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Utilization of a Standardized Tracheostomy Capping and Decannulation Protocol to Improve Patient Safety

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Objectives/Hypothesis: To develop and assess the feasibility of a new standardized protocol to guide tracheostomy decannulation.

Study Design: Descriptive review of quality improvement project.

Methods: A quality improvement project was conducted in the inpatient setting of a tertiary urban academic hospital. Adult patients who had received a tracheostomy and for whom the indication for tracheostomy had resolved were included. A multidisciplinary task force reviewed input from clinicians caring for tracheostomy patients and developed a protocol for screening, capping, and decannulation. The primary outcome measured was successful decannulation.

Results: Fifty-seven patients were screened for a capping trial over a 12-month period; 54 were capped. Six patients were lost to follow-up. Fifty patients passed the capping trial, and all 50 were decannulated successfully. When decannulation was pursued in one patient who had twice failed the screening criteria and subsequent capping trials, the patient failed decannulation and ultimately required reintubation for the management of secretions. The screening tool had high sensitivity (90%) and positive predictive value (100%) for successful decannulation. Additionally, the number of reported patient safety concerns decreased from seven in the 6 months preceding implementation of the program to one report in the 6 months after implementation.

Conclusion: The new tracheostomy capping and decannulation protocol assisted in predicting both successful and failed decannulation. Although several patients failed certain capping criteria initially, the protocol stipulated modifications of care that enabled successful decannulation. The screening tool had high sensitivity and promoted communication, standardization of practice, and patient safety.

Key Words: tracheostomy, capping, decannulation, patient safety.

Level of Evidence: 2b.

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Additional Supporting Information may be found in the online version of this article.

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INTRODUCTION

The incidence of tracheostomy has nearly tripled in recent years in patients requiring prolonged mechanical ventilation.[1,2] Major indications for tracheostomy include chronic mechanical ventilator dependence and airway protection[3]; however, once the acute indication for tracheostomy has resolved, the patient needs to be evaluated for safe decannulation. For decannulation to be successful, the patient must be able to ventilate around the tracheostomy tube using the natural airway. Clinicians evaluate this ability by occluding or capping the cuffless (deflated, cuffed) tracheostomy and determining if the patient tolerates this challenge. If tolerated, the patient may be eligible for decannulation. If this process is performed prematurely or without proper monitoring, this challenge could lead to respiratory failure, loss of airway, and death.[4]

Few studies have addressed tracheostomy tube capping and decannulation. Several factors, such as a patient's age, level of consciousness, duration of spontaneous breathing prior to decannulation, cough effectiveness, secretions, and oxygenation, have been identified as predictors of successful decannulation.[4–6] However, eligibility for capping based on formal criteria has not been studied.

