Informed Consent and Ethical Best Practices in Dysphagia and Diet Consistency Decisions Part 1

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1

Disclosures

- Mary Casper receives a salary for employment at the American Speech-Language-Hearing Association (ASHA).
- Mary is a Contributing Faculty at the University of Saint Augustine for the Health Sciences, teaching Dysphagia.
- Mary received complimentary registration and travel expenses from SHAV for her participation as an invited speaker.
- She has no non-financial disclosures.

2

Learning Outcomes

1. Describe the components of informed consent in dysphagia management involving diet consistency modification
2. Explain ethical best practices for dysphagia management involving diet consistency modification
3. Discover the regulations in the SNF environment that support engagement of the patient in the decision-making process

3

What is informed consent?

- An ethical and legal obligation of health care providers in the US
- *The patient has the right to direct what happens to their body*.
- Emerged in the 1950s; first real conversations in the 1970s
  - Simultaneously with the emergence of the field of bioethics
  - Law, ethics, medicine, and research all affected by issues of individual liberty and social equality in society.
  - Technological and impersonal medical care.
  - Informed consent and the birth of bioethics occurred at the same time.
- "Consent" did not necessarily empower the patient.

• Beauchamp, T. L. (2011). Informed consent: its history, meaning, and present challenges. *Cambridge Quarterly of Healthcare Ethics*, 20(4), 515-523. Thornton (2000) Informed Consent. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1312305/

4

(Historical) Concept of Paternalism

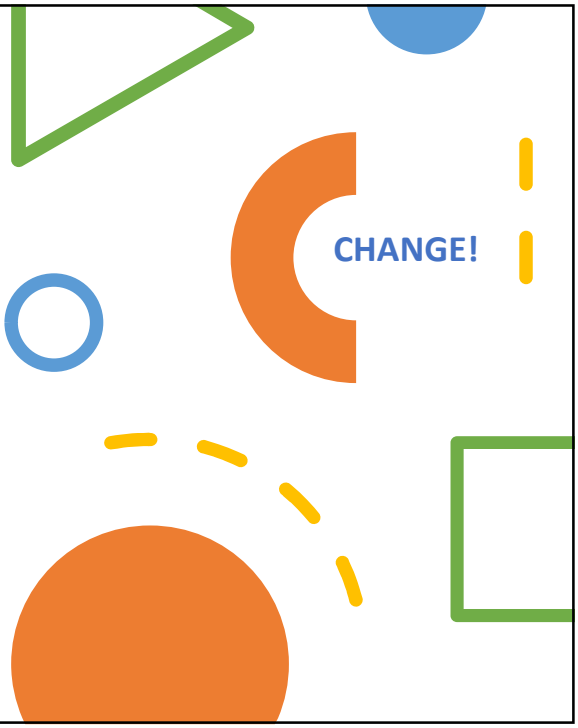
- "Benevolent decision making" – Care decisions made for the patient by the physician
- "The doctor knows best."
- The "risk vs benefit" decision was made with someone else's values and belief system.
- May honestly believe they are doing the right thing, but it violates both law and ethics
- (Autonomy, beneficence, nonmaleficence, justice)
- Long history in USA of medical paternalism

Tuckett, A. G. (2006). On paternalism, autonomy and best interests: Telling the (competent) aged-care resident what they want to know. *International journal of nursing practice*, *12*(3), 166-173.

5

History: Dysphagia assessment and treatment

- Larsen (1972) *JSHD*
- Larsen & Mikulik (1976). *Rehabilitation Nursing*
- Buckley, Addicks & Maniglia (1976) *Nursing Forum*
- Winstein (1983) *Physical Therapy*



6

REHABILITATION FOR DYSPHAGIA PARALYTICA

George L. Larsen

Veterans Administration Hospital, Seattle, Washington

Dysphagia paralytica is a disorder of swallowing resulting from a lesion of the cranial nerves or brain stem, in particular the medulla oblongata. Rehabilitation of this disorder depends on careful assessment of spared and damaged processes responsible for swallowing. The management technique is maximum use of assets, capitalizing on intelligence to support reflex bahavior. The various roles of the rehabilitation team are described.

