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for the Study of Bioethical Issues

TRANSCRIPT

Member Discussion

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SESSION 3: MEMBER DISCUSSION [CONSENT CAPACITY FRAMING AND POSSIBLE RECOMMENDATIONS]

DR. WAGNER: Welcome back everybody. We are back on the record. Our next topic is consent capacity. More specifically, research with participants and care of patients whose capacity to consent might be absent, impaired, fluctuating, or somehow in question.

Neuroscientists often work with such individuals as many of the conditions of neuroscience studies can affect capacity. To generate knowledge about and treatment for these conditions, affected individuals must be included in research, critically, with ethical safeguards in place, of course.

Several ethical considerations arise, broadly. For example, how do we ensure adequate protections for research participants with impaired capacity, what procedures should be in place to assess consent capacity, and how might we address stigma associated with impaired capacity?

Christine and Dan have volunteered—I don't know who is going first. Dan is going first—to kick off our discussion. They have been asked the same two questions that the entire Commission is ultimately asked to consider, and that is, what should we say about this issue in the report; and second, specific recommendations that we might make. So with that, Dan, I'll turn it over to you.

DR. SULMASY: Thanks. And yes, we do have a very difficult act to follow from Steve and Anita this morning. The question, I guess, of capacity assessment has been a big, longstanding one in bioethics. And the advent of clinical neuroscience research does raise the question, as you suggested, because of the need to include patients with diminished capacity or perhaps absent capacity in research.

And so while it raises that question, I think our hope might be, at least Christine and I

would like to suggest to you, is that we think a little bit more broadly about this as an opportunity to think about capacity assessment. We could think about it in the research setting but also think about it in the clinical setting, as well. There are some sort of tools for assessing decision-making capacity that are out there, but they are sort of not universally—there's no one that is very universally accepted. There are no real clear standards for it. Largely, clinical decision-making capacity and research capacity are based on clinical exams of patients. And one of the things that we thought might be very useful in developing better tools would be to actually marry the opportunity of doing clinical neuroscience research with a capacity not only to think about who could be a subject but to make capacity assessment itself one of the subjects of neuroscience research, which we thought would be an important step forward.

To my knowledge, people have not been doing things like functional MRIs or continuous—even something like continuous EEG monitoring of persons who are delirious to sort of get a better assessment of what's actually going on in the brains of such persons and help us to better understand what capacity is from a scientific point of view; how to assess it, how to assess it, again, along the very complicated continuum. Sufficient capacity for what decision? And then if there are ways, how do we improve or restore the capacity of someone who is lacking in decisional capacity?

So, for instance, something that comes up very often in a clinical setting, and can come up in the setting of neuroscience research, as well, is someone who is delirious. Are the points—delirium is actually characterized by fluctuating levels of consciousness and capacity, it seems, at least. And there are some people who think that when the person is in their lucid moments when they're delirious, that they can actually then give consent. But there may be questions about

whether that's true or not, that we might be very much help for if we had a better understanding of what was going on in their brains at the time that they appear to be lucid.

Also, it seems to us that this would be an enormously good opportunity for very interdisciplinary work because this requires law, as there are legal issues in terms of capacity assessment, clinical ethics, neuroscience, and clinical psychiatry. It really takes an effort of all those disciplines in doing that.

And so one of our main hopeful recommendations would be that we will see funding for clinical neuroscience about decision-making capacity in the service of the possibility of assessing that capacity in people who would be subjects of clinical neuroscience research, but with redounding to the betterment of all persons who have impaired decision-making capacity in a clinical setting or in a research setting. So that's at least the part that I thought I'd take, and I'll leave the rest to Christine.

DR. GRADY: So just to—I have some other things I want to add to what Dan said. But just to expand on one thing that he did say, I think in light of the question that you posed, Jim, what should we say, I think that it—just like in terms—just as we discussed before lunch about the need to be clear about what we mean by "enhancement," I think it would be helpful for us to be clear about what we mean by "capacity" and to talk about what capacity is.

