

Stakeholder Engagement in Type 1 Diabetes Research, Quality Improvement, and Clinical Care

Nicole Riales, MA^a, Christine March, MD, MS^b,
Cynthia E. Muñoz, PhD, MPH^c, Jeniece Ilkowitz, RN, MA^d,
Amy Ohmer^e, Risa M. Wolf, MD^{f,*}

KEYWORDS

- Stakeholder engagement • Type 1 diabetes • Quality improvement
- Partnership approaches • Public and patient involvement

KEY POINTS

- The integration of stakeholder engagement in diabetes research, quality improvement (QI), and clinical care is growing.
- Many funding organizations promote partnerships with key stakeholders in the planning and conduct of research to ensure that research outcomes match the values of the patient and provider communities.
- The creation of family and youth stakeholder committees has furthered the integration of the patient and caregiver voice in implementation and dissemination of research findings in the clinical setting. The T1D Exchange QI Consortium is an example of a national QI organization that has fostered a strong Patient/Parent Advisory Committee that contributes to research design, implementation, and dissemination of research findings.

INTRODUCTION

The management of type 1 diabetes (T1D) is complex and requires the collaboration of patients, parents/caregivers, multidisciplinary care teams, and other community

Funding statement: No funding was secured for this study.

^a T1D Exchange, Boston, MA, USA; ^b Division of Pediatric Endocrinology and Diabetes, University of Pittsburgh, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA, USA; ^c Department of Pediatrics, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; ^d Pediatric Diabetes Center, NYU Langone Health, New York, NY, USA; ^e International Children's Advisory Network, Atlanta, GA, USA; ^f Department of Pediatrics, Division of Endocrinology, Johns Hopkins University School of Medicine, Baltimore, MD, USA
* Corresponding author. Department of Pediatrics, Division of Endocrinology, 200 North Wolfe Street, Baltimore, MD 21287.

E-mail address: RWolf@jhu.edu

Endocrinol Metab Clin N Am ■ (2023) ■-■

<https://doi.org/10.1016/j.ec.2023.09.007>

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supports.¹ As an integral part of clinical care, quality improvement (QI) and research, stakeholder perspectives, and stakeholder engagement (SE) require effective approaches and strategies to ensure all voices are integrated. The concept of SE, defined as the engagement of patients, caregivers, and other health care stakeholders as partners in planning, conducting, and disseminating clinical interventions, QI, and research, was first initiated by the Patient-Centered Outcomes Research Institute (PCORI) in 2010.^{2–4} The increasing amount of literature and funding opportunities involving SE clearly demonstrates an increased acceptance of SE in all aspects of patient care and health outcomes, including a more patient-focused research agenda.⁵ Over the last decade, the integration of SE has gained significant traction, yet there is a limited body of literature on SE in T1D scholarship, specifically.

In this article, the authors describe the current framework for SE and its application to T1D research, QI, and clinical care across the lifespan, highlighting efforts by the T1D Exchange (T1DX).

FUNDAMENTALS AND FRAMEWORK OF STAKEHOLDER ENGAGEMENT

Since the inception of the PCORI initiative, the mission of PCORI has been to shift the paradigm of clinical research such that patients are not just participants, but active collaborators in the design, implementation, and formulation of outcomes, so that the research better matches values meaningful to the patient community. The PCORI mission statement suggests active and sustained engagement of patients and other key stakeholders in determining research priorities as well as recommendations for research funding.^{3,6} To do this, PCORI developed a rubric to provide a framework for engaging patients and other stakeholders in all phases of research.³ It includes definitions of stakeholder types, examples of stakeholder roles, and considerations in the planning, conducting, and dissemination of stakeholder-engaged research.^{3,5}

Stakeholders include patients, providers, and both community and commercial partners.³ Patient stakeholders include individuals with the lived experience of the condition of interest, in addition to their caregivers and family members, as well as advocacy or community organizations that represent patients and caregivers.^{7,8} Provider stakeholders include clinical health care professionals and their institutions (hospitals and health care systems), researchers of the condition of interest, health care industry players (purchasers and payers), and policymakers. Adequate diversity in stakeholder representation is important to ensure that the research endeavors and outcomes reflect the values of the patient community.

STAKEHOLDER ENGAGEMENT IN RESEARCH

It is recommended to include stakeholders in all stages of the research process, from conception to dissemination. Researchers should partner with stakeholders, allowing for open dialogue, bidirectional sharing, and meaningful contributions from stakeholders, as well as establishing expectation of roles at the outset to ensure a productive and meaningful working relationship.^{9–11} PCORI researchers have recommended that stakeholders have a collaborative role and partnership rather than a consulting or advisory role.^{12–15} A review by Harrison and colleagues¹⁵ summarized foundational principles of SE, including respect, equitable power between all team members, open discussion forums, and creating trust between stakeholders and researchers. Experienced programs in engaging stakeholders have also suggested providing compensation and/or reimbursements to patients and other stakeholders contributing time and expertise.^{16,17} Stakeholders should be engaged early in the process to help with the conceptualization and prioritization of the research questions and to co-

design the research protocol and can also contribute to developing optimal strategies for recruitment and retention of study participants, as well as engaging representative and hard-to-reach populations for greater external validity.^{18,19}

When involving SE in research design, it may be helpful to the patient or family member to better understand research methodology, recruitment, and participant characteristics. Some institutions have created training programs for stakeholders to introduce them to the purpose of research, research ethics, and human subject protections.²⁰ Such training helps to prepare stakeholders and may also help to sustain ongoing engagement.²¹ Regardless of how SE is being used to contribute to the overall applicability and success of a project, efforts to include stakeholders that have been well planned and continually monitored are necessary for optimal SE and adequate representation among patient communities.²² Outreaching to stakeholders from diverse backgrounds that include representation across age groups, income and education levels, and races and ethnicities can help to ensure that traditionally underrepresented stakeholders have a voice at the table. Bringing patient stakeholders to research and opening dialogue to allow bidirectional teaching can help to create an environment of true collaboration, where patient knowledge and experience are valued as a subject matter expertise, fostering an environment of co-design and collaboration.

Dissemination of research findings supported by community engagement can lead to expanded applicability of the findings particularly in hard-to-reach populations, and accelerated uptake in communities through community ambassadors. Furthermore, some argue that SE in research design and execution results in better quality research and engages and empowers patients to play a more active role in their care and that of their community. Furthermore, the integration of SE ensures that research and clinical initiatives are, by design, more appropriate for the community.^{19,22}

As SE in research becomes increasingly prioritized, investigators and funding bodies need to consider its quality and effectiveness. Although there are many published best practices for SE, methods to evaluate the processes and outcomes of stakeholder inclusion in research are varied in scope and content.^{3,23–26} SE evaluations have spanned which stakeholders were represented, characteristics of engagement, stakeholders' experiences with the collaboration and perceptions of their contributions, and descriptions of how stakeholders affected the research plans.²⁶ The inconsistency across studies highlights the lack of a common framework by which to appraise the impact of SE. The need remains for consensus on how to partner with all stakeholders equitably, selection of valid measures for SE assessment, and the identification of reportable outcomes for stakeholder-engaged research.^{27,28} Regardless, there is widespread initiative from funding organizations to enhance meaningful SE with patient and community-based organizations in order to meet the needs and priorities of stakeholders and to promote health equity among all stakeholders in the long term.

