

MEETING SUMMARY
PRESIDENT'S CANCER PANEL
**REDUCING CANCER CARE INEQUITIES: LEVERAGING
TECHNOLOGY OPPORTUNITIES TO ENHANCE PATIENT
NAVIGATION:**
***POLICY CONSIDERATIONS AT THE INTERSECTION OF TECHNOLOGY AND
PATIENT NAVIGATION***

December 7, 2023
Bethesda, Maryland

This meeting was the third in the President's Cancer Panel's (the Panel's) 2023 series on patient navigation and technology. The meeting brought together stakeholders from many sectors, including health policy, the technology industry, research, and patient advocacy. Participants discussed the current state of policies and regulations related to patient navigation and technology, barriers, and opportunities for the future. The meeting was available to the public via live feed, and members of the public were invited to submit written comments and questions during and afterward. Participants were encouraged to continue the conversation on social media using the hashtags #Tech4CancerNavigation, #PatientNavigation, and #NationalCancerPlan.

This meeting summary was prepared to satisfy requirements established by the Federal Advisory Committee Act. The summary provides an overview of presentations and discussions occurring as part of the workshop and does not necessarily reflect the views of Panel members.

President's Cancer Panel

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WELCOME AND INTRODUCTIONS

Dr. Elizabeth Jaffee welcomed attendees. She invited Panel members, speakers, working group members, and other attendees to introduce themselves. Dr. Jaffee then reviewed the history of the President's Cancer Panel, which was established by the National Cancer Act of 1971 and charged with monitoring the activities of the National Cancer Program and reporting to the President of the United States on barriers to progress in reducing the burden of cancer.

In April 2023, with leadership from then-NCI Director Monica Bertagnoli, U.S. Department of Health and Human Services (HHS) released the National Cancer Plan, a long-term initiative to meet the goals of President Biden's Cancer Moonshot.

Two of the eight goals of the National Cancer Plan are to Eliminate Inequities and Deliver Optimal Care. Through this meeting series, the Panel will prospectively assess the needs related to these goals, focusing on gaps and opportunities related to the use of technology to support cancer patient navigation. To assist

with the meeting series planning, the Panel created the Working Group on Addressing Inequities in Cancer Care through Innovative Navigation Models.

There are many definitions of the term “patient navigation.” Dr. Jaffee shared the definition that the Panel would be using for the day’s meeting.

Patient navigation is a person-centered healthcare service delivery model that aims to overcome individual and systemic barriers to accessing timely and quality cancer care. It is an evidence-based intervention demonstrated to reduce disparities in cancer care.

Navigation may be carried out by various members of the healthcare team, including, but not limited to, patient navigators, community health workers, social workers, physicians, and nurses.

Navigation may also be achieved through systems and resources that are not directly managed or delivered by a member of the healthcare team.

For this series, discussion is focused on navigation to improve access to care for patients from the time of suspected or confirmed cancer diagnosis through the end of active treatment.

The first and second meetings of this series were held in October and November of 2023. Themes that emerged during those meeting’s discussions included the importance of trust between communities, health systems, and technology; navigation and technology considerations that account for age, geography, and culture; including patients, navigators, and other end users in the entire continuum of health technology development; how to develop and implement best practices for navigation technologies; and how to evaluate technologies to enable continual improvement and demonstrate success. More information about those meetings is available on the Panel website.

Dr. Jaffee introduced meeting facilitator Mr. Scott Wheeler, who reviewed guidelines for the day’s discussion.

POLICIES IMPACTING PATIENT ACCESS TO NAVIGATION TECHNOLOGIES

Mandi Pratt-Chapman, PhD, Associate Director, George Washington University Cancer Center

Patient navigation has been shown to improve myriad outcomes, including uptake of cancer screenings, patient adherence, timeliness of treatment and diagnosis, treatment completion, patient knowledge and satisfaction, and patient quality of life. It is an important and personalized intervention by a human to assess and address barriers across the continuum of care. The evidence for patient navigation’s efficacy is based on in-person interactions, with trained and compassionate human providers interacting with patients in need. Technology cannot replace this experience or its value, but it can optimize time to help humans have more time with humans and rapidly and continually assess outcomes.

The financial, legislative, educational, and economic systems of the United States were built on a legacy of colonialism and capitalism that create and perpetuate inequities to this day. These inequities extend into healthcare, resulting in worse outcomes and higher rates of cancer mortality in racial and ethnic minority populations. When developing and introducing new technologies, it is important to begin from a place of conscientiousness and awareness to avoid exacerbating these issues.

