

Popular Topics for the Boards

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**CONTINUING MEDICAL EDUCATION
DEPARTMENT OF MEDICINE**



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

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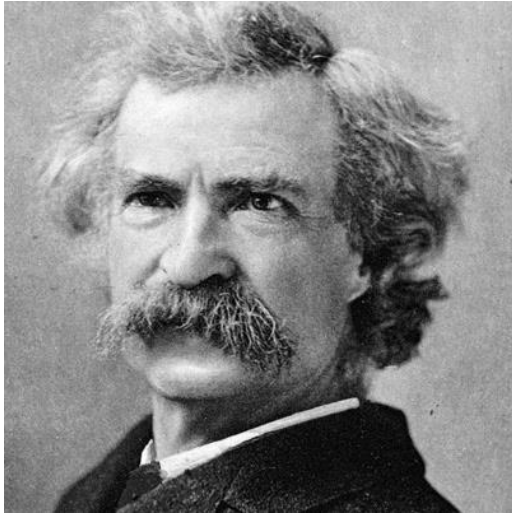
Conflict of Interest/Financial Disclosure

- I am a co-investigator on the NIH-funded PrecISE Trial Network and the IDEA trial. Within the last three years, the following companies have provided study drugs for the PrecISE Trial Network: GlaxoSmithKline, Laurel, Sun Pharma, Vifor, Vitaeris/CSL Behring, Vitaflo. The following companies have provided study drugs for IDEA: Regeneron Pharmaceuticals, Organon and Sanofi/Aventis.
- I am a co-investigator for the industry-sponsored LEVANTE trial, for which Astra-Zeneca provides study drugs.

Themes/Objectives

- Medical statistics
- Surrogate decision makers
- Iatrogenic problems/Medication effects
- Weakness in ICU patients/ Prolonged critical illness
- Systems Improvement

Allow Me to Introduce You...



Mark Twain

*There are three kinds of lies: lies, d—d lies,
and statistics*

Thomas Bayes (professional clergyman and
amateur mathematician) – formulated
Bayes theorem



References for Images:

Mark Twain. The Biography Channel website. 2013.

Available at: <http://www.biography.com/people/mark-twain-9512564>.

Thomas Bayes: Celebrating Statisticians: Thomas Bayes

Available at: <http://www.blogs.sas.com>

Case 1

- You are the attending for a 75yo woman admitted with diarrhea, fever, tachycardia and leukocytosis
 - Her symptoms started 1 week after completing a course of antibiotics for a UTI
- Fortuitously, Grand Rounds this week reviewed *C. difficile*
 - Approximately 60% antibiotic-associated diarrhea is caused by *C. difficile*
- Your hospital has recently changed its laboratory assay for *C. difficile*
 - The new assay has a sensitivity of 70% and a specificity of 95%
- Your patient's test comes back negative



Case 1

- What does the negative test mean?
 - A. Specificity must be put into the context of the underlying prevalence. Since both are high, the negative predictive value is also high – the patient is unlikely to have C. difficile.
 - B. A specificity of 95%, means that there is a 95% chance that the negative test result is a true negative regardless of the disease prevalence. The negative predictive value is therefore 95%
 - C. The Negative predictive value is 68%.
 - D. The population prevalence is 60%, so a specificity of 95% gives a negative predictive value of 57%.
 - E. The likelihood ratio of a negative test (LR-) in this assay is 4.9



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 - **C. The Negative predictive value is 68%.**
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Calculating Predictive Values

- Positive Predictive Value
 - Probability of X (usually a disease) in all patients having a positive test result
 - $\text{True Positives} / (\text{True positives} + \text{False positives})$
- Negative Predictive Value
 - Probability of being without X (usually a disease) in all patients with negative test result
 - $\text{True Negatives} / (\text{True Negatives} + \text{False negatives})$
- In our patient:
 - Actual incidence of disease = 60%
 - Test sensitivity = 70%
 - Test specificity = 95%
 - For 100 patients:
 - $38 / (38 + 18) = 0.68$