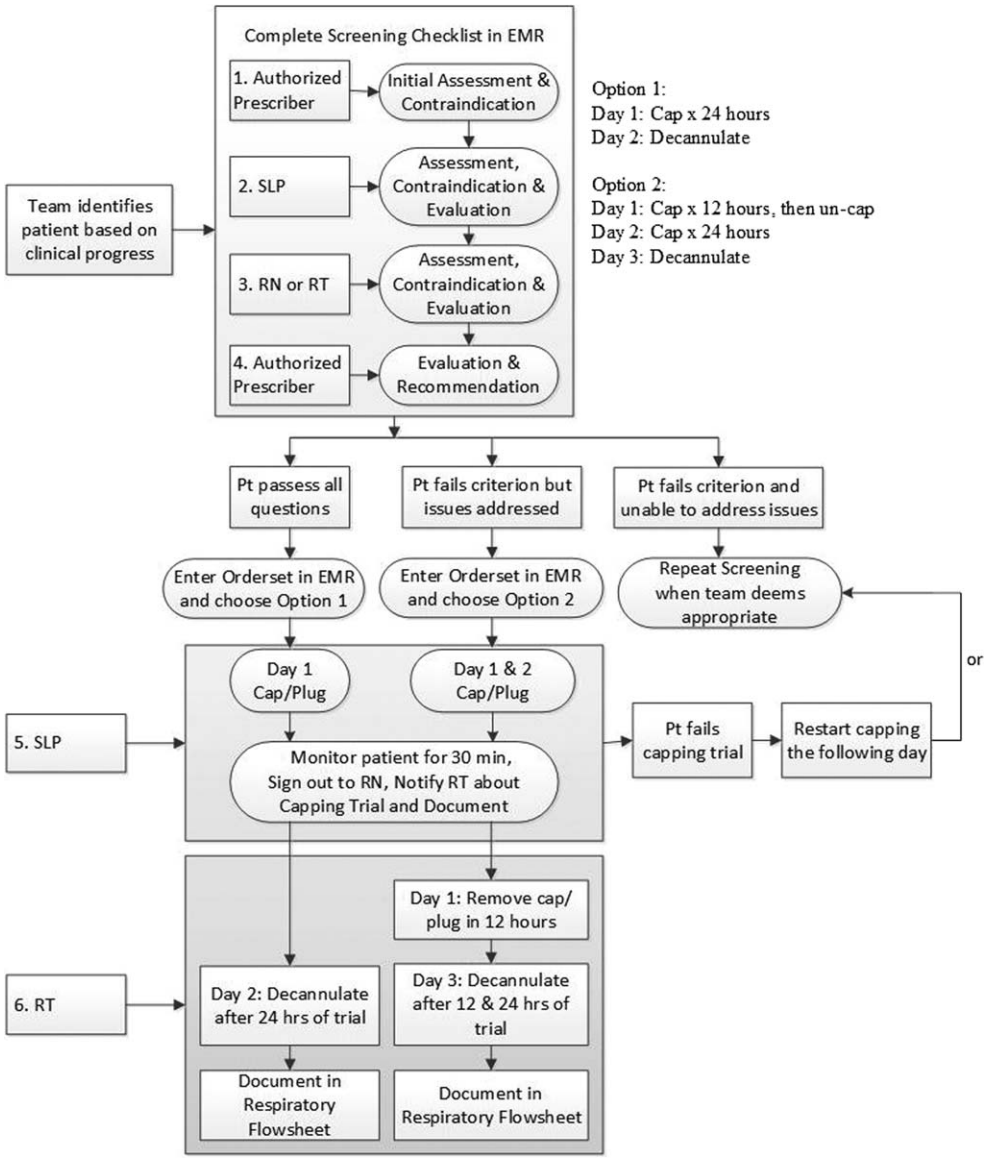

Fig. 1. Tracheostomy capping and decannulation algorithm. The algorithm shows the roles of each team member and two options for the capping trial: the routine approach and the conservative 12–24 sequential approach. Moreover, it offers a map regarding how to proceed if someone fails a capping trial. EMR = electronic medical record; RN = registered nurse; RT = respiratory therapist; SLP = speech-language pathologist.

Additionally, the few national guidelines that provide some guidance for decannulation practice are limited to expert opinions.[7–9]. Services that care for patients in the hospital setting have varied levels of experience and comfort in caring for tracheostomy patients. Physicians, nurse practitioners, nurses, respiratory therapists (RTs), and speech-language pathologists (SLPs) often approach the capping and decannulation process differently. In a survey of decannulation practices, Stelfox et al.[5] reported that RTs rely on patient tolerance of capping, whereas physicians depend on the level of consciousness. The duration of capping also varies between 48 and 72 hours before the patient is decannulated.

The purpose of our quality improvement project was to develop a standardized protocol to guide the tracheostomy capping and decannulation process and thereby improve patient safety and the rate of successful decannulation.

MATERIALS AND METHODS

The Johns Hopkins Institutional Review Board Committee X (NA_00071840) approved the presentation of findings from the quality improvement project. The project involved patients who were admitted to various wards at the Johns Hopkins Hospital.

Development and Implementation of Standardized Protocol

A multidisciplinary task force was created and led by the Multidisciplinary Percutaneous Tracheostomy Team (MPTT)[3,10] in response to concerns raised by medical teams regarding lack of standardization and the absence of clear guidelines on how to proceed with capping trials. The multidisciplinary task force was composed of otolaryngology head and neck surgeons, trauma surgeons, interventional pulmonologists, anesthesiologists, a tracheostomy nurse practitioner, RTs, nurses, and SLPs. After a series of meetings, the committee developed a protocol that consists of the tracheostomy capping screening checklist (Appendix 1), capping and decannulation algorithm (Fig. 1),

