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Assessing the quality of democratic deliberation: A case study of public deliberation on the ethics of surrogate consent for research

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Abstract

"Deliberative democracy" is an increasingly popular method for soliciting public input on health care policies. There are a number of ways of organizing deliberative democracy (DD) sessions, but they generally involve gathering a group of citizens, supplying them with information relevant to the policy in question, giving them time to interact with each other and with experts in the policy area, and collecting their informed and considered opinions. As the method has become more widely used, some have questioned the quality of the public input it generates. Although theorists of DD agree that "good" input – i.e., input that is the product of careful and thorough reflection – is an essential aspect of useful and effective deliberation, few have actually measured the quality of deliberative sessions. As part of a DD project organized to help guide policies on the morally complex question of allowing surrogate permission to enroll persons with dementia in medical research, we developed and tested measures of "quality of deliberation." After a brief discussion of the substantive results of our research – survey data from participants in the DD sessions and control groups showed a significant change in participants' attitudes toward surrogate consent – we examine the process by which this change occurred, describing and assessing the characteristics of our DD sessions. We use both quantitative and qualitative data from our DD sessions, conducted in southeastern Michigan, United States, to examine four dimensions of the quality of deliberation: 1) equal participation by all members of the session, 2) respect for the opinions of others, 3) a willingness to adopt a societal perspective on the issue in question (rather than a focus on what is best for participants as individuals), and 4) reasoned justification of one's positions. We demonstrate that DD can be reliably used to elicit

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opinions of the public and show how analysis of the quality of deliberations can offer insight into the ways opinions about ethical dilemmas are formed and changed.

Keywords

USA; deliberative democracy; surrogate based research; research ethics; dementia

Introduction

"Deliberative democracy" is a relatively new and increasingly popular method of soliciting and incorporating public opinion in the policy-making process (Mitton, Smith, Peacock, Evoy, & Abelson, 2009). The goal of the method is to inform, and perhaps transform, the opinions of citizens by a fair, respectful, and transparent interchange of viewpoints and then to use these informed views as the basis for democratic policy-making (Fishkin, 1997; Freeman, 2000). Deliberative democracy (DD) is seen as an alternative to "policy-making as usual," a top-down process that is heavily influenced by expert and interest group testimony. Advocates of DD value public deliberation because it gives citizens the opportunity to articulate the normative assumptions and the values that influence the way "hard scientific facts" are interpreted and used in the creation of policy (Lehoux, Daudelin, Demers-Payette, & Boivin, 2009).

The practice of deliberative democracy is built on normative theory that regards citizens' views as an important and necessary source of public policy. There is a substantial philosophical literature on DD devoted to working out the essential elements and critiques of the idea of citizen deliberation as the basis of governance (Bohman & Rehg, 1997; Chambers, 2003; Elster, 1998; Freeman, 2000). These theories do not prescribe a single method of "doing" deliberative democracy. There are, in fact, several models designed to implement deliberative democratic methods in policymaking: Deliberative Polling (Fishkin, 1997), Citizens Jury (Crosby, Nethercut, Gastil, & Levine, 2005), 21st Century Town Meetings (Lukensmeyer, Goldman, Brigham, Gastil, & Levine, 2005), and National Issues Forums (Melville, Willingham, Dedrick, Gastil, & Levine, 2005). Some policy makers and researchers have adapted and combined these methods in an effort to improve public deliberative input into policy (Carson, Hartz-Carp, Gastil, & Levine, 2005; Kim, Wall, Stanczyk, & de Vries, 2009).

Deliberative approaches are becoming an important tool for those who make health policy. After their study of the use of deliberative processes to generate public opinion data and policy recommendations regarding infrastructure issues (many of which were implemented), researchers in Western Australia concluded "that the processes could work well in health" (Gregory, Hartz-Karp, & Watson, 2008, p. 8). In the past few years DD sessions have been used to address a variety of health policy issues: pre-implantation genetic diagnosis in the UK (Scully, Banks, & Shakespeare, 2006), medical records research within the United States Veterans Association (Damschroder, et al., 2007), biobank research in British Columbia (Secko, Preto, Niemeyer, & Burgess, 2009), and breast cancer screening in New Zealand (Paul, Nicholls, Priest, & McGee, 2008).