The dysphagia evaluation showed aspiration of water as it spilled readily into the larynx and did not produce a swallow reflex. Blender-textured foods did not produce a swallow and were contraindicated because of the danger of aspiration pneumonia. The semisolid quality of sliced canned peaches proved most satisfactory because its specific gravity was adequate to stimulate sensors of touch and pressure, the flavor produced salivation, and the texture allowed easy mobility through the oropharynx and into the esophagus.

7

nursing interventions in dysphagia rehabilitation

by George L. Larsen, Ph.D and Mary Ann Mikulic, R.N., M.N.

The patient with a swallowing disorder has usually gone through an acute illness and is in a state of convalescence when the swallowing problem is first considered. It is precisely at this time that the nurse in the extended role of evaluator and healthplanner must be prepared to differentially evaluate the swallowing problem and develop a rehabilitative plan of treatment. The purpose of this paper is to provide guidelines for a differential evaluation of swallowing disorders and to offer practical suggestions in the rehabilitation of these patients.

To effectively implement a treatment plan directed toward maximizing the rehabilitation potential of patients with swallowing problems the nurse must be able to establish what the specific disability is. An understanding of normal swallowing is basic to differential evaluation.

8

FEEDING PATIENTS WITH DYSPHAGIA

Buckley J, Addicks C, Maniglia J. (1976) Feeding patients with dysphagia. *Nursing Forum*;15:69-85

It is, however, possible for the nurse to stimulate, facilitate, and establish normal eating and swallowing patterns. The authors hope the guidelines offered in this article may provide an alternative to nasogastric and intravenous feedings. The recommended procedures employ sensorimotor reflex positioning and stimulation techniques which increase and maintain muscle tone, provide afferent, intercalated, and efferent bombardment, excite certain normal and desired reflexes, and correct and encourage normal sensory feedback of the sucking, swallowing, and chewing mechanism. The techniques attempt to stimulate reflexes which enhance labial, lingual, palatal, mandibular, laryngeal, and glottal movement, strength, and coordination.

9

☐ If coughing occurs or if the swallow comes too slowly, press down on the patient's head with the palm of your hand. This decreases laryngeal tension and facilitates swallowing. (Figure 4) Also you may press the larynx lightly from side to side. This passive range of motion helps stretch and relax the laryngeal muscles. (Figure 5)

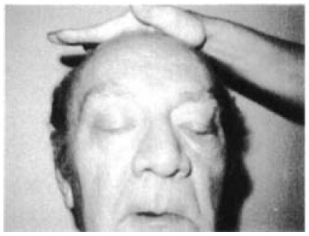


Figure 4: If coughing occurs during feeding or if the swallow comes too slowly, place the palm of the hand on the top of patient's head and press down to decrease laryngeal tension and facilitate swallowing.

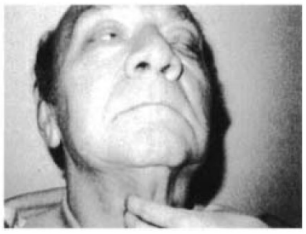


Figure 5: If coughing continues, press the patient's larynx lightly from side to side to stretch and relax the laryngeal muscles.

10

☐ Have the patient chew and swallow slowly concentrating only on the feeding process. Encourage him to close his lips once the food is in the mouth and remain closed until the food is swallowed. You may have to manually close the patient's lips if he cannot perform it voluntarily. When lips are in a sealed position the swallowing reflex is initiated. (Figure 8)

Figure 8: To create a tight labial seal close the patient's lips in a sealed position to help initiate the swallowing reflex.

