Clinical research in palliative care in an age of collaboration and innovation:

Together we can do bigger and better!

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Why is Clinical Nutrition SO Undervalued?

- Numerous challenges to providing optimal nutrition to individual patients in our health care system.
- Partly due to devaluation or de-prioritization of nutrition issues relative to other clinical problems our patients face.
- As a consequence:
  - malnutrition continues to go unassessed,
  - significant underfeeding continues in institutionalized care, and
  - patients experience the attendant negative consequences of nutritional insufficiency

Why is Clinical Nutrition SO Undervalued?

- Large part of the problem due to weak or absent evidentiary basis that informs our clinical practice guidelines.
- Evidence for this assertion comes from a review of recent clinical practice guidelines and the nature of the evidence informing these guidelines that reveals few strong clinical recommendations and numerous small, low-moderate quality single center randomized trials.

Can we say the same about P/EOL care?

Is the problem the way we create and disseminate research?

Possible Solutions?

- Formation of Research networks to foster the growth or large scale projects
- Creation of volunteer-driven, registry-based RCTs
- Engagement of patients and families as our partners

Creation of Research Networks

CCCTG Canadian Critical Care Trials Group

InFACT

ANZICS

icnarc

SEPNET TRIALS GROUP

ARDSnet

PETAL NETWORK

USCIITG

The United States Critical Illness and Injury Trials Group

Protocol Development Meetings

- Multi-disciplinary
- Face-to-face, round table, open discussion about research protocols
- Stand alone meetings or in conjunction with society meetings
- Mix of funding strategies
  - industry support, meetings grants or self-funding

Protocol Development Meetings

- Community-mentoring model
  - Set priorities
  - 'best' methods
  - 'best' operational aspects of protocol
  - Recruit other interested sites (buy-in)
  - Provide mentoring and career development

single-center Inconsequential trials → Larger, muliti-center, Practice-changing trials

How do we enable the generation of higher quality, larger scale, multicenter, randomized clinical trials of homogenous patient populations that will inform more robust future practice guidelines?

Large Scale trials are Expensive!

RE-ENERGIZE STUDY

A RandomizEd Trial of ENtERal Glutamine to MinimIZE Thermal Injury:

2700 patients with TBSA

≥ 20% if 18-59 yrs age

≥ 15% if 18-59 yrs age with inhalation injury

≥ 10% if ≥ 60 yrs age

R

EN glutamine

Concealed
Stratified by site
Double-blind

→ 6 month mortality

Maltodextran

$6 million CDN from CIHR
$6 million USD pending

But even RCTs have their limitations!

- Very costly
- Fail to show a 'signal' of benefit
- Limited generalizability

The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

- Clinical registries are established tools for auditing clinical standards and benchmarking QI initiatives
- Data from clinical registries can be used to formulate hypothesis
- With appropriate methods, make causal inferences (albeit weaker inference)
- Results more generalizable

Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE trial). A multicenter, prospective, randomized, controlled clinical registry trial based on the Swedish angiography and angioplasty registry (SCAAR) platform. Study design and rationale

- Used existing national cardiac registries
- Randomized patients undergoing angioplasty to manual thrombus aspiration or usual care.
- Over 7000 patients were efficiently recruited from the registry to evaluate the study question and aside from the randomized intervention, the trial imposed no other study procedures and all data were collected by existing registries supported by funds from national or other hospital sources.

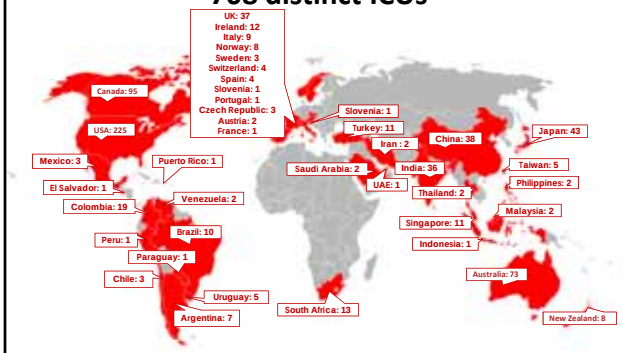
Registry-based Randomized Clinical Trials (RRCT): A possible solution?

- Recent experience with large scale, multicenter, observational studies conducted by volunteers in hundreds of ICUs around the world opens the possibility of using the same International Nutrition Survey infrastructure to support large scale, randomized trials.