Given the growing popularity of DD, it is imperative that we understand what actually happens during deliberation sessions. We know very little about the quality of the deliberations that occur in these sessions. Do participants listen to one another? Do they modify their views after listening to the reasoned views of others? Do the sessions encourage compromise positions, or does the majority simply overrule minority voices? If DD is to be more than window-dressing, more than a polemic exercise or charade to convince members of the public that they have a voice in policy, we must be able to answer questions about the quality of deliberation. We must understand not just the outcome, but the *process* of DD sessions.

The primary goal of this paper is to report on our development and use of measures of the quality of deliberation. To pursue that goal we use data gathered as part of our DD project on the use of surrogate consent to enroll persons with dementia in research. We begin with an explanation of why we chose surrogate consent for research as a target for a DD study. Although we point to some of the ethical issues at play in the use of surrogate consent for research, our focus here is methodological. Readers interested in the ethical issue of surrogate consent should consult our other papers that address the issue (e.g., Kim, Uhlmann, et al., 2009, and Kim, Appelbaum, Jeste, & Olin, 2004). Our case study illustrates how DD methods can be used to address controversial ethical issues.

Our study: Informing policy for the use of surrogate consent to enroll persons with dementia in clinical research

Enrolling decisionally-impaired adults in research based on surrogate permission (surrogate-based research, or SBR) is increasingly common, but it is being done in the absence of widely-accepted policy guidelines (Orgogozo, et al., 2003; Silverberg, et al., 2002; Tuszynski, et al., 2005). With the 'graying' of populations in industrialized countries – and the consequent increase in the number of persons with dementia – the demand for high-quality research on Alzheimer's and other diseases of dementia is acute. This research often requires persons with dementia to become research subjects and yet, after decades of controversy and debate, we have been unable to resolve the ethical problems associated with SBR, including questions of respect for autonomy, protection from harm, and the appropriate use of substituted judgment (Brody, McCullough, & Sharp, 2005; Kim, et al., 2004; Kim, Uhlmann, et al., 2009).

Most would agree that public opinion should inform policies on SBR, but the issue is too complex to explore with standard survey methods alone. For example, Wendler, et al. (2002) used a telephone survey to measure public attitudes about SBR, but their design – asking subjects to respond to one-sentence descriptions of research scenarios – could not sufficiently address the complex nature of the scientific and ethical concepts involved. Similarly, researchers in Quebec – prompted by a unique set of regulations that require a legal guardian for SBR – surveyed public opinion and discovered their results were difficult to interpret. Subjects were asked to choose between different types of surrogate consent (legal guardian versus concerned family member versus a combination of the two) with no measure of respondents' assumptions and concerns in choosing one surrogate mechanism over another. The authors acknowledge that they did not explain or give examples of "serious risks" and "potential benefits" (Bravo, Paquet, & Dubois, 2003). They conclude that their survey offered "little insight into the rationale behind a respondent's answer" (p. 62).

We therefore designed a project to examine the efficacy of a deliberative democracy approach for generating informed public opinion on the ethically challenging issue of SBR. Our study had a quantitative, survey-based component and a qualitative component. We have reported the results of our survey data elsewhere (Kim, Uhlmann, et al., 2009). In this paper we use both quantitative data and qualitative data to examine the quality of deliberation in our study.

Methods

Participants

Our sample was drawn from the population of those who were either caregivers or primary decision-makers for persons with dementia living within driving distance of our deliberation site. Although not a representative sample of the general population, these are individuals who would function as surrogate decision-makers for persons with dementia if SBR becomes the norm. Subjects for this study were recruited using mailing lists of the local Alzheimer

Association (AA) chapter and an Alzheimer Disease Research Center and by advertisements on the University of Michigan research website and in a local AA chapter newsletter. We mailed persons on those lists and provided information in the advertisements, asking potential subjects to contact us if they met the enrollment criteria (i.e., if they were caregivers or primary decision-makers for persons with dementia) and were interested in participating in our study. Of the 212 volunteers we recruited in this manner, 109 were randomly assigned to attend the all-day DD session and 103 were assigned to the control group. Both groups completed a study survey three times: one month before the DD session date, at the end of the DD day (for DD group) or around that date (by mail, for the control group), and one month after the DD date. The survey we used is a shortened version of an instrument that has been validated and used in a previous study (Kim, Kim, McCallum, & Tariot, 2005). The survey elicits respondents' attitudes toward the use of surrogate consent in various types of research on dementia, using four research scenarios of about 120 words each that depict 1) a lumbar puncture study, 2) a randomized clinical trial for a medication, 3) a vaccine trial, and 4) an early phase gene transfer trial (a copy of the survey is available from the authors upon request).