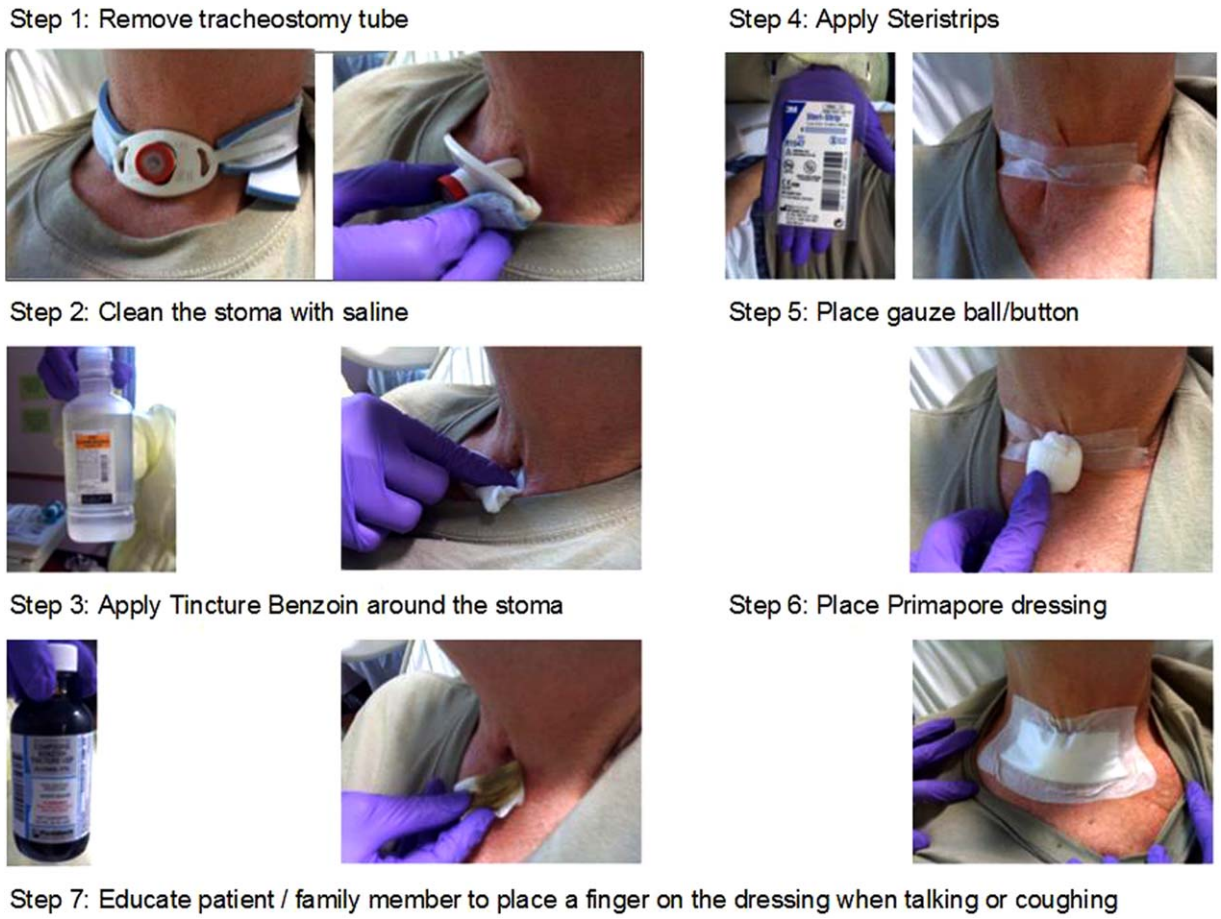

Fig. 2. Tracheostomy decannulation guidelines. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

capping order set (Appendix 2), and decannulation guidelines (Fig. 2). To ensure safe implementation, the committee created a decannulation procedure note template and door signs that alert providers to an ongoing capping trial and designate a provider to contact if a problem occurs.

Once the protocol was developed, the MPTT executed the protocol and conducted this quality improvement project. The MPTT collaborated with the nursing education committee to incorporate the protocol into their curriculum through educational sessions. The protocol was piloted on four medical and surgical floors over 6 months. Refinements to the protocol were made during the pilot and then expanded to the rest of the hospital for an additional 6 months. The final version of the protocol was approved by the Johns Hopkins Policies and Protocols Committee and adopted as a policy in our institution. The nursing, RT, and SLP Education Committees incorporated this protocol into training and the required annual competencies.

