original reports

Effect of Public Deliberation on Patient Attitudes Regarding Consent and Data Use in a Learning Health Care System for Oncology

Reshma Jagsi, MD, DPhil[1]; Kent A. Griffith, MPH, MS[1]; Rochelle D. Jones, MS[1]; Chris Krenz[1]; Michele Gornick, PhD[1]; Rebecca Spence, JD[2]; Raymond De Vries, PhD[1]; Sarah T. Hawley, PhD, MPH[1]; Robin Zon, MD[3]; Sage Bolte, PhD[4]; Navid Sadeghi, MD, MS[5]; Richard L. Schilsky, MD[2]; and Angela R. Bradbury, MD[6]

abstract

PURPOSE We sought to generate informed and considered opinions regarding acceptable secondary uses of deidentified health information and consent models for oncology learning health care systems.

METHODS Day-long democratic deliberation sessions included 217 patients with cancer at four geographically and sociodemographically diverse sites. Patients completed three surveys (at baseline, immediately after deliberation, and 1-month follow-up).

RESULTS Participants were 67.3% female, 21.7% black, and 6.0% Hispanic. The most notable changes in perceptions after deliberation related to use of deidentified medical-record data by insurance companies. After discussion, 72.3% of participants felt comfortable if the purpose was to make sure patients receive recommended care (*v* 79.5% at baseline; $P = .03$); 24.9% felt comfortable if the purpose was to determine eligibility for coverage or reimbursement (*v* 50.9% at baseline; $P < .001$). The most notable change about secondary research use related to believing it was important that doctors ask patients at least once whether researchers can use deidentified medical-records data for future research. The proportion endorsing high importance decreased from baseline (82.2%) to 68.7% immediately after discussion ($P < .001$), and remained decreased at 73.1% ($P = .01$) at follow-up. At follow-up, non-Hispanic whites were more likely to consider it highly important to be able to conduct medical research with deidentified electronic health records (96.8% *v* 87.7%; $P = .01$) and less likely to consider it highly important for doctors to get a patient's permission each time deidentified medical record information is used for research (23.2% *v* 51.6%; $P < .001$).

CONCLUSION This research confirms that most patients wish to be asked before deidentified medical records are used for research. Policies designed to realize the potential benefits of learning health care systems can, and should be, grounded in informed and considered public opinion.

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INTRODUCTION

Learning health care systems (LHS) are evolving to leverage routinely collected patient data to inform medical discovery, care, and quality, with traditional distinctions between clinical practice, quality improvement, and research becoming less clear.[1-6] Therefore, the ethical and social implications of these developments should be carefully considered.[5,7-10]

New ethical frameworks proposed for LHS implementation include recognizable obligations from research ethics, including the duty to respect the dignity of the persons contributing data and to avoid imposing nonclinical burdens and risks.[7,11] However, the moral presumption shifts in favor of learning, with professionals and institutions obligated to conduct learning activities and patients obligated to contribute their data, laying the groundwork for providing disclosure without necessarily securing explicit consent for participation.[7]

Empirical research suggests that many patients support the use of medical information for research but also identifies the manner of consent to be important and challenging.[12-16] Prior studies suggest that patients with cancer may be more likely to value electronic health information exchange[17] and more willing to share sensitive genetic information for research.[18] Although we have previously reported perspectives of patients with cancer on the ethical implementation of LHS for oncology care, using standard survey and interview methods,[19,20] those findings are limited by respondents' lack of information and the time necessary to deliberate fully about complex scientific, regulatory, and ethical considerations. Bioethicists have recently begun to embrace deliberative democracy (DD) approaches,[21-28] which, unlike standard surveys, can solicit opinions in a manner that is more consistent with normative models of an informed, thoughtful, and community-oriented public. Deliberative

ASSOCIATED CONTENT

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Data Supplement

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procedures emphasize offering reasons and arguments for and against different policies in a cooperative process, rather than simply expressing one's own settled opinions. Participants are encouraged to reconsider their ex ante opinions in light of the interests, perspectives, and arguments of their fellow deliberators. Such approaches have proven to be illuminating in a wide variety of other contexts.[29-36]

We used a DD approach to generate the informed and considered opinions and recommendations of patients with cancer regarding acceptable secondary uses of their deidentified health information and potential approaches for notification and consent in the context of an LHS, using the example of ASCO's CancerLinQ.

