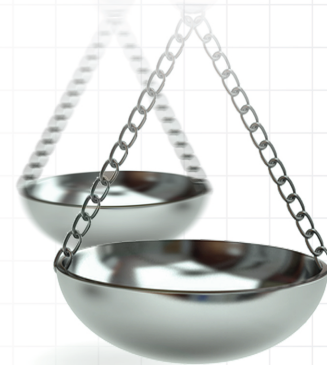




An evaluation of stakeholder engagement in comparative effectiveness research: lessons learned from SWOG S1415CD

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Aim: Stakeholder engagement is central to comparative effectiveness research yet there are gaps in definitions of success. We used a framework developed by Lavalley *et al.* defining effective engagement criteria to evaluate stakeholder engagement during a pragmatic cluster-randomized trial. **Methods:** Semi-structured interviews were developed from the framework and completed to learn about members' experiences. Interviews were analyzed in a deductive approach for themes related to the effective engagement criteria. **Results:** Thirteen members participated and described: respect for ideas, time to achieve consensus, access to information and continuous feedback as areas of effective engagement. The primary criticism was lack of diversity. **Discussion:** Feedback was positive, particularly among themes of respect, trust and competence, and led to development of a list of best practices for engagement. The framework was successful for evaluating engagement. **Conclusion:** Standardized frameworks allow studies to formally evaluate their stakeholder engagement approach and develop best practices for future research.

Plain language summary:

What is this article about? This article is about the evaluation of how effective the stakeholder engagement was in a comparative effectiveness research (CER) study funded by the Patient Centered Outcomes Research Institute (PCORI). The research team found a framework (developed by Lavalley *et al.*) that defined six different criteria for effective stakeholder engagement, and used that criteria to complete semi-structured interviews with the stakeholders involved with our study. These interviews were reviewed to determine what stakeholder engagement processes were successful and helped provide a list of best practices for stakeholder engagement for other researchers doing CER.

What were the results? Stakeholders highlighted respect for their ideas, time to achieve consensus, easy access to information and a continuous feedback loop between study team and stakeholders as effective engagement processes.

What do the results mean? These results can help other researchers doing CER learn best practices to implement from the outset of a study to best engage stakeholders in their research. The results also show that having a standardized framework to evaluate stakeholder engagement is important and allows for research teams to formally evaluate their engagement approach and learn what was successful and where there are areas for improvement in future studies.

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Comparative effectiveness research (CER) centers stakeholder engagement and is designed to compare the effectiveness of two or more interventions or approaches to healthcare [1,2]. The Patient Centered Outcomes Research Institute (PCORI) was created in 2010 to fund and promote CER that is guided by stakeholders and values stakeholders as research partners [3]. While frameworks for the conduct of stakeholder engagement in CER exist, there remains a need to identify and characterize methods to measure the success of engagement in a multi-stakeholder setting, and to provide practical recommendations on how to successfully engage stakeholders in CER [4,5]. PCORI's recent assessment of engagement practices within its own portfolio identified a need to develop validated measures to assess engagement processes and outputs [6]. Recognizing the gap in routine evaluation measures and clear definitions of stakeholder engagement criteria, Lavalley and colleagues identified and defined six meta-criteria for effective stakeholder engagement that consider multi-stakeholder settings and provide a foundation for CER studies to measure the success of stakeholder activities: respect, trust, legitimacy, fairness, competence and accountability [7].

SWOG S1415CD, or TrACER (A Pragmatic Trial Assessing CSF Prescribing and Risk), was a pragmatic cluster-randomized, controlled CER study designed to provide critical evidence to inform physician and patient decision making around PP-CSF use during chemotherapy [8]. TrACER was funded by PCORI as a part of their Pragmatic Clinical Studies Program [9] and was conducted by SWOG through the National Cancer Institute Community Oncology Research Program (NCORP) [10] in 45 community clinics across the United States. The TrACER study was informed by an External Stakeholder Advisory Group (ESAG) comprised of 21 members. The ESAG was assembled prior to the submission of the research proposal and worked in partnership with the research team to guide each phase of the study from the proposal planning through recruitment and dissemination [11].