International Nutrition Survey

- Purpose
  - Illuminate gaps between guideline recommendations and current practice
  - Identify practice areas to target for change
- History
  - Started in Canada in 2001
  - 6 International audits to date (2007, 2008, 2009, 2011, 2013, 2014)
  - In 2014, special focus on recruiting burn units
  - In 2017, special focus on recruiting CVS units
- Methods
  - Observational, prospective
  - Chart audit

Participation over all surveys: 708 distinct ICUs

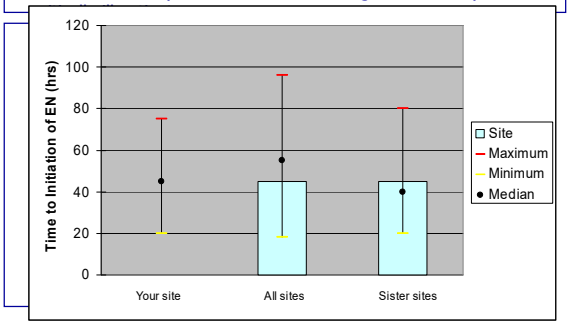


Methods

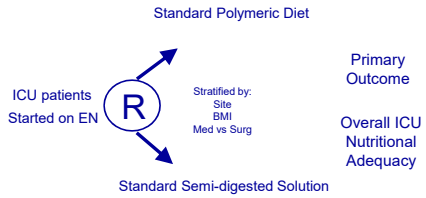
- Each ICU enrolled 15-20 consecutive patients
  - > 18 yrs (or >16 yrs if approved by site)
  - LOS> 72 hrs (interpret as needing enteral nutrition)
  - vented within first 48 hrs of admission (or on admission)
- Data abstracted from chart for **first 12 days of ICU admission**
  - Personal Characteristics
    - Age, sex, adm. diagnosis
  - Baseline Nutrition Assessment
    - Height, weight, prescription
  - Daily Nutrition data
    - route, amount, composition
  - Patient outcomes
    - mortality, length of stay
- Data entered online

Value of Bench-marked Site Reports

Recommendations: Based on 8 level 2 studies, we recommend early enteral nutrition (within 24-48 hrs following resuscitation) in



Could the INS infrastructure be used to Randomize Patients?



The ACCEPT Study

Audit of Communication, CarE Planning, and DocumenTation:

A multicenter, prospective audit of communication/DM best practices

- Versions available for use in primary care, acute care, and LTC
- Both patient and family version

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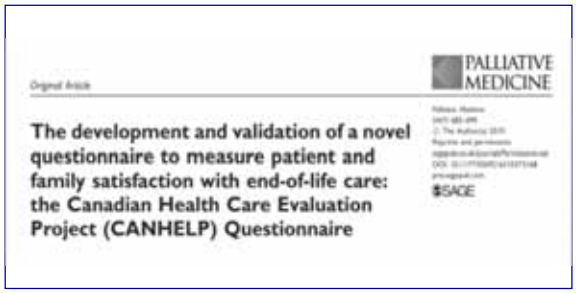
JAMA Int Med 2013

A Novel Satisfaction with EOL care Instrument


Original Article

PALLIATIVE MEDICINE

The development and validation of a novel questionnaire to measure patient and family satisfaction with end-of-life care: the Canadian Health Care Evaluation Project (CANHELP) Questionnaire

SAGE

www.thecarenet.ca

Methods

- Multicenter audit starting on a certain date
- Target 30 patients and families per participating site
- Enrol consecutive eligible patients and family
- Administer questionnaires to answer study questions
- Receive bench marked report; target interventions to overcome barriers following audit
- Cycle of audit and feedback repeats itself annually

Overall goal to inform decision makers of best strategy to inform implementation of ACP/GCD

Results

- Over past 3 years, from 16 acute care hospitals in Canada, 808 patients and 631 family members participated.
- From 24 primary care settings
- Starting long-term care settings

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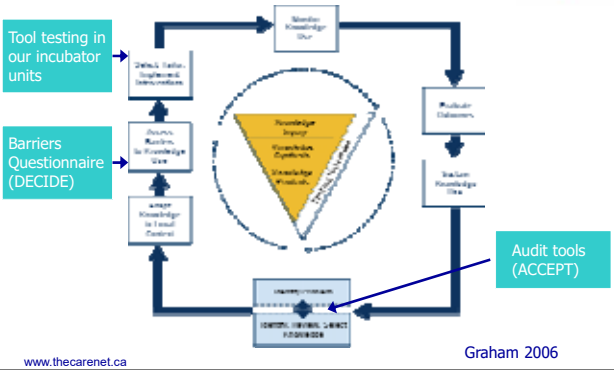
Knowledge-To-Action



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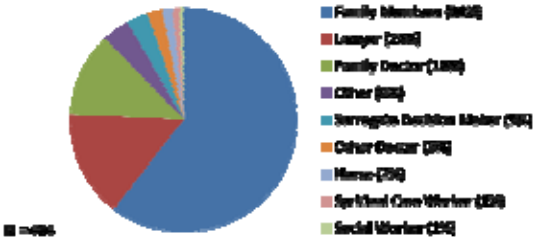
Graham 2006

Audit of Communication, CarE Planning, and DocumenTation (ACCEPT) in Primary Care

- 41% of patients have heard about ACP
- 69% patients thought about what kinds of medical treatments they would want, or not want, if they were to get very sick and be in a hospital

N=760 patients from 24 primary care practices

Who have they discussed their wishes with?



