

Original Communications

Enhancing Patient Safety During Feeding-Tube Insertion: A Review of More Than 2000 Insertions

Rachel Sorokin, MD, FACP; and Jonathan E. Gottlieb, MD, FACP, FCCP

From the Department of Medicine, Jefferson Medical College and Office of Clinical Affairs, Jefferson University Hospital, Philadelphia, Pennsylvania

ABSTRACT. *Background:* An intervention to reduce complications from insertion of small-bore nasogastric feeding tubes was performed. *Methods:* This was a Performance Improvement project with the Plan, Do, Study, Act (PDSA) format; interventions occurred in July 2003. Electronic searches of risk management and radiology databases identified feeding-tube malpositions and complications from January 1, 2001, through December 31, 2004. Chart abstraction and a pre- and postintervention comparison were performed. Interventions were adoption of a more compliant feeding tube, direct supervision of residents, technology-guided insertion, and implementation of explicit policies and procedures. *Results:* Of all small-bore nasogastric feeding-tube placements, 1.3%–2.4% resulted in 50 documented cases of feeding-tube malpositions during 4 years. Over half of the 50 patients were mechanically ventilated, and only 2 had a normal mental

status. There were 13 complications (26% of malpositions), including 2 deaths, which were directly attributed to the feeding-tube malposition. Only 2 of the 13 complications and none of the misplacements had been recorded in the risk management database; most cases were identified from the search of radiology reports. In the 15-month postintervention period, no complications were identified. The control chart showed that after the intervention, there was a significant increase in the “number between” tube insertions without complications, confirming the effectiveness of the performance improvement (PI) project. *Conclusions:* Unassisted feeding tube insertion carries significant risk in vulnerable patients, which can be mitigated. Voluntary reporting appears inadequate to capture complications from feeding tube insertion. (*Journal of Parenteral and Enteral Nutrition* 30:440–445, 2006)

Patient safety requires that hospitals embrace robust methods to respond to medical misadventures, in part by emulating other industries with expertise in safety.¹ The Joint Commission for Accreditation for Healthcare Organizations (JCAHO),^{2,3} the Institute of Medicine (IOM),⁴ and leading authors^{1,5} all promote efforts to view health care as a complex system where many factors contribute to errors. Deming⁶ described a powerful methodology to continuously augment performance of complex systems, often abbreviated as the Plan, Do, Study, Act (PDSA), or Deming cycle.⁷ Deming and others focused on the important premise that any process creates information that people can harness to improve that process.⁸ Yet, implementing organizational change in health care remains challenging and the pace is slow.^{3,5}

In the spring of 2003, a thoracic surgeon at Thomas Jefferson University Hospital (TJUH) remarked in passing to the chief medical officer that his fellows had, on more than 1 occasion, inserted a chest tube to treat pneumothorax from a malpositioned feeding tube. In the lexicon of Deming and Juran, such a defect represents a “treasure,” an opportunity to analyze a process and refine performance.⁸ Many clinicians presume

nasogastric feeding tube placement carries a low risk of misadventure despite reported complications rates from 0.2% to 7.6%.^{9–13} In most hospitals, students, house staff, and nurses place small-bore nasogastric feeding tubes in a wide variety of settings. Thus, the outcomes of nasogastric feeding tube placement are dispersed and often overlooked by formal monitoring systems. Therefore, special effort must be expended to detect and correct these errors.

TJUH undertook an effort to convert this mishap into an opportunity. Thus, the casual comment initiated a complex series of events described below in the PDSA format. The process included a failure mode effects analysis (FMEA) and a computer-assisted text search algorithm to gather data. It resulted in a change in the feeding-tube product and in the procedure of feeding-tube insertion for specific patient populations. Although the potential dangers of feeding-tube placement have been previously reported in surgical and critical care populations,^{9–17} we describe the practical application of performance improvement methodology to address these potential dangers in a hospitalwide initiative and to create a safer environment for patients.