11

The swallowing difficulty diet should be modified to the patient's needs and adjusted to the stage of swallowing where he is having the most trouble. The following are some general diet guidelines:

1. Milk and milk products stimulate thick saliva, which is difficult to swallow and, therefore, should be avoided.
2. Juices should be diluted with water, especially in the initial stages.
3. In the initial stages of feeding, avoid difficult-to-swallow foods, e.g., plums, prunes, apricots, strawberries, hamburger patties, onions, milk soups, mashed potatoes, white bread, cola-flavored carbonated beverages, custards, ice creams, puddings, and all crackers except biscuits.

12

4. Use foods with some texture, especially if the patient can chew. Textured foods are better than smooth, and chewing stimulates a better swallow, e.g., toast instead of white bread, baked and boiled potato instead of mashed potatoes.

5. Most patients respond to mildly sweetened and salted foods. Room temperature, mildly flavored solids and liquids are better than weak or strong flavored foods. Avoid acid or bitter flavors except for lemon mixed with other foods.

6. Keep the diet flexible and adapt it to the patient's needs.

13

Neurogenic Dysphagia

Frequency, Progression, and Outcome in Adults Following Head Injury

The diagnosis of dysphagia is an often overlooked and poorly managed sequelae in the head-injured adult. A review of the literature revealed very little information about frequency or treatment of this problem in the head-injured adult.[1–5] Renewed interest in the pathophysiology of dysphagia is, however, developing. This interest is partially the result of the greater number of patients who now survive the injury and subsequently are treated in rehabilitation centers.[6]

Winstein, C. (1983). Physical Therapy, 63:12; 1993-1997.

The physical therapists chose one of three programs to plan and implement the management of nonoral feeders.

