011). The incidence of cardiac arrest decreased from 1.8% (14/785) in the early cohort to 0.8% (32/3925) in the current cohort. The incidence of non-severe complications did not differ significantly between cohorts (18.8% (738/3925) current vs 19% (149/785) early, OR 0.99 95% CI 0.8–1.2, p = 0.9).

Criterion 1—poor view on direct laryngoscopy by a consultant or attending anaesthetist

We performed a prespecified analysis of patients who entered the registry for poor direct laryngoscopy view by a consultant or attending physician between the matched groups, as this subgroup represents the patients in whom the recommendations to minimise attempts with direct laryngoscopy and transition to alternative techniques would be most applicable (Supplemental Table S2). Baseline demographics revealed that the median age of patients entered as criterion 1 in the current cohort was older than in the early cohort (2.9 years, IQR 0.3–11.8 years current vs 1.7 years, IQR 0.3–11.8 years early). There were fewer attempts at tracheal intubation in the current cohort than in the early cohort (3.2 attempts current vs 3.9 attempts early, regression coefficient -0.7, 95% CI -0.93 to -0.46, p < 0.001). The current cohort also had fewer attempts with direct laryngoscopy (1.6 current vs 2.1 early, regression coefficient -0.5, 95% CI -0.67 to -0.31, p < 0.001). In the current cohort, there was less persistence with direct laryngoscopy (21.7% (247/1137) current vs 34.9% (81/232) early, OR 0.52, 95% CI 0.38–0.7, p < 0.001).

There were differences in the first attempt device between the current and early cohorts driven by an increase in the use of standard blade video laryngoscopy

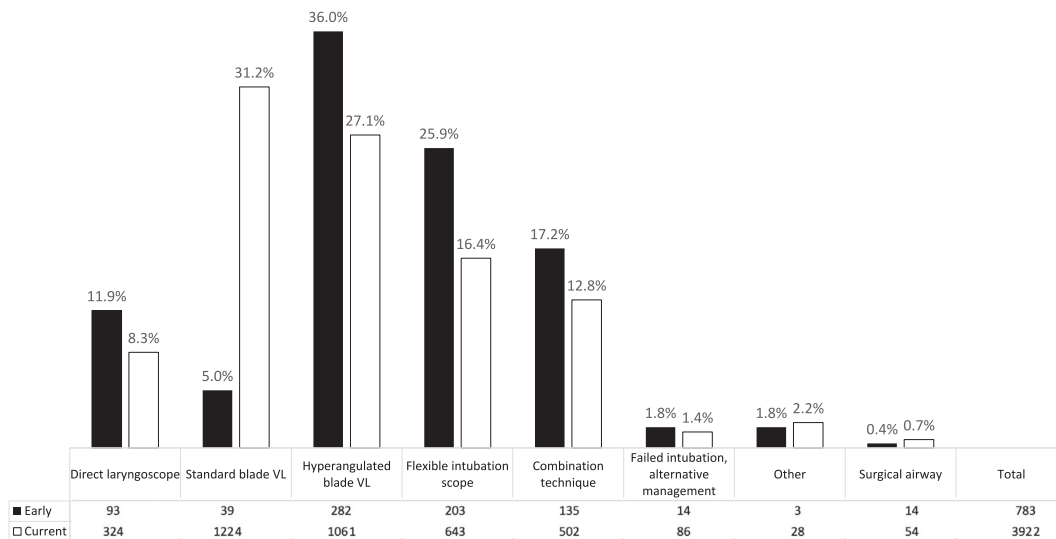


Fig. 1: Successful technique for tracheal intubation in early and current cohorts. The frequency of successful use of different techniques for tracheal intubation in the early and current cohorts are provided with percentages as well as numerators and denominators. The successful use of standard Macintosh or Miller blade video laryngoscopy increased significantly from 4% of cases (39/783) in the early cohort to 31.2% of cases (1224/3922) in the current cohort and the successful use of direct laryngoscopy, hyperangulated blade video laryngoscopy, flexible intubation, and combination techniques decreased from the early cohort to the current cohort.

for the first attempt (12.7% (144/1137) current vs 2.6% (6/232) early). There were also differences in the successful device between the current and early cohorts driven by an increase in the use of standard blade video laryngoscopy (26.7% (304/1137) current vs 5.2% (12/

230) early) and a decrease in the use of flexible intubation scopes (7.5% (85/1137) current vs 15.7% (36/230) early) for the successful attempt.

