



Achieving Equity in Diabetes Research: Borrowing From the Field of Quality Improvement Using a Practical Framework and Improvement Tools

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There are limited tools to address equity in diabetes research and clinical trials. The T1D Exchange has established a 10-step equity framework to advance equity in diabetes research. Herein, the authors outline this approach and expand on its practical application.

The incidence and prevalence of diabetes have been steadily increasing (1,2). The burden of disease is more significant for minoritized communities, including Hispanic, non-Hispanic Black, Asian American, and Native American people (2,3). There are widespread inequities in access to care, use of technology, and outcomes for people with diabetes (3–7). Unfortunately, the coronavirus disease 2019 pandemic has amplified these inequities (8–11).

Research and clinical trials are valuable to determine the effectiveness, safety, and acceptability of clinical interventions and drugs that have the potential to promote equity in a host of outcomes (12). However, minoritized communities are less likely to be represented in diabetes research (13–17). Thus, opportunities are lost to include and tailor approaches to underserved populations to help increase equity or achieve more generalizable outcomes outside of traditionally recruited research cohorts. Regulatory bodies and journals do not mandate or enforce the representation of minorities in research, so most trials do not prioritize diverse recruitment (18,19). Moreover, a legacy of unethical research practices contributes to distrust and low participation in medical research among minoritized communities that remain unaddressed (20).

The diabetes research field would benefit from reframing race/ethnicity as a social construct with historical and structural considerations and developing tools to make

representation and interventions equitable. To date, there is limited literature on practical tools to guide researchers in making diabetes research more equitable. This publication aims to describe how a practical equity framework, developed using quality improvement (QI) principles and multidisciplinary stakeholders, can increase equity, diversity, and inclusion in diabetes clinical research to improve outcomes for all people with diabetes.

Practical Framework to Advance Equity in Diabetes Clinical Trials and Outcomes

QI can support health equity by monitoring outcomes across populations, identifying root causes contributing to inequities, and testing targeted clinical interventions in real-world settings to address unique needs across diverse groups (21,22).

In 2020, the T1D Exchange Quality Improvement Collaborative (T1DX-QI), a learning network of more than 40 U.S.-based endocrinology clinics (23), developed an equity-adapted QI framework (subsequently referred to as “the Framework”) (24) that describes 10 steps to improve QI initiatives and advance equity (Figure 1). Since its development in 2020, the T1DX-QI has been piloting these steps across seven endocrinology clinics and has identified specific tools to support the use of the framework to advance equity in

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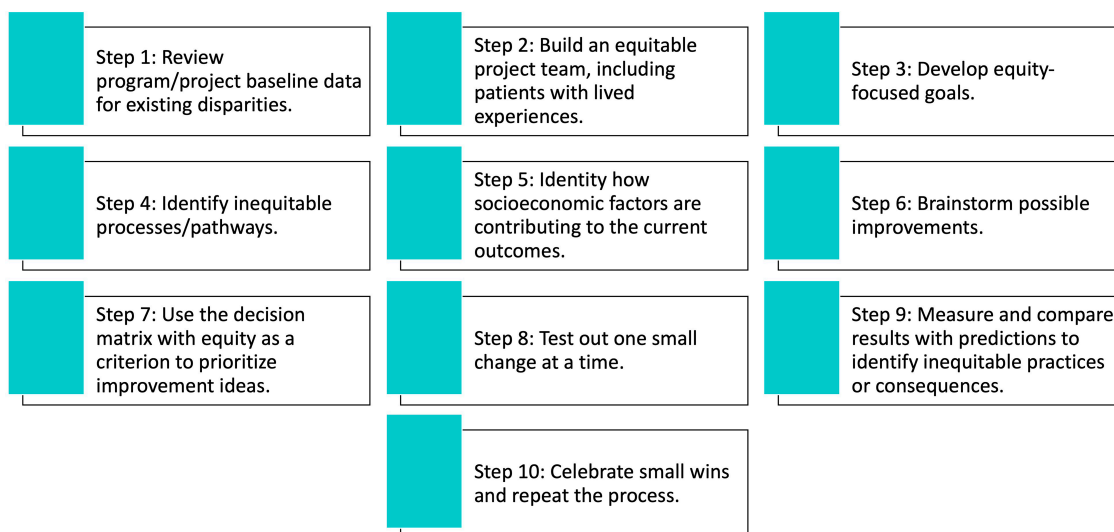


FIGURE 1 Ten-step equity-adapted QI framework. This framework describes 10 steps to adapting equity principles in a project.

diabetes health outcomes (Table 1). The goals of the framework are to increase diverse research participation, better represent patient stakeholder voices, and guide research and clinical trial equity initiatives.

