Postoperative Sleep as a Patient-Centered Outcome After Hospital Discharge – Implications for QOL and Safety

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Disclosures

- I have no financial disclosures to make.
- I will not reference any unlabeled/unapproved use of a drug or product.
- Grant support:
“Why me? I’m a critical care anesthesiologist and palliative care physician and researcher…”
“But you are an expert in patient-centered outcomes research (PCOR) and we want to know more about PCOR!”

Krish Ramachandran, MD
Beth Israel Deaconess Medical Center

Objectives

- Define patient-centered outcomes research (PCOR)
- Empower you to consider incorporating PCOR through examples from my own research portfolio
What is patient-centered outcomes research?
What is the Patient-Centered Outcomes Research Institute?

- Founded in 2010 through the Patient Protection and Affordable Care Act

- Goal to promote comparative effectiveness research to:

  “Assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis.”

Selby JV, Beal AC, Frank L. JAMA 2012

What is patient-centered outcomes research?

- Research centered on decisions and outcomes important to patients and family members

- Trans-disciplinary teams are essential

- Diverse stakeholders (including patients and family members) are integrated into the team throughout all stages of research

Selby JV, Beal AC, Frank L. JAMA 2012
Krumholz HM, Selby JV. Ann Intern Med 2012
Fleurence R et al. Health Affairs 2013
Frank L, Basch E, Selby JV. JAMA 2014
The PCORI Perspective on Patient-Centered Outcomes Research

The Patient-Centered Outcomes Research Institute (PCORI) was established as part of the US Patient Protection and Affordable Care Act of 2010 to fund patient-centered comparative clinical effectiveness research, extending the concept of patient-centeredness from health care delivery to health care research. In the United States, patient-centered outcomes research is new and not defined in the legislation, and the rationale is unclear to many. In this Viewpoint, we address 2 related questions: 1) What does patient-centeredness in research mean? Why conduct patient-centered outcomes research? 2) The essence of the PCORI definition of patient-centered outcomes research is the evaluation of questions and outcomes meaningful and important to patients and caregivers. The definition rests on the axion that patients have unique perspectives that can change and improve the pursuit of clinical questions. Relevant to both the definition and rationale is the hypothesis that including the perspectives of end users of the research—which include patients, physicians, and other health care stakeholders—will advance the role of patients in research. Evolution and shows both positive and negative effects. Beneficial outcomes of engagement include improved relevance of study results to patients, improved research recruitment and retention rates, and improved content and construct validity of measures. Negative consequences include added financial and staff resources needed to establish and maintain engagement and a sense of work burden among patient participants.

How do you do PCOR?

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What is palliative care?

- Specialized medical care
- For patients with serious illness and their family members
- Goal is to improve quality of life
- Appropriate at any age and at any stage of serious illness
- Can be provided together with curative illness

Center to Advance Palliative Care. http://www.capc.org/
Kelley AS & Morrison RS. NEJM 2015.

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What is palliative care?

- Aggressive symptom management
- Psychosocial support of family
- Expert & compassionate communication

Patient & Family

Center to Advance Palliative Care. http://www.capc.org/
Kelley AS & Morrison RS. NEJM 2015.
Our task from the Patient-Centered Outcomes Research Institute (PCORI):

- To develop and test a patient and family-centered advance care planning instrument for patients and families preparing for major pancreatic cancer surgery.
- Team of patients, family members, surgeons, SICU intensivists and nurses, anesthesiologists, palliative care providers, and health care quality experts.
- $2.15 million contract: July 2013 – Nov 2017
Conceptual Approach

An Environmental Scan of Advance Care Planning Decision Aids for Patients Undergoing Major Surgery: A Study Protocol

Rebecca A. Aslakson, Anne L. R. Schuster, Judith Miller, Matthew Weiss, Angelo E. Volandes & John F. P. Bridges

Written data sources
- Systematic review
- Grey literature review
- Patient & family engagement

Verbal data sources
- Key informant interviews

Environmental scan – data sources and perspectives

Aslakson et al, The Patient 2014
Websites

- American Cancer Society
- American Geriatrics Society
- The American Academy of Hospice and Palliative Medicine
- The Center to Advance Palliative Care
- The National Palliative Care Research Center
- National Institute of Health-National Institute for Aging
- The Coalition to Transform Advanced Care
- The Informed Medical Decisions Foundation
- The Center for Shared Decision Making
- The International Patient Decision Aids Standards
- National Quality Forum
- Family Caregiver Alliance, Gerontological Society of America
- Medline Plus (NIH)
- National Cancer Institute
- American Association of Retired Persons
- National Hospice and Palliative Care Organization
- Heart Failure Society of America
- Agency for Healthcare Research and Quality
- Mayo Clinic
- Pancreatic Cancer Action Network
- American Society of Clinical Oncology
Grey Literature search

Newspaper articles
- >400 articles, didn’t yield much

Ongoing studies
- Found many of the researchers from the systematic review

PhD dissertations and abstracts
- Unpublished – not much of interest

YouTube – “advance care planning”
- LOTS!

