“Standard of Care” Research

Communicating Reasonably Foreseeable Risks to Research Participants

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Three situations

1) I have a personal physician with whom I have a patient-doctor relationship, and my physician is not a researcher

2) I have a personal physician with whom I have a patient-doctor relationship and my doctor conducts research on a condition for which I have been diagnosed and treated

3) I am a patient without a personal physician, I obtain my medical care at a public hospital and I typically see a medical resident
Situation 1

- My doctor tells me the risks and benefits only for the medicine that he normally prescribes, without informing me of the risks and benefits of other treatments that other doctors prescribe for the same condition
- He refers me to a colleague conducting research
- The consent form says that I will be assigned by chance to one of two treatments that are “standard of care”
  - The medical treatment my doctor has told me about
  - A surgical treatment for the same condition
Situation 1

• The consent form says only that both treatments are “standard of care” for my condition, so I will not be exposed to any additional risks by enrolling in the study.
• The consent form does not describe the risks of the treatments because they are not “experimental”
• My doctor told me the risks of the medicine he prescribes but I have no idea what are the risks of surgery
Situation 2

- My physician has already explained the known risks and discomforts of the medicine she normally prescribes, which include headache and fatigue.
- But now she is a researcher inviting me to be a subject in a clinical trial.
- The consent document says “the risks to you are the same as you would undergo if you don’t enroll in the trial because whichever treatment you will get is the standard of care.”
  > I am surprised when I experience nausea but no headache.
Situation 3

• I have not yet been treated for my condition, and therefore have not been told anything about the risks and benefits of the standard treatment

• The consent form says

  > “This is a study to see whether one of two treatments that are the ‘standard of care’ for your condition are better than the other. Since there are no experimental treatments, the risks of entering this research are no different than what you would experience if you decide not to enroll in this study”

• But I have never received any “standard of care” treatment
Situation 4

- I am a patient with a family history of colorectal cancer
- The gastroenterologist invites me to participate in a “standard of care” clinical trial
- The consent form says
  > “This is a trial to compare two ‘standard of care’ screening methods for colorectal cancer. One commonly used procedure is colonoscopy. The other is fecal immunochemical tests (FITs), a non-invasive option. There are no experimental treatments in this research. You will not be at any increased risk over standard treatments by entering in the study.”
I search the web and read about the proposed study.

“Colonoscopy Versus Fecal Immunochemical Test in Reducing Mortality From Colorectal Cancer (CONFIRM),” processed by clinicaltrials.gov on November 27, 2014

FIT is a proven, noninvasive screening method

Study hypothesis is that colonoscopy will be superior to FIT in the prevention of colorectal cancer mortality measured over 10 years.

At first I think of not joining the study and asking for the non-invasive screening. But I am intrigued by the hypothesis and enroll in the research.
What should be disclosed?

- An objection that physicians should describe risks and benefits of “standard of care” before enrolling patients in research is beside the point
  > They may or may not describe all alternatives
- The key point is what should be disclosed by way of risks of the alternatives in “standard of care” research
  > Assumption is that the risks of routine procedures in medical care are “reasonably foreseeable”
- Potential research subjects may equally want to know about the reasonably foreseeable benefits
Disclosure of risks of routine care

• The idea that potential subjects will be “scared away” from participating in research when significant risks of standard of care interventions are disclosed is silly
  > People are not scared away from the same standard treatments when the risks are described by their doctors
  > Potential subjects are prepared to enter investigational research when risks are described and the consent form mentions unknown risks
  > While we are promoting evidence-based medicine in conducting these “standard of care” clinical trials, we should also practice evidence-based ethics.
Conclusions

- Consent documents should disclose *all* reasonably foreseeable risks, clearly distinguishing the risks of experimental treatments, if any, from those a patient would undergo in routine medical treatment.
- Reasonably foreseeable benefits of standards of care should also be described.
  - If there are no increased risks in “standard of care” research, neither can there be any increased benefits.