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Perceptions of Academic Health Science Research Center Personnel Regarding Informed Consent Processes and Therapeutic Misconception

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Abstract

Introduction—Instrumentation exists to measure voluntariness and misunderstanding in informed consent processes. However, research personnel's perspectives about using instrumentation to measure therapeutic misconceptions in research participants has not been reported. We designed a workshop to promote research personnel knowledge of emerging instrumentation and to study the perceptions of research personnel regarding such instruments.

Methods and Findings—Two nationally recognized experts who have developed psychometric instruments to measure aspects of informed consent presented their recent findings to research personnel of the Medical University of South Carolina at a one-day workshop. Following the presentations, workshop attendees divided into two focus groups and shared their perceptions regarding the presentation content. Inductive thematic analysis detected themes related to informed consent processes including: investigator/provider role clarity; investigator transparency; therapeutic misconception; and screening subjects for understanding.

Conclusion—Our findings suggest future directions in applied, proactive empirical research to better understand investigator perceptions and practices related to transparency in research, and to develop instrumentation to detect risks to the integrity of informed consent in order to promote voluntariness and autonomy and minimize therapeutic misconception in research practices.

Keywords

autonomy; ethics; informed consent; instrumentation; therapeutic misconception; voluntariness

INTRODUCTION

Recent advances in empirical investigation of informed consent processes include development of scales to measure variables embedded in participant perceptions during research processes (Joffe et al., 2001; Miller et al., 2009). As more is learned about

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DISCLOSURE

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perceptions of participants in informed consent processes, recognition of the risk for therapeutic misconception (TM) increases. The term TM was originally coined to describe research subjects' confusion of the purposes of research with the goals of clinical care. Despite being informed of the purposes and processes of research, particularly randomization, many subjects mistakenly believe that they will receive therapy best suited for their personal needs (Appelbaum et al., 2012; Lidz and Appelbaum, 2002; Henderson, 2011). If research participants indeed believe they will receive the therapy best suited for their needs, this may effect the voluntariness of their consent, as they may feel they have no better choice than to participate. Investigations of TM have focused on potential subjects' perceptions (Gammelgaard et al. 2006; Hoehn et al. 2009) in clinical trial contexts of study enrollment and informed consent processes (Nathan et al., 2010; Pletsch and Stevens, 2001; Stone et al., 2005; Tait et al., 2003). In recent years, empirical research expanded its scope to include TMs of health care providers who simultaneously serve as investigators, finding that they, too, sometimes conflate the goals of research and clinical care (Howard et al., 2012; Miller, 2000; Mueller, 2004). Moreover, the scope of inquiry about TM is widening beyond clinical trials and initial informed consent processes to other contexts. Recent studies identify TM as incidental findings in genomic research sample collection, for example, while others note that TM risks may arise after the consent process and at later stages in a study timeline (Halverson and Ross, 2012; Instone et al., 2008; van der Graaf and Van Delden, 2012).

Against this landscape of TM inquiry, academic health science personnel's perspectives, concerns, and experiences with TM in their research environment remain largely unreported. In September 2011, the Medical University of South Carolina (MUSC) hosted a one-day workshop featuring two presenters with experience in developing methods to detect and quantify TM held by research participants during the informed consent process. The purpose of the workshop was to educate workshop participants about TM and methods to detect or measure it, and to collect and analyze perceptions of workshop participants. The research question driving the analysis was the following one: What themes of concern and interest regarding the informed consent process and risks for TM emerge from the content of perceptions expressed by this group of academic health science center personnel? Thematic analysis and conclusions derived from it inform research ethics stakeholders and suggest areas for future empirical study of strategies to address problems related to informed consent processes, investigator–subject interactions, and risks for TM.

