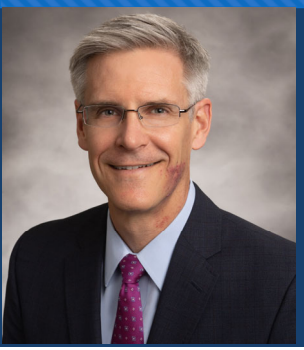
Partnering with Patients to Make Consent More Meaningful



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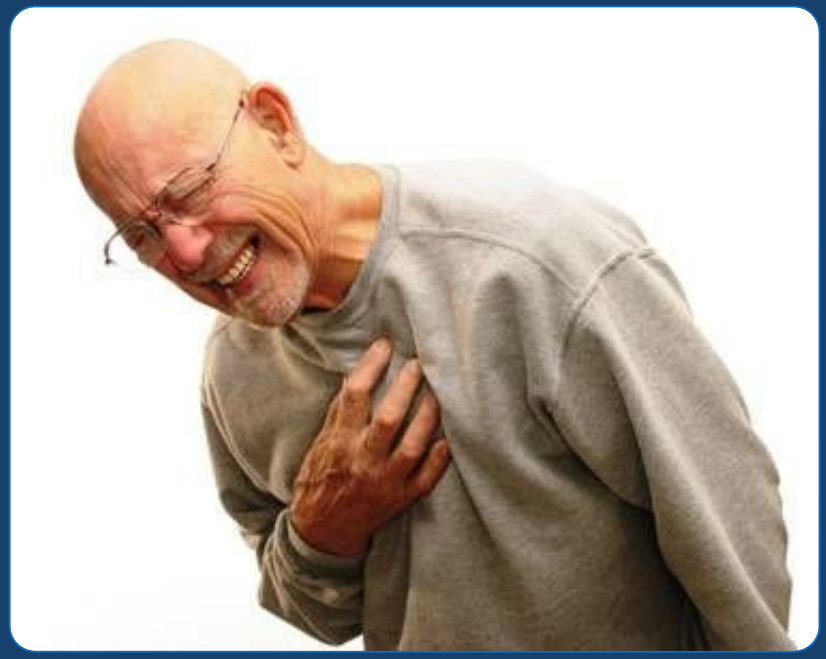
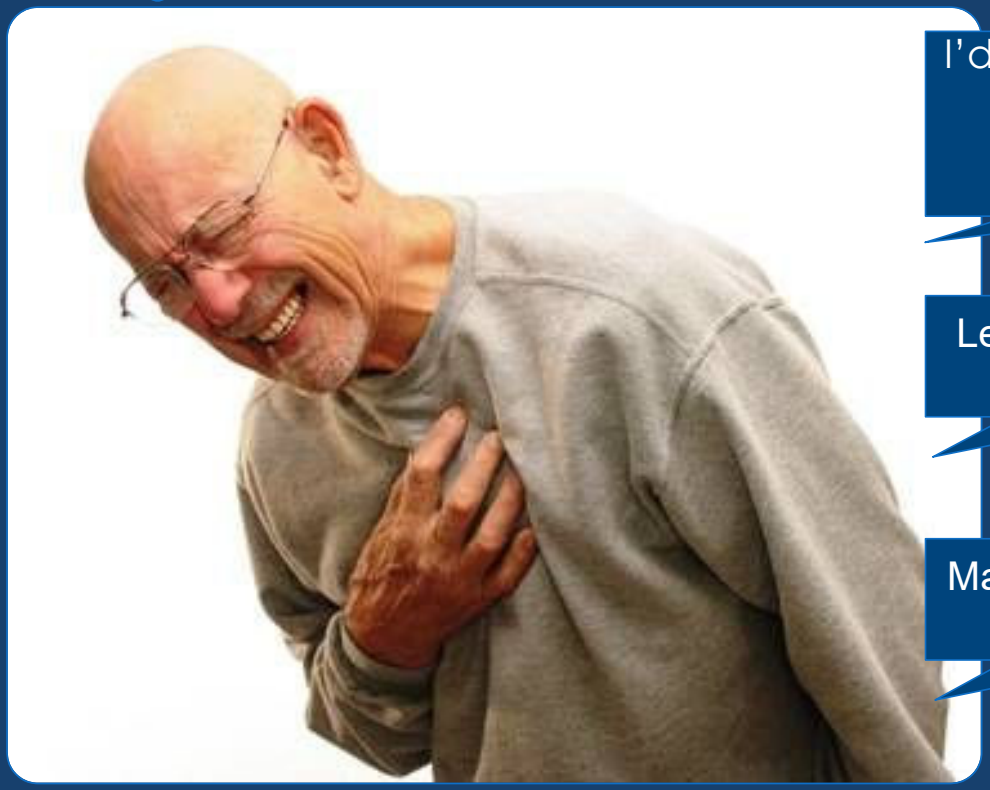
Where I Started

70 yo man having STEMI. He needs to go to the cardiac cath lab quickly. He is with his wife. He is in pain but is lucid, and his vitals are stable.