Although hypothetical, the scenarios are modeled after actual research protocols and are associated with varied levels of risk to subjects. Respondents were asked about the use of SBR in each of the four different research scenarios for: 1) oneself (“Suppose you wanted to give a close family member instructions for the future, in case you ever became unable to make decisions for yourself. Would you say you would want to participate in the study?”), 2) for a loved one (“Suppose you have a loved one who has Alzheimer's disease and cannot make decisions for himself or herself. Would you give permission for your loved one to be part of this study?”), and 3) as a social policy (“If patients cannot make their own decisions about being in studies like this one, should our society allow their families to make the decision in their place?”).

Eighty of the 109 (73%) assigned to one of the two DD session days actually attended. There were no meaningful or statistically significant differences in baseline characteristics of the attendees and the control group, measured in terms of gender, ethnicity, age, marital status, financial position, and level of education (Table 1). Of the 103 controls, 98 (97%) completed at least one survey.

This project was reviewed by Institutional Review Board (IRB) of the University of Michigan, and was deemed exempt from formal IRB review, in accordance with U.S. Federal regulations (45 CFR 46.101b). In the US, when studies are declared “exempt,” there is no formal requirement for informed consent: cooperation of subjects in interviews and surveys in exempt studies is regarded as sufficient, albeit informal and implicit, consent.

DD Session

As participants arrived on the day of the DD session (held in April and June, 2007) they were randomly assigned to tables in groups ranging from 6 to 8 persons per table. There were 6 groups on each of 2 session days, and each of these 12 groups was led by a trained facilitator. The facilitators played an important role in encouraging equal participation from participants and keeping the small group discussions (i.e., the discussions among the people assigned to each table) on track with the tasks at hand.

We began the day with a plenary introduction, followed by a small group ice-breaker exercise. Next were two plenary interactive presentations (i.e., audience members were free to ask questions) on “Clinical Research in Alzheimer's Disease” and on “Ethical Issues in Surrogate-Based Research.” A second small group discussion reviewing the reasons for and against SBR followed the two plenary presentations. Extreme care is required to insure that the presentations on clinical research and on the ethics of SBR are balanced and fair. The presentations also must

be audience-friendly and comprehensive enough for informed opinion formation, revision, or refinement. Recognizing this, the research team developed the presentations in consultation with an advisory panel that consisted of a political science expert in deliberative democracy methods, a senior AD researcher, a bioethicist-sociologist, a geriatrician, a director of a human subject protections program at an academic medical center, a qualitative research expert, a gerontological nurse, and a caregiver of a person with AD (copies of the powerpoint presentations are available upon request).

The final interactive plenary presentation of the day focused on the four research scenarios included in the survey described above: a study requiring a lumbar puncture (LP), a randomized controlled trial (RCT) of a new drug, a vaccine study, and a gene transfer study. A third small group discussion followed. Participants at each table were asked to apply what they had learned in the course of the day to specific clinical research scenarios and to reach a group decision, by consensus or majority, for the following question, “If patients cannot make their own decisions about being in studies like this one [referring to one of the four scenarios], should our society allow or not allow their families to make the decision in their place?” The groups were also asked to provide their rationale as to, “Why should surrogate consent be allowed or not allowed?” To maintain balanced expert responses to all questions, the two experts (an Alzheimer's disease clinical researcher and a bioethicist) were available and traveled together from table to table during the small group sessions to answer questions.

Measuring quality

After review of the literature on DD (e.g., Steiner, Bachtiger, Sporndli, & Steenbergen, 2004; Thompson, 2008) we developed four dimensions of quality of the deliberation process: 1) equal participation, 2) respect for the opinions of others, 3) the adoption of a societal perspective on the issue in question, where the deliberation focuses on what is best for society, rather than on what is best for individual participants, and 4) reasoned justification of ideas. Because no single metric can capture all four dimensions, we used a variety of approaches to explore the quality of small group discussions, some quantitative and some qualitative. We used quantitative evidence to measure the first three dimensions of quality.