In the sections below, we describe how the 10-step framework can be implemented using common QI tools to advance the equity impact of research projects.

Step 1: Review program/project baseline data for existing disparities.

Before you know where you are going, you first need to know where you are. In this initial step, baseline data are

collected to understand the present state of a process or project.

In QI, this step is often performed with a run chart, which is a line chart–like tool to aid in understanding trends and changes in a process. This tool helps to determine how a process is performing and whether changes are improving the process (25). Run charts allow teams to evaluate baseline data and monitor processes to determine when improvement has occurred and been sustained (see also framework Step 9). In equity-focused work, run charts can also help to visualize disparities in outcome metrics. Using a run chart to display shifts in outcomes by race/ethnicity can be a vital process in

TABLE 1 Tools to Implement the 10-Step Equity Framework

| Framework Step | Tool |
|---|---|
| Step 1: Review program/project baseline data for existing disparities. | Run charts |
| Step 2: Build an equitable project team, including patients with lived experiences. | “What Matters to You” tool |
| Step 3. Develop equity-focused goals. | “What Matters to You” tool, SIPOC framework |
| Step 4. Identify inequitable processes/pathways. | “Five Whys” tool |
| Step 5. Identify how socioeconomic factors are contributing to the current outcomes. | “Five Whys” tool, driver diagram |
| Step 6. Brainstorm possible improvements. | “Five Whys” tool, driver diagram |
| Step 7. Use the decision matrix with equity as a criterion to prioritize improvement ideas. | Effort/impact matrix |
| Step 8. Test one small change at a time. | Plan-Do-Study-Act cycles |
| Step 9. Measure and compare results with predictions to identify inequitable practices or consequences. | Run charts |
| Step 10. Celebrate small wins and repeat the process. | — |

monitoring advancements and affirming that initiatives are not increasing disparity gaps.

In research, teams can incorporate this step to gather information on important knowledge gaps to form meaningful research questions, plan important study milestones such as recruitment and enrollment, and define the best outcome metrics (e.g., use a run chart to plot the current enrollment rates and identify what will represent equity in enrollment of diverse participants). Teams should consider metrics using participant demographics, geographical location, socioeconomic status, or other measures that serve as proxies for diversity. For example, specific considerations can be made for tracking participant-reported race/ethnicity, private versus public insurance status, and zip code. This process drives teams to gather information to understand the current state before proceeding with a project.

Step 2: Build an equitable project team, including patients with lived experiences.

An essential element of meaningful equity work is empowering patients/participants to be coleaders in their health care experience. The T1DX-QI has found several ways to codesign QI projects with patients, including inviting patients or parent advisors to participate in projects on a patient-parent advisory committee. The T1DX-QI also convened a health equity advisory committee of HEAL (Health Equity Advancement Lab) advisors that meets quarterly to advise on equity-focused initiatives (26).

Research teams should aim beyond diverse participation and incorporate diverse patient voices and leadership in research efforts wherever possible. This effort supports more meaningful research with sustainable results and impact (27,28), especially in racially/ethnically minoritized groups and in the lesbian, gay, bisexual, and transsexual community. The National Institutes of Health and National Institute of Diabetes and Digestive and Kidney Diseases have also strongly encouraged incorporation of stakeholder groups in research (29) and have set up new initiatives that provide funding to recruit underserved minorities on clinical research staff (30).

One practical tool to help in this effort is the “What Matters to You?” tool (31), which builds trust and co-ownership in a QI or clinical trial process, which is a significant consideration for minoritized people (32). This tool has been used to improve person-centered care among people with diabetes and could extend to higher acceptability of and participation in research procedures (33,34). Researchers should actively listen to and incorporate responses to the question “What matters to you?” before an improvement project or clinical trial

begins. The researchers can then share how the project will address what matters to the person or seek ways to incorporate new strategies to address patient outcomes intentionally. For example, a researcher could mention to potential non-White participants that the lack of inclusion of non-White people in research that informs major insurance policies is a growing problem and that their participation would give them a voice. In this way, research leaders need to transparently communicate efforts to address identified concerns and in so doing may increase engagement and trust (35).

