Informed Consent: Is It Really?

In a rare moment of weakness, I agreed to serve on UCSF's Institutional Review Board. This is a big deal. In addition to meetings every 2 weeks, members need to learn a complex electronic content system (not easy for this Luddite). Members have 3 to 4 assignments involving reams and reams of paper (real or electronic) and each must read the informed consent document in excruciating detail. But I did it because this is important and it was the right thing to do.

However, I must say that if I were a patient, sick and afraid, I would find these informed consent documents to be overwhelming. Although I think we have improved our simplification of language, we have lost our course in making this document easy for patients to navigate.

Let's take a couple of examples. Any patient with cancer on a clinical trial involving a therapeutic intervention will undergo blood tests and imaging. Current rules require that these procedures be detailed in the informed consent document. Sometimes there are more pages on this than on the risks related to the experimental intervention! It doesn't make sense. Because most of our patients have had these procedures as part of their standard of care, could we simply provide a reference compendium in case a patient wants to know more? That alone might eliminate several pages from each document.

Another example is the risk associated with checkpoint inhibitors, such as CTLA-4 inhibitors or PD-1 or PD-L1 inhibitors. The last consent document I looked at included 4 pages of painful details for every possible organ system that could be affected by an autoimmune reaction. Why not just make it simple? We could include something like: "This class of drugs can turn your own immune system against virtually any tissue in your body. Fortunately, this is uncommon and reversible, but the most frequent tissues affected are listed in the following table." Wouldn't that be more straightforward?

Other sticky issues are related to biopsies obtained for research purposes, the risks of genetic analysis on tissue, and the ownership and custody of tissue. But those topics need to be saved for another day.

Right now, I am focused on a template for a clear and understandable informed consent document that does not require an advanced degree to understand. I think that we can personalize these documents according to the patient experience. For instance, a first-line clinical trial might need more detail on procedures than a second-line trial. For drugs that are already FDA-approved for another indication, do we need to detail every possible adverse event? Couldn't we include a statement such as: "DRUG X is already FDA-approved and in wide use for another form of cancer. The most common side effects are listed in the following table."

Finally, I think we need to remember that patients rely more on their trust in us than in an informed consent document. Let's honor that and make this process simpler for everyone!

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