There's been quite a bit of literature on this and there have been a number of commissions and other working groups that have done some work on this before. So we need to say, you know, what's the sort of fruits of those endeavors and where can we go from building on that.

A couple of things that I have thought about, and Dan and I talked about earlier, one I think important one is that we focus on capacity to consent because it is an important way to be

able to get people who have diminished capacity into research that might be really important for understanding the kinds of diseases that neuroscience often deals with. But I think we need to also keep in mind that even after somebody consents to a research study or to a treatment in a clinical environment, there's a sort of set of ongoing decisions that need to be made over the course of time and that that also needs some monitoring in terms of ability to make those decisions. So the ongoing capacity assessment.

And as Dan mentioned, capacity, depending on what is the reason that it's diminished, can change. So it can be fluctuating. Sometimes people who can't make a decision at one end of the spectrum of a research study or a treatment might actually regain some of their capacity. And out of respect for them we should include them as much as we can in decision making.

So then I think the other really important things that we can say something about have to do with, in the event that we have determined, with good assessment tools and good understanding of what capacity is, that someone doesn't have the capacity to make a specific decision, what do we do about it?

And in the research context, what we've been relying on are the federal regulations that say, it's not the most perfect protection for someone who can't consent, but to allow a surrogate to make decisions for them in the context of research. And the federal regulations appeal to the applicable law, which in reality or in practice means that every state—the law of every state dictates how one determines who can make decisions for someone who cannot make decisions for themselves. And this creates a very difficult problem across studies that maybe are multi-site but also across, you know, different kinds of studies in terms of understanding what the law allows in terms of research -- in terms of decision-making, surrogate decision-making.

I think a further issue with the state laws is that very few of them explicitly say anything about research, making decisions for research. Most of them are set up as surrogate decision makers for health care decisions. And to the extent that the federal regulatory bodies have made statements about this, they say that, you know, those laws that govern surrogate decision making or legally authorized representatives for health care can, in some cases, be used to make decisions about research. But the question still remains what cases can't they do that? And there's variable interpretations. So I think others have made some recommendations, I think SACHRP in particular made some recommendations about the need for more uniform—either uniform state law about who can serve as a legally authorized representative, or federal guidance on who can serve as a legally authorized representative so that the different state laws don't make a patchwork that's untenable. And so I think we can reinforce that recommendation and suggest that guidance is actually essential on this topic of who can serve as a legally authorized representative.

And I think there's an interesting deeper question, certainly one that goes beyond what the law says, and that is, who should be able to serve as a legally authorized representative for the purposes of enrolling people in research.

And some of the work that's been done in the past suggests that this may depend a little bit on the kind research or the kind of legally authorized representative. So we could probably say more about those two things, as well. I think in the same area, in addition to sort of clarifying the laws on legally authorized representatives and digging a little bit into who should be able to serve as a legally authorized representative for research, there may be some interesting suggestions to make on strategies for decision-making that involve or that are sort of joint

decision-making individuals plus their legally authorized representative in ways that are creative and I think could be legally acceptable but certainly might be ethically preferable.

So the other thing we talked about is that, unfortunately, people who have diminished capacity for a variety of reasons are often misunderstood and therefore subject to some stigma and discrimination. And how might we make some suggestions about what could be done in that area? And I think in keeping with some of the other kinds of recommendations we have made in a number of reports, that certainly one way to address stigma and discrimination is public awareness and public education.

I think in this particular area we might want to think about public awareness, public education, including awareness and education of clinicians and researchers about what capacity means, what diminished capacity means and how it can be addressed; that all of that kind of education might go pretty far, actually, in reducing the amount of stigma that vulnerable people who have diminished capacity might experience. I think that's pretty much all I was going to say.

DR. WAGNER: Thank you both very much. I want to open the conversation. Are there any—I hope we will spend time on each of your recommendations and maybe some others.

What do you folks think are the—and maybe there aren't any—unique challenges for this issue of capacity to consent when it is, or when it involves neuroscience research as opposed to any other form of research where we might have a subject that's compromised?