1. For equal participation we counted the number and length of comments for all participants in the six groups we analyzed. Each time a person spoke was counted as a comment: thus if Participant 12 was speaking, was interrupted by Participant 9, and then resumed her commentary, she was counted as making two comments. Text volume is simply a measure of total words contributed to the discussion.

2. Respect for the opinions of others is a more difficult characteristic to measure. When reading through transcripts it is difficult to tally instances of respect/disrespect. We searched through our transcripts, looking to create a “typology of disagreement,” but we found nothing we could identify as “heated argument,” “stubbornness,” or even “tension.” Of course this does not mean that participants felt their opinions were respected, so we gathered self-report data on this dimension. We asked those who participated in the deliberative democracy session – at the end of the DD session day – to complete a survey regarding their view of the quality of the sessions.

3. Our survey data allowed us to measure the degree to which participants were willing to adopt a societal perspective. Using survey responses, we can compare personal preferences with regard to surrogate consent for research with preferences for social policies governing the use of surrogate consent.

Our fourth dimension – reasoned justification of ideas – is measured via our qualitative data. It is difficult, if not impossible to measure this dimension without examining the content of

the deliberations, the give and take among participants, and the kinds of support they muster for their positions.

Qualitative Data Analysis

In addition to the data collected on the surveys, we digitally recorded the discussions of all 12 small groups, transcribed them, and imported the text into NVivo qualitative data analysis software for coding and analysis (QSR, 2006). We used a systematic and iterative coding method common to qualitative analysis (Charmaz, 2006). Three team members independently coded the transcripts for one group (RU, AS, RdV); the coders then met and agreed upon a common set of codes that was used by two team members (RU, AS) to code six groups. We began our coding using three groups chosen randomly from each session day. During the coding of the fifth group we reached theme saturation; we coded the sixth group to insure that we had not missed novel themes, and indeed we had not. Before analyzing the data, the codes were reviewed by RU, AS, and RdV, and discrepancies in coding were resolved by discussion.

Results

Our survey data showed that DD had a sustained influence on participants' opinions of SBR. When compared to the control group, DD participants became more supportive of SBR from a societal perspective, and this change was sustained after one month. Because the baseline support was already high, this change resulted in very high support (ranging from 76% for the gene-transfer scenario, to 94% for the scenario involving a randomized controlled trial of a new drug) for a societal policy allowing SBR. Among DD participants, a transient increase occurred in the acceptance of SBR for oneself and for a loved one in the lower-risk studies (lumbar puncture and drug study scenarios), but these increases were not sustained. Further, we discovered the change in attitude toward SBR as a societal policy was not accompanied by a change in perceived risk of the studies or an increase in favorable attitude toward biomedical research in general on the part of DD participants. Thus, the sustained change was quite specific for allowing SBR as a social policy (Kim, Uhlmann, et al., 2009).

Policymakers can use our survey data to better understand the informed opinions about SBR held by members of the population responsible for loved ones with dementia. Survey data are also useful for measuring attitudes about the deliberative process and consequences of that process, but these quantitative data do not tell us much about what happened during the deliberations. In order to explore the *process* of deliberation we must look more deeply into the discussions among the small groups.

Measures of quality

1. Equal participation—In all six groups we found participation by all members of the group; in each group there were some who spoke more, some who spoke less (summaries of all tables are available from the authors upon request). In Table 2, we summarize our findings for two small groups; we chose these two small groups from among the six because they highlight some interesting differences between the groups.

Notice that while everyone participates, the number of comments is not always associated with the volume of text contributed by participants. In small group A, Participant 64 makes 15.6 percent of the comments, representing a bit more than 15 percent of the text; compare this with Participant 66, who makes 14.2 percent of the comments, but commandeers nearly 25 percent of the conversation.

Notice also the role of the facilitator. The facilitator in small group A directs the conversation with few words, while in small group B the facilitator makes the most comments and takes the

largest share of the conversation. In general, we believe that facilitators should facilitate and not lead, but we are aware that the composition of a small group will affect the amount of encouragement and guidance a facilitator must provide. Counting comments and measuring text volume are useful ways of measuring participation and of generating feedback that can be used to promote better facilitation (Sarangi, forthcoming).