53% patients have discussed their wishes with someone

Audit of Communication, CarE Planning, and DocumenTation (ACCEPT) in Primary Care

- 35% of patients said they have written down their wishes
- 51% of patients said they have named someone, in writing, to be their SDM

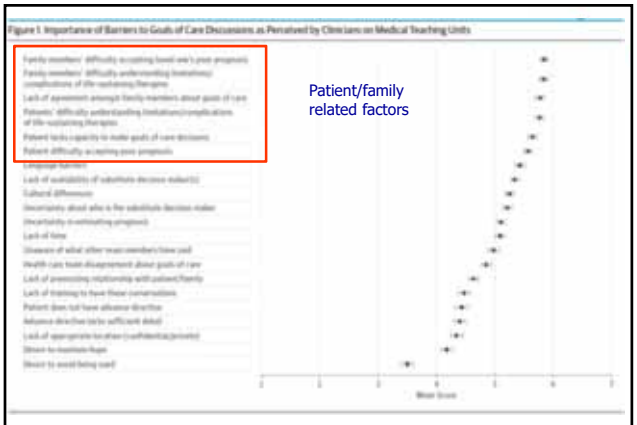
Based on level of ACP engagement amongst lay public and primary care….

Are patients adequately prepared for 'in the moment' decision-making when they get sick?

Failure to Engage Hospitalized Elderly Patients and Their Families

- Multicenter (16) ACCEPT survey of 283 older, seriously ill patients/families on hospital wards
- Majority had thought of EOL wishes and could express preference for treatment at EOL
- Less than 1/3 had spoken to health care professional
- Fewer than 20% acknowledged a prognostic disclosure
- Expressed preferences and documents 'goals of care' only agreed 1/3 time

Heyland JAMA Int Med 2013



1255 Health Care Professionals from 13 sites across Canada (DECIDE STUDY)

You, JAMA Inter Med Feb 2015

Where do we go from here?

To better prepare patients for in the moment decision-making

Interactive, multi-media website

www.prepareforyourcare.org

Values Clarification Tools

CPR Decision Aid
(paper and video version)
Available on
www.thecarenet.ca

What if more centers took an interest in auditing communication and decision-making quality?

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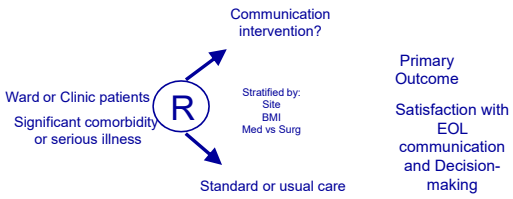
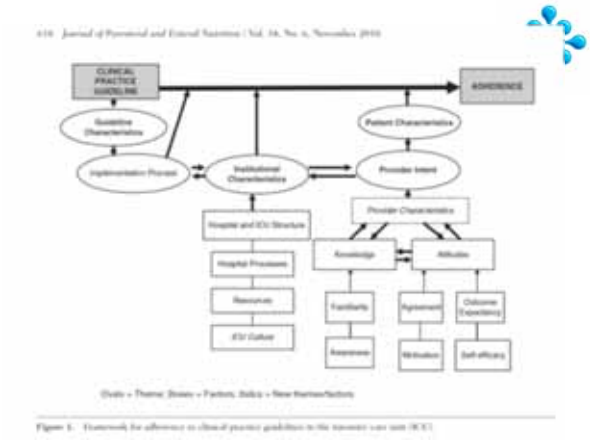
Could the ACCEPT Infrastructure be used to Randomize Patients?



Patient/family Engagement

The New Haven Recommendations on partnering with patients, families and citizens to enhance performance and quality in health promoting hospitals and health services

Today, partnerships with patients and families are at the forefront of healthcare service delivery and quality improvement efforts globally (Conklin et al. 2010). Yet, within the International Network of Health Promoting Hospitals and Health Services (HPH Network), a systematic strategy to involve patients, families and citizens in health promoting healthcare is yet to be developed.



