



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-17-NH

DATE: March 8, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: F tag 322—Naso-Gastric Tubes - Revised Advance Copy

**This memorandum replaces a previous version of
S&C: 12-46-NH dated September 27, 2012.**

Memorandum Summary

- **Revisions:** Additional revisions have been made to Surveyor Guidance at F tag 322 in Appendix PP of the State Operations Manual (SOM) and the associated training slides since the release of S&C 12-46 on September 27, 2012. The revisions include:
 - Revision of the Regulatory Language format.
 - Additional clarification regarding the Centers for Medicare and Medicaid Services (CMS) expanded definition of “Naso-Gastric tubes.”
 - Updating the Power Point training slides.
- **Advance Copy Interpretive Guidelines:** Revised advance copy of surveyor guidance is included in this memorandum.
- **Power Points:** The revised Power Point training material with speaker notes is provided.

Background

Since the release of S&C 12-46-NH, the CMS conducted a further review of the interpretive guidelines for F tag 322 in Appendix PP of the SOM. Based on additional internal and external stakeholder feedback this guidance and related training materials have been revised to provide additional clarification when determining compliance with §483.25(g).

Revisions

The revisions have been highlighted in the Advance Copy Interpretive Guidelines and include:

- Revision of the regulatory language to now resemble the formatting of §483.25(g) in the Code of Federal Regulations (CFR).

- Additional clarification related to the expanded definition of “Naso-Gastric tubes.”
- Updated Power Point Training slides to correlate with revisions made to the Surveyor Guidance at F tag 322. Revisions made to the training slides have a red font color.

Please note that the manual changes to Surveyor Guidance for F tag 322 will not be issued with highlights.

For questions on this memorandum, please contact Kathleen Johnson at 410-786-3295 or via email at Kathleen.Johnson@cms.hhs.gov.

Effective Date: This clarification is effective no later than 30 days after release of the memo. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

Training: The revised training materials should be distributed immediately to all SA training coordinators.

/s/

Thomas E. Hamilton

2 Attachments

Advance Copy Interpretive Guidelines
Power Point training slides with speaker notes

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date: -----

SUBJECT: Revisions to Appendix PP – “Interpretive Guidelines for Long-Term Care Facilities F tag 322 (Feeding Tube)”

I. SUMMARY OF CHANGES: This instruction revises F321 by incorporating the regulatory language into F322.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F tag 321
R	Appendix PP/F 322// §483.25(g)(1)(2)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

F322

(Rev.)

483.25(g) Naso-Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

INTENT: (F322) §483.25(g)(1) and (2)

The intent of this regulation is that:

- The feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- A feeding tube is utilized in accordance with current clinical standards of practice and services are provided to prevent complications to the extent possible; and*
- Services are provided to restore normal eating skills to the extent possible.*

NOTE: For the purpose of the interpretative guidelines at F tag 322 the regulatory title “§483.25(g) Naso-gastric tubes” is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake. Since the regulation was promulgated, use of naso-gastric tubes has become extremely rare, and use of other types of enteral feeding tubes (such as those listed in the definitions section) has become prominent.

DEFINITIONS

“Avoidable/Unavoidable use of a feeding tube”

- “Avoidable” means there is not a clear indication for using a feeding tube or there is insufficient evidence that it provides a benefit that outweighs associated risks.*
- “Unavoidable” means there is a clear indication for using a feeding tube or there is sufficient evidence that it provides a benefit that outweighs associated risks.*

“Bolus feeding” is the administration of a limited volume of enteral formula over brief periods of time.

“Continuous feeding” is the uninterrupted administration of enteral formula over extended periods of time.

“Enteral nutrition” (a.k.a. “tube feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

“Feeding tube” refers to a medical device used to provide enteral nutrition to a resident by bypassing oral intake.

“Gastrostomy tube” (“G-tube”) is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.

“Jejunostomy tube” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) is a feeding tube placed directly into the small intestine.

“Nasogastric feeding tube” (“NG tube”) is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.

“Transgastric jejunal feeding tube” (“G-J tube”) is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

“Tube feeding” (a.k.a. “enteral feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

OVERVIEW

A decision to use a feeding tube has a major impact on a resident and his or her quality of life. It is important that any decision regarding the use of a feeding tube be based on the resident’s clinical condition and wishes as well as applicable federal and state laws and regulations for decision making about life-sustaining treatments.

The use of feeding tubes varies widely within and among states. Reasons for this variability are unclear, but they may include diverse opinions about the benefits and risks of non-oral nutrition, and variable facility policies and usual practices.^{1,2,3,4,5}

NOTE: Refer to §483.10(b)(4) and (b)(8), Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives; and §483.15(b), Self-Determination and Participation, in order to determine if the use of a feeding tube is consistent with the wishes and instructions of the resident, if known (e.g., verbal or handwritten instructions, advance directive or living will) or the instructions

of the resident's legal representative, if the resident is unable to make his or her wishes known.

RESOURCES

- ***The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)** is dedicated to improving patient care by advancing the science and practice of nutrition support therapy. A.S.P.E.N. maintains a Guidelines and Standards Library. The Guidelines and Standards make specific practice recommendations.
<http://www.nutritioncare.org/Library.aspx>*
- ***The Alzheimer's Association** offers a fact sheet regarding care and patient rights: Ethical Issues in Alzheimer's Disease, Assisted Oral Feeding and Tube Feeding.
http://www.alz.org/alzwa/documents/alzwa_Resource_EOL_FS_Oral_Feeding.pdf*

***NOTE:** References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

CONSIDERATIONS REGARDING THE USE OF FEEDING TUBES

The regulations at §483.25(g) require that the resident's clinical condition demonstrates the use of a feeding tube to be unavoidable. A feeding tube may be considered unavoidable only if no other viable alternative to maintain adequate nutrition and/or hydration is possible and the use of the feeding tube is consistent with the clinical objective of trying to maintain or improve nutritional and hydration parameters.⁶

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident's ability to maintain appropriate nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery), the need to improve the resident's nutritional status or level of comfort, or the desire to prolong the resident's life. The duration of use of a feeding tube may vary, depending on the clinical situation.

The interdisciplinary team, with support and guidance from the physician, is responsible for assuring the ongoing review, evaluation and decision-making regarding the continuation or discontinuation of all treatments, devices or approaches implemented to care for the resident. Involving the resident, family, and/or the resident's legal representative in discussions about the indications, use, potential benefits and risks of tube feeding, types of approaches, and alternatives helps support the resident's right to make an informed decision to use or not use artificial nutrition and hydration.

A clinically pertinent rationale for using a feeding tube includes, but is not limited to:

- *An assessment of the resident's nutritional status, which may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes;*
- *An assessment of the resident's clinical status, which may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis;*
- *Relevant functional and psychosocial factors (e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating); and*
- *Interventions prior to the decision to use a feeding tube and the resident's response to them. (Refer to F325 for discussion and examples of interventions to improve and restore normal nutritional parameters.)*

***NOTE:** Refer to §483.20 Resident Assessment and the Assessment Section of the General Investigative Protocol at Quality of Care (F309) for discussion of the comprehensive evaluation that comprises an assessment.*

The use of a feeding tube may potentially benefit or may adversely affect a resident's clinical condition and/or psychosocial well-being. Examples of some possible benefits of using a feeding tube may include:

- *Addressing malnutrition and dehydration;*
- *Promoting wound healing; and*
- *Allowing the resident to gain strength, receive appropriate interventions that may help restore the resident's ability to eat and, perhaps, return to oral feeding.*

Examples of some possible adverse effects of using a feeding tube may include:

- *Diminishing socialization, including, but not limited to, the close human contact associated with being assisted to eat or being with others at mealtimes;*
- *Not having the opportunity to experience the taste, texture, and chewing of foods;*
- *Causing tube-associated complications; and*
- *Reducing the freedom of movement related to efforts to prevent the resident from pulling on the tube or other requirements related to the tube or the tube feeding.*

In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative

psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room). Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).

Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson's disease present a particular set of issues and considerations that are discussed in F325. The extended use of enteral feeding tubes in individuals with advanced dementia remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality).^{7,8,9,10,11,12}

Resident Rights

The regulations at 483.10(d)(2) state that the resident has the right to be fully informed in advance about care and treatment and of any changes in the care or treatment that may affect the resident's well-being. In addition, the regulations at 483.10(b)(4) state that the resident has the right to refuse treatment and to formulate an advance directive.

If a resident has had a feeding tube placed prior to admission or in another setting while residing in the facility, the physician and interdisciplinary care team review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a legal representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident's goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES

It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and clinical standards of practice.

Technical Aspects of Feeding Tubes

Facility procedures regarding the technical aspects of feeding tubes include, but are not limited to, the following:

Location of the feeding tube. Direction to staff regarding how to monitor and check that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) or verify that placement was checked, such as:

- Techniques to verify that tube placement is appropriate before beginning a feeding and before administering medications; and
- The frequency with which staff should monitor for proper location of the feeding tube to assure that the enteral retention device is properly approximated to the abdominal wall and the surrounding skin is intact.

Care of the feeding tube. Direction to staff on how to provide care such as:

- Securing a feeding tube externally;
- Providing needed personal, skin, oral, and nasal care to the resident;¹³
- Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;
- Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and
- Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.

Feeding tube replacement. Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:

- When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);
- How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;
- Instances when a tube can be replaced within the facility and by whom;
- Instances when a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center); and
- Notification of the practitioner when the need for a tube change arises unexpectedly.

Nutritional Aspects of Feeding Tubes

When a resident is receiving nutrition via a feeding tube, the practitioner and the interdisciplinary team identify the resident's nutritional needs and facility procedures that direct staff in providing care and services to the resident. The practitioner's orders related to tube feeding typically include the following components: kind of feeding and its caloric value; volume, duration, and mechanism of administration (e.g., gravity or pump); and frequency of flush.

Facility procedures regarding the nutritional aspects of feeding tubes include, but are not limited to:

Enteral nutrition. *Direction to staff regarding the nutritional product and meeting the resident's nutritional needs such as:*

- *Types of enteral nutrition formulas available for use;*
- *How to determine whether the tube feedings meet the resident's nutritional needs and when to adjust them accordingly;*
- *How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;*
- *Ensuring that the selection and use of enteral nutrition is consistent with manufacturer's recommendations;*
- *Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner's orders; and*
- *Ensuring that the product has not exceeded the expiration date.^{14 15}*

Flow of feeding. *Direction for staff regarding how to manage and monitor the rate of flow, such as:*

- *Use of gravity flow;*
- *Use of a pump;*
- *Periodic evaluation of the amount of feeding being administered for consistency with practitioner's orders;*
- *Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident's care plan; and*
- *Periodic maintenance of feeding pumps consistent with manufacturer's instructions to ensure proper mechanical functioning.*

Complications Related to the Feeding Tube

An enteral feeding tube may be associated with significant complications, including aspiration, leaking around the insertion site, abdominal wall abscess, or erosion at the insertion site including the nasal areas. Feeding tubes can perforate the stomach or small intestine, with resultant peritonitis. Esophageal complications of feeding tubes may also occur including esophagitis, ulcerations, strictures, and tracheoesophageal fistulas. The use of tubes not designed or intended for enteral feeding may increase the risk of complications.^{16,17}

Tubes may clog for various reasons, including plugging by formula, pill fragments, or the precipitation of medications incompatible with the formula.¹⁸ Flushing feeding tubes regularly and in association with medication administration, as indicated by current clinical standards of practice and provided in the resident care policies, can help reduce the risk of clogging.

Complications Related to the Administration of the Enteral Nutrition Product

The administration of an enteral nutrition product may be associated with other complications including, but not limited to, nausea, vomiting, diarrhea, abdominal cramping, inadequate nutrition and aspiration. Additionally, interactions between the formula and various medications can affect the absorption and/or effectiveness of the medication. For example, the effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels. These risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.

While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors, such as moderate or less severe swallowing abnormalities. Aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly positioned within the stomach or intestine. The evidence is inconsistent and conflicting regarding any connection between gastric residual volume and the risk or occurrence of aspiration.¹⁹

Risk of aspiration should be assessed individually and appropriate interventions (e.g., proper positioning, rate of flow) implemented accordingly. There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle.

Complications Management

The facility is expected to identify and address actual or potential complications related to the feeding tube or tube feeding and to notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.²⁰

ENDNOTES

- ¹ Teno, J.M, Mitchell, S.L., Gozalo, P.L., et al. (2010). Hospital characteristics associated with feeding tube placement in nursing home residents with advanced cognitive impairment. *Journal of the American Medical Association*, 303: 544-550.
- ² Lopez, R.P., Amella, E.J., Strumpf, N.E., et al. (2010). The influence of nursing home culture on the use of feeding tubes. *Archives of Internal Medicine*, 170: 83-88.
- ³ Finucane, T.E., Christmas, C., Leff, B.A. (2007). Tube feeding in dementia: how incentives undermine health care quality and patient safety. *Journal of American Medical Directors Association*, 8: 205-208. (<http://www.ncbi.nlm.nih.gov/pubmed/17498602>)
- ⁴ Mitchell, S.L., Teno, J.M., Roy, J., et al. (2003). Clinical and organizational factors associated with feeding tube use among nursing home residents with advanced cognitive impairment. *Journal of the American Medical Association*, 290: 73-80.
- ⁵ Mitchell, S.L., Kiely, D.K., Gillick, M.R. (2003). Nursing home characteristics associated with tube feeding in advanced cognitive impairment. *Journal of American Geriatric Society*, 51: 75-79. (<http://www.ncbi.nlm.nih.gov/pubmed/125348499>)
- ⁶ Pearce, C.B. & Duncan, H.D. (2002) Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations. *Postgraduate Medical Journal (a UK journal)*, 78: 199-203. (<http://pmj.bmj.com/content/78/918/198.abstract>)
- ⁷ Genao, L., White, H., Twersky, J. (2010). The clinical course of advanced dementia. *New England Journal of Medicine*, 362: 363-364.
- ⁸ Kim, K.Y., Yeaman, P.A., Keene, R.L. (2005). End-of-life care for persons with Alzheimer's disease. *Psychiatric Services*, 56: 139-141.
- ⁹ Meier, D.E., Ahronheim, J.C., Morris, J., et al. (2001). High short-term mortality in hospitalized patients with advanced dementia: lack of benefit of tube feeding. *Archives of Internal Medicine*, 161: 594-599.
- ¹⁰ Gessert, C.E., Mosier, M.C., Brown, E.F., et al. (2000). Tube feeding in nursing home residents with severe and irreversible cognitive impairment. *Journal of American Geriatric Society*, 48: 1593-1600. (<http://www.ncbi.nlm.nih.gov/pubmed/11129748>)