MATERIALS AND METHODS

Study Design and Recruitment

Deliberative sessions were held at four geographically and sociodemographically diverse sites between June 2017 and May 2018. Participants attended day-long events including educational presentations and facilitated small-group discussions, and completed three surveys. Participants completed survey 1 before the start of any presentations or discussions (baseline), survey 2a immediately after the first small-group discussion about disclosure and consent policies, survey 2b immediately after the second small-group discussion about data use and governance policies, and survey 3 1 month after the session (follow-up).

Patients with cancer who were at least 18 years old were recruited from three sites by oncology providers and staff circulating fliers, and from one site by posting the opportunity on a Website. Eligible patients provided verbal informed consent to participate by telephone and were compensated with $100 for attending the event and $25 for completing the final survey. This study was deemed exempt by the University of Michigan's Institutional Review Board.

Procedures

Deliberation attendees were randomly assigned to tables of four to eight persons (mean, 6) and one trained facilitator, with eight to 10 tables per deliberation. Each deliberation had two main small-group discussions, each preceded by educational presentations by experts in ethics and LHS, including CancerLinQ, and opportunities for patients to ask questions. Discussions were audio recorded, transcribed, and deidentified.

Participants heard two original, 45-minute educational presentations introducing the concept of LHS and describing CancerLinQ specifically. The first, entitled "Disclosure and Consent," summarized LHS benefits and goals, practical and ethical considerations, and policy options for how to notify patients and obtain consent for data inclusion. The second, "Data Protection, Use, and Governance," covered the potential uses and users of LHS data, ethical issues pertaining to data protection and system oversight, and policy options regarding to whom and for what purpose LHS data should be released.

After each presentation, participants were asked to discuss and vote to choose among prespecified policies corresponding to each of the discussion topics. Voting was intended to enhance discussion by encouraging people to take and defend a position on potential policies. Participants were encouraged to explain the rationale for their votes and to think like citizens who form a community to decide which policy would be the best for society. Qualitative analysis of the discussions requires more extensive description than can be accommodated in this manuscript and is presented separately (Jones et al, manuscript submitted for publication).

Surveys

Survey instruments (Data Supplement) were developed using literature review and input from experts. Some items were drawn from previously validated instruments; others were adapted from prior instruments. We cognitively pretested the full instruments using verbal probing and think-aloud reasoning.[37]

Measures. **Sociodemographics, clinical features, and health experience–related factors.** Before deliberation, participants self-reported standard sociodemographic and clinical characteristics, including age, sex, race, ethnicity, education, current health, cancer type, and whether cancer was metastatic or incurable, using items from our prior work.[21] Satisfaction with health care, familiarity with legal requirements for health information confidentiality, and attitudes about health information privacy were evaluated using previously developed items.[12,38]

Comfort with secondary uses of health information. At baseline, after small-group discussions, and 1 month later, we evaluated perceptions in several scenarios involving secondary use of electronic health information, using nine items adapted from prior studies.[19,20,39] Participants were asked if they were comfortable (on a 4-point response scale from very uncomfortable to very comfortable, dichotomized for analysis) with various secondary use scenarios, after presenting a question stem describing a system collecting information on patients with cancer from routine clinical care about which patients are notified but not asked for explicit opt-in consent.

Attitudes about importance of secondary research use of data and consent for that use. At three time points, we also evaluated patients' perceptions regarding competing considerations of the need for research using secondary data and the need to gain consent for data use. The 5-point response scale was dichotomized for analysis (critically or very important *v* moderately, somewhat, or not at all important).

Statistical Analysis

We describe baseline sociodemographic, clinical, and health experience–related factors. We then describe

TABLE 1. Sociodemographic, Clinical Features, and Health Experience-Related Factors for Total Sample (N = 217)

