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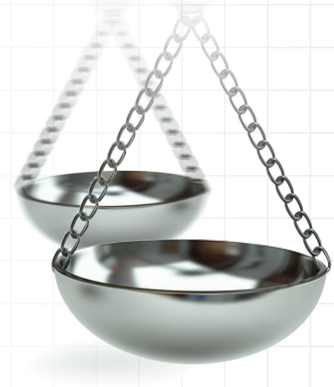

Journal of **Comparative Effectiveness Research**

Promoting community stakeholder engagement in research on treatment for pregnant women with opioid use disorder

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Aim: Community stakeholder engagement in research (CSER) can improve research relevance and efficiency as well as prevent harmful practices, particularly for vulnerable populations. Despite potential benefits, researchers lack familiarity with CSER methods. **Methods:** We describe CSER strategies used across the research continuum, including proposal development, study planning and the first years of a comparative effectiveness study of care for pregnant women with opioid use disorder. **Results:** We highlight successful strategies, grounded in principles of engagement, to establish and maintain stakeholder relationships, foster bidirectional communication and trust and support active participation of women with opioid use disorder in the research process. **Conclusion:** CSER methods support research with a disenfranchised population. Future work will evaluate the impact of CSER strategies on study outcomes and dissemination.

Tweetable abstract: Community stakeholder engagement in research on treatment for pregnant women with opioid use disorder builds and maintains stakeholder relationships, fosters communication and trust and supports active patient participation.

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Health services researchers increasingly recognize the need to engage communities and diverse stakeholders in the research process to increase the relevance of research and the likelihood that findings will be translated to policy and practice, as well as to promote representation and equity in research [1,2]. The terms 'community' and 'stakeholder' in this context refer to groups who share an identity (e.g., patients or clinical providers) and have a stake in the healthcare questions being addressed in a research endeavor. Definitions of engagement vary. The National Center for Advancing Translational Sciences recently defined stakeholder engagement as "*how an organization involves people who may be affected by the decisions it makes or can influence how the decisions are carried out*" [3]. The Patient-Centered Outcomes Research Institute (PCORI) similarly defines community engagement as "*the meaningful involvement of patients, caregivers, clinicians and other healthcare stakeholders throughout the entire*

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research process – from planning the study to conducting the study and disseminating study results" [4]. There is general acknowledgment that partnerships with community members with diverse skills, knowledge and experiences related to a health condition increase the ability of researchers to better understand the health needs of populations [5]. Yet operationalization of such engagement is inconsistent, in part due to uncertainty about how to engage with relevant communities or stakeholders [6,7].

Community stakeholder engagement in research (CSER) aims to meet the utilitarian needs of research to improve process efficiency and external validity of results [8]. CSER also supports a broader social justice agenda by improving the quality, representativeness and relevance of research for a stakeholder group and empowering them to have an active stake in knowledge generation relevant to their healthcare needs, thereby promoting health equity [8,9]. Additionally, CSER may prevent harmful research practices by ensuring that researchers understand and address the values and vulnerabilities of a population in the conduct of research and the dissemination of findings into practice [10,11]. Better description and measurement of CSER strategies and results are needed to assess the impact of engagement on research processes and on the communities and stakeholders affected by the research.

As described in a number of reviews, CSER may include an array of activities on a continuum of intensity of engagement that spans from lower intensity outreach, consultation and cooperation to higher-intensity collaboration and, finally, to shared leadership of the research process and co-ownership of research findings, such as occurs in community-based participatory research [5,11–15]. These reviews have identified core tenets and processes of CSER [2], including the capacity to address issues of power imbalance between researchers and stakeholders [15]. Goals of collaborative CSER include sharing control across all phases of the research process, including study design and implementation and supporting ongoing community stakeholder participation to inform the research over these phases. At its foundation, the conduct of CSER requires building trust, cooperation and mutual commitment among diverse stakeholders. Successful CSER includes open dialogue and clear delineation of roles and expectations regarding the study, mutual learning, shared decision-making and flexibility. Communication is central to CSER, because partners must address the challenges that inevitably occur in bringing multiple viewpoints together while maintaining engagement among partners [11,16].