Utilizing the six meta-criteria for stakeholder engagement provided by Lavalley *et al.*, we evaluated the successes, challenges and lessons learned from the stakeholder engagement process during the TrACER study. This evaluation is described below, and provides practical recommendations for how to engage stakeholders in future CER studies.

Methods

Formation of the ESAG & ESAG contributions

TrACER's ESAG is comprised of volunteer community members with an interest and expertise in the project subject matter and outcomes. Many members were identified through the research team's individual networks, informed by years of working closely with payer, patient and provider communities on issues related to colony stimulating factor use for oncology, cancer care delivery research and cancer patient advocacy. Additional patient partner members were recruited from the SWOG Cancer Research Network Patient Advocate Committee [12]. ESAG members were reimbursed for travel expenses and compensated based on hours of contribution to the project.

An engagement plan for the study was developed and informed by PCORI's Engagement Principles [13]. In preparation for the study, an original group of 16 stakeholders were recruited in 2014 to serve on the ESAG representing the following areas: medical ethics, national guidelines, clinical oncology, nursing, patient advocacy, insurance providers and pharmacy. This early iteration of the ESAG was engaged in development of the research proposal for PCORI, including assisting with the formulation of research questions, reviewing the intervention, study design, setting, patient populations, recruitment procedures, feasibility and impact of the intervention and study end points [11]. The ESAG was convened regularly and provided feedback to refine the study design in two separate webinars.

The final ESAG membership at the time of study activation was expanded to 21 individuals: ten patient partners, two payers, two pharmacists, two guideline experts, four providers and one medical ethicist. ESAG member demographics were not routinely collected by the study team. All patient partners had prior experiences working with cancer care professionals and/or researchers and navigating the healthcare system in their roles as patient advocates, research partners, patients/survivors and caregivers. Membership was consistent over the 6-year research period with only two people, a patient partner and a payer, eventually leaving the project and being replaced with new members recruited through existing stakeholder networks.

The ESAG was convened annually through one in-person meeting, two patient partner webinars and two full ESAG webinars. Additionally, study staff maintained communication with ESAG members through targeted

Impact on trial design	Impact on trial implementation	Impact on recruitment	Impact on early dissemination planning
- Revised study endpoints - Advised FN risk algorithm and regularly reviewed regimens and FN risk levels - Advised development of cohort and usual care arms - Added questions to patient surveys to capture: - Out-of-pocket cost of CSF - Socioeconomic status - Survey completion by caregiver - Reason for declining CSF - Donation of leftover CSF doses - Added pharmacy related questions to component application that assesses order entry system - Reviewed a statement clarifying that the study is not endorsing CSF; advised on dissemination to clinics	- Co-developed patient brochure with research team - Enhanced study summary called TrACER talking points by recommending: - Lay language about trial - Inclusion of a diagram to briefly describe study arms - Compilation of financial resources for patients, given the expensive cost of CSF	- Advised strategies for patient approach, including: - Approach patients during chemotherapy teaching session or call prior to first day of treatment - Consider that patients may feel overwhelmed, anxious, or overloaded with information - Ensure that patients feel welcomed and cared for when approaching them	- Served as co-authors on manuscript and a conference poster presentation - Identified strategies for broad dissemination of study results, including: - Scientific and health journals - Partnerships with national non-profit organizations (e.g., newsletters, websites) - Radio and podcast coverage - Communication mechanisms of participating hospitals - Social media (e.g., Twitter, Facebook, patient blogs) and collaboration with SWOG digital engagement committee

Figure 1. External Stakeholder Advisory Group impact on research activities and conduct.

emails, a monthly dashboard with study specific updates, and an annual report detailing major activities, study updates and the impact of the ESAG on that year's project activities. Over 7 years of engagement, ESAG members contributed to many different areas of the project, including study design and implementation, site recruitment and retention strategies, patient accrual strategies, and dissemination planning (Figure 1) [11]. The research period concluded in August 2021.