DR. GRADY: I guess in my view I think for a large part of the neuroscience research, the issues are not probably different. But the fact that neuroscience focuses on people who have disorders of the brain or disorders of consciousness creates a sort of suspicion, I guess, at the front end that they may have less ability to—less capacity to make decisions for themselves.

And I think there's another group that I think we should at least recognize, and that is people who for—often because of neurological disorders, have never had capacity. They never lost capacity, but their entire life they've had developmental issues that have put them in a position of diminished capacity to make decisions. And they are a very special and vulnerable population in terms of this issue.

DR. SULMASY: Just to add something that should be obvious. But generally it's the brain disease itself that is the cause of the lack of capacity for the person, which makes them then the proper subjects for research about that condition, but of course also then makes them particularly vulnerable. And that's the sort of tension we are dealing with.

DR. GUTMANN: Christine and Dan, thanks. It struck me—this is more something that I think it would be worth our observing. It struck me that one of the reasons it's so important for us as a society to have answers to these questions, or as best answers as we can have as the basic BRAIN Initiative goes forward—so this addresses, Jim, your concern—is that once we do get the scientific ability to make improvements as we hope to in the capacity of the brain to function normally, it's going to be incredibly important that we be able to have a clear view as this progresses of what the ethical basis is for engaging people with impaired brain capacity in the research.

So as we've said before, one really horrendous case derails science often for a generation. And if we can avoid that and make sure we have the right -- really the best possible set of guidelines for this, we will be able conversely to make sure that the science moves forward as well as it can move. And so I think research—we have to specify where—I think, Christine, the question would be can you, not right now but as we move the report forward, we get a group, a

subgroup of our committee, to look at what recommendations are already in the literature that we can just echo and ask to run with and where there's still holes and big controversies that need more research to settle.

DR. KUCHERLAPATI: Dan, I like the idea that you proposed about conducting research about capacity, for two reasons. One is, I think as Amy pointed out, that having objective measures of what everybody would agree that scientists and ethicists would agree is great. Then you can apply those five measures across, you know, a lot of people. So that's one good thing.

The second thing that's also good is that I like the idea that this has to be done by neuroscientists and ethicists together, right? Otherwise it won't work. And that this is one of the things that we have been trying to advocate in our *Gray Matters* report. And this sort of brings a specific way, a concrete way in which we can accomplish the goal. And I think that's really great.

DR. SULMASY: Perfect. Thank you.

DR. GUTMANN: Can we say also that in keeping with the earlier discussion, there's a continuum here but there are going to have to be some bright lines drawn in order to implement research, and there never—you know, when you draw bright lines when there's a continuum there are always these gray areas. But you just bring research to a standstill if you can't do that. And if you have uncertainty, uncertainty is the worst possible situation to be in.

So this has a kind of urgency to it as well as an importance to it for the reasons that—and underscore that it has to be—by its inherent and its practical and its ethical nature, it has to be bringing the neuroscience and the ethics together.

DR. KUCHERLAPATI: It also has implications far beyond neuroscience or neuroethics, of all clinical research.

DR. SULMASY: And clinical medicine.

DR. GRADY: It also seems like the tools that the BRAIN Initiative will bring will give us, I hope, more sophisticated ways to understand the brain circuitry and the kinds of -- parts of the brain where capacity to make the decisions is focused. And so our understanding of what capacity is may evolve with the kind of neuroscience that's at least envisioned with the BRAIN Initiative.

DR. HAUSER: This is a question. Obviously the tension here is between an individual's autonomy and their capacity to consent. And the question is, is there something special about clinical research that is different from treatment or financial decision making or other areas where really protecting people against making poor decisions because of a neurological problem is the key question?