Substance use disorder (SUD) research is particularly well suited for CSER. For example, full partnership community engagement has been used to redesign services for young people who use substances [17] and has been proposed to identify appropriate evidence-based approaches to address the opioid epidemic among disadvantaged populations [18]. This approach is also being utilized in the multi-state 'Communities That HEAL' initiative, wherein phased planning for implementing an array of SUD interventions is taking place in partnership with communities [19]. CSER has also been used to select, adapt, implement and disseminate evidence-based practices for SUD in historically marginalized communities such as indigenous populations [20,21].

In this paper we describe how we implemented CSER in a large multi-state PCORI-funded comparative effectiveness study of models of SUD treatment in maternity care settings for perinatal women with opioid use disorder (OUD) in northern New England. Of note, we use the term 'women', although we recognize that some pregnant individuals may identify as non-binary or male. We describe the CSER strategies used during proposal development, study preparation and the first 3 years of study implementation.

Methods & results

CSER in research proposal development: obtaining input & establishing relationships

At the time the original research proposal was developed, the standard of care for pregnant women with OUD was recognized as early engagement in prenatal care, as well as psychosocial and medication treatment of OUD during pregnancy [22–24]. However, it was not clear whether integrated OUD treatment (i.e., treatment provided along with prenatal care in the same setting) produced better outcomes than referral-based OUD treatment (i.e., treatment provided in a different setting). To incorporate stakeholder perspectives on how best to evaluate this question and also to recruit stakeholders to participate in the advisory committee and workgroups, the researchers drew on their networks of pregnant and parenting women with OUD, regional maternity care providers, SUD treatment providers and administrators of service and funding agencies. The research team partnered with these stakeholders to shape the research questions and study design for the proposal through an iterative process that included formal surveys (Supplementary Table) and informal discussions with members of these key stakeholder groups, each contributing their unique perspectives.

Based on this stakeholder input, the study was intentionally designed to minimize burden on patients, clinicians and administrators. Specifically, patients and clinician stakeholders were not enthusiastic about an experimental

design that included randomization to one model of care versus another because of the practice change demands of such a design. Their input, including concerns about the ethics of randomizing vulnerable women to different treatments, led to the selection of an observational comparative effectiveness design that utilized existing clinical service and outcomes data and prospectively collected patient-reported outcomes. This design optimized external validity to answer pragmatic questions about which type of care delivery is most effective using methods deemed acceptable by potential research participants and the settings providing their care. As the study design was refined, stakeholders identified key outcomes of most importance to them, which were also incorporated into the proposed research.

The iterative conversations and qualitative interviews as we developed our research proposal also served to establish partnerships with the maternity care settings and to promote stakeholder buy-in for the study proposal. A majority of the participating maternity care practices provided letters of support, which were submitted with the proposal to the potential funder. This engagement work enhanced the relevance of the research by ensuring that it took place in real-world practices so that outcomes would be applicable to current care settings. It also enhanced the speed with which the research could be initiated, by gaining early buy-in from setting administrators and clinicians.

Using CSER during study implementation: developing a framework for collaboration

Developing community practice–academic relationships

While the relationships that were initiated with maternity care practice stakeholders in the proposal-generation phase provided a foundation for study partnerships, the research team invested additional activities to foster trust, establish clear mutual expectations for the partnership and address infrastructure capacity and needs to support the partnership (e.g., institutional review board [IRB], data privacy, processes for accessing electronic health records for data collection). In several instances, ongoing communication was needed to address concerns related to prior experiences with research and the academic institution, as well as concerns about research participation interfering with clinical care.

To build stronger community–academic relationships, the research team conducted in-person meetings at each of the maternity care partner practices to describe the study, identify what the practice hoped to learn and gain from the study, develop a shared understanding of what the practice needed to support research activities and clarify what the practice could expect from the research team during and after the study. Each practice partner was unique, requiring individualized communication and problem-solving. Most practice stakeholders expressed interest in learning about study findings and participating in manuscript preparation. All were interested in obtaining practice-specific data for local quality improvement and research training initiatives. Consistent with CSER principles to promote partnership equity [11], the researchers and each interested practice implemented a formal memorandum of understanding (MoU) that clearly outlined what the practice could expect from the study partnership based on the expressed needs and interests of practice stakeholders.