Evaluation framework

The original evaluation plan for TrACER was informed by PCORI's engagement principles, which include reciprocal relationships, co-learning, partnership, trust, transparency and honesty [13]. To determine an appropriate framework for evaluating stakeholder engagement, the research team performed a literature review, prioritizing frameworks that overlapped with PCORI's engagement principles and that could be applied to a multi-stakeholder setting and would generate actionable metrics to guide future practice. We determined that the meta-criteria for effective engagement provided by Lavallee *et al.* was the most comprehensive framework to evaluate the stakeholder engagement processes that were implemented through TrACER. The framework considers multi-stakeholder engagement as opposed to solely considering the public sector [7], and is based on a conceptual model developed by the authors to facilitate the design, implementation and evaluation of stakeholder engagement activities in CER that includes both process and outcome criteria that can be measured to determine the effectiveness of stakeholder engagement [14]. Additionally, the framework incorporates PCORI's engagement principles (i.e. co-learning is considered a part of respect) and expands on the principles in areas the study team felt were important, such as legitimacy and accountability. The six meta-criteria for evaluation defined by Lavallee *et al.*, and used for this evaluation, are rooted in the normative theory of public participation and deliberation [15–19].

Interview guide development & conduct

The study team partnered with the American Institutes for Research (AIR) [20] to develop and conduct semi-structured interviews with the ESAG with the goal of learning about the ESAG experience working on the TrACER study and the successes and challenges of the engagement processes implemented by the study team. Starting with the meta-criteria outlined and defined by Lavallee *et al.*, a semi-structured interview guide was developed by the research team with questions that mapped back to each of the six criteria. The interview guide and criteria were then reviewed by staff at AIR and refined for flow, priority setting and to ensure questions were reflective of the interview goals. The final interview guide is included as Appendix 1.

ESAG members were recruited over email and asked to participate in one hour semi-structured interviews that took place between May–July 2021. To keep ESAG interviews anonymous to the study team, we worked with AIR [20] to complete the interview process. Interviews were conducted by AIR staff, transcribed verbatim, deidentified and returned to the study team. All identifying information was removed from interviews and transcriptions were labeled as either PP (patient partner) or S (non-patient stakeholder). The study team held regular meetings with AIR staff during this time to ensure the interview guide was sufficient to obtain the desired information. The evaluation was reviewed and approved as exempt by the Fred Hutchinson Cancer Research Center Institutional Review Board.

Data analysis

The six meta-criteria (respect, trust, legitimacy, fairness, competence and accountability) were used for thematic analysis of the interviews. Interviews were coded in a deductive approach, with the meta-criteria and their definitions used as a codebook. Quotes throughout the interviews that related to the themes of the meta-criteria were grouped and analyzed to determine the ESAG's perceptions on the process and outcomes of the engagement process.

Results

Thirteen of 21 ESAG members participated in semi-structured interviews, including six patient and seven non-patient stakeholders. ESAG members that were unable to participate mainly cited schedules as a barrier, with work or other obligations taking precedent. Non-respondents were four patient partners and four non-patient stakeholders.

Results from the interviews are reported in relationship to the meta-criteria for stakeholder engagement [7]. Table 1 details the definition of each meta-criterion and representative quotes from the interviews. The study team processes to address each meta-criteria also are outlined in the results.

Respect

Themes relating to respect were identified in 10 (76.9%) of the ESAG interviews. ESAG members largely felt that their ideas were considered and respected by the study team, as well as other members of the group and that they were asked to provide input related to their areas of expertise. The patient partners participating in interviews recognized that the relationship for the study team was mutually beneficial and allowed the researchers to learn about the study from a patient or caregiver perspective and the patients to learn more about some of the scientific and regulatory processes that go into a large clinical trial. ESAG members felt that the theme of respect showed up consistently through the project.