Overall complications did not differ significantly between groups, with complications occurring in 28.5%

	Matched early cohort	Matched current cohort	Odds Ratio (95% CI)	p-value
Number of patients	785	3925		
Any complications	158 (20.2%)	762 (19.4%)	0.95 (0.79, 1.16)	0.633
Severe complications (any)	25 (3.2%)	70 (1.8%)	0.55 (0.35, 0.87)	0.011 ^a
Death	4 (0.5%)	9 (0.2%)		
Cardiac arrest	14 (1.8%)	32 (0.8%)		
Severe airway trauma	11 (1.4%)	25 (0.6%)		
Oesophageal intubation with delayed recognition	0 (0%)	3 (0.1%)		
Aspiration	0 (0%)	8 (0.2%)		
Pneumothorax	1 (0.1%)	6 (0.2%)		
Non-severe complications (any)	149 (19%)	738 (18.8%)	0.99 (0.81, 1.2)	0.907
Hypoxemia	70 (8.9%)	392 (10%)		
Minor airway trauma	33 (4.2%)	116 (3%)		
Oesophageal intubation with immediate recognition	20 (2.6%)	102 (2.6%)		
Laryngospasm	26 (3.3%)	76 (1.9%)		
Bronchospasm	0 (0%)	31 (0.8%)		
Pharyngeal bleeding	8 (1%)	107 (2.7%)		
Epistaxis	6 (0.8%)	51 (1.3%)		
Arrhythmia	1 (0.1%)	7 (0.2%)		
Emesis	1 (0.1%)	14 (0.4%)		
Other	23 (2.9%)	108 (2.8%)		

Data are presented as n (%) or mean ± SD. Odds ratios, 95% confidence intervals, and p values were calculated using GEE modelling to account for clustering of patients within matched sets. Fisher's exact test was implemented for categorical data. ^aStatistically significant at p < 0.05.

Table 3: Airway management complications.

(324/1137) of cases in the current cohort and 29.3% (71/232) of cases in the early cohort (OR 0.9, 95% CI 0.66–1.23, $p = 0.521$). The rate of severe complications was also comparable, with 3.8% (43/1137) in the current cohort and 6.5% (15/232) in the early cohort (OR 0.57, 95% CI 0.31–1.05, $p = 0.07$). In both the early and current cohorts, complication rates were higher in patients who entered the registry for criterion 1 than in the full cohorts: Current cohort criterion 1: 28.5% any complication, 3.5% severe complication vs current cohort all criteria: 19.4% any complication, 1.8% severe complication; Early cohort, criterion 1: 29.3% any complication, 6.5% severe complication vs early cohort all criteria: 20.2% any complication, 3.2% severe complication.

Factors associated with severe complications in current cohort

We performed an analysis of the unmatched current cohort to identify factors associated with severe complications. This unmatched cohort included 5224 patient encounters; 91 (1.7%) encounters had one or more severe complications and 5133 (98.3%) did not have severe complications (Supplemental Table S3). As the number of attempts at tracheal intubation increased, incidence of all complications and of severe complications increased (Fig. 2). For patients who did not experience severe complications, there was a median of two attempts at tracheal intubation (IQR 1–3), while for patients who did experience severe complications there was a median of three attempts at tracheal intubation (IQR 2–5) (OR 1.58, 95% CI 1.45–1.73, $p < 0.001$).