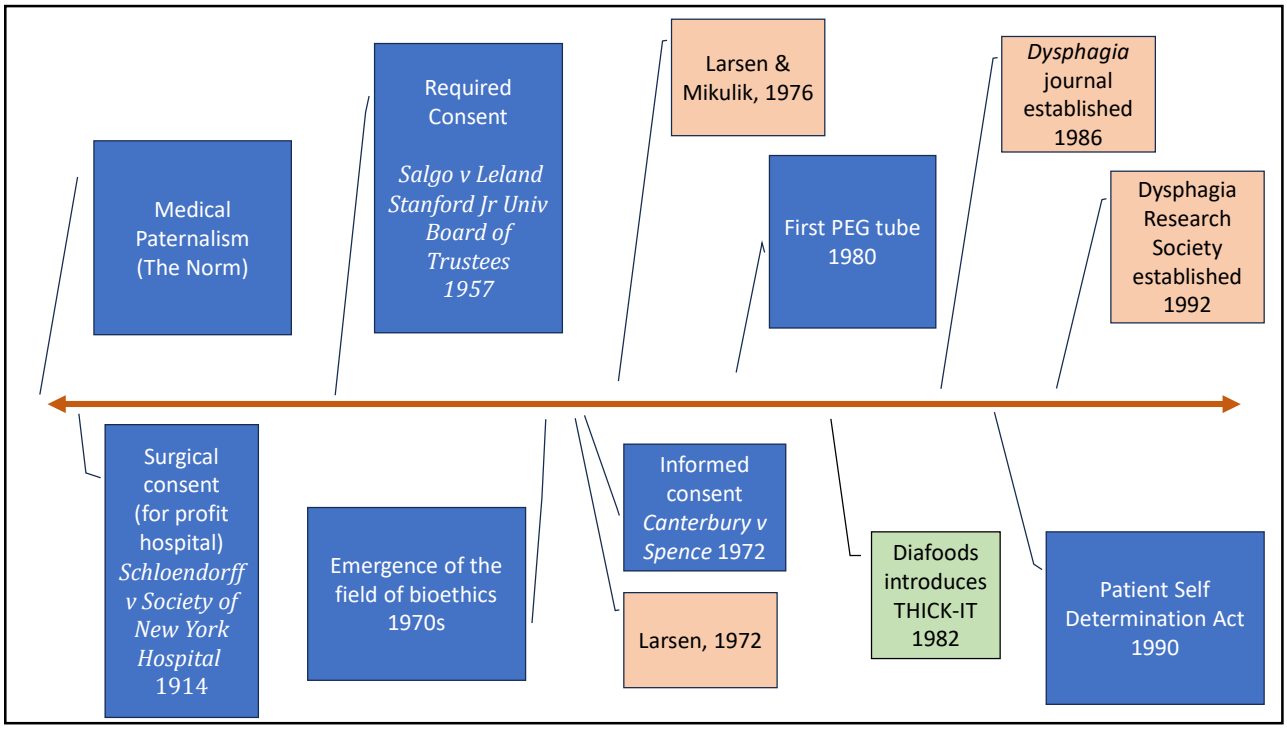
14

. Initially, the physical therapist fed the patient. When one full meal was finished without difficulty in one-half hour, the nursing staff or the family assumed responsibility for feeding after receiving instructions from the physical therapist. Progression to three full meals a day was further guided by the physical therapist. Self-feeding was the occupational therapist's goal for the patient. In addition, the speech pathologist often worked with the physical therapist to obtain better intraoral and respiratory control for the patient's vocalizations.

15

TIME LINE

16



17

Timeline to Establish Informed Consent[2]

Court Case	Year	Significance
Schloendorff v. Society of New York Hospital	1914	This case used the idea of self-determination to articulate the need for consent from patients.
Nuremberg Doctors' Trial	1946	This determined that consent must be voluntary, competent, informed, and comprehending for human subjects in studies requiring human test subjects.
Salgo v. Leland Stanford Jr., University Board of Trustees	1957	This case coined the term "informed consent" by emphasizing the need for recognizable and adequate consent.
Natanson v. Kline	1960	This helped establish what was required to be disclosed before a procedure, helping to set the boundaries of informed consent. Negligence could be used in informed consent cases.
Cobbs v. Grant	1972	This case caused the courts to define consent as being patient-based: "what would a competent patient need to know to make a rational decision."
Canterbury v. Spence	1972	This was another influential informed consent case where the (unsuccessful) plaintiff claimed that they were not sufficiently warned of the potential dangers.

Jennings B. (2014). Bioethics (4th ed.). Macmillan Reference USA a part of Gale Cengage Learning. Retrieved September 20 2023 from http://go.galegroup.com/ps/i.do?p=GPS&sw=w&u=vol_b92b&v=2.1&it=aboutBook&id=GALE|4PDC.

18

Informed Consent

- The AMA defines informed consent as:

"a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."

19

Components of Informed Consent

- ✓ Comprehension
- ✓ Choice
- ✓ Consequences
- ✗ ~~Coercion~~

20

Standards of Informed Consent

What does it mean to BE ”informed?”

Subjective standard: *What would this patient need to know and understand to make an informed decision?*

**Reasonable patient standard: *What would the average patient need to know to be an informed participant in the decision?*

Reasonable physician standard: *What would a typical physician say about this procedure?*

Siminoff, L. A., & Fetting, J. H. (1991). Factors affecting treatment decisions for a life-threatening illness: the case of medical treatment of breast cancer. *Social science & medicine*, *32*(7), 813-818.

21

What must be shared?

- Information about the diagnosis/finding
- Information about all the different approaches to care for the problem, including doing nothing.
- Risks and benefits of each of the approaches, including doing nothing.
- Must be communicated in a NON-BIASED fashion

Horner, J., Modayil, M., Chapman, L. R., & Dinh, A. (2016). Consent, refusal, and waivers in patient-centered dysphagia care: Using law, ethics, and evidence to guide clinical practice. *American Journal of Speech-Language Pathology*, *25*(4), 453-469.