To achieve feelings of respect, the study investigators and staff spent time at the outset of the study to learn how to communicate with (i.e. avoid jargon and acronyms), elicit input from and listen to stakeholders as well as how to address patient and other stakeholder concerns during meetings. This created an environment that allowed for partnership and co-learning between stakeholders and study team members. In addition, study team members recognized the expertise of each stakeholder group and elicited feedback from relevant stakeholders through the course of the study. For example, pharmacy and guideline experts were asked to help develop a list of appropriate chemotherapy regimens for the intervention while patient partners were asked to provide input on patient-facing materials such as consents and study brochures (see Figure 1).

Trust

Themes relating to trust were brought up in 8 (61.5%) ESAG interviews. ESAG members discussed feeling like there was adequate time in meetings to discuss opinions and come to consensus. Patient partners also mentioned the value that separate webinars were set up for patient partners early in the study prior to full ESAG webinars. ESAG members also discussed the importance of relationship building and providing time around in-person meetings to connect on a more personal level.

Trust was built throughout the project by allowing ample time for feedback in a variety of settings. Over the course of the project, webinars were held bi-annually and one in-person meeting was held each year. ESAG members were also able to reach out via email directly to the study team at any time. Patient partners were provided with a separate webinar before the full ESAG convened to orient patient partners to more technical topics, provide an opportunity for patient partners to raise questions or concerns and discuss any needed refinements to the agenda

Table 1. Meta-criteria definitions and representative quotes.

Meta-criterion	Definition [7]	Representative quotes
Respect	Regard for stakeholders and their ideas is consistently demonstrated.	<i>"I've been involved in this project for quite a few years, from the very beginning. The feedback and inclusion has always been consistent and the interaction is not just with the staff, but even with the PIs. They would reach out to talk to me and inquire. I think, to me, I admire that and I really want to recognize that. I feel very positive after all these years because it hasn't changed—their engagement and the desire to include hasn't changed. They have had staffing changes, which is not unexpected. But that's a good thing – they grow. But despite that, the message hasn't changed, and to me, that speaks about the core values in how the group is set up." – S1. "I think they lead by example. You know it's hard not to when the leadership team is treating you with the level of respect and importance that your voice is bringing to the conversation. It's hard for that not to trickle down to those that are within that group to say, well, if they're leading by example by treating us as if we were equal partners in this whole thing, then that's the kind of the way we need to be treating each other." – PP2</i>
Trust	Stakeholders are confident that project outcomes reflect the discussions and decisions reached through a deliberative process. Trust is built through the course of the project and involves relationship building between the study team and stakeholders as well as within the stakeholder group.	<i>"They would assemble ESAG as a whole, where the patient advocates were part of it, and then they would have a separate meeting for just the patient advocate team, which I thought was super important because, first of all, sometimes you may not want to speak openly if you know there's a payer on the call or if there's a rep from a pharma company." – PP2. "They made a good effort to get to know us as individuals as well. We usually go out to lunch or something when we were there together and those kinds of things really do help to build relationships and just comfort level working together." – PP1</i>
Legitimacy	The process allows a diverse, balanced and informed group of stakeholders to make decisions based on a collective understanding of the issue(s).	<i>"... I think it was a very well established group of people on this board from position investigators to pharmacists to patient advocates nurses and beyond... so it was a great group of people to work with that had incredible amount of expertise and knowledge and in advocacy to you know to do the right thing for patients." – S6. "... they were diverse in different diseases, because, as I tell you I think there were three breast cancer survivors, and one from colon, and the other one was the husband that died from pancreatic on the patient side. So, in terms of the cancer it was diverse, but not in terms of ethnicity or other. They weren't that diverse and to their benefit, you know there's not many of me around, Latinas, you know they're not too much involved in this advocacy area so that's what I'm trying to do, increase that participation and involvement of other people to become advocates and have that voice." – PP3</i>
Fairness	A process free from bias, just to all stakeholders and consistent with logic.	<i>"... I think there were plenty of opportunities for people to give their feedback share their concerns during the meeting. After the meeting there were always feedback reports requested after the meeting asking are you happy with how things are going and the opportunity to express oneself was quite open. This was by no means a closed door, you know rubber stamp kind of committee I think everybody had the opportunity to tell everyone else what they thought, both electronically as well as an open session and I never got a sense that people were silenced, in one way or another." – S3. "(My role is) to provide the patient advocate perspective so putting myself in the shoes of a potential study participants to understand what they're going to have to deal with how much of a stressor it's going to be if they understand the nature of the study because it's kind of complicated. Just to make it easier for them to understand what's involved and what they will experience." – PP5. "So I was invited, because I am a healthcare professional as opposed to a patient advocate. So, my role in the group, as I understood it was to bring provider perspective to questions that the group had on protocol development, on consent development, on communication and dissemination of findings, and patient brochure." – S5</i>
Competence	Meaningful participation is supported by providing stakeholders with appropriate information, ensuring that they understand the information and are able to contribute to discussions and decision making.	<i>"And then I really appreciated seeing agendas in advance so communicating ahead of time, making sure we knew what to expect then during the meeting well-presented slides and facilitation always time for Q and A." – PP5. "From emails and then regular reports that we got regular accrual reports of how the study was progressing, which I thought were quite informative and so I would be looking back. I think we were all kept well informed almost up to the minute this trial was unfolding and how well patients were enrolling in all the different sites. It was impressive." – S3</i>
Accountability	The sponsoring agency and research team are responsive to stakeholder input in achieving the goals of a process and take responsible and justifiable actions based on project outcomes	<i>"But then every single suggestion that got brought back to them was either adopted or it was explained to us why it couldn't be adopted, which to me, is of equal importance. I understand that there are regulatory, but I think that some of us that sit with the advocate hat on don't understand you have to stay within very stringent guidelines and so we can make a suggestion, and [it may] fall flat. But to the credit of the team and I can't say this enough, they would always come back and explain: We can't do that because – it wasn't because I said so, like the mother saying to the kid saying why, and the answer is "because I said so." We never got "because I said so" back." – PP2. "I feel like when I suggested something or when I observed something that I shared, I never felt that it just went into a dark hole and you don't even know if people care. That is something that I remember very clearly and was the first thing that I wanted to share when you asked me that question. They actually come back and ask more questions to clarify exactly what my concerns are or exactly what my suggestions are. I think that is the type of communication that is very mindful of others that are involved." – S1</i>