Variable	No. (%)
Age, years	60.1 (11.4)
Age range	28 to 84
Sex	
Male	71 (32.7)
Female	146 (67.3)
Race	
Not reported	6 (2.8)
White	142 (65.4)
Black	47 (21.7)
Asian/Pacific Islander	10 (4.6)
American Indian/Alaska Native	5 (2.4)
Other	7 (3.2)
Hispanic ethnicity	
Not reported	11 (5.1)
Yes	13 (6.0)
No	193 (88.9)
Education	
Not reported	2 (0.9)
High school graduate or less	38 (17.5)
Some college	66 (30.4)
College graduate or more	111 (51.2)
General health status	
Missing/not reported	2 (0.9)
Excellent	17 (7.8)
Very good	55 (25.3)
Good	93 (42.9)
Fair	39 (18.0)
Poor	11 (5.1)
Cancer type	
Breast	91 (41.9)
Prostate	23 (10.6)
Lung	13 (6.0)
Colorectal	12 (5.5)
Leukemia/lymphoma	23 (10.6)
Kidney/bladder	6 (2.8)
Head/neck	2 (0.9)
Other cancer(s)	47 (21.7)
Metastatic or incurable cancer diagnosis	
Missing/not reported	4 (1.8)
No	147 (67.7)
Yes	66 (30.4)
Satisfaction with health care	
Missing/not reported	1 (0.5)
Satisfied	207 (95.4)
Neither satisfied nor dissatisfied	2 (0.9)
Dissatisfied	7 (3.2)
Familiarity with HIPAA	
Missing/not reported	15 (6.9)
Yes	192 (88.5)
No	10 (4.6)
Agreement with statement: "I am concerned about the privacy of electronic medical records."	
Missing/not reported	2 (0.9)
Strongly agree	54 (24.9)
Agree	91 (41.9)
Disagree	59 (27.2)
Strongly disagree	11 (5.1)

NOTE. The demographics of patients attending each session were similar by age ($P = .203$) and sex distribution ($P = .805$). However, the race ($P < .001$), ethnicity ($P < .001$), and education ($P < .001$) distributions were significantly different between deliberative democracy sessions. We compared covariates and categorical covariates using the F-statistic and χ^2 statistic, respectively, by deliberative democracy session.

Abbreviation: HIPAA, Health Insurance Portability and Accountability Act.

comfort and attitudes and how they changed over time. Comparisons of how responses evolved after deliberation were performed by comparing responses at baseline versus after deliberation, and at baseline versus at follow-up, for the same person (restricted to those answering at both time points), using the McNemar test of dependent proportions. Finally, we describe and compare participants' ultimate considered judgments, as measured by their postdeliberation follow-up comfort and attitudes, by race (dichotomized as non-Hispanic white *v* other), by educational attainment (dichotomized as some college or less *v* college graduate or more), and by age (younger than 60 years or 60 years or older). Analyses were conducted using SAS, version 9.4 (Cary, NC). $P < .05$ was considered significant.

RESULTS

Of 266 patients contacting us, 217 attended a day-long DD-session (82%); 201 completed the follow-up survey 3 (93% of those who attended a deliberation).

Sociodemographics, Clinical Features, and Health Experience–Related Factors of Participants

The mean age of participants was 60.1 years; 67.3% were women, 21.7% were black; 6.0% were Hispanic; and 17.5% had completed high school or less (Table 1). The most common cancer types were breast (41.9%), prostate

(10.6%), and leukemia/lymphoma (10.6%). Nearly one-third (30.4%) reported having been told their cancer was metastatic or incurable. The majority agreed or strongly agreed that they were concerned about the privacy of electronic medical records (66.8%).

Evolution of Perspectives With Deliberation

As shown in Table 2, comfort with the secondary use of deidentified medical information varied depending on context and, in some cases, did change after deliberation. At baseline, most participants were comfortable with researchers at a university conducting a study about cancer (96.3%). This did not change with deliberation.

When local hospitals were the users, almost all participants were comfortable if the purpose was making sure patients with cancer were getting the right treatments (97.7%) or providing people with information about how they might benefit from the hospitals' programs to prevent cancer (93.1%). However, only 64.4% were comfortable at baseline if local hospitals were using the data to market themselves to nearby patients. The proportion of those indicating comfort with these secondary use scenarios remained relatively consistent at follow-up.

When drug companies were the users, at baseline, most participants were comfortable if the information was being used to help develop new treatments (92.6%) or understand which patients benefit from certain drugs (92.1%), but only 59.8% were comfortable if the purpose was marketing. At follow-up, we observed a small but significant ($P = .05$) decrease in comfort with use of patient information by a drug company to develop new treatments, with 88.6% indicating comfort in this scenario at that time.