DR. SULMASY: Yeah. I think generally people with diminished decision-making capacity have been thought to be of a special, vulnerable population. And so the concerns have always been about the potential for exploitation. So typically people have said that we can guard against this to some extent by making sure that the disease that the person suffers from is the subject of the research if it's going to have some sort of clinical implication, because you could go into a nursing home and find lots of demented people and sign them up for treatment or for investigating something that doesn't necessarily have anything to do with their Alzheimer's disease, et cetera. And people worry about that being exploitive. Whether it is or not is certainly a question. But that's the sort of view that's been out there on the table.

DR. WAGNER: Excuse me, I'm just—

DR. GUTMANN: Just to follow up—

DR. WAGNER: Go ahead.

DR. GUTMANN: —and build on what Dan said, because Steve also asked what the difference between clinical research and treatment is here. And while there's been a concern even for treatment, that if a person is incapable of consenting, or doubtful, is there a surrogate who—treatment has the clear direct intent of—the direct first order intent of the treatment is to help the person. Whereas clinical research, the first order direct intent is to get more knowledge base in order to then see if that protocol actually is able, both for safety and efficacy terms, to go into recognized treatment.

And so you could see why the bar has always been higher there with regard to any subject who isn't clearly capable of full consent. And that the flip side, of course, is—and this is why we don't want to err on one side or the other. The flip side is if that clinical research doesn't go forward, then you don't get the knowledge of the safe and efficacious treatments. But I think—so that's the answer to Steve's question—I think the larger issue that Dan and Christine bring up, or the complication to this—so that's the sort of basis. The complication is there's a range, it's not an all-or-nothing thing with regard to ability to exercise your autonomous choice. And it would be good to have some clear standards, getting to what Raju emphasized on this. We should, we have plenty of time, but we should at some point ask some of the hard—you know, the hard questions that come up here.

DR. FARAHANY: On those hard questions, this, to me, is one of the most challenging and difficult areas that is posed by neuroscience research. And I echo and agree that research is needed. But research is needed in more than just the clinical setting.

So one challenge, especially in the legal system, as a number of different contexts have come up where consent matters—like, for example, some of the interesting research on minimally conscious state versus people who are in vegetative states and the fact that some people may be misdiagnosed in a vegetative state who are, in fact, in a minimally conscious state. That's raised the question ahead of the science of if we can get to the point of testing capacity, what types of rights might individuals who are in a minimally conscious state but accessible for communication via fMRI technologies actually have?

Which means we need to understand capacity to consent and capacity in many different contexts based on the types of decision making that people have to make. And in trying to get to the bottom of this in working with some people in that context, it seems there's been very little work that has been done to try to understand the different capacities necessary for decision-making in different contexts. And something that would be extraordinarily useful, not something we could do but something that I think we could call for, is to try to have a mapping of what are the decisions in different contexts that need to be made; what are the necessary capacities for making those types of decisions; and what type of research could support understanding the capacities that individuals have when they have impairments; and, you know, to what extent can neuroscience help that. This is a mixed question. It's not something neuroscience can answer. It's a mixed question of ethics and legal standards and science. But it is something that neuroscience can certainly bear on once we have done the hard work of trying to say what are the different capacities for decision making necessary, by context.

DR. GUTMANN: Could I add to this that, here again, capacity doesn't capture all that is really at issue, because even if you can—suppose we can establish the capacity of someone to consent. There's also the act of consent. What constitutes an act of consent? And there has to be something specific there because of what's at stake and because of any legal system we operate in, whether you want ours or not, any legal system will have to both establish capacity and establish an act of consent. By "act" I mean that in the broadest sense.

So if you—and I was glad Nita brought this up because this is not science fiction. Even if we know from an fMRI that somebody has capacity, we still have to know what would constitute giving consent. And that's where we need to figure this out ahead of time. You cannot do this on the fly. You cannot have some scientist testify that, "Oh, yes, I've seen fMRIs like this and in nine out of ten cases that person, if fully capacitated, would say yes." You have to have some certain standards by what counts as an act of consent. And that's as neuroscience-y as you get, these kinds of cases. So that answers Jim's question about—at one end, neuroscience raises this in very high relief. And I think it's fascinating and it's important for us to have some research. And the research will have to be clinical research in this case.