Artificial intelligence (AI) and other technologies are well positioned to improve the efficiency of transactional work and decision aids, rather than making care decisions or providing care itself. Technology could aid in scheduling, appointment and screening reminders, resource referrals, updating documentation, flagging issues and prompting navigator intervention, and analyzing unstructured data.

Reducing the risk of exacerbating existing disparities with new technology will require effort from all sectors to:

- Center inclusivity and the patient experience.
- Develop, train, and support a diverse professional workforce with complementary expertise and lived experience.
- Incorporate health equity principles by design.
- Require auditable clinical algorithms and continual updating and improvement.
- Foster a transparent organizational culture.
- Accelerate research to identify bias.
- Establish governance and accountability structures.

A qualitative study by Dr. Pratt-Chapman and her colleagues found that using accurate, patient-reported demographic data to stratify quality milestones and health outcomes in real time is critical to determining whether technologies are increasing or decreasing disparities, particularly in race, ethnicity, and language; sexual orientation and gender identity; and social determinants of health (SDOH). The federal government could support this work by incentivizing health equity reporting.

The Accountability for Cancer Care through Undoing Racism and Equity (ACCURE) trial is one of several important examples of success in using technology to reduce disparities in cancer care. Critical components of that intervention included a multidisciplinary team, a real-time registry, patient navigation, race-specific feedback, and health equity training for staff.

Dr. Pratt-Chapman noted that effective interventions already exist. To make progress, next steps should include:

- Leveraging existing evidence-based tools.
- Allocating funding to translate evidence to practice.
- Creating mental health supports, mentorship, peer learning opportunities, and supervision for patient navigators.
- Conducting health impact assessments on all policies to assess unintended impacts on health disparities.

Additional and more politically complex recommendations include:

- Implementing single-payer insurance to equalize health insurance coverage and benefits.
- Requiring employers with more than 50 employees to pay taxes for those making less than \$50,000 a year or eliminating taxes for those same individuals.
- Closing tax loopholes for the wealthiest Americans and using the recovered funds to invest in infrastructure for education, safe neighborhoods, and clean work environments.
- Divesting from tobacco in all employer-based retirement plans.

QUESTIONS AND COMMENTS FOR PRESENTER

- It is important for all healthcare settings to systematically capture patients' demographic data. Progress in this area has come as a result of mandates at the health system, locality, state, or federal level and building mandatory demographic data collection into clinical workflows.

DISCUSSION

Payment and Other Policies to Provide Equitable Access to Navigation Technology

- An important next step is finding ways to optimize existing policies, resources, and technologies. The use and efficacy of current supports should be assessed, and lessons learned should be integrated into strategies for future work. It is important to determine whether patients and navigators want to and are able to use the tools that are already being offered. There may be ways to improve uptake of existing resources and to ensure that policies that work, such as expanded access to telehealth and Medicare, receive continued support from the government.
- Digital navigators and health navigators serve different but overlapping functions. Cross-training professionals in these fields, as well as community health workers (CHWs), could facilitate more effective patient support and care delivery.
- There are opportunities to expand access to clinical trials through telehealth and connecting local clinics with larger cancer centers.
- There are also opportunities to build trusted platforms for patients to connect with one another to share information and offer peer support.

Policies Related to Payment and Reimbursement

- Reimbursement of community-based providers has proven a successful approach.
 - In Arizona, legislators adopted a policy to provide reimbursement to certified CHWs. The process enabled trusted community organizations to sustainably provide navigation support to their patients.
- Reimbursing not only the use of the technology but its development would incentivize progress. Funding could be provided for projects that meet standards of equity-first development, including electronic health record (EHR) integration and collaboration with target users in under-resourced communities.
 - Identifying desired outcomes and working backward may be another useful approach.
- Success will depend on interoperability and the creation and implementation of standardized criteria.
 - Interoperability is an important component and is currently a requirement for funding support from the Office of the National Coordinator for Health Information Technology (ONC).
 - Current interoperability requirements may be challenging for smaller hospitals and health systems to implement, as the criteria were developed using information from larger organizations and settings.