When insurance companies were the users, 79.5% of participants felt comfortable if the purpose was to make sure patients receive recommended care, but only 50.9% felt comfortable if the company was using the information to determine eligibility for coverage or reimbursement. Moreover, the most notable changes in perceptions after participating in the deliberation were related to use by insurance companies. After discussion, 72.3% of participants felt comfortable if the purpose was to make sure patients receive recommended care (change from baseline, $P = .03$), and only 24.9% felt comfortable if the company was using the information to determine eligibility for coverage or reimbursement (change from baseline, $P < .001$). At follow-up, 73.0% felt comfortable if the purpose was to make sure patients receive recommended care (change from baseline, $P = .05$), and only 35.7% felt comfortable if the company was using the information to determine eligibility for coverage or reimbursement (change from baseline, $P < .001$). The latter constituted the single scenario in which a majority of participants were not comfortable at follow-up after having had a chance to reflect on their deliberations.

As shown in Table 3, an overwhelming majority of participants thought it was important to be able to conduct

TABLE 2. Pre- and Postdeliberation Responses Regarding Comfort With Secondary Uses of Health Information

Secondary Use Scenario	Comfortable, No. (%)*			P†
	Baseline	After Discussion	Follow-Up	
Researchers at a university conducting a study about cancer	207 (96.3)	208 (98.6)	198 (98.5)	.132, .317
Drug company that will use the information to help guide the development of new treatment of cancer	200 (92.6)	202 (94.4)	178 (88.6)	.548, .050
Drug company interested in understanding which patients with cancer benefit from a drug it produces	197 (92.1)	188 (87.9)	183 (91.0)	.059, .513
Drug company interested in marketing new drugs and other health care products to patients with cancer	128 (59.8)	119 (55.6)	113 (56.8)	.317, .378
Insurance company interested in making sure patients with cancer receive the most recommended care	171 (79.5)	154 (72.3)	146 (73.0)	.033, .053
Insurance company interested in determining which cancer treatments are eligible for coverage or reimbursement	110 (50.9)	53 (24.9)	71 (35.7)	<.001, < .001
Local hospital interested in providing people with information about how they might benefit from its program to prevent cancer	201 (93.1)	201 (94.4)	183 (91.0)	.532, .433
Local hospital interested in making sure patients with cancer are getting the right treatments	210 (97.7)	207 (96.7)	196 (97.5)	.563, .739
Local hospital interested in marketing itself to nearby patients for cancer treatments	139 (64.4)	151 (71.6)	134 (66.7)	.059, .627

*Percentage calculated after excluding item nonrespondents.

†*P* values are comparing whether comfort was reported at baseline versus after discussion (first *P* value) and at baseline versus at follow-up (second *P* value) by the same person, using McNemar tests of dependent proportions, among the 213 participants with completed surveys at both baseline and after discussion and 201 participants with responses at both baseline and at follow-up.

medical research using deidentified electronic health records (91.6% at baseline and 93.5% at follow-up). Only a minority expressed that it was important for doctors to get a patient's permission each time deidentified medical record information is used for research, even if it means that a great deal of research will not be done. The proportion of participants responding this way was 38.4% at baseline, decreased to 28.5% after discussion (P for change = .01), and returned to a level similar (P = .17) to baseline by the time of follow-up (32.7%). A majority indicated that it was important for there to be a way to share a patient's deidentified medical record for research purposes without having to ask permission each time (57.7% at baseline, 59.3% after discussion, and 57.0% at follow-up).

The most notable durable change observed with deliberation about secondary research uses related to the proportion of participants reporting that it was important for doctors to ask patients at least once whether researchers can use deidentified data from their medical records for future research. Although the majority thought this was important at all three time points, the proportion indicating the importance of this item decreased from baseline (82.2%) to 68.7% immediately after discussion (P < .001), and remained decreased at 73.1% (P = .01) at follow-up.

Differences in Considered Judgments by Participant Demographic Features

Perspectives differed by race/ethnicity (Table 4) and education (Table 5) for several items. Compared with participants of other races/ethnicities, non-Hispanic whites were less likely to be comfortable with drug companies marketing to patients with cancer (50.8% *v* 67.6%; P = .03) and insurance companies making sure patients with cancer receive the most recommended care (66.4% *v* 84.6%; P = .008). In addition, non-Hispanic whites were more likely to think it is highly important to be able to conduct medical research with deidentified electronic health records (96.8% *v* 87.7%; P = .01) and less likely to think it is highly important for doctors to get a patient's permission each time deidentified medical record information is used for research (23.2% *v* 51.6%; P < .001). Compared with participants who were at least college graduates, participants with some college or less were more likely to be comfortable with drug companies marketing to patients with cancer (65.6% *v* 47.5%; P = .01) and insurance companies making sure patients with cancer receive the most recommended care (82.1% *v* 64.1%; P = .004). Perspectives on these items did not significantly differ by age.