Establishing a representative study advisory committee

To ensure that representative perspectives were incorporated in the study implementation phase, the research team established a stakeholder study advisory committee. Committee members represented multiple stakeholder groups, including healthcare professionals, health educators, regional payors and policymakers and pregnant and parenting women with lived experience of OUD. The charge of the committee was to advise the researchers on study design and implementation via semiannual full committee meetings and to participate in study activities through targeted workgroups. All meetings were co-chaired by a woman with lived experience of OUD and either a clinician or a policy stakeholder with administrative or leadership experience. Committee members were compensated for their time in the form of gift cards of their choice, reimbursed for travel and provided with free childcare at meeting locations.

To facilitate power balance among committee members, the team set clear expectations for the goals of the committee and how committee members and researchers would work together. To this end, committee members created an MoU for the Committee (see Supplementary Material), which outlined expectations for members and the research team. The language of the MoU demonstrated mutual respect and support for the purpose of the study, for the target population and for committee members. The MoU also highlighted confidentiality, given the sensitive nature of the study topic and the vulnerability of the study population.

The study advisory committee also developed a charter that included a mission statement and a description of the study governance structure. The mission statement conveyed the purpose and values of the committee: "*to lend*

guidance and input during all phases of the study to ensure relevance, data integrity, meaningful interpretation and broad dissemination of the results of the study to inform practice and policy with regard to optimal care for women with opioid use disorder and their children". Consistent with CSER principles, the governance structure and guidelines were established to support mutual decision-making, bidirectional learning, shared power and collaboration between the study advisory committee and the study team members. The charter also described the responsibilities and functions of the study advisory committee for all phases of the study. Members could choose to participate in workgroups focused on specific study activities (described below). Workgroup members presented their activities at semiannual study advisory committee meetings of all study stakeholder groups.

Educating stakeholders about research & educating researchers about stakeholder perspectives

Bidirectional (reciprocal) learning is a key principle of CSER to support balancing of power dynamics [2]. To promote bidirectional learning, the study team invited interested committee members to learn more about research methods by completing the online Collaborative Institutional Training Initiative program basic course on human research, community-based research module [25], which is required of all researchers at the study academic institution. A 2 h group meeting was scheduled to complete the course using a seminar approach, where the group gathered around a large table, each with a computer. The study director and a research assistant facilitated the meeting. Each member logged into the program and volunteers took turns reading sections aloud, which were then discussed by the group to clarify meaning. After each content section was discussed and clarified, members independently completed the associated test questions. Incorrect responses were discussed among the group until consensus understanding was reached. Upon course completion, each participant received a framed certificate and was encouraged to include this training on their personal resume (Table 1).

Committee members with lived experience also expressed a desire to read the original research plan to better understand research processes and language. Each member was given a copy of the funded proposal and asked to highlight words and phrases they did not understand. A meeting was held with the study principal investigators to discuss terminology and language that was unclear. This co-learning activity led to creation of a glossary of research terms for all study advisory committee members to ensure equity in understanding of key terms.

Study advisory committee workgroups: co-learning & co-production activities

Individual workgroups were developed within the study advisory committee to promote co-learning and coproduction activities focused on three study domains: assessment and measurement, recruitment and retention and communication and social media. These time-limited workgroups met weekly to monthly, depending on study needs. The work of the groups was grounded in the committee's charter and MoU, ensuring a shared understanding of expectations. The study director provided skilled facilitation [26] that included: provision of detailed meeting agendas; inviting participation of all members with respectful acknowledgment and response to all opinions, ideas and questions; active listening and observing to track and respond to participants' needs and level of engagement; vigorous management of group decision-making processes; guiding and maintaining focus on the agenda; and effective communication using lay language before, during and after meetings. In the final 5–7 min of each meeting, the leader elicited feedback from each participant. Participants were asked to comment on what went well or what they liked about the meeting and what could make the next meeting better. This evaluation/feedback of each meeting informed the structure, timing, facilitation and management of future meetings. The research team routinely communicated back to the workgroups how their input was incorporated during the study, which served to promote a sense of purpose and engagement.

The assessment and measurement workgroup was established to provide feedback on selecting study outcomes and how to measure them, selecting established questionnaires and developing additional relevant survey and interview questions for assessing study participants and study clinical care sites. Specifically, the workgroup reviewed each outcome measure developed or selected by the research team (e.g., questionnaires to measure substance use, depression and anxiety symptoms and experiences of care) and identified additional outcomes of interest. Workgroup members reviewed and piloted drafts of assessment batteries and provided feedback about language comprehension and cultural appropriateness, order of sensitive questions and time burden for completing assessments; for example, questions about adverse childhood experiences were moved from early in the assessment survey to the final quarter of the survey. This workgroup also codeveloped qualitative interview guides that explored experiences of delivering and receiving care within different treatment models. This workgroup then assisted in piloting surveys and interviews for patient and provider study activities and helped to establish study procedures for implementing these assessments.