In addition to PCORI, other funding bodies have promoted SE in their funding announcements and research partnerships, including the Institute for Patient and Family Centered Care, the Agency for Health Care Research and Quality, the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), and the American Diabetes Association (ADA).^{29–32}

STAKEHOLDER ENGAGEMENT IN DIABETES RESEARCH

In chronic disease conditions like diabetes, the use of SE to guide and inform research at the design stage, through the implementation, recruitment, and retention as well as

the dissemination of results can lead to more relevant and meaningful outcomes for both the patient and the provider.^{7,33} Schmitt diel and colleagues³³ describe their experience in engaging stakeholders in comparative effectiveness research in the field of diabetes, and their five-step process for assessing data gaps and translating gaps into critical concepts to be addressed in pilot studies of patient-centered research outcomes. This process entails a survey to elicit ideas for a research agenda, followed by a representative stakeholder in-person meeting to discuss which topics can translate into potential studies. Step 3 involves the refinement of ideas into a smaller number of pilot projects that are innovative, feasible, sustainable, and patient-centered while advancing diabetes knowledge and care. These ideas are further narrowed in step 4, with the final projects selected by the stakeholders in step 5. Other studies have used engagement logs, interviews, focus groups, and surveys in diabetes research studies at singular or repeated intervals and to different ends as a means to evaluate outcomes related to SE.^{26,34–36}

Patient-reported outcomes (PROs) and advisory committees can also inform the development, implementation, and interpretation of pediatric research, as previously mentioned, and can promote positive health outcomes.^{37–41} The use of parent or proxy reports is commonly used to gain insight of the child, youth, and family experience. Researchers have identified possible limitations in this use of data and have suggested that self-report by children with T1D may provide important subjective data from the child's perspective.⁴² In a study involving children aged 10 to 15 years, Wiebe and colleagues⁴³ evaluated the impact of maternal involvement on coping with T1D from the child's perspective. In a study of the T1D pediatric experience with the use of PROs, Lassen and colleagues³⁹ similarly concluded that the inclusion of self-report measures is valuable and also recommended consideration of the child's age as well as their reading and writing skills.

In a more formalized process, the Development and Evaluation of a Psycho-social Intervention in Children and Teenagers Experiencing Diabetes (DEPICTED) study created a stakeholder action group (SAG) to inform their research intervention.⁸ The planned research intervention was to be deployed in the context of routine diabetes care, so they needed to ensure acceptability by all stakeholders involved, including children and teenagers with diabetes. The DEPICTED SAG participated in meetings, as experts by experience, to actively collaborate on the design of a research and clinical care intervention for patients with diabetes. The funding body for this study required SE, and the investigators cited benefits of stakeholder involvement in contributions to the research intervention design as well as the promise of acceptability of the intervention. In a similar project aimed at personalizing evidence-based interventions to meet individual families' needs, the Achieving control, Connecting resources, and Empowering families (ACE) study also engaged stakeholders in the research process.⁴⁴ This study randomized children and their parents to a family-centered approach for diabetes care and measured outcomes of HbA_{1c} and Quality of Life (QoL). Recognizing the importance of SE and collaboration in the generalizability to real-world implementation, the investigators used SE to optimize trial recruitment, retention, and integration into routine clinical diabetes care.⁴⁴

Across every disease state there are patients and families with varying demographics, including culture, gender, language, ethnicity, race, age, education level, socioeconomic status, and setting (urban vs rural).⁴⁵ Therefore, when engaging with stakeholders, a diverse group should be included. Engagement logs, interviews, focus groups, and surveys have been used in diabetes research studies at singular or repeated intervals and to different ends.^{26,34–36,46} In addition, diverse representation

among those who provide feedback is important (eg, patient vs the parent or legal guardian, a single parent, sibling). When using SE in a research project, special attention must also be given to ensure that SE groups involve members beyond the “usual contributors.”⁴⁷ If this occurs, the risk for marginalization may be minimized when the effort is to tailor the interventions to the entire patient population and not just one subset.⁴⁷ As an example, there are inequities in diabetes care and management with regard to diabetes technology prescription and utilization. To this end, Agarwal and colleagues⁴⁸ address the needs of the diverse population of people with diabetes (PWD) and further diabetes disparities research by using intervention ideas recommended by multidisciplinary stakeholders to reduce inequities in diabetes technology use among people with T1D.

STAKEHOLDER ENGAGEMENT IN DIABETES AND DIVERSITY

SE may help mitigate underrepresentation of individuals from diverse racial/ethnic backgrounds and disparities in T1D research.^{48–53} In general, individuals from diverse racial/ethnic and/or low-income backgrounds are underrepresented in clinical trials, and reporting of study results by racial/ethnic subgroup populations is also inconsistent.⁵⁴ For example, there is a wide body of literature describing underrepresentation of racial/ethnic populations in diabetic eye disease intervention trials. A review of clinical intervention trials for diabetic retinopathy and diabetic macular edema (DME) from 2001 to 2020 demonstrated that black patients with DME were 3 times less likely to be represented in National Institutes of Health (NIH) trials and 4.5 times less likely to be represented in industry trials, despite this population bearing a significant burden of diabetic eye disease in the United States.⁵¹ Furthermore, clinical trial participants are often supported by the study team and by financial compensation in maintaining adherence to trial therapies, which may overrepresent the efficacy of treatments, thereby limiting the generalizability, especially in communities with fewer clinical and social supports.⁵² Clinical trials of diabetes technology are also overrepresented by white participants with few individuals from diverse racial/ethnic backgrounds represented.^{55,56} Given the known disparities in glycemic control, where non-white individuals have up to 2% higher HbA_{1c} levels than their white peers, the larger improvements in HbA_{1c} seen in these automated insulin delivery trials may have greater applicability to black and Hispanic individuals.^{57,58} Especially in diseases with known disparities, such as diabetes, it is even more important to include PWD from diverse racial/ethnic backgrounds so that results are generalizable and applicable to all populations.

