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Gastrostomy Tube Complications and Management

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Date of submission: April 16, 2019
Abstract

The avoidable complications of clogging and dislodgement of gastrostomy tubes (g-tubes) place a tremendous burden on patients, caregivers, healthcare providers, and the entire medical system. These complications are associated with $130 million in healthcare utilization each year. Insufficient education of patients and personal caregivers regarding the prevention of complications of clogging and dislodgement of g-tubes is identified as a major barrier.

Preintervention and postintervention education program models were established, which include a preprocedure clinic visit with education as well as scheduled follow-up phone calls. A chart review and follow-up phone call was used to evaluate the effect of providing consistent evidence-based education to patients and caregivers. The results of this study showed that none of the participants had a complication of clogging or dislodgement within 30 days of placement.

Keywords: gastrostomy tube, patient education, complication prevention, management
Dedication

I dedicate this scholarly project to my father, Ray A. Garcia. You were my biggest fan and always believed in me, giving me the confidence to believe in myself. I thank you for all of your support and love throughout my life. You always understood the importance of a higher education. Though you never saw my final degree to the end, I somehow know you are now smiling.
Acknowledgments

Countless thanks go to the UNM faculty, my colleagues, friends, and family. I would like to thank my committee chair, Dr. Joanne Haeffele, and committee members, Dr. Ruth De Rego, and Dr. William Schaeffer, and statistical expert, Blake Boursaw; I could not have completed this project without your encouragement, valuable advice, and support during my DNP program. I also extend my genuine thanks to my friends and colleagues, Felicia Nieto, CFNP and Marlen Piersall, PA-C for their unwavering encouragement and understanding throughout this program. A special thanks to the physicians and staff in Interventional Radiology, it is because of you that I go to work every day. A heartfelt thank you to Michael Walling, Mike, Cynthia, Patricia and Bethany Garcia, and Ed Sandoval for always knowing when to be there for me and for knowing when to stay away.
List of Acronyms

APP.......... Advanced Practice Provider

ALS.......... Amyotrophic Lateral Sclerosis

ED.......... Emergency Department

EMR......... Electronic Medical Record

G-tube........ Gastrostomy tube

IRB........... Institutional Review Board

IR............ Interventional Radiology

HLT......... Parnell’s Health Literacy Tapestry

HIPAA....... Health Insurance Portability and Accountability Act of 1996

HRRC........ Human Research and Review Committee

ml.......... Milliliter

PEG......... Percutaneous endoscopic gastrostomy

UNMH....... University of New Mexico Hospital

UNM......... University of New Mexico
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Chapter 1

Introduction and Background

The first gastrostomy tube (g-tube) was placed in 1980 by a pediatric surgeon and an endoscopist, who inserted the tube in a 4-month-old baby who was failing to thrive, to achieve an adequate nutritional state (Wisniewski, Torres, Renda, & Bayouth, 2014). It is estimated that 215,000 g-tubes are placed each year in the United States (Rosenberger, Newhook, Schirmer, & Sawyer, 2011). A g-tube is a common alternative for patients unable to support their nutritional needs by oral intake. G-tubes can be a temporary source of nutrition, such as for patients with head and neck cancer or trauma to the head and neck, who will need nutritional support during treatment, and a g-tube also can be a permanent source of nutrition, for patients unable to get adequate oral intake of food, liquids, or medications, often related to a neurological disorder such as stroke or head injury (Kalmin & DeLegge, 2012).

Since the introduction of g-tubes, the indications for use and utilization have vastly increased. Advancement of medical care has resulted in patients living longer, largely because of improved technology, better treatment, and increased resources (Griscti, Aston, Martin-Misener, Mcleod, & Warner, 2016). As patients live through previously nonsurvivable conditions, the need for alternative nutritional sources has grown as has the improvement of the placement technique of g-tubes. There are complications related to g-tubes, the most common of which are clogging and inadvertent dislodgement (Lord, 2009). Reasons patients experience these complications are complex but might be linked to conditions when patients experience (a) lack of standardized patient education, (b) lack of best-practices guidelines, (c) lack of written education material, or (d) failure to provide expert resource contacts (Lord, 2009).
The complications of unintentional removal and clogging pose a major burden to patients, the hospital system, and the medical (Rosenberger et al., 2011). Without nutritional access, patients in which a g-tube was used have increased health risks related to dehydration, malnutrition, and the inability to receive medications. Patients with dislodged and clogged g-tubes often present to an emergency department (ED) to have the g-tube replaced, exchanged, or unclogged. Because these conditions are considered as nonemergency, patients will wait for many hours without nutrition, hydration, and medication, waiting for the appropriate referral, often to an interventional radiology (IR) department to replace or exchange the g-tube (Correa et al., 2014).

Each avoidable ED visit costs approximately $1,200 and interferes with patient throughput within the ED, leading to frustration of patients, caregivers, and healthcare professionals (Rosenberger et al., 2011). With the increased use of g-tubes, the development of sustainable quality care is of utmost importance, especially due to current health consciousness and healthcare reform; every effort must be put forth to develop and maintain delivery systems that benefit both the consumer and stakeholders (Knickman & Kovner, 2015). The financial impact and burden to the healthcare community cannot be minimized, and the potential cost savings with a thorough, standardized, evidence-based education protocol is significant (Schweitzer et al., 2014).

Frustration and stress are the most common emotion that patients and personal caregivers use to express their feelings of having to return to IR or the ED to have their g-tube complication managed (Henegan, 2016). Patients often complain that they were not taught how to address and how to avoid the complications of a clogged or dislodged g-tube. Schweitzer et al. (2014) explained that in their Magnet-recognized hospital, the lack of patient education led to
preventable complications and subsequent ED visits. In reviewing data at the University of New Mexico Hospital (UNMH), it was determined that many of the preventable complications occurred within the first 30 days of initial g-tube placement. It is hypothesized that a well-planned, evidence-based education program would reduce the incidence of unplanned IR and ED visits for g-tube complications.

**Problem Statement**

G-tube complications are frequent and can be frustrating for patients, families, and healthcare professionals. Moreover, complications can have significant consequences. The most common complications are g-tube dislodgment and clogging, which are usually preventable occurrences. These complications are often the result of a poor understanding of the appropriate management of g-tubes or of inadequate training to patients and personal caregivers, including general care of the g-tube, proper flushing techniques, and medications that are safe to administer through the g-tube (Lord, 2009). The complication rate for g-tubes placed by the IR staff at UNMH is more than 35%. i.e., unintentional removal or clogging within the first 30 days of g-tube placement in the adult population. It is estimated that the complication rate for a clogged gastrostomy tube is between 12.5% and 45% nationally (Fisher & Blalock, 2014).