O'Keeffe, S. T., Leslie, P., Lazenby-Paterson, T., McCurtin, A., Collins, L., Murray, A., ... & SPARC (Swallow Perspectives, Advocacy and Research Collective). (2023). Informed or misinformed consent and use of modified texture diets in dysphagia. *BMC Medical Ethics*, *24*(1), 7.

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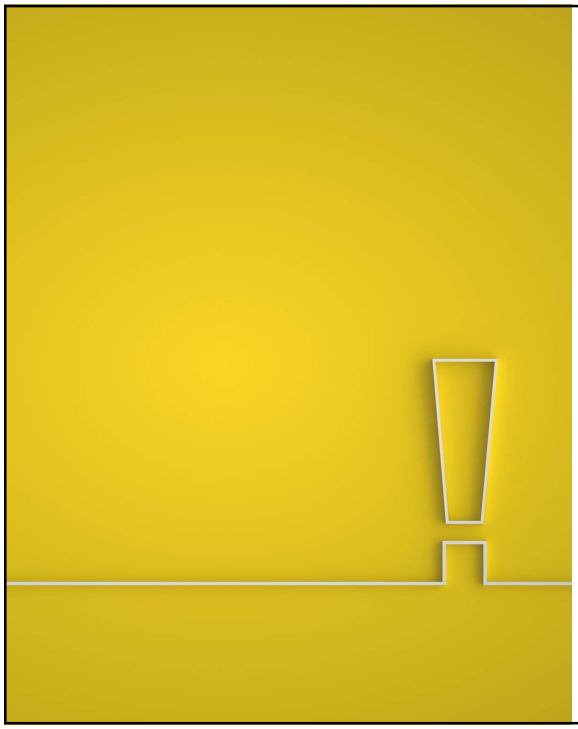


Informed Refusal

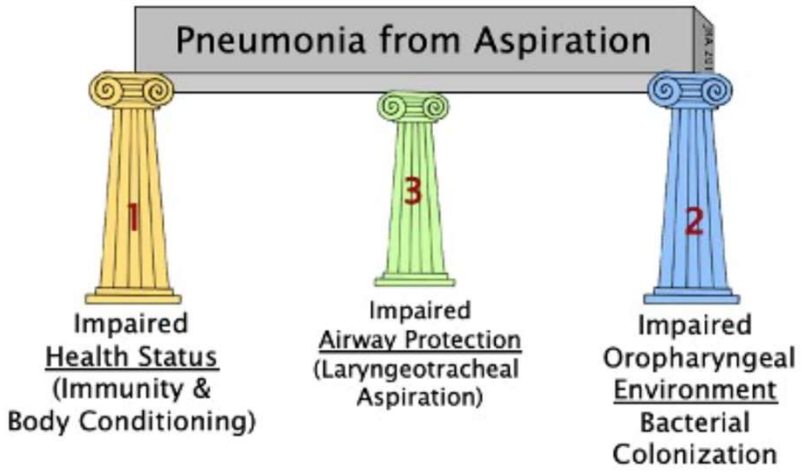
- https://www.thedoctors.com/articles/informed-refusal
- An extension of informed consent; the patient declines a recommended intervention.
- Documentation is vital for BOTH

23

Are we providing ACCURATE information to patients?

24

There is no linear relationship between aspiration and disease consequences.



https://www.sasspllc.com/

25

Pneumonia "Risk" Predictor

Scenario	Immune System Status	+	Oral Health Status	+	Laryngeal Valve Integrity	=	Predicted Outcome
1	Normal	+	Healthy	+	No Aspiration	=	No Pneumonia
2	Normal	+	Healthy	+	Aspiration	=	No Pneumonia
3	Normal	+	Unhealthy	+	No Aspiration	=	No Pneumonia
4	Normal	+	Unhealthy	+	Aspiration	=	No Pneumonia
5	Compromised	+	Healthy	+	No Aspiration	=	No Pneumonia
6	Compromised	+	Unhealthy	+	No Aspiration	=	No Pneumonia
7	Compromised	+	Unhealthy	+	Aspiration	=	Pneumonia