2. Respect for the opinions of others—At the end of the session day, 79 of the 80 participants (99%) completed a brief survey on the quality of the sessions. When asked, "Do you feel your opinions were respected by your group?" (on a scale ranging from 1 = "not at all" to 10 = "very much") the average (mean) response was 9.4 (SD = 1.0) When asked (on the same scale), "Do you feel that the process that led to your group's responses was fair?" the mean response was 9.7 (SD = 0.7). This quantitative measure shows that the deliberative process was characterized by respect. Nothing in our qualitative analysis contradicts this conclusion.

3. Adoption of a societal perspective—As we noted above, many of those who participated in the DD session changed their minds about SBR policy. Before the session, slightly more than half of the participants (53%) supported a societal policy of family surrogate consent for the most invasive of the research scenarios – a gene transfer study for Alzheimer's disease; after the session that number grew to 75%. This changed attitude was sustained one month later (76%). No change in attitude was found in the control group (see Kim, Uhlmann, et al., 2009, for more detail). Interestingly this attitude shift was not present when DD participants were asked about their personal preferences. When asked if they would allow a surrogate to decide to enroll *them* in a gene transfer study 49% said yes one month before the session, immediately after the session 54% agreed, and one month after the session 45% said yes. When asked if they would use surrogate consent to enroll *a loved one* in a gene transfer study 33% said yes one month before the session, immediately after the session 41% agreed, and one month after the session 36% said yes.

4. Reasoned justification of ideas—We used our qualitative data to see if participants justified their positions by calling on information learned at the DD session, previous knowledge of the subject, or the ideas of other participants – rather than simply asserting, "Because I said so." In the analysis that follows we show the extent to which our participants engaged in a collaborative, thoughtful reasoning process.

Assessing the content of deliberations as a reflection of quality of deliberation

In analyzing the reasoning used in the small group discussions we noticed a tension between the *practical* but abstract need to create a policy to allow surrogates to enroll persons with dementia in research and the *emotional* desire to protect loved ones from pain and suffering. As providers of care to persons with dementia, participants understood well the devastation of the disease and the urgent need to develop new therapies. However, the caregiving role also generated a strong protective urge. Thus, understanding the ethical dilemmas of surrogate-based research in the abstract was fairly easy for participants, finding a solution to those dilemmas was not. In order to explore the reasoning used by participants, we organized their responses into three major categories: 1) the need for sacrifice, 2) the difficulty of deciding for others, and 3) the search for an answer.

1. The need for sacrifice—The presentations of the experts made clear that, like all clinical research on therapies for disease, progress in developing effective treatments for dementia would require research subjects willing to make some level of sacrifice. Caregivers weighed sacrifices that ranged from minor discomfort (a lumbar puncture) to substantial risk (the placing

of modified genetic material in the brain). The participants clearly admired those who had sacrificed to help develop today's therapies:

> Participant 17: You know whether it's open heart surgery or brain … Any of those wonderful things we now take for granted, there were individuals who were the first ones and then it proceeded along with the various stages of a clinical trial and now we just take them for granted…
>
> Participant 60: I can't tell you how many times I thought to myself: Thank God for those people who participated in research. My dad has been on all those medications, and we have definitely seen the difference because he got on them early…How is he still like smiling and doing the things he does? And I think, thank goodness somebody took a risk, signed some papers, because we personally have experienced the benefit of these drugs…They did their part.

But while nearly all agreed that sacrifice is necessary, can caregivers sacrifice their own loved one to develop new therapies?

2. The difficulty of deciding for others—Participants were acutely aware of the moral difference between deciding for oneself and deciding for others:

> Participant 57: I agree with [Participant 60] that I would want to be able to make that decision myself. If someone were to ask me, would you be willing to undergo this? I'd like to be able to say "yes." I would be willing to be … put my life on the line, you know. Patriotic. Some people have to go to war, but I can't send somebody else. You can send me. So, in that sense, I would want to be the one. I don't know if I would be, but I wish I had that kind of moral backbone that I can do that. But can I do that for somebody else?
>
> Participant 21: It seems that we're all talking about this for ourselves. Do you pick up on that? Or, maybe it's just me. That we're all saying that, "Yes, I'd look to do this." My thoughts keep going back to that, too, making the decision just for myself, and I keep trying to push myself in the place of my mother. It was even difficult for me to put my dog down. I felt like I was playing God… I can endure all kinds of things, and I believe that my mother would have wanted to…But, you know, without sitting down and having her say, "Do this for me," I'm not quite sure I would have sacrificed….my mother…even though I believe it is correct.