Table 1. Community engagement components with elements and time estimates.

Component	Elements	Estimated time
Developing community practice–academic relationships	1. Identify and connect with key contact(s) at each partner practice	2–3 h/month per site for 3–6 months
	2. Schedule, prepare for and convene partner practice 'onboarding' meeting	2–4 h/week per site for 4–6 months per site and ongoing
	3. Prepare and update database with partner practice team member names, contact information and role for the study	Ongoing
	4. Prepare and execute a partner practice memorandum of understanding	2–4 h/week per site for 1–2 months and ongoing
	5. Establish what the CPHS/IRB requirements are for partner practice participation	3–5 h/month per site for 3–15 months
	6. Complete necessary institutional paperwork for partner practice IRB submissions	Ongoing
	7. Develop a relationship with own study CPHS/IRB analyst (i.e., telephone conversations, emails)	Ongoing
	8. Interface with multiple partner practice and institutional staff to establish processes for accessing EHR for data collection, including completion of confidentiality statement and business agreement	3–5 h/month per site for 1–3 months
Establishing a representative SAC	1. Identify, contact and enlist key community stakeholders	2–4 h/week for 3–4 months and ongoing
	2. Identify and interview potential patient partner committee members	1–2 h/week for 3–4 months and ongoing
	3. Prepare, review and execute memorandum of agreement for all SAC members	Ongoing
Educating stakeholders about research and educating researchers about stakeholder perspectives	1. Distribute research plan to community and patient stakeholders, obtain feedback on words, phrases, sections unclear to stakeholders	2 weeks
	2. Collect and collate all questions and identify areas in the research plan where there needs to be clarification	3–5 h
	3. Prepare for and convene meeting with project PI(s) and project director and meet with stakeholders to review research plan	4 h
SAC meeting	1. PIs, co-investigators and project director meet to identify potential SAC members	1–2 h/week for 1 month
	2. Contact and follow up with potential SAC members	3–5 h/week for 6–8 weeks
	3. Establish date, time and location of semiannual SAC meeting and whether it is a face-to-face or virtual meeting	2–3 weeks/meeting
	4. Meet with PIs to discuss agenda items for semiannual meeting	2–4 h/meeting
	5. Meet with co-facilitators to establish meeting agenda	2–4 h/meeting
	6. Prepare and distribute agenda and any meeting materials to SAC members	4–6 h/meeting
	7. Conduct SAC meeting	1.5 days* or virtual 1.5–2 h
		6 months
	8. Document meeting minutes and action items, review with SAC facilitators and distribute to SAC membership	4 h/meeting
Study advisory committee workgroup meetings	1. Prepare agenda and appropriate materials for SAC monthly workgroup meetings and disseminate meeting summary	2-3 h/meeting

*If SAC meeting is 1.5 days, must secure location, catering, lodging, childcare etc.
CPHS: Committee for the Protection of Human Subjects; EHR: Electronic health record; IRB: Institutional review board; PI: Principal investigator; SAC: Study advisory committee.

The recruitment and retention workgroup codeveloped materials and strategies for participant recruitment and retention, including a logo to convey an appealing study identity to participants and stakeholders. The workgroup also reviewed the study consent form that had been developed using a best practice template required by the study institution's IRB [27]. Workgroup members provided feedback regarding the difficult-to-understand language and organization of the form. The workgroup revised the form so that the language and content flow were more understandable and relevant to stakeholders with lived experience. The IRB initially did not approve the more patient-centered consent modifications, but ultimately approved the revised form after several conversations between the study team and the IRB analyst to promote greater understanding by the IRB members.

Workgroup members iteratively developed appealing, attention-getting language and graphics for recruitment flyers, adapting materials as language evolved over the course of the study (e.g., from 'medication-assisted treatment'

to 'medication for OUD'). Members with lived experience also proposed that the workgroup and study team participate together in culturally relevant activities to reach potential participants, leading to the hosting of study information tables at regional recovery rallies and memorial vigils. Workgroup members also distributed recruitment flyers at relevant locations identified by members.

