

A Novel Stakeholder Engagement Approach for Patient-centered Outcomes Research

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Introduction/Objectives: The engagement of patients and other stakeholders is a critical element in the design of patient-centered outcomes research studies. However, methodology for scalable engagement in research management particularly activities such as operationalization of principles and setting of priorities is not well-developed. The objective of this study is to describe a novel approach for scalable stakeholder engagement in research aligned with the Patient-Centered Outcomes Research Institute (PCORI) engagement principles, which was evaluated in a national clinical data research network.

Materials and Methods: Patient, patient advocate, clinician, and researcher stakeholders were recruited from clinical sites, as well as social media sites related to the 3 conditions of focus, heart failure, obesity, and Kawasaki disease. The engagement strategy was designed, implemented, and mapped to the PCORI engagement principles. Evaluation included internal assessment and quantitative measures of online engagement.

Results: We operationalized the PCORI principles with 12 stakeholder engagement strategies and convened stakeholder advisory boards and online research prioritization panels to determine research priorities in a rigorous, deliberative process. A total of 46 advisors

(20 patients) and 339 panelists (159 patients) actively participated. There were not significant differences between patients and clinicians in level of online engagement. Nonetheless, while patients reported a slightly greater challenge with following online discussion, they overall had a more favorable opinion about use of the online format.

Discussion/Conclusion: An efficient way to engage large numbers of representative stakeholders in research is a necessary first step to assure the public of trustworthy use of data networks for health research. This paper describes a comprehensive approach to engagement in patient-centered outcomes research management that informs ongoing development of rigorous methodologies in this area.

Key Words: patient-centered outcomes research, community-based participatory research, modified Delphi, stakeholder engagement

(*Med Care* 2018;56: S41–S47)

BACKGROUND

The engagement of patients and other stakeholders has been considered an important element in the design and conduct of health research and health policy for at least 20 years.¹ The field known as community-based participatory research (CBPR) provides a foundation for substantial engagement of stakeholders in the full life cycle of research.^{2,3} Stakeholder engagement has recently achieved national attention in the United States due to initiatives such as the Patient-Centered Outcomes Research Institute's (PCORI's) national data research network (DRN) called PCORnet⁴ and All of Us: The Precision Medicine Initiative,⁵ which call for comprehensive engagement and rapid progress through the life cycle of health research. These national initiatives also rely on DRNs for efficient operationalization of governance and stakeholder engagement, which is the foundation for establishing relevant research priorities, and delivering technology, data infrastructure, and excellent research. This requires knowledge of how principles of engagement are translated into practices, and evidence for best practices in stakeholder engagement in governance. While CBPR has been applied to public health issues, it has not to our knowledge been used with patient communities around clinical research or research governance. There is interest from these national initiatives to conduct substantial engagement using existing and new methods.

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Research reported in this article was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (Contract CDRN-1306-04819). The views, statements, opinions in this article are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

The authors declare no conflict of interest.

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ISSN: 0025-7079/18/5610-0S41

Two definitions of stakeholder engagement related to comparative effectiveness research and health care share key concepts: stakeholder engagement is a process of building relationship through communications and shared decision-making about study topic selection, data collection and analysis, as well as interpretation and dissemination of research findings.^{6,7} Hence, in this paper we use the term engagement to refer to the relationship between stakeholders and the researchers that supports the development of research management policies.

A few studies have shown that the involvement of patients and consumers can alter the types of research questions that are considered and their relative priority.^{8,9} In addition, a systematic review of public involvement in health care policy reported moderate quality evidence that “consumer-informed” material—patient information material that is reviewed and refined by input from consumers—results in more relevant, readable, and understandable information and can also improve patients’ knowledge.¹⁰ The national Health Research Authority in the United Kingdom also encourages involving the public in prioritizing research projects.¹¹ However, the small number of available studies underscores the nascency of this area of inquiry.

While there are no widely adopted frameworks or operationally defined principles of stakeholder engagement in research, one effort comes from the recent PCORI principles of patient and stakeholder engagement.¹² The principles, promulgated as guidance to grantees, may be viewed as a framework for implementing engagement. The 4 principles are:

- Principle A. Reciprocal relationships: roles and decision-making authority of all partners, including patient and stakeholder partners, are clear.
- Principle B. Co-learning: patient and stakeholder partners understand the research process and researchers understand patient and stakeholder engagement and patient-centeredness.
- Principle C. Trust, transparency, and honesty: major decisions are made inclusively; there is commitment to open and honest communication; study findings are communicated to the community studied, in a meaningful and usable way.
- Principle D. Partnership: time and contributions of patient partners are valued and demonstrated in fair financial compensation, as well as reasonable and thoughtful time commitment requests.