Increasing representative SE, particularly in underrepresented communities, can help guide advancement in diabetes care and research.⁴⁸ Given the stark disparities in advanced diabetes technology use with white individuals more likely to use continuous glucose monitors (CGM) and insulin pumps than black and Hispanic individuals with T1D, Agarwal and colleagues^{48,58–60} convened a multidisciplinary stakeholder group of patients and providers to develop solutions to increase technology uptake in diverse and underresourced communities. They determined that providing standard and equitable diabetes technology recommendations, offering hands-on and visual demonstrations of technology, providing peer and social supports, and assisting in navigating insurance and financial coverage would be helpful in increasing technology use among racially and ethnically underrepresented populations with T1D. Similarly, the NIDDK has prioritized SE in informing trial interventions and enhancing participation in communities generally underrepresented in NIH-funded research.

STAKEHOLDER ENGAGEMENT IN QUALITY IMPROVEMENT OF DIABETES CARE

In addition to research, there is also QI work in the health care setting that seeks to systematically plan and implement actions that lead to measurable improvement in the quality and safety of health care services. There are several examples of SE in the QI process in general pediatrics and T1D care. The Roadmap Project was initiated in 2017 by the American Board of Pediatrics after 3 parents of children with chronic conditions requested the creation of a roadmap to improve the emotional health of their children and their families. Through this effort, clinicians, psychologists, and subject matter experts, including patients and families living with a chronic condition, developed a roadmap to identify tools and strategies that could help improve emotional health among children with chronic disease.⁶¹ Family and youth advisory committees have been increasingly created and relied on in research and initiatives associated with diabetes care and QI. In an example in medical education to engage stakeholders with chronic disease, and specifically, T1D, a curriculum was established to engage PWD to learn about research and clinical care at their institution to engage them as meaningful stakeholders.⁶²

One of the largest efforts to incorporate SE into QI for diabetes is through the T1D Exchange Quality Improvement Collaborative (T1DX-QI). This is a national consortium of 55 health care institutions working together in QI initiatives to improve care and outcomes for PWD.⁶³ SE, including patients with diabetes, parents/guardians, clinical collaborators, and industry partners, governs the framework of the T1DX-QI in research design, and qualitative and quantitative surveys. The T1DX-QI also has a Patient/Parent Advisory Committee (PPAC) that includes representation from patients with diabetes and their families to support patient engagement and shared decision making for the Collaborative. The PPAC offers personal expertise on diabetes management and insights on person-centered approach to care in all QI initiatives. Health equity work is governed by members of the Health Equity Advancement Lab Committee, which is composed of clinicians, researchers, industry partners, and PWD working together to design the strategy for the Collaborative's equity work.

Clinical centers that join the T1DX-QI are encouraged to engage PWD and their family members in QI work and interventions. PWD and parent team representatives complete online training in QI fundamentals. They are also invited to attend in-person semiannual learning sessions to supplement the fundamentals training, as well as provide advice and input on the design and development of QI goals and objectives. They provide feedback for educational materials designed for clinician training and PWD/family education sessions. The partnership seeks to better understand the patient and family perspective and experience to prioritize and improve comprehensive and compassionate person-centered and family-centered health care.

The T1D Exchange Registry is an online, longitudinal research study designed to capture the experiences and challenges of individuals living with T1D. It tracks disease progress over time and includes more than 18,000 people living with T1D in the United States. The T1D Exchange Registry gathers information directly from PWD, including data on disease management, CGM data, and self-reported outcomes. Participants of the registry can also complete an annual questionnaire and subsequently have the option to participate in additional research studies that are shared on behalf of industry and academic health care partners throughout the year.

The T1D Exchange Registry provides participants with an online dashboard of curated T1D research opportunities, which can facilitate research participation among people with T1D, and has contributed to thousands of people engaging in research studies through the T1D Exchange Registry. The T1DX also manages an

Online Community with more than 50,000 participants that represent an anonymous, uncharacterized population who can participate in research surveys. In addition, the T1DX's Web site hosts The Question of the Day, a survey that is answered by an average of 500 people daily from the Online Community. These surveys consist of daily queries, and responses are received from a diverse stakeholder group, composed of PWD, parents and caregivers of PWD, and health care professionals who care for PWD.

STAKEHOLDER ENGAGEMENT IN DIABETES CLINICAL CARE

SE and the involvement of patients as partners extend to the implementation and dissemination of clinical care initiatives. Considering diverse patient perspectives and experiences of communities with varied backgrounds in the delivery of health care can ensure that patients and their supports (caregiver/family) receive optimal clinical care.⁶⁴ Various questionnaires have measured patients' experiences with both outpatient and inpatient health care and have highlighted several components that are meaningful to patients, including physical comfort, quality of care, emotional support, communication and education, involvement of supports such as family and friends, scheduling and timeliness of appointments, organization and coordination of care, and the physical environment.⁶⁵⁻⁶⁷ In clinical care, SE has been used with patients and families to co-design, involving patients in the operational and process improvement goals of the practice with the long-term goals of improving patient experiences and health outcomes. In diabetes care, considering the patient experience at diagnosis and throughout ongoing treatment across the lifespan is critical to ensure that the needs and priorities at each stage and transition are addressed.

Essential forms of SE have included the use of PROs, Parent Advisory Committees, and Patient and Family Advisory Councils. These types of SE promote the consideration of pediatric and adolescent patient and parent perspectives and engagement in shared decision making throughout the course of pediatric patients' health care. Hospitals, for example, are more commonly using family/parent or patient advisory committees to comment on or suggest adjustments to all areas of hospital care and research by creating child- and family-centered programs and services.⁶⁸ These committees provide a space to identify a wide range of personal biases and obstacles that should be discussed to better support self-management behaviors and therefore have a positive impact on clinical outcomes.⁶⁹ In the next section, the importance of SE throughout childhood and adolescence and the unique aspects of adulthood and elder care in diabetes care are expanded upon.

Pediatric and Adolescent Care

Caregiver and parent support as well as team decision making are critical for children with T1D and require communication between many stakeholders, including endocrinologists, pediatricians, and daycare or school team members. For children with additional special health care needs, communication with special education and mental health care team members is also important to promote both informed and shared decision making.

The development of optimal pediatric and adolescent treatment models and research programs is complex, as physiologic and psychosocial issues shift over time. Better understanding the experience of children and adolescents with diabetes is critical to achieve optimal diabetes management during these stages of development, which has remained a challenge despite improvements in diabetes treatment options.^{70,71} Developmentally appropriate diabetes care is complex and, according

to the ADA Position Statement on Type 1 Diabetes in Children and Adolescents, “Diabetes management for children must not be extrapolated from adult diabetes care.”⁷²

Stakeholder engagement in pediatric clinical care

In another example of patient-centered care, Davis and MacKay⁷³ qualitatively interviewed a group of young adults and adolescents with T1D to understand their use of the electronic medical record (EMR) to design it with their input.