- Health information technology (IT) is often siloed by vendor. Technology developers must be incentivized to create software and other tools that can interface with products from other companies.
- ONC released a final rule in conjunction with the Centers for Medicare & Medicaid Services (CMS) rule on interoperability. A core component of the ONC rule was the United States Core Data for Interoperability (USCDI), which requires that specific data fields, such as a patient's date of birth, be portable across systems.
- EHR vendors could be required to create programs that are interoperable with navigation and other health platforms.
- True interoperability is dependent upon significant support from the IT workforce. Smaller health systems and clinics may not have the staff to implement and maintain these technological tools.
- The number and type of data elements incorporated into health technologies are expanding, which increases the complexity and volume of data as well as interoperability challenges.
- In a sense, technology development is already reimbursed, as government-supported health organizations use their funding for infrastructure, including health technologies.
- Under-resourced and community-based organizations do not have the infrastructure or IT staff to meet existing baseline interoperability criteria. Direct federal funding for these aspects would support the inclusion of smaller health systems and clinics.

Relevant Existing Policies

- This year, HHS Secretary Xavier Becerra announced a policy to inform the alignment of health IT standards across all HHS health IT investments. HHS is collaborating with the Substance Abuse and Mental Health Services Administration on developing similar standards for behavioral health.
- In 2021, ONC launched an initiative called USCDI+, which supports the identification and establishment of domain- or program-specific data element lists that operate as extensions to the existing USCDI. These programs are not specific to cancer patient navigation.
- There is a lag time of two to three years between the enactment of a policy or regulation and its implementation in health and technology systems.
- The Food and Drug Administration (FDA) is working to help facilitate patient navigation.
 - The agency is developing guidance that will encourage the sponsors of clinical trials to incorporate telemedicine, local healthcare providers, and electronic consent processes, all of which will reduce the burden of travel and cost for participating patients.
 - A separate effort, Project Pragmatica, offers oncology-specific guidelines for clinical trial sponsors to help reduce barriers for cancer patients.
- Patient participation in remote and other technology-facilitated clinical trials depends on access to the relevant tools. Trial sponsors may be wary of providing devices for fear of incurring civil monetary penalties. Designating these devices as allowable reimbursements through

congressional action or the HHS Office of Inspector General could create a safe harbor and improve patient access.

- The Internet for All initiative is supported by the Broadband Equity, Access, and Deployment program, which earmarks federal funding exclusively for creating and supporting infrastructure in rural areas. This limitation excludes the large proportion of Americans without sufficient access who live in urban areas and consequently exacerbates existing health disparities.
 - The National Digital Inclusion Alliance (NDIA) advocates for expanding infrastructure support to these communities. NDIA is currently gathering data on digital health equity from healthcare and equity-focused organizations in the field to identify challenges and solutions.
- Digital navigators are members of the communities they serve. There are no national certifications or commonly accepted credentials. Some digital navigators have master's degrees, and some are certified CHWs. These professionals often work in libraries and other educational settings, such as community colleges. Google has given \$10 million to NDIA to provide digital navigators in Tribal communities. AmeriCorps has its own program to train digital navigators.

Policies Needed to Support Telehealth for Cancer Navigation

- Expanding telehealth regulations for cancer navigation will require congressional action.
- Existing state policies around licensure and medications can complicate blanket federal regulations regarding telehealth.
- At present, clinicians who wish to provide telehealth services to patients in other states must become licensed in those states. This presents a significant administrative burden and deters many providers from offering these services.
- Incorporating telehealth into a patient's care plan could help make a case for reimbursement.
- Potential new policies could include flexibility for geographic regions that have shortages of medical and navigation professionals.

POLICIES PROTECTING PATIENTS, THEIR PRIVACY, AND THEIR DATA

Sara Gerke, Dipl-Jur Univ, MA, Assistant Professor of Law, Penn State Dickinson Law

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 is the primary federal law protecting patient data privacy in the United States. This legislation, while vitally important, was crafted before the advent of the current digital health age and does not cover many of the ways protected health information (PHI) is generated, transmitted, and used today. Patients often share their own health information online, particularly through social media, and additional data are captured through wearables, mobile applications, and other direct-to-consumer products. Entities such as Google, Microsoft, and Amazon invest heavily in healthcare and collect health-related data about their users but are not considered covered entities under HIPAA. These companies can legally use these data to develop new products, including AI, and share them for commercial research purposes.

Other jurisdictions have adopted new regulations to address gaps in digital privacy protection. In 2016, the European Union enacted the General Data Protection Regulation (GDPR), which protects citizens' privacy and gives individuals more agency regarding how and whether their data are collected and used. Twelve U.S. states have recently enacted their own comprehensive privacy laws; similar laws will take

effect in another seven states over the next two years. Consequently, the level of privacy protection for Americans currently depends on their state of residence. To address legal gaps and harmonize the current patchwork of state privacy laws, the U.S. will need a comprehensive federal privacy law.