	Disease		Totals
	+	-	
Test +	42	2	44
Test -	18	38	56
Patients	60	40	100

Medical Statistics: Definitions

- Sensitivity: Positive test in pts having X
 - High sensitivity means few false negatives
 - $\text{True Positive} / (\text{True positive} + \text{False negative})$
- Specificity: Negative test in pts without X
 - High specificity means few false positives
 - $\text{True Negative} / (\text{True negative} + \text{False positive})$
- Predictive Values: Probability that the test result predicts the disease (or lack thereof)
- Odds Ratio and Likelihood Ratio
 - Tests the test
 - Useless tests have $\text{OR} = 1$ and $\text{LR} = 1$

More Definitions

- Absolute Risk
 - Difference between proportions of patients with and without a characteristic developing condition X
- Number Needed to Treat (or Harm)
 - $1/\text{Absolute Risk}$
- Relative Risk (Risk Ratio)
 - Comparison of the proportion of patients with and without a characteristic who develop condition X
- Confidence Intervals
 - Distance away from 1 indicates strength of effect
- “Real-World” Example
 - Dabigatran vs. warfarin in patients with atrial fibrillation¹
- Annual incidence of serious bleeding in patients on 110 mg dabigatran was 2.71%, vs. 3.36% in patients on warfarin
 - Absolute risk reduction with dabigatran was 0.65%
 - Number needed to treat = $1/0.0065 = 154$
 - Relative Risk of serious bleed with dabigatran = $0.0271/0.0336 = 0.81$
 - The confidence intervals were 0.69 – 0.93, favoring dabigatran over warfarin

Reference:

1. S.J. Connolly et al., NEJM 2009, vol. 361, pp. 1139 - 1151

Another Consideration

- The Best Medical Journal has just published a non-inferiority study on a new antihypertensive regimen compared to a commonly used regimen.
 - No overall superiority was shown compared to the usual therapy.
 - Patients over 70 years old had significant decreases in both systolic and diastolic BP on the new regimen.
 - What is the significance of this?
- This is an example of “Post Hoc” Analysis
 - Be careful! If the subgroup wasn’t included in the original design, it can’t be relied upon for analysis
 - Instead, it is “hypothesis generating” and requires further testing

General Board Point

- There will be several questions involving medical statistics



Case 2

- Your patient is an 86yo man, h/o DM, CHF, and severe COPD, who has been intubated for 3wks due to ARDS complicating SARS-CoV-2 (COVID-19) infection
 - His hospital course has been complicated by delirium, renal failure, pulmonary edema and ventilator-associated pneumonia
 - His BMI is 35
 - He is requiring less PEEP and FiO₂ compared to earlier in his course, but he has not been able to tolerate weaning attempts
- The social worker provides the following regarding the patient's family information:
 - He is widowed. He has had two marriages, and has five adult children
 - 2 daughters and a son from his second marriage
 - 2 daughters from his first marriage
 - The children from the two marriages do not get along and therefore do not interact with each other
 - His son is the patient's healthcare agent, and has not visited
 - He calls only during the night shift and has only spoken with the overnight nurse
 - The oldest daughter visits daily but doesn't update the son
 - She does not have the son's contact information
 - She states that she was her father's healthcare agent until two years ago

Case 2, continued

- You have consulted Surgery regarding a tracheostomy tube
- They recommend changing to a comfort-oriented plan
 - The patient's operative risk is increased due to his multiple comorbidities
 - The surgeon cites the high rate of poor outcomes in elderly patients with prolonged intubation
- You agree that the patient's prognosis is poor
 - You update the patient's daughter at her next visit
 - She states that her father would "never want any of this"
 - She also states that she would be willing to resume the role of healthcare agent