METHODS

Two scientists who developed tools to measure voluntariness and TM in informed consent, Steven Joffe, M.D., M.P.H. (Joffe et al., 2001) and Victoria Miller, Ph.D., (Miller et al., 2009) presented their recent findings to the workshop. After the presentations, workshop attendees were invited to discuss informed consent processes and TM in small group discussions. Moderators guided the groups with Institutional Review Board (IRB)-approved, openended probes. The probes were designed in advance (Table 1). The workshop's registration process included notification of the intent to record discussions and use a focus group format for sharing perceptions, and that subsequent qualitative thematic analysis and publication of findings would follow. IRB approval for focus groups was obtained prior to

the workshop. Protection of attendees' identities in subsequent reports was facilitated by assigning alias names to participants so that individual identities were not linked with the recordings or their transcriptions. Identifying personal characteristics of the workshop participants were not collected; however, all were actively involved in the design and conduct of research as primary investigators, doctoral students, social scientists, and research administration specialists. The participants (n = 10) were divided into two groups of five. Each group's discussions lasted two hours and were audiotaped. A formal informed consent from the participants of the focus sessions was not obtained. Participants were informed of all details of the focus groups, and only those who volunteered to participate were included. Consent was implied by agreement to participate.

Data Analysis

Tapes of the focus group discussions were transcribed verbatim into a Microsoft Word document that was uploaded into NVIVO 9.0 (QSR International, Pty, Doncaster, Victoria, Australia) software, which supported qualitative analysis of the data. Two persons trained in thematic analysis separately prepared the codebooks, coded nodes/categories, refined the categories into subcategories. A shared audit trail was developed to allow each coder/analyst to track the grouping process of the other, and promoted consensus building where and when they independently coded differently. Mutual auditing of the coding and grouping process adds to the integrity of the analysis because it reinforces credibility and validity (Wolf, 2003).

Analysts used iterative, inductive approaches to identify the emergent themes (Elo and Kynges, 2008; Bradley et al., 2007). Initially the analysis took an inductive approach, then reviewed all statements and grouped them according to their reference to explicit research ethics-related terminology or jargon such as "informed consent," "autonomy," or "privacy." Statements containing no explicitly identified ethics-related jargon were grouped for analysis of implicit, latent ethics-related meanings in the statements. For example, statements expressing concern that relationships between research subjects and clinical personnel might evolve into bonds of personal trust, respect, or familiarity over the months and years of a clinical trial were grouped because of the implied risk of compromising transparency in distinguishing research protocols from personalized treatment relationships. In this example, after iterative review and refinement of the grouping statement content, an abstracted meaning for the identified emergent theme became "concern for durability of distinction between research protocol and therapeutic treatment." This inductive analytical process was applied to other statements with distinguishable latent research ethics content (Bradley et al., 2007).

RESULTS

The content of the recorded statements reflected divergent contexts among the participants' research experiences. The statements contained examples of clinical trials with diverse populations and study designs. Examples of contextual settings other than clinical trials are genomic research sample collection in clinical settings and intervention testing in geriatric nursing homes.

The themes identified through content analysis are described in Table 2, with their corresponding abstracted meaning and examples from the data. We found 6 domains of concern and 5 subdomains, and developed 20 meaning abstractions.

DOMAINS

Domain 1: Autonomy

Autonomy emerged as a theme from statements focusing on potential vulnerability of research subjects and their ability to choose to enroll in research without coercion. Focus group participants described coercion as "the use of force" or the "threat of the use of force." Participants were also concerned with the use of the term vulnerability and suggested there be a "more narrow definition of 'vulnerable' so that it doesn't include everything and everybody under the sun."

Domain 2: Researcher Role Boundaries

A major context for the emergent themes was behaviors within the researcher-subject relationship, particularly where the primary investigator is also the subject's physician/provider. Focus group participants defined the roles as separate. "The major goal of patient care is to do whatever is best for the patient. The goal of the investigator or scientific investigation is to advance the knowledge that underlies science and those two are quite different and sometimes incompatible." Focus group participants acknowledged that often the decision of subjects to participate in research is based predominantly on trusting the clinician without fully understanding the distinct dual roles that individual may carry. An example of this is "somebody who is perfectly bright, college graduate, etc., who just is bound and determined that he loves his doctor so much that there's no way that this doctor would ever do anything that would expose him. . . that wasn't for his benefit. . . . doesn't really care about all of the other stuff and isn't really listening, and he's under a therapeutic misconception."