Step 3: Develop equity-focused goals.

This step encourages teams to expand beyond traditional goal-setting and explicitly state equity in the project aim. Research teams striving to improve the equity impact of their research should lead their efforts with an equity-focused project goal. Ideally, this step occurs before project protocol development and incorporates multiple perspectives, strengthening the impact and reach of research results. Like Step 1, an equity-focused goal supports teams in prioritizing efforts to advance equity. Research teams should incorporate results from a tool such as “What Matters to You?” to incorporate minoritized participant voices into the research design directly, such that research study marketing, inclusion criteria, recruitment and screening procedures, adherence, and outcomes are directly matched to enable participation.

Additionally, the Suppliers, Inputs, Processes, Outputs, and Customers (SIPOC) framework (36) could be used to improve patient experiences and outcomes by understanding relationships between the process and the observed result, enabling prioritization of interventions with tangible impact (37,38). Used commonly in QI, the SIPOC framework could be used by research teams to identify opportunities to recruit diverse project participants such as identifying the need to have materials available in languages other than English or addressing transportation barriers to meet project recruitment goals (Figure 2).

Step 4: Identify inequitable processes/pathways.

Another key element of the Framework is to perform an objective review of current processes to identify improvement opportunities. This process can include reviewing for bottlenecks, pain points, and steps in the research process that contribute to inequitable outcomes. Researchers can incorporate tools to review recruitment procedures or study protocols to enhance systems for equity either in the planning or implementation phases.

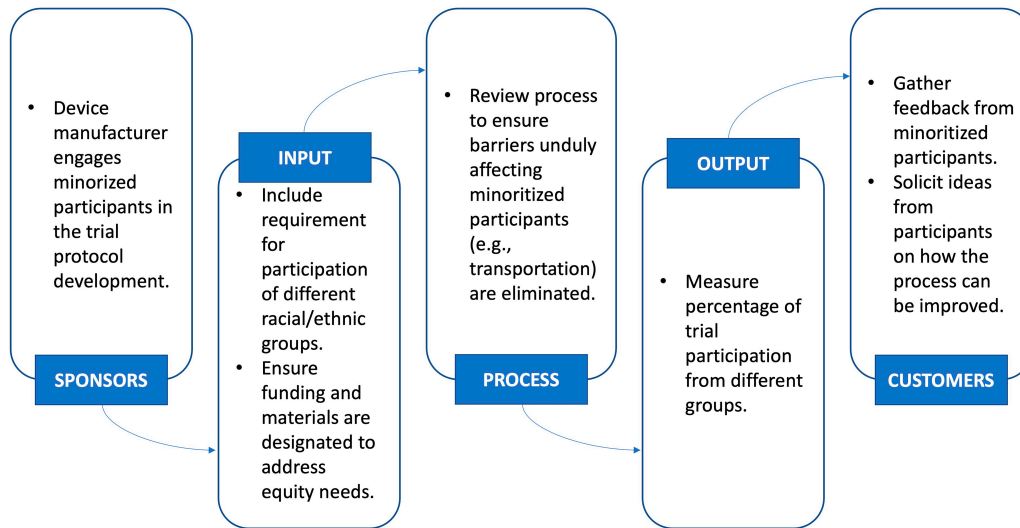


FIGURE 2 Sample SIPOC framework adaptation for research. The SIPOC diagram is useful in understanding the relationship between various aspects of any process. In this example, the SIPOC has been adapted for research purposes to identify opportunities to increase diversity among study participants.