Case 2

- What is true about the next steps in this patient's care?
 - A. The son's lack of engagement with the healthcare team means that he has abandoned his role as the healthcare agent and therefore is disqualified from serving this function. The patient's daughter was recently the healthcare agent, comes in daily, and is willing to take on the role of decision-maker; therefore, the team can go to her for healthcare decisions.
 - B. The team should apply for legal guardianship for the patient since the healthcare agent is not available.
 - C. Since the healthcare agent is not available, the healthcare team can use a consensus decision from the other children to guide treatment decisions.
 - D. The team should obtain more information about the barriers regarding the son's visitation and engagement in his father's care.
 - E. Since the patient has a poor prognosis, he would not benefit from long-term mechanical ventilator support. Therefore, the team should institute the hospital's protocol regarding non-beneficial (futile) care

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Explanation

- A healthcare agent is appointed by the patient and so changing to another person who is not listed as an alternate agent is not permitted.
- The patient has identified a healthcare agent, although they have not engaged with the healthcare team significantly. The next step is to identify what the barriers are to such engagement and to determine if the barriers can be removed.
- There has been heightened appreciation of the profound impact of factors arising from a person's social milieu. These factors are outside of the direct control of patients and their families and have immense effects on disease development, progression and the ability to engage with healthcare systems. These factors have been broadly termed, "social determinants of health"¹.

Reference:

1. <https://www.cdc.gov/socialdeterminants/about.html>

General Board Tips

- Be prepared to analyze questions about healthcare agents – their roles, responsibilities, and limits to their authority
- Be prepared to address general questions about the impact of social determinants of health



Case 3

- You are the attending for a 56yo man, h/o DM and asthma, who was admitted 21 days ago for pneumonia following H1N1 influenza.
- His initial hospital course included an emergent traumatic intubation
- Hospital course was significant for refractory hypoxemia requiring paralysis (48hr) and ECMO.
- He gradually improved and was decannulated 2 days ago.



This morning...

- On exam, he is afebrile with stable VS.
- Mental status exam shows him to be awake, and nodding appropriately to Y/N questions.
- His chest shows basilar crackles, and his heart is regular and without murmurs.
- On neurologic exam, your patient cannot lift either his arms or legs, although he can move his fingers and toes to command.

The least likely cause would be

- A. Medications
- B. Low potassium
- C. Consequence of traumatic intubation
- D. Undiagnosed premorbid neuromuscular disease
- E. Critical illness associated weakness

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ICU-Acquired Weakness (ICU-AW)

- Approximately 75,000 patients annually develop ICU-AW (Fan et al., AJRCCM, 2014)
- Patients with ICU-AW have 30% higher acute hospital costs (Hermans et al. AJRCCM 2014) than ICU patients without weakness
 - This doesn't count costs of rehabilitation, readmission, post-rehabilitation support
- Patients with ICU-AW have higher mortality compared to non-weak ICU patients
 - Higher post-ICU mortality in first year: 28 vs 11%
 - Possible higher in-hospital mortality (inconsistent study results)

Weakness Increases Mortality??

- Unknown mechanisms, probably multiple
 - Difficulty swallowing
 - Poor cough
 - Prolonged ventilation
 - Poor balance
 - Difficult to move in bed so increased decubitus ulcer incidence
 - Possible persistent inflammatory process

ICU-Acquired Weakness

- Can occur very early in course
 - Generally seen after 1 wk in ICU
- Common
 - Clinically significant findings in up to 2/3 patients requiring mechanical ventilator for over 1 week
 - Depending on study >80% of patients on mechanical ventilation have evidence
- Persists
 - 6-minute walk test only 70% age-predicted maximum in ARDS survivors 5yrs after acute illness (Herridge et al., NEJM 2003)
- Subtypes
 - Myopathy
 - Neuropathy
 - Combined myopathy/neuropathy

