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Monograph

University of Pennsylvania Telehealth Research Center of Excellence

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Abstract

Drawing from insights from communication science and behavioral economics, the University of Pennsylvania Telehealth Research Center of Excellence (Penn TRACE) is designing and testing telehealth strategies with the potential to transform access to care, care quality, outcomes, health equity, and health-care efficiency across the cancer care continuum, with an emphasis on understanding mechanisms of action. Penn TRACE uses lung cancer care as an exemplar model for telehealth across the care continuum, from screening to treatment to survivorship. We bring together a diverse and interdisciplinary team of international experts and incorporate rapid-cycle approaches and mixed methods evaluation in all center projects. Our initiatives include a pragmatic sequential multiple assignment randomized trial to compare the effectiveness of telehealth strategies to increase shared decision-making for lung cancer screening and 2 pilot projects to test the effectiveness of telehealth to improve cancer care, identify multilevel mechanisms of action, and lay the foundation for future pragmatic trials. Penn TRACE aims to produce new fundamental knowledge and advance telehealth science in cancer care at Penn and nationally.

In the United States, cancer is the second leading cause of death, and lung cancer is the leading cause of cancer death (1). Persistent barriers to better lung cancer outcomes include low uptake of annual lung cancer screening with low-dose computed tomography (CT) that could help identify patients earlier and at more easily treated stages, and the underuse of molecular testing, a diagnostic approach that could help direct the treatments of patients diagnosed with lung cancer. The underuse of these available technologies in the face of convincing evidence of their efficacy argues for new approaches in cancer care delivery.

Clinical trials have demonstrated that annual lung cancer screening in eligible adults reduces mortality and improves survival (2,3). In 2021, the US Preventive Services Task Force released updated lung cancer screening guidelines that expanded recommended eligibility criteria from previous guidelines (4). The expansion had high relative increases in lung cancer screening eligibility for groups with disproportionate lung cancer burden including women, Black and Hispanic adults, and individuals with lower socioeconomic status (5-7). Yet, of the 14.5 million US adults now estimated to be eligible for lung cancer screening, the vast majority have not been screened, and uptake varies widely across states (8-11).

Barriers to lung cancer screening include the challenges of identifying screening-eligible patients (12) and supporting the shared decisions that communicate the benefits of screening and its potential risks of false positives, radiation exposure, complications of diagnostic evaluation, and other documented harms (13-16). Shared decision making is required by the Centers for Medicare and Medicaid Services for lung cancer screening reimbursement (17), and several organizations including the US Preventive Services Task Force, Veterans Health Administration, and American Thoracic Society recommend it as a best practice

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(4,18). Although the inclusion of shared decision making has been identified as a barrier to uptake and a time constraint for primary care physicians, many patients, clinicians, and organizations continue to support its importance in helping patients make informed decisions regarding lung cancer screening yet raise the need for strategies to increase shared decision-making quality (15,19). The majority of patients who engage in shared decision-making as part of lung cancer screening prefer to proceed to low-dose CT (19). However, just as completion of lung cancer screening with low-dose CT is abysmally low (<5% of those eligible for lung cancer screening), so too is documentation of shared decision-making among those who undergo low-dose CT (<10% of those who have low-dose CT) (20). Synchronous (real-time video or telephone conferencing) and asynchronous (sequential health information exchange through texting or secure patient portals) telehealth approaches have been proposed as strategies to expand access to shared decision making, and subsequent lung cancer screening, but they have yet to be rigorously tested in real-world settings (21,22).

Despite low screening rates, dramatic advances have been made in the past decade in lung cancer treatment and identification of therapeutically actionable molecular targets. Because of the ever-expanding toolbox of targeted therapies and immune-checkpoint inhibitors, upfront comprehensive molecular testing, generally performed by tumor and plasma next-generation sequencing, is now considered an essential step in guiding treatment decision making in the management of patients with advanced non–small cell lung cancer (NSCLC) (4,23). The use of molecular testing among oncology practices, however, is suboptimal overall and even lower among Black patients with NSCLC compared with White patients (24).