Currently, IR staff provides no written or verbal education to patients or caregivers at UNMH about unintentional removal or clogging of g-tubes; it is never addressed in the consenting process or during the immediate postprocedure period. The referring service will address why it is necessary to insert the g-tube and generally how the procedure is performed; IR staff will provide detailed information about the procedure, risks, and benefits of the procedure and the immediate postprocedure care and complications; the dietician will provide nutritional information; and, lastly, the nursing staff will provide instructions for tube feedings and g-tube
care. In this division of roles and responsibilities, no one discusses the complications of unintentional removal or clogging of g-tubes.

The complications of clogging and dislodgement are not unique to UNMH, to Albuquerque healthcare facilities and providers, or even to healthcare in the United States. In fact, the literature indicates that clogging and dislodgement is a global problem that can be remedied, initially, by educating patients and personal caregivers. In a retrospective literature review of 332 articles, Schrag et al. (2007) examined the major complications of percutaneous endoscopic g-tubes (PEG) and found that the occurrence of clogging and dislodgement were similar to data reported in the literature, with dislodgement occurring in 1.6% to 4.4% of patients and clogging in up to 45% of patients with g-tubes. Schweitzer et al. (2014) concluded that preprocedure education resulted in improved patient satisfaction and outcomes and in fewer complications.

Structured education about g-tube complications at UNMH is in great need. Increasing patient and personal caregiver knowledge, as well as reducing avoidable complications, is critical to decrease the frequency and severity of consequences of these avoidable complications of unintentional removal or clogging of g-tubes. The purpose of this project is to measure the effect of g-tube education on the rate of unintentional removal or clogging of g-tubes.

**PICOT Question**

In patients with gastrostomy tubes, will a preprocedure clinic visit with verbal and written education regarding clogging and dislodgment for patients and family members, compared to no education reduce the frequency and severity of unintentional dislodgment and clogging of g-tubes?
Aims

The purpose of this project is to maximize education regarding the complications of unintentional dislodgment and clogging to patients who have g-tubes and to family members and personal caregivers involved in the care and management of g-tubes. The specific objectives of this study:

- Identify current evidence-based interventions.
- Develop a preprocedure clinic to include verbal and written education related to the care and management of gastrostomy tubes in adult patients. The emphasis of such education should be the prevention of clogging and dislodgement.
- To reduce readmission of patients with g-tubes to IR or the ED within 30 days due to clogging or dislodgement by educating patients and families about the care of g-tubes.

The specific aims of this study:

- To evaluate if educating patients preprocedure about the complication of unintentional dislodgment and clogging of their g-tube will reduce readmission rates to IR and ED within 30 days of the placement of the g-tube.
- To implement a full, standardized, evidence-based education protocol.

The specific pilot aims for this study are to evaluate feasible outcomes:

- To establish and sustain a preprocedure g-tube educational clinic.
- To deliver education to 75% of eligible patients.
- To implement a practice change that will impact patient outcomes.
Chapter 2

Summary of Literature

Description of Search

Literature was obtained for review including CINAHL, PubMed, and Google Scholar. The articles in this review were published between 2011 and 2017, were written in the English language (or translated into English), and were peer reviewed. This literature review comprises these key terms: gastrostomy tube, complications, emergency department, interventional radiology, and long-term care facilities. Additionally, the search included any community education related to the care of g-tubes.

Although a number of studies have retrospectively reviewed g-tube complications, only two current quantitative studies were found. Shipley, Gallo, and Fields (2016) developed a formal evidence-based educational program to be delivered to the nursing staff at two skilled nursing facilities in their city. The authors developed and administered a pretest, provided an educational in-service, and then administered a post-test. While their initial results were positive, the authors cautioned that limitations of the study included a small sample size of only two skilled nursing facilities, and the post-test was not completed by all of the nurses who took the pretest (Shipley, Gallo, & Fields, 2016). In another study, Schweitzer et al. (2014) developed a preprocedure-postprocedure evidence-based education protocol to evaluate the benefits of a preprocedure g-tube education program. The results showed improved patient/caregiver responses and an improved understanding of postprocedure g-tube care (Schweitzer et al., 2014). There are evidence-based recommendations for the care and management of g-tubes as well as a national organization whose members specialize in enteral and parenteral feeding protocols (Fisher & Blalock, 2014).
These studies found that education is the key to prevention of g-tube complications and that the relationship between education and positive patient outcomes can be correlated. It is determined that at UNMH, patient education for g-tube complications is unacceptably inadequate, which results in significant preventable complications. Further research is indicated to substantiate these findings and to demonstrate the value of a g-tube educational program at UNMH.

G-tube Use and Popularity

In a comprehensive, systematic review, Rahnemai-Azar, Rahnemaiazar, Naghshizadian, Kurtz, and Farkas (2014) described the major indications and contraindications to g-tube placement, typical diagnosis of patients referred for g-tube placement, and common complications associated with g-tube placement. Rahnemai-Azar et al. (2014) determined that enteral nutrition has become a standard of care in the acute care setting and that initially, the most common route of administration is nasoenteric. Because nasoenteric feeding has a greater risk to patients needing longer than two or three weeks of enteral feeding, the use of a g-tube is considered superior. Additionally, the researchers pointed out that enteral feeding is preferred to parental nutrition, especially because of an increased risk of complications related to intravenous access, a higher incidence of bacteremia associated with parenteral nutrition, and higher costs associated with parenteral nutrition (Rahnemai-Azar, Rahnemaiazar, Naghshizadian, Kurtz, & Farkas, 2014).

Because g-tubes are often mandatory for patients being discharged to a rehabilitation center, skilled nursing facility, or long-term care facility, there is an increase in the popularity of g-tubes in the acute hospital setting, and this led to the indication for placement and use to vastly increase; it is estimated that currently, 215,000 g-tubes are placed each year in the United States.
In 2009, the National Center for Health Statistics reported that more than 245,000 discharges from acute care settings had a code for enteral nutrition (Bankhead et al., 2009).

**Financial Impact of Gastrostomy Tubes**

Over a three-year period, Rosenberger et al. (2011) described a retrospective analysis of all percutaneous endoscopic gastrostomy tubes placed by a single surgeon in their institution. They examined the data for mortality, complications, and long-term management of g-tubes. The authors surmised that because the sequela of late unintentional removal of gastrostomy tubes holds a much lower risk of mortality, it might be underreported, and the true economic impact is not necessarily recognized (Rosenberger et al., 2011).