References:
Tobin & Grenik (1984) *Crit Care Med*
Shockley (1995) *Am J Med*
Nakajoh et al. (2000) *J Intern Med*
Terpenning et al. (2001) *J Am Geriatr Soc*
Ashford (2005) *Persp Swal & Swal Dis*
Halton Region's Health Dept (2007) *OHAT - online*

https://www.sasspllc.com/

26

Aspiration is not the devil

MAKING IT THE PRIORITY IS NOT THE ANSWER

27

What should happen next?

- Patient (family) makes an informed decision after having been provided with all options.
- Must assure that the patient understood and document the conversation
- This was required by physicians from 1972
- Later legislation required this from ALL providers

Horner, J., Modayil, M., Chapman, L. R., & Dinh, A. (2016). Consent, refusal, and waivers in patient-centered dysphagia care: Using law, ethics, and evidence to guide clinical practice. *American Journal of Speech-Language Pathology*, *25*(4), 453-469.

O'Keeffe, S. T., Leslie, P., Lazenby-Paterson, T., McCurtin, A., Collins, L., Murray, A., ... & SPARC (Swallow Perspectives, Advocacy and Research Collective). (2023). Informed or misinformed consent and use of modified texture diets in dysphagia. *BMC Medical Ethics*, *24*(1), 7.

Canterbury v. Spence (464 F.2d. 772, 782 D.C. Cir. 1972)

28

The Patient Self-Determination Act

Passed in 1990 (amendment to OBRA)

Required Medicare and Medicaid providers to give individuals information about their rights under state law related to advance directives.

Patients have the right to refuse medical treatment

Recognizes that the patient is the recipient of care.

They have the right to direct that care

Rehabilitation providers must follow this law

Providers must consider the values, opinions and wishes of the recipient.

Patient's choice need not be what the provider feels is the best choice

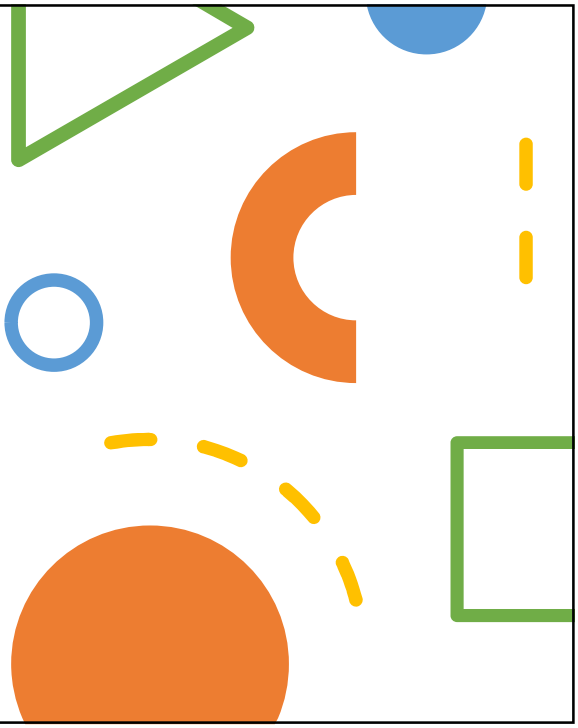
The Patient Self-determination Act of 1990. *§§4206, 4751 of the Omnibus Reconciliation Act of 1990, Pub L No* 101- 508

29

Shared decision making

- An approach between paternalism (the doctor knows best) and basic autonomy (the patient knows best).
- Includes both beneficence (to do good) and patient authority (it's my body)
- Protects and supports patient autonomy.
- Evidence based practice vs. "fear-based practice."

- **Neither informed consent nor shared decision-making is "I shared my recommendation and the risks of not following, but the patient refused."**



Childress, J. F., & Childress, M. D. (2020). What does the evolution from informed consent to shared decision making teach us about authority in health care?. *AMA Journal of Ethics*, 22(5), 423-429.