To address these disparities and other challenges, the University of Pennsylvania Telehealth Research Center of Excellence (Penn TRACE), based at the Penn Center for Cancer Care Innovation at the Abramson Cancer Center, is conducting pragmatic randomized trials within clinical services across Penn's primary care and cancer care systems. As 1 of 4 National Cancer Institute Telehealth Research Centers of Excellence supported by the White House Cancer Moonshot, Penn TRACE is applying insights from communication science and behavioral economics to design and test innovative telehealth approaches across the cancer care continuum toward the goals of reducing barriers in the lung cancer screening process, advancing health equity, and improving utilization of evidence-based treatments.

Penn TRACE design, objectives, and settings

Penn TRACE comprises a Research and Methods Core, Administrative Core, Clinical Practice Network (CPN), Junior Investigator Program, and a research agenda that includes a pragmatic sequential multiple assignment randomized trial and several pilot studies (Figure 1). The Penn TRACE Administrative Core, Research and Methods Core, and CPN provide ongoing logistical support and resources to help execute our research projects and increase the likelihood that successful telehealth approaches will be developed and widely disseminated. Penn TRACE also includes an internal advisory board that consists of senior Penn Medicine physicians and researchers with a track record of operational and academic leadership and an external advisory board, comprising scientific, technology, health system, and cancer advocacy leaders, as well as health-care providers, patients, and representatives from local community organizations. Both groups provide key guidance on Penn TRACE initiatives, help monitor and evaluate progress, and assist with strategic planning.

In addition to seeking guidance from established researchers and stakeholders, Penn TRACE offers opportunities for junior scientists, graduate students, postdoctoral researchers, and other trainees to break new ground in telehealth, cancer care, and health equity research. The Penn TRACE Junior Investigator Program was established to foster mentorship and engagement among junior researchers and trainees who have interests at the intersection of cancer control and telehealth. The junior investigators receive ongoing mentorship from senior investigators and board members and are included in regular project meetings where relevant scientific topics are discussed.

The various components of Penn TRACE work together to achieve 4 core aims:

- Aim 1. Apply concepts, strategies, tools, and methods from communication science and behavioral economics to design and test synchronous telehealth approaches, supported by asynchronous elements, to improve access, quality, outcomes, equity, and efficiency for patients across the care continuum within our CPN.
- Aim 2. Conduct a pragmatic randomized clinical trial to compare the effectiveness of telehealth strategies to increase shared decision making for lung cancer screening using a sequential multiple assignment randomized trial design.
- Aim 3. Conduct 2 rapid-cycle pilot projects with methods and measures aligned with the pragmatic trial to design and test the effectiveness of telehealth to improve cancer care, identify multilevel mechanisms of action, and lay the foundation for future, more definitive pragmatic trials.
- Aim 4. Build capacity to advance a national telehealth research agenda and train the next generation of investigators with expertise in cancer care, telehealth, and health equity.

The Penn TRACE CPN brings together these areas of study. The CPN comprises a network of academic and community clinical sites under the Penn Medicine umbrella that deliver primary care, cancer screening, and oncology care. Penn Medicine includes a hybrid Lung Cancer Screening Program with 5 main campuses with screening locations in southeastern Pennsylvania and southern New Jersey. Lung cancer screening scans can be ordered by any health system provider or referred to a centralized lung cancer screening program based at one of the health system hospitals located in Philadelphia (25). In addition to providing access to a diverse patient population, the CPN provides leadership, resources, and the telehealth, clinical informatics, and data infrastructure needed to execute the proposed pragmatic trial and pilot projects.

With support from the CPN, the Penn TRACE Research and Methods Core serves as the hub for the development of new methodological approaches to telehealth integration and evaluation. Human behavior can be redirected toward improved health outcomes through simple and scalable interventions based in behavioral economics theory (26). Several elements of this theory are being used to design and evaluate our interventions, including assessing biases in decision making and the effects of changing default options for shared decision making.