We developed a multivariable model for severe complications in this current cohort (Table 4). While younger age and lower weight were significantly associated with the incidence of severe complications in univariate analysis (median age no severe complications 5.8 years, median age severe complications 1.2 years, median weight no severe complications 17.6 kg, median weight severe complications 9.2 kg), those associations did not persist in the multivariable model (aOR for weight 0.99, 95% CI 0.97–1.01, $p = 0.131$, colinear with age). In the multivariable model, the presence of airway and/or craniofacial abnormalities on preprocedural physical examination (Appendix 2) was associated with an increased incidence of severe complications (aOR 2.89 95% CI 1.35–6.21, $p = 0.006$). Higher ASA physical status was associated with increased incidence of severe complications relative to ASA I and II patients (ASA IV aOR 5.16 95% CI 2.45–10.9, $p < 0.001$, ASA V aOR 8.04% CI 1.49–43.4, $p = 0.015$). Emergency procedures were also associated with an increased incidence of severe complications relative to non-emergent procedures (aOR 2.4 95% CI 1.37–4.2, $p = 0.002$). Although 9% (468/5224) of cases were categorised as emergency procedures, 38% (35/91) of severe complications occurred in emergency cases including 4/10 deaths, 19/41 cardiac arrests, and 2/10 aspiration events.

Training level of the initial clinician managing the airway was not significantly associated with the incidence of severe complications in the multivariable model. Encounters in which the anaesthesia team did not induce anaesthesia (e.g., called to assist in an emergency in another location) were associated with

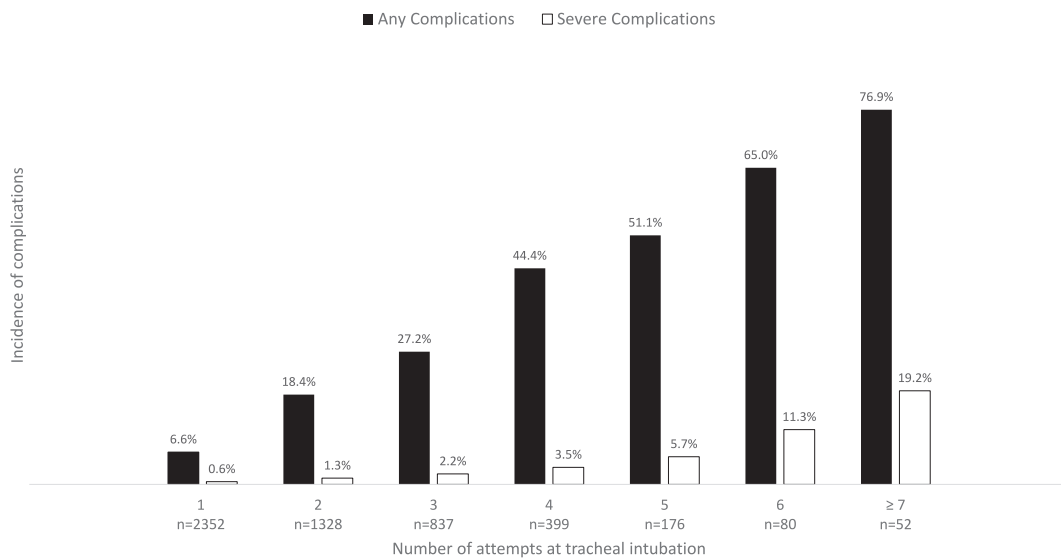


Fig. 2: Incidence of complications increases with number of attempts in full current cohort. The incidence of all complications and severe complications during each intubation attempt in the full unmatched current cohort are provided. The incidence of complications and severe complications increased with each additional intubation attempt.