Domain 3: Instruments and Screening Tools

The best uses of instruments and screening tools in the future were believed to be for identification of thresholds for excluding subjects and for determining voluntariness, autonomy, and decisional capacity. "People haven't looked at voluntariness, though, as an outcome, to my knowledge, because there haven't been good measures until now." One focus group participant stated, "What I'd like to see is an investigation of the use of these instruments to identify thresholds for excluding subjects from research projects. . . subjects considered so far from understand what's going on that they shouldn't be allowed to participate." Focus groups agreed that the definitions of voluntariness, decisional capacity, and vulnerability could have gray areas, especially when the clinical trial is particularly complex or when the research subject's cognition fluctuates, such as with early-stage dementia or during extremely stressful conditions.

Domain 4: Research Participant Understanding of Study Purpose and Goals

Research subjects' understanding of the goals and purpose of research was a theme that emerged from some divergence of opinions within the focus groups. For example, all agree

that subjects' understanding is not only essential for a valid informed consent, but also for obtaining high quality data. A focus group participant mentioned, "You can use all of these intensive recruitment and retention techniques, but are you going to end up with a bunch of patients who didn't really want to be on the study or they didn't really understand that study; are they going to drop out? How good's your data? So there's a scientific reason to really care about this." However, eliminating potential subjects from participating in a study based on their lack of understanding of the research protocol was thought necessary by some, but was believed by others to violate the ethical principle of justice. Health literacy was mentioned as another issue in research subject's understanding in the informed consent process, especially with lengthy informed consent forms. As one participant mentioned, "Consent process can be cumbersome, long, and genetic consent are even more cumbersome."

Domain 5: Informed Consent Process

Content also addressed language used in the recruitment and informed consent process. For example, focus group participants suggested that the use of the term "trials" or "therapy" instead of "experiment" might be misleading and, therefore, contribute to the misunderstanding of the differences between standard care and research. One focus group participant mentioned that "very rarely the drug is described as an 'experimental agent' it's typically called 'the therapy'. . . it's potentially a little misleading." The discussion about the informed consent process is consistent with previous research that found potentially misleading language in consent forms and in the language used by research staff (Howard et al., 2012). Not only can this language lead to TM in research subjects, but the language also can be an indication of TM of the research staff. It is interesting to note that the focus groups did not discuss their own possible TMs, even though opportunities for such discussions arose during conversations of blurred relationships and the potential for TM.

The content related to trust in the informed consent process reflected perceptions that even highly educated and healthcare-savvy patients can be vulnerable to misconception that their provider would never recommend research unless it was purely for their benefit. A focus group participant stated, "I think people put so much trust in physicians, it's almost that whatever you tell that patient to do, I would guess that 8 out of 10 times, they'll probably say 'yes.'" The potential for misestimation of benefit vs. risk related to language in informed consent forms is also problematic according the focus groups; "The benefits statements in those consent forms had to be very vague, and so it's not surprising that people should overestimate benefits because nobody actually ever told them that the chance that they would benefit was 5%."

Domain 6: Theoretical Constructs of Informed Consent Instruments

Focus groups discussed the definition and consequences of therapeutic misconception. "It's one thing to believe that the purpose of research is to actually help you versus produce generalizable knowledge, but in terms of that TM2 and the idea of therapeutic optimism and misestimation, I think that's kind of a stickier subject." Hope and optimism were discussed as potential precursors to TM but also as essential elements in research and disease management. Focus groups agreed that "the idea of therapeutic optimism and misestimation,

I think that's kind of stickier subject in terms of how problematic it is, and people hold those beliefs because there certainly is a role of hope in people's coping and adaptation, and I don't think depriving people of that or correcting their perceptions to the extent that you deprive them of hope is a goal that we should have at all." The goal was discussed as "hope with realistic expectation."