The “Five Whys” is an example of an improvement tool research teams can use to explore the causes of inequities in their current processes (Figure 3). As Sakichi Toyoda, who developed the tool, stated, “By repeating ‘why’ five times, the nature of the problem becomes

clear” (39). This tool is designed to bring clarity and simplicity to a problem statement or a potential solution. The “Five Whys” technique is one of the most frequently taught approaches in health care, and its use is promoted by the World Health Organization, the

FIVE WHY QUESTIONS

POTENTIAL SOLUTIONS

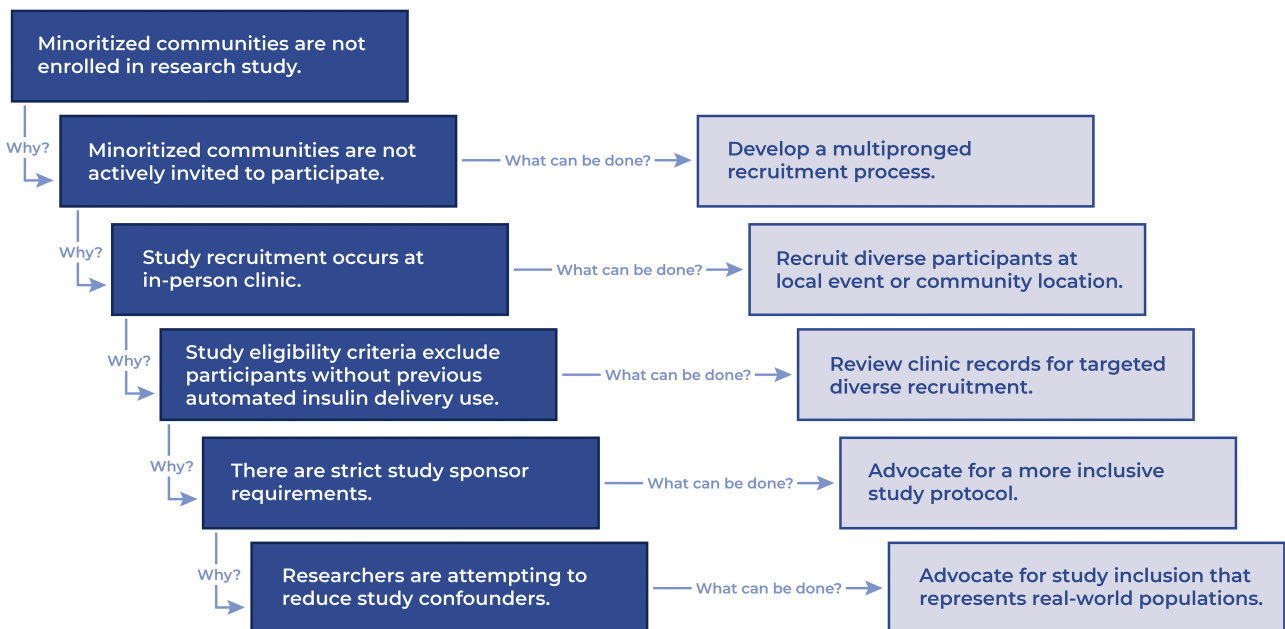


FIGURE 3 Sample “Five Whys” diagram for research. This diagram allows research teams to identify root causes to an equity issue. In this example, a diagram was completed to explore root causes and potential solutions to increase the percentage of minoritized communities represented in a research study.

Institute for Healthcare Improvement, the Joint Commission, and other health care quality and safety organizations (40). This activity should be done with a diverse team, including researchers, coordinators, study participants, and other stakeholders, to isolate and identify equity problems in research procedures.

Step 5: Identify how socioeconomic factors are contributing to current outcomes.

In QI, teams dedicate time to reviewing factors that contribute to the current process design. This pursuit enables the team to explore the socioeconomic and racial/ethnic factors that contribute to health inequities and identify feasible opportunities to address these differences with an equity focus.

A driver diagram is a visual tool to help organize theories and ideas in an improvement effort and can answer the question, “What change can we make that will result in an improvement?” (Figure 4) (41). The process requires teams to identify leading causes/key drivers of improvement and brainstorm solutions to address those drivers. Driver diagrams have been demonstrated as being practical tools in

bringing diverse stakeholders together to codesign solutions (42). Because a driver diagram shows the relationship between the overall project aim and project tasks, it is easily applied to research settings. Understanding how socioeconomic factors influence key drivers should become a standard part of developing driver diagrams and will help to evaluate factors influencing study enrollment, participation, and completion across diverse participant groups.

Step 6: Brainstorm possible improvements.

Improvement teams use the knowledge gathered from baseline data review, setting an equity aim, and examining the current process and contributing factors to brainstorm possible improvements. This step purposefully occurs after much planning and information-gathering to support change ideas rooted in the project’s real-world context. Research teams can benefit from this approach to ground study protocols and processes in the socioeconomic realities that contribute to health inequities. The driver diagram described in Step 5 can also be used as a tool to brainstorm potential change ideas to increase the percentage of racially/ethnically diverse participants, as in the example shown in Figure 4.