Reviewing financial data, Rosenberger et al. (2011) determined that for major complications, such as peritonitis, the average added cost to treat the infection was at least $5,160 per person, while the average cost to replace an uncomplicated unintentional removal was $1,200. For patients managed in a clinic setting and who did not need radiographic confirmation, the average cost to replace a g-tube was $500. Generally, the cost to the hospital to replace the 72 patients with unintentional removal of their g-tube was an additional $61,900 (Rosenberger et al., 2011).

Rosenberger et al. (2011) reported unintentional g-tube removal was 45.1% of their complications, and tube dysfunction was the leading problem addressed by a physician or nurse. There were 92 unscheduled healthcare interactions related to complications with g-tubes in a 17.5-month period. In conclusion, patients had frequent visits to the ED and unscheduled clinical visits, which was similar to the statistics experienced with the patients in IR at UNMH, who reported a 35% complication rate for unintentional removal or clogging within the first 30
days of g-tube placement. The researchers concluded that a better mechanism used to secure the g-tube would help to reduce the risk of dislodgement.

The cost and risk of replacing a clogged tube is significant. With each replacement comes the risk of malplacement, patient discomfort, and additional radiation exposure. Rosenberger et al. (2011) calculated that the cost for bedside replacement of a g-tube, when radiography was not part of the procedure, was about $91. This cost goes up exponentially if the patient must be transported to the hospital, visits the ED, visits the radiology department, or if the g-tube is replaced using fluoroscopy.

**G-tube Complications of Clogging and Dislodgement**

The avoidable complication of g-tube clogging is a substantial problem, and the remedy to the problem starts with the education of patients, family members, and caregivers caring for the tubes. While there is not one single cause for g-tube clogging, all possible reasons must be considered so that the risk of clogging is minimized. Education of nurses, caregivers, and providers is essential (Fisher & Blalock, 2014). Clogged g-tubes create an enormous burden for patients, caregivers, and the medical community. Hospital visits by g-tube patients are often avoidable and cost a substantial amount of money for each incident. It is estimated that the complication rate for a clogged gastrostomy tube is between 12.5% and 45% (Fisher & Blalock, 2014).

In an attempt to assess the complications related to enteral feeding tubes and the effect on healthcare systems, Alivizatos, Alexopoulos, Bajrcevic, Gavala, and Apostolopoulos (2012) evaluated preinsertion patient education along with postinsertion follow-up care from the Department of Surgery and Artificial Nutrition Unit at St. Andrew General Hospital in Patra, Greece. The authors found that the most common complications were accidental removal and
clogging (45%), tube leaking (6.4%), irritation of stoma (6.4%), and diarrhea (6.4%). All of the patients included in the study were discharged using home enteral nutrition (Alivizatos et al., 2012). The authors evaluated the presence of preprocedure and postprocedure education of multiple team members, comprised of the physicians, nurses, and dieticians, and assessed whether the education made a difference in the rate of unscheduled return visits to the hospital. Additionally, an assessment was performed to evaluate patients’ and caregivers’ ability to negotiate all aspects of enteral feedings, including equipment management, care of the tube and skin care, and potential problems that could arise and how to manage them. All of the patients were contacted by a nurse every month to address any concerns. In conclusion, the researchers determined that ED visits were prevalent and there was a need for an educational program that specifically addressed the areas of avoidable complications. A limitation of this study is that it was a retrospective chart review of 31 patients who reviewed preprocedure and postprocedure education. The education was provided by various members of the healthcare team. The authors said that further studies were needed to determine the relationship between education and outcome nutrition (Alivizatos et al., 2012).

In Correa et al.’s (2014) resource utilization review, the authors looked at ED visits at less than 30 days post g-tube placement and ED visits 30 days to 365 days’ post placement over 21 months. The visits were then sorted as either mechanical issues (dislodgement, clogging, or leaking) or wound-related (infection, skin breakdown, bleeding, or granulation tissue). Additional sequelae assessed included readmission, reoperation, and the use of gastrostomy contrast studies. This was a retrospective study that looked at the medical records of 247 pediatric patients who had a g-tube placed during the study period. The purpose of the study was to evaluate the frequency of and reason for ED visits so an educational program could be
developed to decrease ED visits and to improve the quality of patient care (Correa et al., 2014).

The results showed that of the 247 patients in which g-tubes were placed, 219 were discharged in less than 30 days. Of the 219 patients, 42 returned to the ED 44 times in less than 30 days after placement of the g-tube. Seventeen patients (44%) were seen for avoidable visits to the ED, such as for mechanical issues (clogged or leaking) or granulation tissue; 25 patients (61%) were seen for necessary visits, such as dislodgement and infection; 40 patients visited the ED a total of 71 times in the period between 30 days postprocedure and one year later. Fifty-nine patients (83%) had avoidable and/or nonemergent complications; 12 patients (17%) were seen for necessary visits, such as infection or obstruction; and 64 patients (26%) returned to the clinic for 89 unplanned visits (Correa et al., 2014).

As a result of their findings, Correa et al. (2014) realized that education was lacking in their facility, and they have developed written educational material that is provided to every patient and caregiver. The education material is customized to specifically address the major known complications of g-tube placement. For example, one handout addresses clogging and dislodgement, while another addresses wounds and skin care. The healthcare facility now also has a nurse dedicated to provide all post-g-tube patient and caregiver education prior to their discharge from the hospital. At the time of publication, the authors had developed a prospective study and were in the active study state.

The increased popularity of g-tubes, along with a policy that mandates g-tube placement for discharge, makes it imperative that education about the care and management of g-tubes be thorough. The impact of uninformed patients and caregivers results in enormous financial burdens on the healthcare system. The key is early education for patients and caregivers so that unplanned ED and clinic visits might be avoided. Teaching patients and their caregivers how to
care for g-tubes will create considerable cost savings to consumers and to the healthcare system in general (Correa et al., 2014).

**Complications of Delay in Care**

It is reasonable to consider that if more patients, families, caregivers, and staff at healthcare facilities are educated about the care of g-tubes, fewer complications will occur, resulting in fewer hospital readmissions. In a paper that addresses the hazards of dehydration in patients with enteral feedings, Lord (2009) explained how quickly patients can become dehydrated, both with feedings, delay in feedings, and in cases when the g-tube is clogged or dislodged. Boullata states that the most vulnerable populations are the elderly, the young, and those with confounding diagnoses. The consequence of a clogged g-tube depends on how long it has been nonfunctioning, the length of time to replace it, and the frequency in which it occurs. Untoward consequences of a clogged or dislodged g-tube include dehydration, lack of medications, and potential malnutrition (Boullata et al., 2017).