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- ¹¹ Murphy, D.J. & Santilli, S. (1998). *Elderly patients' preferences for long-term life support*. *Archives of Family Medicine*, 7: 484-488.
- ¹² Sheiman, S.L. (1996). *Tube feeding the demented nursing home resident*. *Journal of American Geriatric Society*, 44: 1268-1270.
- ¹³ Guenter, P & Silkroski, M. (2001). *Tube Feeding, Practical Guidelines and Nursing Protocols*. An ASPEN Publication, 70-72, 78.
- ¹⁴ Barrett, J.S., Shepherd, S.J., Gibson, P.R. (2009). *Strategies to Manage Gastrointestinal Symptoms Complicating Enteral Feeding*. *Journal of Parenteral and Enteral Nutrition*, 33: 21-26. (<http://pen.sagepub.com/content/33/1/21.abstract>)
- ¹⁵ A.S.P.E.N. Board of Directors and Task Force on Parenteral Nutrition Standardization. (September -October Issue 2007). *A.S.P.E.N. Statement on Parenteral Nutrition Standardization*. *Journal of Parenteral and Enteral Nutrition*, 31; 441-448. (<http://pen.sagepub.com/content/31/5.toc>)
- ¹⁶ Mitchell, S. L. & Tetro, J.M. (2000). *Survival After Percutaneous Endoscopic Gastrostomy Placement in Older Persons*. *Journal of Gerontology: Medical Sciences*, 55(12): 738. (<http://biomedgerontology.oxfordjournals.org/content/55/12/M735.abstract>)
- ¹⁷ Guenter, P. & Silkroski, M. (2001). *Tube Feeding, Practical Guidelines and Nursing Protocols*. A.S.P.E.N. Publication, 108, 109, 114-117, 119.
- ¹⁸ Buchman, A. *Practical Nutritional Support Techniques; Second Edition*. (2004). SLACK Incorporated, 63-68
- ¹⁹ Bankhead, R., et al. (Published online Jan 26, 2009). *A.S.P.E.N. Enteral Nutrition Practice Recommendations*. *Journal of Parenteral Nutrition*, 33; 163-165. (<http://pen.sagepub.com/content/33/2/122.full.pdf+html>)

INVESTIGATIVE PROTOCOL FOR FEEDING TUBES

Objectives

- *To determine if a feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- *To determine if a feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and*
- *To determine if services are provided to restore normal eating skills to the extent possible.*

Use

Use this protocol for a resident who has a feeding tube.

Procedures

The surveyor(s) should conduct the following observations, interviews and record reviews. If there are concerns regarding the facility's use and care of feeding tubes, review facility policies and practices with regard to the use and care of feeding tubes.

Observations

During various shifts, observe staff interactions with the resident and provision of care including: initiation, continuation, and termination of feedings; care of the tube site and equipment; and medication administration via the feeding tube, if possible. Use the observations to determine whether staff follow clinical standards of practice, facility policy, the resident care plan, and prescriber's orders and if they try to minimize the risk for complications including but not limited to:

- *Implementing interventions to minimize the negative psychosocial impact that may occur as a result of tube feeding;*
- *Providing mouth care, including teeth, gums, and tongue;*
- *Checking that the tubing remains in the correct location;*
- *Properly positioning the resident consistent with the resident's individual needs;*
- *Using universal precautions and clean technique and following the manufacturer's recommendations when stopping, starting, flushing, and giving medications through the feeding tube;*

- *Ensuring the cleanliness of the feeding tube, insertion site, dressing (if present) and nutritional product; and*
- *Providing the type, rate, volume and duration of the feeding as ordered by the practitioner and consistent with the manufacturer's recommendations.*

Note staff response if there is evidence of possible complications, such as diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort (if a nasogastric tube is being used); evidence of leakage and/or skin irritation at the tube insertion site; or risk of inadvertent removal of the tube.

Interviews

Resident/Representative

Interview the resident and/or resident's legal representative (as appropriate) regarding involvement in development of the care plan including goals and approaches; whether the interventions reflect the resident's choices and preferences; and the resident's response to the tube feeding, including the following:

- *Whether staff provided assistance to the resident to increase the food intake, prior to inserting a feeding tube (e.g., identifying underlying causes of anorexia; hand feeding; changing food consistency, texture, form; offering alternate food choices; and/or providing assistive devices);*
- *Whether the resident and/or the resident's legal representative (as appropriate) was informed about the relevant benefits and risks of tube feeding, and involved in discussing alternatives and making the decision about using a feeding tube;*
- *Whether the resident has had any significant new or worsening physical, functional or psychosocial changes; whether the resident informed the staff; and how the problems were addressed;*
- *Whether there has been a reassessment and discussion with the resident or the resident's legal representative regarding the continued appropriateness/necessity of the feeding tube.*

NOTE: *Prior to inserting a feeding tube, the prescriber reviews the resident's choices/instructions and goals, including all relevant information that may be identified in advance directives (See F155, F156 and F242).*

Facility staff

Interview staff that provide direct care on various shifts to determine:

- *How staff and practitioner determined the cause(s) of decreased oral intake/weight loss or impaired nutrition and attempted to maintain oral intake prior to the insertion of a feeding tube, such as did staff collaborate with the physician to identify medical causes of decreased appetite or try to help the resident eat enough food (e.g., cueing or hand feeding; changing food consistency, texture, form; seeking and addressing causes of anorexia; providing assistive devices);*
- *What the specific care needs for the resident are (e.g., special positioning, personal care, insertion site care, amount of feeding taken in);*
- *How the staff determined the resident's nutritional status was being met such as periodically weighing the resident and how they decide whether the tube feeding is adequate to maintain acceptable nutrition parameters;*
- *Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding (e.g., nausea or vomiting, diarrhea, pain associated with the tube, abdominal discomfort, depression, withdrawal); and how these problems have been addressed;*
- *To whom a staff member has reported the resident's signs or symptoms; and*
- *Whether there has been a periodic reassessment and discussion with the resident or his/her legal representative regarding the continued appropriateness/necessity of the feeding tube; and whether the care plan has been revised and implemented as necessary.*

Health care practitioners and professionals

The assigned surveyor should review, as indicated, the facility's policies, procedures, records of incidents and corrective actions related to feeding tubes; documentation of staff knowledge and skills related to the aspects of administering tube feeding; and should, as necessary, interview facility staff with responsibility for overseeing or training in this aspect of care to determine:

- *How the facility identified the resident at risk for impaired nutrition, identified and addressed causes of impaired nutrition, and determined that use of a feeding tube was unavoidable;*
- *How staff calculated nutritional needs for the resident and how they ensure that the resident receives close to the calculated amount of nutrition daily;*
- *How staff monitor the resident for the benefits and risks related to a feeding tube, and address adverse consequences of the feeding tube use (e.g., altered mood, nausea and vomiting, pain, or restraint use to try to prevent the resident from removing the feeding tube);*

- *How staff are trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident;*
- *Whether the physician and staff attempted to identify the circumstances that led to the placement of the feeding tube (e.g., when the tube was placed in another facility); and*
- *Whether the resident was periodically reassessed for the continued appropriateness/necessity of the feeding tube; and whether the care plan was revised and implemented, as necessary, with input from the resident or his/her legal representative, to the extent possible.*

NOTE: *During the course of the review, if the surveyor needs to contact the attending physician regarding questions related to the treatment regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries. If the attending physician is unavailable, interview the medical director, as appropriate.*

Record Review

Review information such as physician orders, tube feeding records, multidisciplinary progress notes, RAI/MDS and any available assessment regarding the rationale for feeding tube insertion and the potential to restore normal eating skills, including the interventions tried (to avoid using the feeding tube before its insertion, restore oral intake after tube insertion, and prevent potential complications). In order to identify concerns or to further investigate identified concerns about tube feedings, review to determine:

- *How the staff verify that the feeding tube is properly placed;*
- *That staff are assigned responsibilities for various aspects of enteral feedings consistent with their position and training (e.g., administering the feeding, determining and verifying correct formula; calculating the amount of formula, feeding intervals, flow rate);*
- *How staff have monitored a resident for possible complications (e.g., depression, nutritional deficits, withdrawal, aspiration, aspiration pneumonia, dehydration, metabolic abnormalities, diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort, nasal-pharyngeal ulcer, etc.) related to a feeding tube and the tube feeding, and have identified and addressed such complications; and*
- *That the resident was periodically reassessed and the care plan was revised and implemented, as necessary with input from the resident or his/her legal representative, to the extent possible.*

Review of Facility Practices

Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (including facility management). If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

DETERMINATION OF COMPLIANCE

Synopsis of Regulation (F322)

The feeding tube requirement has two aspects. The first aspect requires that the facility utilizes a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable. The second aspect requires that the facility provides to the resident who is fed by a tube, services to prevent complications, to the extent possible, and services to restore normal eating skills, if possible.