Standardized Approach to Capping the Tracheostomy Tube

Primary service physicians caring for patients with a tracheostomy identified potential adult candidates for the capping trial and requested evaluation for decannulation when the patient's underlying indication for tracheostomy had resolved. One authorized prescriber (physician, nurse practitioner, or physician's assistant) and two other providers (nurse, RT, or SLP) evaluated patients according to the tracheostomy capping checklist (Appendix 1). Patients were eligible if they met the criteria in Table I.

If the patient did not meet the criteria, modifications were made to allow the capping trial to proceed safely. For example, if the tracheostomy tube was size $\geq$ 6.0, then the tube was changed to 4.0 cuffless. If the patient had air trapping, bronchoscopy was used to evaluate the underlying cause, such as airway edema or tracheal stenosis/malacia, and the capping trial was delayed until such issues were resolved. Patients who were unable to remove the tracheostomy cap or use their call device were monitored with continuous pulse oximetry. Patients who passed screening criteria were challenged with a 24-hour capping trial. If criteria were not initially met but subsequently addressed, a more conservative approach was taken in which the patient was capped initially for 12 hours and then uncapped for 12 hours before proceeding to the 24-hour capping trial. The primary physician ordered the appropriate protocol with the tracheostomy capping order set (Appendix 2).

Before initiation of capping, emergency airway equipment was placed at the bedside (Appendix 3). Patients who required oxygen were switched to nasal cannula or facemask. An SLP initiated the capping trial by replacing the inner cannula with the tracheostomy cap or plug (Fig. 1). The SLP directly

TABLE I.
Patient Eligibility Criteria for Capping Trial.

Criteria	Definition
Airway device	Tracheostomy tube should be size 4.0, preferably cuffless.
Patient capabilities	Breathe comfortably with continuous finger occlusion of tracheostomy tube for 1 minute without trapping air so that there is no release of positive pressure from tube with removal of finger.
	Tolerate speaking valve during waking hours without distress.
	Mobilize secretions from tracheostomy/oropharynx with adequate cough.
	Maintain stable oxygen saturation.
	Demonstrate adequate dexterity and alertness, defined by being able to remove cap from tracheostomy tube independently in less than 30 seconds, and use call bell for help in an emergency.
Nursing requirements	Nursing staff demonstrate that prior to capping, suctioning was required less frequently than every 4 hours.
Additional clinical considerations	During capping trial, patient must not have had an anticipated need for sedation or anesthesia that required a protected airway with a mechanical device, or have left floor for a study or procedure other than inpatient rehabilitation or a swallowing study.
	Patients who met above criteria but had a "difficult airway," a designation that is applied to a patient by anesthesia or surgical provider based on intubation or surgical history, were evaluated by Otolaryngology-Head and Neck Surgery. Evaluation included airway history; physical exam; and flexible fiberoptic evaluation of pharynx, larynx, and tracheostomy. Otolaryngology-Head and Neck Surgery then recommended for or against proceeding with a capping trial based on findings

monitored the patient for the first 30 minutes and then transferred care to the nurse.

Outcome Measures

Capping was defined as successful if the patient had no occurrence of oxygen desaturation; increased oxygen requirement to $> 40\%$ FiO_2; or removal of the cap or plug for any reason, such as suctioning, desaturation, shortness of breath, or hemodynamic instability. If the patient did not tolerate capping, the trial was aborted, the tracheostomy service was notified, and the capping trial was restarted the following day using the conservative approach discussed above. If the patient passed the capping trial, the RT removed the tracheostomy tube using the standardized decannulation procedure (Fig. 2).

All staff were instructed to use the Patient Safety Network (PSN) to report capping issues. A PSN query was conducted 6 months before and after incorporation of the tracheostomy protocol. We searched this database with the stem word "trach" and reviewed all reports to determine relevance to capping or decannulation.

Next, we evaluated the effectiveness of our screening tool. Six patients who did not complete the quality improvement project for reasons unrelated to tracheostomy were excluded from the sensitivity and specificity calculations. Patients who passed screening criteria and were successfully decannulated were true positives. Those who passed screening and were not decannulated (capping trial failure, trial aborted for reasons unrelated to tracheostomy, etc.) were false positives. Patients who failed screening but were successfully decannulated after modifications were made were false negatives. Patients who failed screening and were not decannulated were true negatives.

Statistical Analysis

Means and standard deviations were calculated for data that followed Gaussian distribution; medians and ranges were calculated for data that followed non-Gaussian distribution. Frequencies and percentages were calculated for categorical variables. Sensitivity, specificity, and positive and negative predictive probability were calculated for the screening tool.