MATERIALS AND METHODS

Plan: Design the Approach for Taking Action

TJUH is a 690-bed tertiary-care academic medical center in Philadelphia, providing residency and fellow-

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Correspondence: Rachel Sorokin, MD, 1015 Chestnut Street, Second Floor, Philadelphia, PA 19107. Electronic mail may be sent to rachel.sorokin@jefferson.edu.

ship training to more than 760 trainees. Attendings, fellows, residents, students, nurse practitioners, and physicians' assistants on most clinical services insert small-bore nasogastric feeding tubes. Through informal discussion, the PI department became aware of 2 cases of malpositioned feeding tubes and confirmed that several had resulted in injuries. This triggered an FMEA, a formal technique that dissects a process (in this case, feeding-tube insertion) into multiple steps and analyzes each step for the likelihood, severity, and consequences of error.^{2,18} Each step is scored and the probability weighted score guides priorities for action. The FMEA revealed feeding-tube complications were more likely and the outcome most hazardous when inexperienced residents placed the small-bore tubes without supervision in sedated or intubated patients. In addition, clinicians participating in the FMEA wondered if the design of the feeding tube stylet facilitated inadvertent malposition.

The effort was limited to small-bore feeding tubes as no adverse events had been reported from Salem sump tubes or other stylet-free nasogastric insertions. Malposition was defined as placement external to the gastrointestinal tract, as the goal was to identify and prevent adverse events from insertions. (The effectiveness of duodenal intubation was not assessed.) Thus, we planned 3 changes: we would initially limit who inserted tubes in vulnerable patients and subsequently evaluate the benefit of using a safer tube and a safer method of insertion. We obtained rates of tube insertion, malposition, and adverse events from malposition to determine whether the changes reduced the risk of feeding-tube insertion.

Do: Implement Change

In July 2003, a memorandum to the entire hospital staff imposed an immediate moratorium on feeding-tube insertion by resident staff for intubated or sedated patients. This policy mandated either (1) fluoroscopic or endoscopic guidance for feeding-tube placement in these patients or (2) the attending physician personally insert the tube; the policy prohibited house staff from inserting feeding tubes in these patients without attending supervision. Concurrently, an expert group, including an internist, a gastroenterologist, a general surgeon, a critical care attending, and 2 nutritionists, evaluated several FDA-approved feeding tubes for stylet design and compliance by visual and tactile inspection. A new, more compliant tube was piloted in 2 intensive care units (ICUs) from December 2003 to April 2004. Intensivist physicians graded ease of insertion of the new tube on a standardized form using a Likert scale. In June 2004, the new tube replaced the old tube. In addition, the group sought evidence from the medical literature to help develop a procedure for tube insertion that would minimize the likelihood of malposition and minimize the likelihood of adverse events if the tube were malpositioned.

We gathered data about TJUH's feeding-tube insertion by querying our risk-management database (Access, Version 2000, Microsoft Corporation, Seattle, WA) for the period from January 1, 2001, through

December 31, 2004. We hoped that this database of adverse events, which included all incident reports, would identify potential cases of malpositioned feeding tubes. For the same time period, we also searched the text of electronic radiology reports stored in the hospital-developed radiology system (IBM) by combining the terms *feeding tube* or *Dobhoff* (with alternate spellings) with *lung* or *pneumothorax* or *bronchus*. The authors reviewed individual radiology reports to eliminate false positives (eg, "feeding tube in stomach, no pneumothorax"). At our institution, all small-bore feeding tubes were stylet containing, FDA-approved tubes, and it was not possible to retrospectively determine from chart reviews which tube (old or new) was selected. However, after June 2004, only the new tube was available throughout the hospital.

Medical records from cases with apparent tube malposition or with ambiguous reports were abstracted. We categorized *sequelae* of malpositions as none, radiographic pneumothorax only, pneumothorax treated with chest tube, or radiographic or clinically documented pneumonia treated with antibiotics. Pneumonia was defined as a new infiltrate on a radiograph, treated with antibiotics within 48 hours of pulmonary intubation by a feeding tube. For this study, a pneumonia temporally related to a malposition was assumed to have been caused by the malposition, although clearly aspiration of posterior pharyngeal secretions could not be excluded. Abstracted fields included patient age, gender, clinical service, mental status, and airway status; date, time, and hospital location at the time of tube placement; type of malposition or complication; and patient outcome. We designated feeding-tube insertions before the July 2003 memorandum as "preintervention" and those inserted afterwards "postintervention."