Risk Factors

- Age
- Sepsis
- Duration of organ failure
- Mechanical Ventilation
- Premorbid functional status
- Female sex (inconsistent)
- Medication (inconsistent)
 - Aminoglycosides
 - Neuromuscular blockers
 - Glucocorticoids

Weakness in ICU patients - Etiologies

- Primary neuromuscular disease
 - Increases likelihood of critical illness
 - Critical illness can unmask neuromuscular disease
- New, but separate, event complicating critical illness
 - New CVA, embolism due to endocarditis, spinal cord ischemia
- Complication of therapy
 - Meds
- Metabolic derangements
 - Hypokalemia
- Due to critical illness
 - ICU-Acquired Weakness (ICU-AW)

Diagnosis - Approach

- Differential can be summarized by MUSCLES
(Maramattom BV and Wijdicks EF, Critical Care Medicine 2006, vol. 34, pp 2835 – 2841)
 - M: Meds – steroids, amiodarone, NMB, aminoglycosides, furosemide
 - U: Undiagnosed primary neuromuscular disease
 - S: Spinal cord problem such as ischemia
 - C: Critical illness associated weakness
 - L: Loss of muscle such as rhabdomyolysis
 - E: Electrolytes: low K, low phos, high Mg
 - S: Systemic illness: Hypothyroidism, adrenal insufficiency, porphyria

Prolonged Critical Illness

- Prolonged critical illness is associated with significant morbidity and healthcare costs
- Recent studies of survivors of ARDS show persistent physical and neuropsychiatric limitations for up to 5 years after discharge from the acute hospital
 - Near-normal pulmonary function tests by 1-year
 - 6-minute walk test below range expected for age
 - Over half of ARDS survivors report significant anxiety and/or depression up to 5 years after their acute illness
- Predictors of decreased functioning after ARDS
 - Age greater than 52
 - Critical illness-associated weakness
 - Comorbid disease

General Point for the Boards

- Be prepared for questions highlighting the substantial personal and societal costs of prolonged critical illness



Case 4

- You are the attending for a 58yo man admitted with respiratory failure due to hospital-acquired pneumonia.
 - He has a history of “red man” syndrome after vancomycin.
 - His antibiotics include linezolid and meropenem.
- His course has been complicated by agitated delirium and atrial fibrillation with rapid ventricular response.
 - VS during event: Afeb, HR 160, BP 155/70, RR 30
- Overnight events:
 - His agitated delirium was treated with Haloperidol (8PM), but his symptoms recurred and dexmedetomidine was started (2AM).
 - His atrial fibrillation was treated with metoprolol (9PM, 11PM, and 1AM) with improved heart rate control.

Case 5, continued

- This morning, he is calm with the following vital signs:
 - Temp 100.5
 - HR 50
 - BP 85/50
 - RR 14 (vent settings AC/VC, RR 10)

Your best course of action is to:

- A. Stop linezolid
- B. Decrease or stop metoprolol dose
- C. Send cultures to evaluate for new septic source
- D. Decrease or stop haloperidol
- E. Decrease or stop dexmedetomidine

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Dexmedetomidine

- Alpha-2 agonist used for IV sedation
 - Minimal effect on respiratory drive
 - Potentiates analgesic effects of opioids and additionally has mild independent analgesic effects
 - Used to treat symptoms of agitated delirium
 - Known side effects include hypotension and bradycardia

Take home point for the boards

- Look for medication effects as an explanation for symptoms.
 - Known medication side effects
 - Toxidromes
 - Important drug interactions
- These are well-described, occur commonly in practice, and have clear answers.