RESULTS

There were 61 requests for screening over a 12-month period. Fifty-seven patients were enrolled and four patients were delayed for reasons unrelated to tracheostomy. Thirty-five patients had received tracheostomy on their current admission, and 22 patients were admitted with a tracheostomy and then were identified as potential candidates for decannulation. Demographics are presented in Table II. Seventy-nine percent of the patients had received a percutaneous tracheostomy. The remainder underwent open tracheostomy. Of the 57 patients enrolled, 17 patients were from the medicine services; 14 patients were from Otolaryngology-Head and Neck Surgery (OHNS); 12 patients were from surgery; four patients were from neurology; four patients were from physical medicine and rehabilitation; three patients were from cardiology; two patients were from oncology; and one patient was from the surgical intensive care unit. Fifty-four patients were capped, and all 50 patients who passed the capping trial were successfully decannulated (Fig. 3). Three patients who passed all criteria had a history of difficult airway, a designation that is applied to a patient by an anesthesia or surgical provider based on intubation or surgical history. These three patients were evaluated by OHNS. For one patient (E, Fig. 3), the capping trial was not initiated because of significant upper airway edema. Two patients proceeded with the capping trial based on OHNS recommendations and were successfully decannulated.

Of the patients who failed screening criteria because of altered mental status or dexterity, three patients were evaluated by OHNS, and all patients proceeded to successful capping and decannulation. Two

TABLE II.
Patient Characteristics.

	Overall (n = 57)	Successfully Decannulated (n = 50)	Aborted (n = 6)	Failed (n = 1)
Age in years (mean ± SD)	58.07 ± 14.97	57.62 ± 15.61	58.83 ± 7.47	76
Sex, n (%)				
men	39 (68.42)	32 (68)	4 (66.67)	1 (100)
women	18 (31.58)	16 (32)	2 (33.33)	0
Indication for tracheostomy, n (%)				
chronic ventilator dependence	43 (75.44)	36 (72)	6 (100)	1 (100)
airway protection	14 (24.56)	14 (28)	0	0
Tracheostomy technique, n (%)				
percutaneous	45 (78.95)	38 (76)	6 (100)	1 (100)
open	12 (21.05)	12 (24)	0	0
Intubation days, median (range)	13 (1–28)	13 (1–28)	10.5 (7–15)	3
Mechanical ventilation days, median (range)	21 (1–71)	19 (1–71)	26 (11–40)	42
Tracheostomy days, median (range)	16 (1–86)	13 (1–86)	19 (15–60)	72
Hospital length of stay, median (range)	19 (5–184)	21.5 (5–184)	50 (29–105)	99
Death during capping, n (%)	2 (3.51)	0	2 (33.33)	0

n = sample size; SD = standard deviation

additional patients were not evaluated by OHNS and not capped during the quality improvement project. Patient D had altered mental status, and the primary team delayed capping until the patient's mental status improved. Patient G had dexterity problems and was capped with observation; however, this patient was discharged to a nursing home and lost to follow-up.

One patient (A) failed the screening criteria and capping trial on two separate occasions because of increased secretions and suctioning needs. Despite this, the patient was decannulated and discharged to a chronic ventilator facility. This patient was reintubated for management of secretions within 3 days (Fig. 3).

Of the 50 patients who were successfully decannulated, 45 patients met all criteria, giving the screening tool a 90% sensitivity for identifying which patients could be decannulated. The screening tool had 100% specificity for identifying patients in whom decannulation would not be successful. Positive predictive value was 100%; negative predictive value was 16.7% (Table III).

PSN data demonstrated that the number of reported events decreased from seven in the 6 months before incorporation of the new tracheostomy protocol to one event in the 6-month period after protocol implementation (Table IV).

DISCUSSION

Our quality improvement project has shown that the development and implementation of a multidisciplinary standardized capping and decannulation protocol is associated with a significant decrease in adverse events associated with tracheostomy decannulation. When capping is initiated, patients risk adverse consequences from increased airway resistance. Lack of communication between providers, premature capping/decannulation, inappropriate patient selection, and lack of monitoring and reevaluation after capping contribute to compromised patient safety and poor outcomes. This was exemplified in our patient (A) when the standardized protocol was overridden by the primary service. Patient A's clinical situation has led to the implementation of an additional safeguard feature in our standardized protocol. If an attending physician decides to override the standardized protocol, the physician is expected to discuss this with the charge nurse or nurse manager, develop a plan for monitoring, and document in the patient's chart with the plan to proceed. Since the completion of the quality improvement project, the standardized protocol has been approved by all departments and established as a policy. To date, no one has deviated from the standardized protocol since it has been adopted as a policy.