He is eligible for the TOUGH trial evaluating a new stent for heart attack. You are telling him about the trial and asking whether he wants to enroll in it.



Likely Reactions?



I'd like to know a little bit about how my information will be shared…

Let's talk a little bit about alternatives…

Maybe I could have some reading materials…

This is What He Really Wants

Limitations in Acute Situations

- Limited time
- Physical symptoms- e.g. pain, shortness of breath
- Mental symptoms- e.g. fear and stress
- Clinical condition is likely new for the patient
- Lack of familiarity with research (which can be very complicated)
- Lack of trust in researchers or institutions
- These issues affect all sorts of conditions

What do Patients Want?

	Scenario 1: Medicine vs. Medicine (CER)	**Scenario 2:** Experimental medicine vs. Placebo	**Scenario 3:** Medicine vs. Procedure (CER)
Tell you then ask for consent	24 (80%)	24 (80%)	22 (73%)
Include you without asking	3 (10%)	2 (7%)	3 (10%)
Trial should not happen	3 (10%)	4 (13%)	5 (17%)

- Desire for involvement independent of study type

Dickert NW, et al. *Journal of Medical Ethics*. 2016.

Key Questions

- Knowing they want to be involved, what is it that patients want and need out of these interactions?
- Can patients help us to make the process better?
- Can we implement (*get approved…*) something that seems more appropriate?

P-CARE and MOST-CONSENT Studies

- Phone interviews- 176 patients/surrogates in 11 STEMI and acute stroke trials; follow-up, in-depth interviews with 27
- Collaboration with 9-member patient advisory panel to construct patient-driven consent processes
- Implementation within
  - Multi-center trial for acute hemorrhagic stroke
  - Multi-center trial for acute ischemic stroke (MOST-CONSENT)

The Greenwall Foundation
pcori PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

P-CARE Study

Views and Preferences of Consent	Stroke N = 75	MI N = 57	p-value
I am glad that I was asked before the patient was included/being included…			
Agree	69 (92.0)	47 (82.5)	
Not agree ‡	3 (4.0)	9 (15.8)	p = 0.0378 ǂ
No answer**	3 (4.0)	1 (1.8)	
I wish that I had not had to sign a consent form…			
Agree	13 (17.3)	20 (35.1)	
Not agree ‡	58 (77.3)	35 (61.4)	p = 0.0570 ǂ
No answer**	4 (5.3)	2 (3.5)	
Instead of asking me before including me/the patient in the study, I would have preferred it if the doctor treating me/the patient had made the decision for me…			
Agree	12 (16.0)	15 (26.3)	
Not agree ‡	62 (82.7)	40 (70.2)	p = 0.2222 ǂ
No answer	1 (1.3)	2 (3.5)	

*** Responses are missing because not all participants were asked this question due to a skip pattern**
****No answer implied participants either did not provide an answer or werenot asked the questionn**

ǂ Fisher's exact test, all else is Chi-Square
‡ Includes those who responded don't know

Dickert NW, et al. *JAHA*, 2019.

Quality of Interactions

Making participants feel like more than just a number

"They took the time to let you know that they knew you were very – you weren't just something that they were learning from, you know? You were somebody to them." (#31)

Professionalism

"It was the way he talked and the way I could tell that he was doing what he needed to do to get me the help I needed. It was – well, his tone of voice, for one thing. I mean, he was professional, yet compassionate." (#31)

Non-Pressuring

"I remember just saying, 'Just go away. Please leave me alone,' and then he said, 'If you just sign here we can proceed and I won't bother you anymore.' ... But at the time I felt already, you know, beleaguered, and so that just added to my stress at the time." (#57)

Scicluna VM et al. *JAHA*. 2019

Attitudes Towards Consent Forms

Form proves study legitimacy	"I'm military, very detail-oriented. You know, for action there needs to be something signed to say it happened or why it happened. So to me that's the norm." (#37)
Signing form made participant feel like part of the research	"I'm giving consent for this to take place, you know. Made me feel like I was a part of what was actually going on." (#61)
Signing form caused aggravation	"It is kind of a moot point to have a signature, and it was distressing at the time because I couldn't see, I couldn't read what it said, and I certainly wasn't listening to what it said." (#25)
Form serves a legal function	
Form is a resource to refer to later	

Scicluna VM et al. *JAHA*. 2019

P-CARE Consent Approach

Developed with Patient Advisory Panel

- Be realistic and context appropriate
  - Form should be readable in the timeframe
- First Impressions Matter
  - Lose upfront "filler;" important information first
- "Negative" tone is not protective
  - Be honest about reasons to do the study and potential benefits of participation
- Eliminate/minimize extraneous information
  - Focus on the study itself
  - Boilerplate language risks compromising trust
- Information sheet and other materials as an adjunct
  - Not written as part of the consent
- Post-enrollment communication matters

Dickert NW, Bernard AM, Brabson JM, Hunter RJ, McLemore R, Mitchell AR, Palmer S, Reed B, Riedford M, Simpson RT, Speight CD, Steadman T, D Pentz R. Partnering With Patients to Bridge Gaps in Consent for Acute Care Research. *Am J Bioeth*. 2020.

