Mixed Methods Research & Evaluating Complex Interventions

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Take Home Points

1. Qualitative and mixed methods research are **crucial** tools to improve serious illness care.

2. When evaluating complex interventions to improve serious illness care, rigorous plans are needed to monitor and maintain intervention fidelity.

Definitions

Qualitative research: a type of research that aims to gather and analyze non-numerical data in order to gain an understanding of individuals' social reality, including understanding their attitudes, beliefs, and motivation.

Mixed methods research: "Research that includes both QUAL and QUANT data collection and analysis in parallel form or in sequential form (in which one type of data provides a basis for collection of another type of data).

St. Clair E; *Research methods and Design: Qualitative Research methods; 2022*

Tashakkori and Teddlie; *Handbook of mixed methods in social and behavioral research;* 2003

Purposes of Quantitative and Qualitative Research

Quantitative

- Establish incidence and prevalence
- Measure risks and frequency of events
- Determine treatment efficacy

Qualitative

- Describe phenomenon
- Understand attitudes and behavior
- Describe “why” interventions do or don’t work

Western Bioethics on the Navajo Reservation

Benefit or Harm?

Joseph A. Carrese, MD, MPH, Lorna A. Rhodes, PhD

Objective.—To understand the Navajo perspective regarding the discussion of negative information and to consider the limitations of dominant Western bioethical perspectives.

Design.—Focused ethnography.

Setting.—Navajo Indian reservation in northeast Arizona.

Objective: To <u>understand</u> the Navajo perspective regarding the discussion of negative information and to consider the limitations of dominant Western bioethical perspectives?

'I Don't Want to Be the One Saying 'We Should Just Let Him Die': Intrapersonal Tensions Experienced by Surrogate Decision Makers in the ICU

Yael Schenker, MD, MAS[1], Megan Crowley-Matoka, PhD[2], Daniel Dohan, PhD[3], Greer A. Tiver, MPH[1], Robert M. Arnold, MD[1], and Douglas B. White, MD, MAS[4]

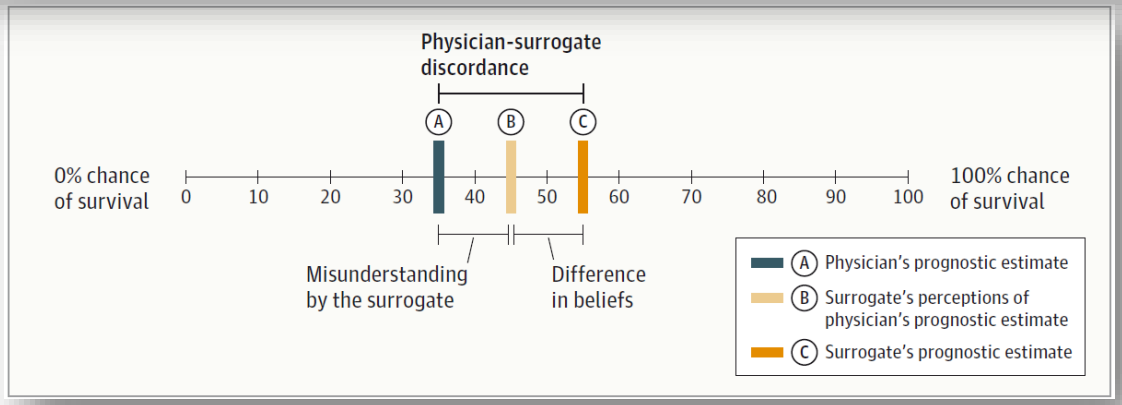
Objective: To <u>characterize</u> key intrapersonal tensions experienced by surrogate decision makers in ICUs and <u>explore</u> associated coping strategies.

Carrese J. JAMA; 1995; Schenker YS. JGIM. 2012

Prevalence of and Factors Related to Discordance About Prognosis Between Physicians and Surrogate Decision Makers of Critically Ill Patients

Douglas B. White, MD, MAS; Natalie Ernecoff, MPH; Praewpannarai Buddadhumaruk, RN, MS; Seoyeon Hong, PhD; Lisa Weissfeld, PhD; J. Randall Curtis, MD, MPH; John M. Luce, MD; Bernard Lo, MD

What do you think are the chances that the patient will survive this hospitalization?



What do you think *the doctor thinks* are the chances that the patient will survive this hospitalization?

43% of surrogates held optimistic expectations about prognosis compared to the attending physician.

