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A Framework for Assessing the Quality of Democratic Deliberation: Enhancing Deliberation as a Tool For Bioethics

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Abstract

The goal of democratic deliberation (DD) bioethics research is to elicit informed and considered opinions on ethically controversial issues. But the trustworthiness of DD outcomes depends on the quality of deliberations. We provide a framework to evaluate the quality of deliberations and apply that framework to a DD project on surrogate consent for dementia research involving randomly selected samples of the older general public. Using a mixed method approach, we found that participants were very satisfied with the sessions, learned and used new information, were respectful and collaborative, and were able to “reason together” to arrive at societal policy recommendations. Implications and limitations of the paper are also discussed.

Keywords

surrogate consent; dementia; deliberative democracy; quality of deliberation

Deliberative democracy is increasingly and widely cited as an ideal method for soliciting public opinion on controversial policies (Mitton et al., 2009). Methods of deliberation vary. Citizens’ Juries (Crosby & Nethercut, 2005), 21st Century Town Meetings (Lukensmeyer, Goldman, & Brigham, 2005), National Issues Forums (Melville, Willingham, & Dedrick, 2005), and Fishkin’s (1997) “Deliberative Polling” are among the most commonly used forms of deliberation. In particular, deliberative polling has been used for deliberation on a wide variety of issues, including housing shortages in California (Threshold 2008), climate change and immigration in the European Union (EuroPolis, 2009), and educational policy in Northern Ireland (Fishkin et al., 2007; Fishkin, 2009).

Deliberative methods may be especially suited for issues in health care and bioethics (Gutmann & Thompson, 1997; Kim et al., 2009) and are now increasingly used to solicit public input. In Brazil, Health Councils were created to deliberate on healthcare budgeting and planning (Cornwall & Shankland, 2008). In Ontario, a Health Policy Citizens’ Council reviewed the implementation of new health technologies (Chafe et al., 2010), and in the United Kingdom, the National Institute for Clinical Excellence (NICE) relies upon a Citizen Council to review a wide range of bioethical and health policies (Daniels, 2010; Wise, 2010). In the U.S., the Community Forum initiative, funded by the American Recovery and Reinvestment Act of 2009, seeks general public and stakeholder input on comparative effectiveness research related to drugs, medical devices, and other health interventions (Agency for Healthcare Research and Quality, 2010). In its 2010 report on the ethical issues generated by synthetic biology, the U.S. Presidential Commission for the Study of Bioethical Issues recommended democratic deliberation to assess public opinion.

We have used deliberative methods to solicit the opinions of the general public (aged 50 years or older) on surrogate consent for dementia research (Kim et al., 2009; Kim et al., in press). Because the method is relatively new in bioethics, we used a randomized experimental design to measure the influence of deliberation on the opinions of participants. When compared to two types of controls (those who received educational materials but did not deliberate with peers, and those who received no educational materials and did not deliberate with peers), participants in deliberative sessions exhibited significant change in their opinions about surrogate consent for dementia research. Support for a policy of family surrogate consent (regarding four different types of clinical trials) increased significantly after deliberation, with much of the increase sustained one month after the deliberative session (Kim et al., in press).

The goal of deliberation is to generate informed and considered opinion, but if the deliberative process is to be trusted, we need to know more about *what happens as people deliberate*. Surveys of participants in deliberative sessions can measure opinions and changes in opinion, but they cannot tell us fully if those opinions are the result of respectful and informed discussion or are, instead, the result of less than optimal processes. In an effort to improve deliberative methods, we provide a framework to evaluate the quality of deliberative sessions and apply this framework using a mixed methods approach to evaluate our deliberative project on surrogate consent for dementia research.

Quality of Deliberation

Although political philosophers and political scientists interested in the theoretical foundations of deliberative methods have designed theoretical models for determining the quality of deliberation (Chambers, 2003; Fleck, 2007; Thompson, 2008), only a few researchers have conducted empirical studies on the issue (Edwards et al., 2008; Rowe, Marsh, & Frewer, 2004; Steenbergen et al., 2003; Stromer-Galley, 2007; Timotijevic & Raats, 2007; Webler, Tuler, & Krueger, 2001).

None of the models—theoretical or empirical—offers a “gold standard” of deliberative quality. Rowe and Frewer (2000) propose two major criteria to measure the *effectiveness* of deliberation: acceptance and process. “Acceptance” refers to aspects of the deliberation that increase the acceptability to stakeholders and the general public such as representativeness, independence, involvement, influence, and transparency. “Process” describes aspects of deliberation that increase the likelihood of a reasonable and consistent outcome; included here are resource accessibility, task definition, structured decision making, and cost-effectiveness. Timotijevic and Raats (2007), in their evaluation of a food-policy deliberation, also use two criteria for evaluation: process and outcome. Their “process” criteria combines elements of Rowe and Frewer’s “process” criteria (task clarity and resource accessibility) and “acceptance” criteria (representation, independence, and transparency) and add five more: trustworthiness, credibility, group dynamics, efficacy, and fairness. Their “outcome” criteria include transformation in the understanding and awareness of issues, group identification, task-related outcomes, and satisfaction.

Edwards and colleagues (2008) developed a threefold model to assess the quality of deliberation on climate change: input, process, and output. Their seven “input” criteria measure the breadth and opportunity for participation, initial participant inputs (influence, involvement), and logistics. They use no fewer than 26 (!) *process* criteria separated into three categories: dialogue (capacity, bias, solutions, reasoning, questioning, amicability, trust, structural issues), knowledge and understanding (variety of knowledge/learning styles, understanding of materials and others, learning, communication, openness, collectivity, awareness), and process logistics (numbers, information access, inclusivity, pluralistic,

group ownership, power, good facilitation, documentation, and reflection). Their three “output” criteria measure the creation of new discourses, networking, and policy impact.