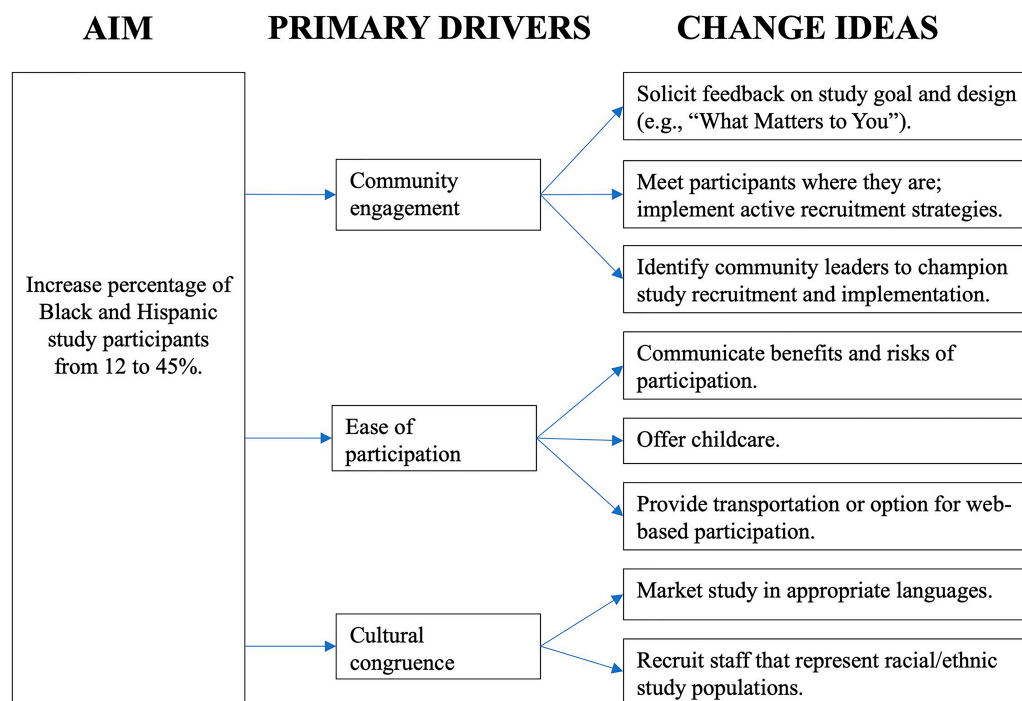


FIGURE 4 Sample driver diagram for research. A driver diagram displays the relationship between a project aim, primary drivers that support achievement of the aim, and tangible change ideas that can be implemented to achieve the aim. In this example, a driver diagram was completed to increase the percentage of Black and Hispanic study participants from 12 to 45%.

Step 7: Use a decision matrix with equity as a criterion to prioritize improvement ideas.

Although many ideas on improving diverse study participation will be generated through this process, research teams will be unable to implement every single idea because of time and resource constraints and thus must prioritize feasible and impactful ideas. In QI efforts, teams often use a decision matrix to support objective and participatory prioritization of ideas.

An effort/impact matrix (EIM) (Figure 5) is one such matrix that prioritizes improvement ideas according to their relative effort and impact on process change. Positive results may come more quickly by first identifying and implementing the lower effort/higher impact interventions. These prioritizations can be motivating, reduce project costs, and establish proof of concept (43).

Developing an EIM is a participatory exercise that includes the voices of all project stakeholders. Diversity in thought and experience provides great benefits when valuing the

relative influence of the intervention among numerous racial/ethnic patient communities.

Ideas are valued according to effort (easy vs. difficult to get done) and impact (minor vs. major benefit). Four categories are then segmented, and interventions are prioritized for action as follows:

- Easy to do/major benefit = top priority, begin implementation here
- Difficult to do/major benefit = secondary priority, get a head start on these
- Easy to do/minor benefit = work these in as time permits
- Difficult to do/minor benefit = set aside

From this exercise, the team would have clear guideline on which ideas to prioritize, beginning with the top-priority ideas, followed by the secondary-priority ideas. The team can then determine how to address ideas listed under “as time permits” and revisit those that fall under “set aside” if circumstances shift later.