- Black vs White patients: (68% vs 40%; p=0.01)
- Strongly religious vs not religious: (52% vs 20%; p=0.07)

Optimistic expectations arose from:

- **Miscomprehension** and
- **Differences in belief**

White DB. Crit Care Med. 2019 White DB. JAMA. 2016

Prevalence of and Factors Related to Discordance About Prognosis Between Physicians and Surrogate Decision Makers of Critically Ill Patients

Reasons for Overly Optimistic Estimates by Surrogates

Reason	Exemplar
Surrogate believes they better know patient's fortitude	"I know him more than what the doctor do. And when you don't know a person, it's pretty much, "This is what I read in a book". And I'm not reading from no book. I'm reading from experience. "
Optimism grounded in religious beliefs	"I believe the doctor would only believe in what he can do for my son. I believe what he can do and what God can do."
Defensive processing of prognosis	"I guess I understand that he might die, but that's not something I'm quite able to look at right now".

White DB. JAMA; 2016

Excellent Recommendations for Reporting (and Designing) Qualitative Research

Standards for Reporting Qualitative Research: A Synthesis of Recommendations

Bridget C. O'Brien, PhD, Ilene B. Harris, PhD, Thomas J. Beckman, MD, Darcy A. Reed, MD, MPH, and David A. Cook, MD, MHPE

International Journal for Quality in Health Care; **Volume 19, Number 6:** pp. 349–357
Advance Access Publication: 14 September 2007
10.1093/intqhc/mzm042

Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups

ALLISON TONG[1,2], PETER SAINSBURY[1,3] AND JONATHAN CRAIG[1,2]

O'Brien BC. Acad Med. 2014

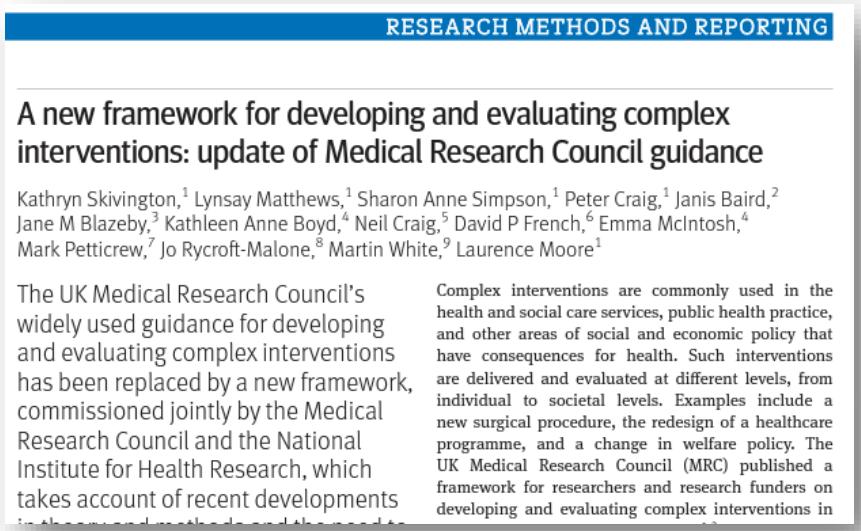
Tong A. Int J Qual Health Care. 2007.

Take Home Points

1. Qualitative and mixed methods research are crucial tools to improve serious illness care.

2. When evaluating complex interventions to improve serious illness care, rigorous strategies are needed to monitor and maintain intervention fidelity.

What are Complex Interventions?



RESEARCH METHODS AND REPORTING

A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

Kathryn Skivington,[1] Lynsay Matthews,[1] Sharon Anne Simpson,[1] Peter Craig,[1] Janis Baird,[2] Jane M Blazeby,[3] Kathleen Anne Boyd,[4] Neil Craig,[5] David P French,[6] Emma McIntosh,[4] Mark Petticrew,[7] Jo Rycroft-Malone,[8] Martin White,[9] Laurence Moore[1]

The UK Medical Research Council's widely used guidance for developing and evaluating complex interventions has been replaced by a new framework, commissioned jointly by the Medical Research Council and the National Institute for Health Research, which takes account of recent developments

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of social and economic policy that have consequences for health. Such interventions are delivered and evaluated at different levels, from individual to societal levels. Examples include a new surgical procedure, the redesign of a healthcare programme, and a change in welfare policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on developing and evaluating complex interventions in

What are complex interventions?

An intervention might be considered complex because of properties of the intervention itself, such as the number of components involved; the range of behaviours targeted; expertise and skills required by those delivering and receiving the intervention; the number of groups, settings, or levels targeted; or the permitted level of flexibility of the intervention or its components. For example, the Links Worker

Skivington K. BMJ. 2021

Why Monitor and Report Intervention Fidelity in RCTs of Complex Interventions?

Because interpreting the results of trials is impossible without knowledge of treatment fidelity.

- A negative trial can arise from several causes with different implications.

Intervention was unsuccessful due to failure to deliver the intervention as intended.

vs

Intervention was delivered with high fidelity, but just didn't work.