Because feeding-tube placement does not require informed consent and lacks a billing record, we could not determine the number of feeding tubes placed from chart documentation. We estimated the number of tubes placed with 2 independent methods: we assumed that the number purchased would approximate the total number placed because the TJUH Materials Management Department stores only 3 days of inventory, and wastage of feeding tubes was surmised to be low. We also recorded the number of patients with any chest radiograph report mentioning "feeding tube" or "Dobhoff" as a second method to estimate total number of tubes placed. These methods provided a denominator to permit comparison of malposition rates preintervention with those in the postintervention period, accounting for possible differences in frequency of tube placement. The number of malpositions and complications was analyzed as statistical control charts,¹⁹ and the "number between" tube insertions without complications²⁰ was also calculated. The project was approved by the Institutional Review Board for Human Subjects at Thomas Jefferson University.

RESULTS

Study: Measure and Analyze the Results of the Change

The risk-management and incident-report database initially identified 69 potential cases, of which only 2

represented complications of feeding-tube insertions. Search of the radiology information system database yielded 2079 patients, with 7678 chest radiograph reports including the words *feeding tube* or *Dobhoff*. This was filtered to 152 reports in 133 patients that also included the words *lung*, *bronchus*, or *pneumothorax*. Review of these reports resulted in 55 patients (56 reports) with documentation of feeding-tube malposition or complication. Only 1 case was found by both searches. Two of the “word-of-mouth” cases had not been identified in either the radiology or incident databases and were included. Thus, 59 malpositions were identified in 58 patients (1 patient experienced 2 malpositions) for subsequent chart abstraction (Appendix). After careful chart review, we discarded 9 cases where no complication or malposition could be documented.

We confirmed 50 cases of feeding-tube malposition, for a malposition rate of 1.3% (50 cases of malposition/3789 feeding tubes placed) using purchasing data from January 1, 2001, through December 31, 2004, for the denominator, or 2.4% (50/2079 patients) over the same period using the number of patients with any chest radiograph report including the terms *feeding tube* or *Dobhoff* as the denominator. The patients ranged in age from 22 to 91 years, with a mean age of 71.1 years. Two-thirds were over 60 years old. There were 38 men and 12 women. Twenty-six of the patients were mechanically ventilated, 1 was receiving positive-pressure mask ventilation, and 23 were spontaneously breathing. Thirty-four (68%) of the malpositions occurred in the right bronchus, and 16 occurred in the left. These resulted in 5 pneumonias, 8 instances of pneumothorax requiring chest tubes, and 1 intubation. Thus, 28% of the malpositions led to a serious complication.

Nine malpositions occurred during the night, 40 occurred in the daytime, and in 1 case time could not be determined. The relationship between malposition and complication was similar during day and night; 3 complications occurred in 9 nocturnal malpositions (33%), and 11 complications occurred in 40 daytime malpositions (27.5%). We could not determine the distribution of malposition rate with regard to time of day.

Only 2 patients (4%) had a normal mental status at the time of tube insertion. Twelve patients were awake with decreased mental status, whereas the remaining 36 were markedly sedated or obtunded. Thirty-seven patients were in an ICU, 9 were in an intermediate-care telemetry unit, and only 2 were in a general medical-surgical unit. One tube was malpositioned in the postanesthesia care unit, and 1 patient’s location could not be determined at the time of tube insertion. Thirty-three patients (66%) survived to hospital discharge. Two of the 17 patient deaths were related to the malposition of the feeding tube.

