Systemwide Change of Sedation Wean Protocol Following Pediatric Laryngotracheal Reconstruction

Elliott D. Kozin, MD; Brian M. Cummings, MD; Derek J. Rogers, MD; Brian Lin, MD; Rosh Sethi, BS; Natan Noviski, MD; Christopher J. Hartnick, MD

IMPORTANCE Pediatric laryngotracheal reconstruction (LTR) remains the standard surgical technique for expanding a stenotic airway and necessitates a multidisciplinary team. Sedation wean following LTR is a critical component of perioperative care. We identified variation and communications deficiencies with our sedation wean practice and describe our experience implementing a standardized sedation wean protocol.

OBJECTIVE To standardize and decrease length of sedation wean in pediatric patients undergoing LTR.

DESIGN, SETTING, AND PARTICIPANTS Using Institute for Healthcare Improvement (IHI) methodology, we implemented systemwide change at a tertiary care center with the goal of improving care based on best practice guidelines. We created a standardized electronic sedation wean communication document and retrospectively examined our experience in 29 consecutive patients who underwent LTR before (n = 16, prewean group) and after (n = 13, postwean group) wean document implementation.

INTERVENTIONS Implementation of a standardized sedation protocol.

MAIN OUTCOMES AND MEASURES Presence of sedation wean document in the electronic medical record, length of sedation wean, and need for continued wean after discharge.

RESULTS The sedation wean document was used in 92.3% patients in the postwean group. With the new process, the mean (SD) length of sedation wean was reduced from 16.19 (11.56) days in the prewean group to 8.92 (3.37) days in the postwean group (P = .045). Fewer patients in the postwean group required continued wean after discharge (81.3% vs 33.3%; P = .02).

CONCLUSIONS AND RELEVANCE We implemented a systemwide process change with the goal of improving care based on best practice guidelines, which significantly decreased the time required for sedation wean following LTR. Our methodological approach may have implications for other heterogeneous patient populations requiring a sedation wean.

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Laryngotracheal stenosis remains a significant issue in the pediatric population. Originally introduced in 1972, laryngotracheal reconstruction (LTR) has evolved to include a variety of techniques for expanding a stenotic airway, including airway reconstruction with a rib cartilage graft. Through open surgical techniques, success rates in achieving decannulation and avoiding tracheotomy approached 90%. Perioperative management involving a multidisciplinary team is vital to the success of airway reconstruction.

During the postoperative period in the pediatric intensive care unit (PICU), the patient is usually nasotracheally intubated, requiring sedation and analgesia with or without neuromuscular blockade. The physical and pharmacologic precautions minimize excessive neck movement that could place tension on the newly repaired airway and decrease movement of the endotracheal tube that could disrupt suture lines and cartilage grafts, cause repeated trauma to the airway mucosa, or result in accidental extubation. Pharmacologic restraints and mechanical ventilation in the PICU typically are necessary for 3 to 7 days, depending on the type of airway reconstruction. Following extubation, tapering of sedative medications becomes the primary focus of postoperative care with the goal of avoiding sedative medication withdrawal syndromes. Ineffective tapering may result in analgesia-related complications, prolonged hospital stay, increased hospital costs, and family dissatisfaction. Research on the best pharmacologic approaches to sedation, neuromuscular blockade, and withdrawal monitoring is ongoing.

Similar to other airway centers around the world, at our tertiary care center, sedation wean is recognized as a major postoperative concern in the LTR patient population. While a suggested sedation wean protocol exists in the PICU based on best practice guidelines, actual provider practice varies and the wean approach often changes on transfer to the ward, as implementation of standardized approaches to sedation weaning algorithms in all locations has proven difficult. Furthermore, there is no standardized approach to communication of the sedation wean algorithm during the transfer of LTR patients from the PICU to the ward. Consequently, systemwide variability has resulted in avoidable complications, including oversedation, prolonged weans, and miscommunication among health care practitioners (i.e., otolaryngologists, intensivists, hospitalists, residents, pharmacists, nurses, and social workers) in our LTR patient population.

To address systemwide issues in implementing commonly accepted sedation wean protocol, we turned to the Institute for Healthcare Improvement (IHI) methodology. Herein, we describe our experience in applying the IHI methodology to (1) identify key issues regarding transitions of care, and (2) implement a standardized sedation wean protocol. Given the relatively few patients, as well as similar patient demographics and medical backgrounds, the LTR population represents an ideal patient population to trial a rigorous approach to standardize sedation weans.