All proposed activities within the Research and Methods Core are guided by an integrated conceptual model developed by Penn TRACE investigators, named the Framework for Integrating Telehealth Equitably (FITE) (27). The FITE model draws from key constructs of communication science including, the Patient-Centered Communication Framework (28) and the Health Equity

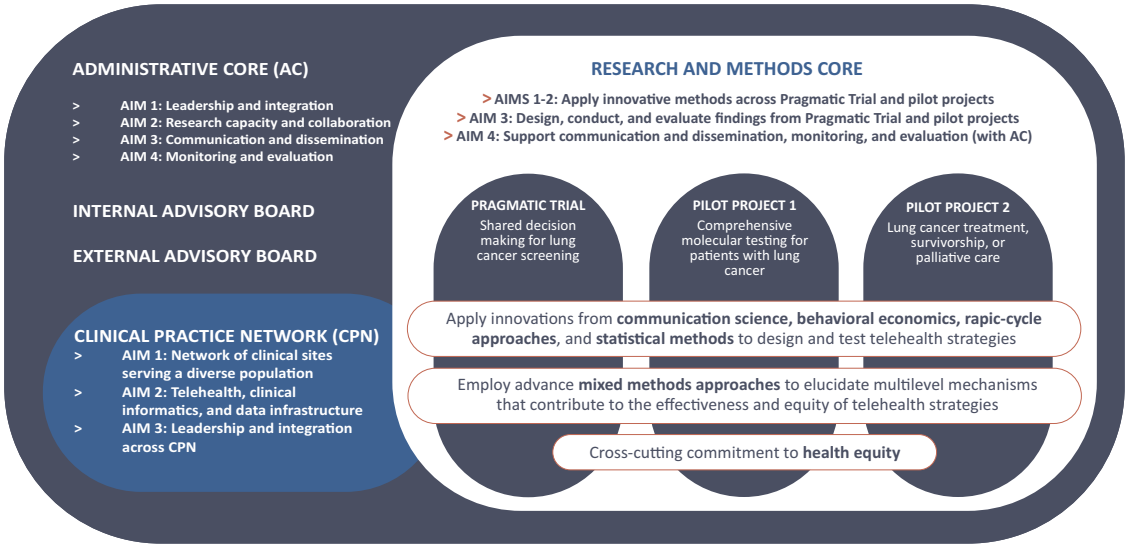

Figure 1. University of Pennsylvania Telehealth Research Center of Excellence organizational framework.

Implementation Framework (29). This model is developed to target communication processes and evaluate multilevel determinants shaping the effectiveness and equity of proposed telehealth-care delivery strategies. Additionally, our projects will evaluate mechanisms of action through qualitative comparative analysis. Qualitative comparative analysis can be used to examine mechanisms in situations that are causally complex or where traditional statistical approaches may not be possible because of limited sample size or study design. Therefore, it is well suited to evaluate telehealth in real-world care where factors related to patients, clinicians, practices, and organizational policies can all influence outcomes.

Penn TRACE applies these vital elements from communication science and behavioral economics to create synchronous telehealth strategies, supported by asynchronous elements, that are likely to be effective and scalable, utilizing technology to increase the likelihood of eventual widespread dissemination and implementation. We also employ the discipline of healthcare innovation (30) to accelerate early learning and experimentation in real-world settings.

Evaluating eligibility for lung cancer screening

A key challenge in lung cancer screening is determining which patients are likely to be eligible for screening because pack-year data are often missing in the electronic health record (EHR). In a prior cross-sectional study, we developed and tested the accuracy of using 2 yes or no questions to estimate pack-year eligibility for lung cancer screening in comparison to open-ended assessment and found that the yes or no questions showed high sensitivity (85.7%-100.0%) for estimating eligibility (12). Therefore, as part of a pretrial assessment in the first 2 years of Penn TRACE, we used direct text messages to identify patients who are most and least likely to be eligible for shared decision making and lung cancer screening. We incorporated randomization to evaluate if different messaging impacts response rates and to inform the larger trial. Initial results showed a much higher response rate than anticipated and no signs of inequity by race or sex in reach or response. Of 13 245 patients contacted as of November 30, 2023, 46% (n = 6105) responded to initial outreach. We are evaluating the survey completion data and will continue to assess the accuracy of our questions to estimate lung cancer screening eligibility in comparison to tobacco history in the EHR and data collected from shared decision-making visits in the pragmatic trial. Patients who do not respond to the text messages will be sent a mailed letter or contacted by phone to foster equity in our outreach.