ESAG: External stakeholder advisory group; PI: Principal investigator; PP: Patient partner; S: Non-patient stakeholder.

in order to better address patient-important topics. In addition, the study team provided time outside of meetings, such as group lunches, for ESAG and study team members to socialize and get to know each other as individuals.

Legitimacy

Themes relating to legitimacy were mentioned in 7 (53.8%) of the ESAG interviews. Stakeholders felt that there was a wide variety of backgrounds, including patient advocates from different cancer disease groups, represented on the ESAG. However, there was also commentary that the group could benefit from more racial and ethnic diversity.

The study team invited stakeholders to participate in the advisory group through individual networks, informed by years of working closely with payer, patient and provider communities on issues related to colony stimulating factor use for oncology, cancer care delivery research and cancer patient advocacy. Pulling on existing networks with wide expertise in the area of research allowed for a diverse and informed stakeholder group to provide input throughout the study.

Fairness

Fairness, as defined by Lavalley *et al.*, means that stakeholders understand their role, have equal access to information and ample time to provide input [7]. Themes relating to fairness were mentioned in 7 (53.8%) of the ESAG interviews. ESAG members felt that meeting facilitators made sure all opinions were considered and that they had ample time to give feedback and voice any concerns. When asked to define their roles on the study, both patient partners and non-patient stakeholders were able to clearly define their purpose on the project.

To ensure a fair process, the study team provided clear definitions of stakeholder roles and expectations at the outset of the study. Meetings were structured in a way that provided ample time for stakeholder feedback and discussion. Additionally, an annual survey was developed and distributed to stakeholders that included questions around whether members felt they had adequate access to information and opportunity to provide input to ensure that the steps the study team were taking to keep stakeholders informed were appropriate.