Methods

Ethical Concerns and Study Setting
The institutional review board of the Massachusetts Eye and Ear Infirmary (MEEI) approved the retrospective review of patient data. As specific pharmacologic approaches to sedation wean guidelines had previously been established at Massachusetts General Hospital for Children (MGHfC), these guidelines served as a basis for patient management and implementation, ensuring equivalent standard of care to all patients.

The study took place at MGHfC and MEEI. MGHfC is a pediatric tertiary care academic hospital that is physically integrated within the Massachusetts General Hospital (MGH). MGHfC has a dedicated PICU, neonatal ICU, pediatric operating rooms, and pediatric patient wards. MGHfC patient wards are managed by pediatricians and associated pediatric specialists. MEEI is an adjacent tertiary care academic medical hospital that treats both adult and pediatric patients. MEEI has a dedicated space for pediatric outpatient visits, operating rooms, and inpatient rooms that are largely managed by pediatric otolaryngologists and pediatric consultant subspecialists. The 2 hospitals share academic affiliations, some physician and resident coverage, and an electronic health record (EHR) system. MGHfC and MEEI are otherwise distinct facilities in terms of space, support staff, management, and hospital policies.

The Pediatric Airway, Swallowing and Voice Center is an unique collaboration between the MEEI and MGHfC. Patients who require intensive care are transferred from the MEEI operating room to the MGHfC PICU. Pediatric airway reconstruction patients, such as those undergoing LTR, constitute most of these transfers. Following postoperative care in the PICU, patients are either transferred to the floor at MGHfC or MEEI, depending on individual patient needs. The physically and organizationally unique MEEI-MGHfC relationship potentially exposes our patients to risk for communication breakdown between the health care practitioners within each institution.

Planning the Intervention
The Institute for Healthcare Improvement is a recognized health care quality improvement organization that provides resources, such as white papers and “Field Guides,” for implementing systemwide change. We used the IHI Field Guide’s 7 steps to implement change across 2 institutions. The 7 steps comprise form a team, identifying opportunities for improvement, developing clear aims, designing and testing standard work for key changes, identifying failures or problems and redesigning the process, displaying measures over time to assess progress, and implementing and spreading the reliable design and processes (Figure 1).

The first step, building a team, is a challenging task, especially with multiple physician subspecialists and other health care practitioners across hospital systems. One strategy to engage health care practitioners in safety efforts is to focus on projects that are important to the entire medical staff. At the onset, we organized a focus group led by a senior otolaryngology attending physician (C.J.H.). In IHI terms, this individual was the “physician champion.” Focus group participants con-
vened in August 2012 and included attending pediatric otolaryngologists, pediatric intensivists, hospitalists, fellows, residents, nurses, pharmacists and social workers. The multidisciplinary focus group reviewed our center’s experience for all LTR patients in 2011 and 2012. Three issues stood out among LTR patients related to sedation wean: (1) prolonged and disparate wean protocols, (2) unanticipated transfer from floor to ICU-level care because of oversedation, and (3) confusion among health care practitioners regarding sedation wean protocol.

The focus group identified key communication breakdowns typically occurred during transfer of care from the PICU to the MGHfC ward or MEEI ward. The group identified that existing hospital documents, in the PICU and on patient transfer notes to the ward, did not routinely convey a plan for weaning sedation, arguably the main reasons for continued postoperative inpatient status. Sedation wean approaches, which typically consists of methadone and lorazepam tapered at regular intervals, were communicated from physicians to physicians or nurses to nurses, in inconsistent fashion. In addition, sedation weans typically required management on MGHfC wards instead of MEEI wards due to lack of existing wean protocols at MEEI and training.

On the basis of information gathered at the focus group, we formulated an IHI-based action plan and developed a “sedation wean document” that contained essential information about the postoperative sedation wean, including dates, times, and dosages of key medications, that was readily comprehensible to all team members. The document was based on previously established MGHfC sedation wean medication calculations and documents; original documents were authored by the MGHfC PICU Withdrawal Committee and adapted from published literature.19 Because we previously determined that transfer from the PICU to the ward was the most likely time for communication breakdown, it was determined that the document should be placed in the EHR as a stand-alone document at the time of patient transfer. Because the intensivists and associated pediatric residents in the PICU are in charge of the sedation wean medications, it was agreed that they would be the authors of the document and communicate its information to other health care practitioners, including otolaryngology and nursing staff.