With increasing numbers of patients receiving tracheostomy,[2] more patients will require decannulation. Therefore, it is imperative that the predictors for decannulation readiness and criteria for capping be identified to minimize the risk of respiratory compromise. The new Johns Hopkins Hospital tracheostomy standardized capping and decannulation protocol outlines these criteria; and to our knowledge this is the first attempt to provide a standardized, user-friendly algorithm for evaluating tracheostomy patients for decannulation. In addition, it provides a protocol for evaluating and optimizing further care for patients who do not meet the delineated criteria for capping.

Successful implementation of this protocol involved extensive education of nursing staff, RTs, SLPs, and physicians. The solicitation of input from multiple disciplines in the task committee and the subsequent educational component of the trial were critical to gaining "buy-in" from all providers involved in the care of these

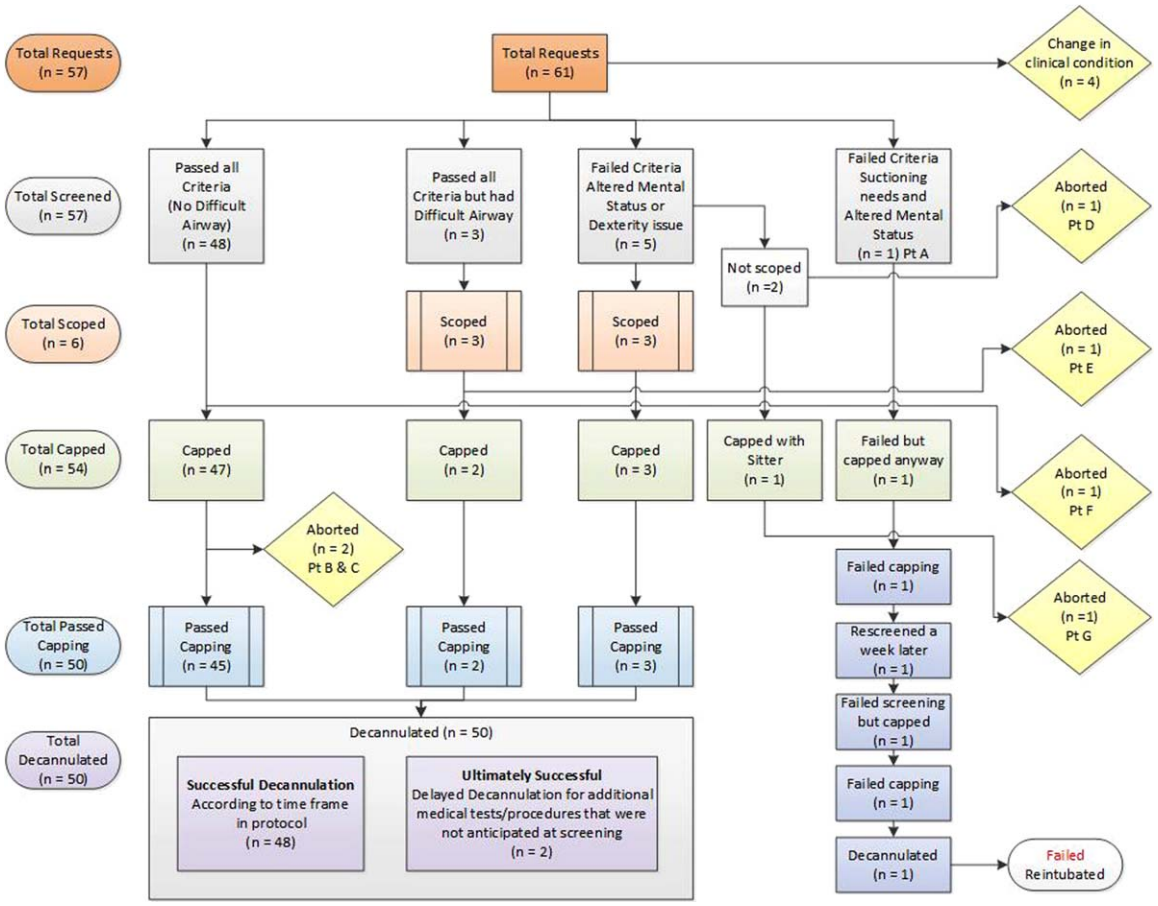

Fig. 3. Flow chart of the clinical pathways by which all patients in the quality improvement project progressed toward various outcomes: successful decannulation, capping trial aborted, and failed decannulation. Specifically, patients whose capping trial was aborted or who failed the capping trial, were labeled with letters A through G. (A) Failed screening because of increased secretions, failure to follow protocol; had two capping trials and was decannulated. Reintubation was required. (B) Passed screening; capping trial initiated; died from biliary bleed; no decannulation. (C) Passed screening; capping trial initiated; died from myocardial infarction; no decannulation. (D) Failed screening because of altered mental status. Quetiapine dose was increased; no capping attempted; no decannulation. (E) Failed screening because of difficult airway. Bronchoscopy revealed significant upper airway edema; no capping attempted; no decannulation. (F) Passed screening; capping trial initiated; discharged to nursing home before completion of capping trial. (G) Failed screening because of inadequate dexterity; capping trial initiated with sitter; discharged to nursing home before completion of capping trial. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

patients. The launch of the quality improvement project and educational efforts increased awareness of capping issues and produced a more cohesive team approach to selecting appropriate patients and coordinating a safe capping trial.

Anecdotal evidence from providers suggests that the protocol had a positive impact on team dynamics. Team members, using their specialized expertise, are empowered to apply the screening checklist and determine independently whether the patient is ready for capping. The authorized prescriber then assimilates this information to determine whether a capping trial should be initiated. This process has led to increased satisfaction and confidence in team members involved in capping and decannulation.

TABLE III.
Sensitivity and Specificity Analysis of the Screening Checklist.