DR. FARAHANY: So, wholeheartedly agree. It's not just the capacity consent, it's also what constitutes an affirmative act of consent. But as an example which I think could be useful for us to draw out, because I think examples can be really useful to illuminate this area. So Adrian Owen's lab is one of the labs that has done some of the important work on the differences between people who are in a minimally conscious state versus a vegetative state. And people immediately—and one of the key studies that they did was to ask people a very simple set of questions while they were in an fMRI, who potentially were misdiagnosed as being in a vegetative state, that were simple yes/no answers but that could be answered by imagining

spatial reasoning versus motor reasoning. Imagine walking through the rooms of your house versus imagine playing tennis. And what the immediate response to this was, well, can you ask them whether or not they want the machines turned off?

And of course they recognized that there were significant ethical and other considerations to take into account before you would go there. But one thing that they're doing that's useful is they are doing a number of follow-on studies to see if they can get at capacity for reasoning. And they are getting at capacity for reasoning by doing some simple things like trying to figure out mathematical calculations, if a person can perform, and having measures that they can assess through BOLD responses on an fMRI.

But they've reached out to me and to others to say that's one aspect that we think might be relevant to understanding both the capacity to consent and whether or not we have an affirmative response. What are the other capacities that would be necessary to get at understanding what would competency for decision making in this context mean?

And so it's an area where research is essential because they can start to test the different types of decision making that might be impaired or still available to an individual in that kind of a state. And then we'd have to ask questions like, how do we know if the person has just fallen asleep in the fMRI or if they actually are not answering and what would constitute an act of affirmative consent in that kind of context.

And that's a nice but a kind of "out there" example of what constitutes an act of consent. But I think the work that they are doing gives us a good example, too, of calling for more research that gets at different types of decision-making capabilities and reasonings that a person may have when they might be impaired. That you can answer yes or no to if that's my name and

what my father's name is, may not get at whether or not you are able to still engage in complex reasoning that would be necessary for other types of decision making.

DR. GRADY: I think related to that, probably work at the other end in the sense of, what are the decisions that people need to make and what kind of consent do we need? What kinds of capacity do we need for them to have to be able to make that kind of decision? So I think Nita definitely pointed to this with the yes/no questions versus something more complex, reasoning of some sort.

I think this gets to the heart of Steve's question about the difference between research and care. People tend to think that, you know, what you need to understand in order to consent—to give consent, excuse me—for treatment for an infection you have is different than what you need to understand in order to give consent for a complex research study that might involve a procedure or two that's just totally for research purposes.

And one of the ways that this has come out currently, because there's been some research to show that some people who don't have the capacity to consent by clinical measures, don't have the capacity to consent to certain complex research studies, might still retain the capacity to appoint a surrogate to make decisions for them in this context. And so there's a lot of debate about whether that's okay, whether legally it's okay, whether ethically it's okay. How do you understand those two different capacities as different? And how do you measure them?

DR. GUTMANN: But it's not —what's at stake there is not only the capacity but also where we want to set the bar for—with how much certainty and how high do we want to set the bar for clinical research as opposed to treatment? And there is a very firm ethical route to that distinction between things that directly—people taking risks and being, we taking risks with

people for the sake of directly helping them versus we taking risks with people—and there always are some risks—for the sake of using them to help others, and possibly helping them.

And so I'm in total agreement with what you said, but just add another, again, why we need the ethical part here, which is there will be a decision that has to be made as to where to set the bar, and we ought to know—I think the thing—there will be disagreement in a lot of these cases. But I think there can be no disagreement on how clear and transparent that should be so that people know and can assent or debate it and we can move forward as a society.

DR. SULMASY: Just to add to this, I think, Nita, your cautions are very well placed. In calling for this kind of research we want to make sure that we are not expecting too much of it too quickly, that we caution against the kind of simplistic reductionism: The brain lights up here therefore this person has capacity. The difference between being able to reason versus exercising judgment, the ability to communicate, make a choice and then to communicate the choice, all these sorts of parts of moral psychology that then maybe have physical correlates would be extraordinarily exciting to look at. And—but cautious about how much we can expect how quickly.