Classic Medication Effects

- Beta blockers, calcium channel blockers
 - Hypotension, bradycardia
 - High dose insulin can be effective
 - Calcium (calcium channel blockers) and glucagon (beta blockers)
- Methadone
 - Prolonged QT interval
- Linezolid, SSRI
 - Serotonin syndrome
 - Signs: fever, altered mental status, flushing, clonus, rigidity
 - If QRS prolonged treat with magnesium to decrease V-tachycardia (torsades de pointes) risk
 - If severe symptoms treat with cyproheptadine
 - Effects can be additive and may only appear in the context of polypharmacy
- Antipsychotics
 - Prolonged QT syndrome
 - Neuroleptic malignant syndrome – “lead pipe” rigidity, no clonus
- Propofol
 - Hypotension
 - Propofol infusion syndrome, usually associated with high triglycerides

Toxidromes and Therapies

- Tricyclic antidepressants
 - Prolonged QRS
 - Bicarbonate drip
- Aspirin
 - Mixed respiratory alkalosis and metabolic acidosis
 - Enhance excretion by alkalization of urine
- Anticholinergics
 - “Red as beet, mad as hatter, dry as a bone, blind as a bat, full as a flask, hot as a hare”
 - Symptomatic management, but avoid phenothiazines and butyrophenones
 - Physostigmine can be used as antidote
- Sympathomimetics
 - Mydriasis, agitation, hypertension
 - Avoid cardio-selective beta-blockade

Drug Interactions

- Clopidogrel – requires cytochrome P450 activation
 - Cytochrome CYP2C19 critical for activation
 - Avoid PPIs, azoles
- Atypical antipsychotics (haloperidol, quetiapine, olanzapine)
 - Do not use in elderly patients (FDA black box warning)
 - Risk is cardiovascular events and infection (pneumonia)
- Strong dopaminergic (D2) antagonists and Parkinson's disease and Lewy Body dementia
 - Primarily haloperidol
 - ↑ motor symptoms and agitation and antagonizes disease therapy
- Meperidine and MAOI (antidepressants, linezolid)
 - Causes serotonin toxicity
 - Mechanism not clear, possible baseline hyperphenylalaninemia

Case 5

- You are reviewing the safety reports from your unit and notice that there have been several pressure ulcers in patients who have been mechanically ventilated. After an initial review, you conclude that a QI project will help address the problem.
- Which of the choices below contain elements that are frequently used for QI work?
 - A. Case review, stakeholder engagement, scatter plot
 - B. Case review, Plan-Do-Check-Act, histogram
 - C. Stakeholder engagement, Pareto graph, Plan-Do-Study-Act
 - D. Stakeholder engagement, Case review, Manhattan plot
 - E. Logistic regression analysis, Kaplan-Meier curve, Needs assessment

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Quality Improvement

You do not rise to the level of your goals, you fall to the level of your systems
James Clear, author of Atomic Habits

Under pressure you don't rise to the occasion you sink to the level of your training"
Anonymous Navy Seal

We don't rise to the level of our expectations, we fall to the level of our training
Archilochus, Greek poet

Explanation

- Multidisciplinary teams rely on their systems
- Quality Improvement (QI) starts with identifying a problem, then postulating contributing and modifiable factors
 - Fish Bone chart can facilitate brainstorming
 - Pareto chart quantifies associated factors
- A tentative plan is made to address identified factors; plans are modified after initial results.
- QI projects depend heavily on stakeholder support
- QI cycle is summarized by “Plan-Do-Study-Act”

Explanation – Data Presentation

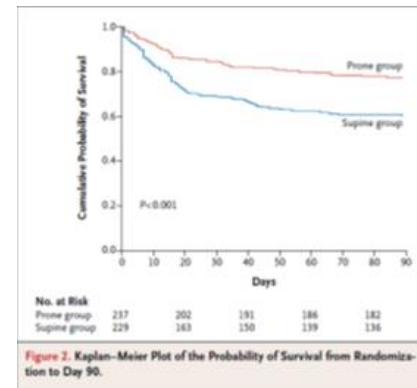
- Scatter plots and histograms present data having straightforward associations (A and B are not correct)
- More complicated analyses convey multiple and/or complex relationships with one image
 - Survival/time to event (Kaplan-Meier curve; D is not correct)
 - Genomic analyses (Manhattan plot; E is not correct)
 - Relative contribution from several factors (Pareto)
 - Brainstorming tools (Fishbone/Ishikawa diagram)
 - Either Quality Improvement or Root Cause Analysis