The communications and social media workgroup was charged with developing an effective digital approach to publicize study activities. Workgroup members worked closely with the research team and a website developer to inform design and content for a study website (www.MOREstudy.org). The website included information about the study, the research team, the study advisory committee and the practice partners and served as a platform for accessing study newsletters and blog posts from committee members. This workgroup also developed a study Facebook page, allowing easy access to study information on a familiar platform. No identifiable information in text form was posted by the study team; when pictures or video were posted, we obtained signed permissions. If anyone from inside or outside the study posted on our study Facebook page, this would be identified by their own Facebook profile and confidentiality would be handled via their agreement with Facebook. The study website and Facebook page (@MORECommunityConnect) are also intended as platforms for dissemination of study findings.

Evolution of the study advisory committee & workgroups

Workgroups will contribute to the interpretation of study results and the dissemination of findings in the next phase of the study. Through working with the study advisory committee, members built professionally and personally supportive relationships with each other and across stakeholder groups. Committee members with lived experience reported developing skills and confidence from their meaningful involvement in the study. Membership has evolved over time. Several members with lived experience of OUD ended their participation due to competing demands (e.g., work commitments, older children's activities) or for other personal reasons. Because the group had developed close relationships over the course of the ongoing active participation in study activities, member departures were experienced as losses that naturally required processing by the group.

Measuring engagement: process evaluation & continuous research quality improvement

Operationalization and measurement of engagement has been an important recent focus of CSER [13,28,29]. To monitor the engagement of study advisory committee stakeholders over time, the study team tracked attendance, sought verbal feedback after workgroup meetings and deployed confidential surveys following each semiannual study advisory committee meeting [29,30]. Members consistently reported high-quality engagement (e.g., all composite means were greater than or equal to four on the five-point scale) across a range of core principles, including levels of reciprocal relationships, co-learning, partnership, power balance, transparency and trust demonstrated in CSER activities. Evaluation results and member feedback guided the committee leaders and research team in future CSER activities.

Discussion

This paper highlights community and stakeholder engagement strategies that were utilized from proposal generation through data collection in an observational comparative effectiveness study of treatment models for pregnant women with OUD. As in other SUD treatment research, CSER methods enabled the study team to more fully understand the needs of the target population, the contexts in which OUD was experienced and the perspectives of care provider and payor stakeholders regarding the needs of this patient population. CSER strategies, including formalization of relationships, co-learning and coproduction activities, ongoing stakeholder input and intensive engagement with maternity care practice stakeholders, led to research methods that improved study relevance and participation equity; for example, the observational study design was preferred by stakeholders over a randomized design to ensure that the research would not be disruptive and that study results would be applicable to pregnant women with OUD and easily disseminated. CSER also ensured that the patient participant consent form was easy to comprehend, increasing the likelihood of equitable participation. Changes to question wording and order based on stakeholder question review and testing improved comprehension and acceptability, increasing the validity of subjects' answers. Other examples are shown throughout the paper.

Our team used strategies to promote engagement similar to those reported by other PCORI-funded researchers [16]. In a sample of 235 PCORI-funded studies, challenges to community and stakeholder engagement were encompassed in three domains: infrastructure to support engagement; building relationships; and maintaining relationships [16]. As described above, our team used multiple strategies within each of these domains. Our

research team had existing relationships with providers in maternal–child health and SUD treatment as well as with healthcare administrator communities, which enabled the team to engage a broad array of partners from the outset of the study. The funding by PCORI specifically to support engagement was essential for the research team to dedicate time to engagement activities and build capacity for many types of stakeholders to engage with the study. The creation of a functional study advisory committee and topic-focused workgroups also provided critical infrastructure for ongoing engagement activities and stakeholder contributions to the research.

Despite a general interest in engaging with research [31–33], considerable effort was still needed to build and maintain trusting relationships with practice stakeholders, as has been reported with other PCORI-funded projects [34]. Consistent with other reports [16], the process required more time than expected and ongoing engagement efforts were essential, especially given frequent staff turnover at maternity care practices. For some practice partners, multiple visits and virtual meetings were needed to develop an understanding of study expectations and to establish trust in the partnership [35]. Additionally, as in other studies [36], consistent meetings with practice partners to share study progress and site-specific descriptive data demonstrated the benefits of study involvement to practice stakeholders. Some practice partners have utilized these summary data in their quality improvement processes. Together, these activities helped maintain positive relationships between practice stakeholders and the research team.