And then secondly, to say that there may be, once we have understood these things, then also the possibility to improve neurological functioning along the lines of capacity. So there's somebody—if the lights are on but they can't communicate—say somebody with a pure expressive aphasia, right? We think they understand everything but they can't communicate. If we could find a way to allow them to express the choices they can make through this type of research, that would be wonderful.

So a word of caution and a word of optimism both at the same time, which is probably appropriate for most of what we say about the subject.

DR. WAGNER: Say something about your—I'm sorry, were you going to comment? No, I was going to change the subject.

DR. GRADY: I just want to say something about what Amy just said about setting the bar. I think this is a really important issue and one that's been, I think, debated to some extent before. And it's difficult, because the question is in the context of research, let's just start there, what do we—what kinds of decisions do we allow people to make when they can consent, when they have diminished capacity to consent, or when they can't consent? And that's the question that needs to be answered.

And we have some guidance, for example, with children that we use. Whether or not that's the kind of guidance that would be helpful in the setting of adults without the capacity to consent is something that people have debated. I don't know if we want to go there or not but it's one way to think about it.

DR. ATKINSON: And just before you change the subject on this one, these are such important issues and such important neurologic diseases that it seems to me that this is a little different than children where you want to protect them at all costs pretty much. I mean, that's basically our assumption. And here, there might be ways they could make partial decisions. That they might be able to say, if this much worse is going to happen to me then it would be treated for the disease, because it's three more tests or it's whatever, they might be able to say I'm okay with those three tests. Whereas they couldn't say I want to be part of a clinical trial. I'd be tempted to say that that's okay if you had diminished capacity because I just feel like this is a

research that needs to move forward, and that in general—I guess I'm personalizing this. If I had one of those diseases that couldn't consent, I'd rather be on the side of getting the study done than not.

DR. GUTMANN: So there's a whole—there's the possibility of pre-commitment, right? We all are given the opportunity to pre-commit to organ donation or not. We all have the opportunity to do living wills. I understand how hard it is to get people to do that. But as Alzheimer's becomes more and more prevalent, as these diminished capacity diseases and research that is promising becomes more and more potentially productive, then the cleanest, most ethically defensible way of doing this is through giving people at least the opportunity and encouragement to pre-commit when they—in the cases where they have fuller capacities than they will have later when the research becomes relevant. Now, that's not applicable to all cases, but it's applicable to an awful lot of cases these days, given how much diminished capacity is taking place in later stages of life.

And that has a tremendous amount to recommend itself, both scientifically and ethically speaking. It avoids a lot of the harder issues that there are no easy answers to. But this has the—and people will, of course, change their—their minds literally will change, as well. But it would be very helpful if we develop more protocols that were of the kind of living wills with regard to research.

DR. ATKINSON: If I can just even add to that. It brings the public education piece really into it, into sharp focus. Because I moved from a city, Kansas City, that has a Center for Practical Bioethics. And there, the level of what the background population understands about living wills and early consent and appointing surrogates is very high in that community. To a community that

doesn't have anything like that at all and nobody has any ideas about this, the understanding of these issues is very, very low because bioethics, as a discipline who is out there talking to the public, doesn't exist. And I imagine that my current city is much more like many cities than Kansas City was, than our cities were.

DR. WAGNER: It's interesting. We have done quite a—done a little bit of thinking and work on this issue of how one educates a population about advance directives and other things only to discover that our best educators, best possible group of educators, physicians themselves, seem to be—yeah, physicians is all I can speak to right now—seem to be ill prepared to do that. In fact, often not considering advance directives for themselves, and resisting considering advance directives for themselves. But one could imagine—

DR. GUTMANN: They don't trust each other.

DR. WAGNER: Maybe it's an acknowledgement of defeat. I don't know.

DR. GUTMANN: I don't know, but it's interesting.