DISCUSSION

Content included discussion of future directions for improvement of the informed consent process and the mitigation of TM included education for investigators on transparency and maintaining boundaries between standard care and research. Participants believed that many senior researchers were not formally trained in the protection of human subjects and, therefore, TM may not be foremost on their minds. Increased awareness of transparency related to financial disclosure and in assuring that research subjects understand that when they receive study results they are actually "getting back research data, as opposed to a clinical treatment finding" need to be included in the training of future researchers.

Patient–subject advocates, independent of the research staff, who can assist potential research subjects in navigating through the informed consent process, were also thought to be important for future improvement of subjects' understanding and protection of autonomy. Focus groups agreed that the definitions of voluntariness, decisional capacity and vulnerability could have gray areas, especially when the clinical trial is particularly complex or when the research subject's cognition fluctuates, such as with early-stage dementia or during extremely stressful conditions. Finally, focus groups discussed the best uses of instruments and screening tools in the future were thought to be for identification of thresholds for excluding subjects and for determining voluntariness, autonomy and decisional capacity.

LIMITATIONS

Because this was a convenience sampling of only participants who attended the workshop, themes in the two groups cannot be generalized to represent the perceptions of all research personnel at MUSC or at other comparable health science centers. In addition, because the small sample size reaching thematic saturation cannot be assured. The investigators did not collect demographic or other descriptive data on the participants which may have revealed relevant variables related to their perceptions of informed consent and TM. The description of the emergent themes and reported data collection approach, however, does suggest future aims for empirical study in informed consent and risk for TM.

CONCLUSION

Members of the MUSC academic health science center research community share concerns about transparency, which is needed in the informed consent process to promote potential subjects' ability to distinguish research participation from ordinary clinical care. Lack of transparency can limit understanding, thereby reducing autonomous decision-making and contributing to TM. A related concern is the fragility of role separation: as mutual trust and familiarity grow, the ability of both the research subject and research personnel to maintain

the role distinction may diminish. As the constructs of research and ordinary clinical care are separate and distinct, so should be the roles of investigator and care provider in order to mitigate confusion.

The workshop participants were interested in methods to promote full transparency and to educate junior and senior investigators and research staff in strategies that foster valid informed consent to research participation in a wide range of contexts. Dimensions of autonomy in research participants, particularly understanding of research, were considered a key consideration for human subjects' protection. Continued discussions such as those engendered by this workshop are important in maintaining awareness of the potential for TM and for advancing future research in this area.

INFERENCES

Open dialogue across disciplines, job responsibilities, and levels of research experience may increase awareness of the need to maintain best practices and transparency in clinical trials and other research contexts. Several directions for future research in informed consent and TM are suggested by our study. How might transparency and perceptions about the nature of the investigator–subject relationship fluctuate over the duration of a clinical trial or other longitudinal investigation? What are ethical best practices at the termination of a clinical trial in which subjects must navigate the transition from clinical trial to standard care? The widely shared concerns for participant autonomy and its dimensions imply a need for future research to develop ways to detect risks to the quality of informed consent processes. In this regard, currently available instruments are promising.

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Table 1

Probes for Discussion Group

1	What are your observations, reactions, and concerns about the informed consent process and risks for therapeutic misconception as you experience them with research? Consider including relationships of research personnel and potential subjects during and after the consent process?
2	When we consider the vulnerability of subjects in the research context, how should we use the instruments discussed by our expert presenters to assess voluntariness, decisional capacity, and knowledge of the subject?
3	When (in what context) have you observed a potential subject's autonomy to be a problem, and what was the problem?
4	What concerns do you have about potentially blurred distinctions between the health care provider and the investigator roles, and between the patient and subject roles? When during an ongoing research relationship should the blurring be addressed?
5	How does health literacy influence the consent process, and how can it be addressed?