The departmental distribution of the residents placing the malpositioned tubes (Figure 1) confirmed our impression that feeding tube insertion was dispersed throughout the institution. With the exception of medical critical care, most malpositions occurred in small numbers in any given department or hospital area. The rate of malpositions and complications declined dramatically after the interventions (Figure 2). In particular, there were no complications of feeding-tube inser-

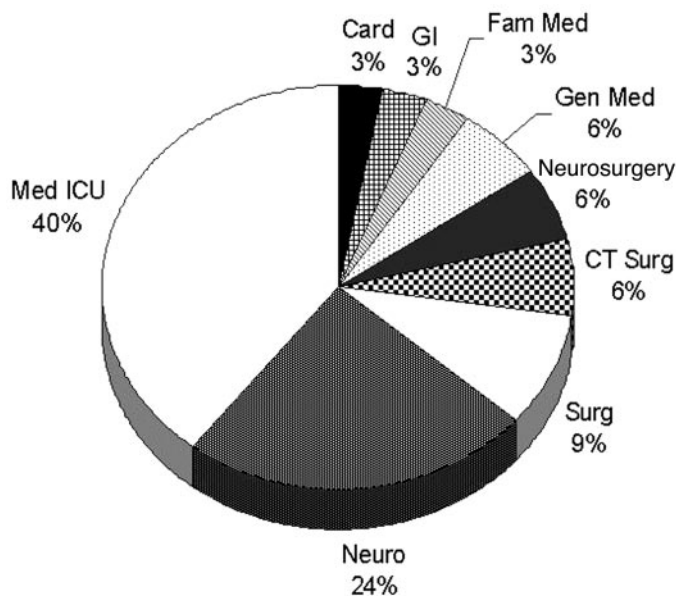


FIGURE 1. Distribution of feeding tube malpositions by specialty of physician performing insertion. More malpositions occurred in the Medical Intensive Care Unit than on any other service, but nearly every service that inserted feeding tubes experienced malpositions.

tions after July 2003. Using the method of Benneyan,²⁰ we found that there was a significant increase in the “number between” tube insertions without a malposition, beyond the upper control limit at 3 standard deviations from the centerline (Figure 3). This increase in “number between” tubes without malposition supported our impression of a decrease in malposition rate.

Act: Maintain, Extend and Refine the Improvement

Our temporary policies prohibited house staff from inserting feeding tubes in the vulnerable high-risk patient. This was neither practical nor consistent with our long-term educational goals, so we standardized and adjusted our approach to feeding-tube insertion.

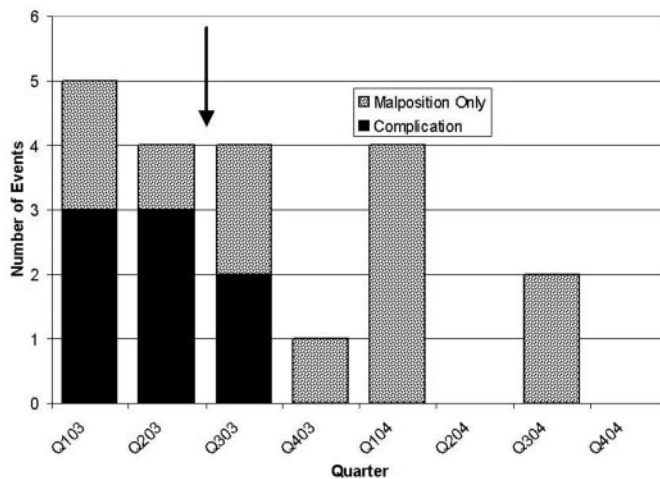


FIGURE 2. Number of malpositions with (solid areas) and without (stippled areas) patient injury. Vertical arrow indicates intervention. Numbers of malpositions and complications dropped dramatically after intervention.

Three specific processes were put in place in an attempt to “maintain the gain”:

1. The Critical Care Committee mandated in the spring of 2005 that feeding tubes inserted in the vulnerable patients must either not be advanced beyond 35 cm until a confirmatory radiograph is obtained or must be advanced under endoscopic, indirect laryngoscopic, fluoroscopic, or capnometric guidance.
2. Feeding-tube malposition and related adverse events were monitored and reported regularly to the clinical staff using the developed search strategies.
3. We began institution-wide resident education, including medical literature summary and our own institution-specific study data.