There are few exemplars of comprehensive stakeholder engagement designs in research networks or comparative effectiveness research that fulfill the PCORI principles.

Traditional methods of engagement including focus groups, in-depth interviews, surveys, email communication, conference calls, patient home visits, patient advisory boards, deliberative sessions, and consensus-building techniques have relied primarily on in-person or small-group interaction.^{6,13–16} In-person engagement is hampered by logistical barriers, expense, and potential selection biases.¹⁷ Although communication technologies may help enable larger-scale participation through online surveys, email communication, conference calls or webinars, they may be perceived as

impersonal and the depth of engagement may thus be shallow.¹⁷ New engagement strategies that can scale to large numbers of stakeholders and still enable meaningful participation are needed to accomplish the stakeholder-engaged visions promoted by national research initiatives.

The objective of this study is to develop a novel approach for scalable stakeholder engagement in research aligned with the PCORI engagement principles. The approach was demonstrated in pSCANNER: patient-centered SCALable National Network for Effectiveness Research, a stakeholder-governed, distributed clinical DRN of over 24 million patients from public and private institutions such as the University of California, Veteran’s Health Administration, University of Southern California, Cedars-Sinai Medical Center, San Mateo Medical Center, and affiliated community clinics. pSCANNER aims to make health data more accessible and usable for the generation of scientific evidence that patients, clinicians, and other stakeholders together can use to make informed health decisions.¹⁸ This article describes the methodology for the development of this approach which was created during an 18-month network planning and startup period of PCORnet in 2014–2015 (phase I) and assessment of the engagement activities.

METHODS

We applied the patient-centered outcomes research (PCOR) engagement rubric¹² to 2 areas of research appropriate to the early stage of network development, creation of network policies and determination of research priorities. A core 4-person stakeholder engagement team, 2 researchers, 1 project manager, and 1 patient co-investigator, planned a high level stakeholder engagement approach (Table 1). Then, we designed detailed engagement strategies which we organized according to the PCOR principles to explore if the activities potentially demonstrated operationalization of the principle (Table 2).

The high level engagement approach incorporated 2 primary venues for engagement. The first venue was stakeholder advisory boards (SABs) that were involved in planning and developing governance activities and refining policies, fulfilling the research management and participant protection elements of research governance. There were 4 SABs planned, 1 responsible for governance, and 3 others representing each of the 3 conditions of focus—weight management/obesity (WMO), heart failure, and Kawasaki disease (KD). Each SAB was expected to include around 10 stakeholders. In all engagement activities, we include patients, advocates, clinicians, and researchers as stakeholders.

The second venue was the stakeholder research prioritization panels (panels). Prioritization of research topics by stakeholders fulfills the accountability element of research governance, in which those who make decisions about the research topics are held accountable to stakeholder’s expressed priorities.

The panels were convened to set research priorities using an online, modified Delphi (OMD) method—a deliberative and iterative approach to attaining consensus with discussion and statistical feedback. The ExpertLens online platform¹⁹ was

TABLE 1. Planned Stakeholder Engagement Activities

Activity	Participation by SAB		
	SAB-Governance	SAB-Education WMO, HF, KD	Prioritization Panels
Scheduled teleconferences	Yes	Yes	
Discussion of governance principles	Yes		
Development of informational module on pSCANNER		Yes	
Development of informational module on PCOR		Yes	
Development of informational modules on current science for WMO, HF, KD		Yes	
Refinement of ExpertLens Delphi software for online prioritization panels	Yes	Yes	
Recruitment of online prioritization panels	Yes	Yes	
Conduct of online prioritization panels			Yes
Analysis and interpretation of research priorities	Yes	Yes	
Making recommendations on research priorities	Yes	Yes	
Dissemination of panel priority results	Yes	Yes	Yes

HF indicates heart failure; KD, Kawasaki disease; PCOR, patient-centered outcomes research; pSCANNER, patient-centered SCALable National Network for Effectiveness Research; SAB, stakeholder advisory board; WMO, weight management/obesity.

used to facilitate rating and interaction among a large number of stakeholders in a series of condition-specific panels. ExpertLens permits an unlimited number of people interested in a topic to express their opinions, have their opinions read, and conveniently organizes those opinions into topic areas by replacing traditional face-to-face meetings with asynchronous, moderated online discussion boards.²⁰

ExpertLens harnesses the wisdom of “select crowds” by allowing participants:

- (1) To independently generate candidate ideas for research topics and evaluation criteria—round 0.
- (2) To respond to a set of predetermined questions about those ideas and submit ratings on evaluation criteria for each idea—round 1.
- (3) To familiarize themselves with the answers given by others and to discuss the group responses via asynchronous and (partially) anonymous and moderated online discussion boards—round 2.
- (4) To modify their original answers in light of the group discussion and submit new ratings—round 3.