Only a few researchers have examined the quality of deliberation by focusing on the internal dynamics of deliberative conversations. In their analysis of the discourse within a parliamentary debate, Steenbergen and colleagues (2003) utilize a “Discourse Quality Index” to examine deliberation in terms of participation, the level and content of justifications, respect, and constructive politics. In her content analysis of Pittsburgh school policy deliberations, Stromer-Galley (2007) found six essential elements of deliberation: reasoned opinion expression, sourcing (use of evidence, materials), disagreement, equality, (being on) topic, and engagement. In our previous deliberative study of surrogate consent for research participation (De Vries et al., 2010), we also used a “discourse quality” approach, looking at: (1) equal participation, (2) respect for the opinions of others, (3) adoption of a societal perspective (that is, deciding what society should allow as opposed to what an individual would do), and (4) reasoned justification of ideas.

A Framework for Assessing the Quality of Democratic Deliberation

The growing focus on the quality of deliberation, together with the lack of consensus on how to measure quality, prompted us to develop a practical framework to guide those who wish to assess the quality of their deliberative exercises. We drew on three sources in developing our framework. First, we began with core concepts articulated by most theoretical and empirical accounts of quality deliberation discussed above, including criteria such as equality of participation, respect among participants, “reason giving” or justifying to one another with reasons, among others. These ideas embody key principles of deliberative democracy (DD). Second, we built on (and went beyond) our previous effort at outlining the quality of deliberation among caregivers of persons with dementia (De Vries et al., 2010). Third, we carefully reviewed, in an iterative fashion, the transcripts from our most recent DD exercise (Kim et al., in press). This step was particularly useful in providing insight into specific instances of quality (i.e., instances of both good and bad deliberation) that are possible to detect, within the broad categories dictated by theory. It is important to note that our work in this paper is focused on how to evaluate the quality of deliberation. We are *not* examining the main themes and narratives that emerged from our deliberation; that analysis will be presented elsewhere.

Our framework has three broad domains: process, information, and reasoning (Table 1).

Process

Quality deliberation requires careful attention to both the *design* and *implementation* of the deliberative exercise. We have previously described the important features of design including access to accurate, balanced, and understandable materials, knowledgeable experts, well-trained facilitators, and adequate facilities and resources (Kim et al., 2009). Our focus in this article is whether a carefully designed DD study has been implemented adequately.

1. *Facilitation* is one of the most important aspects of implementation and is key to ensuring the credibility of the deliberative process. Good facilitators keep the discussion moving forward, keep participants on task, encourage participation, and elicit viewpoints from all participants. Good facilitators are also good listeners who avoid inserting their own opinions in the discussion, while managing unanticipated problems and keeping the discussion within the time allotted.
2. *Equality of participation* is a common criterion analyzed in evaluative studies and relates to the fairness of the deliberative process (Thompson, 2008; Steenbergen et

al., 2003). Word counts and “turns taken” by participants are direct and simple measures of participation, but are, of course, qualified by the recognition that perfect equality of contributions is not necessary for good deliberation.

3. *Participant engagement* measures the degree to which participants are engaged in the process, interact with one other, and question and build on others’ ideas. Is there evidence of genuine dialogue and interchange of ideas?
4. *Respect* is an oft-cited criterion of a successful deliberative process (Abelson et al., 2003; Edwards et al., 2008; Steenbergen et al., 2003; Timotijevic & Raats, 2007). Positive group dynamics and amicability— even when there are disagreements— are indicators of a respectful process.

Note that process criteria need not have absolutely clear boundaries between them. Respect embodies another sense of “equality”—i.e., the participants act as equals in the deliberation. True engagement will involve a certain degree of respect among participants.

Information

Democratic deliberation is particularly useful when public opinion is needed on issues that are new, complex, or technical (Kim et al., 2009). Indeed, one of the theoretical strengths of DD is that the participants are given much more in-depth and detailed information than would be the case in opinion surveys. But does that make a difference? Do participants want more information and do they actually use it in deliberation accurately? Thus, the quality of deliberation will critically depend on whether the participants are indeed incorporating this new information into their deliberations.

1. *Use of on-site experts.* Do the participants appropriately recognize when more information is needed, and then seek out further information from the on-site experts?
2. *Use of incorrect information.* It is important to be alert to instances where incorrect information enters the conversation, especially when such incorrect information goes unchallenged or uncorrected by other members of the group or by the facilitator. What impact, if any, did such errors have on the direction of the deliberations?
3. *Learning new information.* This can be measured by assessing unprompted remarks in the transcripts, as well as by self-report questionnaires to assess any change in knowledge. If there are no “I didn’t know that before” moments, it is questionable whether participants have acquired new information and knowledge.
4. *Understanding and application of information.* There are various ways in which participants reveal that they have understood the information they have been given. One example is when participants correct each other. In the act of correction participants illustrate the ability to sort through new information in order to come to a common and correct understanding of the issues at hand. Another indicator of understanding is the ability of participants to make key distinctions important to policy, distinctions without which a proposed policy will not make sense. In general, it is important to assess whether the deliberators are actually using the information presented, and this may become evident in a variety of ways.
5. *Impact of information on opinions.* How does the new information learned affect opinion? This is a more specific instance of using information, but it is worth considering separately because evidence that participants have developed new opinions or perspectives as a result of learning new information can reveal how deliberative methods may work.

Reasoning

An important aspect of good deliberation is the ability of participants to use the resources they have been given to build reasoned arguments (Edwards et al., 2008; Steenbergen et al., 2003; Stromer-Galley, 2007). An essential premise of DD is that persons “reason together” and are able to take up different points of view, as they arrive at a collectively reasoned policy position. Our measures of quality in this domain include:

1. *Justification of opinion* considers how participants justify their positions on the issues discussed. Do they give reasons based on what they have learned? Do they call upon a moral framework?
2. *Openness to complexity* is acknowledgment by participants that there are no simple and easy policy solutions. Deliberative exercises are used to gather public opinion when the policies in question are complicated and in dispute. It is important that participants recognize this complexity and avoid simplistic responses.
3. *Adoption of a societal perspective* reflects the ability of participants to go beyond self-interest to consider the “common good.” Public-spiritedness is critical to the success of public deliberations and often has been cited as an important criterion in assessment (Edwards et al., 2008; Rowe & Frewer, 2000; Steenbergen et al., 2003; Thompson, 2008). Evidence of this attitude can be found in the willingness of participants to take the point of view of a policy-maker, rather than looking at the issue only from how it affects their personal situation.