Prevention is the priority to reduce the potential consequences of clogged or dislodged g-tubes. Fisher and Blalock (2014) have presented evidence-based guidelines to providers caring for patients with g-tubes to prevent and manage clogging. The evidence-based guidelines are comprised of flushing the g-tube with 30 milliliters of water prior to each feeding and 60 milliliters of water after each feeding. Additional flushing is needed prior to and after any medication administration. If a feeding pump is used, it is recommended that the pump is stopped and that the tube be flushed with 30 milliliters of water every four to six hours (Fisher & Blalock, 2014).

Unintentional dislodgment of a g-tube can be prevented by educating patients about the most common acts that result in dislodgement, such as the g-tube dangling instead of secured on
the abdomen with tape, the lack of use of an abdominal binder to protect the g-tube, and excess tubing getting caught on a doorknob or furniture, for example (Boullata et al., 2017). The education provided to patients, families, long-term care facilities, healthcare providers, and caregivers is critical. By addressing barriers to care and bridging gaps in knowledge and by creating champions in the medical community, the incidence of malfunctioning g-tubes could be greatly reduced.

In conclusion, the consequences of clogged and dislodged g-tubes impact safe and judicious delivery of care to patients. Avoidable ED and provider office visits are a tremendous burden to the medical system, and patients risk physical harm from delayed nutrition, dehydration, and the inability to take medications. The education of patients, families, and caregivers will promote safe care to patients with g-tubes.

Chapter 3

Theoretical Model and Methodology

Theoretical Model

Adoption of a comprehensive, standardized, evidence-based education protocol into daily practice can be a difficult change for an organization to undertake. In order to ensure successful implementation of evidence-based practice, an appropriate theoretical framework must be established. Parnell’s Health Literacy Tapestry (HLT) conceptual framework is a beneficial theoretical model to examine the significance of health literacy and its relationship to health outcomes. The HLT is important to this project because it supports the fact that patients who are having a newly placed g-tube, when provided with health education that is written and verbalized in clear language, will have improved understanding as well as fewer unplanned visits to IR or the ED.
U.S. Department of Health and Human Services and the Institute of Medicine (2004) described health literacy as “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Kutner, Greenberg, Jin, & Paulsen, 2006). Only 12% of American adults understand health information and are able to apply the information to their healthcare needs (Kutner et al., 2006). This means that most patients have difficulty understanding healthcare instructions, which puts them at greater risk of making medical errors and having complications related to poor understanding. It is critical that every effort is made for patients to understand their healthcare and are given the opportunity to make appropriate, informed healthcare decisions (Kutner et al., 2006).

The Health Literacy Tapestry Conceptual Framework

The HLT conceptual framework recognizes that health literacy is not just understanding spoken words but is a partnership between individuals, families, communities, and the healthcare team (Parnell, 2015). The tapestry is woven together by threads, domains, borders, and overlapping circles. Each of these components intertwines and contributes to the complexity of health literacy (Parnell, 2015). Parnell identified the threads as (a) media and marketplace; (b) health knowledge and experience; (c) demographics; (d) overall patient health status; (e) community; and (f) social, spiritual, and cultural influences. Parnell explained that the domains of health literacy are (a) oral communication; (b) written communication; and (c) environmental communication, which includes access and navigation through the healthcare system (Parnell, 2015).
The Health Literacy Task Force of the Quality Health Care Expert Panel of the American Academy of Nursing prepared a policy brief that outlined recommendations to promote health literacy and to state that health literate techniques need to be used by every healthcare provider at every patient encounter (Loan et al., 2018). In the first meta-analysis to compare health literacy with health outcomes, Miller (2016) found a positive correlation between health literacy interventions and compliance to treatment, especially in vulnerable populations.

The HLT is a pertinent framework for this project because it builds on the framework that health literacy is directly related to health outcomes. Communication is the foundation of this theoretical framework and the key to this project. Using the domains of health literacy as depicted in the above image, oral communication was achieved during a preprocedure clinic visits where g-tube teaching began; written communication was implemented by educational handouts provided to each patient; and environmental communication was achieved through
recognizing and addressing barriers that exist, such as language and cultural barriers, providing education through the use of an interpreter service.

Recognizing the threads of the tapestry--demographics, health status, community, and social, spiritual, and cultural influences--helped the study Advance Practice Provider (APP) to understand potential barriers to learning (Parnell, 2015). It was critical for the study APP to invest the time to explore potential barriers, thus making the educational clinic visit supportive and positive for the patient. During the education process, the study APP asked for teach-back to assess understanding of the information taught. Incorporating communication into the development of a comprehensive g-tube education program is essential to draw on patients’ strengths and to build on their knowledge base to assure that every effort is made for patients to understand their care and is able to apply the fundamental defenses needed for successful management of their g-tube.

The use of follow-up phone calls, using specific questions, allows for the tapestry border of evaluation and teach-back. The study APP was able to assess any knowledge deficit of patients regarding the care of their g-tube and their understanding of how to prevent clogging and dislodgement. By addressing questions stated by patients during the follow-up calls, their misconceptions were replaced with understanding, which led to enhanced outcomes and well-being, the final border of the tapestry (Parnell, 2015).

Methodology

This was a prospective cohort study with retrospective controls to which outpatients referred for g-tube placement were asked if they would volunteer to participate in this study to evaluate the influence of preprocedure teaching about the outcome regarding g-tube clogging or dislodgement. Written informed consent was obtained from all prospective patients enrolled in
the study (Appendix A). A retrospective data analysis was conducted to compare the number of
patients who did not receive preprocedure teaching who had experienced the complication of g-
tube clogging or dislodgement. The data was collected from UNMH’s electronic medical records
(EMR). Fisher’s exact test and Cramer’s V were used to analyze the data.

**Project and Study Design**

**Ethics and Human Subjects’ Protection**

In an effort to minimize any potential ethical issues associated with this study, informed
consent was obtained from each patient enrolled in the prospective study; anonymity and
confidentiality of patients was maintained by assigning a study number to all individuals; and no
identifying information was used in reference to this study, thus respecting the privacy of every
patient. Beneficence was always a consideration: in that, if a patient at any time during the
course of this study asked to be withdrawn, for any reason, that request would be granted without
rebuttal. Additionally, approval from UNM’s Institutional Review Board (IRB) was obtained
from UNM’s Human Research Protection Office.

**Risks**

The only foreseeable risks are that of inconvenience related to having to make a clinic
visit for the g-tube education regarding clogging and dislodgement and to respond to phone calls
at the described times. This potential inconvenience is for the study period of 30 days. There is
the risk that confidentiality could be breeched. There is a risk of emotional discomfort. There is
no money available for patients to travel to the clinic.