Methods of Evaluation and Statistical Analysis
We compared the primary outcome of sedation wean length in LTRs from baseline period of 2011 through 2012 (prewean group) and after implementation of the sedation wean document (LTR in 2013-2014; postwean group). Additional outcomes included presence of sedation wean document at time of transfer to the floor and discharge (process measure), location of discharge, hospital length of stay (LOS), and need for continued wean at time of discharge (balance measures). A statistical process control run chart of sedation wean length with baseline data and 99% confidence intervals was constructed with an Xmr chart and then reanalyzed following new process using Minitab version 17.1 (Minitab Inc). Descriptive statistics were used with parametric data presented as mean and standard deviation. The t test (unpaired) and Fisher exact test were used for study arm comparisons. Statistical analyses were performed by Stata version 12.1 (StataCorp). Results were considered statistically significant at \( P < .05 \).

Results
Implementation of New Process
The sedation wean document was revised several times by stakeholders, with the final form completed in February 2013 (Figure 2). The document was converted into an EHR template titled “MGH/MEEI Sedation Wean Plan,” accessible by health care practitioners at both hospitals and all 3 locations. Physicians and nurses at all locations received in-service training for its implementation as a new standard communication tool.

Figure 3 provides a run chart of 29 consecutive LTR patients over 3.5 years, with a baseline period (prewean, \( n = 16 \)) and postprocess implementation (postwean, \( n = 13 \)). The process measure of an electronic sedation wean plan was adopted in 12 of 13 eligible patients (92%). There are 2 notable patient outliers in the prewean group, with length of wean longer than others in the study cohort. These patients had pro-
longed length of wean because of communication breakdown between health care practitioners, resulting in sedation withdrawal syndromes, transfers to the ICU from the floor, and prolonged hospital stays. The first patient in the postintervention period did not have the formal electronic sedation document placed in the EHR. The multidisciplinary team noted the failure and recognized education gaps in pediatric house staff rotating in the PICU and subsequent training was provided. Assurance of the presence of the wean document at the time of transfer from the PICU became the responsibility of 2 physician leaders, a pediatric intensivist (B.M.C.) and otolaryngology resident (B.L.). Because the first postwean implementation period patient did not have a standardized wean document, the patient was excluded from subsequent outcome analyses of the process.

### Table

<table>
<thead>
<tr>
<th>Day/Date</th>
<th>Infusions for 7-14 days SHORT-TERM THERAPY PROTOCOL</th>
<th>Infusions &gt; 14 days LONG-TERM THERAPY PROTOCOL</th>
<th>Plan following, doses as below:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Dose “Original Dose (OD)” every 6 hours for 24 hours</td>
<td>Dose “Original Dose (OD)” every 6 hours for 24 hours</td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>Consider change to PO (no dose change) for 24 hours</td>
<td>Consider change to PO (no dose change) for 24 hours</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>Decrease OD 20%, every 8 hours for 24 hours</td>
<td>Decrease OD 20%, every 6 hours for 48 hours</td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td>Decrease OD 20%, every 8 hours for 24 hours</td>
<td>No change</td>
<td></td>
</tr>
<tr>
<td>Day 5</td>
<td>Decrease OD 20%, every 12 hours for 24 hours</td>
<td>Decrease OD 20%, every 8 hours for 48 hours</td>
<td></td>
</tr>
<tr>
<td>Day 6</td>
<td>Decrease dose 20%, every 24 hours for 24 hours</td>
<td>No change</td>
<td></td>
</tr>
<tr>
<td>Day 7</td>
<td>Discontinue</td>
<td>Decrease OD 20%, every 12 hours for 48 hours</td>
<td></td>
</tr>
<tr>
<td>Day 8</td>
<td></td>
<td>No change</td>
<td></td>
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<tr>
<td>Day 9</td>
<td></td>
<td>Decrease OD 20%, every 24 hours for 48 hours</td>
<td></td>
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<tr>
<td>Day 10</td>
<td></td>
<td>No change</td>
<td></td>
</tr>
<tr>
<td>Day 11</td>
<td></td>
<td>Discontinue</td>
<td></td>
</tr>
</tbody>
</table>

**Rescue:** If symptoms appear through weaning, consider providing additional dose of medications to treat. Dose that captured patient in PICU was:
- Morphine _ mg
- Lorazepam _ mg

*Consider patient condition has changed and expert consultation (pain team) is needed.*

Patient transferred out of PICU on day ___ of planned ___ day wean. See chart for further dose adjustments.