These attitudes also are evident in the survey results: the data show that in each of the four research scenarios participants were more willing to enroll themselves than they were to enroll a loved one with limited decisional capacity (Kim, Uhlmann, et al., 2009).

Much time in the small group discussions was spent ruminating on the problem identified by participants 57 and 21. Yes, we need research, but how can I possibly subject my spouse, my parent, my sibling – who is already confused – to experiments that may harm them and will likely not offer immediate help? In their struggle with this question, participants revealed several dimensions of the problem of deciding for others.

First and foremost on the minds of caregivers was the need to protect their vulnerable loved one:

> Participant 18: I'm very negative about putting my mom through any kind of pain. At this age and stage of her Alzheimer's, she is 87, I would not let her have a lumbar puncture, but I would be very open to doing the autopsy and letting that happen…
> Participant 26: Not knowing how much pain she might endure because she has really no way of communicating that…I found just dealing with her in her doctors'

> appointments and stuff like that, some things might be painful for her, but she won't tell me, but when I ask her and then it isn't until like a couple of days later that I find out that she was experiencing pain…
>
> Participant 25: My mother…cries when you take her blood pressure because it hurts. She cries when you do her nails because it hurts. If you hit her in the back of her legs when you push a chair under her, she cries. I could never, ever consent to anything as long as she feels that way.
>
> Participant 34: I think, from an altruistic standpoint, that this is a good thing to be able to do this type of research. However, I too would like to be the one to say "no" because I know my wife would not like it.

Several participants suggested that one way to resolve the problem of deciding for others was to look to the character of the person *before* they suffered from dementia.

> Participant 26: I think [Participant 24] hit it on the head earlier that you have to know what type of person your loved one is. Were they the type that did want to do other things for other people? Were they the type that would want to help other people? And then you just have to decide that through your talks with the other family members. You know, what they notice early on if they were that type of person and then … I guess that would be your decision then. Because otherwise…it would be my thoughts and what my morality and ethics are, not hers. So, I would have to talk to my daughter or my brother or mother and say, "What has she said in the past about stuff like that?"
>
> Participant 32: I'm a surrogate for an elderly woman who had only two nephews and they really didn't want to be involved with her care. So, her only recourse, as a long-time family friend, was with me, and I accepted that because she and her husband and I had discussed in some detail what they wanted and what they expected. Knowing her, there again it comes down to the individual person. What would she do if she were able to make that decision? I knew absolutely that she would never agree to it. She was paranoid and suspicious from Day 1 in her life, and there is no way I would have volunteered her into a program.

On the other hand, use of the character of the person as the basis of the decision to enroll (or not enroll) a loved one in clinical research was problematic for some. These caregivers pointed out that changes wrought by the disease made it impossible to use what the person was in the past to make decisions today.

> Participant 71: I think that's one of the drawbacks of thinking…if I fill this form out when I'm of sound mind and body, that in 30-40 years, my husband or my caregiver is going to be able to make this decision for me because I said three decades or four decades ago, "Yeah, go ahead. Put me under the train and let's see what happens"… I can sit here now and say, "I've seen research. I've seen the results of research. I've seen phenomenal things happen because people have stepped forward …so, okay, you can do whatever you want to me, but when I'm 80 years old and you ask me, am I going to remember?" I mean, it's like, "What are you talking about?"

Here we see participants reconciling the "hard fact" that research is critical for developing new therapies with their values related to autonomy, experiencing and inflicting pain, and the particular responsibilities of caregivers. In the context of complex ethical issues that need policy guidelines, these rationales are critical. The use of DD allows researchers (and policymakers) to go beyond public "temperature taking" to the exchange of ideas (with reasons to back them up) needed for informed policy.

3. The search for an answer—We noticed that as the discussion progressed and participants struggled together with the question: "If patients cannot make their own decisions about being in [clinical studies], should our society allow or not allow their families to make the decision in their place?" They began to see beyond their own experience, to see their personal problems in the context of larger societal issues.

> Participant 66: My view is changing a little bit…my view has definitely been affected by just realizing that there have been areas where all of research has been basically halted or projects have been halted because I do feel that we can't make progress without the research. So, my view is starting to be formed a little more concise. You know as long as there's not reasons, selfish reasons for it, if the intent is right, I do feel that for the greater good, as a general rule [SBR] should be allowed, especially if an agreement was made by the person in advance for a specific person and it wasn't the family politics that formed who was the guardian or power of attorney (in general, a power of attorney (POA) is an authorization to act on someone else's behalf in a legal or business matter; in the United States the rules governing POA vary by state).