In the meantime, stakeholders—including health systems, providers, clinical researchers, and technology companies—should be actively engaged in protecting patient privacy. At minimum, they should always adhere to current data privacy and security laws and best practices, such as ensuring the proper deidentification of PHI, to prevent privacy breaches. They should also be as transparent as possible with patients about data collection, storage, use, sharing, and processing. Additional suggestions from Ms. Gerke include:

- Thoroughly evaluating and selecting third-party vendors based on their data security and privacy practices. Particular caution should be exercised when services are offered for free.
- Drafting Data Use Agreements (DUAs) with careful consideration of privacy and security safeguards.
- Establishing an independent and diverse committee to oversee data use and sharing.

QUESTIONS AND COMMENTS FOR PRESENTER

- While HIPAA may not be sufficient to cover all aspects of PHI, the act is still an important component of protecting patient privacy in the clinic.
- HIPAA preempts state law in jurisdictions with less protective regulation. Stronger protections are not preempted. This inconsistency across state lines contributes to ambiguity and gaps in data protection.
- Several privacy laws have been introduced in the House and Senate. There is generally an agreement, even within the technology sector, that greater federal regulation of privacy protections is needed.
- Local privacy regulations, including the GDPR and state laws, may extend across borders, depending on the specifics of the law.
- Enacting a single regulatory framework, rather than different rules for different entities, would be the best way to ensure consistent privacy protection.
- Due to the high volumes of personal data generated by every individual, data brokers and companies may be able to reidentify patients even when providers and health systems have adhered to HIPAA and internal privacy safeguards. Any privacy regulations should take caution in spelling out rules around deidentification and anonymization.

DISCUSSION

Policies Needed to Protect Patients from AI Bias

- The use of geolocation is widespread and currently represents a significant threat to privacy. Discrete data points can be triangulated to identify individuals and infer sensitive information. These concerns are exacerbated for under-resourced populations, who are often concentrated in urban areas.
- Mitigating bias begins long before algorithms are developed, with the creation of a diverse and representative workforce and careful consideration of research questions. Investing in the

research, development, and healthcare pipelines in communities that have historically been most harmed will help prevent bias at its source.

- Capturing metadata such as location and timestamps helps ensure data quality and inform improvements. Granular data are also important for SDOH research and providing truly equitable care. There is a tension between the utility of this information and the risks it can present. This is true for individual patients, who often want to contribute their data to research despite concerns about privacy.
- An Executive Order from the White House released in November charged HHS Secretary Becerra, among other agency leaders, with establishing a framework for the development and implementation of responsible AI.
- The FDA monitors drug-related adverse events. A parallel reporting system could be created for health-related AI.
- Three important aspects of mitigating harm are ensuring the inclusion of communities who have been left out of technological advancements in the past; ensuring algorithmic data are not the sole data source for decision-making and research, taking care not to overlook the human component; and including marginalized communities as co-creators in the development of health algorithms that will affect them.
- Algorithmic transparency is another important aspect of bias mitigation, and one that should be regulated.
 - A lack of transparency can also impede research and healthcare delivery.
 - Prescription drugs could serve as a useful model for the categories of essential information for algorithm developers to provide.
 - Transparency is needed not only when an algorithm is introduced, but continually throughout its use, as algorithms learn and change over time.
 - Regulations around transparency should also pertain to the source of the data and the data's function. Patients have a right to know how, and by whom, their health information is being used.
 - The MITRE-led Coalition for Health AI (CHAI) is working to harmonize standards and reporting for health AI and educate end users on how to evaluate these technologies to drive their adoption. The CHAI mission is to provide a framework for the landscape of health AI tools to ensure high-quality care, increase trust among users, and meet healthcare needs.
- The quality and diversity of data significantly influence the quality of an algorithm. Using nationally recognized guidelines can help reduce inequity earlier in the pipeline.
- When making recommendations, it is important to specify which aspects of health AI potential policies or regulations should cover.
- Some AI tools are considered medical devices and fall under the FDA's purview. Others, including some clinical decision tools, do not. The FDA and other agencies may need to create new shared standards to ensure that relevant technologies can be assessed and regulated. Policies should include guidance regarding liability in the event of algorithmic patient harm.