Our framework provides an efficient way to evaluate the dimensions of quality important to successful and useful democratic deliberation. Attention to the quality of deliberation allows us to see not just the outcome of the exercise, but the process by which that outcome was achieved. We now turn to an application of this framework to our deliberative exercise on the ethics of surrogate consent for dementia research.

Methods

Using the Framework for Quality Assessment

A comprehensive discussion of the rationale for the overall methodology of our study as well as details of the sampling and recruitment procedures, a detailed description of the development of our educational materials by an interdisciplinary panel, and a description of the facilitator training have been previously published in this journal (Kim et al., 2009). The readers can also view the actual educational materials used, the recruitment results, and the detailed methodology at <http://tinyurl.com/DD-methods-PDF>. Our study was reviewed by the University of Michigan’s Institutional Review Board and deemed exempt from federal regulations.

In brief, our study consisted of a general public sample of 503 adults 50 years old and older recruited via random digit dialing (recruitment flowchart available at <http://tinyurl.com/DD-FlowChart>). These subjects were randomized into three groups: a deliberative democracy (DD) session group (n = 212, of whom 160 attended a DD session), an education-only group (receiving educational materials but not attending DD sessions, n = 141) and a control group (no intervention, n = 150). The participants were surveyed at baseline, after the DD session (or approximately around that date for the education and control groups), and one month after the DD session. The results of these quantitative surveys are published elsewhere (Kim et al., in press). The present article focuses on the quality of deliberations exhibited by those who attended the DD session.

PROCEDURES—On the day of the DD exercise attendees were randomly assigned to tables in groups of 5–7 persons per table. There were 27 tables (in two cohorts); each table was led by a trained facilitator. Participants were informed that the group discussions at each table would be recorded. Table 2 describes how the DD sessions were organized.

As described in Table 2, the deliberative session involved three small group sessions: The first small group session was primarily designed to “warm up” the group to the process of group discussion, including an icebreaker exercise and general discussion of reactions to an informational video presentation on Alzheimer’s disease (AD). The second small group session immediately followed an extensive educational session by experts in AD clinical research and in research ethics (presentations are available at <http://tinyurl.com/DD-Presentations>). During this session, the participants were asked to engage in general discussion about the presentations and also about the ethical dilemma of involving decisionally impaired dementia patients in clinical research. They were not asked to provide specific recommendations at this point. The third small group session followed another plenary session in which the two experts discussed four specific research scenarios and answered questions regarding them: a study requiring a lumbar puncture, a clinical trial of new drug, a vaccine study, and a study of a therapy requiring the insertion of genetic material directly into the brain of a subject (Table 3). This third session specifically asked the participants to evaluate each scenario and provide recommendations regarding whether our society should have a policy of family surrogate consent for studies such as the ones described, and to reach a group decision, by consensus or majority. The participants were also asked to provide a rationale for their recommendations.

The experts who gave the presentations on AD clinical research and on research ethics were available throughout the day to answer questions, clarify points of fact, and clear up misunderstandings. Participants were able to ask questions during the presentations, at the lunch break, and during the small group sessions. Because the issue of surrogate consent often involves overlap between substantive questions about dementia and ethics questions, our experts always addressed participant questions together.

DATA FOR QUALITY ASSESSMENT—In order to assess the quality of our deliberative sessions we drew on three data sources:

- *Evaluation of the DD Session by Attendees.* Attendees were surveyed at the end of the day in order to assess their experience of the deliberation day. The survey included eight questions answered on a 10-point scale (1 = Not at all, 10 = Very Much) (Table 4).
- *Knowledge Questionnaire.* We used a 17-item questionnaire (12 multiple-choice and 5 true/false; range of scores 0–17) to test subjects’ level of knowledge (pre- and post-DD exercise) about AD (prevalence, risk factors, course of disease, treatment options), purpose and types of clinical research in AD, regulation of clinical research, and current policy regarding surrogate consent for clinical research.
- *Analysis of Small Group Deliberation Transcripts.* All recordings of the group discussions were transcribed verbatim. One member of the study team read all 27 transcriptions and checked them against the audio recordings to ensure accuracy. Twelve group transcriptions were selected to be coded: six were randomly chosen from the groups that agreed—by majority or unanimous vote—that society should allow surrogate consent for all four scenarios (N = 18), and six were randomly chosen from groups where there was at least one vote (by consensus or majority) to

not allow surrogate consent for at least one scenario ($N = 8$), or where there was a tied vote ($N = 1$).

We used the transcripts to perform both quantitative and qualitative analysis. In order to measure equality of participation and facilitator behavior we counted both the number of words and the number of times facilitators and participants spoke. In order to examine the substance of group conversations we developed a coding scheme building on codes used in a previous study (De Vries et al., 2010). Earlier codes were elaborated using an iterative process in which four study team members (SK, RDV, AS, and another assistant) met regularly to discuss, clarify, and refine code definitions and add new codes as needed. Coding was done by two team members using NVivo qualitative software. Coding discrepancies were discussed and resolved by three team members (AS, RDV, KR). Theme saturation was reached after coding nine of the 12 transcripts; our analysis is based on these nine transcripts (five of which came from the groups that voted to allow by majority or consensus for all four scenarios, and four from groups that voted to not allow by majority or consensus [or were tied] for at least one scenario).

Results

Process

FACILITATION—The boundary between good and poor facilitation can sometimes be difficult to discern. For example, too strong a hand in directing participants—an important function of the facilitator—can inadvertently stifle conversation if not done sensitively. Similarly, a good facilitator should not insert her own opinions into the deliberation, and yet it can be very useful for a facilitator to share personal experiences to open up the conversation.

Table 5 reports how many words and how many times (“turns”) each facilitator spoke. On average, facilitators spoke 22% of the words, not too different from what one might expect given an average group size of six persons (including the facilitator) and given that the facilitators had “required” words that had to be spoken (texts introducing sections, reading questions and scenarios to be discussed, etc.). Closer qualitative inspection of the outliers (the more talkative and the quieter facilitators) offers a sense of whether or not the facilitator was dominating the discussion or encouraging participants to speak. Facilitator 9, the most talkative of the tables that were coded, had two of the quietest participants at her table. In reading through her group, we find her asking questions of participants, encouraging them to explain their reasoning and summarizing their rationales. On the other hand, in reading through the transcripts from group 8, which included the quietest facilitator, our overall impression was that he should have been more active and provided more direction to his group and the facilitation could therefore have been better.