30

Neither informed consent nor shared decision-making is "I shared my recommendation and the risks of not following, but the patient refused."

31

What must all providers do?

Disclose information in a nonbiased fashion and participate in shared decision making.

Best way is at a care plan meeting with family and key team members present.

(Timing may not permit the standard meeting)

Patients cannot make their own decisions if they have not been provided the necessary information to do so.

Childress, J. F., & Childress, M. D. (2020). What does the evolution from informed consent to shared decision making teach us about authority in health care?. *AMA Journal of Ethics*, *22*(5), 423-429.

32

Patients cannot make their own decisions if they have not been provided the necessary information to do so.

33

What about cognitive impairments?

Patients do not lose their rights to autonomy

Can the patient choose?

Can the patient participate in the discussion of informed consent?

"Legal health care decision maker" – whomever that might be.

If there is doubt, involve the family.

Regardless, correct and consistent information must be conveyed, whether the decision is made by the patient or by a surrogate.

O'Keeffe ST, Leslie P, Lazenby-Paterson T, McCurtin A, Collins L, Murray A, Smith A, Mulkerrin S; SPARC (Swallow Perspectives, Advocacy and Research Collective). Informed or misinformed consent and use of modified texture diets in dysphagia. BMC Med Ethics. 2023 Feb 7;24(1):7. doi: 10.1186/s12910-023-00885-1. PMID: 36750907; PMCID: PMC9903443.

34

Clinical capacity vs Legal capacity

- Clinical decision making- about their care.
- Clinical team
- "Capacity"
- Ability to make a decision today, now.
- Part of every encounter.

- Legal - about their lives
- Presumed in adults
- A Judge
- "Competency"
- Make a will, execute legal documents, vote, marry, drive, etc.

Horner, J., Modayil, M., Chapman, L. R., & Dinh, A. (2016). Consent, refusal, and waivers in patient-centered dysphagia care: Using law, ethics, and evidence to guide clinical practice. *American Journal of Speech-Language Pathology*, *25*(4), 453-469.

35

Regulations

The Center for Medicare and Medicaid Services (CMS) Requirements of Participation explicitly state that patients have the right to be informed of and participate in his or her treatment plan

F tags are used by state surveyors and by CMS to document deficiencies in compliance with these regulations.

Deficiencies come at various levels of severity

36

Relevant F Tags

- *F552 - The resident has the right to be informed of and participate in his or her treatment including the right to be informed in advance by the physician or other practitioner or professional* ***of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or options he or she prefers.***
- *F553 – The facility shall inform the resident of the* ***right to participate in his or her treatment and shall support the resident in this right****. The planning process must incorporate the residents'* ***personal and cultural preferences*** *in developing goals of care.*
- *F692 – Nutrition/hydrations status – resident is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diets*
- *F807 – Food and drink – each resident receives and the facility provides drinks, including water and other liquids* ***consistent with resident needs and preferences and sufficient to maintain resident hydration****.*

37

GUIDANCE: INTERVENTIONS: Diet Liberalization: Based on the resident's assessment, it could be beneficial to minimize restrictions, such as therapeutic or mechanically altered diets, and provide preferred foods before using supplementation. However, it is the responsibility of the facility to talk with the resident, their family and representative (whenever possible) and provide information pertaining to the risks and benefits of a liberalized diet

DEFICIENCY CATEGORIZATION: Examples of Severity Level 4 Noncompliance: ***Immediate Jeopardy to Resident Health or Safety*** *include Dietary restrictions or downgraded diet textures, such as mechanical soft or pureed textures, were provided by the facility against the resident's expressed preferences and resulted in substantial and ongoing decline in food intake resulting in significant or severe unplanned weight loss with accompanying irreversible functional decline to the point where the resident was placed on hospice.*