- Investing in infrastructure and institutions that serve and support historically under-represented communities will contribute to more equitable distribution, use, and benefit of new health technologies.
- An equity committee could provide continuous oversight of algorithms to ensure that the tools are serving their intended purpose and that they are not increasing disparities or leading to worse outcomes.
 - Tools may perform differently in different care settings.
 - Even an algorithm that is initially trained on a diverse dataset will become less accurate for diverse populations over time if it continues to incorporate data from a less diverse patient pool.
- Individuals should be able to opt out of the use of their health data.
- The FDA and Federal Trade Commission are both working to address the gray area of health information technology.

Policies Needed to Protect Patient Privacy and Ensure HIPAA Compliance

- Educating providers about privacy rules will help protect patients' data.
- HIPAA applies whenever patient data flow into or out of a healthcare setting. The law does not currently cover data contributed through direct-to-consumer platforms like mobile applications.
- HIPAA-covered entities are required to enter into business associate agreements with any third party that handles PHI. Manufacturers of devices like pacemakers have access to raw patient data. Despite the business associates' status as covered entities, those raw data fall outside of HIPAA and are not shared with clinicians or patients. This may be a lesser concern in the area of patient navigation.
- EHRs are not considered medical devices and thus do not fall under the FDA's jurisdiction.
- Any potential policy should focus on safety, effectiveness, and privacy protection.

Additional Comments

- There is a precedent for enforcing anti-bias in technology. In November 2023, the Federal Communications Commission (FCC) adopted final rules to prevent digital discrimination of access to broadband services based on income level, race, ethnicity, color, religion, or national origin. The FCC definition of discrimination includes both intentional and unintentional bias.
- Preventing bias in health technology depends on having comprehensive, diverse datasets to train algorithms. Truly diverse datasets can only exist when patients of all backgrounds feel comfortable engaging with healthcare and participating in clinical trials. Building trust is essential, as is reducing barriers to access, including the cost of care.
- The rapid and relatively unchecked development and implementation of AI in healthcare is likely already causing damage to historically marginalized communities. It is important to analyze the current landscape and its downstream effects.

CERTIFICATION AND REGULATION OF PATIENT NAVIGATION TECHNOLOGIES

Ron Kline, MD, FAAP, Chief Medical Officer, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality, CMS

Quality measurement is a routine part of daily life and business, and healthcare is no exception. As a major payer, CMS relies on metrics to inform reimbursement decisions. These measurements and their repercussions help quantify performance, link to payment programs, enable consumer awareness and action, and drive continual improvement within health systems and practices.

CMS uses many levers to ensure continued high-quality care, including:

- Payment
- Conditions of participation
- Survey and certification
- Quality Improvement Organization networks
- Clinician engagement groups
- Quality measures
- Value-based programs, including payment and public reporting
- Extensive stakeholder engagement

Dr. Kline described three approaches to quality measurement, a framework first proposed in the middle of the 20th century by Dr. Avedis Donabedian. Structural measures quantify the attributes of care provision settings, including material and human resources and organizational structure. Process measures assess the quality of care itself and include both patient and provider activities in making a diagnosis and recommending or implementing treatment. Finally, outcome measures evaluate the effects of care on the health status of patients and populations.

Quality measures consist of numerators (a population size) and denominators (the number of desirable or undesirable events that occurred within that population). When constructing a measure, CMS takes into account exclusions in the numerator or denominator groups, as well as risk adjustment or population stratification.

Structural measures for patient navigation include the establishment of a dedicated navigation program and staff within an oncology program, a minimum patient-to-staff ratio, and specific educational or clinical experience requirements for care navigators. Process quality measures include the percentage of patients who receive communications after an abnormal screening, biopsy, or imaging. Outcome quality measures include patient satisfaction, patient-reported outcome measures, the percentage of patients who receive a recommended therapy by a given time point, and the percentage of patients who receive timely follow-up care after an abnormal screening exam or biopsy.

CMS has set a new course for digital quality measurement aimed at contributing to a learning health system to optimize patient safety, outcomes, and experience. These efforts will:

- Enable a future in which care quality is only measured electronically, using standardized, interoperable data.
- Reduce the burden of EHR data transfer.

- Provide usable, timely data from multiple sources to support the delivery of high-quality care and management.
- Produce valid, reliable, and common measurement results across multiple programs and payers.

Research into electronic quality measures has found that they minimize both administrative burden and cost.