Table 2

Thematic Analysis of Focus Group Discussions

Domains of Concern (number of statements)	Meaning Abstraction (number of statements)	Demonstrative Quotes
Autonomy (29)	Choice without coercion (13)	• "The way I think of autonomy is pretty straightforward, and that is, having the capacity of, or having the capability of making decisions, making choices, without coercion, which I define narrowly as the use of force, the threat of the use of force-without anycoercion limiting your choices."
Vulnerabi	Participants have characteristics of vulnerability requiring relatively higher-level consideration of protection. (16)	• "Well, I have 2 concerns. One is the use of the term vulnerability. You know, just, in general…in general, I object to the use of the term 'vulnerability.' I'm not sure what it means. Especially as the classification of vulnerability expands…I would like to have a very narrow definition of 'vulnerable' so that it doesn't include everything and everybody under the sun."
Domains of Concern	**Meaning Abstraction**	**Demonstrative Quotes**
Researcher Role Boundaries (26)	Perceptions can blur distinction between care provider and research roles	• "One of my long-term concerns is about the relationship between the researcher and the subject when the researcher is also the care-giving physician for that patient before the patient becomes a subject because I've always thought that there was a substantial conflict between the roles of the scientist and physician, which most people don't really recognize. And that is that the primary goals of medicine and of research are entirely different." • "The major goal of patient care is to do whatever is best for the patient. The goal of the investigator or scientific investigation is to advance the knowledge that underlies science and those two are quite different and sometimes are incompatible."
Subdomains		
PI Transparency can contribute to maintaining distinction between research and standard care boundaries (12)	Disclosure processes for potential conflicts of interest	• "My concern is financial disclosure that occurs at the outset and then over a longitudinal study that goes on for 4 or 5 years, what are our duties to be informing them about financial interest, and financial development, and investment into different things. Is it a continuing obligation from the point of start to the end? Or is it just at the front end? These things concern me."
Sharing Results with Participant (7)	Returning findings to study participants is not traditional part of research communication-risks confused perceptions about shared information	• "But one of the issues that comes up there, and that's another place I see therapeutic misconception being a problem, do participants understand they are getting back research data, as opposed to a clinical treatment finding, and the potential confusion of therapeutic misconception to that individual."
Future Direction to raise Investigator awareness (3)	Reflections on how to promote	"The question of training and educating people to do this well…that has not been taken seriously."
	best practices	• "Senior people themselves weren't trained, so they're not sure how to train the junior people. So I think it's a really important area."
Domains of Concern	**Meaning Abstraction**	**Demonstrative Quotes**

Domains of Concern (number of statements)	Meaning Abstraction (number of statements)	Demonstrative Quotes
Research Participant Understanding of study purpose and goals (23)	Expressing implications of poorly informed consent	• "You can use all of these intensive recruitment and retention techniques, but are you going to end up with a bunch of patients who didn't really want to be on the study or they didn't really understand that study; are they going to drop out? How good's your data? So there's a scientific reason to really care about this."
Subdomains		
Justice (8)	Equitable distribution of the opportunity to be part of research	• "You want to find patients that are going to understand the consent process and enroll them for them to meet your goals, so people who could benefit from the research are being left out, and they don't get a chance to actually participate, I think that would be a concern."
Subdomains		
Health literacy (8)	Understanding medical language as a factor in providing informed consent	• "So the challenges that we have is how do you take the long consent process and redesign it so that it can be lower literacy but still have all of the information." • "The whole idea of health literacy, which to me is more than just reading level, it's all of these phrases that the IRB makes huge."
Domains of Concern	**Meaning Abstraction**	**Demonstrative Quotes**
Theoretical constructs of informed consent instruments (12)	Workshop focus group participants expressing thoughts regarding multiple dimensions to measure	• "… 2 kinds of therapeutic misconception, whether or not you're confused about your benefit, and whether or not you're confused about whether it's treatment or research."
Subdomains		
Hope (3)	Optimism about what can be accomplished by research	• "As far as the people that don't really buy into the therapeutic misconception, and it should not exist at all, and that one example is hope, not squashing hope because that is enormously helpful in the healing process but that sometimes can be a slippery slope." • "Hope with realistic expectations"
Domains of Concern	**Meaning Abstraction**	**Demonstrative Quotes**
Informed Consent Process (23)	Implementing protection has implications for steps in the research process	• "I think that IRBs have gone way overboard and in many different areas, the biggest one I think is in the area of informed consent forms…you know when you get up to 30 or 40 pages, who is going to read those?"