DISCUSSION

In this review of >2000 feeding tube insertions over a 4-year period throughout a major teaching hospital, nasogastric feeding tubes were malpositioned in 1.3%–2.4% of all insertions, and 28% of these malpositions resulted in pneumonia or pneumothorax; we attributed 2 deaths to these complications. Two-thirds of patients were in an ICU at the time of malposition. Our 28% complication rate is similar to the 26.9% pneumothorax rate reported by Mardenstein et al¹³ before their quality initiative. They did not evaluate pneumonia after intrabronchial insertion of a feeding tube. It is lower than the 37%¹⁶ and 57%¹⁷ complication rates reported from series limited to the ICU. Only 2 of our patients had a normal mental status at the time of insertion, and half were mechanically ventilated, confirming the vulnerability in these patients predicted by the FMEA and noted in the literature.^{14,21}

Widely practiced since the mid-1980s, nasal insertion of small-bore feeding tubes has been associated with complications of pneumothorax (including tension pneumothorax), intrapulmonary feeding, lung abscess, esophageal perforation, and pneumonia,^{9,14,15,21,22} and the incidence depends in part on patient population.^{10–13} The tubes also have been shown to coil in the pharynx, loop back up the distal esophagus from the stomach, and (in older tubes) leak mercury into the gastrointestinal tract.¹⁰ Not all investigators have found that bedside insertion of feeding tubes is accompanied by risk of injury; Powers and coauthors²³ reported no complications placing small-bowel feeding tubes in 357 ICU patients. Presumably, most of these patients were intubated or sedated, but details were not provided.²³ Previously believed to secure protection from an intratracheal cuff, patients with endotracheal or tracheostomy tubes more recently have also been recognized to incur significant risk from feeding-tube placement.^{13–15,21}

After our changed processes surrounding tube insertion, we experienced 15 complication-free months. Mardenstein et al¹³ reported that their complication rates from malpositioned feeding tubes plummeted with their strategy, proposed over a decade ago,¹⁴ of checking radiographs at 35 cm. Their decline in complications occurred despite a rising malposition rate,¹³ whereas our malposition rate appeared to decline (Figure 3); we certainly did not see a rise in the malposition rate.

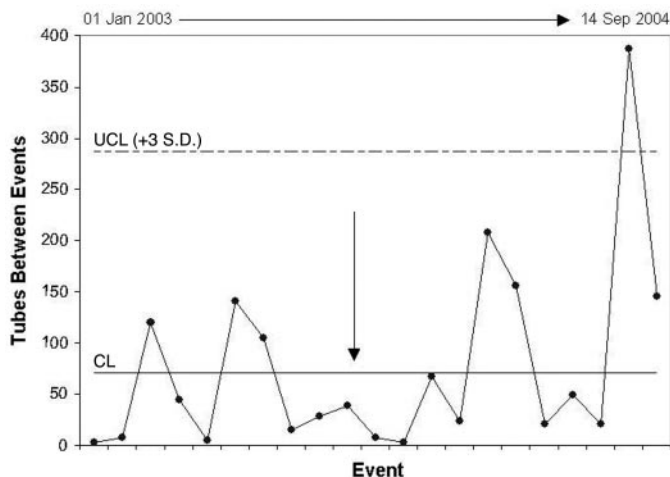


FIGURE 3. Number-between g-type control chart. Vertical arrow indicates intervention. Visually, increasing values represent increasing time between events and thus decreasing rates. CL, centerline; UCL, upper control limit, which was set at 3 standard deviations from the centerline. Second-most point from the end exceeds the UCL, suggesting successful special cause variation resulting from intervention.

An unanticipated finding of our study was that few malpositions or tube-related complications were delineated in our risk-management database. Although we gather all written and telephonic incident and adverse event reports into this formal database, the database contained none of the malpositions and only 14% (2/14) of the complications from feeding-tube insertions. Others, however, also corroborate that formal databases of incident reports may underestimate the true number of adverse events. Incident reports gather far fewer adverse events than house staff receiving daily e-mail prompts²⁴ and in 1 study identified only 6% of adverse drug events.²⁵ Calculations of adverse patient event rates from retrospective record review^{26,27} far exceed the numbers detailed through hospital risk-management or performance-improvement departments. Thus, although our approach of using clinical radiology reports rather than incident reports resulted in greater sensitivity of detection, we speculate that a comprehensive review of every placement could have yielded even greater numbers of errors.