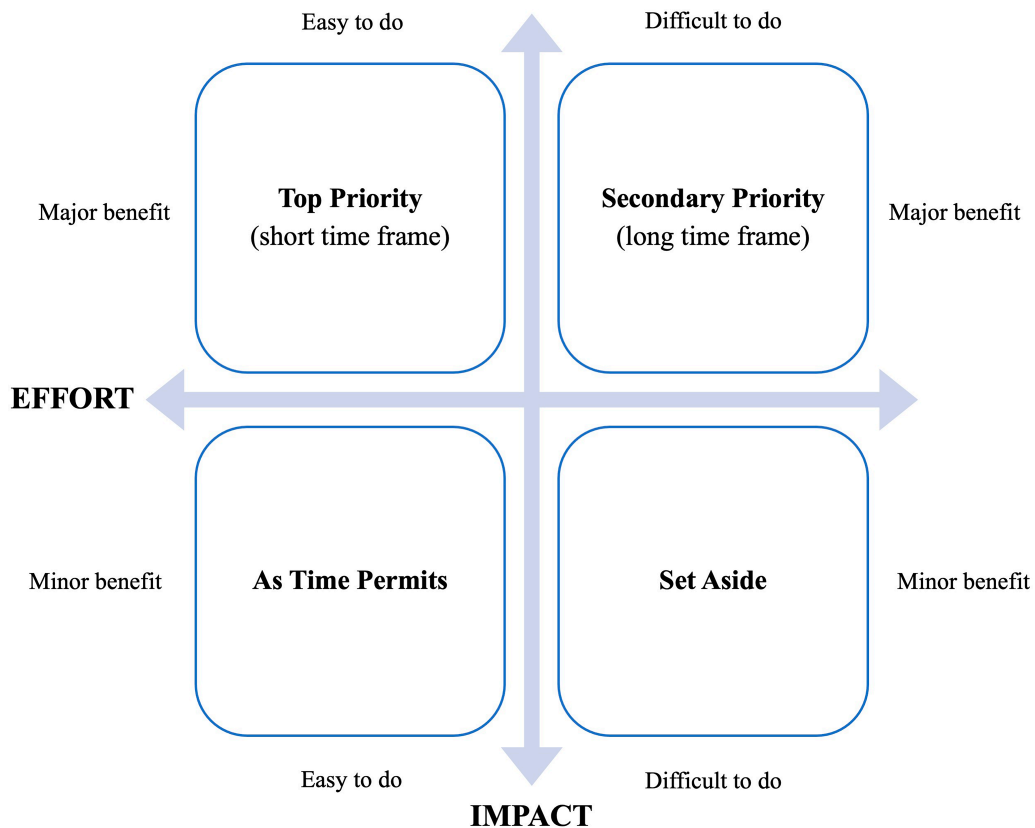


FIGURE 5 EIM for research. An EIM is a tool that allows project teams to prioritize interventions efficiently and collaboratively. Teams identify change ideas that have major benefit and are relatively easy to do as their top priorities. Interventions determined to have minor benefit and to be difficult to do are set aside.

PDSA CYCLE 1

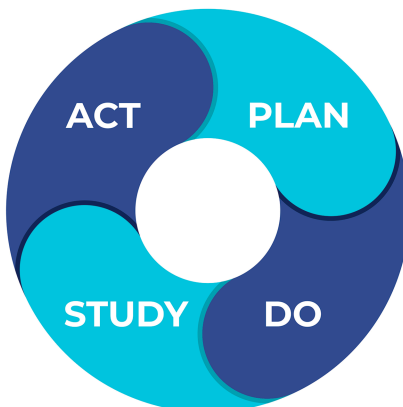
Test attendance at a local community fair as a recruitment strategy.

ACT

- Translate materials into Spanish.
- Incorporate community events into ongoing study recruitment protocols.
- Identify resources for Spanish-speaking participants.

STUDY

- Fourteen new participants were recruited (11 identify as Black or Hispanic).
- Two Spanish speakers showed interest, but translation/interpreter was not available.



PLAN

- Attend one community event with study materials and sign-up sheet.

DO

- Two staff attended local community fair in predominantly Latinx neighborhood; staff attended for 4 hours.