Pragmatic trial: shared decision making for lung cancer screening

The overall objective of the pragmatic trial, to be launched in year 2, is to compare the effectiveness of 4 adaptive telehealth strategies on shared decision making for lung cancer screening. Guided by the FITE model, we hypothesize that our proposed telehealth strategies will increase high-quality shared decision making for lung cancer screening. Additionally, we will use noninferiority testing to assess equity of the telehealth strategies by race and sex. Annual lung cancer screening using low-dose CT is associated with decreased lung cancer mortality but also with harms including radiation exposure, high rates of false positives, and potential downstream invasive diagnostic and surgical complications (2,3,13,14). The Centers for Medicare and Medicaid Services requires that patients complete shared decision making prior to screening to discuss potential risks and benefits in the context of patient values (15,17,18). Despite guidelines that recommend screening and national insurance coverage of shared decision making and of low-dose CT, uptake of lung cancer screening in the United States is suboptimal, with known disparities by race, sex, geography, and socioeconomic status (8,9,11,31). Additionally, the quality of shared decision making is often low, due in part to limits in clinician time or training that inhibit full engagement with patients resulting in suboptimal patient awareness and use of low-dose CT (15,20,32).

We aim to improve the delivery of high-quality shared decision making by comparing adaptive telehealth strategies informed by communication science and behavioral economics in a pragmatic sequential multiple assignment randomized trial (33,34), complemented by qualitative comparative analysis (35,36). After initial randomization, sequential multiple assignment randomized trial designs allow study participants to be

randomly assigned to other interventions, dosages, or combination therapies at critical decision points during treatment based on intermediate measures of response or nonresponse. Data collected from a sequential multiple assignment randomized trial design can be used to develop personalized, adaptive treatment strategies that are tailored to the needs of individual patients over time. We designed a 2-stage sequential multiple assignment randomized trial that will allow us to examine multilevel determinants contributing to effectiveness of the 4 adaptive strategies embedded in the design across diverse patients, with a health equity lens (34,36).

In the first stage, patients identified as potentially eligible for lung cancer screening through EHR data or the pretrial eligibility assessment will receive a letter offering a telehealth shared decision-making visit alone or an active choice of telehealth or in-person shared decision making. Active choice interventions, which are highly effective, allow people to actively choose an option aligned with their preferences (eg, telehealth rather than in-person) (37). Thus, they may be more acceptable to patients than default options. For those who don't respond within 30 days, we will send asynchronous framed messages alone via text message (low touch) or in combination with synchronous digital care coordination (high touch). The digital care coordination will be performed using telephone only or a telehealth platform depending on the patient's comfort level and access to resources. All barriers to using telehealth will be assessed as part of this intervention. If patients identify a barrier to access, they will be provided with regional resources to access devices or use computers at designated locations. All patients will be sent a validated decision aid before their shared decision-making visit, and a validated decision tool will be used during the shared decision-making encounter (38). The primary endpoint is completion of an in-person or telehealth shared decision-making visit. Secondary endpoints include reach (eg, proportion of patients who schedule a shared decision-making visit after receiving the outreach letter), timeliness of shared decision-making visit, and clinical outcomes (eg, low-dose CT). Additionally, we will perform a cost analysis to estimate the cost of each intervention strategy at the health-care system level (Penn Medicine) to inform sustainability and scale to other health-care systems. We will capture these costs prospectively and pragmatically using methods developed and validated in previous work (39).

Pilot projects: timely treatment across the care continuum

The Penn TRACE pilot projects focus on the use of telehealth strategies at crucial points in the lung cancer care continuum outside of screening. Whether in screening or treatment, patient-clinician interactions are defined by a critical need for effective communication between the patient and clinical care teams, and within care teams themselves, on concepts such as cancer risk, value elicitation, rationale for additional diagnostic tests, and harms and benefits of alternative approaches. These interactions also require improvement in evidence-based clinical practice and show evidence of disparities, making them important intervention targets (28,40).