Health Psychology
2004, Vol. 23, No. 5, 443–451

0278-6133/04/$12.00 DOI: 10.1037/0278-6133.23.5.443

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TABLE I. Definition of Components of Treatment Fidelity

Component of Treatment Fidelity	Definition and Description
Design	Treatment fidelity practices related to study design are intended to ensure that a study can adequately test its hypotheses in relation to the underlying theory and clinical processes.
Training	Assessment and ongoing evaluation of the training of interventionists to ensure that they have been satisfactorily trained to deliver the intervention to study participants.
Delivery	Treatment fidelity processes that monitor that the intervention is delivered as intended.
Receipt	Receipt of treatment focuses on the participant and assures that the treatment has been received and understood by the participant (e.g., that he or she is able to perform treatment-related behavioral skills and cognitive strategies as intended).
Enactment	Enactment of treatment skills monitors that the individual performs treatment-related behavioral skills and cognitive strategies in relevant real-life settings as intended.

Resnick B. Nursing Research. 2005

Bellg AJ. Health Psych. 2004

Randomized Trial of a Family Support Interventionist for Surrogate Decision Makers in ICUs

Design: patient-level randomized, parallel-group superiority trial in comparing the Four Supports intervention to usual care augmented with two 30-minute education sessions.

Patients: 450 surrogates of incapacitated, critically ill patients at high risk of death and/or severe long-term functional impairment.

Intervention: multifaceted family support intervention delivered by trained nurse interventionist who collaborated with the ICU team.

No Improvement in Primary or Secondary Outcomes:

Family-centered: Sx of depression, anxiety, post-traumatic stress @ 6 months

Patient-centered: Patient-centeredness of care; hospital & 6m survival; functional status @ 6 months

Healthcare utilization: ICU and hospital LOS; duration of MV.

R01AG045176 Protocol paper: Seaman JB. Annals ATS. 2018 Manuscript under review

Methods Used to Establish, Monitor, and Maintain Intervention Fidelity

Fidelity Domain	Elements
Design	Clearly defined core elements of intervention
Training	Detailed intervention manual; 40 hours of standardized behavioral training; defined performance criteria; certification exam prior to study initiation; weekly supervision sessions for interventionists
Delivery	Audiorecording and coded all intervention encounters; daily recording of intervention delivery each day
Enactment	Assessment of surrogates' prognostic expectations; decisional conflict, ratings of emotional support

High Fidelity to Intervention Protocol

eTable 1. Overall Adherence to the Intervention Protocol

	Interventionist- Reported Compliance Score[†]	Analysis of Audio-recorded Sessions by Independent Raters[‡]		
Measure	What is the overall compliance with conducting daily sessions?	What proportion of key components were addressed in the session?	What is the quality with which key components were addressed? (on a scale of 1-3[§])	What is the global assessment of quality of the session? (on a scale of 1-3[§])
Intervention Arm				
Overall FSI Adherence to Protocol: Family meetings*	97.1% (n=146)			
First interaction with family within 24 hrs. of enrollment[†]	99.3%	94.9% (n=35)	2.86	2.94
Pre-conference prior to each clinician-family conference[†]	97.4% a,g,i,c,s	95.6% (n=26)	2.82	2.96
Clinician-family conference within 48 hrs. of enrollment/readmission and q7 days[†]	94.3% b,c,d,l,q	100.0% (n=38)	2.99	3.00
Post-conference after each clinician-family conference[†]	95.4% a,e,g,i,j,s,c	98.8% (n=28)	2.94	2.98
Daily check-in with family[†]	99.4% f	100.0% (n=51)	3.00	3.00
Life closure session[†]	96.4% k	97.8% (n=6)	2.92	2.92
Overall FSI Adherence to Protocol: Physician Meetings*	91.4% (n=146)			
First conversation with Physician[†]	89.0%	85.1% (n=18)		
Pre-conference MD[†]	90.6% a,g,h,i	96.9% (n=11)		
Post-conference MD[†]	95.3% a,e,g,i,h	100.0% (n=5)		
Daily Check-In[†]	94.0% f,k	91.2% (n=19)		
Rate of clinician-family meetings[‡]	**0.20**			

Intervention Had Mixed Results on Enactment

Intervention arm:

- High ratings of emotional support
- High ratings of communication quality
- Increased frequency of clinician-family meetings
- No improvement in surrogates' clarity about patient values
- No improvement in rates of prognostic discordance (~50%)

Four Supports intervention was ineffective <u>despite</u> being delivered with high fidelity.

- **Enactment:** Intervention improved families' ratings of feeling emotionally supported, but did not improve their prognostic awareness or values clarity.

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