Domains of Concern (number of statements)	Meaning Abstraction (number of statements)	Demonstrative Quotes
Subdomains		
Benefit vs. Risk (4)	Risks different than standard care	• "The benefits statements in those consent forms had to be very vague, and so it's not surprising that people should overestimate benefits because nobody actually ever told them that the chance that they would benefit was 5%."
Contextual Influences on voluntariness (13)	Workshop participants recognize that the approach process can have implications	• "I think if depends on the context and how it's done…same with the use of intensive retention methods…it's again not necessarily manipulative, but there's a sense of…'we're going to keep asking you no matter what', it's almost like harassment I think.
Altruism (4)	Research personnel bring their own motivations and goals	• "A patient was laying down…I just kind of asked him, 'why are you doing this?' and he clearly said to me 'I'm doing this so my grand kids don't have to suffer."
Text Language in informed consent documents (8)	Workshop focus group sharing	• What if we called them 'experiments' instead of 'trials'…whole different thing is we want you to participate in an experiment.
	thoughts about the consent forms	• "Very rarely the drug is described as an 'experimental agent' it's typically called 'the therapy'…it's potentially a little misleading."
Trust (7)	Focus group expressions of perceived status of trustworthiness	• "Somebody who is perfectly bright, college graduate, etc. who just is bound and determined that he loves his doctor so much that there's no way that this doctor would ever do anything that would expose him…that wasn't for his benefit…. doesn't really care about all of the other stuff and isn't really listening, and he's under a therapeutic misconception. He thinks that what the doctor is recommending is for his benefit, just because of his trust in the doctor."
Patient Advocate Role (9)	Ideas about development of potential roles and responsibilities of the investigative team	• "The role of recruiter should fall to someone who is not involved in the study, something like a patient advocate….advises the patient about what's going on, if the patient looks puzzled at some point, takes the patient aside and straightens them out."
Domains of Concern	**Meaning Abstraction**	**Demonstrative Quotes**
Instruments and Screening Tools (25)	Focus group's perceptions of screening potential research subjects' voluntariness and decisional capacity	• "What I'd like to see is an investigation of the use of these instruments to identify thresholds for excluding subjects from research projects… subjects considered so far from understand what's going on that they shouldn't be allowed to participate." • "It's kind a burdensome, especially for…the caregivers I work with are just super stressed out people and…to interject another screen at that point (informed consent) to determine if they really did have…voluntariness and knowledge of the subject…decisional capacity, I would be worried about that."
Subdomains		

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Domains of Concern (number of statements)	Meaning Abstraction (number of statements)	Demonstrative Quotes
Decisional Capacity (9)	ideas about screening research subjects' ability to make informed decision about research participation	• "I think it would be really worthwhile to have a good, sure decisional-capacity screen for me because a lot of times, I have a spouse signing consent…but I wanna be sure that this person is also cognitively able to understand."
Voluntariness (7)	perceptions regarding voluntariness	• "People haven't looked at voluntariness, though, as an outcome, to my knowledge, because there haven't been good measures until now."