In a study focused on the health care transition for young adults with T1D to adult care, Pierce and colleagues included the perspectives of young adults with T1D, parents, providers, and other health care transition experts to develop a measure for evaluating outcomes. Before this study, the focus of health care transition outcomes was often on glycemic control, hospitalization rates, and loss to follow-up.⁷⁴ However, by involving all key stakeholders in qualitative interviews, Pierce and colleagues⁷⁵ determined that in addition to markers of glycemic control, other important aspects of transition to adult care included navigating a new health care system, confidence in self-management skills, integration of care in the adult role, and autonomy and ownership in T1D management.

Stakeholder engagement in pediatric research

PROs and advisory committees can also inform the development, implementation, and interpretation of pediatric research, as previously mentioned, and can promote positive health outcomes.^{37–41} The use of parent or proxy reports is commonly used to gain insight of the child, youth, and family experience. Researchers have identified possible limitations in this use of data and have suggested that self-report by children with T1D may provide important subjective data from the child’s perspective.⁴² In a study involving children aged 10 to 15 years, Wiebe and colleagues⁴³ evaluated the impact of maternal involvement on coping with T1D from the child’s perspective. In a study of the T1D pediatric experience with the use of PROs, Lassen and colleagues³⁹ similarly concluded that the inclusion of self-report measures is valuable and also recommended consideration of the child’s age as well as their reading and writing skills.

In a more formalized process, the DEPICTED study created a SAG to inform their research intervention.⁸ The planned research intervention was to be deployed in the context of routine diabetes care, so they needed to ensure acceptability by all stakeholders involved, including children and teenagers with diabetes. The DEPICTED SAG participated in meetings, as experts by experience, to actively collaborate on the design of a research and clinical care intervention for patients with diabetes. The funding body for this study required SE, and the investigators cited benefits of stakeholder involvement in contributions to the research intervention design as well as the promise of acceptability of the intervention. In a similar project aimed at personalizing evidence-based interventions to meet individual families’ needs, the ACE study also engaged stakeholders in the research process.⁴⁴ This study randomized children and their parents to a family-centered approach for diabetes care and measured outcomes of HbA_{1c} and QoL. Recognizing the importance of SE and collaboration in the generalizability to real-world implementation, the investigators used SE to optimize trial recruitment, retention, and integration into routine clinical diabetes care.⁴⁴

Stakeholder engagement in the pediatric school setting

The close collaboration and coordination of care between the student with T1D and their family, diabetes care team, and school team members responsible for supporting a student’s diabetes care during school activities are necessary, as children often spend significant amounts of time at school. School team members involved with a

student's diabetes care may include a school nurse, health aide, teacher, administrator, 504 Plan or IEP team members, school psychologist, coach, school bus driver, and/or other designated trained adults.^{76,77}

As SE in research naturally leads to team science, another useful application is in studies involving community-based services or programs, such as in schools, child-care programs, camps, or other settings. Indeed, several studies on diabetes care in the school setting have integrated the perspectives of parent, school staff, and diabetes provider stakeholders to varying degrees. In a qualitative study by March and colleagues⁷⁸ on school nurse experiences with modern diabetes technologies, vested stakeholders participated in the design of study materials (eg, interview guide), subject recruitment, and the analysis of emerging themes.³⁵ A similar approach has been applied to subsequent studies examining other aspects of school-based diabetes care delivery, including surveys targeting both school health staff and diabetes care providers.^{79–81} In these studies, partnering with community members purportedly strengthened the study's validity, as the stakeholders provided input on whether the findings resonated with their real-world experiences.

Women's Health in Diabetes Care

Women with T1D who are planning for pregnancy or who become pregnant face morbidity and mortality risks that are 2 to 3 times higher than women without diabetes.⁸² The health risks and complications associated with T1D include preeclampsia, hyperglycemia, hypoglycemia, macrosomia, preterm labor, miscarriage, birth injury, macrosomia, C-section, retinopathy, postpartum hemorrhaging, and perinatal mortality.^{83,84} These pregnancies require frequent follow-up and close monitoring by specialty care; fetal movement counting, ultrasounds, and nonstress testing are managed solely or co-managed by endocrinology, primary care, maternal-fetal medicine (MFM), and obstetrics. Adults with T1D who are not pregnant are recommended to have 2 diabetes care visits annually, whereas prenatal women with T1D require monthly to multiple visits per week, depending on the gestational age and the risk of complications.^{31,85}

The chronic disease nature of diabetes means that people will often receive care from the same clinic or practice for long periods of time, sometimes decades, whereas the pregnancy remains a relatively short, critical period of approximately 40 weeks, plus postpartum care. There is a quintuple impact on women experiencing one of the most challenging times for diabetes management: (1) her diabetes care team often changes completely, with care transitioning from diabetes and endocrinology to obstetrics and/or MFM; (2) she experiences rapid changes in insulin resistance and insulin requirements; (3) blood glucose goals change drastically from 70 to 180 mg/dL time in range (TIR) to less than 95 mg/dL fasting and 120 mg/dL 2 hours postprandial; (4) many diabetes devices are not US Food and Drug Administration approved for use during pregnancy; and finally, (5) she manages the stress of knowing that the daily decision making of diabetes impacts her health and the health of her fetus, and this may influence treatment decisions that result in hypoglycemia, which may lead to further challenges.^{86,87}

It is critical that, throughout the pregnancy period, women should not be sequestered to a single specialty area for their care needs. Instead, they should have access to the expertise of all their subspecialists and specialists, including their endocrinologists and diabetologists. SE communication can be used to empower teams and support women during pregnancy planning, the pregnancy term, and perinatal care. Building communication paths that flow between endocrine, primary, MFM, obstetrics, and PWD will lessen opportunities for errors or gaps in care. Instead, collaborating care

teams that build a true multidisciplinary network that extends beyond the walls of a practice and specialty can understand and communicate changes, needs, and patient preferences that evolve over pregnancies.

Patient and provider collaboration in perinatal care

One of the greatest challenges at this time is the confluence of change and uncertainty.⁸⁸ During pregnancy, PWD will often defer to medical decision making because of their concern for the health and safety of the fetus, especially women experiencing pregnancy for the first time.^{89,90} Endocrine and diabetes providers are often out of the loop for the pregnancy term and may believe that the PWD's health is best managed by the obstetrics teams during pregnancy. Obstetrics and MFM teams often struggle with diabetes management owing, in part, to limited knowledge about the PWD's diabetes management style and diabetes-related experiences. This time of transition and lack of care continuity can lead to many challenges that impact patient-provider trust.⁹¹

There are opportunities to build relationships, SE, and continuity during the prenatal, perinatal, and postnatal periods.⁸⁵ Understanding that, sometimes, new and additional specialty care teams are necessary to support PWD during their pregnancies, the authors suggest these 5 following steps be taken to improve PWD experience and support their engagement⁹²:

1. Optimize communication between care provider teams: Facilitate teamwork by hosting a (virtual or in-person) hand-off meeting between the diabetes care team and MFM/obstetrics specialist; PWD should be central in the decision making and communications of preferences, priorities, and concerns, whereas the logistics of communicating and follow-up between care teams should remain the responsibility of the care team, not the PWD.
2. Facilitate ongoing communication: If the department managing the pregnancy term uses an EMR system that is separate from the diabetes care EMR system, make the follow-up appointment notes accessible for all.
3. Coordination of care: Make staff introductions between members of the MFM, diabetes, endocrinology, obstetrics, and primary care teams to improve communication, coordination, and continuity.
4. Postpartum hand-off: Host a second hand-off meeting postpartum to communicate priorities with the endocrinology and primary care team members so that they can continue the PWD's care management informed by the pregnancy period and support the PWD's postpartum health.
5. Include PWD in all decision making and communications.