Criteria for Compliance

The facility is in compliance with 42 CFR §483.25(g), if staff:

- Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;*
- Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and*
- Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.*

If not, cite at F322.

Noncompliance for F322

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;*

- *Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;*
- *Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or*
- *Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.*

Potential Tags for Additional Investigations

If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirements. Some examples include, but are not limited to, the following:

- *42CFR §483.10(b)(3);(d)(2), F154, Right to Be Fully Informed*
 - *Determine if the facility has fully informed the resident of his or her total health status and has provided the resident with information about the use of a feeding tube (including risks, benefits and alternatives) so that an informed decision can be made.*
- *42 CFR §483.10(b)(4)(8), F155, Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives, Maintenance and Provision of Written Policies of These Rights*
 - *Determine if the facility has given the resident or legal representative the opportunity to participate in the decision about tube feeding and informed the resident of the right to make advance directives and to decline life-sustaining treatments including artificial nutrition and hydration;*
 - *Determine if the facility maintains written policies and procedures regarding advance directives; and*
 - *Determine if the facility informs and provides written information to all adult residents concerning the right to accept or refuse medical treatment and formulate advance directives.*
- *42 CFR §483.10(b)(11), F157, Notification of Changes*
 - *Determine if staff notified:*

- *The physician when they suspected or identified inability to maintain adequate oral intake or complications related to use of the feeding tube; and*
- *The resident and the resident's legal representative (if known) of significant changes in the resident's condition in relation to the feeding tube or inability to take nutrition orally;*
- *42 CFR §483.15(a), F241, Dignity*
 - *Determine whether the staff provided respectful care for the resident being tube fed to maintain and enhance the resident's dignity;*
- *42 CFR §483.15(b), F242, Self-determination and Participation*
 - *Determine whether staff provided the resident with relevant information and choices regarding feeding tubes;*
- *42 CFR §483.20(b), F272, Comprehensive Assessments*
 - *Determine if the resident's comprehensive assessment reflects the resident's nutritional status, including factors that may have contributed to inadequate oral intake, and evaluates the resident's response to the implementation of tube feeding, including nutritional and psychosocial aspects;*
- *42 CFR §483.20(g), F278, Accuracy of Assessments*
 - *Determine whether the assessment accurately reflects the resident's status;*
- *42 CFR §483.20(k), F279, Comprehensive Care Plans*
 - *Determine if the resident's comprehensive care plan includes measurable objectives, time frames, and specific interventions consistent with the resident's specific nutritional status, risks, needs, and current clinical standards of practice. This includes interventions prior to the insertion of the feeding tube to attempt to avoid tube feeding and after the insertion of the tube to prevent tube-related and tube-feeding related complications and restore, if possible, adequate oral intake;*
- *42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision*
 - *Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to try to meet the resident's*

nutritional and hydration needs; reduce, prevent, or address potential complications; and attempt to restore normal eating skills, if possible;

- *42 CFR §483.20(k)(3)(i), F281, Services Provided Meet Professional Standards of Quality*
 - *Determine if staff provided care in accordance with accepted professional standards of quality to maintain or restore adequate oral intake, if possible, and to manage the feeding tube to maintain or improve nutrition and prevent complications, to the extent possible;*
- *42 CFR §483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with the Plan of Care*
 - *Determine whether care of the resident with a feeding tube is being provided by qualified staff and/or whether the care plan is adequately and/or correctly implemented;*
- *42 CFR §483.25(i), F325, Nutrition*
 - *Determine if the facility has managed the resident's nutritional interventions to meet the resident's nutritional needs, while using a feeding tube;*
- *42 CFR §483.25(l), F329, Unnecessary Drugs*
 - *Determine if the facility has reviewed the resident's medication regimen for medications that may have caused or contributed to a decline in oral intake, or ability to chew and/or swallow, that may have contributed to the decision to place a feeding tube or affected the efforts to restore normal eating;*
- *42 CFR §483.30, F353, Nursing Services*
 - *Determine if the facility has sufficient nursing staff that is qualified to provide necessary care and services to the resident being fed by a feeding tube;*
- *42 CFR §483.40(a), F385, Physician Supervision*
 - *Determine if a physician is supervising the medical aspects of the tube feedings including assessment of causes of impaired nutritional status, development of a treatment regimen consistent with current clinical standards of practice, monitoring, and response to notification of change in the resident's medical status;*

- 42 CFR §483.60, F425, Pharmacy Services
 - Determine if the policies were developed and implemented for the safe administration of medications for a resident with a feeding tube;
- 42 CFR §483.65, F441, Infection Control
 - Determine if the facility established and maintained an infection control policies for safe and sanitary care and services for a resident being fed by a tube;
- 42 CFR §483.75(i), F501, Medical Director
 - Determine whether the medical director helped the facility develop and implement policies addressing the assessment and management of individuals with impaired or at-risk nutrition and hydration status and recognizing, addressing, and preventing complications related to tube feedings;
- 42 CFR §483.75(l), F514, Clinical Records
 - Determine whether the clinical record:
 - Accurately, completely and, in accordance with current clinical standards, documents: the resident's status (including changes in condition), care and services provided to the resident with a feeding tube, response to treatment and the resident's goals; and
 - Provides the basis for determining the continued need for tube feeding and whether changes in treatment are necessary.

DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident.

The key elements for severity determination for F322 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate care and services.** Actual or potential harm/negative outcomes for F322 may include but are not limited to:
 - Failure to adequately assess a resident's nutritional status and the care and services needed to maintain or improve the resident's nutritional status and/or to identify why the use of a feeding tube was medically unavoidable;

- *Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration;*
 - *Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration; and*
 - *Failure to use and monitor a feeding tube per facility protocol and current clinical standards of practice or to identify and manage feeding tube-related or tube-feeding related complications, thereby allowing the complication to continue without appropriate intervention.*
2. ***Degree of harm (actual or potential) related to the noncompliance.*** *Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm.*
- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
 - *If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.*
3. ***The immediacy of correction required.*** *Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity. First, the team must rule out whether Severity Level 4 (immediate jeopardy to a resident's health or safety) exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Determining Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- *Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident, who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.*

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- *The facility failed to train staff about how to ensure proper placement of a feeding tube, and/or to ensure that staff were checking for tube placement consistently and correctly. As a result of staff failure to verify tube placement, a resident got peritonitis (infection of the lining of the abdominal cavity) and died following the administration of tube feeding; or*
- *As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident's tube feeding, the resident aspirated some of the tube feeding and acquired aspiration pneumonia.*

NOTE: *If Severity Level 4 (immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Severity Level 2 exists.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that resulted in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable, actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications; or*
- *As a result of facility failure to assess the resident's nutritional needs and to continue to administer, monitor, and adjust tube feeding accordingly, a resident experienced significant weight loss that cannot be otherwise attributed to a medically unavoidable cause.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or had the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable outcomes at Severity Level 2 include, but are not limited to:

- As a result of staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications;*
- As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications; or*
- As a result of staff failure to consistently flush a resident's feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.



§483.25 Naso-Gastric Tubes (F322 Feeding Tubes)

Surveyor Train the Trainer:
Interpretive Guidance
Investigative Protocol



Federal Regulatory Language

483.25(g) Naso Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

- (1) A resident who has been able to eat enough alone or with assistance is not fed by naso gastric tube unless the resident's clinical condition demonstrates that use of a naso gastric tube was unavoidable; and**



Federal Regulatory Language (cont)

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.