The group’s final answer is determined statistically by analyzing the last set of responses provided by each individual using the RAND/UCLA Appropriateness Method’s approach to determining the existence of group consensus.²¹ A productive engagement of stakeholders with different perspectives is difficult with an in-person format within any reasonable time-frame, but it becomes feasible using an online format. The

OMD approach has demonstrated utility in engaging patients in health care planning,²² exploring performance measurements for arthritis,²³ and research goals for suicide prevention.²⁴ However, researchers have not previously evaluated the differences in stakeholder opinions about OMD in large multi-stakeholder panels. In this study, we recruited 360 stakeholders who self-identified their role as patient, clinician, or researcher. Then, grouped by conditions, patients and clinicians were randomly assigned to either solo-stakeholder panels or mixed panels involving patients, clinicians and researchers. Researchers were only assigned to mixed panels.

The initial research topics for consideration and the evaluation criteria used by the panels during voting rounds were selected by the SABs. The WMO panel considered 9 topics while the heart failure and KD panel considered 7 topics each. In rounds 1 and 3, all panels rated topics using the same 5 criteria (contribution to more informed health care decision-making, collaboration among patients, caregivers and clinicians, relevance to a large proportion of patients and caregivers, impact in health care goals, and innovation) and were able to explain their ratings. None of the rating questions or explanations (eg, rationale comments) were required.

SAB and panel candidates were recruited through personal contacts of pSCANNER investigators, clinicians, and staff, referrals from patient co-chairs or other SAB members. Notices inviting participation were also sent by email through supportive partnering organizations such as the Kawasaki Disease Foundation, the Society for Participatory Medicine, and by SAB

TABLE 2. Implemented Strategies Organized by Patient-Centered Outcomes Research Institute Stakeholder Engagement Principle

A. Reciprocal Relationships	B. Co-Learning	C. Trust, Transparency, Honesty	D. Partnership
Written charter for each SAB	Brief educational modules on patient-centered outcomes research and other topics.	Stakeholder research prioritization panel using online Delphi consensus process	Honoraria for all advisors
Clear expectations for participation	Patient co-chairs partnered with investigators to develop meeting agendas and materials	SAB-driven nomination of goals, criteria, and initial research topics	Logistics for meetings and conferences flex to enable varied needs of attendees
Multiple options for participation	Online discussion boards within the prioritization panels	Dissemination of community briefs on results	Options for online and asynchronous review and input

SAB indicates stakeholder advisory board.

members to online patient communities and social media. Advisors had to be patients (including parents/guardians/caregivers of KD patients who were minors), patient advocates, clinicians, or researchers interested in and experienced with issues related to one of the 3 conditions of interest. Candidates completed a brief questionnaire about their background and interest in participating. Eligible candidates were accepted until a specific deadline date or the targeted numbers were achieved (30 SAB members and 360 OMD panelists).

The stakeholder engagement activities occurred over 18 months. These activities are described in Table 1. Feedback was obtained from stakeholders through email or verbally. This project was reviewed by the Institutional Review Board at UC Davis and RAND and determined not to constitute human subjects research.

The activities for both SAB and panel were supported by the pSCANNER stakeholder engagement team of investigators and staff who implemented the activities. The core stakeholder engagement team included 2 researchers, 1 project manager, and 1 patient co-investigator. There were 6 additional ad hoc staff. The patient co-investigator served as co-chair of the SAB with another patient representative. These 1 patients worked closely with the stakeholder engagement team to plan the activities and content for all SAB meetings. The disciplines represented in the full team included community outreach, CBPR, health education, graphic design, health services research, Delphi experts and programmers, clinical experts, meeting facilitation, and project management.

Evaluation

The level of engagement in SABs was measured by tracking the participation rate for each activity by stakeholder group. In addition, an internal assessment consisted of gathering email feedback after each meeting in order to improve conduct of the meetings as well as at conclusion of the final SAB meeting.