Schuster et al. BMC Palliative Care 2014, 13:32
http://www.biomedcentral.com/1472-6947/13/32

Creating an advance-care-planning decision aid for high-risk surgery: a qualitative study
Anne LR Schuster¹, Rebecca A Adakson² and John FP Bridges³
Stakeholder Summit – Findings

Content
- Vignettes – real stories
- Less “death/dying” more about “how you want to live”
- Specific to surgical population

Style
- Upbeat
- Involving younger and older subjects
- Involving multiple ethnicities

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Research

Why don’t end-of-life conversations go viral? A review of videos on YouTube

Imogen A Mitchell,1,2 Anne L R Schuster,2 Thomas Lynch,3 Katherine Clegg Smith,4 John F P Bridges,2 Rebecca A Aslakson3

Mitchell IA, et al. BMJ Supportive & Palliative Care 2015;0:1–8. doi:10.1136/bmjspcare-2014-000805

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Systematic Review of YouTube “advance care planning”

- Over 23,000 hits
- 9 videos with >1,000 views
- Eliminate the “death panels” and “Obamacare is SATAN”
- 42 videos with relevant content

Mitchell et al., BMJ Supportive & Palliative Care 2015

Developing the video – conceptual model

<table>
<thead>
<tr>
<th>Basic Design Phase</th>
<th>Purpose</th>
<th>Stakeholder Involvement</th>
<th>Media Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Environmental Scan</td>
<td>Gather and analyze pre-existing ACP instruments of all media types.</td>
<td>Discuss merits and drawbacks of ACP instruments.</td>
<td>Determine scope of and gaps in available content.</td>
</tr>
<tr>
<td>2. Content Synthesis</td>
<td>Determine communication goals and content of new ACP video.</td>
<td>Participate in Stakeholder Summit to discuss and identify relevant video content.</td>
<td>Generate video concepts.</td>
</tr>
<tr>
<td>3. Prototype Production</td>
<td>Translate content elements into provisional ACP video design and storyline.</td>
<td>Contribute to and critique ACP video script and storyboards.</td>
<td>Develop ACP video script and storyboards.</td>
</tr>
<tr>
<td>4. Evaluation</td>
<td>Evaluate provisional ACP video design and storyline.</td>
<td>Participate in evaluation of the storyboards.</td>
<td>Revisions, if applicable</td>
</tr>
</tbody>
</table>

Aslakson et al, J Pall Med 2018
Isenberg SR et al, BMJ Pall Supp Care 2018

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Scene 3: The Pre-Operative Waiting Area

Screen 8: Having a Conversation with Family and Friends

Aslakson et al, J Pall Med 2018
Isenberg SR et al, BMJ Pall Supp Care 2018

Narrator: Anytime you have surgery, there will be times when you are under anesthesia or are too sick to be able to communicate. For many, those times are short and are limited to the time when you are having the actual surgery. However, for some, those times can last days to even weeks. We cannot predict exactly who will or will not get very sick after major surgery.

You can prepare for any situation through some simple steps with the help of your family and those closest to you. You can designate the friend or family who would make decisions for you if you cannot speak for yourself.
“Phase I trial” - Maryland State Fair
August 22-Sept 1, 2014

Storyboards ("Phase I") study...

Aslakson et al. J Palliat Med 2018

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The video

- Collaboration with Angelo Volandes
- Filmed 16 interviews with patients, family members, surgeons, surgical nurses, and anesthesia providers
- Interviews reviewed at stakeholder summit
- Broadened inclusion criteria to any type of major cancer surgery
- Editing took ten months
  - 14 different version of video
  - Reviewed by 70 different stakeholders
Integrating Advance Care Planning Videos into Surgical Oncologic Care: A Randomized Clinical Trial

Rebecca A. Alsheimer, MD, PhD, MD; Davia R. Isenberg, MA, PhD; Lea A. C. Kreulen, MD; Minna M. Chang, MD; Eileen T. O'Dowd, MD, PhD; Anshay Shemesh, MD; Shiva Mina, BS; Chad Miller, MD, CCE; LEE, MD; Saurabh Singh, MD; Sagarika M. Sridhara, PhD, MS; Timothy M. Pawlik, MD, MPH, PhD; Matthew Weiss, MD; Angela Vangjelj, MPH, MD; Thomas A. Smith, MD; John F. Bridges, MD, PhD; and Elena L. Hester, MPH, DPH

Abstract

Randomized, prospective, 2-arm, controlled clinical trial of 202 patients undergoing major surgery.

Objective: To evaluate feasibility, safety, and efficacy of video-based ACP in a surgical population.

Study Design: Randomized controlled trial with two study arms.

Setting: Single academic, tertiary care cancer hospital.

Intervention: Video-based ACP counseling was provided in the intervention arm.

Outcomes: Patients were randomized to either the intervention (n=100) or control (n=102) arm. The primary outcome was patient satisfaction, as measured using a validated 7-item questionnaire.

Results: There were no significant differences in patient satisfaction between the two arms. The intervention arm showed a trend towards improved satisfaction, but this did not reach statistical significance (p=0.05). However, there were no significant differences in secondary outcomes, such as patient education or treatment adherence.

Conclusions: The use of video-based ACP in this cohort of patients undergoing major surgery was feasible and safe. However, further research is needed to determine the efficacy of this intervention in improving patient outcomes.
Conclusions

- PCOR involves:
  - Intense engagement with all stakeholders
  - Transdisciplinary research teams
  - Balancing diverse voices with different priorities and perspectives

- PCOR enables:
  - Novel approaches to complicated clinical scenarios
  - Interventions with “baked in” patient and stakeholder priorities and perspectives

Any ?’ s:
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