Notice, however, Participant 66's qualification: "especially if an agreement was made by the person in advance…" Many caregivers felt this way – that decisions to enroll persons with dementia in research should be based on a power of attorney or expression of willingness to be a research subject made before they lost decisional capacity. Many caregivers were hesitant about moving forward without some type of written document from the loved one or some legal appointee, at a point in their life where they were capable of expressing their wishes.

> Participant 17: I think the best thing would be to have a specific advanced directive for research that indicates what types of research you'd be willing to have yourself be a subject of and also who you indicate as the proxy to make those decisions for you when you're unable to before that has an opportunity to develop.

But of course, as one person put it, "Any policy that's set has the potential to limit somebody who didn't have the foresight to do a durable power of attorney. You would have to live under a rock probably to not know that that is a smart idea, but there's got to be millions of Americans who don't do it" (Participant 71).

For most of our participants, a rational way out of this emotional dilemma was the creation of a policy that allows family members to decide whether a decisionally-impaired (adult) loved one should be enrolled in clinical research. This policy solution allowed participants to slip between the horns of the ethical dilemma: it permits desperately needed research but gives family members the power to protect their loved ones.

> Participant 24: I believe, as I did before, that the family has the right to decide if they would like their loved one to be in this study or not. They are the best person who is going to ask the questions.

However, given their experience as caregivers and decision makers, our participants recognized that this policy solution was not perfect. The most obvious problem was getting family members to allow loved ones to enroll in research. Witness this exchange:

> Participant 75: Want my vote? I would allow [SBR], but if I were the surrogate, I wouldn't allow it for my wife.

> Participant 79: …and I think again this comes down to the question: If we don't allow [our loved ones to be enrolled], what are the consequences of not doing this research?

There is also the problem of trust. The caregivers in our study regarded themselves as thoughtful, loving individuals who wanted the best for their loved ones, but how could they be sure that others would be just as loving and thoughtful?

> Participant 23: What about the person who has basically no one and doesn't have the advanced directives? I think that's what we're looking at. Who do you trust if you're in that situation where you don't have family members?

Even family members may not be suitable surrogates. Participant 67 used the story of her parents to illustrate this problem. She explained that her father, who could no longer care for her incapacitated mother, nevertheless refused to let her be admitted to a nursing home:

> My dad couldn't accept the fact that she was really actually at that point dying. So here was the advocate, who cared so much about her and loved her dearly, but … What's your objectivity and what's your knowledge base and what's your emotional state at that time?

Participants also recognized that having the choice of whether or not to enroll their loved one in research added to their burden. Some were quite forthcoming about the burden of choice:

> Participant 28: I guess what it all boils down to for me is that I'm just torn on this issue because intellectually I understand the need to have the research done and believe that this is the only way to find out more about the illness and to bring about some real progress. Okay. I support that; I really do. Emotionally speaking, I don't think I could bear to see my mother suffer.

During the small group discussion where they were asked to come to a decision about a social policy governing SBR, participants grappled with the ethical dilemmas of surrogate consent. Drawing on their experience as caregivers and what they learned in the course of the session day, participants demonstrated a clear understanding of the need for sacrifice, the difficulty of deciding for loved ones, and the lack of easy answers. Their response to the problems of SBR was reasoned, grounded in the values of relationship and care and more abstract ideas about autonomy and beneficence.

Limitations

Our study has several limitations. First, although the internal validity was high, external validity was limited by our self-selected sample. However, AD research tends to rely on similarly self-selected samples (Schneider, Olin, Lyness, & Chui, 1997) and the caregiver-decision-maker samples recruited for this study are highly relevant to the overall debate, because these are the persons likely to function as research surrogates. Furthermore, we have no reason to expect that those inclined *for* or inclined *against* SBR would be more likely to participate. Second, our conclusions cannot be generalized to other settings, such as research in intensive care units. Third, variability in the abilities of facilitators introduces variability in the quality of group deliberation. We believe our selection and training of facilitators reduced this variability; while we noted different levels of involvement of facilitators in group discussions, our analysis suggests that different groups require different levels of direction from facilitators. Finally, although we followed the conventions for qualitative analysis, there is the possibility that our coding scheme suffers from bias and selective observation. The use of two or more coders safeguards against these tendencies.