DR. WAGNER: If, in fact, we imagine one of the mechanisms, both for this purpose and around stigma, is educating physicians as well as the general public, we may find a different barrier there than we find with the general public. I apologize. Steve, and then you, Nita.

DR. HAUSER: Just one comment here is that I think we had a case that dealt with this earlier, that it's also—we also frequently change our mind, certainly in the clinical context.

DR. GUTMANN: Yes.

DR. HAUSER: And when crises hit we may think differently than we did before. And I think we'll need standards that are flexible enough to balance a prior view with a revised view that is still within the bell curve of reasonableness with respect to some specific health decisions.

DR. FARAHANY: I think the advance directives conversation is a really good one and it's a potentially challenging one in the area of advance psychiatric directives and the differences that they may have between ordinary advance directives.

And I know that there's been some groundwork that's been done on this, particularly Richard Bonnie has done some work at the University of Virginia that's been useful in trying to come up with some frameworks for how you might think about when you can bind your future self and when you could get out of an advance psychiatric directive, what kinds of capacities you would need in order to decline to apply your advance psychiatric directives. Because a lot of times these happen in the case of schizophrenia, for example, where, by the time the advance psychiatric directive may apply, the person may not wish to have the things they have set out apply.

And so here again, there needs to be a lot more study that's done to try to think about the similarities but also the differences that might exist to help set up some guidelines, ethical and legal guidelines that would be useful to look at where there are differences, and to set clear standards to—not just to educate individuals and physicians, but to try to set up a way of understanding where there are some tensions between binding future selves and being able to apply and enforce those directives.

DR. GUTMANN: So let's just move to become more specific with this. There is a possible, I think, an actual moral asymmetry between doing an advance directive that says, yes,

under these circumstances I would want to be enrolled in clinical research, and then when the time comes you still have that view but you have impaired capacity. So if you didn't have the advance directive, it would be a really hard question as to whether you could be enrolled in a clinical trial but now it's not that hard because you have the advanced view and the view. That is asymmetrical with—you gave the advance directive and now you're about—and this is true for organ donations. So you have just been in an automobile accident, you know you are going to die and you say, "No, I don't want my organs—" you have this advance directive that says—"No, I don't want, I don't want it."

Well, that's asymmetrical, I think. You don't do it. I mean, if somebody is still—in the case I just gave, if you still have your full faculties about you, you signed the advance directive but there's no reason to think you're impaired and you're right at the point of giving your organs and you say no, I think it would be—a doctor would be loath to take organs under those situations.

So at least you get half—but some proportion, if we are worried about having ethical bases for conducting clinical research on impaired capacity, at least you have one stream that cuts through some of the worst ethical nightmares that we could have. The other stream, which Steve and Nita are alluding to, still raises important questions and we ought to figure more about that.

DR. FARAHANY: And I wasn't just imagining in the clinical research setting. I was imagining the treatment setting.

DR. GUTMANN: Treatment—

DR. FARAHANY: Yeah. But I think you're right, which is a subject—

DR. GUTMANN: Everything we have said is inter alia for treatment, as well.

DR. FARAHANY: But I think you're right. I think that's great that you could have a pathway forward where you couldn't have a pathway forward before in binding your future self in enabling research, treatment, or other things to go forward.

But there's a difference potentially in this category of refusing treatments that you don't have with a person who is in a car accident and still has mental faculties but doesn't have physical capabilities that has to be fleshed out more in this area. And so I think part of the reason there's been so little uptake in advance psychiatric directives compared to advance directives is because of this uneasiness about applying it, imagining your future self in a situation where you no longer want that treatment option but not allowing that future self to have the ability to make choices that change those decisions.

So I think theoretical foundational work needs to be done in that area. And then again, this goes back to the conversation of figuring out those capacities from neuroscience and being able to inform those capacities as to whether or not they exist at a later time and existing time.

