

## ***First poke, then hope...***

I'm a pediatric oncologist who inherited a research project from a colleague. The project involved a one-time phlebotomy draw of 2 to 4 milliliters of blood from a pediatric population aged 3 to 21 years. These research participants are recruited from the regular patient population of our clinic who come for routine blood draws on their medical visits.

The problem we encountered involved the work flow of our clinic. Before our patients arrived, I would review the list of who is coming in that day for regular clinic visits and decide if the patient was eligible for the blood study research project. Very frequently, however, and before I would see a newly arrived patient, a Tech would weigh the patient and draw blood per his or her routine visit. I usually had a very hard time catching the patient before the Tech did the blood draw, so I regularly found myself asking the patient and his or her family member for permission to be enrolled in the study that would then require the unpleasantness of a second venipuncture. Even when I did get to the patient before the Tech did, the informed consent conversation would be rushed and they would have to decide quickly if we could draw some extra blood.

It then occurred to us that if we would simply draw an additional 2-4 milliliters of blood at the time of the Tech's routine blood draw, these problems would be solved. Once the blood is drawn and I subsequently see the patient, I could explain to the patient and his or her family member that we would use some of the blood that had just been taken. If they refused participation, we just wouldn't use their blood in the study. This approach seemed much kinder to the patient in precluding the need for a second venipuncture; the patient and his or her family would not be delayed any further; and having already secured their blood, we thought it more likely that patients would consent to participating. The strategy seemed to present a clear win-win situation. Does it?

## ***Opinion***

This case presents us with a physician-researcher who is enrolling patients in a study that involves one-time blood draws. The research intervention, a venipuncture, seems very modest and can occur simultaneously with the patient's regular blood draw at his or her clinic visit. What might also seem a great moral comfort to the physician-researcher is knowing that after having had an additional (but unconsented) 2-4 milliliters of blood taken with that routine draw, that extra blood will be discarded if the patient subsequently refuses to participate in the study when the formal consent process is broached. So, the patient's right of refusal is seemingly respected. Of course and like all researchers, this physician is under pressure to recruit a sufficient number of participants and doubtlessly believes in the value of his or her study. Given all these factors, it is easy to understand how the physician might justify the "first poke, then hope" enrollment strategy to his or her satisfaction.

Nevertheless, these justifications do not trump the fundamental moral obligation to respect patient autonomy. While there may be a terrific temptation to succumb to the "convenience factors" of the nonconsented blood draw, those temptations must be stoutly resisted. One recalls John Rawls's famous statement on the first page of *A Theory of Justice*: "Each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override." This moral intuition not only serves as the signal restraint on crude utilitarianism (i.e., acting so as to bring about as much satisfaction or happiness as possible for the greatest number of persons), it captures an appreciation of the "otherness" of the potential research participant that, in liberal, democratic societies, foregrounds his or her inviolability. No researcher, no matter how well intentioned, has a unilateral right to breach that otherness. By taking even the paltry amount of 2 to 4 milliliters of the patient's blood without consent, the researchers will have violated the individual's right to control what happens to his or her body. To excuse such a breach, no matter how modest, is to start a slide down a slippery slope whose terminus is the kind of mindset that was representative of our society's most acute ethical embarrassments in research with human participants.

The "inviolability" factor might be especially easy to overlook in this case. Indeed, if the researcher in this case is also the patient's treating physician, he or she might feel extremely comfortable, even entitled, to do so as a derivative of his or her professional authority. Regardless of whatever relational comfort or informality that physician might already have established with previous patients, once they are approached as potential research subjects, their ethical status recalls a Rawlsian "otherness" with all the respect and dignity it deserves.

There is an interesting sidelight to this case that persons familiar with blood draws will recognize. It is that even for routine, clinical blood draws, extra blood is usually taken. Standard lab practices vary, but saving blood samples for a day to a week is common for quality control or just keeping extra blood on hand until one is sure that the lab results are all right, e.g., are readable or if the data are unexplainably strange, extra blood is available for a repeat test.

The standard practice, however, of taking enough blood for a lab test such that some of it is usually discarded does not preclude the ethical concern about the content of the patient's consent: that is, that patients having routine blood draws are consenting to blood analyses for clinical or health-related purposes. The purpose of having additional blood available remains consistent with a clinical, not research, objective to which the patient has consented. If all the patient's blood is not needed, as it usually isn't, then discarding what is left over would be ethically required if the patient hasn't consented to its use for the purposes of research.

Interestingly, the customary drawing of more blood than is generally needed for clinical purposes suggests a "neat" resolution to this case: At the time when the researcher meets with the patient and or family to secure consent to the research study, he or she can explain to them the high probability that some of the blood drawn earlier could be used for the research study. That is, that a certain amount of blood is customarily left over from the lab analysis, but that the patient and or family would

nevertheless have to consent to the analysis of that blood for research purposes. The downside of this strategy might be, however, that if the lab needs all the blood drawn earlier for clinical purposes, then implementing the lab analysis for research purposes will have to wait until the patient's next visit.

Indeed, perhaps discussing the research project with the patient and family when they make their clinic visit but deferring the actual blood draw and the patient's formal consent until their next clinic visit is the best approach. While a downside of this strategy is its requiring some patience on the researcher's part, it would adequately acknowledge the patient's right (or the right of his or her surrogate) to formally and thoughtfully consent or refuse participation in the project. The time afforded to the patient and his or her family to contemplate research participation until the next clinic visit seems an ideal acknowledgment of the patient's autonomous right to participate or not.

Nevertheless, the "neat" approach seems ethical as well: i.e., securing the patient's consent for research use of left over blood that was originally drawn for clinical purposes.

Summary: Although it may seem convenient, taking blood without prior participant consent is not appropriate because it violates the potential participant's autonomy. A better approach is to discuss the research project and then either secure the participant's consent to use whatever blood is left over from the clinic visit for research purposes, or defer both the consent and blood draw until the next visit.

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