Postpartum diabetes care also brings many transition periods with PWD experiencing a change in insulin sensitivity and additional risks for hypoglycemia during breastfeeding.⁸⁵ This may also be a time that PWD transition their care back to their primary care or Endocrinology teams while they are still experiencing postpartum symptoms and concerns. It is important to maintain open communication between MFM, obstetrics, primary, and endocrine care providers to best support the PWD.

Diabetes and Elder Care

T1D management becomes more complex for people over the age of 65 years and for people with long diabetes duration. High HbA_{1c} and high glucose variability are associated with a decline in cognitive function.⁹³ ADA Standards of Care recommend using assessments to identify appropriate targets and therapeutic approaches for older adults (OA). It is appropriate to screen for risks that are prevalent for OA with diabetes,

including cognitive impairment, vision and hearing loss, falls, depression, and cardiovascular diseases.^{31,94}

Hypoglycemia unawareness is more common for people over the age of 65 years, and glucose targets should be personalized appropriately for QoL and safety.⁹⁵ HbA_{1c} targets of 7.5% to 8% may be more appropriate for adults over the age of 80 years and adults aged 65 to 80 years who are managing comorbidities and/or hypoglycemia unawareness. CGM use is recommended for OA, considering the dangers of severe hypoglycemia events that are exacerbated by hypoglycemia unawareness.⁹⁶ Minimizing hypoglycemia, maximizing QoL, and reducing burden of disease management should all be considered with age-related changes.⁹⁷ OA with T1D also experience changes in dexterity, vision, hearing, and strength and are diagnosed with Alzheimer disease and dementia at higher rates than peers without diabetes.⁹⁸

Engaging OA in their health care and involving family members and caregivers, and empowering them to support the well-being of the OA with diabetes are important ways to build SE in this population.⁹⁹ Patients and caregivers should be the decision makers in how and at what level they engage with their health care teams.⁹⁹ Assessment and reassessment of OA diabetes management needs should be considered often because of the potential for acute changes in health. Care teams should consider the goals and wishes of OA with diabetes by involving them directly in considering the advantages and disadvantages of care management and QoL decisions. Teams should be intentional to avoid bias and age discrimination and to avoid making assumptions about OA capacity.

Active listening and asking open-ended questions help care teams understand where they can match support and resources to PWD and family preferences.¹⁰⁰ Devices should accommodate OA needs and preferences; care teams should help to make them accessible, knowing that OA with arthritis or OA who have experienced a stroke may have more challenges with devices that require fine dexterity and fine motor skills. Small print and small screens may be additional barriers where OA may need more accommodations. Events like falls have significant health impacts for OA. Addressing individual needs to accommodate health changes with age and involving family members and caregivers in education and training sessions can support SE and increase participation in diabetes management through the lifespan.¹⁰¹

Because OA can transition to a more fragile state that requires additional support, it is critical to periodically reassess to understand what the new needs, goals, and preferences are, as they may change over time and after acute health events. These events may also change the OA outlook such that they may benefit from mental health counseling. Offering psychosocial support and communicating referrals to psychosocial professionals may benefit OA mental health, supporting overall diabetes management and whole person health.¹⁰²

OA have complex needs in managing their diabetes and their overall health. Collaborating with them and their caregivers to know their preferences and priorities is paramount. Care teams can help support their needs by communicating across primary, specialty, and tertiary care providers to improve care coordination, safety, and satisfaction. Clinicians and other stakeholders in OA diabetes care should advocate for OA needs with public and private insurers to ensure that care is comprehensive, supporting medication and device access so that costs are not overwhelming barriers.¹⁰³ This is especially critical for a population with a fixed income and limited financial resources. Comprehensive care should also include free/affordable occupational therapy/physical therapy, behavioral and mental health, as well as prevention services.¹⁰⁴ Diabetes care teams should communicate OA needs with device manufacturers to ensure that devices and products are designed to meet the needs of the population. The health

of OA and their self-management capacity can change rapidly.¹⁰⁵ Staying up-to-date with their needs by assessing changes in the domains of their health is essential; communicating across stakeholder groups to have agreement and understanding of health priorities and approaches is also important. For successful engagement, barriers should be removed by making the clinic and hospital spaces accessible and comfortable for older people, ensuring that lighting, text/print size, floor spaces, seating, and tables do not limit OA. Spaces and materials should be designed to match the requirements and preferences of the people receiving care.^{94,106}

SUMMARY

The engagement of stakeholders in T1D research has increased over the last 10 years and has led to patient-centered research and interventions, as well as wider representation among diverse populations in research. Dissemination of clinical interventions has further expanded the role of stakeholders in QI initiatives and the clinical care setting. The management of diabetes across the lifespan is dynamic and changes with each life stage, which further highlights the importance of engaging stakeholders in the design and implementation of multidisciplinary clinical care from childhood, through adolescence, adulthood, pregnancy care, and elder care. The addition of patient and family advisory panels has facilitated a focus on patient-centered care and PROs that ensure research, QI, and clinical interventions match the values and goals of the patient populations. Although funding agencies are increasingly requiring SE in diabetes research, the integration of stakeholders in QI and clinical care is still in the early stages. The T1DX has facilitated a robust engagement of patient and provider stakeholders in their QI efforts that can provide a framework for other programs and initiatives, as well as in the clinical realm. Although currently there is a limited body of literature on SE in T1D, the authors anticipate that future collaboration among funding agencies, QI consortiums, health care systems and providers, community organizations, and PWD will facilitate growth of SE initiatives that will have a significant impact on outcomes for PWD. By providing a voice to all those involved in the care of PWD, the care and outcomes for PWD can be advanced.

ACKNOWLEDGMENTS

The authors acknowledge Neha Parimi for her assistance with formatting and references.

AUTHORS' DISCLOSURES

R.M. Wolf receives research support from Novo Nordisk as the site PI of a clinical trial.