Common Graphs and Analysis Tools

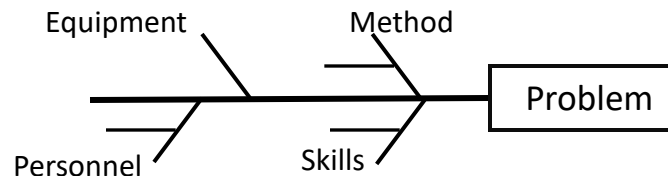
- Pareto



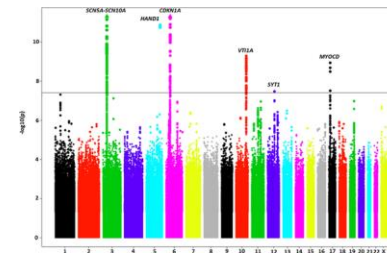
- Kaplan Meier Curve¹



- Fishbone (Ishikawa²)



- Manhattan Plot³



References:

1. C Guerin et al., *New Engl. J. Med.* 2013; Vol. 368 pp. 2159 – 2168
2. K Ishikawa 1990 *Introduction to Quality Control*; Tokoyo: 3A Corporation
3. BR Swenson et al., *PLOS One* 2019; Vol. 14(6): e0217796.

Making it stick: Implementation

- Implementation

- A QI project is analogous to a “proof of concept” trial
- Implementation provides sustainability/longevity
- Multiple frameworks:
 - Expert Recommendations for Implementing Change (ERIC)¹
 - Proctor framework²
 - Consolidated Framework for Implementation Research (CFIR)³
 - Promoting Action on Research in Health Services (PARIHS)⁴
 - Normalization Process Theory (NPT)⁵

References

1. Powell BJ et al. Med Care Re Rev 2012; 69:123 - 157
2. Procter EK et al. Implementation Sci 2013; 2015:139
3. Damschroder LJ et al. Implementation Sci 2009; 4:50
4. Kitson A et al. Qual Health Care. 1998;7:149–59
5. May CR et al., Implementation Sci 2009; 4:29

Common considerations

- Identify needs
- Recruit local “early adopters”/“champions”
- Identify possible barriers to implementation
- Determine desired/feasible outcomes
- Procedures to monitor outcomes
- Ongoing education and outcome monitoring

Reference

Huang, K-Y et al. Frontiers in Pub Health 2018;6;190

Take home point for the boards

- Optimizing care systems is important when managing complicated teams
- Be ready for questions on Quality Improvement techniques
- Be ready for analyses that use a variety of graphical presentations



Summary

- Statistical analyses are an integral part of evaluating medical data.
- System improvement is an essential part of critical care medicine.
- Social determinants of health have significant effects on patients and their families but can be challenging to identify. Management of these issues individual and systems-level approaches.
- Iatrogenic injury is a favorite target for the boards – be on the lookout for drug-associated syndromes, such as drug-induced pneumonitis and known toxidromes
- Survivors of prolonged critical illness experience many physical and neuropsychiatric sequelae for several years after their acute illness.
- Weakness following critical illness is common and can be severe.

References

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- Prolonged Critical Illness
 - M. S. Herridge et al. NEJM 2011, vol. 364, pp.1293 – 1304.
- Critical Illness-Associated Weakness
 - S.E. Jolley, A.E. Bunnell, and C.L. Hough. Chest 2016, vol. 150, pp 1129-1140.



GOOD LUCK WITH YOUR BOARDS !!