**Contact Information:**
- PICU and PICU pharmacist for prior wean information
- Pain team for new patient withdrawal concerns

**Patient Demographics Before and After Implementation of Sedation Wean Document**

Basic demographic information of the baseline prewean and postwean patients were similar. There were no statistical differences between mean (SD) age (2.55 [1.42] vs 1.89 [1.29] years; P = .22), female sex (50% vs 17%, P = .11), mean (SD) continuous sedation infusion duration (8.94 [3.47] vs 9.17 [3.13] days; P = .86), mean (SD) length of mechanical ventilation (10.56 [4.59] vs 10.25 [3.41] days; P = .84), mean (SD) PICU LOS (13.44 [5.37] vs 13.75 [4.07]; P = .87), and patients with rib cartilage graft (68.8% vs 91.7%; P = .20).

**Outcomes Following Implementation of Sedation Wean**

The Table summarizes outcomes between the baseline group and patients following the new process. For the primary out-
come, mean (SD) length of sedation wean was 16.19 (11.56) days in prewean group compared with 8.92 (3.37) days in the postwean group ($P = .045$). Less variation in sedation wean length was also noted with the new process (Figure 3). Fewer patients postwean process required continued sedation wean after hospital discharge (81.3% vs 33.3%; $P = .02$). In terms of discharge location, there was a decrease in the number of patients discharged from the MGHfC ward (87.5% prewean vs 41.6% postwean; $P = .02$), representing an increase in discharge from the PICU and MEEI ward.

In terms of other balance measures, mean (SD) hospital LOS was 17.9 (5.5) vs 16.9 (4.0) days ($P = .62$) in prewean and postwean group, respectively. Mean length of days spent on the ward was also similar (5.27 days prewean vs 4.3 days postwean; $P = .47$) (Table). In the prewean baseline, 1 patient was required to be transferred from the MEEI ward to PICU because of oversedation during the sedation wean. No patients required return to PICU because of sedation wean failure or oversedation in the postintervention group.

### Discussion

Our quality improvement project using IHI methodology demonstrates a significant impact on length of sedation wean following LTR, a critical aspect of postoperative patient care. The new process was well accepted and used in 92% of eligible patients. Like all process improvement, implementation at the user level is paramount, and we quickly responded to our first missed opportunity, dedicating process champions that likely ensured its use. Our primary outcome of sedation wean length demonstrated a nearly 50% decrease in duration, and fewer patients were discharged requiring a narcotics prescription for continued sedation wean, putting less burden on families. Another beneficial impact to the new process was streamlined care, with fewer patients requiring MGHfC ward care. Prior to the new process, patients would often be transferred to the MGHfC ward for sedation weaning because nursing and physician staff at MEEI did not have a robust policies of sedation wean practice. The sedation wean multidisciplinary process change enabled PICU and MEEI health care practitioners to better manage LTR patients and streamline discharges and location management.

The 2 groups, prewean and postwean, were well matched. We had an equivalent patient population between the prewean and postwean groups in terms of age, sex, and need for a rib graft, which may be considered a general proxy for extent of surgery and potential source of considerable postoperative pain. It is important to account for potential differences in the study population in terms of length of mechanical ventilation and continuous sedation because this may be associated with potential increased sedation wean duration. For example, a patient on mechanical ventilation and continuous sedation for 3 days has a much lower risk for dependence and need for sedation wean compared with a patient receiving mechanical ventilation and continuous sedation for 8 days. We found there was no difference in length of continuous sedation or number of days of mechanical ventilation, which could have a potential impact on duration needed for sedation wean since longer exposure worsens risk for withdrawal.

In terms of LOS outcomes, including PICU, ward, and total LOS, we did not identify any differences between the prewean and postwean study groups. This result was expected, and there are several possible explanations. Principally, LOS depends more on the timing of the postoperative bronchoscopies than the sedation wean. At our institution, the LTR is followed by 2 bronchoscopies, the first at the time of extubation when patient is admitted to the PICU and a second around the time of discharge when the patient is on the ward, ensuring the continued patency of the airway. The exact timing for the first “second look” bronchoscopy is based on both historic and contemporary LTR studies and typically occurs at our institu-

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**Figure 3. Length of Sedation Wean Run Chart**