Competence

Themes relating to competence were brought up in 8 (61.5%) ESAG interviews. ESAG members felt they received meeting materials in advance and had adequate time to review materials before meeting, allowing for robust discussion during meetings. ESAG members also discussed being kept abreast of study updates and having the ability to be involved in several study activities, including the opportunity to be co-authors on publications.

The study team developed and distributed agendas at least one week prior to any meetings to ensure ESAG members had time to review materials and come to meetings prepared for discussion. Between meetings, the study team provided regular monthly updates to the ESAG via email to keep members abreast of study progress. During the accrual period of the study, the study team developed a monthly accrual dashboard that was sent out to ESAG members to keep them in the loop on how accrual was progressing, which ESAG members highlighted as a tool that kept them well informed in real-time.

Accountability

A key component of accountability is a feedback loop to stakeholders, ensuring that their input is received, considered and they are aware and understand the decision to ultimately incorporate or not incorporate their specific feedback [7]. Themes relating to accountability were mentioned in 7 (53.8%) of the ESAG interviews. Stakeholders highlighted that they were consistently able to provide input and that study team members followed up on that feedback, whether their suggestions were incorporated or not.

At the outset of the study, the study team developed a spreadsheet to track ESAG input. The study coordinator tracked any ideas provided by ESAG members and ensured that all suggestions were discussed and considered by investigators. The tracking sheet provided a way to track input and outcomes of that input, which allowed for a feedback loop to ESAG members about how their suggestions were incorporated or reasons why suggestions could not be incorporated.

Discussion

Starting with an existing framework for the conduct of effective stakeholder engagement in CER, we were able to develop and complete semi-structured interviews with a subset of our ESAG members and learn about their experiences working on the TrACER study. Analysis of these interviews provided us with areas where we were

Table 2. Best practices for stakeholder engagement in comparative effectiveness Research.

1. Assemble your stakeholder advisory group prior to submitting an application for funding.
2. Set expectations for effective engagement at the outset and remain consistent in the approach to engagement throughout.
3. Recognize the expertise that patients bring to research and the opportunities for mutual learning between patients and study investigators and staff.
4. Compensate stakeholders for their time and contributions to the research.
5. Plan time for in-person meetings and allow extra time for non-study related interactions to encourage personal relationships to develop. Provide a separate meeting time for patient partners to give them a space where they feel comfortable to speak openly about their ideas.
6. Select stakeholders with intention rather than relying on convenience samples to achieve a more equitable representation of key stakeholder groups. Tools such as stakeholder mapping and frameworks that center equity and inclusion may be useful to guide the selection process.
7. Allow ample time during meetings for stakeholders to provide input, have robust discussions and come to conclusions. Points of contention should be addressed and discussed in a way that all stakeholders feel their voices are heard and valued.
8. All stakeholders should have access to meeting materials including agendas, slides and other documents being discussed ahead of meetings to provide time to review.
9. When requesting input from stakeholders on study documents, allow stakeholders to choose their level of involvement and give ample time for feedback to be provided.
10. Throughout the study, develop communication tools to keep stakeholders engaged in the study.
11. Develop a method to capture and track stakeholder input.
12. Clearly communicate with stakeholders how their input was either incorporated or reasons why the input could not be incorporated.
13. Create opportunities for stakeholders to continuously provide feedback on how the process is going and ways that engagement can be improved.
14. Dedicate resources and effort toward building and maintaining productive relationships with stakeholders before, during and after the research project has ended.
15. Develop and implement strategies to continuously evaluate the effectiveness of stakeholder engagement throughout the project.

successful in our approach to stakeholder engagement and areas that could be improved, as well as the ability to distill our best practices from this study to help inform stakeholder engagement approaches in future CER. Overall, feedback from ESAG members was very positive, particularly in the domains of respect, trust and competence. The main criticism mentioned was around lack of racial and ethnic diversity, relating to the criteria of legitimacy. Practices the study team implemented that were mentioned most frequently by the ESAG as positives included providing ample time and appropriate outlets for communication (i.e. separate patient partner webinars from full ESAG), an organized and consistent feedback loop around ESAG suggestions and opportunities for up-to-date study information such as the TrACER accrual dashboard.