QUESTIONS AND COMMENTS FOR PRESENTER

- CMS does not require affiliated health systems to have formalized cancer patient navigation programs.
- The primary measure of the effectiveness of patient navigation for CMS is patient outcomes.
- CMS has begun providing confidential feedback reports to hospitals based on race stratification and is now collecting data on health-related social needs.

DISCUSSION

Assessing the Quality of Navigation Technologies

- Rapid data collection can flag concerns for clinicians and expedite the connection of patients with navigators or other supports.
- Quality assessors must take caution not to devise metrics that would incentivize the treatment of or special attention to some patients, particularly healthier patients or “easier” cases, over others. Health systems should not be penalized for taking the time to provide support for patients with complex SDOH needs.
- Research into SDOH screenings indicates that only a small proportion of patients agree to be referred. The causes behind this gap should be investigated before evaluating health systems based on the rate of patients who accept referrals.
 - The Patient Advocate Foundation conducted a large patient survey on SDOH screenings and referrals. The results of this survey could help inform screening-related metric development.
- Other useful metrics to consider when evaluating the effectiveness of navigation technology include:
 - Patients’ acceptance and use of technology, a factor that can greatly influence the effectiveness and uptake of a given intervention.
 - How well an intervention or technology was implemented.
 - The reliability of the data that an intervention gathers and interprets.
 - Structural measures such as navigator-to-patient ratio.
 - Process metrics like timeliness.
 - Patient satisfaction.
 - Patient and navigator digital literacy at baseline, as per the unified theory of acceptance and use of technology.

- Increased navigator efficacy.
- The quality of care delivered.
- Improved equity in health outcomes.
- Reducing the need for navigation within a community.
- Metrics should be analyzed in the context of each practice, as resources, staffing, and infrastructure vary significantly. Interventions may need to be adapted to be effective. Health systems also vary widely in terms of digital maturity.
- Implementation science examines how, and how well, solutions are implemented. The core principles of implementation science could serve as a meaningful framework for assessing quality.
- Patients' navigation needs vary, including the extent to which support is needed. Technology could help fill in the gaps for patients with more administrative or routine support needs.

Policy to Influence the Quality of Information Provided to Patients Through Technology

- Technologies must be developed in collaboration with the end users, including clinicians, navigators, and patients.
- Navigation and oncology guidelines should be incorporated into technology development. National Comprehensive Cancer Network (NCCN) is in the process of digitizing guidelines to facilitate their inclusion in new technological tools.
- MITRE investigated COVID-19–related misinformation and disinformation broadly, then narrowed the focus to California's Central Valley. The results identified key differences in messaging. This information was then transmitted to navigators and CHWs, who subsequently tailored their approaches.
- Because cancer patient navigation has been proven to improve health outcomes, these outcomes are a useful broad measure of quality.
- Patient representation throughout the entire technology development continuum should be prioritized. Patient voices should not be an afterthought or sought only in testing. It is equally important to collaborate with and support the grassroots and community organizations that serve these patients.
- In the past, health systems have been slow to adopt policies and guides until those rules were enforced or incentivized.
- Technologies should be evaluated for their appropriateness for the patients and communities they are intended to serve.
- Existing systems automatically capture data that could be more closely analyzed and put to better use. Qualitative data on the quality of care are also meaningful.
- Patients are already using technological tools to help understand and navigate the cancer care process. Providing credible resources and tools, as well as education on how to detect misinformation, will help prevent harm.

- ONC has an accreditation program for technology vendors. Accreditation through this program is mandatory for vendors seeking reimbursement. The FDA similarly requires verification and validation of any digital health technology that will be used in clinical trials. These regulations are congressionally authorized.
- A similar approach could be proposed for navigation technologies. The first step would be to develop standards. Accreditation bodies in other fields create consensus-based standards through a federated model.

Certification and Regulation of Patient Navigation Technologies

- Accreditation for navigators and CHWs exists and will be required in some cases for reimbursement through CMS. Some states have their own certification requirements. At present, there are no certifications for the use of technology.
- When considering accreditation, it is important not to create such restrictive requirements that they limit the pool of eligible professionals. If quality standards are not balanced with realistic expectations and support for the workforce, disparities will increase. Progress should not exacerbate the divide.