The OMD engagement was evaluated in 2 ways. First, engagement activity level was assessed quantitatively through objective participation metrics collected by the system using participant logins (deidentified for the analysis). Second, engagement experience data were collected using an online questionnaire

at completion of the OMD panels. We report in this paper on 10 statements (listed in Table 4) regarding opinions about the online discussions, and use of the OMD software, which were rated using a 7-point Likert scale (from 1 =strongly disagree to 7 =strongly agree). The items are from the authors’ previous OMD studies of professional stakeholders.^{19,25} We compared activity level and experience between 2 groups: patients/parents (parents in the KD panel) and clinicians/researchers which were analyzed using descriptive statistics and *t* tests.

RESULTS

The engagement strategies as implemented are summarized in Table 2. Implemented strategies organized by PCORI stakeholder engagement principle, and described in detail in an Appendix (Supplemental Digital Content 1, <http://links.lww.com/MLR/B457>).

SAB Engagement

Forty-six individuals participated in the SABs, including 16 patients/parents who had experience with one of the 3 clinical conditions, 4 patient advocates with experience in some aspect of research governance, and 26 clinicians with experience with one of the 3 clinical conditions. Of the SAB members, 25 (54%) were women. The breakdown by stakeholder group is shown in Table 3.

Attendance, a measure of engagement, was fairly high, ranging from 64% to 75% for the SAB meetings (Table 3). The meeting to refine the online Delphi software and to review panel results were offered as “optional” to all the members and had lower levels of attendance. Most SAB members agreed to continue in phase II: a 3-year research implementation and sustainability period: 93% of patients/parents, 83% of patient advocates, and 69% of clinicians. In total, SAB members spent 130 hours in meeting time: 52 hours by clinicians, 56 hours by patients/parents, and 22 hours by patient advocates.

A small number of emailed comments from the SAB were received. The quotes below were received after the final SAB meeting. Most comments were positive ones regarding structure:

TABLE 3. SAB Members

Stakeholder Representation*	No. Members Involved in Activity					
	SAB Governance	SAB Heart Failure	SAB Weight Management/Obesity	SAB KD	Demo and Meeting to Refine Online Modified Delphi Software†	Meeting to Interpret Panel Results‡
Patients (parents for KD)	5	4	4	6	11	9
Patient advocates	5	1	0		1	4
Clinicians (not pSCANNER funded)	0	8	13	2	8	7
pSCANNER clinicians	2	1	1	1	0	2
Total members	12	14	18	9	46	46
No. meetings	4	2	2	2	2	1
Attendance (%)	69	71	64	75	44	48

*Eligible members could be in multiple groups.

†All members were invited to meetings.

KD indicates Kawasaki disease; pSCANNER, patient-centered SCALable National Network for Effectiveness Research; SAB, stakeholder advisory board.

I truly enjoyed the collaborative effort of the SAB group and think it was well organized and executed. As a result, the group developed important goals that I am sure will make a difference within the KD community down the road (KD parent, SAB-KD and panel member).

I'm really learning a lot about the processes involved! Thank you for being flexible with call times to accommodate different schedules! (clinician, SAB-WMO).

Several comments suggested changes to facilitation strategies.

You may want to try smaller groups to get broader participation and more consensus. Otherwise, it has been a very equitable and productive process (KD parent, SAB-KD and panel member).

I like the methodical nature of this, sometimes it was hard to get in on the discussions on the conference calls- not your problem, but could make use of "raise your hand" feature to call on individuals who are not as assertive; especially patients (clinician, SAB-WMO).

Lessons Learned Regarding SABs

The need for collaborative planning and preparation became evident quickly. In the first SAB meeting, the

stakeholders raised the need to have a more in-depth understanding of how pSCANNER's technology and organization differed from other networks. A brief introduction was not sufficient. Meeting with the patient co-chairs to assure that this information was relevant and understandable led to a compelling presentation of this material and ultimately to a professionally designed informational module. This also became the standard practice of setting agenda items and vetting materials before each meeting with the patient co-chairs.