There are no undisclosed risks to subjects that are more than minimal. To minimize the
above risks, patients will be informed of their right to withdrawal from the study at any time if it
is too inconvenient or if it causes them undue emotional discomfort. All information will be de-
identified protecting patient rights to privacy of confidential health information.

**Benefits**

Potential benefits of the study include building on an opportunity to improve outcomes for patients who currently have compromised health and to decrease preventable complications of clogging and dislodgement. Potential benefit of the proposed research includes the identification of a teaching materials when deployed appropriately could decrease hospital readmissions impacting improved health outcomes for patients, improved quality of care and decreased financial burden and penalties to hospitals.

**Study Design**

The study included a standardized, evidence-based education protocol provided to patients, families, and personal caregivers, which included offering a preprocedure clinic visit with the study APP for all outpatients prior to g-tube placement. During the clinic visit, the study APP provided verbal, written, and hands-on education, using a g-tube to demonstrate flushing and securing methods. An educational handout (see Appendix B) was given to patients, families, and personal caregivers and teach-back was given during the clinic visit to verify that everyone involved in the care of the patient understood the measures that could be taken to address problems. Additionally, the study APP provided follow-up phone calls at one week, two weeks, and 30 days postprocedure to address questions and concerns. After an introduction on the phone, the same specific questions were asked of each patient or caregiver during each follow-up phone call. If patients were unsure of flushing or securing techniques or had any answers that indicated a lack of understanding of their g-tube care, additional teaching was provided during each phone conversation. Specific questions asked were:

- Is the g-tube working?
• Where do you keep the “Preventing Problems after Your G-Tube Procedure: Patient Education” information instruction sheet that was handed out at the clinic?
• How often are you flushing the g-tube?
• What are you using to flush the g-tube?
• How much liquid are you flushing the g-tube with each time?
• How have you secured the g-tube?
• Have you had any complications of clogging of the tube in the past week?
• Have you had any complications related to dislodgement?
• What other problems have you had with your g-tube?
• Have you called any medical provider about your g-tube in the past week (or month)?
• Have you been to any hospital, doctor’s office, urgent care or emergency department because of a problem with your g-tube?
• Do you have any questions for me about your g-tube?

Setting

The study took place in Albuquerque, NM. The setting for this study was a 527-bed Level 1 trauma center and academic medical center that serves patients from across the state of New Mexico and the Southwest region of the United States and with patients with g-tubes placed by IR at UNMH.

Study Population

The study population included all cognitively intact outpatients, determined by assessment using observation and communication, for whom new g-tube placement had been
scheduled for placement by IR at UNMH. Inclusion criteria were (a) patients 18 and older and (b) patients who were cognitively intact and in whom g-tubes had been placed by IR. Exclusion criteria were (a) patients younger than 18, (b) patients in whom a g-tube was not placed by IR at UNMH, and (c) patients who were not cognitively intact.

Sources of Data

All data for the study, comprised of referral to IR, date of procedure, diagnosis, and demographic information, was retrieved from the patient electronic medical record and radiology dictation system. Prospective data was collected for all patients enrolled into the study. Retrospective data was collected to identify patients in whom g-tubes had been placed during the previous six months prior to starting the study to evaluate how many unscheduled visits were made to IR or the ED. During this data collection period, patient education was implemented, and the IR staff was educated about the study.

Data Collection Process and Tools

Data was collected for all prospective patients using the G-tube Data Subtraction Tool (Appendix C) and demographic information such as sex, age, and diagnosis. Data collected from the EMR of the retrospective patients comprised of date of g-tube placement; type of complication, clogging or dislodgement; and demographic information, including sex, age, and diagnosis.

Data Protection Plan

All data collected for the study was de-identified, coded specifically for the study, and stored in a locked cabinet accessible only to the principle investigator and co-investigators. Any patient-identifiable information was placed in a locked HIPAA bin located in the UNMH Radiology Department and will be kept for five years.
Statistical Analysis

Based on preliminary analyses of the original statistics, physicians in IR placed g-tubes in approximately 34 eligible patients in a three-month period, approximately 35% of whom were re-admitted within 30 days for clogging and dislodgement. A sample size of 68 patients in the six-month retrospective period and 34 patients in a three-month prospective period with $\alpha = .05$ for a Fisher’s exact test comparing independent proportions, the readmission rate will need to change from 50% in the retrospective period to 22% in the prospective period in order for this study to have sufficient (80%) statistical power. The aim was to review 68 patients in the six-month retrospective period so that a medium effect size using Cramer’s V could be achieved. The aim was to enroll 34 patients in three months and no more than 60 patients required to achieve a medium effect size. The prospective enrollment began following approval of the IRB, and postimplementation of the educational materials consisted of all 30-day readmissions within the three-month period after implementation of the educational materials, not to exceed 60 patients.

While a power analysis presents an ideal sample size, the current project did not utilize predictive or correlational analysis. The researcher attempted to reach the suggested power sample size of 34 but was unable to so, resulting in a smaller sample size than suggested by the power analysis (Cohen, 1992). Cohen (1992) suggested that power analysis is most relevant when statistical significance and effect size must be considered in an analysis. For the current study, though its power is not achieved due to low sample size, the effect size is a good result of this research.
Budget

Minimal costs were anticipated for this study. Because the g-tube intervention was designed for a patient population that already had visited the IR, the changes pertained primarily to an attention to detail and documentation. As for the cost of teaching, it was estimated that each clinic visit took 30 minutes and two patients per month, which translates to hour of time, at $50 per hour, and a total cost of $100 per month during the study period. At the time of the study, the APPs were on a salary and the IR clinic already existed, which means the project was completed as a part of existing clinic, and therefore, there was no additional staffing cost. Additional educational materials were made and were given to patients and families. At the time of the study, however, the IR staff was adding procedural education for procedures performed in IR; that information was deemed necessary and should be provided at each encounter.

Quality

The validity of the research design was maintained by enrolling patients in the prospective group and comparing complications of clogging and dislodgement to the retrospective group obtained from the IR dictations system and UNMH EMR. Internal validity is defined as whether an experimental treatment or condition makes a difference to the outcome and whether sufficient evidence exists to substantiate the claim (Yu & Ohlund, 2010). For this project, internal validity was shown through the results, specifically, that patients who received preprocedure education about the complications of clogging and dislodgment also had no unplanned return visits to the ED or IR within 30 days after the insertion of their g-tube.

Timeframe

The patient education handout developed and sent to the Health Literacy Department at UNMH. The study APP verified existing APP IR clinic time to see scheduled g-tube patients.
Human Research and Review Committee (HRRC) approval was granted September 27, 2018 and implementation of the prospective study began on September 27, 2018. Retrospective data was collected for date ranges March 27, 2018- September 26, 2018. Prospective data was collected from September 27, 2018-January 26, 2019.