In analyzing our data it became clear that good facilitation is often less a matter of “dos and don’ts” than it is a matter of subtle but clear direction of the conversation. In our qualitative analysis we found many examples of high quality facilitation. Facilitators often directed discussion back to the main topic of surrogate consent:

FAC3: *So I want to bring it back.* You’ve made an interesting point, F15,¹ about when you said . . . , “It’s hard to . . . watch my mother knowing that there aren’t any drugs, even though the drugs wouldn’t help her.” So, . . . can you talk about this

¹In order to protect the identity of participants we replaced names with alphanumeric IDs: F = Female, M = Male, # = participant number; for facilitators, FAC = Facilitator, # = group number. For example, F15 = participant number 15 who is female, FAC6 = Facilitator from group 6.

idea of participation in research and a surrogate deciding when they know . . . that research will not benefit that person, their loved one? [emphasis added]

Facilitators also encouraged reluctant participants to speak more. Noticing a quiet member of the group, Facilitator 9 said: “I haven’t heard much from you. Were there any things about the presentation that really kind of struck you, at least in terms of ‘Wow,’ or ‘I don’t agree?’”

Facilitators often encouraged participants to give reasons for their views. In one example, Facilitator 12 asked: “What would we respond to people who disagree with us? How would we try to convince them of our stance, to make this into a policy?” Another way facilitators encouraged discussion was by restating a participant’s opinion in order to get the group to respond:

FAC10: It sounds to me like you’re advocating for making that happen in some way, but that there is a potential problem with it and that there are some things that could be done to mitigate that. How about everybody else? Do you agree or disagree?

Although rare, there were a few instances in which facilitation was less than optimal. In one case a facilitator allowed a discussion to go on too long, in another instance a facilitator inserted personal opinion, and in a third case a facilitator failed to call on the experts when expert advice was needed. We coded 10 segments for “poor facilitation,” although none appeared to have a dramatic impact on the deliberation.

Overall, the participants had a very positive view of the facilitators: they felt listened to by the facilitators and felt the deliberation process was fair, with an average score for both items of 9.7 out of 10 (SD 0.7, see Table 4).

EQUALITY OF PARTICIPATION—Table 6 below presents a breakdown of participant contributions to the group conversation. The number of words spoken by participants ranged from a low of 296 to a high of 3,999. It is unrealistic to expect perfect equality of contributions given that people are simply different—some are shy, others concise, and others talkative. But it is important to know that the differences in amount of speech are not due to stifling of conversation or dominance by a few. Having qualitative data allows us to look beyond the numbers to the content of the contributions.

We discovered that some participants were able to make their viewpoints known with very few words. For example, F33, who spoke only 750 words and was one of our quietest participants, made clear to her group what she believed (allowing surrogate consent) and gave reasons for her belief (because there are so many people with the disease and something needs to be done, and allowing surrogate consent still preserves patients’ and surrogates’ right to say no). On the other hand, F23, who spoke 3,999 words, did not appear to dominate or overwhelm the conversation; she related the issues to personal experiences and narratives—both of her parents had AD—which required more words; yet she also discussed the problem from a policy perspective.

PARTICIPANT ENGAGEMENT—A reliable sign of engagement is the acknowledgment of one another’s deliberative contributions, a behavior that was very common in our sessions. We coded more than 100 instances of a participant responding directly to a colleague’s comments. In some cases participants expressed agreement:

F31: So I do believe society should allow those persons who wish to be able to make this choice. Because it’s allowed doesn’t mean everybody has to choose it.

F33: I agree with F31, that it should be out there available if that person chooses or the surrogate chooses.

Or they referred back to what another participant said. F50 commented: “I want to go back to what F52 said. It’s got to be through an education vehicle... I didn’t know exactly what the process was of the disease until we had the diagram here.”

In other instances, participants asked each other questions in order to achieve a better understanding. In an effort to better understand the value of advance directives, F28 asked F29 a question about her experience with her mother who was approached to be in a clinical trial: “F28: ...Would it have made a difference to you had your mother, in her healthy days, expressed an interest in research, if you knew where she kind of stood on research?”

These qualitative findings are consistent with the participants’ average score of 9.2 out of 10 (SD 1.1) in response to how helpful they found “discussing the issues with other participants” (Table 4)

RESPECT—The mean response to the evaluation question, “Do you feel that your opinions were respected by your group?” was 9.4 (SD 1.1, Table 4). One situation where respect might be compromised is when people disagree. Does the disagreement degenerate into a stalemate or does it serve to move the discussion forward? In general, we found that disagreements, even when spirited, moved the discussion forward, as in the following “back and forth” interaction:

F23: I can understand why you [support the use of surrogate consent], but I think when you get to individual scenarios, you have to really stop and think...Is there going to be a scenario where the risk is so high that we would not as a society ever want to have a surrogate make a decision? . . . Now let me finish. I can see you’re trying to answer me, but really think about this...Are we ready as a society to say, “Okay. It’s okay to have surrogate consent for a relatively high-risk scenario...” You might be willing to push yourself in a higher risk scenario than you might be as a surrogate.

M20: This is not an argument. This is an exercise from my standpoint. If you and I were married and I was the patient, and there was low risk in research, do you feel that society should let you make that decision if I couldn’t?

F23: Yes, yes.

M20: ...Let’s take it up another notch. I’m the Alzheimer’s patient. I cannot make a decision on my own...There is high risk involved in the research...Should society allow you, my wife, to make a decision regarding my participation?

F23: See, that’s where it gets fuzzy for me because... from a societal point of view, ...it would have to be that proper risk-reward ratio, and I think that would be up to societal debate.

When F23 says, “Now let me finish,” one wonders whether the exchange will remain civil, but then she makes it clear that she is trying to focus the discussion—“but really think about this.” M20 takes the cue and acknowledges that “this is not an argument” and then engages in a back and forth thought experiment in which F23 clearly participates.

We also actively sought and coded for *uncivil* interactions but they were rare. We found only three instances. For example, a participant is sarcastic:

M21: If your son’s death could result in saving millions of lives, you wouldn’t love those people more than you would love your son in order to give him up for others?