The use of a synchronous telehealth nurse navigation visit to improve timeliness of treatment recommendations and initiation for patients with metastatic lung cancer is being studied in the first pilot project titled, Telehealth Based Synchronous Navigation to Improve Molecularly-Informed Care for Patients With Lung Cancer. Comprehensive molecular testing and precision cancer medicine hold great promise for improving lung cancer outcomes and survival. For NSCLC, the past decade has been marked by a steady increase in the number of therapeutically actionable molecular targets used to guide care (41,42). Targeted therapy regimens require molecular testing for specific targetable genomic alterations (43). National guidelines currently recommend that molecular genotyping be performed at initial diagnosis, as standard of care (43,44). Despite the importance of molecular genotyping in patients with metastatic NSCLC, considerable barriers exist to timely completion of molecular genotyping prior to initiation of systemic therapy, with evidence of disparities by race (45).

The Telehealth Based Synchronous Navigation to Improve Molecularly-Informed Care for Patients With Lung Cancer pilot study is examining whether telehealth nurse navigation to provide patient education and facilitate completion of comprehensive molecular testing, which includes tissue- and plasma-based testing methods, will result in improved timeliness of guideline-concordant treatment recommendations (primary endpoint) and earlier initiation of guideline-concordant treatment. Individual and contextual factors that shape trial effectiveness and patient experience (eg, treatment knowledge, patient-clinician communication, overall satisfaction among patients and clinicians) will also be assessed through surveys and qualitative interviews with patients and clinicians (35,36,46).

Drawing from systematic evidence on the role of navigation for coordination of cancer care and informed by insights from communication science and behavioral economics, the specific telehealth strategy being tested is synchronous telehealth nurse navigation in combination with default ordering of plasma-based molecular testing. In alignment with the pragmatic trial, this project is guided by the FITE model (27) to assess multilevel determinants shaping the effectiveness and equity of telehealth strategies for cancer treatment initiation.

In future years, Penn TRACE will select an additional pilot project relevant to telehealth cancer care delivery or survivorship. Our prior work has led to the identification of several points in the lung cancer care continuum that are well suited for a telehealth intervention including symptom management during active treatment and surveillance for cancer survivors.

Qualitative comparative analysis and implications for future research

Embedded in the pragmatic and pilot studies, we will administer surveys and conduct semistructured interviews with subsets of trial patients and clinicians to evaluate how and why proposed strategies worked or failed for different groups. The mixed-methods data will be analyzed using qualitative comparative analysis (35,36) to characterize relationships between conditions and effectiveness of each strategy (Figure 2). Given our overall focus on effectiveness and equity of cancer care, our qualitative comparative analysis methods will focus on assessing multilevel determinants of success and failure of novel interventions across and within different patient groups. By harnessing the strengths of pragmatic randomized trials with qualitative comparative analysis, our innovative design will rigorously evaluate not only if the telehealth strategies work in practice but also how, why, and for whom.

The results of the Penn TRACE pilot projects and pragmatic trial will inform clinical practice and policies at Penn Medicine and be leveraged to support new grant applications that will further advance telehealth approaches in cancer care delivery. This