Screening Test Outcome	Decannulated		Predictive Value
	Yes (n = 50)	No (n = 1)	
Passed (n = 45)	True positive (n = 45)	False positive (n = 0)	Positive predictive value 45/45 = **100%**
Failed (n = 6)	False negative (n = 5)	True negative (n = 1)	Negative predictive value 1/6 = **16.7%**
Sensitivity/specificity	Sensitivity 45/50 = **90%**	Specificity 1/1 = **100%**	

TABLE IV.
Patient Safety Network Reports.

Patient Safety Network Reports	
Preprotocol	Postprotocol
1. Tracheostomy tube was capped when patient was not able to manage secretions. Patient desaturated. Speech-language pathologist visiting patient removed cap.	1. Respiratory therapist capped tracheostomy tube without order from physician.
2. Tracheostomy tube was capped while cuff was inflated.	
3. Capping trial failed twice secondary to dyspnea.	
4. Physician ordered to remove cap after 12 hours of trial, but respiratory therapist forgot to remove cap.	
5. Tracheostomy tube was removed, but no dressing was placed. Air was leaking from stoma.	
6. Nurse and respiratory therapist were not aware that tracheostomy tube was capped by physician.	
7. Tracheostomy tube was accidentally decannulated while capping trial was in process.	

Only four of 61 (6%) patients were not screened and excluded due to changes in clinical condition, suggesting that we have developed a robust system for identifying patients who are eligible for capping. We demonstrated a high rate of successful decannulation when the screening tool and algorithm were appropriately applied (Fig. 3). Patients who initially failed screening were successfully decannulated after alternate pathways were followed, as indicated by the protocol. The decrease in tracheostomy capping—and/or decannulation-related adverse events—helps to validate this standardized approach to increasing patient safety. Monitoring for adverse events continues in an ongoing effort to improve the process.

Limitations

Our quality improvement project has a few limitations. This project was initiated when we determined that lack of standardization was adversely affecting patient safety. Therefore, we did not randomize patients, and all participants proceeded through the trial with the guidance of a protocol. The sample size in our quality improvement project was small. Additionally, the protocol is labor-intensive, and not all hospitals will be able to provide this investment. A prospective multicenter study using large sample sizes is required to further test the efficacy of the new protocol.

CONCLUSION

We describe a multidisciplinary protocol for determining the readiness of patients with tracheostomy for a trial of capping prior to decannulation. The protocol has excellent sensitivity and specific recommendations for addressing the factors that cause patients to fail screening criteria. Reduction in formally reported safety concerns after implementation of the protocol underscores the value in this type of protocol for improving safety in the high-risk group of tracheostomy patients and the satisfaction of multiple services that intersect in their care.

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