M20: I don't think I would be willing to offer my son or daughter to save millions, thousands.

M21: My God did that.

M20: Yeah. Well, I'm not God.

OTHER FEATURES OF PROCESS—No process of implementation will be perfect: unanticipated problems will arise. This was true of our deliberative exercises. We had a few participants who had difficulty keeping up with the conversation because of background noise and their impaired hearing ability. A larger room would have allowed groups to spread out more to reduce noise problems for those with hearing impairment. Time was also an issue. There is a need to balance time for presentation of materials and time for thoughtful deliberation. In a few instances experts had insufficient time to answer questions from participants, and some groups had to hurry their deliberations at the end of the day, but in no cases did a group fail to complete the assigned tasks.

Information

USE OF ON-SITE EXPERTS—The participants frequently sought out further information. They asked a number of questions in the plenary and small group sessions. There were specific questions about the four scenarios and questions about the biological and social aspects of dementia, policies in other countries, the difference between consent and assent, the welfare of patients, and advance directives. Our experts answered questions for 11 of our 12 groups and they visited nine of the groups more than once during the course of the day. Here is a typical exchange:

FAC9: What if somebody . . . I guess this is in the case of later stages of Alzheimer's and not being able to communicate that they're in pain so that they would be able to say, "Stop." In some cases people are hypersensitive, but in other cases . . . Are there cases where people would not be able to communicate?

EXPERT1: That's a great question. This came up [in several groups]. In general, the research in this field [involves] much milder patients, so that people, a year from the beginning of the study, can still say whether they have pain or not. But let's just say that you enrolled somebody who then progresses rapidly and they're 12 months into the study and they're not speaking . . . Probably in most drug trials, they will drop out because a requirement for doing the clinical trials of drugs is that they be able to speak and express themselves because that's what our testing is based on.

USE OF INCORRECT INFORMATION—In order to ascertain if participants were using false information in their deliberations, we looked for instances where inaccurate information was given by a participant (or a facilitator) and was not corrected at the table or by calling on one of the experts during the small group session. Because we had difficulty identifying instances of uncorrected factual errors (as they were so rare), we took a conservative approach so that statements that *could* be regarded as potentially incorrect were brought to the coding team meeting. We identified only six instances of potentially false information that went uncorrected. After further review by the team, we found only one unambiguously incorrect statement (regarding living wills covering research participation) and this occurred during the first small group session prior to the two expert presentations. Of the remaining five, two were found to be factually correct in context and three were too ambiguous to be categorized as "incorrect information." This is not to say that there were no instances of incorrect information or beliefs. For example, we coded 94 instances in which incorrect or misleading information was corrected or clarified by facilitators, experts, or

other participants. Also, our analysis could not account for incorrect beliefs that were not stated or, indeed, those that may have persisted despite correction.

LEARNING NEW INFORMATION—We examined both unprompted mentions in the transcripts that indicated that the participants had learned important new information as well as prompted (via a 17-item Knowledge Questionnaire) self-reports of learning.

In each of the groups, participants indicated that they had learned something new. We discovered, for example, that most participants in our sessions seemed to have known very little about the system of human subject protections that oversees clinical research. This exchange was typical:

FAC5: So was that the first you had heard of an

IRB? Have you all heard of or understood the role or knew about the IRBs before today?

M27: I have never heard about the IRBs until today.

FAC5: And most of you are shaking your head “no.”

Most participants knew something about Alzheimer’s disease, but our information session added to that knowledge. For example, F45 commented: “Well, I didn’t know Alzheimer’s disease was so common, so prevalent. I really thought it was less common than it appears to be.”

The participants in our DD session increased their understanding of ethical, scientific, and clinical aspects of AD research as reflected in their performance on the 17-item knowledge questionnaire. They showed significant increases in mean scores from Survey 1 (11.5 ± 2.6) to Survey 2 (14.5 ± 2.3 , $p < 0.001$) and Survey 3 after 1 month (14.1 ± 2.6 , $p < 0.001$) (Kim et al., in press).

UNDERSTANDING AND APPLICATION OF INFORMATION—We found evidence of participant comprehension in exchanges where participants corrected each other, sorting through the information presented and coming to a common and correct understanding of the issues at hand. This exchange, where two participants help each other see the difference between personal preference and social policy for surrogate consent, is typical:

F65: ... you’re thinking of your parents. You’re not thinking of John Doe’s parents, and he may have a totally different view than you do ... Do we let him have his opportunity to have this done? Do we allow it to be part of the treatment if he chooses to have it?

M64: So if everybody here says “no, don’t do it,” that means John Doe can never have the right to do it.

Further evidence of participant understanding is found in the ability to make distinctions important to surrogate consent policy. In this example, a participant confirms what she learned about the importance of gaining *assent* from a research subject who is not capable of giving consent:

F31: ...When they came over to our table previously, they also said this is not talking about a situation where a surrogate would say “yes,” and the patient would say “no.”

F35: Right.

FAC6: So, right.

F31: Because they would be disallowed if the patient said “no.”

FAC6: Right, right, right. Exactly.

F31: So we’re not taking a protesting patient and a willing surrogate.

In all groups we found that participants were able to recall and use material from presentations in their deliberations. Here a participant, F41, calls on the presentation about the history of research abuses to inform her thinking about the risks of research and the protections that exist for research subjects today:

F41: I guess I have faith in how it was described earlier in how it went through these different boards and getting the study approved. I mean I put a lot of faith in that system.

M36: Right.

F41: So there aren’t those Nazi doctors and some of those other things that we saw earlier. So, therefore, I have my confidence in that there aren’t going to be butchers out there cutting open peoples’ heads . . .

Another type of evidence of participants’ understanding was when they were able to use concepts they learned using analogies. We found participants using the information they had learned to develop analogies that helped in making their points. Here a participant describes how organ donation and surrogate consent for research are different:

F35: Like if you’re donating an organ, you already know exactly what you are going to be doing and you’ve weighed the ethical question out. I think [the expert] is saying that when it comes to research, you don’t know what they’re going to be doing, and so you don’t know if you would have agreed with it ethically or not.