POLICIES TO INCENTIVIZE NEW PATIENT NAVIGATION TECHNOLOGIES AND THEIR USE

Doug Jacobs, MD, MPH, Chief Transformation Officer, Center for Medicare, CMS

Dr. Jacobs gave an overview of a new CMS rule. The rule, issued on November 2, 2023, announces finalized policy changes for Medicare payments under the Physician Fee Schedule and other Medicare Part B issues and will take effect on or after January 1, 2024. One of many significant changes in the rule provides payment for principal illness navigation services to help patients and their families navigate cancer treatment and treatment for other serious illnesses, supporting the Biden–Harris Administration’s Cancer Moonshot mission to accelerate progress against cancer.

The two most relevant components of the rule pertain to separate payment for Community Health Integration (CHI) and Principal Illness Navigation (PIN) when these services are deemed medically necessary. CHI services are typically performed by CHWs, patient navigators, and peer support workers for patients with medical or SDOH needs that affect their diagnosis or treatment.

Services must be provided under the supervision of a physician, nurse practitioner, or certified nurse specialist, who will bill Medicare directly for services rendered. The specific services provided will depend on the patient and their unique needs. The services consist of:

- A person-centered assessment to understand the patient’s life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and unmet SDOH needs.
 - Patient-driven goal setting and the creation of an action plan
 - Tailored support as needed to accomplish the practitioner’s treatment plan
 - Referral of the patient and their family or caregiver, where applicable, to appropriate support services
- Help accessing community-based social services as needed to address SDOH needs.

- Assistance in understanding health information provided by a patient’s treatment team and education regarding how to best participate in medical decision-making.
- Building patient self-advocacy skills.
- Supporting access to healthcare and navigation of the healthcare system.
- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals.
- Social and emotional support to help a patient cope with their condition and SDOH need(s) and adjust daily routines to better meet diagnosis and treatment goals.
- Leveraging knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, and inspiration to meet treatment goals.

Both CHI and PIN begin with a 60-minute initiating evaluation and management visit performed by the billing practitioner. Subsequent visits are 30 minutes in length and may be scheduled as often as is necessary. Federally qualified health centers (FQHCs) and rural health centers can bill for the same services. Like all Medicare services, CHI and PIN are associated with cost sharing.

A billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice—such as through a community-based organization (CBO) that employs CHWs—if all of the “incident to” and other requirements and conditions for payment of CHI services are met. There must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided.

QUESTIONS AND COMMENTS FOR PRESENTER

- The 30-minute visits are provided by patient navigators and CHWs.
- To prevent fraud, Medicare requires documentation that SDOH concerns affect a patient’s diagnosis or treatment, as well as evidence of supervision.
- PIN work could be sufficient to provide a salary for a full-time patient navigator.
- CHI and PIN providers must be certified or trained in care navigation standards and CHW core competencies. Caregivers may be eligible to provide these services if they have been trained and certified.
- Because CMS renders payment to medical providers and not directly to navigators, CBOs may need to form partnerships with health clinics to provide reimbursable services. This may prove challenging, as CBOs and medical providers do not have a history of smooth cooperation. Many providers would prefer to reimburse in-house staff members rather than partner with an outside organization. Medicare will not mandate collaboration but encourages the Panel and other stakeholders to support efforts to bridge the divide.
- CMS does not have a process in place to capture data on health outcomes related to these changes.
- The rule covers entities that can currently bill CMS for services. There is not a provision for other individuals or organizations to be reimbursed for these services.
- Financial navigators are eligible to provide PIN if they are both certified and equipped to offer the full complement of services listed above.

- CHI and PIN may be provided at any point along the cancer care continuum, including before diagnosis, as long as a clinician has deemed a patient’s condition high risk.
- The services may be delivered via telehealth, as long as the visits meet all other requirements.

DISCUSSION

Resources and Training for Patients and Navigators

- The business case for patient navigation includes keeping patients within a health system by meeting their needs, and navigators may be motivated to avoid sending patients elsewhere. Policies or training supports should consider how to ensure that navigators remain objective and make decisions and recommendations with their patients’ best interests in mind.
- Effective trainings for navigators already exist; for example, the Academy of Oncology Nurse and Patient Navigators offers a certification. Leveraging available trainings is a low-lift solution, although in most cases the trainings are not focused on technology.
- It could be argued that digital inclusion should be considered an SDOH, as access to modern healthcare—as well as education, housing, and employment—requires the use of technology.
- Insurance plans limit which providers a patient can see, and lists of covered providers rarely include community-based health organizations. This framework locks smaller organizations out of reimbursement and prevents patients from accessing the care that may be preferable to them.
- Accreditation for navigators reimbursed by CMS should include basic technology training for daily tools like email, EHRs, and clinical trial registration.
- Digital literacy can be paired with health literacy in trainings for CHWs or *promotoras*. Organizations will need additional financial support to offer these resources.