We found that Lavalley *et al.*'s meta-criteria for effective engagement was a sufficient framework for evaluating our stakeholder engagement. The criterion and definitions provided a comprehensive evaluation of the processes and outcomes of our stakeholder engagement and allowed us to learn from the stakeholders about where we were successful and specific processes that can be applied to future CER studies. While the meta-criteria are comprehensive, one area we felt was missing was highlighting the importance of compensating stakeholders. Several stakeholders highlighted in our interviews that they felt our compensation model of providing travel reimbursement and an hourly stipend of \$100 for study involvement helped them feel valued. Table 2 provides a list of best practices implemented in the TrACER study that can be used to guide future stakeholder engagement in CER.

Limitations

We acknowledge some limitations to our approach. There is not one accepted framework for the evaluation of stakeholder engagement in CER, thus researchers may choose to evaluate stakeholder engagement in a variety of ways. Another limitation is that we have not routinely collected demographic information from our ESAG members and thus cannot evaluate the representativeness of the ESAG in that regard or the role of factors such as age, gender, or race in our engagement practices and outcomes, particularly in relation to the study participants. ESAG members were selected as a convenience sample through formed connections with a focus on professional and lived cancer experience. We also acknowledge that not all ESAG members chose to participate in these interviews and the feedback is reflective of the subset of members that chose to participate. However, we were able to obtain feedback from a majority of representatives with six patient partners and seven non patient partners participating and 4 representatives from each group choosing not to participate. This evaluation allowed us to distill our successes and lessons learned into a list of best practices for stakeholder engagement in CER. Future CER studies can use these best practices to develop their engagement plan.

Conclusion

Stakeholder engagement is a key part of CER but few studies formally evaluate the impact of engagement [4] and what makes engagement successful using standardized frameworks. Formally evaluating our stakeholder engagement helped to highlight the successes of our efforts, including engaging stakeholders early in the process, compensating stakeholders, creating continuous feedback loops and creating time to cultivate personal and professional relationships. The use of a standardized framework, such as Lavalley's meta-criteria for effective engagement, to evaluate stakeholder engagement in CER can allow studies to formally evaluate their engagement and utilize the lessons learned from their evaluations to provide best practices for stakeholder engagement in CER and other research.

Future perspective

To improve knowledge of routine stakeholder evaluation measures and best practices, researchers in the field should develop and test more standardized frameworks for stakeholder engagement. This can be accomplished by designing CER studies to include an engagement plan that involves comprehensive evaluation as a key component. As the field evolves, funders should be committed to supporting the full spectrum of stakeholder engagement, including evaluation, by providing adequate resources in their funding opportunities.

Summary points

- There are not standardized methods to evaluate stakeholder engagement in comparative effectiveness research (CER), limiting the ability to design and evaluate effective stakeholder engagement across the research lifecycle. We used a process measure, the meta-criteria for stakeholder engagement, to evaluate engagement in our research.
- Semi-structured interviews were completed with members of our external stakeholder advisory group and coded for themes relating to the meta-criteria for stakeholder engagement. Stakeholders highlighted that ideas were respected, they had time to reach consensus, and a continuous feedback loop as successes of this project. Key criticism included lack of diversity among stakeholders.
- Conducting interviews and analyzing for themes relating to the meta-criteria for stakeholder engagement informed a list of best practices for stakeholder engagement in CER that can be used to inform the design, conduct, and evaluation of stakeholder engagement in future studies.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/cer-2022-0158

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Ethical conduct of research

The evaluation was reviewed and approved as exempt by the Fred Hutchinson Cancer Research Center Institutional Review Board. Due to the exempt status of the project, written consent was not required, however, a recruitment email that contained a consent disclosure was sent to all ESAG members prior to their participation in an interview.

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