

Partnering with Patients to Make Consent More Meaningful

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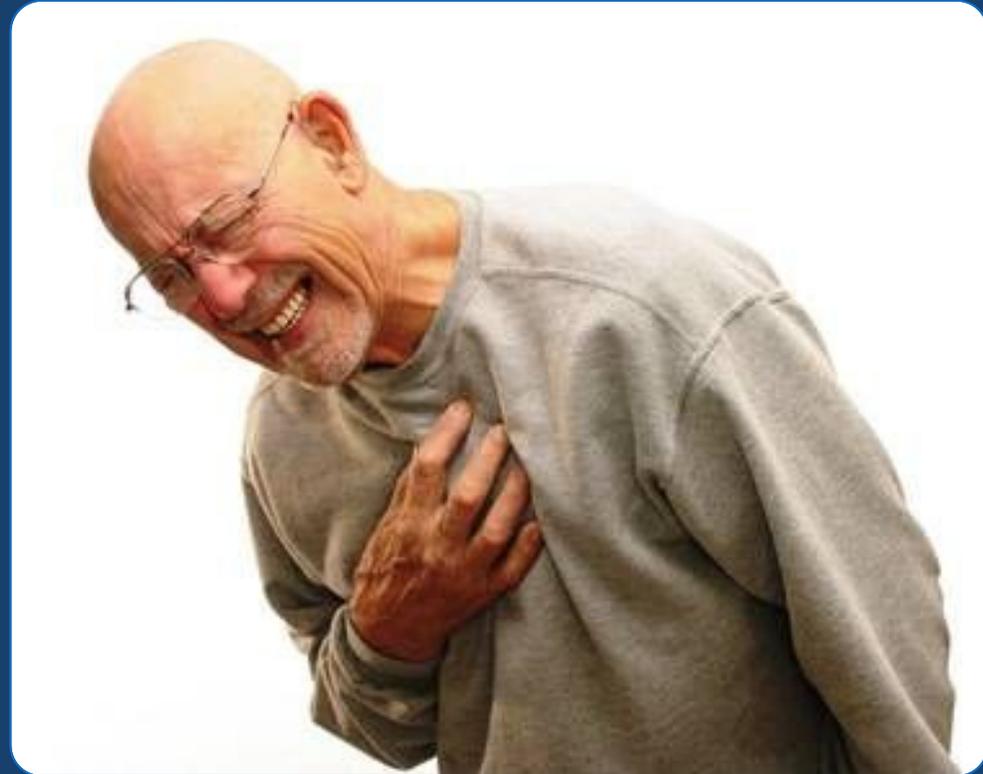
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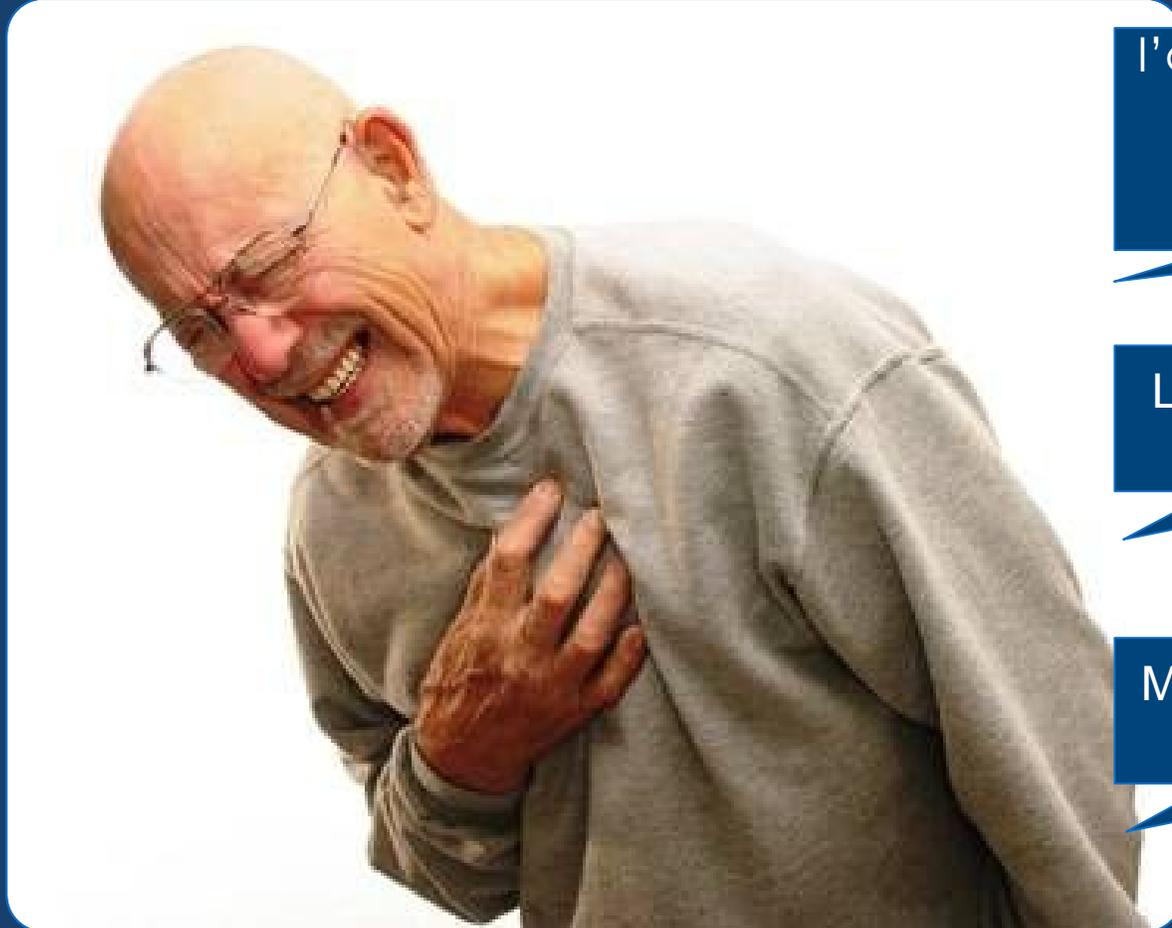
Where I Started

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?

	<u>Scenario 1:</u> Medicine vs. Medicine (CER)	<u>Scenario 2:</u> Experimental medicine vs. Placebo	<u>Scenario 3:</u> 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

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)

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)

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

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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