Variable	No severe complications	Severe complications	Univariate analysis		Multivariable analysis	
	n = 5133	n = 91	OR (95% CI)	p-value	aOR (95% CI)	p-value
Age (years)	5.8 (0.9, 12.8)	1.2 (0.4, 7.4)	0.92 (0.88, 0.96)	<0.001 ^a	Omitted due to collinearity with weight	
Weight (kilograms)	17.6 (7.7, 36.3)	8.8 (4.5, 21)	0.98 (0.96, 0.99)	<0.001 ^a	0.99 (0.97, 1.01)	0.131
Sex						
Male	2876 (56%)	51 (56%)	1 (0.66, 1.52)	0.998		
Female	2257 (44%)	40 (44%)	Reference			
Abnormal physical exam?	4120 (80.3%)	81 (89%)	2 (1.03, 3.86)	0.041 ^a	2.89 (1.35, 6.21)	0.006 ^a
Airway associated syndrome?	3302 (64.3%)	54 (59.3%)	0.81 (0.53, 1.23)	0.326		
ASA-PS						
I/II	1237 (24.1%)	12 (13.2%)	Reference		Reference	
III	3228 (62.9%)	41 (45.1%)	1.31 (0.69, 2.5)	0.414	1.57 (0.79, 3.14)	0.198
IV	647 (12.6%)	35 (38.5%)	5.58 (2.87, 10.8)	<0.001 ^a	5.16 (2.45, 10.9)	<0.001 ^a
V	21 (0.4%)	3 (3.3%)	14.7 (3.86, 56.1)	<0.001 ^a	8.04 (1.49, 43.4)	0.015 ^a
Emergency status	443 (8.6%)	25 (27.5%)	4.01 (2.51, 6.42)	<0.001 ^a	2.4 (1.37, 4.2)	0.002 ^a
Anticipated difficulty?	4405 (85.8%)	74 (79.1%)	0.63 (0.38, 1.04)	0.073	1.08 (0.54, 2.18)	0.828
Initial clinician managing the airway						
Trainee	2933 (57.1%)	59 (64.8%)	1.05 (0.65, 1.7)	0.831	1.36 (0.8, 2.3)	0.255
CRNA	662 (12.9%)	3 (3.3%)	0.24 (0.07, 0.79)	0.019 ^a	0.32 (0.09, 1.15)	0.081
Attending anaesthesiologist	1257 (24.5%)	24 (26.4%)	Reference		Reference	
Otolaryngologist	182 (3.6%)	3 (3.3%)	0.86 (0.26, 2.9)	0.812	0.43 (0.11, 1.68)	0.225
Other	99 (1.9%)	2 (2.2%)	1.06 (0.25, 4.54)	0.939	0.51 (0.1, 2.49)	0.404
Induction technique n = 5131						
Mask	2705 (52.7%)	38 (41.8%)	Reference		Reference	
IV induction	2220 (43.3%)	37 (40.7%)	1.19 (0.75, 1.87)	0.463	1.1 (0.67, 1.81)	0.703
IV sedation	122 (2.4%)	6 (6.6%)	3.5 (1.45, 8.43)	0.005 ^a	2.23 (0.8, 6.2)	0.125
Tracheal induction (pre-existing tracheostomy)	41 (0.8%)	1 (1.1%)	1.73 (0.23, 12.9)	0.59	0.88 (0.11, 7.2)	0.906
Not applicable	43 (0.8%)	9 (9.9%)	14.9 (6.8, 32.7)	<0.001 ^a	7.33 (2.65, 20.3)	<0.001 ^a
Actual ventilation technique n = 5126						
Spontaneous ventilation (with or without CPAP)	954/5126 (18.6%)	16/90 (17.8%)	Reference		Reference	
Controlled ventilation without muscle relaxant	1313/5126 (25.6%)	23/90 (25.6%)	1.04 (0.55, 1.99)	0.895	1.83 (0.9, 3.69)	0.094
Controlled ventilation with muscle relaxant	2849/5126 (55.6%)	48/90 (53.3%)	1 (0.57, 1.78)	0.988	1.6 (0.82, 3.15)	0.17
Impossible ventilation	10/5126 (0.2%)	3/90 (3.3%)	17.9 (4.5, 71.2)	<0.001 ^a	21.8 (3.1, 153.6)	0.002 ^a
Criteria for registry entry?						
1—Poor DL view by attending	1191 (23.2%)	56 (50.6%)	3.38 (2.23, 5.13)	<0.001 ^a	6.34 (2.42, 16.6)	<0.001 ^a
2—Limited mouth opening	617 (12%)	8 (8.8%)	0.71 (0.34, 1.46)	0.349	1.71 (0.63, 4.6)	0.29
3—Failed DL in last 6 months	426 (8.3%)	7 (7.7%)	0.92 (0.42, 2)	0.835	1.18 (0.47, 2.94)	0.726
4—Anticipated difficulty, attending DL deferred	3133 (61%)	40 (44%)	0.5 (0.33, 0.76)	0.001 ^a	2.31 (0.91, 5.85)	0.078
First attempt device						
Direct laryngoscope	1322 (25.8%)	40 (44%)	Reference		Reference	
Standard blade VL	1520 (29.6%)	16 (17.6%)	0.35 (0.19, 0.62)	<0.001 ^a	0.69 (0.32, 1.49)	0.343
Hyperangulated blade VL	1028 (20%)	14 (15.4%)	0.45 (0.24, 0.83)	0.011 ^a	1.11 (0.48, 2.59)	0.806
Flexible intubation scope	722 (14.1%)	10 (11%)	0.46 (0.23, 0.92)	0.028 ^b	1.4 (0.56, 3.53)	0.475
Combination technique	403 (7.9%)	8 (8.8%)	0.66 (0.3, 1.41)	0.282	1.03 (0.37, 2.81)	0.96
Other	118 (2.3%)	3 (3.3%)	0.84 (0.26, 2.76)	0.774	1.96 (0.51, 7.51)	0.327
Surgical airway	20 (0.4%)	0 (0%)	^b		^b	
Number of attempts with DL	0 (0, 1)	1 (0, 2)	1.6 (1.41, 1.83)	<0.001 ^a	Omitted due to collinearity with greater than 2 attempts with DL	
Greater than 2 attempts with DL	302 (5.9%)	20 (22%)	4.51 (2.71, 7.5)	<0.001 ^a	2.92 (1.41, 6.06)	0.004 ^a