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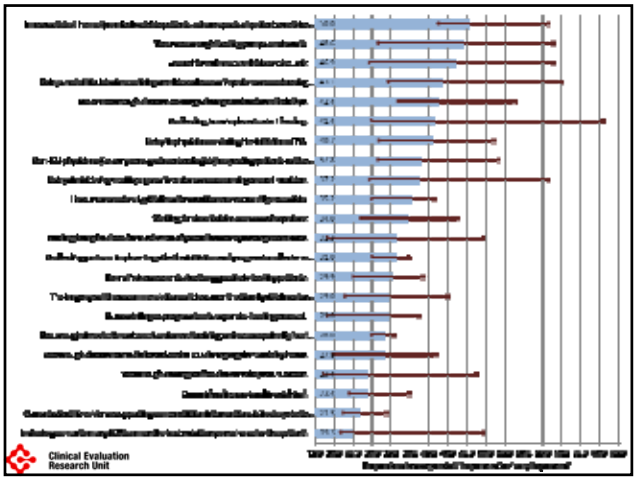

A Quotable Quote

"With critical illness, nutrition is often one of the last things on the minds of the health care team…."

Nurse in OPTICS study

How do we change the culture and make nutrition a higher priority?
Airway, Breathing, Circulation, D(Digestion), E(Early EN)

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Partnering with Patient and their Families

- Partnering with families members of critically ill patients has been shown to
  - decrease patient anxiety, confusion and agitation,
  - reduce cardiovascular complications,
  - decrease length of stay in the ICU,
  - make the patient feel more secure and
  - increase patient satisfaction.
- Reduces family stress
- Overall, it is thought to promote quality and safety in the ICU.

Partnering with Patient and their Families

- However, the optimal means by which we engage families of adult critical care patients
  - the role they can play
  - how best to capacitate them as advocates of or partners in best practices is unknown.

Improving Partnerships with Family Members of ICU Patients: The IMPACT Trial

impact

Study Design

150 Eligible 'high-risk' patients and their family member

R

- Nutrition Intervention (OPTICS)
- Decision Support Intervention (My ICU Guide)
- Usual Care

Process Measures and Short-term outcomes

The randomization system will use a computer generated randomization schedule allocating consented families 1:1:1 to either nutrition intervention, the decision support intervention or usual care

OPTimal Nutrition by Informing and Capacitating Family Members of Best Practices

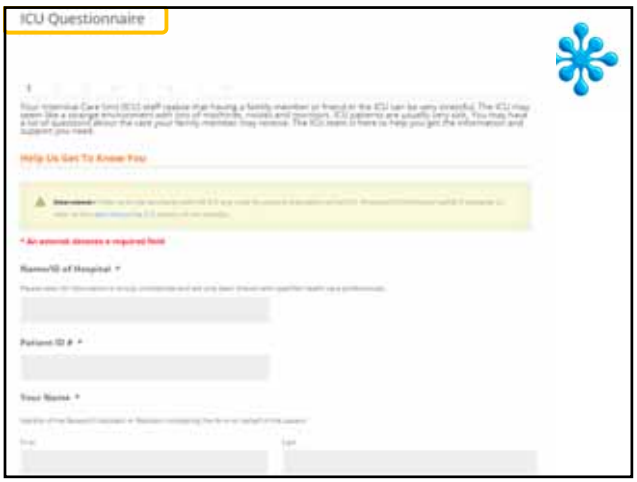
A multifaceted intervention

Family Facing

- Educational sessions after ICU admission and on transfer to ward
- Educational Booklet and videos
- Instructional video
- Nutrition Diary tool
- Dietitian Support thru out
- Nutrition discharge plan

Health Care Professional Facing

- Dietitian led engagement
  - Obtaining nutrition history
  - Providing educational sessions in ICU and ward
  - Responsible for developing care plan and handover to ward staff
  - Introduce Nutrition Diary tool
  - Follow up in ICU and on ward
  - Nutrition discharge plan for home
- 3-day calorie counts
- Training materials (NIBBLES) for other HCP on nutrition and recovery
- Orientation to the family facing materials
- Posters/info graphics



Example of output from MY ICU Guide that would go onto medical record

Significance

- First RCT of Family-engagement strategy in adult critical care
- We propose to transform the experience of older patients with life-threatening illness and their families with a novel family capacitation strategy.
- We plan to create the evidentiary basis for a family-partnered care pathway that will improve outcomes for both these patients and their family members.

Conclusions (1)

- Poor evidentiary basis for clinical interventions at EOL
- Limitations of large-scale RCTs need to drive us to develop alternative solutions for some research questions
- RRCT is a possible solution
- Can the ACCEPT 'registry' be adapted to generate high(er) level evidence that broadly applicable?
- Creation of clinical research networks has the potential to accelerate and support large-scale innovative trials

Conclusions (2)

- Devaluation/Deprioritization of P/EOL care results in inadequate care at EOL
- Engaging patients and families in our efforts will transform the valuation of P/EOL and impact on outcomes

The Canadian Researchers at the End of Life Network (CARENET)

Next Protocol Development Meeting
March 2017

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