DISCUSSION

To our knowledge, this constitutes the first study to use the innovative approach of DD to generate the informed and considered judgments of a diverse sample of patients with cancer on the ethical implications of LHS implementation, using a real-world example. Growing recognition of the need to respect those whose data are collected motivates ongoing investigation to ensure that policies reflect patient values and preferences. Particularly illuminating is the finding that a majority of patients, albeit a smaller proportion after deliberation than at baseline, believe it is important to obtain consent at least once before embarking on secondary research using data collected. Given that these

TABLE 3. Pre- and Postdeliberation Attitudes About Importance of Secondary Research Use of Data and Consent for That Use

Secondary Research Scenario*	Rating as Critically or Very Important, No. (%)†			
	Baseline	After Discussion	Follow-Up	P‡
To be able to conduct this kind of research	196 (91.6)	200 (93.0)	188 (93.5)	.432, .532
For doctors to get a patient's permission to use his/her medical record each time his/her medical record is used for this kind of research, even if it means a great deal of research will not be done	83 (38.4)	61 (28.5)	65 (32.7)	.010, .173
For there to be a way to share a patient's medical record with researchers to do this kind of research without having to ask permission each time	124 (57.7)	127 (59.3)	114 (57.0)	.633, .913
For doctors to ask a patient at least once whether researchers can use his/her medical record for all future research of this kind	175 (82.2)	147 (68.7)	147 (73.1)	<.001, .016

*Participants were asked: "When medical researchers study the causes of diseases, the effectiveness of medications, or ways to improve medical care, it is often necessary for them to use medical records from hospitals, doctors' offices, or other health care institutions. With the development of electronic health record systems, it is also possible to collect this information and remove details that identify patients (such as name and date of birth), before providing the information to researchers. WHEN THIS KIND OF RESEARCH IS DONE, NO PERSONALLY IDENTIFIABLE HEALTH INFORMATION IS GIVEN TO THE RESEARCHER. IN YOUR OPINION, HOW IMPORTANT IS IT..."

†Percentage calculated after excluding item nonrespondents.

‡P values are comparing whether comfort was reported at baseline versus after discussion (first P value) and at baseline versus at follow-up (second P value) by the same person, using McNemar tests of dependent proportions, among the 213 participants with completed surveys at both baseline and after discussion and 201 participants with responses at both baseline and at follow-up.

TABLE 4. Considered Judgments in Follow-Up by Race/Ethnicity

Judgment	Non-Hispanic White (n = 126)	Other Race/Ethnicity (n = 65)	*P**
Comfortable, No. (%)†			
Researchers at a university conducting a study about cancer	124 (98.4)	64 (98.5)	.980
Drug company that will use the information to help guide the development of new treatment of cancer	111 (88.1)	58 (89.2)	.816
Drug company interested in understanding which patients with cancer benefit from a drug it produces	114 (90.5)	60 (92.3)	.674
Drug company interested in marketing new drugs and other health care products to patients with cancer	63 (50.8)	44 (67.6)	.026
Insurance company interested in making sure patients with cancer receive the most recommended care	83 (66.4)	55 (84.6)	.008
Insurance company interested in determining which cancer treatments are eligible for coverage or reimbursement	40 (32.0)	27 (41.5)	.192
Local hospital interested in providing people with information about how they might benefit from its program to prevent cancer	115 (91.3)	61 (93.9)	.531
Local hospital interested in making sure patients with cancer are getting the right treatments	123 (97.6)	63 (96.9)	.775
Local hospital interested in marketing itself to nearby patients for cancer treatments	83 (65.9)	45 (69.2)	.640
Rating as critically or very important, No. (%)†			
To be able to conduct this kind of research	122 (96.8)	57 (87.7)	.014
For doctors to get a patient's permission to use his/her medical record each time his/her medical record is used for this kind of research, even if it means a great deal of research will not be done	29 (23.2)	33 (51.6)	<.001
For there to be a way to share a patient's medical record with researchers to do this kind of research without having to ask permission each time	73 (58.4)	37 (56.9)	.845
For doctors to ask a patient at least once whether researchers can use his/her medical record for all future research of this kind	95 (75.4)	46 (70.8)	.491