One issue raised by the patient co-chairs is selection of key patient partners. Patients have expertise in their lived experience and can provide patient perspective, that is, needs, preferences, potential solutions, to research governance. Patient partners in research governance, however, may need to represent more than individual experience and be interested and willing to extend from personal perspective to stakeholder group perspectives. Patients may face logistical barriers to engagement such as lack of access to the internet for viewing webinar materials during meetings, or familiarity with document management websites for accessing documents such as presentations and minutes. Accommodations may also be needed for individuals with visual or hearing impairments or other conditions that challenge the use of telephones and computers. Still others work or have other obligations that require flexibility in schedule to avoid conflicts with work or personal activities. There is little evidence or guidance about how to identify and foster patient partners

TABLE 4. Engagement of Stakeholders Via Online Modified Delphi by Stakeholder Type

Participant Engagement	Total (N = 339)	Patients/Parents (N = 159)	Clinicians/Researchers (N = 180)	P
Round 1: ratings and rationale comments				
Participants who answered any rating questions [n (%)]	287 (85)	132 (83)	155 (86)	0.430
Participants who provided any rationale comments [n (%)]	266 (78)	123 (77)	143 (79)	0.640
Percent of rating questions answered by participants [M (SD)]	95 (17)	93 (17)	97 (14)	0.081
Percent of rationale comments provided by participants [M (SD)]	75 (34)	77 (34)	74 (33)	0.418
Round 2: online discussion				
Participants from round 1 who posted comments in round 2 [n (%)]	268 (93)	122 (92)	146 (94)	0.548
No. comments posted in round 2 [M (SD)]	29 (33)	36 (35)	23 (30)	<0.001*
Round 3: ratings and rationale comments				
Participants from round 1 who answered any rating questions in round 3 [n (%)]	252 (88)	119 (90)	133 (86)	0.262
Percent of rating questions answered by participants [M (SD)]	94 (16)	91 (20)	96 (11)	0.030*
Percent of rationale comments provided by participants [M (SD)]	53 (45)	61 (45)	47 (44)	0.009*
	Total (N = 292)	Patients/Parents (N = 133)	Clinicians/Researchers (N = 159)	
Online discussion experiences[†] [M (SD)]				
The discussions gave me a better understanding of the issues	5.37 (1.26)	5.63 (1.17)	5.14 (1.30)	0.002*
had trouble following the discussion [‡]	3.76 (1.74)	3.24 (1.60)	4.21 (1.72)	<0.001*
Participants debated each others' viewpoints during the discussions	4.94 (1.15)	5.07 (1.11)	4.83 (1.17)	0.11
The discussions brought out views I had not considered	5.25 (1.32)	5.46 (1.36)	5.06 (1.27)	0.02*
The discussions brought out divergent views	5.31 (1.08)	5.27 (1.15)	5.34 (1.03)	0.62
Participants sometimes misinterpreted each others' comments during the discussion	4.40 (1.35)	4.34 (1.33)	4.46 (1.37)	0.47
The discussion round caused me to revise my original answers	4.80 (0.88)	4.83 (1.40)	4.77 (1.38)	0.73
I was comfortable expressing my views in the discussion round	5.91 (0.88)	5.94 (0.94)	5.89 (0.82)	0.63
ExpertLens system experiences [M (SD)]				
The ExpertLens system was easy to use	5.39 (1.44)	5.58 (1.39)	5.21 (1.47)	0.04*
I would like to use ExpertLens in the future	5.31 (1.31)	5.73 (1.13)	4.95 (1.34)	<0.001*

All statements rated on a scale of 1 (strongly disagree) to 7 (strongly agree).

[†]Results on online discussion and ExpertLens experiences previously reported in Khodyakov et al.²⁵

[‡]This item was reverse-coded so that 1 was least favorable and 7 was most favorable.

*Significant at the 0.05 level.

and support the diversity of personal circumstances they bring to the engagement relationship.

OMD Engagement

There was a high level of engagement by participants (Table 4). A total of 85% of participants in round 1 answered at least on rating question and 78% gave at least one rationale comment. On average, participants completed 95% of rating questions and commented on 75% of their ratings. There were no significant differences between participation of patients/parents and clinicians/researchers. Overall, 88% of participants were retained from round 1 to round 3 and there was a very small reduction in percent participation. However, in round 3, there were small but significant differences in both percent of questions answered ($P=0.03$) and percent of comments made ($P=0.009$) between patients/parent and clinicians/researchers groups.