DR. ALLEN: So the last ten, fifteen minutes have been focusing on people who have impaired cognition due to Alzheimer's, dementia, minimally conscious states, accident victims, I assume. But what worries me about—in the consent context also are this category of people who have always been mentally impaired with conditions like schizophrenia or borderline personality disorder or some other such condition, and who can drive cars and have conversations and order food in restaurants but who have terrible judgment. Just terrible judgment. The kind of person who, if you gave them \$10 today, they would spend it today; if you gave them \$100 today, they would spend it today; if you gave them \$1000 today, they would spend it today; \$10,000 today,

they would spend it today; who just don't have a good set of capacities about making judgments that further their own welfare.

And I believe that there are actually a lot of people like this in the world, and we need to study them. We need to better understand people with those kinds of partial—capacity to function in the world, but with a very, very impaired set of judgment skills.

So how do you get informed consent from someone like that? Because they can drive to your research facility, find you on the fourteenth floor of the blah blah building, talk you to about the last football game, but they really have terrible judgment about their own welfare, how to take care of—how to save money for the future, how to plan, how to work a normal work life. They can't do those kinds of things.

But yet—so I'm just wondering, how do we think about consent for research, research on the brain, involving people whose brains are not normal but who have a very, very high degree of functionality in the world?

DR. WAGNER: I think this gets back to one of the first points that was raised. What does "capacity" mean, right?

DR. ALLEN: Yes.

DR. WAGNER: Obviously they are functional in certain ways but not functional—have insufficient capacity.

DR. ALLEN: And the challenge here, these people may not be the kind of people—and believe me I know them and I love them. But these may be the kind of people who—for whom a

proxy solution is not a solution. They will always say no. And an advance directive is inapplicable. So how do we think about helping and researching on that class of Americans?

DR. WAGNER: You know, so much of what's been said over the past fifteen minutes has said we need to study this more, we need to understand the relationship between capacity and the kind of questions, et cetera. Study, study, study, research, research.

A couple of questions. Is that going to feature—should that feature prominently in a report? And secondly, do we imagine that it's a gating issue; that is to say, that as a Commission we wouldn't really recommend using any such subjects until these questions are addressed through research?

DR. SULMASY: I don't think it's either/or, but both/and. I think that there are already—and this is part of what I think Christine was suggesting. We can look back fruitfully at the work of other commissions and places like the New York State Task Force on Life and the Law, SACHRP, and others who have thought about these questions and tried to sort of propose best practices, et cetera, for what we have now, which will be important. Because some of that will be important precisely in advancing the kind research that we would want to do that would get us to have an improved sense of what decision-making capacity is, how we might be able to improve it. And particularly in something as complex as judgment. I mean, maybe we can get the fMRI to light up in certain places and say one and one is two. But judgment, where does that lie within the brain? How are we going to assess that? Those are incredibly complicated long-term issues that deserve some study but we can't study them until we start studying some people who have impaired judgment. So we need to have a sort of starting set of—given the fact that we live in the real world, where we are now, what information we have, the wisdom of others before as to our

recommendations for decision-making capacity to participate in this kind of research. But to improve all of that, we'd like to see some—a good deal of the research be about decision-making capacity itself from a neurologic perspective.

DR. ATKINSON: I'll just raise one issue that I'm not sure I would apply here. But there is a community consent that you could ask for people—usually it's done I think for car accidents and people that are temporarily incapacitated and you can ask for that. I'm not sure that it would apply in any of these things. But if you wanted to break that chicken and egg cycle, there might be a way to do it for people that have impaired judgments.

DR. GUTMANN: Jim, I think it is going to be really important—we said it in an earlier report, but to repeat—when we discuss this, that some standards, defensible standards of content are necessary but not sufficient. And that's very important in answering your question. There's still a level of risk involved that is important and protective. And it becomes all the more important when you are talking about surrogates for people, decision-making.

DR. WAGNER: We are a half hour ahead of schedule. And the question is, do you want to take a break?

DR. GUTMANN: Let's take a break because I'm sure everybody could use it, and reconvene at—

DR. WAGNER: 2:15?

DR. GUTMANN: —2:15. And we'll start the next session at 2:15. Okay? Great. Thank you.