letters

Obtaining informed consent in extremis

Dear Editor,

I ask your readers to consider the following scenario. A 40-year-old male cardiology patient arrives in the emergency room with clear symptoms of a serious heart attack. He is eligible for a six-week clinical trial and you would like to enrol him. You have 90 minutes to begin treatment. He appears to be coherent. He has a significant chance of dying in the next six weeks, whether or not he enrols in the study. How do you ethically obtain informed consent?

This situation is problematic for true informed consent. Although coherent, your patient is vulnerable. He has a lot on his mind, may not be fully rational, may be frightened, may not be accompanied by the people who normally help him make important choices, and yet he has to make a quick decision.

Patients give informed consent for regular medical care every day, in worse circumstances and with much less ado. Clinical research, however, requires a higher standard. In addition to all the regulations and ethical guidelines, litigation for wrongful death is a real possibility; defective informed consent is a claim in 100% of clinical research liability cases.

Verify your patient's comprehension of the important points

Given the extreme circumstances, you probably want to take every reasonable precaution to ensure true informed consent. Options that you may want to consider include:

- As a practical matter, you cannot help but exert influence on your patient. He has to assume that you would not be risking his life with an unwarranted clinical trial. Therefore, ask someone who does not have an existing relationship with your patient to obtain consent.
- There should be no question about the impartiality of the witness. Hospital chaplains and bioethicists are good options.
- Verify your patient's comprehension of important points. A prepared quiz would come in handy. And if your patient knows in advance that he will be quizzed, he may be more attentive.
- Encourage your patient's family and friends, if available, to participate in the process. Give your patient an opportunity to discuss the study privately with them.
- Although one signature is adequate, it is advisable to obtain informed consent from both your patient and a legally authorised representative or other family member, if present.
- Give your patient at least a few minutes to reflect privately before giving consent.
- After your patient's physical and mental condition stabilises in a few days, review the study with him again and allow him to drop out if he wants.

Now let us imagine that you follow some or all these procedures, your patient does or does not give consent, and you are back in your office tomorrow morning. Another patient arrives in your office. She is a good candidate for a low-risk hypertension study. Does she deserve any less consideration in the informed consent process?

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LETTERS TO THE EDITOR

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