Findings meeting the criteria for the presence or absence of abnormal physical exam findings on the treating clinician's preanaesthetic assessment and the presence or absence of a syndrome associated with airway involvement are listed in the appendices. Patients could meet multiple criteria for Registry entry. Data are presented as n (%) or median (IQR). Variables with p < 0.1 upon univariate analysis were included in the multivariable model. ASA-PS—American Society of Anesthesiologists Physical Status, CPAP—continuous positive airway pressure, CRNA—certified registered nurse anaesthetist, IV—intravenous, DL—direct laryngoscopy, VL—video laryngoscopy. ^aStatistically significant at p < 0.05. ^bCannot calculate due to zero cell counts.

Table 4: Multivariable model for factors associated with occurrence of severe complications in current cohort.

increased incidence of severe complications (aOR 7.33, 95% CI 2.65–20.3, $p < 0.001$). Induction of anaesthesia followed by controlled ventilation was not associated with a difference in the incidence of severe complications relative to spontaneous ventilation. Impossible ventilation was associated with the occurrence of severe complications (aOR 21.8, 95% CI 3.1–153.6, $p < 0.001$). Registry entry for criterion 1 (direct laryngoscopy by a consultant or attending physician with a poor view) was associated with an increased incidence of severe complications relative to other criteria for registry entry (i.e., limited mouth opening, failed direct laryngoscopy within six months, deferred direct laryngoscopy due to perceived risk or poor chance of success) (aOR 4.96 95% CI 2.01–11, $p < 0.001$). In the univariate analysis, compared with direct laryngoscopy, use of video laryngoscopy or flexible intubation scope as the initial technique for airway management was associated with lower incidence of severe complications; however, these associations did not persist in the multivariable model. More than two attempts with direct laryngoscopy was associated with an increased incidence of severe complications in the multivariable model (aOR 2.92 95% CI 1.41–6.06, $p = 0.004$).

Discussion

The usual rate of translation of published clinical research to medical practice is around 17 years,¹⁶ although frameworks have been developed to speed the transition.^{17,18} We found that in a current cohort of paediatric patients with difficult tracheal intubations in the PeDI Registry, first attempt success rates increased, as did the use of supplemental oxygen during intubation attempts compared to the early cohort. The number of intubation attempts, number of attempts with direct laryngoscopy, and persistence with direct laryngoscopy all decreased. Most importantly, the incidence of severe complications was nearly halved. This demonstrates a rapid change in practice and improvement in patient outcomes in participating PeDI Registry centres. Although adoption of the PeDI collaborative recommendations may have contributed to these findings, other external factors likely contributed as well, including the increasing availability of video-laryngoscopy, new societal guidelines and a general appreciation for the consequences of repeated direct laryngoscopies. Future study will be required to evaluate the impact on the broader paediatric anaesthesia community, although recent reports indicate that direct laryngoscopy for children with difficult tracheal intubation remains common.^{6,7}