Policies, Payment Models, and Incentives to Enhance Adoption of Existing Technologies

- Before creating policies, the first step must be to define what is meant by “technology” and “proven.” There is no gold-standard methodology for proving that a technology works.
- Incentivizing technology development may lead to increased adoption and other downstream effects.
- In the past, blanket policies requiring the adoption of specific technologies like EHRs have achieved the stated goal without necessarily addressing the underlying concern. Under-resourced health systems may have transitioned to electronic platforms without the infrastructure to support them, thereby creating additional burden and barriers to effective care.
- Interoperability should be an important part of any reimbursement criteria.

Balancing the Need for Rapid Advancement with Establishing Standards

- The primary standard should be equity.
- Some health systems use platforms that automatically track a patient’s milestones and flag concerns for a clinician or navigator. This approach could lead to rapid improvement in outcomes with relatively low administrative burden.
- Many lessons can be learned from the rollout of mandatory EHR adoption.

- At the time, there were many different EHR vendors, and health organizations selected the platforms they could afford.
 - Those systems largely do not interact with one another.
 - Many of the vendors have since gone out of business, leaving health systems with no support or system maintenance.
 - The one-time influx of funding was insufficient to produce effective and sustainable change.
- There is not currently a single national governing body that oversees equity and related risk-benefit calculations. Some states, including California, have their own models for health equity impact assessments.
 - It is important to define “navigation technology” and to specify its intended use and functions. Navigators and patients must be consulted to identify needs and find solutions.
 - Patients and community organizations should also be consulted regarding the rollout of new technologies. Technology should be cocreated with those who will use it.
 - Standards should be flexible enough to support a diverse landscape of health providers and systems but consistent enough to be effective.
 - Transparency of data and code could be a requisite for technology vendors seeking reimbursement from the National Institutes of Health (NIH).
 - Providing digital education increases the uptake and use of technology and reduces susceptibility to misinformation. It should therefore be a priority when considering equity.
 - Policies should protect patients and help them take advantage of new tools, particularly patients in the most need.
 - Generative AI is tailored to a user’s question; this can be more dangerous than one-sided internet searches, as the results can appear more specific but are not necessarily accurate. Also, consumer-facing platforms on the market today do not protect privacy; patients should be informed that their data are not secure and warned not to share personal health information.
 - The German government has created a registry for health applications. New programs are evaluated for privacy, security, accuracy, and evidence of efficacy via clinical trial data. Programs that join the registry are reimbursed. This model is worth considering.

FINAL IMPRESSIONS

Meeting participants shared their final thoughts and takeaways.

- The federal government has already made significant investment in programs to support better healthcare and technology access. An important first step is leveraging those existing efforts.
- To ensure true equity, the voices of those who have been under- or unrepresented in cancer care and research in the past must be heard and amplified.
- Technology should facilitate and not replace human interaction and support.

- Continual and timely data analysis will help reduce the risk of and mitigate any negative effects of technology on health disparities.
- Advancement should build on previous successes and correct for previous failures, rather than reinventing solutions.
- The issues discussed in this meeting are not exclusive to the United States. Gaps in access and outcome disparities are global concerns.
- Financial transparency is an aspect of care delivery that should not be overlooked. Patients need to know in advance what their copays and bills for services and care will be.
- The new CMS rule represents important progress. It is unclear whether private insurers will follow suit.
- Standardization, metrics, and transparency were three themes that surfaced in the meeting.
- Even with the best of intentions, institutional and government work with marginalized populations can become extractive if it is not approached with care. It is very important that health disparities research returns value directly to the communities involved.

CLOSING REMARKS

Panel members thanked presenters and participants for their productive input and discussion. The Panel and Working Group will consider the information provided during this meeting and others in the series as they develop recommendations to be included in the Panel’s report to the President. Additional written testimony and comments can be submitted at any time to the President’s Cancer Panel via email (PresCancerPanel@mail.nih.gov).

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President’s Cancer Panel meeting *Reducing Cancer Care Inequities: Leveraging Technology Opportunities to Enhance Patient Navigation: Policy Considerations at the Intersection of Technology and Patient Navigation*, held on December 7, 2023, is accurate and complete.

Certified by: _____ Date: February 11, 2024

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