Chapter 4

Results and Discussion

Project initiation. The patient education handout was developed and sent to the Health Literacy Department at UNMH for modifications to assure it was easy to understand. The handout was then translated into Spanish and Vietnamese using an outside translation company that was certified to be compliant to protect health information as well as to guarantee accuracy of the handout translation. The proposal was then sent to UNM’s HRRC (#18-346) for approval. HRRC approval was granted on September 27, 2018.

The project was implemented on September 27, 2018. The study APP provided patients with the consent form and the educational handout. The IR APPs, unit-based educator, registered nurse supervisor, and IR scheduling coordinators were given in-service training to introduce the study. The study APP spent time with the scheduling coordinators to review the project, to explain their role in the project and its goals and objectives, and to convey enthusiasm regarding the project. A box was made in the scheduling office for any outpatient g-tube request that had approval from the attending physician and that would be placed in the intake box for the study APP to review and arrange the preprocedure clinic appointment. Questions and concerns were addressed during this meeting.

The study APP checked the intake box daily for new referrals and discussed the project with the scheduling coordinators a minimum of once a week to ensure they remembered the
importance of giving referrals to the study APP and to remind them of the project. Additionally, the electronic schedule was checked frequently to confirm that no patients had been placed on the procedure schedule prior to being seen in clinic. The study APP sent an email to the referring physicians in Hematology Oncology and Otolaryngology departments and attended the head and neck cancer tumor board to review the project, its goals and objectives, and to convey enthusiasm regarding the project. The study APP approached all patients who met study criteria and spoke to them about participation in this study.

Findings

There were 11 eligible patients during the course of this project. Nine patients enrolled, one patient declined, and one patient was eliminated due to psychiatric issues. No enrolled patients dropped out of the study, and all follow-up calls were made on time. Patients were called at weeks one, two, and four, and specific questions were asked of each patient during each follow-up call (see Appendix C). No ED or IR visits were made by the enrolled patients, and no incidences of g-tube clogging or dislodgement were reported. One patient phoned a medical provider, suspecting the g-tube was clogged, but it was kinked. Follow-up phone calls gave patients the opportunity to ask questions, such as, How do I treat constipation?, May I put coffee through my g-tube?, and Do I have to flush the g-tube even if I am not using it?

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 1: Is the g-tube working?</td>
<td>Yes: 100%</td>
</tr>
<tr>
<td>Question 7: Any complication with clogging?</td>
<td>No: 100%</td>
</tr>
<tr>
<td>Question 8: Any complication with dislodgment?</td>
<td>No: 100%</td>
</tr>
<tr>
<td>Question 11: Did you go to the hospital, etc., for complications?</td>
<td>No: 100%</td>
</tr>
</tbody>
</table>

Table 1. Summary of questions for which answers were elicited 100% of the time.
Of the remaining questions, patients were asked, “Where do you keep the “Preventing Problems after Your G-Tube Procedure: Patient Education” information instruction sheet given in clinic at this time?” Nineteen times (70.4%), patients answered “in the folder”; five times, (18.5%) patients answered somewhere else, including “in the car,” “on the table,” and “in a file”; three times, (11.1%) a patient answered “I don’t know.”

![Q2 - KEEP INSTRUCTIONS](chart.png)

Figure 1. Where Patient Instructions are kept.

During the initial clinic visit, all of the patients were instructed to flush their g-tube with tap water prior to and following each feeding and throughout the day if they were unable to orally take fluids. Patients were asked how often they flushed their g-tube. Eleven of the (40.7%) patients answered that they flushed it one to four times per day; four (14.8%) said they flushed it five to 10 times per day; and 11 (40.7%) said they flushed it prior to and following each feeding.
During patients’ visit to the clinic, they were instructed to flush their g-tube with 30 ml of water prior to each feeding and with 60 ml of water following each feeding. Patients were asked, “How much are you using to flush the g-tube”? The majority of patients answered 31-60 ml (55.6%); five (18.5%) patients answered 0-30 ml; and six (25.9%) answered “other,” which included answers such as 90 ml and a cupful.

Included during the clinic visit, patients were shown pictures of securing devices, e.g., tape or an abdominal binder. The study APP also showed the empty package with an image of a
g-tube securing belt that was offered as an option to patients (available on Amazon for $5 to $20). Patients were asked how they secured the g-tube. Nine (33.3%) patients answered “with tape”; 13 (48.1%) patients answered “with a binder”; three (14.8%) answered “other” because a pocket belt securing device was being used; one patient answered “it’s not secured,” stating it was “tucked in pant waist” and “it just hangs.” The study APP used this opportunity to re-educate the patient who said the g-tube was not secured was given an opportunity to receive additional training regarding securing techniques and options. During the final follow-up phone interview, that patient said the g-tube was being secured with tape.

![Q6 - HOW SECURED](image)

**Figure 4. How g-tube is secured.**

When patients were asked if they were having other problems with their g-tubes, 22 (77.7%) said they had no problems; five (22.2%) answered that they experienced other problems, including upset stomach after changing tube-feeding formula, irritation at the exit site of the g-tube, constipation, itching, and mucous at stoma. These interviews with the patients gave the study APP an opportunity to discuss concerns and to offer advice to the patients regarding remedies to their problems.
The readmission rate in the preprocedure education group was 0% (0/9), and the readmission rate in the group that did not receive preprocedure education was 35% (8/23). This result was not statistically significant (p = 0.7) but did reflect a medium effect size difference (ρ = .36) (see Appendix D).

A retrospective chart review was conducted for the six months prior to the prospective study period. This chart review revealed that 23 patients met the prospective enrollment criteria, eight of whom returned to the ED or IR with g-tubes that were clogged or dislodged. Data collected from the retrospective group was (a) the date of the placement of the g-tube; (b) date of complication; (c) type of complication, clogging or dislodgement; and (d) demographic information, including sex, age, and diagnosis (See Table 2).

<table>
<thead>
<tr>
<th>Week</th>
<th>Clogged</th>
<th>Dislodged</th>
<th>No complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>4%</td>
<td>0%</td>
<td>96%</td>
</tr>
<tr>
<td>Week 2</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Week 3</td>
<td>13%</td>
<td>0%</td>
<td>87 %</td>
</tr>
<tr>
<td>Week 4</td>
<td>4%</td>
<td>13%</td>
<td>83%</td>
</tr>
</tbody>
</table>

Table 2. Complications in Group Not Receiving Education
Demographic information was collected from the retrospective and prospective groups. The use of demographics provided a general description of the population receiving g-tubes as outpatients. The demographic information collected was gender, age, and a description of the diagnosis that led to the need for a g-tube.