Merging Tags F321 and F322

- The revisions to appendix PP – Interpretive Guidelines for Long Term Care Facilities at §483.25(g)(1)(2) combines F321 and F322, and incorporated the guidance into F322.



§483.25(g) Naso-Gastric Tubes*

****For the purpose of the interpretative guidelines at F tag 322 the regulatory title “§483.25(g) Naso-gastric tubes” is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake.***



Intent

The intent of this regulation is that:

- The feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;
- A feeding tube is utilized in accordance with current clinical standards of practice and services are provided to prevent complications to the extent possible; and
- Services are provided to restore normal eating skills to the extent possible.



Definitions

“Avoidable/Unavoidable use of a feeding tube”

“Avoidable” -- there is not a clear indication for using a feeding tube, and there is insufficient evidence that it provides a benefit that outweighs associated risks.

“Unavoidable” -- there is a clear indication for using a feeding tube, and there is sufficient evidence that it provides a benefit that outweighs associated risks.



Definitions (cont'd)

“**Bolus feeding**” means the administration of a limited volume of enteral formula over brief periods of time.

“**Continuous feeding**” means the uninterrupted administration of enteral formula over extended periods of time.



Definitions (cont'd)

“Enteral nutrition” (a.k.a. “tube feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

“Feeding tube” means a medical device used to provide enteral nutrition to a resident by bypassing oral intake.

Definitions (cont'd)

“**Gastrostomy tube**” (“G-tube”) means a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.



Definitions

“Jejunostomy tube” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) means a feeding tube placed directly into the small intestine.

“Nasogastric feeding tube” (“NG tube”) means a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.



Definitions

“Transgastric jejunal feeding tube” (“G-J tube”) means a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

“Tube feeding” (a.k.a. “enteral feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.



Overview

The decision to use a feeding tube:

- Has a major impact on a resident and his or her quality of life; and
- Is based on the resident's clinical condition and wishes and federal and state laws.

Use of feeding tubes varies widely among states depending on opinions about non-oral nutrition and varied facility policies and usual practices.

Considerations Regarding The Use of Feeding Tubes

The resident's clinical condition must demonstrate the use of a feeding tube to be “unavoidable”:

- No viable alternative to maintain adequate nutrition and/or hydration; and
- Use is consistent with the clinical need to maintain or improve nutritional /hydration parameters.

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Other factors that may be associated with use:

- Medical conditions that impair nutrition;
- Need to improve nutritional status or comfort;
- To provide comfort; and
- Desire to prolong life.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Clinical rationale supporting the use of a feeding tube includes:

- Assessment of the resident's nutritional and clinical status;
- Relevant functional and psychosocial factors (such as potential ability to maintain activities of daily living ADL); and
- Prior interventions (nutrition therapy and medical intervention tried) and the resident's response.



Considerations Regarding The Use of Feeding Tubes

Potential benefits of feeding tube use include:

- Addressing malnutrition and dehydration;
- Promoting wound healing;
- Allowing the resident to gain strength (for ADL) including appropriate interventions that may help to restore the residents ability to eat; and
- Improving the resident's ability to make decisions about their care and ability to interact with others.

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Possible adverse effects of feeding tube use include:

- Diminished socialization;
- Decreased opportunity to experience taste, texture and chewing of foods;
- Complications related to the tube; and
- Restricted movement.

Decisions to Use Feeding tube

Decisions to continue or discontinue the use of a feeding tube:

- Are collaborative and involve the resident (or legal representative), physician and interdisciplinary team; and
- Include the relevance of a feeding tube to the resident's treatment goals and wishes.

Technical and Nutritional Aspects of Feeding Tubes

Facility protocols assure that staff implement and provide care and services related to feeding tubes according to the resident's need and clinical standards of practice.

Protocols regarding some technical aspects include:

- Location – where inserted, when to verify;
- Care – secured externally, cleaning insertion site; and
- Replacement – when, by whom.

Technical and Nutritional Aspects of Feeding Tubes (cont'd.)

Protocols regarding some nutritional aspects include:

- Enteral nutrition – meeting the resident's nutritional needs;
- Feeding flow – managing and monitoring the rate of flow.

The practitioner's feeding tube order typically include: kind of feeding, caloric value, volume, duration, mechanism of administration, and frequency of flush.

Significant Complications Related to the Feeding Tube

- Aspiration
- Leakage around the insertion site
- Stomach or Intestinal perforation
- Abdominal wall abscess
- Erosion at the insertion site (including nasal area)

Esophageal Complications Related to the Feeding Tube

- Peritonitis
- Esophagitis
- Ulcerations
- Strictures
- Tracheoesophageal fistulas
- Clogged tube

Complications Related to the Administration of the Enteral Nutrition Product

- Nausea;
- Vomiting;
- Diarrhea;
- Abdominal cramping;
- Inadequate nutrition;
- Aspiration;
- Reduced effectiveness of various medications; or
- Metabolic complications.

Aspiration

- Can be dependent on other risk factors;
- Is not necessarily related to gastric residual volumes; and
- Should be assessed individually to implement interventions accordingly (e.g., positioning).

Enteral Formula May Reduced the Effectiveness of Some Medications

- For example: The effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic Complications

- Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels.

Complications Management

The facility is expected to:

- Identify and address actual or potential complications related to the feeding tube or tube feeding; and
- Notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.



Investigative Protocol

Objectives

To determine if:

- A feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;
- A feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and
- Services are provided to restore normal eating skills to the extent possible.



Procedures

- Observations
- Interviews
- Record Review

Observations

During various shifts, observe staff interactions with the resident and provision of care including:

- Initiation, continuation, and termination of feedings;
- Care of the tube site and equipment; and
- Medication administration via the feeding tube.

Observations (cont'd)

To determine whether staff follow:

- Clinical standards of practice;
- Facility policy;
- Resident care plan; and
- Prescriber's orders.

Observations (cont'd)

Use to determine whether staff try to minimize the risk for complications. For example:

- Providing mouth care, including teeth, gums, and tongue;
- Checking that the tubing remains in the correct location; and
- Properly positioning the resident consistent with the resident's individual needs.

Interviews: Resident/representative

Determine if the facility has involved the resident (or legal representative) in the care plan process to reflect the resident's choices, preferences, and response to tube feeding. For example, determine whether:

- The resident (or legal representative) was informed about benefits and risks of tube feeding and possible alternatives; and/or
- There has been reassessment and discussion with the resident (or legal representative) re: continued appropriateness/necessity of the feeding tube.

Interviews: Facility Staff

Interview the facility staff, who provide direct care, to determine, for example:

- Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding:
 - Nausea and/or vomiting
 - Diarrhea
 - Pain associated with the tube
 - Abdominal discomfort
 - Depression and/or withdrawal

Interviews: Facility Staff (cont'd)

Interview the facility staff, who provide direct care, to determine, for example:

- How these problems have been addressed; and
- To whom a staff member has reported the resident's signs or symptoms.

Interviews: Facility Staff (cont'd)

Interview staff with responsibility for overseeing or training regarding care related to feeding tubes to determine, for example:

- How does staff calculate nutritional needs for the resident and ensure that the resident receives close to the calculated amount of nutrition daily?
- How are staff trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident?

Record review

Review the resident's record for evidence of rationale for feeding tube insertion (including interventions tried), and the potential to restore normal eating skills. For example, did the staff:

- Verify that the feeding tube was properly placed?
- Monitor the resident for possible complications related to a feeding tube and the tube feeding?



Review of Facility Practices

Related concerns may have been identified that would suggest the need for interviews with staff (including facility management) and a review of:

- Facility practices;
- Staffing;
- Staff training; and
- Functional responsibilities.

Review of Facility Practices (cont'd.)