REFERENCES

1. ElSayed NA, Aleppo G, Aroda VR, et al. Classification and diagnosis of diabetes: standards of care in diabetes-2023. *Diabetes Care* 2023;46(Suppl 1): S19–40.
2. Institute, P.C.O.R. PCORI engagement rubric for applicants. 2014 06/06/2016 (cited 2023, 10 July 2023); Available at: <https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>.
3. Sheridan S, Schrandt S, Forsythe L, et al. The PCORI engagement rubric: promising practices for partnering in research. *Ann Fam Med* 2017;15(2):165–70.
4. STROKOFF SL. Compilation of patient protection and affordable care act. In: Subtitle D of Title VI. U.S.H.O. Representatives; 2010.

5. PCORI. patient centered outcome institute (cited 2023 06/16/2023); Available at: <https://www.pcori.org/>.
6. PCORI Methodology Committee. The PCORI Methodology Report. Patient-Centered Outcomes Research Institute (PCORI). Washington, DC; 2013.
7. Hoddinott P, Pollock A, O’Cathain A, et al. How to incorporate patient and public perspectives into the design and conduct of research. *F1000Res* 2018;7:752.
8. Lowes L, Robling MR, Bennert K, et al. Involving lay and professional stakeholders in the development of a research intervention for the DEPICTED study. *Health Expect* 2011;14(3):250–60.
9. Forsythe L, Heckert A, Margolis MK, et al. Methods and impact of engagement in research, from theory to practice and back again: early findings from the patient-centered outcomes Research Institute. *Qual Life Res* 2018;27(1):17–31.
10. Forsythe LP, Ellis LE, Edmundson L, et al. Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med* 2016;31(1):13–21.
11. Manafo E, Petermann L, Vandall-Walker V, et al. Patient and public engagement in priority setting: A systematic rapid review of the literature. *PLoS One* 2018;13(3):e0193579.
12. Bennett LM, Gadlin H. Collaboration and team science: from theory to practice. *J Investig Med* 2012;60(5):768–75.
13. Motu’apuaka M, Whitlock E, Kato E, et al. Defining the benefits and challenges of stakeholder engagement in systematic reviews. *Comp Eff Res* 2015;5:13.
14. Hahn DL, Hoffmann AE, Felzien M, et al. Tokenism in patient engagement. *Fam Pract* 2017;34(3):290–5.
15. Harrison JD, Anderson WG, Fagan M, et al. Patient and family advisory councils (PFACs): identifying challenges and solutions to support engagement in research. *Patient* 2018;11(4):413–23.
16. Arkind J, Likumuwa-Ackman S, Warren N, et al. Lessons learned from developing a patient engagement panel: an OCHIN Report. *J Am Board Fam Med* 2015;28(5):632–8.
17. Sheridan S, S.S. A framework for financial compensation for patient partners in research. 2018, (cited 2023, July 11, 2023); Available from: <https://www.pcori.org/blog/framework-financial-compensation-patient-partners-research>.
18. CD M, Integrating patients’ voices in study design elements with a focus on hard-to-reach populations, 2012, Patient-Centered Outcomes Research Institute, (PCORI). Accessed July 10, 2023.
19. Viswanathan M, Ammerman A, Eng E, et al. Community-based participatory research: assessing the evidence. *Evid Rep Technol Assess* 2004;(99):1–8.
20. Yonas MA, Jaime MC, Barone J, et al. Community partnered research ethics training in practice: a collaborative approach to certification. *J Empir Res Hum Res Ethics* 2016;11(2):97–105.
21. Petkovic J, Riddle A, Lytvyn L, et al. PROTOCOL: Guidance for stakeholder engagement in guideline development: A systematic review. *Campbell Syst Rev* 2022;18(2):e1242.
22. O’Haire C., McPheeters M., Nakamoto E., et al., Engaging Stakeholders To Identify and Prioritize Future Research Needs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011. (Methods Future Research Needs Reports, No. 4.) Executive Summary. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK62559/>.

23. Concannon TW, Fuster M, Saunders T, et al. A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. *J Gen Intern Med* 2014;29(12):1692–701.
24. Concannon TW, Grant S, Welch V, et al. Practical guidance for involving stakeholders in health research. *J Gen Intern Med* 2019;34(3):458–63.
25. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. *J Comp Eff Res* 2015;4(2):133–45.
26. Martinez J, Wong C, Piersol CV, et al. Stakeholder engagement in research: a scoping review of current evaluation methods. *J Comp Eff Res* 2019;8(15):1327–41.
27. Bowen DJ, Hyams T, Goodman M, et al. Systematic review of quantitative measures of stakeholder engagement. *Clin Transl Sci* 2017;10(5):314–36.
28. Ray KN, Miller E. Strengthening stakeholder-engaged research and research on stakeholder engagement. *J Comp Eff Res* 2017;6(4):375–89.
29. (IPFCC), I.o.p.a.f.c.c. Effective patient and family advisory councils. Available from: <https://www.ipfcc.org/bestpractices/sustainable-partnerships/engaging/effective-pfacs.html>. Accessed July 10, 2023.
30. AHRQ. Agency for Healthcare Research and Quality (AHRQ). (cited 2023 7/11/2023); Available at: <https://www.ahrq.gov/>.
31. ElSayed NA, Aleppo G, Aroda VR, et al. Summary of revisions: standards of care in diabetes-2023. *Diabetes Care* 2023;46(Suppl 1):S5–9.
32. NIDDK. National Institute of Diabetes and Digestive and Kidney Diseases (cited 2023 7/11/23); Available from: <https://www.niddk.nih.gov/>.
33. Schmittiel JA, Desai J, Schroeder EB, et al. Methods for engaging stakeholders in comparative effectiveness research: a patient-centered approach to improving diabetes care. *Healthc (Amst)* 2015;3(2):80–8.
34. Greenwood DA, Litchman ML, Ng AH, et al. Development of the intercultural diabetes online community research council: codesign and social media processes. *J Diabetes Sci Technol* 2019;13(2):176–86.
35. March CA, Kazmerski TM, Moon C, et al. Evaluating the impact of stakeholder engagement in a school-based type 1 diabetes study. *Diabetes Spectr* 2021;34(4):419–24.
36. McElfish PA, Ayers BL, Felix HC, et al. How stakeholder engagement influenced a randomized comparative effectiveness trial testing two Diabetes Prevention Program interventions in a Marshallese Pacific Islander Community. *J Transl Med* 2019;17(1):42.
37. Gianini A, Suklan J, Skela-Savič B, et al. Patient reported outcome measures in children and adolescents with type 1 diabetes using advanced hybrid closed loop insulin delivery. *Front Endocrinol* 2022;13:967725.
38. Hannon TS, Moore CM, Cheng ER, et al. Codesigned shared decision-making diabetes management plan tool for adolescents with type 1 diabetes mellitus and their parents: prototype development and pilot test. *J Particip Med* 2018;10(2):e8.
39. Lassen RB, Abild CB, Kristensen K, et al. Involving children and adolescents with type 1 diabetes in health care: a qualitative study of the use of patient-reported outcomes. *Journal of Patient-Reported Outcomes* 2023;7(1):20.
40. Lassen RB, Abild CB, Kristensen K, et al. Patient-reported outcome instruments for assessing the involvement of children and adolescents with type 1 diabetes in their treatment: a scoping review protocol. *JBIM Evid Synth* 2023;21(3):609–16.
41. Yu CH, Ivers NM, Stacey D, et al. Impact of an interprofessional shared decision-making and goal-setting decision aid for patients with diabetes on