IMPACT OF INFORMATION ON OPINIONS—We also found several instances of participants changing their minds or developing new perspectives as a result of what they had learned.

M63: I think I’ve changed my mind because of all of the discussion we had. [She] brings up a wonderful point. It’s not whether or not I would allow that for my mother. It’s whether or not I would allow other people to make that decision for their loved ones.

In another instance, a participant describes a “lightbulb moment”:

F23: Right, right, exactly. . . . I’m having my lightbulb moment here, that that would really help me be comfortable saying . . . assigned this responsibility to surrogates overall because the patients are not at end-stage Alzheimer’s. They’re at mild or sort of early moderate stages of Alzheimer’s where they are assenting or not, and if they’re saying “no” . . . If the patient is saying “no” and can’t cooperate, then it doesn’t matter what the surrogate says. It’s not going to happen. So I just had my lightbulb moment, and that really does add a comfort level to me of giving the surrogate this responsibility to give the final okay because the patient is also participating in the “yes” decision.

Reasoning

JUSTIFICATION OF OPINION—In seeking to discover the reasoning behind participant opinions—changed and unchanged—we looked at how participants justified their points of view. Here, a participant who is voting against a policy that would allow surrogates to decide if a person with impaired decisional capacity should be enrolled in a vaccine study

explains her position by referring to the adverse events that occurred in an earlier vaccine study that was described in that research scenario:

F15: I look at the 6 out of 18 persons that have permanent problems. Out of 300 people, 18 developed brain inflammation; 6 of the 18 had permanent problems—seizures, headache, vomiting. To me, that's a little high risk, and I'm going to go with M14. I don't think society should allow surrogates to make that decision.

And here a participant supporting the use of surrogate consent for a study involving a lumbar puncture justifies her vote by appealing to the societal benefit of research:

F47: Why should surrogate consent be allowed? I believe it should be allowed for the betterment of the future as well as the fact that we have to go forward in learning about this disease and being able to cure it. At this point, we don't have a known cure, but this will be the start of one. That's why I believe that it should be allowed.

OPENNESS TO COMPLEXITY—The issues around surrogate consent for dementia research are complex. Good deliberation on this topic must take that complexity into account. In our sessions we discovered a recurring pattern on a topic that provides an illustration of this concept. In our DD sessions, some participants initially sought to simplify the complexities of surrogate consent by advocating advance directives: Why not require everyone to fill out an advance directive specifying their wishes about research participation? But in most cases, as the groups deliberated, they recognized that advance directives have important limitations. For example, one participant states:

F39: Requiring research advance directives would be ideal, and more education might bring more people to do that, but in reality, it's a very small percentage as far as how many people actually go through . . . Everybody knows they should have a will. Everybody knows they should have a durable power of attorney, but very few people . . . percentage might have it.

Further evidence of the appreciation for complexity is found in the ability of participants to discuss both sides of an issue. We found several examples of participants discussing both the burdens and opportunities from the perspective of a surrogate having to make a decision for a loved one:

F22: I think a con [of surrogate consent] would be in the event that something happened... You give your consent for, you know, your loved one to participate and something happens to that person as a result of the experiment, and then you have to deal with the other family members who say, "Well, you shouldn't have done it." And now they're going to blame you for being...you know, for giving the consent, *but then conversely*, what if it helps? If it improves the life of the person, you know, then you've given them an opportunity to spend more time with the family or to be around the family a little bit longer. So, you know, that's a pro. So, you know, I think having to deal with consequences might be the hardest of the cons if something goes wrong." [emphasis added]

ADOPTION OF A SOCIETAL PERSPECTIVE—In our deliberative exercise, we asked participants to adopt a *societal* perspective on whether to allow surrogate consent for research. We asked them to think about what they would want to tell policymakers. This was no easy task for some participants who had to be reminded they were not making decisions for a family member, but about the permissibility of a social policy that would *allow* surrogate consent (or refusal). Here a participant struggles to balance the need to protect

decisionally incapacitated adults with the need to make progress against a devastating disease:

F30: I guess, again, what my concern is partially based on is that I think that even though...you're talking about policy...in order to have the right kind of empathy for the patient, you have to put yourself in their shoes and realize that...they're going to become confused and they're not going to know what's going on with them.

Here a participant emphasizes the social value of a policy allowing surrogate consent for research:

F44: ...the conclusion that I came away with is that if surrogate...consent does not become acceptable in this area, that there will essentially be no meaningful Alzheimer's research. It seems like that would be a train wreck for our society. So it seems as though we almost have no choice but to have some form of surrogate consent...

Discussion

Democratic deliberative methods are becoming an increasingly important tool for gaining public input on health policy and bioethical issues. As we noted in our introduction, the U.S. Presidential Commission for the Study of Bioethical Issues identified democratic deliberation as one of the five basic ethical principles for assessing emerging technologies: in their report, commission members describe democratic deliberation as an inclusive process of “respectful debate” that is “informed by relevant facts and sensitive to ethical concerns” and encourages participants “to adopt a societal perspective over individual interests” (Presidential Commission for the Study of Bioethical Issues, 2010). We agree that DD is indeed a useful tool, but absent standards of quality for DD exercises, and methods for assessing that quality, DD is in danger of being criticized as an exercise in persuasion rather than solicitation of informed opinion.

Overall, our results show that the quality of deliberation in our DD sessions on surrogate consent for dementia research was quite good. Using self-report, a knowledge measurement, and a thorough analysis of the session transcripts, we found that participants were very satisfied with the process and content of the sessions, learned new information and used that information in sophisticated ways, dealt with each other respectfully and collaboratively, and were able to take up a societal perspective and “reason together” to arrive at policy recommendations as a group. There were remarkably few negative interactions. It was also clear, however, that these are very human processes complete with all the imperfections of human interaction. For example, the great disparity in the number of words spoken and turns taken indicate that the idea of “equality of participation” cannot be captured by the expectation that all laypersons, regardless of personality and style, will engage in equally verbal ways, suggesting that the principle of equality of participation needs to be assessed in terms of “equality of opportunity of participation.” This will require qualitative analysis to capture the substance and force of participants’ comments.