If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

Synopsis of F322 Regulation

The regulation requires that the facility:

- Utilize a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable; and
- Provides the resident who is fed by a tube services to prevent complications and restore normal eating skills to the extent possible.

Criteria for Compliance with F322

The facility is in compliance if staff:

- Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;

Criteria for Compliance with F322 (cont'd.)

The facility is in compliance if staff:

- Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and
- Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.

Noncompliance at F322

Noncompliance with F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;
- Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;

Noncompliance at F322 (cont'd)

Failure to:

- Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or
- Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.



DEFICIENCY CATEGORIZATION (Part IV, Appendix P) Severity Determination Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.

Determining Actual or Potential Harm

Actual or potential harm/negative outcome at F322 may include:

- Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration; and
- Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration.

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.



The Immediacy of Correction Required

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.



Severity Levels

Level 4: Immediate Jeopardy to Resident Health or Safety

Level 3: Actual Harm that is Not Immediate Jeopardy

Level 2: No Actual Harm with Potential for More than
Minimal Harm that is Not Immediate Jeopardy

Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 4 Immediate Jeopardy

- Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and

Severity Level 4: Immediate Jeopardy (cont'd)

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.



Severity Level 4 Example

Severity Level 4 Example

As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident's tube feeding, the resident aspirated some of the tube feeding and acquired aspiration pneumonia.

Severity Level 3: Actual Harm that is *not* Immediate Jeopardy

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Severity Level 3 Example

Severity Level 3 Example

The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications.



Severity Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.

Severity Level 2 Example

Severity Level 2 Example

As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.



§483.25 Naso-Gastric Tubes (F322 Feeding Tubes)

Surveyor Train the Trainer:
Interpretive Guidance
Investigative Protocol

Objectives:



Federal Regulatory Language

483.25(g) Naso Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

- (1) A resident who has been able to eat enough alone or with assistance is not fed by naso gastric tube unless the resident's clinical condition demonstrates that use of a naso gastric tube was unavoidable; and**

Instructor Notes:



Federal Regulatory Language (cont)

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

Instructor Notes:



Merging Tags F321 and F322

- The revisions to appendix PP – Interpretive Guidelines for Long Term Care Facilities at §483.25(g)(1)(2) combines F321 and F322, and incorporated the guidance into F322.



§483.25(g) Naso-Gastric Tubes*

****For the purpose of the interpretative guidelines at F tag 322 the regulatory title “§483.25(g) Naso-gastric tubes” is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake.***

5

Instructor Notes: Understanding that nursing homes today use many different types of feeding tubes to provide enteral nutrition to residents we added the following definition for the purpose of the interpretative guidelines at F tag 322, to allow the inclusion of all feeding tubes: The regulatory title “§483.25(g) Naso-gastric tubes” is considered to include as any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake. **Since the regulation was promulgated, nasogastric feeding tube use has become rare, with other feeding tube use becoming prominent, therefore, the definition has expanded.**



Intent

The intent of this regulation is that:

- The feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;
- A feeding tube is utilized in accordance with current clinical standards of practice and services are provided to prevent complications to the extent possible; and
- Services are provided to restore normal eating skills to the extent possible.



Definitions

“Avoidable/Unavoidable use of a feeding tube”

“Avoidable” -- there is not a clear indication for using a feeding tube, and there is insufficient evidence that it provides a benefit that outweighs associated risks.

“Unavoidable” -- there is a clear indication for using a feeding tube, and there is sufficient evidence that it provides a benefit that outweighs associated risks.



Definitions (cont'd)

“Bolus feeding” means the administration of a limited volume of enteral formula over brief periods of time.

“Continuous feeding” means the uninterrupted administration of enteral formula over extended periods of time.

Instructor Note:

Bolus Feeding is commonly used to mimic a meal pattern, when transitioning from enteral feedings to oral feedings and/or to allow time away from feeds.



Definitions (cont'd)

“Enteral nutrition” (a.k.a. “tube feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

“Feeding tube” means a medical device used to provide enteral nutrition to a resident by bypassing oral intake.



Definitions (cont'd)

“Gastrostomy tube” (“G-tube”) means a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.



Definitions

“Jejunostomy tube” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) means a feeding tube placed directly into the small intestine.

“Nasogastric feeding tube” (“NG tube”) means a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.



Definitions

“Transgastric jejunal feeding tube” (“G-J tube”) means a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

“Tube feeding” (a.k.a. “enteral feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.



Overview

The decision to use a feeding tube:

- Has a major impact on a resident and his or her quality of life; and
- Is based on the resident's clinical condition and wishes and federal and state laws.

Use of feeding tubes varies widely among states depending on opinions about non-oral nutrition and varied facility policies and usual practices.

Instructor Notes:



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes

The resident's clinical condition must demonstrate the use of a feeding tube to be "unavoidable":

- No viable alternative to maintain adequate nutrition and/or hydration; and
- Use is consistent with the clinical need to maintain or improve nutritional /hydration parameters.

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Instructor Notes:

Ask the surveyors for examples of medical conditions associated with the use of feeding tubes.

What evidence should they look for to provide evidence of improved nutritional status (i.e. labs, weights)?

Reference Definitions:

“Feeding tube” refers to a medical device used to provide enteral nutrition to a resident by bypassing oral intake.

“Avoidable/Unavoidable use of a feeding tube”

“Avoidable” -- there is not a clear indication for using a feeding tube, and there is insufficient evidence that it provides a benefit that outweighs associated risks.

“Unavoidable” -- there is a clear indication for using a feeding tube, and there is sufficient evidence that it provides a benefit that outweighs associated risks.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes
(cont'd.)

Other factors that may be associated with use:

- Medical conditions that impair nutrition;
- Need to improve nutritional status or comfort;
- To provide comfort; and
- Desire to prolong life.

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Instructor Notes:

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident's ability to maintain appropriate nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery), the need to improve the resident's nutritional status or level of comfort, or the desire to prolong the resident's life. The duration of use of a feeding tube may vary, depending on the clinical situation.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes
(cont'd.)

Clinical rationale supporting the use of a feeding tube includes:

- Assessment of the resident's nutritional and clinical status;
- Relevant functional and psychosocial factors (such as potential ability to maintain activities of daily living ADL); and
- Prior interventions (nutrition therapy and medical intervention tried) and the resident's response.

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Instruction Notes: Additional information re: this slide

Bullet #1: An assessment of the resident's nutritional status -- may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes. An assessment of the resident's clinical status -- may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis.

NOTE: Refer to §483.20 Resident Assessment and the Assessment Section of the General Investigative Protocol at Quality of Care (F309) for discussion of the comprehensive evaluation that comprises an assessment.

Bullet #2: Relevant functional and psychosocial factors -- e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating.

Bullet #3: Interventions prior to the decision to use a feeding tube and the resident's response to them – for example, addressing underlying causes of anorexia and weight loss, diet modifications or changes in food consistency, fortifying the food, adjusting the eating environment, hand-over-hand feeding, cueing or staff feeding.

Also: Refer to F325 for discussion and examples of interventions to improve and restore normal nutritional parameters.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes
Potential benefits of feeding tube use include:

- Addressing malnutrition and dehydration;
- Promoting wound healing;
- Allowing the resident to gain strength (for ADL) including appropriate interventions that may help to restore the residents ability to eat; and
- Improving the resident's ability to make decisions about their care and ability to interact with others.

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Instructor Notes:



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes
(cont'd.)

Possible adverse effects of feeding tube use include:

- Diminished socialization;
- Decreased opportunity to experience taste, texture and chewing of foods;
- Complications related to the tube; and
- Restricted movement.

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Instructor Note:

Additional information regarding Bullet #1: In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room).

Possible additional discussion regarding Bullet #2: The resident being fed by a feeding tube may not have as many opportunities to experience the pleasure of eating or tasting their favorite foods. Facility staff may consider appropriate ways to offer some of this experience to the resident.