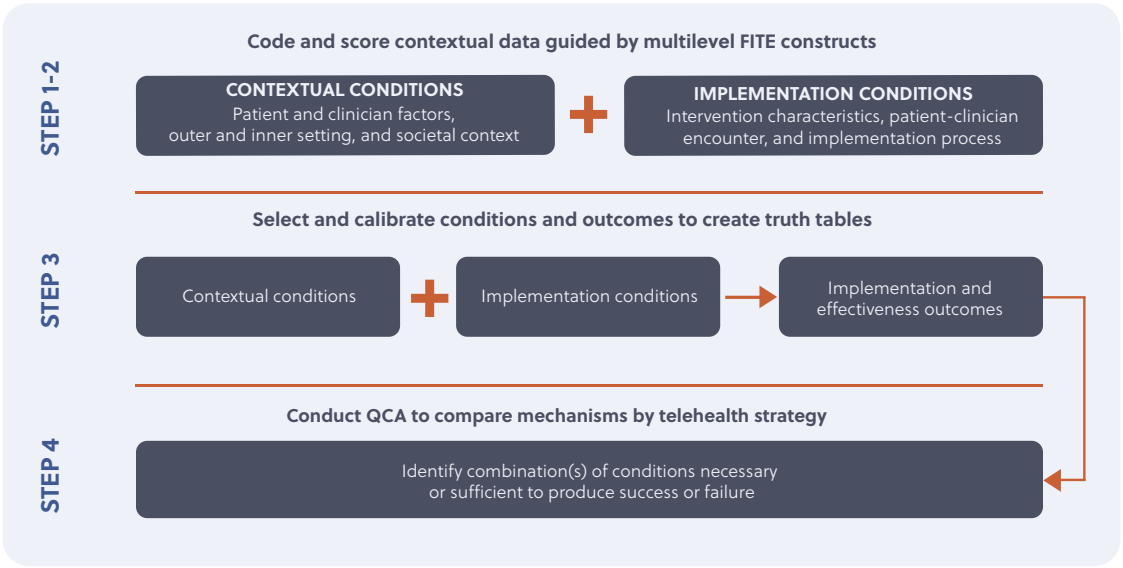

Figure 2. Qualitative comparative analysis. FITE = Framework for Integrating Telehealth Equitably; QCA = qualitative comparative analysis.

will include proposing multicenter trials that will further evaluate successful approaches identified in our initial studies to establish broader generalizability as well as proposals that focus on methodological approaches that will deepen our understanding of how to optimize telehealth-care delivery. Penn TRACE will assist with secondary analyses of our trial and project data to inform these future study proposals and provide expertise in study design and incorporation of research methodology from communication science, behavioral economics, or other relevant approaches that are necessary to maximize the impact of these studies.

Discussion

The need for equitable and sustainable solutions that address care delivery challenges across the lung cancer care continuum is urgent (47,48). The COVID-19 pandemic placed a spotlight on the potential for synchronous and asynchronous telehealth to enhance care delivery (49,50). Effective interventions delivered through telehealth may also facilitate broader availability of specialized care to patients in more remote and rural settings. Telehealth's potential to improve the reach of early detection and treatment is likely to be substantial (21,22), yet whether and how telehealth can close gaps or address inequities in cancer care delivery are unknown. Our Center's overall research theme seeks to merge insights from communication science, behavioral economics, health-care innovation, and mixed methods to dramatically improve telehealth impact, with attention to health equity throughout mechanistic pathways.

Penn TRACE is structured to promote interdisciplinary collaborative research supported by team science best practices (51). The strengths of Penn TRACE include our ability to study telehealth from the perspective of multiple disciplines and our commitment to driving forward dissemination and sustainability of a telehealth evidence base in cancer care delivery rapidly and efficiently. We also face various challenges that came to light in our initial years of funding as we established our center, launched the first pilot project, completed the pretrial eligibility assessment, and prepared for the pragmatic trial. For example, integrating telehealth into care requires structural changes and redesign and issues related to care delivery via telehealth to out-of-state patients persist. We continue to work closely with our advisors, cores, and other relevant stakeholders to identify and address these challenges.

An important objective of our collaborative research is dissemination of study results and lessons learned to the larger stakeholder community and to the public through the diverse disciplines we represent and beyond. We are also committed to collaborating with the other National Cancer Institute telehealth research centers on research topics that are relevant across centers, particularly health equity (27) and telehealth quality. Our research findings on the benefits and harms of telehealth in the context of cancer care will also inform telehealth policy at regional, state, and national levels.

Penn TRACE integrates communication science and behavioral economics to examine the effects of telehealth on cancer care with a lens for health equity. Our interdisciplinary approach enhances our Center's goal to not only evaluate the effectiveness of telehealth strategies but also assess the contextual factors behind why, how, and for whom the strategies work or fail. Achievement of these aims will produce new fundamental knowledge on telehealth, which has the potential to transform cancer care delivery, equity, and outcomes for millions of Americans.