There are several limitations to the work we present here. When using transcripts for analysis the tone of the conversation is lacking, allowing for misinterpretation. A comment that looks benign in print could be delivered in a sarcastic tone of voice. One solution—although costly—is to have the transcriptionist include comments regarding tone in the transcripts. We did, on occasion, go back to the tapes to determine if comments were hostile or sarcastic. As we noted above, one of us listened to all the tapes (to determine accuracy of transcripts) and did not find any striking examples where tone changed the meaning of words recorded. A second limitation is that we used only 9 of the 27 transcripts for our

qualitative analysis, allowing for the possibility that these were not representative. Our decision to stop coding after nine groups was based on theme saturation. After coding seven groups we were not uncovering new codes or finding that group discussions varied widely from the groups already coded. We coded an additional two groups, which confirmed saturation. Third, although we actively sought out instances of negative interactions or incorrect information (and found very few), there were instances of less than optimal facilitation, as when a facilitator at a table was, in our opinion, too passive. Fourth, in developing codes for quality of deliberation, we are at risk of being biased toward finding the presence of something rather than finding an absence of an event. The impact of this inevitability is not known. Finally, there is an inherent conflict in those who design and implement a DD study also conducting an evaluation of its quality—as we have done here. Although it would require more resources, an independent evaluation would, other things being equal, involve lower potential for bias.

Best Practices

Our work has important implications for those who use deliberative methods and for those who evaluate research designs and policy proposals that include these methods. The best practice for deliberation—especially at this early stage of its use in bioethics—must include an assessment of the quality of the exercise. Lacking such assessment it is not clear that deliberation is delivering on its promise to provide informed and reasoned public opinion. We recognize that it can be difficult to add an evaluative component to the already complicated logistics of democratic deliberation. It will be relatively easy to add survey components to a deliberative exercise—our self-report evaluation (Table 4) and knowledge questionnaire were not burdensome for participants to complete and were easily analyzed—but these should be supplemented by at least a minimum of qualitative analysis that gives insight into the substance and quality of participant interaction.

Research Agenda

As the interest in deliberative methods increases, we hope that research on the assessment of its quality will also grow. There are several questions that need exploring. Is it possible to develop a “standard” method of DD such that the quality of its output can be reasonably assumed (without a qualitative evaluation each time), after validation of a few studies using that method? This is important because a thorough, tailored quality assessment, as we have conducted above, is a heavy burden that could potentially impede the progress of research using DD methods. A related question is: What is the essential, minimal set of considerations that need to be included in a deliberation quality assessment? Again, a practical and manageable evaluation scheme will be needed if DD methods are to be used more widely. In general then, we welcome future studies that examine new methods for assessing quality of deliberation and encourage studies that can streamline costly (but necessary) qualitative evaluations.

Educational Implications

As we have discussed elsewhere (Kim et al., 2009), external validity (or generalizability) of a bioethics study is readily measured and understood, but internal validity (whether the study truly measures the phenomenon of interest) is too often neglected. One educational implication of DD research is that it can raise awareness among “consumers” of empirical bioethics research (such as policymakers, bioethicists, and IRB members) regarding the importance of examining internal validity. DD researchers in bioethics thus have the opportunity not only to answer questions that naturally arise from the novelty of the DD method but also to educate others about why, for some bioethics questions, a thorough

evaluation of internal validity is crucial and why an assessment of the quality of deliberation is particularly important.

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TABLE 1

A Framework for Assessing the Quality of Democratic Deliberation.

Process	Facilitation
	Equality of participation
	Participant engagement
	Respect
Information	Use of on-site experts
	Use of incorrect information
	Learning new information
	Understanding and application of information
	Impact of information on opinions
Reasoning	Justification of opinion
	Openness to complexity
	Adoption of a societal perspective

TABLE 2

Sequence and Content of the DD Session Day.^a

Plenary Introduction	<ul style="list-style-type: none"> • Lay out agenda for the day
1st Small Group Session	<ul style="list-style-type: none"> • Icebreaker exercises • Video presentation of background on Alzheimer's disease • Discussion focusing on reactions to the video
1st Plenary Session	<ul style="list-style-type: none"> • The audience is encouraged to ask questions during and immediately following each presentation. Each presentation along with questions and answers takes an hour, for a total of two hours of interactive plenary presentations. (Presentations available at http://tinyurl.com/DD-Presentations) <ul style="list-style-type: none"> – Presentation and Q&A: "Alzheimer's Disease Clinical Research" – Presentation and Q&A: "Ethical Issues in Surrogate-Based Research"
2nd Small Group Session	<ul style="list-style-type: none"> • Participants are given a chance to reflect upon and discuss the two plenary presentations. This allows for reactions and corrections to each other's understanding of the materials presented and to discuss the overall ethical dilemma of surrogate consent for dementia research.
2nd Plenary Session	<ul style="list-style-type: none"> • Question and answer session with the two experts, framed around the scientific and ethical issues regarding the four research scenarios (lumbar puncture study, new drug randomized clinical trial, vaccine study, gene transfer study).
3rd Small Group Session	<ul style="list-style-type: none"> • Participants are asked to reach a group decision for each scenario, by consensus or majority, by answering: "If patients cannot make their own decisions about being in studies like this one, should our society allow or not allow their families to make the decision in their place?" The groups are also asked to provide their rationale: "Why should surrogate consent be allowed or not allowed?"

^aTo maintain balanced expert responses to all questions, the two experts (AD clinical researcher and bioethicist) are available and travel together from table to table to answer questions throughout the day. Breaks and meal times are not shown.

TABLE 3

Four Alzheimer's Disease Clinical Research Scenarios Discussed During Deliberation.

