Increasing Enrollment in ICU trials

Understanding Clinical Research through the PAIR center
Learning Goals

1. Develop a foundational understanding of clinical research process including the design and conduct of clinical trials focused in the ICU and specific challenges associated with this process
2. Identify and build upon essential skills and knowledge of a health service researcher
3. Gain insight into the priorities and concerns of patients and their caregivers affected by serious illness
4. Explore various career paths for a health services researcher and the necessary qualifications and experience associated
Agenda

1. Background
2. Overview of Nudges project
3. Methods
4. Results
5. Shadowing Experience
6. Takeaways
Challenges related to enrollment

- One of the biggest challenges for advancing clinical research in critical care is recruitment of research participants.

Why is Recruitment Difficult?

- Concern for negatively impacting family members’ health
- Requirement of a surrogate
- Nature of ICU
The Nudges Project

Randomized Trial of Nudges To Enhance Enrollment in Critical Care Research

- **Goal** is to understand how surrogates make decisions to participate in research

- **Testing** whether surrogates’ decisions can be influenced by non-financial incentives

- **Consist of** approaching the family members of people on breathing machines in the ICU about a simulated study comparing two different approaches
Current methods to increase study enrollment in ICU settings

- Monetary/financial incentives

Challenges with these methods

- Large up-front cost
- Low rate of retention

Can using framing strategies help address this challenge and increase enrollment numbers?
Using Nudges interventions

- A behavioral economic intervention that steers people toward a particular option while persevering autonomy
- Meant to incentivize a certain decision
- Can they augment enrollment?
Significance behind the Nudge project:

- Difficulties recruiting and retaining patients in randomized clinical trials and longitudinal studies are a major barrier to successful study completion.

- Nonmonetary behavioral interventions may offer easily scalable approaches to increase enrollment without up-front cost.

- More research will be able to be completed, and the results may benefit future patients within the ICU.
Study design

**Two Arms**
- Arm 1 has nudge bundle survey
- Arm 2 is control

**Goal Number of participants** - 182

**Current** - 49

**Selection Criteria**
- Must be on the ventilator
- Must have surrogate in charge of their medical decisions
Methods

1. Patient receives a consent form.
2. 50% of patients are randomized to fill out Nudge bundle survey before being asked about a trial.
3. Patient is given a handout summary about a simulated/fake study their loved one will have the opportunity to participate in.
4. Participant answers a risk survey to indicate how risky the study sounded.
5. Collect patient and surrogate demographics.
6. Debrief the family at the end of the visit.
Nudge Bundle Survey

- Given to only the medical surrogate, who is unaware of deception

- Survey questions require surrogate to think in an altruistic mindset

- Prompts the surrogate to think about the future patients who will hypothetically benefit
Hypothetical Clinical Trial

Group 1

Group 2

Decrease Oxygen

Decrease Pressure
### Risk Assessment Survey

2. Does the study seem...

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>More risky than talking on the cell phone while driving</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>More risky than receiving the flu vaccine</td>
<td>☐</td>
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<tr>
<td>More risky than flying on a plane</td>
<td>☐</td>
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<tr>
<td>More risky than driving 15 mph over the speed limit</td>
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<tr>
<td>More risky than taking 3 times the recommended dose of a pain killer</td>
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<td>☐</td>
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<tr>
<td>More risky than receiving stitches</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>More risky than riding a motor cycle with no helmet</td>
<td>☐</td>
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<tr>
<td>More risky than getting a body piercing</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>More risky than bungee jumping</td>
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</tbody>
</table>

3. What factors influenced your decision to participate or not to participate in this trial?
Results

Taking a look of the first 16 enrolled:

1. Nudge bundle survey: 3/8 people consented (37.5%)

2. Control: 1/8 people consented (12.5%)

*Work in progress*
Shadowing

**Transplant Study Objectives**

1. Determine if guided completion of advance directives prior to stem cell transplantation will improve patients’ self-reported decisional conflict about transplantation.

2. Explore whether palliative care consultation during the post-transplant period will improve quality of life.

**COPD Study Objectives**

**OASIS Study**

1. Assess the accuracy with which patients with severe COPD predict their future health states.
2. Evaluate the relationship between accuracy of expectations.
3. Identify patient characteristics associated with medication non-adherence.
Lessons learned

Research Coordinators

1. Importance of approach
2. Advance directives
3. Administering surveys and data collection

Nudge Project

1. Navigating Epic and RedCap
2. Patient screening
3. Surrogate-dependent relationship
It’s Complicated
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Thank You!

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Why is research in Critical care and Palliative care important?

- Generate evidence to advance healthcare policies and practices that improve the lives of all people affected by serious illness.
  - Improve efficiency for potentially scarce resources.
  - Improve how palliative healthcare services are delivered.
  - Improve quality of life for patient.
- Relatively new field of research