38

4.F. **10.** Wellness for the persons served is promoted through activities that:

a. Are based on input from the persons served.
b. Consider input from families/ support systems.
c. Are purposeful.
d. Provide for daily structured and unstructured activities.
e. Promote healthy behavior.
f. Meet their interests.
g. Align with their cognitive capabilities.
h. Align with their communication capabilities.
i. Reflect their choices.
j. Promote their personal growth.
k. Enhance their self-image.
l. Improve or maintain their functional levels whenever possible.
m. Allow for social interaction.
n. Allow for autonomy.
o. Include opportunities for community integration.
p. Are documented in the individual plan for each person served.

CARF Medical Rehabilitation Standards Manual (2018)

39

Informed consent: *Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.*

Source: The Joint Commission. 2022. Comprehensive Accreditation Manual glossary.

40

What about waivers?

- A document that asks patients/families to absolve the facility of the obligation to provide care as a tradeoff for receiving desired food.

- COERCIVE
- Inconsistent with the science (Pillars and Prediction)

- Coercion is illegal and waivers are coercive.
- Coercion is illegal and biased language is coercive.

41

If not a waiver, then what?

- Nonbiased conversations
- Open discussions conveying <u>correct</u> information
  - Asking of questions
  - Sharing of information
  - Sharing of unknowns
- Then the patient can make their own decision (or the decision maker, if applicable), with the team
- Document all of it.

42

ASHA Practice Portal – Adult Dysphagia

- https://www.asha.org/practice-portal/clinical-topics/adult-dysphagia/#collapse_4
- SLPs practicing with adults with dysphagia are responsible for (among other things …):

- understanding a variety of medical diagnoses and their potential impact(s) on swallowing;
- recognizing possible contraindications to clinical decisions and/or treatment;
- being aware of typical age-related changes in swallow function;
- providing education and counseling to individuals and caregivers;
- incorporating the client's/patient's dietary preferences and personal/cultural practices as they relate to food choices during evaluation and treatment services;
- respecting issues related to quality of life for individuals and/or caregivers;
- practicing interprofessional collaboration

43

Fear based practice (What if? thinking)

- What if there are negative consequences?
  - NOT an ethical and legal violation
  - Informed consent and shared decision making took place.
  - A waiver doesn't protect anyone from not providing basic care
- Why NOT just provide the recommended diet?
  - Ethical and legal violation
  - NO opportunity to make an informed choice.
  - Practice by fear.
- A century of legislation has been trying to change PATERNALISM.

44

Resources

- Horner, J., Modayil, M., Chapman, L. R., & Dinh, A. (2016). Consent, refusal, and waivers in patient-centered dysphagia care: Using law, ethics, and evidence to guide clinical practice. *American Journal of Speech-Language Pathology*, *25*(4), 453-469.
- Sharp, H. M. (2015). Informed consent in clinical and research settings: what do patients and families need to make informed decisions?. *Perspectives on Swallowing And Swallowing Disorders (Dysphagia)*, *24*(4), 130-139.
- Leslie, P., Xia, B., & Yoo, J. (2021). It's not such a small world after all: the intersection of food, identity, and the speech-language pathologist. *Perspectives of the ASHA Special Interest Groups*, *6*(4), 876-884.
- Sharp, H. M. (2005). When patients refuse recommendations for dysphagia treatment. *Perspectives on swallowing and swallowing disorders (Dysphagia)*, *14*(3), 3-7.

45

Resources

- https://ltcombudsman.org/issues/residents-rights
- https://www.pioneernetwork.net/wp-content/uploads/2016/10/The-New-Dining-Practice-Standards.pdf
- https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety--issue-21-informed--consent-more-than-getting-a-signature/informed-consent-more-than-getting-a-signature/
- https://www.asha.org/practice/ethics
- ethics@asha.org

46

THANK YOU!

- Mary Casper, M.A., CCC-SLP, ASHA Fellow, FNAP

47