Scenario 1: Lumbar puncture study	<p>Researchers want to study the fluid that surrounds the brain in patients with Alzheimer's.</p> <p>The fluid is removed by a process called a lumbar puncture. In a lumbar puncture, a doctor inserts a long needle through the lower back into the spinal canal. The patients are given numbing medicine but they may experience a small amount of pain. About 5% of patients get headaches that go away with Tylenol. About 1% get a severe headache that requires a procedure which involves inserting a needle into the lower back again.</p> <p>The study will not directly benefit these patients. But it may lead to better understanding of Alzheimer's disease that may help future patients.</p>
Scenario 2: New drug study	<p>Researchers want to test a new drug to see how well it treats Alzheimer's disease. One half of the subjects will receive the new drug, and the other half of the subjects will get a sugar pill (that has no drug in it). The subjects will be randomly assigned (by chance, like flipping a coin) to get either the drug pill or the sugar pill. The new drug can cause upset stomach in some people, and in rare cases, bleeding in the stomach.</p> <p>The study may benefit some of these patients if the drug proves to be safe and effective. On the other hand, the drug may not work and it has the risks mentioned above.</p>
Scenario 3: Vaccine study	<p>Researchers are developing a vaccine for Alzheimer's disease. It involves getting one shot every three months (for a total of five shots) and two lumbar punctures (in which a long, thin needle is inserted into the lower back to obtain fluid from the spinal canal).</p> <p>In a previous study, 18 out of 300 persons (or 6%) who got the vaccine developed brain inflammation. This brain inflammation caused one or more of the following symptoms: confusion, headache, sleepiness, vomiting, seizures, and difficulty with balance and speech. Seven of the 18 persons had permanent problems.</p> <p>However, in 60 out of 300 persons (or 20%), the vaccine seemed to help their symptoms slightly.</p> <p>Researchers have now changed the vaccine to try to make it safer.</p>
Scenario 4: Gene transfer study	<p>Researchers want to begin testing a treatment for Alzheimer's disease where doctors insert genetic material (DNA) into the brains of Alzheimer's patients using brain surgery.</p> <p>This is to be the first study of this kind involving humans, and the main purpose is to test its safety in just a few people, before moving on to larger studies.</p> <p>One risk of brain surgery is a 1–4% chance of bleeding into the brain. This is usually minor, but rarely it can cause serious harm. It is possible that gene transfer could make Alzheimer's symptoms worse, cause brain tumors, or cause brain inflammation.</p> <p>No one knows how likely these risks are.</p>

TABLE 4

Evaluation of the Democratic Deliberation Session.^a 1 = Not at all, 10 = Very Much. DD Attendees (N = 160).

	Mean (SD)
1. Do you feel that your opinions were respected by your group?	9.4 (1.1)
2. Do you feel you were listened to by your facilitator?	9.7 (0.7)
3. Do you feel that the process that led to your group's responses was fair?	9.7 (0.7)
4. How willing are you to abide by the group's final position, even if you personally have a different view?	8.8 (2.3)
5. How helpful did you find each of the following:	
<i>Question and answer interaction with experts</i>	9.3 (1.1)
<i>The formal presentations given by the experts</i>	9.5 (0.8)
<i>Discussing the issues with other participants</i>	9.2 (1.1)
<i>The video portion of the presentation</i>	9.3 (1.2)
6. How much did attending the session change your <i>understanding</i> about the ethics of research involving people with dementia?	8.2 (2.2)
7. How much did attending the session change your <i>opinion</i> about the ethics of research involving people with dementia?	7.0 (3.0)
8. How useful was the session in helping you answer the survey questions?	9.0 (1.2)

^aTable 4 modified from Kim et al., in press.

TABLE 5

Number of Words Spoken and Turns Taken by Facilitators.

Group #	Facilitators			
	Number of Words Spoken	% of Total	Number of Turns Taken	% of Total
1	1755	13.2	105	21.8
2	2541	15.3	159	29.2
3 *	3089	20.9	205	38.0
4 *	3348	19.6	213	27.8
5 *	3545	22.2	290	31.8
6 *	4949	29.6	285	35.1
7 *	4018	25.2	200	26.7
8 *	1731	12.8	128	18.5
9 *	5344	30.7	308	33.3
10 *	4409	27.7	248	29.8
11	5574	31.8	355	40.8
12 *	1911	12.1	73	16.5
	Mean (SD)		Mean (SD)	
All	3518 (1372)	21.8 (7.3)	214 (87)	29.1 (7.4)

* Groups that were coded.

Note: Analysis is based on the nine coded groups (5 of which came from the groups that voted to allow by majority or consensus for all four scenarios, and 4 from groups that voted to not allow by majority or consensus [or were tied] for at least one scenario).

Note: Percentages are based on total spoken at table by participants, facilitators, and experts.

TABLE 6

Number of Words Spoken and Turns Taken by Participants.

Group #	Number of Words Spoken		Number of Turns Taken	
	Range of words spoken	% of words spoken per participant	Range of turns taken	% of turns taken per participant
1 (n=6)	528–3122	5, 9, 11, 20, 27, 27	32–106	9, 9, 10, 17, 25, 29
2 (n=6)	1383–2742	10, 13, 17, 19, 20, 21	31–77	9, 14, 17, 19, 20, 21
3* (n=5)	1443–2855	14, 16, 20, 21, 29	33–104	12, 12, 16, 21, 39
4* (n=5)	1296–3999	10, 13, 20, 26, 31	42–152	8, 16, 20, 26, 29
5* (n=6)	1025–2750	9, 12, 16, 18, 20, 24	51–127	8, 13, 18, 18, 19, 21
6* (n=6)	750–2940	7, 9, 14, 19, 23, 26	47–148	9, 10, 13, 15, 18, 30
7* (n=6)	922–3046	8, 9, 13, 19, 24, 26	49–136	9, 14, 15, 16, 18, 26
8* (n=6)	1180–2994	10, 12, 14, 17, 20, 25	45–118	8, 12, 14, 16, 20, 21
9* (n=7)	296–2903	3, 3, 7, 13, 20, 25, 27	22–129	4, 8, 8, 14, 15, 20, 22
10* (n=6)	713–2703	7, 10, 14, 21, 22, 26	47–148	8, 13, 13, 14, 23, 27
11 (n=6)	564–3421	5, 10, 17, 18, 20, 30	32–106	7, 14, 18, 20, 20, 22
12* (n=6)	1328–3104	10, 13, 13, 20, 21, 23	45–81	12, 15, 15, 16, 17, 22

* Groups that were coded.

Note: Analysis is based on the nine coded groups (5 of which came from the groups that voted to allow by majority or consensus for all four scenarios, and 4 from groups that voted to not allow by majority or consensus [or were tied] for at least one scenario).

Note: Percentages are based on total participant comments at each table. Unidentified Participant comments (word counts below 280) and general group comments are not displayed.