NOTE. We excluded respondents from this analysis who did not report race.
*P value from the χ^2 or Fisher exact test when cell size is small (< 10).
†Percentage calculated after excluding item nonrespondents.

participants spent many hours in lectures and discussions that ensured they fully understood the promise of LHSs and the importance of complete data, it is noteworthy that many continued to desire at least some level of informed consent beyond notification. Moreover, we found striking the difference in informed and considered attitudes by race/ethnicity, whereby half of our participants whose race and ethnicity was other than non-Hispanic white desired consent to be obtained each time his or her medical record is used, even when clearly aware of the tradeoff that less research might be done.

Our findings regarding the common desire for at least one attempt to be made to obtain consent before secondary research uses of data add meaningfully to prior evidence collected using other techniques.[15,16] In a random-digit dial-telephone survey of California consumers, the vast majority preferred to be asked for permission (86.7%) before sharing of unidentified electronic health data for research, with many preferring consent before each research project (44.8%).[15] In a qualitative study using focus groups and interviews to examine patient perspectives on LHS, a notable theme was the significance of shared decision-making for informed consent and notification, with multiple participants indicating a strong preference for consent or notification to occur through a conversation directly with a physician.[16] As our findings suggest, this desire to maintain a process for obtaining consent persists even after deliberation among patients with cancer specifically and should be viewed as relevant to inform LHS policy.

Our deliberation findings in this population of patients with cancer are comparable to those of our previous survey[19] and others[40] that suggest racial and ethnic minorities may

TABLE 5. Considered Judgments in Follow-Up by Education Attainment

Judgment	Some College or Less (n = 96)	At Least College Graduate (N = 103)	P*
Comfortable, No. (%)†			
Researchers at a university conducting a study about cancer	93 (96.9)	103 (100.0)	.071
Drug company that will use the information to help guide the development of new treatment of cancer	87 (90.6)	89 (86.4)	.353
Drug company interested in understanding which patients with cancer benefit from a drug it produces	87 (90.6)	94 (91.3)	.876
Drug company interested in marketing new drugs and other health care products to patients with cancer	63 (65.6)	48 (47.5)	.011
Insurance company interested in making sure patients with cancer receive the most recommended care	78 (82.1)	66 (64.1)	.004
Insurance company interested in determining which cancer treatments are eligible for coverage or reimbursement	31 (32.3)	39 (38.6)	.354
Local hospital interested in providing people with information about how they might benefit from its program to prevent cancer	88 (91.7)	93 (90.3)	.735
Local hospital interested in making sure patients with cancer are getting the right treatments	94 (97.9)	100 (97.1)	.709
Local hospital interested in marketing itself to nearby patients for cancer treatments	62 (64.6)	70 (68.0)	.614
Rating as critically or very important, No. (%)†			
To be able to conduct this kind of research	88 (91.7)	98 (95.1)	.321
For doctors to get a patient's permission to use his/her medical record each time his/her medical record is used for this kind of research, even if it means that a great deal of research will not be done	37 (38.9)	27 (26.5)	.062
For there to be a way to share a patient's medical record with researchers to do this kind of research without having to ask permission each time	59 (61.5)	55 (53.9)	.284
For doctors to ask a patient at least once whether researchers can use his/her medical record for all future research of this kind	72 (75.0)	73 (70.9)	.513

*P value from the χ^2 or Fisher exact test when cell size is small (< 10).
†Percentage calculated after excluding item nonrespondents.

be particularly concerned about the need to obtain consent in research. These differences likely reflect a number of factors, including the history of racism and legacy of past research violations undermining trust of the black community. Our findings that substantial differences in attitudes persisted even after deliberation are critical to note in ensuring LHSs are designed in ways that address the concerns of communities whose rights have repeatedly been violated in the past. Thus, for LHSs to be successful, communications should clarify the protections in place to ensure respect for these groups and the importance of such systems to gather data to inform care within these groups. Defining how greater individualization of care facilitated by LHSs may directly benefit racial and ethnic minorities should be a central focus of communication efforts.