Data availability

No new data were generated or analyzed for this article.

Author contributions

Jocelyn V. Wainwright, MS (Conceptualization; Project administration; Supervision; Visualization; Writing—original draft), Charu Aggarwal, MD, MPH (Conceptualization; Data curation; Investigation; Methodology; Supervision; Project administration; Validation; Writing—review & editing), Sarah Beucker, MPH (Data curation; Formal analysis; Writing—review & editing), David W. Dougherty, MD, MBA (Conceptualization; Supervision; Writing—review & editing), Peter E. Gabriel, MD, MSE (Conceptualization; Supervision; Writing—review & editing), Linda A. Jacobs, PhD, CRNP (Conceptualization; Supervision;

Writing—review & editing), Jillian Kalman, BA (Project administration; Writing—review & editing), Kristin A. Linn, PhD (Formal analysis; Methodology; Supervision; Validation; Writing—review & editing), Anthony O. Martella, BA (Project administration; Writing—review & editing), Shivan J. Mehta, MD, MBA, MSHP (Conceptualization; Supervision; Writing—review & editing), Corinne M. Rhodes, MD, MPH (Conceptualization; Supervision; Writing—review & editing), Megan Roy, MSN, RN (Project administration; Supervision; Writing—review & editing), Marilyn M. Schapira, MD, MPH (Conceptualization; Supervision; Writing—review & editing), Lawrence N. Shulman, MD (Conceptualization; Supervision; Writing—review & editing), Jennifer Steltz, MRA (Project administration; Writing—review & editing), Alisa J. Stephens Shields, PhD (Formal analysis; Methodology; Supervision; Validation; Writing—review & editing), Andy S.L. Tan, PhD, MPH, MBA, MBBS (Conceptualization; Investigation; Methodology; Supervision; Project administration; Writing—review & editing), Jeffrey C. Thompson, MD, MTR (Conceptualization; Investigation; Methodology; Supervision; Project administration; Writing—review & editing), Hannah Toneff, MSW, MA (Project administration; Writing—review & editing), Richard C. Wender, MD (Conceptualization; Supervision; Writing—review & editing), Sana Zeb, BS (Project administration; Writing—review & editing), Katharine A. Rendle, PhD, MSW, MPH (Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Supervision; Validation; Visualization; Writing—review & editing), Anil Vachani, MD, MS (Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Supervision; Validation; Visualization; Writing—review & editing), and Justin E. Bekelman, MD (Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Supervision; Validation; Visualization; Writing—review & editing).

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Conflicts of interest

KAR reported receiving grants from Pfizer and AstraZeneca paid to her institution, personal fees from Merck for serving as a scientific consultant, and honoraria and travel paid as invited speaker from MJH Life Sciences outside the submitted work.

JEB reported receiving personal fees from Reimagine Care, Healthcare Foundry, and AstraZeneca and grants from Loxo@Lilly, Gilead, and Emerson Collective outside the submitted work.

AV reported receiving grants from MagArray Inc, Precyte Inc, Optellum Ltd, Lungevity Foundation, the Gordon and Betty Moore Foundation, and grants from the National Comprehensive Cancer Network, and personal fees from Johnson and Johnson, outside the submitted work.

SJM reported receiving fees and honoraria from Guardant Health and the American Gastroenterological Association, outside of the submitted work.

CA reported receiving grants from AstraZeneca, Genentech, Incyte, Loxo@Lilly, Macrogenics, Medimmune, and Merck Sharp & Dohme, and personal fees from Genentech, Lilly, Celgene Merck, AstraZeneca, Blueprint Genetics, Shionogi, Daiichi Sankyo/Astra Zeneca, Regeneron/Sanofi, Eisai, BeiGene, Turning Point, Pfizer, Janssen, Boehringer Ingelheim.

AJS reported personal fees from WilmerHale on behalf of Gilead Sciences.

JCT reported receiving grants from Delfi Diagnostics and Incyte and receiving personal fees from AstraZeneca.

MR is on the Speakers Bureau-AstraZencea Pharmaceuticals.

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