Of course, the work and educational efforts in the PeDI Registry occur in a broader context. The development and publication of the paediatric-specific ASA difficult airway algorithm⁹ undoubtedly amplified the educational reach of the message to limit the number of attempts at intubation. Furthermore, the increase in the

use of video laryngoscopy required an increase in the availability of these systems, which has occurred over this same timeframe.

Despite these impressive gains, there is still significant room for improvement. Overall complication rates did not decrease between cohorts with a 10% incidence of hypoxemia in the current cohort. While supplemental oxygen use during intubation attempts increased significantly between cohorts, it still has not been widely adopted in the PeDI Registry patients. We hypothesise that more widespread adoption of routine supplemental oxygen use may help to reduce the incidence of hypoxemia as has been demonstrated in prospective observational studies¹⁹ and randomised controlled trials.^{20–22}

There were 41 cardiac arrests and ten deaths in the current cohort of 5224 patients with difficult tracheal intubations in the PeDI Registry, yielding a cardiac arrest rate of 78 per 10,000 and a mortality rate of 19 per 10,000. While lower than in the early cohort from the registry, this represents an approximately 20-fold increase from rates reported in the general paediatric population.^{6,23} The multivariable model identified patient-related factors, including higher ASA physical status and abnormal physical examination, associated with an increased incidence of severe complications in this cohort. Interestingly, while younger age and smaller size were strongly associated with severe complications in the univariate analysis, the association did not persist in multivariable analysis. We hypothesise that these factors may have been incorporated into the clinician's overall risk assessment and ASA physical status.

The clearest modifiable factor associated with severe complications in the current cohort was persistence with direct laryngoscopy. In the early cohort, delayed transition from direct laryngoscopy to another technique was associated with a higher incidence of complications. The current cohort had a nearly 50% reduction in the rate of direct laryngoscopy persistence compared to the early cohort (7.3% vs 14.1%). Still, persistence with direct laryngoscopy remained significantly associated with severe complications in the current cohort. Persistence with direct laryngoscopy is not unique to the PeDI Registry patients.^{6,7} This is an important target for ongoing education and quality improvement efforts, as ingrained practice and culture require the accumulation of data and experience to overcome.

We also identified that registry entry for poor view on direct laryngoscopy by a consultant or attending anaesthetist was associated with an increased incidence of severe complications in the current cohort. There are multiple explanations for this finding which are not mutually exclusive. In some cases, these were unanticipated difficult intubations; in some cases, there was persistence with direct laryngoscopy when it was failing; in some cases, the child had known difficult airway anatomy, so the most experienced provider made an attempt with direct laryngoscopy. A clear theme in the

work from the PeDI Registry is that direct laryngoscopy has a low chance of success and a high association with complications in children with difficult tracheal intubations.

Efforts to improve first attempt success rates and to reduce multiple attempts and persistence with failing techniques are complimentary, with interventions designed to improve first attempt success rate, including use of video laryngoscopy, consequently reducing multiple attempts as well. A major change from the early cohort to the current cohort has been the dramatic increase in standard blade video laryngoscopy. There is a rapidly growing body of evidence that standard blade video laryngoscopy offers improved first attempt success and reduced rates of complications in infants and children with both normal and difficult airway anatomy,^{22,24,25} which aligns with the most recent Cochrane review in adults.²⁶ Although video systems require a financial investment, these data can support cost effectiveness analysis in improving patient safety. Video-enabled devices have become increasingly available in centres involved in the Registry, but we know these devices are not readily available at all institutions caring for children.

