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16 Do's and Don'ts for Describing the Risks in a Clinical Study

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Informed consent requires that information about the risks of participation in a clinical study be disclosed in a manner that is understandable to prospective study participants ("people"). In addition, this information should be presented in an honest and objective manner in the consent form and/or the consent discussion. However, unless the person is a scientist or healthcare professional with relevant expertise, any explanation of medical risks will, necessarily, be superficial.

Here are 16 do's and don'ts for describing risks in the informed consent process:

1. **Do let people form their own judgments.** For example, do not say, "There's nothing here that *you* can't handle."
2. **Do not say something like: "This study, like other studies, carries risks."** This statement discounts the risks as nothing special. It falsely suggests that all studies carry about the same risks. It makes a false comparison to *other studies* in general, when the correct comparison is to alternative treatments and the hazards of normal life. It suggests that no individual risk deserves close examination.
3. **Do provide a plain-language explanation of the risk.** For example, say "heart attack" instead of "myocardial infarction."
4. **Do not provide a long, disorganized, undifferentiated "laundry list" of risks.** Attorneys generally want to disclose every possible risk, but insignificant risks distract the person's attention from those that really matter. It also dilutes the apparent importance of the all the risks. In addition, when people are presented with a long list of risks, the consent process puts an unfair burden on them to identify those that are significant. (Of course, it might be hard to know which risks people will consider insignificant.)
5. **Do provide guidance as to the likelihood of a risk, when the likelihood is known to a meaningful degree.** When the likelihood of a risk can be estimated, share that information with people.
6. **Do provide guidance as to the severity of a risk.** When the severity of a risk can be estimated, share that information with people. For example, headaches come in a wide range of intensity and duration.
7. **Do advise people on how likely the risks are.** In some studies, the probability of a risk can be estimated with some certainty; in others they can't. Share this information, or lack thereof, with people. For example, say things like:
   a. "We have good evidence to believe that this problem occurs about 10% of the time."
   b. "All we can say is that this problem probably occurs in one or two out of 10 patients,"
   c. "We have very little evidence about how often this problem occurs."
8. **Do not use qualitative descriptors of probability without explaining what they mean.** People can have very different ideas about the meaning of words like "rare." Depending on the condition, a physician might consider "1 in a 10,000" to be a rare side effect, while a patient might think it means "1 in 20."
9. **Do not overstate the certainty of a probability.** If the probability of a risk is uncertain, provide a probability range.

10. **Do not explain that risks have two dimensions.** Many people look at risks as "big," "medium," or "small," without understanding that risks have two dimensions: probability (chance) and severity. Present this information for each risk or category of risks.
11. **Do not understate or overstate the risks.** Understating the risks unfairly influences people to enroll. Overstating them does the opposite.
12. **Do consider risks to others.** For example, if blacking out is a risk, it might happen when the study participant is driving.
13. **Do not ignore non-medical risks.** For example, an inadvertent disclosure of genetic data might be significant to study participants and their family members.
14. **Do consider the seriousness of the condition being treated.** For example, when treating Stage 4 cancer, mild headaches and rashes are significant only to the extent they distract from risks that are significant.
15. **Do not assume people already know about the risks.** For example, psychiatrists might be reluctant to go into detail about severe side effects like neuroleptic syndrome or tardive dyskinesia.
16. **Do not assume you know the person's attitude toward risk.** Even they might not know their level of aversion to a specific set of risks in advance, or how they will weigh them against the benefits.

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