Additional information regarding Bullet #4: Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).



Interpretive Guidance

Decisions to Use Feeding tube

Decisions to continue or discontinue the use of a feeding tube:

- Are collaborative and involve the resident (or legal representative), physician and interdisciplinary team; and
- Include the relevance of a feeding tube to the resident's treatment goals and wishes.

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Instructor Notes:

Important situation to discuss:

What if a resident has had a feeding tube placed prior to admission or in another setting while residing in the facility?

The physician and interdisciplinary care team review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes.



Interpretive Guidance

Technical and Nutritional Aspects of Feeding Tubes

Facility protocols assure that staff implement and provide care and services related to feeding tubes according to the resident's need and clinical standards of practice.

Protocols regarding some technical aspects include:

- Location – where inserted, when to verify;
- Care – secured externally, cleaning insertion site; and
- Replacement – when, by whom.

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Instructor Notes:

Additional Information for Bullet #1: Location

Direction to staff regarding how to monitor and check that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) or verify that placement was checked, such as:

- Techniques to verify that tube placement is appropriate before beginning a feeding and before administering medications; and
- The frequency with which staff should monitor for proper location of the feeding tube and to assure that the enteral retention device is properly approximated to the abdominal wall and that the surrounding skin is intact.

Also for Bullet #1 regarding location , refer to F322 definitions:

“**Gastrostomy tube**” (“G-tube”) is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.

“**Jejunostomy tube**” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) is a feeding tube placed directly into the small intestine.

“**Nasogastric feeding tube**” (“NG tube”) is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.

“**Transgastric jejunal feeding tube**” (“G-J tube”) is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

Additional Information for Bullet #2: Care

Direction to staff includes:

- Securing a feeding tube externally;
- Providing needed personal, skin, oral, and nasal care to the resident;
- Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;

- Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and
- Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.

Additional Information for Bullet #3: Replacement

Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:

- When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);
- How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;
- When a tube can be replaced within the facility and by whom;
- When a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center); and
- Notification of the practitioner when the need for a tube change arises unexpectedly.



Interpretive Guidance

Technical and Nutritional Aspects of Feeding Tubes
(cont'd.)

Protocols regarding some nutritional aspects include:

- Enteral nutrition – meeting the resident's nutritional needs;
- Feeding flow – managing and monitoring the rate of flow.

The practitioner's feeding tube order typically include: kind of feeding, caloric value, volume, duration, mechanism of administration, and frequency of flush.

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Instructor Notes:

Additional Information for Bullet #1: Enteral nutrition

Direction to staff regarding the nutritional product and meeting the resident's nutritional needs such as:

- Types of enteral nutrition formulas available for use;
- How to determine whether the tube feedings meet the resident's nutritional needs and when to adjust them accordingly;
- How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;
- Ensuring that the selection and use of enteral nutrition is consistent with manufacturer's recommendations;
- Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner's orders; and
- Ensuring that the product has not exceeded the expiration date.

Also for Bullet #1 regarding Enteral Nutrition, refer to F322 definitions:

“Enteral nutrition” (a.k.a. “tube feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

Additional Information for Bullet #2: Feeding flow

Direction for staff regarding how to manage and monitor the rate of flow, such as:

- Use of gravity flow;
- Use of a pump;
- Periodic evaluation of the amount of feeding being administered for consistency with practitioner's orders;
- Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident's care plan; and
- Periodic maintenance of feeding pumps consistent with manufacturer's instructions to ensure proper mechanical functioning.

Also for Bullet #2, refer to F322 definitions:

“Bolus feeding” is the administration of a limited volume of enteral formula over brief periods of time.

“Continuous feeding” is the uninterrupted administration of enteral formula over extended periods of time.



Interpretive Guidance

Significant Complications Related to the Feeding Tube

- Aspiration
- Leakage around the insertion site
- Stomach or Intestinal perforation
- Abdominal wall abscess
- Erosion at the insertion site (including nasal area)

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Instructor Notes:

The use of tubes not designed or intended for enteral feeding may increase the risk of complications.



Interpretive Guidance

Esophageal Complications Related to the Feeding Tube

- Peritonitis
- Esophagitis
- Ulcerations
- Strictures
- Tracheoesophageal fistulas
- Clogged tube

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Instructor Notes:

Resident care plan should discuss flushing tubes regularly, (and in association with medication administration), to help reduce the risk of clogging due to:

Formula

Pill fragments

Medications incompatible with the formula



Interpretive Guidance

Complications Related to the Administration of the Enteral Nutrition Product

- Nausea;
- Vomiting;
- Diarrhea;
- Abdominal cramping;
- Inadequate nutrition;
- Aspiration;
- Reduced effectiveness of various medications; or
- Metabolic complications.

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Instructor Notes:

**Interpretive Guidance**

Aspiration

- Can be dependent on other risk factors;
- Is not necessarily related to gastric residual volumes; and
- Should be assessed individually to implement interventions accordingly (e.g., positioning).

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Instructor Notes:

Additional discussion

Bullet #1 -- While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors. For example, aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly positioned within the stomach or intestine.

Bullet #2 -- The evidence is inconsistent and conflicting regarding any connection between gastric residual volume and the risk or occurrence of aspiration.

Bullet #3 -- There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle. Another example of an intervention to reduce the risk of aspiration would be to adjust the rate of flow.



Interpretive Guidance

Enteral Formula May Reduced the Effectiveness of Some Medications

- For example: The effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Instructor Notes:



Interpretive Guidance

Metabolic Complications

- Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels.

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Instructor Notes:

These metabolic risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.



Complications Management

The facility is expected to:

- Identify and address actual or potential complications related to the feeding tube or tube feeding; and
- Notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.

Instructor Notes:



Investigative Protocol

Objectives

To determine if:

- A feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;
- A feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and
- Services are provided to restore normal eating skills to the extent possible.

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Instructor Notes:

Slide 30



Investigative Protocol

Procedures

- Observations
- Interviews
- Record Review

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Instructor Notes:



Investigative Protocol

Observations

During various shifts, observe staff interactions with the resident and provision of care including:

- Initiation, continuation, and termination of feedings;
- Care of the tube site and equipment; and
- Medication administration via the feeding tube. ³¹

Instructor Notes:



Investigative Protocol

Observations (cont'd)

To determine whether staff follow:

- Clinical standards of practice;
- Facility policy;
- Resident care plan; and
- Prescriber's orders.

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Instructor Notes:



Investigative Protocol

Observations (cont'd)

Use to determine whether staff try to minimize the risk for complications. For example:

- Providing mouth care, including teeth, gums, and tongue;
- Checking that the tubing remains in the correct location; and
- Properly positioning the resident consistent with the resident's individual needs.

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Instructor Notes:

Additional examples of care that may minimize risk of complications include:

- Using universal precautions and clean technique and following the manufacturer's recommendations when stopping, starting, flushing, and giving medications through the feeding tube.
- Ensuring the cleanliness of the feeding tube, insertion site, dressing (if present) and nutritional product.
- Providing the type, rate, volume and duration of the feeding as ordered by the practitioner and consistent with the manufacturer's recommendations.
 - Implementing interventions to minimize the negative psychosocial impact that may occur as a result of tube feeding.



Investigative Protocol

Interviews: Resident/representative

Determine if the facility has involved the resident (or legal representative) in the care plan process to reflect the resident's choices, preferences, and response to tube feeding. For example, determine whether:

- The resident (or legal representative) was informed about benefits and risks of tube feeding and possible alternatives; and/or
- There has been reassessment and discussion with the resident (or legal representative) re: continued appropriateness/necessity of the feeding tube.