Furthermore, paediatric airway management is not limited to paediatric anaesthetists, as children requiring tracheal intubation are cared for in a variety of settings. There is a developing body of literature on the high risk nature of tracheal intubation and the role of video laryngoscopy in improving patient safety in paediatric^{14,27–30} and neonatal^{31–33} intensive care units, as well as emergency departments.^{34,35} In the current cohort, encounters in which the anaesthesia team was called to assist in an emergency intubation in another location, often an intensive care unit or emergency department, were associated with increased incidence of severe complications. We believe the findings of this study are broadly applicable for all clinicians performing tracheal intubation in children.

There are several limitations to the present study. This is observational, registry data with all of its inherent limitations. We used robust statistical tools, including propensity score matching and multivariable modelling with generalised estimating equations, to account for potential confounders and make meaningful comparisons between similar groups. We are limited to data collected in the registry and are not able to assess all factors that may have contributed to patient outcomes. Some complications may have been related to factors other than airway management. While we may infer contributory factors to outcomes, we cannot know what factors led clinicians to make a particular decision. Further, some variables, such as anticipated difficulty, were determined at the discretion of the treating clinician as there is not a standardised difficult airway scoring system in use across participating sites. These limitations prompted the

randomised controlled Video Laryngoscopy in Small Infants (VISI) trial, which compared direct laryngoscopy to indirect video laryngoscopy in anatomically normal neonates and infants and demonstrated improved success rates and reduced complications with video laryngoscopy as compared with direct laryngoscopy in anatomically normal infants without anticipated difficult intubations.²⁴

In conclusion, we observed a significant reduction in the number of intubation attempts and persistence with direct laryngoscopy, and a significant increase in the use of supplemental oxygen in paediatric patients with difficult tracheal intubations in the PeDI Registry. We found a significant decrease in the incidence of severe complications in this cohort, demonstrating a strong association between our quality improvement efforts and improved patient outcomes. Ongoing work will encourage routine use of supplemental oxygen and target a continued reduction in the number of intubation attempts and persistence with direct laryngoscopy, not only in PeDI Registry centres but hopefully all centres that care for paediatric patients.

Contributors

All authors had full access to the data in the study and have read and approved the final version of the manuscript. MLS, SJS, RSP, and PGK accessed and verified the data.

MLS: contributed to the conceptualisation, study design, data collection, data analysis and interpretation, and writing—original draft, review, and editing.

LAS: contributed to the study design, data collection, data analysis and interpretation, writing—review and editing, and translation of the Spanish language abstract.

SJS: contributed to study design and statistical analysis.

JH: contributed to the data analysis and interpretation, and writing—review and editing.

CE: contributed to the data analysis and interpretation, and writing—review and editing.

SGF: contributed to the data analysis and interpretation, and writing—review and editing.

SAK: contributed to the data collection and writing—review and editing.

SS: contributed to the study design, data collection, data analysis and interpretation, and writing—review and editing.

BMT: contributed to the study design, data collection, data analysis and interpretation, and writing—review and editing.

FC: contributed to the study design, data collection, data analysis and interpretation, and writing—review and editing.

AB: contributed to the study design, data collection, data analysis and interpretation, and writing—review and editing.

ACL: contributed to data collection and writing—review and editing.

HDA: contributed to data collection and writing—review and editing.

BSvUS: contributed to data collection and writing—review and editing.

RSP: contributed to the conceptualisation, study design, data collection, data analysis and interpretation, and writing—review and editing.

JMP: contributed to the conceptualisation, study design, data collection, data analysis and interpretation, and writing—review and editing.

PNO: contributed to data collection and writing—review and editing.

AIH: contributed to the data collection and writing—review and editing.

AGM: contributed to the data collection and writing—review and editing.

**JEF: contributed to the conceptualisation, study design, data collection, data analysis and interpretation, and writing–review, and editing.

**PGK: contributed to the conceptualisation, study design, data collection, data analysis and interpretation, and writing–original draft, review, and editing.

The corresponding author and senior authors had full access to the data and had final responsibility over the decision to submit for publication.

Data sharing statement

Deidentified participant data and data dictionary are available following approval of a proposal by the PeDI Registry executive committee. Please address enquiries to Dr. Pete Kovatsis at pete.kovatsis@childrens.harvard.edu.

Declaration of interests

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.eclinm.2024.102461>.

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