FIGURE 6 Sample PDSA cycle for research. PDSA cycles are temporary tests in a process to determine the effectiveness of an intervention on a small scale before implementing it more widely. This figure describes an initial PDSA cycle testing attendance at a local community fair as a study recruitment strategy. First, the team determines how the test will run (Plan) and then performs the test by attending the fair (Do). Afterward, the team reviews quantifiable results and qualitative observations of the test (Study). Finally, the team determines whether to adopt a successful test, adapt a test that may need to run again in another cycle, or abandon a strategy that did not serve the goal (Act).

Step 8: Test one small change at a time.

Studies that last for months can borrow the QI philosophy of testing small changes to identify what works as allowable in the research design or protocol. As researchers identify pain points or if the project is not on track to meet equity-focused goals, teams can codesign and test small changes to see what works before redesigning an entire study protocol.

In QI, the Plan-Do-Study-Act (PDSA) cycle is a way to implement a test of a change (Figure 6) (44–46). To conduct a PDSA cycle, first, create a “plan” for what change will be tested. While making the plan, determine the data that will need to be collected to measure whether the change improves the process. Then, implement or “do” the test. During the “study,” review test observations, analysis, and outcomes. Finally, adjustments to the test will be determined in the “act” step and might become the new plan for the next cycle, if needed. PDSA cycles are valuable in testing a protocol change before implementing it in the entire trial, determining how changes affect minoritized populations, and providing additional opportunities to involve participants in study design.

Step 9: Measure and compare results with predictions to identify inequitable practices or consequences.

In QI, iterative tests of change require regular and nearly real-time data review to determine whether process changes

have the desired impact on the outcome. Using the PDSA tool described above, this review occurs in the “study” phase. Research teams can borrow this principle by frequently reviewing progress on equity goals with diverse stakeholders. As described in Step 1, run charts are valuable tools to measure trends over time and demonstrate whether the team has met the goal.

Step 10: Celebrate small wins and repeat the process.

The iterative, experimental nature of QI permits teams to explore what works well and learn what may not. Maintaining team enthusiasm and momentum is vital to both QI and equity work. Research teams should be mindful of opportunities to celebrate progress toward equity goals and be willing to revisit processes to pursue equity.

Discussion

Health equity efforts require multipronged approaches and can often feel unachievable. These frameworks, tools, and examples provide practical guidance and add to existing momentum toward equity. Researchers looking to advance equity need to demonstrate dedicated commitment and proactively include the voices of target populations. Implementing the tools described above requires intentionality, courage, and tenacity to challenge the status quo.

Advancing health equity work in any setting also benefits from engaging organizational and funder leadership to support resource allocation, strategic priorities, and, if appropriate, policy changes. Increasingly, national standards and priorities require organizations to demonstrate health equity through accreditation (47). Research leaders can and should make a case for equity-focused studies to verify adherence to these national standards and guidelines.

Finally, patient voices are crucial to improving the cost, quality, and focus of health care (48). In diabetes, patient-reported outcome measures (PROMs) provide information on patient quality of life, depression, disease burden, diabetes distress, and other outcomes. Researchers have ample opportunities to further incorporate patient voices in study design and implementation. Teams may consider, for example, the intentional incorporation of PROMs into research evaluations, completing the above steps with patient leaders and, where possible, codesigning research initiatives.

The T1DX-QI has multiple strategies for engaging patients that researchers should consider. Overall, including patient voices ensures that interventions are timely, appropriate, and meaningful to people living with diabetes and will improve research translation to clinical care delivery and real-world outcomes.

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DUALITY OF INTEREST

O.E. is a consultant and member of the Medtronic Diabetes Health Equity Advisory Board and is a principal investigator for different research projects funded by Dexcom, Eli Lilly, and Medtronic Diabetes. All the funds for these industry-funded projects and consultant engagement are paid directly through O.E.'s organization, the T1D Exchange. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

O.E. and A.M. researched data and wrote the manuscript. D.B., M.G., R.T., D.S., J.S.H., O.O., M.H., and P.M. researched data and reviewed/edited the manuscript. J.K.D. and S.A. contributed to the discussion and reviewed/edited the manuscript. O.E. is the guarantor of this work and, as such, takes responsibility for the integrity of the review and the content presented.

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