Our report has several limitations. It may underestimate the number of feeding-tube placements, malpositions, and complications because we doubt that every event was captured by a radiograph or reported to risk management. Second, the actual rate of malposition and complication was estimated. The inventory data may underestimate the event rate because clinicians may discard tubes after contamination or without placement attempt. The radiology report data may underestimate the rate if multiple images of the same uncomplicated tube in the same patient were interpreted as separate tube insertions or if complications went unrecorded; conversely, it could have overestimated the rate if not every uneventful tube insertion was captured radiographically or was identified by our search strategy. We believe we reduced the opportunity for observer bias by asking the Department of Radiology

to perform the search and by aggregating the data after all chart-review determinations were complete.

Like most performance improvement processes, we used a historical control in a before-after comparison. Changing patient populations or physician behavior could have reduced the complication rate rather than our intervention. We think this is unlikely, as we have never before experienced such a prolonged complication-free period and the use rate of feeding tubes was relatively constant. However, we cannot be certain whether the group of interventions, a single component of them, or some other factor caused the decrease in complications.

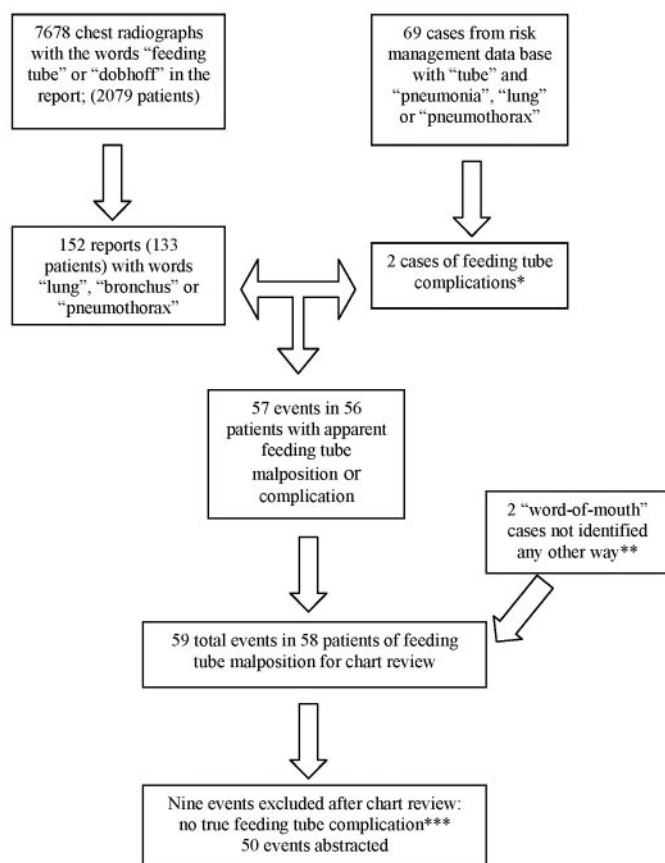
In this era of high complexity, short length of stay, and multiple-practitioner hospital care, danger from feeding-tube placement in vulnerable populations results in an undesirable and, we believe, unacceptable risk. Hospitals must deploy formal policies, procedures, and monitoring to minimize catastrophic outcomes from a procedure erroneously assessed to be innocuous.

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APPENDIX. Flow Diagram of Chart Selection for Abstraction

*One of the 2 cases identified by the risk management database was not found in the radiology database, because the radiograph documenting the feeding tube malposition was not entered into the electronic radiology database; chart documentation confirmed the malposition.

**Two word-of-mouth cases were not identified by any database. In one, the pneumothorax was discovered after feeding tube removal, so no single radiograph report simultaneously reflected a feeding tube and a complication. In the second case, the feeding tube was mistakenly identified in the radiograph report (although clinical documentation revealed it was a small bore feeding tube).

***For example, discarded cases included patients with pneumothorax after prior thoracotomy and unrelated to feeding tube insertion.

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