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>LCL</th>
<th>UCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>20</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>25</td>
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<td>5</td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>35</td>
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<tr>
<td>7</td>
<td>40</td>
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<td></td>
</tr>
<tr>
<td>8</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: patient 17 was excluded from the analysis because this patient did not have a standardized wean document.
Sedation Wean After Laryngotracheal Reconstruction

In this study, we did not examine the efficacy of our wean- protocol in terms of medications or dosages, but rather examined how changing the process of communication among health care practitioners with an initial standardized plan could have an impact on discrete outcomes. We acknowledge that recommendations vary and controversy exists regarding se-
dation wean best practices.21 At our hospital, specific seda-
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<table>
<thead>
<tr>
<th>Outcome</th>
<th>Prewean Document (n = 16)</th>
<th>Postwean Document (n = 12)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of wean, mean (SD), d</td>
<td>16.19 (11.56)</td>
<td>8.92 (3.37)</td>
<td>.045</td>
</tr>
<tr>
<td>Total LOS, mean (SD), d</td>
<td>17.88 (5.51)</td>
<td>16.92 (4.01)</td>
<td>.62</td>
</tr>
<tr>
<td>LOS on ward, mean (SD), d</td>
<td>5.27 (3.56)</td>
<td>4.33 (1.58)</td>
<td>.47</td>
</tr>
<tr>
<td>Continue wean on discharge (yes), No. (%)</td>
<td>13 (81.3)</td>
<td>4 (33.33)</td>
<td>.02</td>
</tr>
<tr>
<td>Discharge location, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MGHfC floor</td>
<td>14 (87.5)</td>
<td>5 (41.7)</td>
<td>.02</td>
</tr>
<tr>
<td>Non-MGHfC floor</td>
<td>2 (12.5)</td>
<td>7 (58.3)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: LOS, length of stay; MGHfC, Massachusetts General Hospital for Children.

* Patients in boldface are statistically significant.

Our study fits into the intersection of research on best clinical practices, checklists, and patient handoffs. In terms of best practices, there is often a discrepancy between hospital policy or published guidelines and actual practice patterns. Previous studies have both investigated the implementation of best practices, as well as examined checklists for implementation with positive results.23-29 Furthermore, numerous studies have identified the need for improved communication at the time of patient handoff.30-32 Our sedation wean document was designed to address actively all of these issues simultaneously: implement a systemwide best practice recommendations, provision of a checklist-style document readily available to all health care practitioners, and focus on communication of the document at time of patient transfer and handoff.

The question arises, “Can IHI methodology be used in other more common procedures in otolaryngology, such as tonsillec-
tomy, tracheostomy, or tympanostomy tube placement?” IHI methodology was used to implement systemwide change for the transfer of airway reconstruction patients from the operating room to the PICU28 and has been used in the anesthesia literature as well.33 In the case of tracheostomy, one can envision generating a uniform electronic form easily interpretable by physicians, nurses, and other health care practitioners that would provide standard information, eg, date of tube place-
ment, type and size of tube, dates of first tracheostomy tube change, and anatomy details, that would travel with the patient during the hospital stay. This type of document would help facilitate communication of critical aspects of patient care, and procedure-specific outcomes may be studied. Furthermore, previous studies in the otolaryngology literature have addressed patient safety initiatives, such as checklists and wrong-sided surgery.34-36 IHI methodology may be used to identify systemwide patient safety issues and implement change.

Several potential limitations exist in our study. Our find-
ings may be related to the Hawthorne effect, a phenomenon whereby an individual improves or changes an aspect of his or her behavior in response to a change in the environment. There may have been improvement in postoperative care owing to a change in attitudes and behaviors regarding communication spurred by the sedation wean multidisciplinary effort. In terms of transfers to MEEI, it is clear that implementation of the sedation wean document set into place new hospital policies that facilitated patient transfers from the PICU. Also, our small cohort limits our ability to draw statistical con-
clusions of our secondary outcome end points. The LTR, while readily performed and well studied, it is not a common pro-
cEDURE. Several years of data may be necessary to detect changes in hospital LOS.
Conclusions

We identified variability in sedation wean practices and opportunities for communication improvement. We implemented systemwide process change using IHI methodology with the goal of improving care based on best practice guidelines, which significantly decreased the time required for sedation wean. Our approach to a sedation wean communication in the LTR patient population may be potentially studied in other more heterogeneous patient populations requiring standardized sedation wean protocols.

REFERENCES