Implementing P-CARE Approach

- ENRICH Study
  - Early minimally invasive surgical evacuation vs conservative management in ICH
  - Involvement of 7 sites
- MOST Study
  - Adding eptifibatide or argatroban to standard therapy in acute ischemic stroke
  - Implemented at all StrokeNet sites

www.pcori.org/Dickert295 ; Dickert NW, et al. Ethics and Human Research. 2022; Speight CD, et al. Ethics and Human Research. In Press.

Concrete Manifestations of the Process

- Brief- ~3 pages of content
- Straightforward language
- Ordered in a way that follows conversation
- Elimination of generic "warning" language and acontextual boilerplate
- Plain-language headings
  - How is this different from what will be done normally?
- Clear statement of benefits and reasons for doing the study
- Separate information sheet
- Debriefing/follow-up opportunity

Implementation and Evaluation

- ***Approval Process***
  - ***VERY*** challenging when working with multiple sites and IRBs, local institutional barriers
  - Highly collaborative and effective when working with a single IRB
  - *The fact that changes were driven by patients had substantial impact on approvability*
- ***Evaluation***
  - Survey of patient/surrogate experiences across all MOST sites
  - Very positive feedback from study teams and local human subjects protections staff
  - Utilization of information sheet needs optimization
  - Unclear whether this will impact enrollment or representativeness
- ***Extension and Growth***
  - Recently utilized for a trial of submassive Pulmonary Embolism
  - Partnering with patient advisors for sepsis biorepository study
  - Establishing a patient advisory panel locally for guidance on consent/recruitment

Summary

- Ethically important to design consent processes around what real users want
- Patients and surrogates have valuable input that can substantively guide the process
- Some well-intentioned "protections" are actually not protective
- Innovations are implementable, especially in collaboration with regulatory bodies and central/single IRBs
- Need to learn more about whether it impacts key outcomes
  - Respect
  - Trust
  - Enrollment and Representativeness
- Core insights from patients are relevant well beyond the acute care context

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References

- Dickert NW, Scicluna VM, Adeoye O, Angiolillo DJ, Blankenship JC, Devireddy, CM, Frankel MR, Goldkind SF, Kumar G, Ko YA, Mitchell AR, Nogueria RG, Parker RM, Patel MR, Riedford M, Silbergleit R, Speight CD, Weinfurt KP, Pentz RD. "Emergency Consent: Patients' and Surrogates' Perspectives on Consent for Clinical Trials in Acute Stroke and Myocardial Infarction." *Journal of the American Heart Association*. 2019 Jan 8(2): e010905.
- Scicluna VM, Goldkind SF, Mitchell AR, Pentz RD, Speight CD, Silbergleit R, Dickert NW. "Determinants of Patient and Surrogate Experiences With Acute Care Research Consent: A Key Informant Interview Study." *Journal of the American Heart Association*. 2019 Nov 19;8(22):e012599.
- Dickert NW, Bernard AM, Brabson JM, Hunter RJ, McLemore R, Mitchell AR, Palmer S, Reed B, Riedford M, Simpson RT, Speight CD, Steadman T, D Pentz R. Partnering With Patients to Bridge Gaps in Consent for Acute Care Research. *American Journal of Bioethics*. 2020 Jun;20(5):7-17.
- Dickert NW, Metz K, Deeds I, Linke MJ, Mitchell AR, Speight CD, Adeoye O. "Getting the MOST out of Consent: Patient-Centered Consent for an Acute Stroke Trial." *Ethics and Human Research*. 2022 Mar;44(2):33-40.
- Dickert NW, Mitchell AR, Speight CD, et al. (2020). *Understanding and Improving Informed Consent for Clinical Trials during Health Emergencies*. Patient-Centered Outcomes Research Institute (PCORI) www.*pcori.org/Dickert295*

Example- Benefits

- Previous Version
  - This study is not designed to benefit you directly. Your condition may improve while you are in this study but it may not, and it may even get worse. The results from this study will help people with ICH in the future. There is no guarantee that you will receive any medical benefits from being in this study.

- P-CARE Version
  - It is possible that removing the blood with very early surgery may reduce disability or impairment from the bleeding stroke. It is also possible that very early surgery will be no better or not as good as standard medical treatment alone. Either way, the knowledge gained from this study will help doctors to know more about what treatments are most effective for a bleeding stroke.

Example- Randomization

- Panel had strong reactions to common metaphors for randomization
- Prior Consent
  - After your consent, you will be randomly assigned (50-50, similar to flipping a coin) to either: surgical intervention or medical management.
- P-CARE Consent
  - A computer will randomly assign you to be in one treatment group or the other. *You will have an equal (50/50) chance of being in either group.*