- decisional conflict–study protocol for a randomized controlled trial. *Trials* 2015; 16:286.
42. Nieuwesteeg AM, Pouwer F, van Bakel HJ, et al. Quality of the parent-child interaction in young children with type 1 diabetes mellitus: study protocol. *BMC Pediatr* 2011;11:28.
 43. Wiebe DJ, Berg CA, Korbel C, et al. Children's appraisals of maternal involvement in coping with diabetes: enhancing our understanding of adherence, metabolic control, and quality of life across adolescence. *J Pediatr Psychol* 2005;30(2):167–78.
 44. Fiallo-Scharer R, Palta M, Chewning BA, et al. Design and baseline data from a PCORI-funded randomized controlled trial of family-centered tailoring of diabetes self-management resources. *Contemp Clin Trials* 2017;58:58–65.
 45. Rolfe DE, Ramsden VR, Banner D, et al. Using qualitative Health Research methods to improve patient and public involvement and engagement in research. *Res Involv Engagem* 2018;4:49.
 46. Poger JM, Yeh HC, Bryce CL, et al. PaTH to partnership in stakeholder-engaged research: A framework for stakeholder engagement in the PaTH to Health Diabetes study. *Healthc (Amst)* 2020;8(1):100361.
 47. Bonet Olivencia S, Rao AH, Smith A, et al. Eliciting requirements for a diabetes self-management application for underserved populations: a multi-stakeholder analysis. *Int J Environ Res Public Health* 2021;19(1).
 48. Agarwal S, Crespo-Ramos G, Leung SL, et al. Solutions to address inequity in diabetes technology use in type 1 diabetes: results from multidisciplinary stakeholder co-creation workshops. *Diabetes Technol Ther* 2022;24(6):381–9.
 49. Berkowitz ST, Groth SL, Gangaputra S, et al. Racial/ethnic disparities in ophthalmology clinical trials resulting in US Food and Drug Administration Drug Approvals From 2000 to 2020. *JAMA Ophthalmol* 2021;139(6):629–37.
 50. Bowe T, Salabati M, Soares RR, et al. Racial, ethnic, and gender disparities in diabetic macular edema clinical trials. *Ophthalmol Retina* 2022;6(6):531–3.
 51. Sanjiv N, Osathanugrah P, Harrell M, et al. Race and ethnic representation among clinical trials for diabetic retinopathy and diabetic macular edema within the United States: A review. *J Natl Med Assoc* 2022;114(2):123–40.
 52. Sherman RE, Anderson SA, Dal Pan GJ, et al. Real-world evidence - what is it and what can it tell us? *N Engl J Med* 2016;375(23):2293–7.
 53. Soares RR, Parikh D, Shields CN, et al. Geographic access disparities to clinical trials in diabetic eye disease in the United States. *Ophthalmol Retina* 2021;5(9): 879–87.
 54. Corbie-Smith G, St George DMM, Moody-Ayers S, et al. Adequacy of reporting race/ethnicity in clinical trials in areas of health disparities. *J Clin Epidemiol* 2003;56(5):416–20.
 55. Beck RW, Kanapka LG, Breton MD, et al. A meta-analysis of randomized trial outcomes for the t:slim X2 insulin pump with control-IQ technology in youth and adults from age 2 to 72. *Diabetes Technol Ther* 2023;25(5):329–42.
 56. Ruedy KJ, Parkin CG, Riddlesworth TD, et al. Continuous glucose monitoring in older adults with type 1 and type 2 diabetes using multiple daily injections of insulin: results from the DIAMOND Trial. *J Diabetes Sci Technol* 2017;11(6): 1138–46.
 57. Agarwal S, Kanapka LG, Raymond JK, et al. Racial-ethnic inequity in young adults with type 1 diabetes. *J Clin Endocrinol Metab* 2020;105(8):e2960–9.

58. Willi SM, Miller KM, DiMeglio LA, et al. Racial-ethnic disparities in management and outcomes among children with type 1 diabetes. *Pediatrics* 2015;135(3):424–34.
59. Agarwal S, Schechter C, Gonzalez J, et al. Racial-ethnic disparities in diabetes technology use among young adults with type 1 diabetes. *Diabetes Technol Therapeut* 2021;23(4):306–13.
60. Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes Technol Ther* 2019;21(2):66–72.
61. PEDIATRICS, A.B.o. Roadmap to Resilience, Emotional, and Mental Health. (Website) 05/22/2023 (cited 2023 06/16/2023); Available from: <https://www.abp.org/foundation/roadmap>.
62. Walker AF, Atkinson MA, Lee AM, et al. Teaching type 1 diabetes: creating stakeholder engagement in biomedical careers through undergraduate research curriculum. *Med Sci Educ* 2020;30(1):69–73.
63. Exchange, T.D. T1D Exchange Available at: <https://t1dexchange.org/>. Accessed July 24, 2023.
64. Schroeder K, Bertelsen N, Scott J, et al. Building from patient experiences to deliver patient-focused healthcare systems in collaboration with patients: a call to action. *Ther Innov Regul Sci* 2022;56(5):848–58.
65. Benson T, Potts HW. A short generic patient experience questionnaire: howRwe development and validation. *BMC Health Serv Res* 2014;14:499.
66. Jenkinson C, Coulter A, Bruster S. The picker patient experience questionnaire: development and validation using data from in-patient surveys in five countries. *Int J Qual Health Care* 2002;14(5):353–8.
67. Kemp K, McCormack B, Chan N, et al. Correlation of inpatient experience survey items and domains with overall hospital rating. *J Patient Exp* 2015;2(2):29–36.
68. Hospital, H.C.s. Family partnership programs. Available at: <https://nyulangone.org/locations/hassenfeld-childrens-hospital/sala-child-family-support/family-partnership-programs>. Accessed July 10, 2023.
69. Hamilton K, Stanton-Fay SH, Chadwick PM, et al. Sustained type 1 diabetes self-management: Specifying the behaviours involved and their influences. *Diabet Med* 2021;38(5):e14430.
70. Demeterco-Berggren C, Ebekozien O, Noor N, et al. Factors associated with achieving target A1C in children and adolescents with type 1 diabetes: findings from the T1D exchange quality improvement collaborative. *Clin Diabetes* 2022;41(1):68–75.
71. Miller KM, Beck RW, Foster NC, et al. HbA1c levels in type 1 diabetes from early childhood to older adults: a deeper dive into the influence of technology and socioeconomic status on HbA1c in the T1D exchange clinic registry findings. *Diabetes Technol Ther* 2020;22(9):645–50.
72. Chiang JL, Maahs DM, Garvey KC, et al. Type 1 diabetes in children and adolescents: a position statement by the American Diabetes Association. *Diabetes Care* 2018;41(9):2026–44.
73. Davis S, MacKay L. Moving beyond the rhetoric of shared decision-making: designing personal health record technology with young adults with type 1 diabetes. *Can J Diabetes* 2020;44(5):434–41.
74. Lyons SK, Becker DJ, Helgeson VS. Transfer from pediatric to adult health care: effects on diabetes outcomes. *Pediatr Diabetes* 2014;15(1):10–7.

