The increasing availability of high-quality, clinical electronic health record (EHR) and health-related social needs data has fostered an expanded focus on observational clinical research to improve health care outcomes and health equity. Well-designed observational studies can make important contributions to health care research, inform development of successful quality improvement interventions, and support vital advances in clinical practice based on sophisticated analyses of clinical, social needs, and other data.

In parallel, commitments to health equity, stakeholder engagement, and participatory research principles have risen. However, most recommendations for engaging patients and communities in research focus on involving their perspectives in intervention studies. Although patients and communities have lobbied for greater involvement in research that affects them, often patients' voices are excluded from research studies that use their electronically available clinical and social needs data.

Recent JAMA guidance on the reporting of race and ethnicity in research studies has highlighted potential "concerns, sensitivities, and controversies" in reporting associations of race and ethnicity with health outcomes in health care research. The authors rightfully propose that disentangling the roles of race, ethnicity, language, ancestry, and structural, socioeconomic, and institutional factors in health outcomes is critical to advancing health equity. Although these are important considerations in observational research, guidance is needed on how to engage patients and stakeholders in this important task.

Observational research studies pose challenges for stakeholder engagement that are distinct from intervention research. These studies may lack phases, such as recruitment and intervention implementation, where stakeholders are traditionally engaged and often involve complex data analytic methods.

Leveraging well-established community engagement concepts, we propose 3 core principles for actively engaging stakeholders in observational clinical research, which are the Clinical Outcomes and Observational Research Design for Implementing Novel Approaches To Engagement (COORDINATE) principles. Our team has successfully incorporated the COORDINATE principles into a current study funded by the PCORI using observational data from 6 health systems to understand the choice and timing of glucose-lowering agents on patient-centered outcomes among adults with type 2 diabetes (Table).

Colearning on the Structure and Use of Observational Data Resources

Observational research often uses EHR data that reflect patient care experiences as perceived and documented by health care professionals. Unfortunately, patients' perspectives are largely absent in these data, and patients are rarely invited to discussions of how to interpret and use these data resources. We recommend bringing all relevant health systems stakeholders, including patients, together as part of 1 stakeholder group when discussing the structure and use of observational clinical research data. Patients can provide important context on the strengths and weaknesses of such data and learn how their pooled individual data are leveraged. Clinicians (eg, physicians, pharmacists) can provide perspectives on the limitations and strengths of how data are documented in EHRs. Health care leaders can discuss how patient and clinician data are aggregated to guide
health system policy and metrics. Having all parties in the same room facilitates meaningful
discussions on the use and interpretation of clinical data for research and social drivers of health
inequities, thereby using the data resources and the wisdom of the group to develop cooperative
strategies to address health equity, cost, patients' experiences, and quality of care.

Valuing Lived Experience Equally to Scientific Expertise

Researchers may believe that observational research studies are too complicated to explain to
patients without statistical methods training, and some researchers may find communicating with
patients, particularly patients who are members of racial and ethnic minority groups, so challenging
that they exclude them from studies.7 We strongly believe that when patients are involved in
selecting and defining outcomes and relevant variables, especially on ways to incorporate health-
related social needs and frame health equity in the analyses, research findings become more relevant
for improving health outcomes and health equity. Research is also more actionable when it leverages
the expertise obtained from people with lived experiences, such as living with a chronic condition
(patient), providing patient care (clinician), and setting organizational priorities (health system
leader).8 By distilling core research ideas into easily interpretable nonspecialist terms so stakeholders
can participate in the research design process, investigators can ensure that research aims, methods,
outcomes, and findings are accessible to diverse populations with differing lived experiences.

Involving Stakeholders in the Research Continuum
and Seeking Patients' Insights to Interpret Study Findings

To effectively engage in colearning and leverage the lived experiences of stakeholders, structured
opportunities to provide study-related feedback are critical. At each stage of research, study teams
should consider relevant questions for stakeholders and elicit feedback. Furthermore, to build trust

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<td>Valuing lived experience equally to scientific expertise</td>
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<td>• Develop discussion prompts based on stakeholder experience</td>
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and demonstrate that stakeholders’ expertise is valued, these teams should provide regular updates to stakeholders on how they have incorporated their input. This process is particularly important in interpreting research results so that stakeholders can help contextualize findings to support more nuanced and meaningful understanding of observed disparities. Without proper contextualization, findings about disparities may increase stigma and bias toward already marginalized populations.5,7

The COORDINATE principles can support researchers in engaging stakeholders in observational research to promote health equity, particularly by unpacking the nuances of observational health data with patient input. Such engagement brings patients into the discussions and decisions in which health system stakeholders are using patients’ data, deciding what they need, and acting on data that affect patients. Implementing the COORDINATE principles requires additional time to build partnerships and trust with relevant stakeholders, and there is a risk of performativity for investigators who may adopt these principles for optics without intentional efforts to address power dynamics, develop trust, and address historic marginalization through systems-based change.9

Relatedly, other health fields (eg, health informatics) have highlighted the limited use of community-engaged research and a need for more meaningful engagement of stakeholders.10 The COORDINATE principles could be applied in these instances as well. Stakeholder engagement is a key strategy to address sensitivities and complexities in the reporting of race and ethnicity. Without truly engaging patients, health care systems cannot achieve more equitable health care and outcomes.