<table>
<thead>
<tr>
<th></th>
<th>Retrospective g-tube group</th>
<th>Prospective g-tube group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (25%)</td>
<td>5 (55%)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (75%)</td>
<td>4 (45%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>2 (25%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>50-59</td>
<td>3 (37.5%)</td>
<td>1 (11.1%)</td>
</tr>
<tr>
<td>60-69</td>
<td>2 (25%)</td>
<td>5 (62.5%)</td>
</tr>
<tr>
<td>70-79</td>
<td>1 (12.5%)</td>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head and neck cancer</td>
<td>3 (37.5%)</td>
<td>6 (66.6%)</td>
</tr>
<tr>
<td>ALS</td>
<td>2 (25%)</td>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (37.5%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 3. Summary of Demographic Information

Interpretation of Findings

A clinic visit to provide preprocedure education eliminated the complication of clogging or dislodgement in the study group; as compared to the retrospective group. As evidenced by the positive comments by patients, this project demonstrated that preprocedure education was important to patients. By providing an APP clinic visit, the questions of many patients were answered and patients were better prepared the day of the procedure. A preprocedure visit to the clinic also provided an opportunity for the medical team to establish a professional relationship and foster trust with patients.
Discussion

This project had the greatest impact on patients. By scheduling patients for a preprocedure clinic appointment, the patients had the opportunity to understand the procedure and to address concerns they might have about their clinic appointment. The addition of a session to teach patients about the complications and to provide the educational handout gave the patients an opportunity to discuss the entire g-tube experience. The complications of clogging and dislodgement then could be readdressed on the day of the procedure. This project also impacted the practice level within the IR division. Because patients are now scheduled for an APP clinic meeting prior to receiving their g-tube, they are given contact information for IR and instructions to call if they have questions or concerns regarding their g-tube. This not only provided patients with confidence that they knew where to call but was a valuable tool to try to reduce the number of ED visits.

Limitations and Strengths of the Study

Limitations. The major limitation to the project was that the projected sample size was too small to achieve statistical significance. The project had fewer than expected patient referrals. Another limitation was the possibility that patients would be disinterested in participating in the study, especially if they were cancer patients who had or will have surgery, chemotherapy, and radiation therapy; such patients might have believed that their participation would be too burdensome. The study APP combated disinterest by assuring that the study did not require additional clinic visits by the patients; instead of clinic visits, the study used follow-up phone calls during which the patients were asked 12 questions about their g-tube. Also, the patients were limited to one institution; therefore, it was difficult to generalize their results to a large population of g-tube patients. Patients in this study were selected from a specific
population within a particular geographic region; therefore, the results might not be representative of other populations in other regions. Additionally, patients were a convenience sample and were not randomized, which means the sample was not necessarily reflective of the population at large.

**Strengths.** The major strength of this project was the change in IR so that all patients now are scheduled for outpatient g-tube placements will be seen in the APP clinic. During this clinic visit, patients will receive the education handout, will have visual teaching with an actual g-tube and a demonstration of how to secure and flush a g-tube. Additionally, the APP will complete a history and physical examination during the clinic visit, will assure laboratory studies are ordered, and the procedural informed consent will be obtained. Another strength of the study was it allowed IR to build a g-tube education program to provide thorough care, which is currently lacking, to patients and families. Additionally, this program is expected to reduce the number of preventable complications of clogging and dislodgement for which patients return to the ED for care. While enrollment in the project was lower than expected, there were no ED visits or unplanned IR visits by the patients enrolled in the study.

IR is in the process of creating an APP clinic at the UNM Cancer Center, where there will be direct collaboration with an oncologist, an otolaryngologist, a dietician, and a laboratory. It is the vision of IR that g-tube placement becomes an outpatient procedure and that patients can be discharged the same day. By collaborating with the key services cited above, patients will be prepared to be discharged the same day they have their g-tube placed.

Another strength of this project was the acceptance of follow-up by patients. Realizing that this is a demanding period in a patient’s life, going through cancer treatment or the neurological disease of amyotrophic lateral sclerosis (ALS), is extremely burdensome and time
consuming. However, patients who participated in this project were very receptive during follow-up phone calls, welcoming the call and taking the opportunity to ask questions.

**Suggestions for Further Research**

Although the sample size was small ($n = 9$), this study provided the opportunity to explore the management of patients presenting to IR for g-tube placement and has heightened awareness of the need to implement changes within the IR division of the radiology department regarding the education of these patients. This is especially with the development of the preprocedure clinic and the subsequent emphasis on the complications of g-tube clogging and dislodgment. This study could be replicated in other IR departments. Furthermore, because the largest population of patients who experience the preventable complications of clogging and dislodgement of a g-tube is patients discharged to rehabilitation or long-term care facilities, additional education to these facilities is warranted.

**Concluding remarks**

The opportunity to complete this capstone project has been invaluable to the study APP. This project was born out of the perplexity of a problem that burdened UNMH’s Interventional Radiology care and the Emergency Department. Yet through the course of the past two years, it has become abundantly clear that the primary beneficiaries of the implementation of health literate education are the patients. While the concept of providing health literate education might appear simple, the reality is that the education was not being provided to patients. The realization that IR now takes ownership of the education process is major positive addition to the department’s practice, has brought heightened awareness to IR providers, and will benefit UNMH’s patients in the future.
References


http://www.surgicalcriticalcare.net/Guidelines/PEG%202014.pdf
Appendix A

The University of New Mexico
Consent to Participate in Research

Gastrostomy Tube Complications and Management

Introduction

You are being asked to join in in a research study that is being done by Joanne Haeffele, PhD, MSN, FNP-BC, RN, who is the Principal Investigator and Deborah Garcia, DNP (c), FNP-BC, from the UNM-College of Nursing. This research is studying the education of patients getting a gastrostomy tube (g-tube) and if education will lower the amount of times patients come back to the hospital for g-tube complications.

You are being asked to join in in this study because you are having a g-tube placed. It is estimated that 40 people will be enrolled into this portion of the study. People will take part in this study at the University of New Mexico.

This form will explain the research study, and will explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to join in, the next things will happen:

You will get an educational handout and be taught how to prevent two common complications with g-tubes, clogging and the tube pulling out (dislodgement). You will also receive a follow up phone call one week after your g-tube is placed, two weeks after your g-tube is placed, and one month after your g-tube is placed.

How long will I be in this study?

Participation in this study will take about 3 hours of your time over a month.

What are the risks or side effects of being in this study?

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study. To reduce these risks, the research team will do all they can to make sure you are comfortable with the research study and be available to talk if you have questions.