75. Pierce JS, Aroian K, Schifano E, et al. Health care transition for young adults with type 1 diabetes: stakeholder engagement for defining optimal outcomes. *J Pediatr Psychol* 2017;42(9):970–82.
76. ADA. Training Resources for School Staff. 06/21/2023; Available at: <https://diabetes.org/tools-support/know-your-rights/safe-at-school-state-laws/training-resources-school-staff>. Accessed July 11, 2023.
77. Jackson CC, Albanese-O'Neill A, Butler KL, et al. Diabetes care in the school setting: a position statement of the American Diabetes Association. *Diabetes Care* 2015;38(10):1958–63.
78. March CA, Nanni M, Kazmerski TM, et al. Modern diabetes devices in the school setting: Perspectives from school nurses. *Pediatr Diabetes* 2020;21(5):832–40.
79. March C, Siminerio LM, Kazmerski TM, et al. School-based diabetes care: a national survey of U.S. pediatric diabetes providers. *Pediatr Diabetes* 2023; 2023:1–10.
80. March CA, Hill A, Kazmerski TM, et al. Development and psychometric analysis of the Diabetes Device Confidence Scale for school nurses. *Pediatr Diabetes* 2022;23(6):820–30.
81. March CA, Hill A, Kazmerski TM, et al. School nurse confidence with diabetes devices in relation to diabetes knowledge and prior training: a study of convergent validity. *Pediatr Diabetes* 2023;2023:2162900.
82. Knorr S, Juul S, Bytoft B, et al. Impact of type 1 diabetes on maternal long-term risk of hospitalisation and mortality: a nationwide combined clinical and register-based cohort study (The EPICOM study). *Diabetologia* 2018;61(5):1071–80.
83. Alexopoulos AS, Blair R, Peters AL. Management of preexisting diabetes in pregnancy: a review. *JAMA* 2019;321(18):1811–9.
84. Jaffar F, Laycock K, Huda MSB. Type 1 diabetes in pregnancy: a review of complications and management. *Curr Diabetes Rev* 2022;18(7). e051121197761.
85. Feldman AZ, Brown FM. Management of type 1 diabetes in pregnancy. *Curr Diab Rep* 2016;16(8):76.
86. Crimmins SD, Ginn-Meadow A, Jessel RH, et al. Leveraging technology to improve diabetes care in pregnancy. *Clin Diabetes* 2020;38(5):486–94.
87. Kitzmiller JL, Block JM, Brown FM, et al. Managing preexisting diabetes for pregnancy: summary of evidence and consensus recommendations for care. *Diabetes Care* 2008;31(5):1060–79.
88. Watkins V, Nagle C, Kent B, et al. Labouring Together: Women's experiences of "Getting the care that I want and need" in maternity care. *Midwifery* 2022;113: 103420.
89. McCance DR. Pregnancy and diabetes. *Best Pract Res Clin Endocrinol Metab* 2011;25(6):945–58.
90. Murugesu L, Damman OC, Derksen ME, et al. Women's participation in decision-making in maternity care: a qualitative exploration of clients' health literacy skills and needs for support. *Int J Environ Res Public Health* 2021;18(3).
91. Nicoloro-SantaBarbara J, Rosenthal L, Auerbach MV, et al. Patient-provider communication, maternal anxiety, and self-care in pregnancy. *Soc Sci Med* 2017;190:133–40.
92. Goldberg H. Informed decision making in maternity care. *J Perinat Educ* 2009; 18(1):32–40.
93. Yaffe K, Falvey C, Hamilton N, et al. Diabetes, glucose control, and 9-year cognitive decline among older adults without dementia. *Arch Neurol* 2012;69(9): 1170–5.

94. McNeil H, Elliott J, Huson K, et al. Engaging older adults in healthcare research and planning: a realist synthesis. *Res Involv Engagem* 2016;2:10.
95. Carlson AL, Kanapka LG, Miller KM, et al. Hypoglycemia and glycemic control in older adults with type 1 diabetes: baseline results from the WISDM study. *J Diabetes Sci Technol* 2021;15(3):582–92.
96. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. *JAMA* 2020;323(23):2397–406.
97. Dhaliwal R, Weinstock RS. Management of type 1 diabetes in older adults. *Diabetes Spectr* 2014;27(1):9–20.
98. Jacobson AM, Ryan CM, Braffett BH, et al. Cognitive performance declines in older adults with type 1 diabetes: results from 32 years of follow-up in the DCCT and EDIC Study. *Lancet Diabetes Endocrinol* 2021;9(7):436–45.
99. Elliott J, McNeil H, Ashbourne J, et al. Engaging older adults in health care decision-making: a realist synthesis. *Patient* 2016;9(5):383–93.
100. Frost H, Campbell P, Maxwell M, et al. Effectiveness of motivational interviewing on adult behaviour change in health and social care settings: a systematic review of reviews. *PLoS One* 2018;13(10):e0204890.
101. Bennett WL, et al. Strategies for Patient, Family, and Caregiver Engagement. Rockville (MD). Agency for Healthcare Research and Quality (US); AHRQ Comparative Effectiveness Technical Briefs; 2020. <https://pubmed.ncbi.nlm.nih.gov/32924385/>.
102. Pennbrant S, Berg A, Fohlin Johansson L. Self-care experiences of older patients with diabetes mellitus: A qualitative systematic literature review. *Nord J Nurs Res* 2020;40(2):64–72.
103. Fitzpatrick AL, Powe NR, Cooper LS, et al. Barriers to health care access among the elderly and who perceives them. *Am J Public Health* 2004;94(10):1788–94.
104. Nicholas JA, Hall WJ. Screening and preventive services for older adults. *Mt Sinai J Med* 2011;78(4):498–508.
105. Taboada Gjorup AL, Snoek FJ, van Duinkerken E. Diabetes self-care in older adults with type 1 diabetes mellitus: how does cognition influence self-management. *Front Clin Diabetes Healthc* 2021;2:727029.
106. Sharma AE, Willard-Grace R, Willis A, et al. How can we talk about patient-centered care without patients at the table?" lessons learned from patient advisory councils. *J Am Board Fam Med* 2016;29(6):775–84.