Case 6

- Your patient is a 74 year old woman who was admitted 2 weeks ago with severe sepsis. Her comorbidities include vascular dementia with mild functional impairment. She has had multiple complications, respiratory failure and altered mental status.
- Although the patient is improving, she is not ready for extubation and has failed the past three daily spontaneous breathing trials due to low tidal volumes, tachypnea and desaturation.
- This morning on rounds your team is discussing whether to consult surgery for a tracheostomy.
- The patient's nurse reports that the patient is "in there", as evidenced by her consistent responses regarding the presence/absence of pain. The nurse advocates for the patient to be involved in the decision about tracheostomy.
- Of note, your impression is that the ICU nurses and the patient's family disagree regarding her wishes for therapy:
 - The nurses report that the patient pulls at her lines and endotracheal tube, and they feel this shows she does not want these interventions
 - The patient's family, including her healthcare agent, report that she "is a fighter" and they feel she would want all possible interventions to treat her illness

Case 6, continued

- On this morning's exam
 - VS Temp 99.2, HR 105, BP 115/65, RR 24, O2 sat 94% on FiO2 35%
 - Chest: Bibasilar rales; Heart: Irreg Irreg; Abd: soft, +BS; Ext: 1+ pedal edema; Neuro: Awake; responds to her name and Y/N questions; has several errors on a bedside test of attention (SAVEAHAART); follows 1-step commands; strength 2/5 bilat upper and lower ext, MAE; unable to use letter board



Case 6, continued

- Of the following, the best next course of action would be:
 - A Consult Ethics since there is conflict between the ICU nurses and the patient's family regarding the patient's wishes
 - B Since the patient has a history of dementia, activate the health care agent for the decision regarding tracheostomy
 - C Since the patient is alert and appropriately interactive, she should be the person to decide about whether to proceed with tracheostomy
 - D Since the patient's decisional capacity cannot be determined, activate the healthcare agent for the decision regarding tracheostomy
 - E Consult psychiatry to evaluate patient's decisional capacity

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 - **D Since the patient's decisional capacity cannot be determined, activate the healthcare agent for the decision regarding tracheostomy**
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Explanation

- The patient's decisional capacity cannot be precisely determined, but it is very likely that she does not have decisional capacity at this time and so her healthcare agent should be activated.
 - Decisional capacity requires understanding the ramifications of the available options and indicating a choice among available options.
 - Decisional capacity depends on the burdens of the therapy being considered.
 - A history of dementia does not preclude having capacity for some decisions.
 - A person can have capacity for one type of decision but not another.
 - Her communication is extremely limited (using "Y/N" only, unable to use a letter board), so it is not clear how she is processing any given piece of information.
 - She is not able to demonstrate attention and focus on a bedside evaluation, so it is very likely that she cannot weigh the burdens and benefits of a given therapy.
 - Patient's actions (pulling at IV lines and the endotracheal tube) may have many causes.
- Ethics consultation will not be helpful at this time. Although the nurses and the family disagree regarding the patient's wishes, there is no clear evidence to suggest that the family is not correct in their assessment.
- Psychiatric consultation will not be helpful because the patient cannot effectively communicate beyond Y/N at this time.

Decisional Capacity – Take Home Points

- Intertwined with informed consent
- Requires
 - Understanding and remembering choices
 - Understanding consequences
 - Being able to rationally consider choices
 - May not arrive at the “right” choice
 - A decisionally capable patient has the right to refuse any type of therapy
 - Being able to indicate a choice
 - Careful bedside assessments can be used to evaluate
- Sliding scale
- Diagnosis of dementia *per se* does not rule out decisional capacity

General Point for the Boards

- Be prepared for questions involving Ethics
 - Most commonly used analysis framework is normative ethics using the principles of autonomy, beneficence, nonmaleficence, and social justice
 - Generally, opt for the answer that best preserves the patient's autonomy
- Given the recent COVID-19 pandemic, prepare for questions involving frameworks for allocation of scarce resources