Participants' comfort with the use of deidentified medical information depended on both the user and the specific use of the data. Consistent with previous studies,[19,20] most patients were comfortable with university researchers conducting a study about cancer and were comfortable when hospitals were the users; however, this comfort decreased when the use involved marketing. This did not increase with deliberation. Most participants were also comfortable when drug companies were interested in using deidentified data to develop treatments or to understand which patients with cancer benefit from certain drugs, but again, comfort was considerably lower when the use was marketing and did not increase with deliberation. Finally, the lower comfort among patients with cancer when insurance companies were the users is consistent with prior research in other populations.[12] Interestingly, deliberation actually led to decreased comfort with drug company and insurance companies as secondary users of health information collected in LHSs. Because trust is essential to all LHSs, strict scrutiny of requests to use data from drug and

insurance companies appears necessary to respect the reasoned and considered judgments of the patients with cancer who served as a citizen's jury in the current study.

A strength of our study is its inclusion of diverse patients informed by experts and peers in a dynamic process. Limitations include the possibility that patients who chose to participate might have more favorable attitudes toward research and fewer privacy concerns than others. Although session materials were developed on the basis of the diverse viewpoints of practicing clinicians, professional-society staff, ethicists, and patients, it is possible that specific elements of those materials may have unduly influenced patients' discussions and opinions. Translating findings into policy is challenging. Nevertheless, current and future LHS stakeholders can learn from the reasoned and considered judgments of patients who have engaged in extensive deliberation as representatives of their communities.

This study demonstrates the value of a deliberative approach for obtaining high-quality feedback from patients with cancer on complex ethical and scientific issues like those that arise in the context of LHSs. Particularly noteworthy is the finding that most patients, even after deliberation, endorse the importance of obtaining consent at least once before secondary research use of data. In-depth qualitative analysis of the deliberation discussions will be reported elsewhere and will be valuable to inform whether the current practice in CancerLinQ—notification with an opt-out consent model—sufficiently addresses the preferences and values of patients. Most importantly, this research confirms the need to continue to ground policy in informed and considered public opinion while seeking to realize the potential benefits of these systems. It should also inspire the application of deliberative methods to address other challenging ethical and policy decisions relevant to patients with cancer.

AFFILIATIONS

[1]University of Michigan, Ann Arbor, MI
[2]American Society of Clinical Oncology, Alexandria, VA
[3]Michiana Hematology-Oncology PC, Mishawaka, IN
[4]Inova Health Foundation, Fairfax, VA
[5]UT Southwestern Medical Center, Dallas, TX
[6]University of Pennsylvania, Philadelphia, PA

CORRESPONDING AUTHOR

Reshma Jagsi, MD, DPhil, Department of Radiation Oncology, University of Michigan, UHB2C490, SPC 5010, 1500 East Medical Center Dr, Ann Arbor, MI 48109-5010; e-mail: rjagsi@med.umich.edu.

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AUTHOR CONTRIBUTIONS

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Administrative support: Reshma Jagsi, Chris Krenz, Michele Gornick, Richard L. Schilsky

Provision of study material or patients: Michele Gornick, , Robin Zon, Sage Bolte, Navid Sadeghi, Angela R. Bradbury

Collection and assembly of data: Reshma Jagsi, Rochelle D. Jones, Chris Krenz, Michele Gornick, Rebecca Spence, Raymond De Vries, Sarah T. Hawley, Robin Zon, Sage Bolte

Data analysis and interpretation: Reshma Jagsi, Kent A. Griffith, Chris Krenz, Michele Gornick, Rebecca Spence, Raymond De Vries, Navid Sadeghi, Richard L. Schilsky, Angela R. Bradbury

Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Effect of Public Deliberation on Patient Attitudes Regarding Consent and Data Use in a Learning Health Care System for Oncology

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Reshma Jagsi
Employment: University of Michigan
Stock and Other Ownership Interests: Equity Quotient
Consulting or Advisory Role: Amgen, Vizient
Research Funding: AbbVie (Inst)
Travel, Accommodations, Expenses: Amgen

Robin Zon
Consulting or Advisory Role: MedPro Specialty Advisory Board

Richard L. Schilsky
Research Funding: AstraZeneca (Inst), Bayer (Inst), Bristol-Myers Squibb (Inst), Roche (Inst), Eli Lilly (Inst), Merck (Inst), Pfizer (Inst), Boehringer Ingelheim (Inst)
Travel, Accommodations, Expenses: Varian

Angela R. Bradbury
Consulting or Advisory Role: AstraZeneca Merck

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