For more information about risks and side effects, ask the investigator.

What are the benefits to being in this study?
You will learn about the common complications of clogging and dislodgement of g-tube as well as how to prevent these common complications.

**What other choices do I have if I do not want to be in this study?**

You do not have to be in the study. If you say yes, you can quit the study at any time. Please take as much time as you need to make your choice. The care you get from your doctor will not change and your medical care will not change in any way if you say no. No one will treat you differently. You will not be penalized.

**How will my information be kept confidential?**

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Study staff use information contained in your study records and, in some cases, it will be shared with the sponsor of the study. Your information will be kept in a locked cabinet and kept for five years. The University of New Mexico Institutional Review Board (IRB) that oversees human subject research and/or other entities may be permitted to access your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

**What are the costs of taking part in this study?**

None

**Will I be paid for taking part in this study?**

No one will be paid to be in the study.

**How will I know if you learn something new that may change my mind about participating?**

You will be told of any important new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

**Can I stop being in the study once I begin?**

Your participation in this study is voluntary. You can stop being in the study at any time. You will not be penalized. While you will not get the benefit of being in this study, you will not lose any other benefits.

**HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)**
As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it is identifiable or “linked” to you.

**Protected Health Information (PHI)**

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: (list PHI, e.g. results of physical exams, medical history, body mass index, etc.)

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

**Right to Withdraw Your Authorization**

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

**Joanne Haeffele**  
CON Main (Building 228), Room 264B  
1 University of New Mexico  
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

**Refusal to Sign**

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

**Whom can I call with questions or complaints about this study?**

If you have any questions, concerns or complaints at any time about the research study, Joanne Haeffele, PhD, MSN, FNP-BC, RN, or his/her associates will be glad to answer them at. You may contact Dr. Haeffele at 505-272-3984.

If you need to contact someone after business hours or on weekends, please call and ask for Deborah Garcia at (505) 401-0761.
If you would like to speak with someone other than the research team, you may call the UNMHSC HRPO at (505) 272-1129.

**Whom can I call with questions about my rights as a research participant?**

If you have questions regarding your rights as a research participant, you may call the UNMHSC HRPO at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the IRB website at [https://hsc.unm.edu/research/hrpo/](https://hsc.unm.edu/research/hrpo/). You may contact Deborah Garcia at (505) 272-5911 at the conclusion of this study to get the results of the study.

**CONSENT**

You are making a decision whether to participate in this study. Your signature below indicates that you/your child read the information provided. By signing this consent form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

____________________________  ______________________________  ____________
Name of Adult Subject (print)  Signature of Adult Subject  Date

**INVESTIGATOR SIGNATURE**

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

____________________________
Name of Investigator/ Research Team Member (type or print)

____________________________  _________________
(Signature of Investigator/ Research Team Member)  Date
Preventing Clogs

Follow these steps so your g-tube does not get clogged.

☑ Flush your tube every 4 hours with 30 mL of tap water, even if you have continuous feedings.
☑ Flush your tube with 30 mL of tap water before and after every bolus feeding. (A bolus feeding is when you give formula through your feeding tube with a syringe.)
- If you’re taking liquid medicines, ask your provider or pharmacist if your medicine can cause clogs. Some liquid medicines that have sugar in them can cause clogging.
- If you cannot get your medicine in liquid form:
  - First, ask your pharmacist if your medicine can be crushed. Some medicines cannot be crushed.
  - If your pharmacist says it is okay, crush your medicine until it is very fine (like powder or dust).
  - Mix the crushed medicine with warm water.
  - Flush the g-tube with 30 mL of warm tap water.
  - Give the medicine.
  - Flush the g-tube with 30 mL of warm tap water again.

If Your Tube Gets Clogged, Follow These Steps

1. Take out any extra feeding from the tube.
2. Flush the tube with 30 mL of warm tap water.
3. Clamp the tube. Leave the clamp on for 5 minutes.
4. Unclamp the tube and flush it with 30-60 mL of warm tap water.

Call Us If You Have Any Problems with Your G-Tube!

- **Monday – Friday, 8am – 5pm:** call 505-272-2883 (Interventional Radiology)
- **Any other time of the week** (after 5pm, before 8am, weekends): call 505-272-2111 and ask to talk to the On Call Interventional Radiology Resident

UNM HOSPITALS
Appendix C

G-tube Data Subtraction Tool

1. Is the g-tube working?
   a. Yes _____
   b. No (explain) ________________________________

2. Where do you keep the “Preventing Problems after Your G-Tube Procedure: Patient Education” information instruction sheet given in the clinic at this time?
   a. On my refrigerator
   b. In the folder
   c. Someplace else (explain) ______________________________
   d. I don’t know

3. How often are you flushing the g-tube?
   a. Never
   b. 1-4 times/day
   c. 5-10 times/day
   d. Before and after each feeding
   e. I don’t know (explain) ________________________________

4. What are you using to flush the g-tube?
   a. Water
   b. Normal saline
   c. Soda
   d. Other (explain) ________________________________
   e. I don’t flush it

5. How much are you flushing the g-tube with each time?
   a. I don’t know
   b. 0-30 ml
   c. 31-60 ml
   d. Other (explain) ________________________________

6. How have you secured the g-tube?
   a. With tape
   b. With a binder
   c. It’s not secured
d. Other (explain) ______________________________________

7. Have you had any complications of clogging of the tube in the past week, past two weeks, or past 30 days (depending on which follow-up call it is).
   a. Yes (explain) ______________________________________
   b. No

8. Have you had any complications of dislodgement?
   a. Yes (explain) ______________________________________
   b. No

9. What other problems have you had with your g-tube?
   a. No problems
   b. Free text _______________________________________

10. Have you called any medical provider about your g-tube in the past week, past two weeks, or past 30 days (depending on which follow-up call it is)?
    a. Yes (explain) ______________________________________
    b. No

11. Have you been to any hospital, doctor’s office, urgent care, or emergency department because of a problem with your g-tube?
    a. Yes (explain) ______________________________________
    b. No

12. Do you have any questions for me about your g-tube?
    a. Yes (explain) ______________________________________
    b. No
### Fisher’s exact test

<table>
<thead>
<tr>
<th></th>
<th>g-tube no education</th>
<th>g-tube education</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmit to ED</td>
<td>8</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>No readmit to ED</td>
<td>15</td>
<td>9</td>
<td>24</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>23</strong></td>
<td><strong>9</strong></td>
<td><strong>32</strong></td>
</tr>
</tbody>
</table>

**Fisher’s exact test**

The two-tailed P value equals 0.0699.

The association between rows (groups) and columns (outcomes) is considered to be not quite statistically significant.