Overall, 292 of the 349 participants who enrolled in the OMD panels completed the online questionnaire about their participation experiences (84% response rate) (Table 5). The majority of questionnaire respondents were female (60%), white (66%) and had graduate or professional degrees (68%). However, there were significant differences between the patient/parent compared with professional group on all 3 characteristics. As might be expected, the professional group had much higher levels of education as they were clinicians and researchers. The 2 groups also differed in their opinions of the online experience, with significant differences on 5 of the 10 statements in the questionnaire (Table 5). The greatest difference in experiences with OMD was on the statement "I had trouble following the discussion" such that patients were almost a full point lower (less favorable). Nonetheless, patients were also more favorably disposed to using the OMD software in future. A more detailed analysis on the factors associated with active OMD engagement is provided in another paper.²⁵

DISCUSSION

The stakeholder engagement approach was designed and implemented in accordance with the PCORI engagement principles. The stakeholders were active in all engagement activities throughout phase I. The very high level of interest in continuing as SAB members in phase II can be interpreted as an indication of advisors' satisfaction with the experience. However, our interpretation is limited due to lack of formal evaluation of the SABs. Although models do exist for program evaluation that may be illustrative for stakeholder engagement, there are distinctions that bear highlighting. For one, metrics for effective engagement remain challenging to define and collect.^{26,27} In addition, stakeholders in PCOR, particularly patients, have a vested interest in the conduct and outcomes of research. Evaluation must take into account fulfillment of those direct interests throughout the research lifecycle.

While we set out to demonstrate a scalable approach to engagement through the online prioritization panels we do not have a good understanding of the scalability of the SABs. As interest in governance among research participants grows, so do needs for guidance regarding feasible and effective processes for such engagement. Scalability may be supported by standard operating procedures as well as technology. The premeeting and postmeeting procedures we implemented for the SAB are one example of standard operating procedures but much more research in this area is needed.

The OMD approach is one example of how technology may be used to deeply engage a much larger group than traditional in-person meetings or even conference calls. The findings presented in this paper suggest that patients find OMD an acceptable mode of engagement for both patients/parents and clinicians/researchers with a high level of retention (88%) which exceeded the 40%–50% retention levels that have been reported in previous in-person and online Delphi studies.^{28,29} There is room for improvement in helping patients to understand the

TABLE 5. Demographic Characteristics of Online Modified Delphi Respondents[†]

	n (%)			P
	Total (N = 292) [‡]	Patients/Parents	Professionals (N = 159)	
Sex				
Female	160 (60)	83 (68)	77 (54)	0.02*
Race				
White	164 (66)	88 (78)	76 (57)	0.02*
Black	13 (5)	8 (7)	5 (4)	
Asian	56 (23)	11 (10)	45 (34)	
Other	14 (5)	6 (6)	8 (6)	
Hispanic origin				
Yes	30 (10)	18 (14)	12 (8)	0.09
Highest level of education				
Up to high school	5 (2)	4 (3)	1 (1)	<0.001*
High school/technical school graduate	4 (2)	4 (3)	0	
Some college or 2-y degree	33 (12)	33 (26)	0	
4-y college degree	42 (16)	35 (28)	7 (5)	
Graduate or professional degree	182 (68)	48 (38)	134 (94)	
Prefer not to answer	2 (1)	2 (2)	0	

[†]Results previously reported in Khodyakov et al.²⁵

[‡]Some variables contain missing values so the total across categories may not add up to 292.

*Significant at the 0.05 level.

content of the discussions related to research. While there appears to be a reduction in participation level with respect to contributing comments, it was fairly small. There was no requirement that participants enter their rationale comments and for those participants whose ratings did not change, they may not have felt the need to enter duplicative comments in round 3.

Another challenge with large-scale engagement could be sustaining the cost of such projects. In addition to the costs of using OMD software which is proprietary to RAND, large-scale engagement activities require staff to recruit stakeholders and design, coordinate, and implement different activities, as well as to pay honoraria to participating stakeholders, all of which may not be possible without grant funds.

CONCLUSIONS

Structured engagement of patients and other stakeholders in research governance can yield rich contributions for PCOR. Advantages of designing research governance activities with deep attention to PCOR principles include potential for meaningful participation of patients, and interaction among diverse stakeholders who might not typically work together. However, there are not well-established methods for evaluating stakeholder engagement which continues to be an area ripe for future research. An efficient way to engage representative stakeholders in research governance is a necessary first step to assuring the public of trustworthy use of data networks for health research. This study describes a PCOR-principled, purposefully designed, approach for research governance that may serve as a model for scalable stakeholder engagement in research networks and PCOR.

ACKNOWLEDGMENT

The authors thank members of the pSCANNER team who contributed to this project: Victoria Ngo, Sean Grant, Dena Rifkin, Carl Stepnowsky, Nikolai Kirienko, Paul Heidenreich, Michael Ong, Jane Burns, and Zhaoping Li.

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