The inclusion of people with lived experience of OUD on the study advisory committee was critically important. The active participation of these stakeholders helped the research team gain perspective on the vulnerabilities of the study population and provided important oversight on study activities to ensure that the research was not burdensome or harmful for participants. The stakeholders provided continuous input, resulting in many types of recommendations, most of which were implemented by the research team, as discussed above and as shown in other studies [34].

Utilizing strategies to balance power between patients, clinicians/administrators and researchers is critical to the success of CSER. In our study, such strategies included formal agreements about roles and mutual expectations between clinical practices and the research team and between study advisory committee members and researchers, co-learning and coproduction activities and co-leadership of all study advisory committee meetings by a person with lived experience with OUD and a clinician. Persons with lived experience of OUD were also well represented on the study advisory committee and were the majority members in all workgroups. The research team and other study advisory committee members expressed that participation in the committee had both professional and personal meaning for them. Committee members developed supportive relationships with each other, as well as useful professional skills and confidence. For members who were parenting, the provision of free childcare at each meeting conveyed the importance of their participation and sensitivity to their needs and was crucial to their participation.

The CSER activities described above built a strong foundation for the dissemination of study findings. Community knowledge about study outcomes will allow patients to make informed decisions among treatment options, clinicians to incorporate research-based approaches in program design and delivery and payor and policy stakeholders to align initiatives with demonstrated evidence. The central role of CSER in this study also built capacity for future research partnerships, including a framework for shared study leadership.

Conclusion & future perspective

Future research on the science of stakeholder engagement is needed, including what engagement strategies work best at what phase of research and for whom, as well as how different engagement strategies impact study processes, outcomes and health equity [15]. Utilizing formal qualitative research methods and data analysis could inform future engagement work. Our work reinforced findings from prior controlled studies [37] indicating that some CSER activities should be universally deployed as best practices. For example, target participant stakeholders should provide input to ensure that consent forms are easily comprehensible and culturally relevant [38], although important questions remain about how to balance patient-centered consent approaches with legal requirements [39,40]. Other future work could focus on how familiar communication platforms, such as social media, can be used to reach target populations to improve understanding of research processes or outcomes, promote engagement in research and improve utilization of research-proven treatments. Future work could also assess what frameworks, individual characteristics or other contextual factors facilitate the disruption of academic research hierarchies and enable engagement in CSER at the highest level. Finally, research could explore how active partnership of vulnerable patient groups in research influences their health and well-being and the communities in which they live and whether such engagement results in measurable changes in health equity.

In summary, the study team deployed multiple established CSER strategies to build trust among multiple stakeholders with different perspectives and to foster engagement in the research. The conduct of CSER was resource-intensive, requiring significant time, effort and organizational skills. In the context of this observational comparative effectiveness study, the time invested in CSER played a critical role in ensuring that research questions, study materials, data collection methods and dissemination efforts were informed and guided by the unique perspectives of a wide range of stakeholders to improve the relevance of the research.

Summary points

- Community stakeholder engagement in research (CSER) improves both the relevance and the effectiveness of study activities, but many investigators lack knowledge about how to operationalize this approach.
- Practical steps in CSER begin during the proposal development phase, with stakeholder engagement in developing research questions and guiding the choice of approach.
- In CSER, both clinician stakeholders and patients bring unique expertise which should be incorporated into the design of study assessments and procedures such as informed consent for participation.
- Long-term engagement with transparency about study aims and methods creates mutual trust between principal investigators, coinvestigators and study advisory committee members, in turn enriching data analysis and interpretation.
- Marginalized populations, including pregnant people with substance use disorders, often experience mistrust regarding research participation but can be engaged to provide impactful input that improves the quality, timeliness and impact of research.
- Meaningful community and stakeholder engagement is critically important in preventing unintended harm due to uninformed research methods and in promoting equity in research.
- Successful community engagement, as part of a research study, will support bidirectional learning, shared power and collaboration during planning, conducting and dissemination.
- Meaningful involvement of key stakeholders and patients from development to dissemination is feasible.

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-2022-0090

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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