Discussion and conclusions

Our analysis provides important insights about DD and breaks new ground in the measurement of the quality of deliberations. Our four criteria of quality, derived from discussions in the philosophical and empirical literature on DD, proved useful in examining the process and assessing the quality of DD. Using our work as a case study, we discovered the quality of our deliberations was high. There was broad participation, and participants felt respected during the deliberative sessions. Those who attended the sessions were engaged in the process, expressed strong opinions without being ill-mannered, showed respect for others' opinions,

and justified their own views by using what they learned about the scientific and ethical issues of SBR *and* what they learned from their conversations with others. Most notably, our participants engaged in vigorous ethical discussions tackling the thorniest dimensions of the SBR issue. The deliberations described above – about the need for sacrifice, the difficulty of deciding for others, and the search for answers – demonstrate the seriousness with which participants took their task. The quality of the conversations (and hence our data) and the real struggle to find solutions are evident in the comments and disagreements found in our transcripts.

In work similar to ours, Scully and her colleagues examined the moral arguments used by lay people deliberating on the ethically complex question of "social sex selection" (parents using pre-implantation genetic diagnosis to fulfill their wish for a boy or girl child) (Scully et al., 2006). Like us, they found that ordinary citizens can articulate basic moral norms, question them, acknowledge competing moral considerations, and provide cogent arguments in support of their positions.

Our study provides an important first step in the effort to measure the quality of DD. The four dimensions of quality of deliberation developed here mark an important advance in the use of deliberative democracy methods and open the door for further research on the use and value of deliberative democracy for the creation of health policy.

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Table 1

Comparison of characteristics of subjects in democratic deliberation (DD) group and control group.

	DD Group (n=80), n (%)*	Control Group (n=98), n (%)*	Pearson χ^2 or *t*-test (*P* value)
What is your gender?			
Female	61 (76)	69 (70)	0.95
What is your current marital status?			
Single	11 (14)	6 (6)	
Married	51 (64)	59 (60)	
Divorced	7 (9)	14 (14)	
Widowed	9 (11)	12 (12)	
Other	2 (3)	0 (0)	0.19
What is your age? (in years)			
Mean	58 (SD, 13)	59 (SD, 14)	0.56
Are you Hispanic or Latino/a?			
Yes	0 (0)	1 (1)	0.35
What is your race?			
White or Caucasion	76 (95)	89 (91)	
Black or African-American	3 (4)	2 (2)	
Other	0 (0)	0 (0)	0.88
What is the highest level of educaiton you have completed?			
High school or less	4 (5)	4 (4)	
Some college	29 (36)	29 (30)	
Bachelor's degree	22 (28)	35 (36)	
More than Bachelor's degree	27 (34)	19 (19)	0.68
In general, how do your finances work out at the end of a typical month?			
Some money left over	54 (68)	67 (68)	
Just enough to make ends meet	18 (23)	16 (16)	
Not enough to make ends meet	8 (10)	7 (7)	0.61
Is the persone with dementia for whom you are/ were a caregiver and/or decision-maker living or deceased?			
Living	49 (61)	53 (54)	
Deceased	29 (36)	37 (38)	0.69

Abbreviation: DD = democratic deliberation.

*Percentages of some variables do not total 100%, because not all respondents chose to answer, or because of rounding.

Table 2

Participation metrics.

Participant ID	Comment Counts (%)	Text Volume (% of total discussion)
Small group A		
63	36 (8.8)	10.4
64	64 (15.6)	15.2
65	34 (8.3)	6.5
66	58 (14.2)	24.8
67	37 (9.0)	15.7
68	75 (18.3)	16.2
Facilitator	59 (14.4)	5.9
Unidentifiable	40 (9.8)	4.2
Experts/SK	5 (1.2)	1.3
Total comments	408	**
Small group B		
75	65 (13.5)	11.1
76	46 (9.6)	11.0
77	71 (14.8)	11.0
78	46 (9.6)	10.3
79	85 (17.7)	15.5
80	55 (11.4)	9.1
Facilitator	99 (20.6)	27.6
Unidentifiable	0 (0.0)	0.0
Experts/SK	14 (2.9)	5.2
Total comments	481	**