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Instructor Notes:

Additional interview questions for discussion:

Has the resident had any significant new or worsening physical, functional or psychosocial changes related to having a feeding tube? Did the resident inform the staff? How were the problems addressed?

Did staff provide assistance to the resident to increase the food intake, prior to inserting a feeding tube (e.g., identifying underlying causes of anorexia; hand feeding; changing food consistency, texture, form; offering alternate food choices; and/or providing assistive devices)?



Investigative Protocol

Interviews: Facility Staff

Interview the facility staff, who provide direct care, to determine, for example:

- Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding:
 - Nausea and/or vomiting
 - Diarrhea
 - Pain associated with the tube
 - Abdominal discomfort
 - Depression and/or withdrawal

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Instructor Notes:

Additional interview questions for discussion:

How did the staff and practitioner determine the cause(s) of decreased oral intake/weight loss or impaired nutrition and attempted to maintain oral intake prior to the insertion of a feeding tube, such as did staff collaborate with the physician to identify medical causes of decreased appetite or try to help the resident eat enough food (e.g., cueing or hand feeding; changing food consistency, texture, form; seeking and addressing causes of anorexia; providing assistive devices)?

What the specific care needs for the resident such as special positioning, personal care, insertion site care and the amount of feeding taken in;

Did the staff member report resident signs and symptoms? To whom were they reported?

How did the staff determine the resident's nutritional status was being met such as periodically weighing the resident and how they decide whether the tube feeding is adequate to maintain acceptable nutrition parameters;

Has there been a periodic reassessment and discussion with the resident or his/her legal representative regarding the continued appropriateness/necessity of the feeding tube; and whether the care plan has been revised and implemented as necessary?



Investigative Protocol

Interviews: Facility Staff (cont'd)

Interview the facility staff, who provide direct care, to determine, for example:

- How these problems have been addressed; and
- To whom a staff member has reported the resident's signs or symptoms.

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Instructor Notes:



Investigative Protocol

Interviews: Facility Staff (cont'd)

Interview staff with responsibility for overseeing or training regarding care related to feeding tubes to determine, for example:

- How does staff calculate nutritional needs for the resident and ensure that the resident receives close to the calculated amount of nutrition daily?
- How are staff trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident?

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Additional interview questions for discussion:

How does the facility identify the resident at risk for impaired nutrition, identify and address causes of impaired nutrition, and determined that use of a feeding tube was unavoidable?

How does staff monitor the resident for the benefits and risks related to a feeding tube, and address adverse consequences of the feeding tube use (e.g., altered mood, nausea and vomiting, pain, or restraint use to try to prevent the resident from removing the feeding tube)?

Does the physician and staff attempt to identify the circumstances that led to the placement of the feeding tube (e.g., when the tube was placed in another facility)?

Is the resident periodically reassessed for the continued appropriateness/necessity of the feeding tube; and was the care plan was revised and implemented, as necessary, with input from the resident or his/her legal representative, to the extent possible?



Investigative Protocol

Record review

Review the resident's record for evidence of rationale for feeding tube insertion (including interventions tried), and the potential to restore normal eating skills. For example, did the staff:

- Verify that the feeding tube was properly placed?
- Monitor the resident for possible complications related to a feeding tube and the tube feeding?

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Additional examples—Review information such as physician orders, tube feeding records, multidisciplinary progress notes and RAI/MDS to determine:

That the resident was periodically reassessed and the care plan was revised and implemented, as necessary with input from the resident or his/her legal representative, to the extent possible.

That staff are assigned responsibilities for various aspects of enteral feedings consistent with their position and training (e.g., administering the feeding, determining and verifying correct formula; calculating the amount of formula, feeding intervals, flow rate).



Review of Facility Practices

Related concerns may have been identified that would suggest the need for interviews with staff (including facility management) and a review of:

- Facility practices;
- Staffing;
- Staff training; and
- Functional responsibilities.

Instructor Notes:



Interpretive Guidance

Review of Facility Practices (cont'd.)

If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

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Instructor Notes:

Refer to 483.75(o)(3) and (4) of F520 Quality Assessment and Assurance: Information from quality assurance committees is protected from disclosure except to determine compliance with committee requirements; and are not to be used as the basis for sanctions.



Determination of Compliance

Synopsis of F322 Regulation

The regulation requires that the facility:

- Utilize a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable; and
- Provides the resident who is fed by a tube services to prevent complications and restore normal eating skills to the extent possible.

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Instructor Notes:



Determination of Compliance

Criteria for Compliance with F322

The facility is in compliance if staff:

- Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;

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Instructor Notes:



Determination of Compliance

Criteria for Compliance with F322 (cont'd.)

The facility is in compliance if staff:

- Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and
- Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.

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Instructor Notes:



Determination of Compliance

Noncompliance at F322

Noncompliance with F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;
- Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;

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Instructor Notes:



Determination of Compliance

Noncompliance at F322 (cont'd)

Failure to:

- Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or
- Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.

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Instructor Notes:



DEFICIENCY CATEGORIZATION
(Part IV, Appendix P) Severity Determination
Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.

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Instructor Notes:

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

**Deficiency Categorization**

Determining Actual or Potential Harm

Actual or potential harm/negative outcome at F322 may include:

- Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration; and
- Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration.

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Additional examples for discussion:

Failure to adequately assess a resident's nutritional status and the care and services needed to maintain or improve the resident's nutritional status and/or to identify why the use of a feeding tube was medically unavoidable.

Failure to use and monitor a feeding tube per facility protocol and current clinical standards of practice or to identify and manage feeding tube-related or tube-feeding related complications, thereby allowing the complication to continue without appropriate intervention.



Deficiency Categorization

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

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Instructor Notes:

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F tag . First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. **(Follow the guidance in Appendix Q).**



Deficiency Categorization

**The Immediacy of Correction
Required**

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.



Deficiency Categorization

Severity Levels

Level 4: Immediate Jeopardy to Resident Health or Safety

Level 3: Actual Harm that is Not Immediate Jeopardy

Level 2: No Actual Harm with Potential for More than
Minimal Harm that is Not Immediate Jeopardy

Level 1: No Actual Harm with Potential for Minimal Harm



Deficiency Categorization

Severity Level 4 Immediate Jeopardy

- Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and

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Instructor Notes:



Deficiency Categorization

Severity Level 4: Immediate Jeopardy (cont'd)

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

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Instructor Notes:

Discuss examples of immediate jeopardy that you have seen in your experiences?



Severity Level 4 Example

Severity Level 4 Example

As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident's tube feeding, the resident aspirated some of the tube feeding and acquired aspiration pneumonia.

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Additional example for discussion:

The facility failed to train staff about how to ensure proper placement of a feeding tube, and/or to ensure that staff were checking for tube placement consistently and correctly. As a result of staff failure to verify tube placement, a resident got peritonitis (infection of the lining of the abdominal cavity) and died following the administration of tube feeding.

Ask for additional examples or how this example could be a level 3. Note: There are typically discrepancies in how surveyors choose severity levels.



Severity Determination

**Severity Level 3: Actual Harm that is
not Immediate Jeopardy**

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

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Instructor Note:

For discussion - What is an example of harm that is not immediate jeopardy?

Severity Determination

Severity Level 3 Example

Severity Level 3 Example

The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications.

55

Additional example for discussion:

As a result of facility failure to assess the resident's nutritional needs and to continue to administer, monitor, and adjust tube feeding accordingly, a resident experienced significant weight loss that cannot be otherwise attributed to a medically unavoidable cause.

Ask for additional examples or how these examples could be modify to fit a level 2 or level 4.



Severity Determination

Severity Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.

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Instructor Notes:

Severity Determination

Severity Level 2 Example

Severity Level 2 Example

As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications.

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As a result of staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications.

As a result of staff failure to consistently flush a resident's feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.

How could this example be modified to a level 3?

Severity Determination

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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Instructor Notes: