

**National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health**

Data Capacity for Patient-centered Outcomes Research for People with Multiple Chronic Conditions

**John Edward Porter Neuroscience Research Center, Building 35A
Bethesda, MD
October 2–3, 2019**

SUMMARY REPORT

WEDNESDAY, October 2, 2019

Opening Remarks

Gopal Khanna, M.B.A., Agency for Healthcare Research and Quality (AHRQ)

Mr. Gopal Khanna, Director, AHRQ, welcomed participants to the meeting and thanked the organizers. He emphasized the challenges associated with multiple chronic conditions (MCC), including quality of life, quality of care delivery, and cost. More than one-fourth of Americans live with MCC, including 80 percent of Medicare beneficiaries, and MCC account for about 65 percent of U.S. health care spending. Mr. Khanna urged participants to explore every facet of this problem to enhance the well-being of people with MCC. He indicated that an interoperable, shared electronic (e-) care plan would serve as a valuable tool to assist patients, caregivers, and clinicians in sharing essential information. Shared e-care plans could reduce health care spending and provide data with which to conduct patient-centered outcomes research (PCOR).

The interoperable AHRQ and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) e-Care Plan Project (or Project), which will be described in detail later in the meeting, is an effort to address MCC and is funded through the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE). The NIDDK, AHRQ, and multiple federal agencies, including the Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), Agency for Community Living, Indian Health Service, Veterans Health Administration, Patient-Centered Outcomes Research Institute (PCORI), Office of the National Coordinator for Health Information Technology (ONC), and other NIH Institutes and Centers, have partnered in this project to enable patients, caregivers, and providers in using information to address MCC. The project will leverage AHRQ's core competencies in systems research, practice improvement, and data analytics.

In closing, Mr. Khanna remarked that the high volume of data the health care system currently receives provides an opportunity to generate unique approaches to manage MCC and commented that leveraging digital tools and scientific research is essential for finding cures and improving care. He added that in the digital age, society needs a modern health care paradigm that is efficient, effective, and patient-centered. Mr. Khanna acknowledged Dr. Arlene Bierman, Director, Center for Evidence and Practice Improvement, AHRQ, for her work in leading AHRQ's efforts in this initiative.

Putting the Project in Context: Building Data Capacity to Conduct Pragmatic PCOR by Developing an Interoperable Electronic (e)-Care Plan

Arlene Bierman, M.D., AHRQ

Jenna Norton, M.P.H., NIDDK

Dr. Bierman presented the background for the AHRQ-NIDDK e-Care Plan Project, which was funded by ASPE in April 2019, and acknowledged Dr. Chun-Ju (Janey) Hsiao, Mr. Steve Bernstein, and other AHRQ staff providing support. The 2017 CMS data on comorbidity for Medicare fee-for-services beneficiaries showed that approximately 50 percent of patients with chronic kidney disease (CKD) have at least five other chronic conditions, whereas only 1 percent of patients with CKD have no other chronic conditions. No more than 4 percent of people with diabetes mellitus (DM), substance abuse, or ischemic heart disease have only one chronic condition. The 17 percent of Medicare beneficiaries with six or more chronic conditions account for 53 percent of Medicare spending. Dr. Bierman emphasized that improving care and outcomes for MCC patients will require focusing on more than a single chronic condition. Although the current NIDDK e-Care Plan for CKD, which is in development, accounts for many of these factors, the joint e-Care Plan Project will strengthen NIDDK's efforts through partnership with AHRQ, particularly regarding AHRQ's approach to delivering patient-centered care in the community.

Dr. Bierman echoed Mr. Khanna on the high percentage of percentage of Medicare beneficiaries with MCC, which is considered to be one of the most prevalent chronic conditions in the United States. Complicating matters is the mismatch between the current disease-specific method of care delivery and patients' needs, resulting in fragmented, suboptimal care, poor outcomes, and increased costs. Disparities related to MCC are significant—lower-income individuals and individuals from racial and ethnic minorities develop MCC at earlier ages, and women are more likely than men to have MCC across all age groups. MCC accounts for 93 percent of Medicare spending, an extremely unbalanced proportion of health care utilization and spending.

The terms multi-morbidity and MCC are used synonymously and often include persons with more than one physical condition, more than one mental health diagnosis, or both. Dr. Bierman emphasized that clinicians and researchers likely are undercounting MCC by considering a narrow list of conditions that likely leaves out many mental health diagnoses, such as substance misuse and serious mental illness. Other factors that contribute to the burden of illness—including disease severity, functional impairments and disabilities, frailty, and social factors (e.g., food insecurity, poverty, homelessness)—also should be included in a care plan. AHRQ researchers have made some progress in interventions for reducing hospital admissions and readmissions for ambulatory care sensitive conditions; improving quality of care for common chronic conditions, including ischemic heart disease; and achieving Medicare savings from improving hospital safety over the past 20 years—but much work remains to be done, particularly in delivering patient-centered care for people with MCC.

Dr. Bierman reiterated that optimizing care for a single disease does not solve MCC problems—a holistic view is necessary, as is communication across the health care team, as well as across health care sites and settings. She commented that MCC patients are best cared for in a medical home that prioritizes a whole-person orientation and care coordination or integration; however, primary care practices often are challenged to acquire all the necessary patient information needed from the many sites where patients receive care (e.g., specialty care, home care, and post-acute care). A medical neighborhood encompassing community and health care delivery organizations is needed to coordinate and integrate home care and post-acute care and to interface with community services, all of which point to a patient-centered care plan. Dykes *et al.* define a care plan as an overarching, longitudinal blueprint of the prioritized concerns, goals, and interventions of all caregivers and the patient.

Although shared interoperable e-care plans will not resolve all the issues in MCC patient care, they begin to address the many barriers to holistic, coordinated care. Dykes *et al.* surveyed and interviewed staff from 17 technically savvy U.S. institutions and found that care plans are used infrequently, often consist of free text or paper documents with little consistency or interoperability across care settings, and include only limited patient involvement in their development. Young *et al.* reviewed 16 Australian care plan templates designed from 2004 to 2016 and found that their format perpetuates a single-disease approach. In a series of white papers by Lynn and Morgan on care planning, they identified multiple limitations and challenges in current clinical practice.

Dr. Bierman conveyed AHRQ's optimism for the e-Care Plan Project, which is addressing the growing demand for value-based care and patient-centeredness, prior and ongoing work, the increasing focus on interoperability, and emerging tools and standards. She announced that AHRQ is establishing a Learning Collaborative for the Technical Expert Panel (TEPs). A Confluence/Wiki collaboration will be available after this meeting and will enable the sharing of project information and provide an online forum for discussion.

Ms. Jenna Norton put the NIDDK-AHRQ e-Care Plan Project in the context of the patient experience, introducing Betsy Johnson, a hypothetical but realistic persona developed by the NIDDK CKD e-Care Plan Working Group. Betsy is a person with multiple chronic conditions: type 2 diabetes, CKD, and congestive heart failure. She is a retired schoolteacher and widow who lives with her daughter. Betsy is stressed. She wants to be healthy and take care of herself, but she is confused. She does not know whom to listen to among her many providers, who sometimes provide conflicting advice. She does not know what diet recommendations to prioritize. This uncertainty leaves Betsy feeling helpless, depressed, and anxious. From her perspective as a patient, Betsy wants the e-care plan to (1) help keep her many providers on the same page, (2) contain a unified summary of goals and plans that is reviewed by her entire care team and works for all her conditions, (3) provide educational resources, and (4) offer an easier way to schedule appointments.

Ms. Norton acknowledged that people with chronic conditions and their families are not alone in struggling with care coordination in the current health information technology (IT) landscape. The clinicians who care for them also struggle. She introduced a second persona, Dr. Vince Johnson, a nephrologist who maintains an office practice, has rounds in three dialysis units, and manages patient consultations. Vince enjoys patient care and strives to provide the highest level of care to all his patients, but patients often arrive with minimal information from the referring provider. Many times, his patients are not aware that they have CKD or why they have been referred to him, translating to increased patient anxiety and stressful office visits for both him and his patients. Vince wants an e-care plan that provides a concise patient summary, takes 5 minutes to review, and provides the information relevant to the practice of nephrology.

The NIDDK e-Care Plan Working Group developed the personas of Betsy and others and associated scenarios through discussions and interviews with key stakeholders to reflect the challenges faced by real patients and providers with regard to coordination of care and data interoperability. The knowledge gained from the NIDDK CKD e-Care Plan Project has provided a framework and starting point for the broader AHRQ-NIDDK Project and will be discussed in more detail by Dr. Theresa Cullen during a later session.

Ms. Norton noted that the current health IT landscape creates substantial burden on the patient and family caregivers, in terms of coordination of care, as well as on primary care providers (PCPs). The e-care plan aims to remove that burden by providing a central location for critical patient data that is accessible to the entire health care team, including the patient and home/community-based providers.

In April 2015, the HHS convened a stakeholder panel consisting of physicians, nurses, policymakers, and patient advocates that defined five requirements for a comprehensive shared care plan:

- Give the person direct access to their information.
- Center decision-making around the person's goals.
- Be holistic, including clinical and nonclinical needs and services.
- Follow the person through high-need episodes, such as acute illness, and periods of health improvement and maintenance.
- Allow clinicians to view information relative to their specific caregiving role, identify the roles of each clinician, and update all members of the interdisciplinary team.

Ms. Norton pointed out that the AHRQ-NIDDK Project is building capacity for pragmatic PCOR by developing an interoperable e-care plan to facilitate aggregation and sharing of critical patient-centered data across home-, community-, clinic-, and research-based settings for people with MCC. The work will occur along four tracks. The Project team will develop and test an e-care plan application for CKD using Substitutable Medical Applications and Reusable Technologies (SMART) on a Fast Healthcare Interoperability Resources® (FHIR), leveraging the work already completed by the NIDDK. Simultaneously, the Project will establish an e-care plan repository and development collaborative to spur further development in the e-care plan space. Working with the TEPs assembled here today, the Project will expand the e-care plan application and implementation guide to include cardiovascular diseases, type 2 diabetes, and chronic pain. Finally, the Project will disseminate all deliverables through open-source channels.

Ms. Norton emphasized that the AHRQ-NIDDK Project is just one piece of the puzzle on the pathway to creating an e-care plan for people with MCC. The Project will leverage the NIDDK work, as well as other ongoing efforts, such as the CMS/ONC Electronic Long-Term Services and Supports (eLTSS) Pilot, the Social Interventions Research and Evaluation Network (SIREN) Gravity Project, and the HHS Substance Abuse and Mental Health Service Agency Omnibus Care Plan. Although this current project will expand existing work to consider three new condition areas—cardiovascular disease, type 2 diabetes, and chronic pain—in order for an e-care plan for people with MCC to be functional, future work will need to expand to include many other diseases and conditions. Finally, fully realizing an e-care plan will also depend on addressing such challenges as medication reconciliation, improving use of clinical terminologies, and expanding health information exchanges (or other pathways for data exchange).

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Defining Care Planning

Malaz Boustani, M.D., Indiana University

In developing an e-care plan, Dr. Malaz Boustani suggested forming a minimally valuable product (MVP) to be upgraded and tweaked through user experiences. Dr. Boustani commented on his work with the Great Lakes Practice Transformation Network (GLPTN), providing technical assistance to Midwest physicians who are not members of accountable care organizations. Many enrolled providers come from

small practices in rural areas with limited resources; GLPTN has implemented a centralized strategy to assist these providers in improving their administrative procedures.

In addition to the patient and specialist perspectives described in the previous presentation, Dr. Boustani detailed the challenges of the PCP and the patient's family members. PCPs must pay attention to conflicting recommendations and drug interactions; older patients with three chronic conditions receive about 12 medications, as well as numerous non-pharmacological regimens. In addition, PCPs are overworked and significant amounts of their time are needed for chronic care management and preventive services for their patients. Often, patients with MCC depend on family members to manage medications and assist with other areas of life.

Dr. Boustani discussed the agile innovation process developed by the Indiana University Center for Health Innovation & Implementation Science (CHIIS) as it relates to care planning. Agile innovation methodologies suggest an eight-step process that involves both planning and execution. The planning phase consists of confirming demand, studying the problem, scanning for existing solutions, and planning for evaluation and termination. The execution phase encompasses collecting and selecting top ideas, doing cyclical innovation sprints of prototyping and testing, validating solutions, and packaging for launch. He emphasized that the specific needs of the patients and families must be well understood so that the correct problems are addressed.

Medicare contains several requirements for PCP care management plans. Plans must meet the patient's needs, address relevant conditions with goals and actions agreed to by the patient, and contain arrangements for providing the treatment and services the patient is likely to need. Plans must be reviewed after specified timeframes and adjusted as necessary to reflect changing goals or conditions. Care plans should contain contact information for all care team members, including clinicians, insurance providers, caregivers, and community-based support. Clinical staff must document their time spent on chronic care management for billing requirements. Dr. Boustani remarked on using motivational interviewing to connect with patient goals and priorities.

Regarding assessments of patients, Dr. Boustani emphasized that many patients come to specialists with the burden of multiple symptoms that might not fit under one disease. With support from the National Institute on Aging, Dr. Boustani and his CHIIS colleagues developed the SymTrak tool for comprehensive reporting of symptoms by patients and their families. He suggested harnessing knowledge engines and artificial intelligence to assist with evidence-based interventions and action plans to manage complex care and medication regimens for people with MCC. Patients should be given self-management tools for their care plan, assisted by caregivers as needed. Evaluation and follow-up is necessary to keep care plans dynamic in light of changing conditions or new information.

Dr. Boustani indicated that current systems for sharing e-care information have cumbersome user interfaces. Plans must be accessible by multiple users in various settings and should link to electronic health records (EHRs) and patient portals, log the historical record of the shared decision-making process, and facilitate patient-centered care over document-centered care.

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Discussion

- Ms. Norton commented that the ability to use data from shared e-care plans in research and pragmatic trials is a goal for this project. Currently, EHR data from individual patients is usually fragmented instead of aggregated.

PANEL 1: Care Planning for MCC—Patient Perspectives

Moderator: Jenna Norton, M.P.H., NIDDK

Panelists: Richard Knight, M.B.A., American Association of Kidney Patients (AAKP); Shabina Khan, PCORI Ambassador; Julisa Voinche, Stanford Health Care Pain Management Advisory Council, Stanford Hospital Caregiver Center, Stanford Health Care Emergency Department Advisory Council

Ms. Norton invited the panelists to recount their personal experiences in managing chronic conditions. Panelists were joined by Ms. Ellen Blackwell, M.S.W., CMS, who shared her experience as a caregiver.

Ms. Shabina Khan, patient, caregiver, and PCORI Ambassador, described her experiences as a person with DM, cardiovascular disease and depression. Ms. Khan expressed concern that the communications between the three facilities she visits are not aligned, requiring her to physically take her own records (e.g., laboratory results) to appointments. She envisions an electronic one-stop-shop system, in which pertinent information from patients, caregivers, physicians, and pharmacies is integrated. Ms. Khan further elaborated on the need for a system that is easier for patients, especially for individuals such as herself—she is managing care for both her own five chronic conditions and the health of her children.

Ms. Julisa Voinche, Chair of the Stanford Healthcare Pain Management Advisory Council, values the opportunity to convey the patient’s perspective about MCC to the clinical community. As a patient, she has felt intimidated by the divide between medical care she received and the personal story she embodied. She learned that details needing attention were not always easy to address. After surgery to remove leiomyomas (i.e., uterine fibroid tumors), Ms. Voinche was left with scar tissue and severe pain. Being in a state of chronic pain meant that her nervous system was continuously in the “fight or flight” mode, leading to episodes of deep anxiety and terror. These episodes prompted thoughts of not being able to handle the pain, especially after three additional surgeries provided no relief or solution.

Ms. Voinche explained that she needed compassionate and knowledgeable health care professionals to attend to her medical needs. She joined the Stanford University Pain Management Advisory Council and also began to facilitate the American Chronic Pain Association meetings for the university to ensure that she interacted with those well-informed about pain management. Recognizing that physical pain and mental health disorders can be interconnected, Ms. Voinche also interacts with the mental health community. She emphasized the importance of imparting hope to patients and connecting them to the appropriate services and resources as they navigate the health care system.

Mr. Richard Knight shared his experience as a former hemodialysis (dialysis) patient and then kidney transplant recipient. He is a member of NIDDK’s National Kidney Disease Education Program (NKDEP) Health IT Working Group. As president of the AAKP, he shares with patients his knowledge about the health care system, listens to patients’ comments, and understands what they are facing. Mr. Knight reported that he was fortunate to become a transplant recipient 13 years ago. Prior to discovering that he needed a donor kidney, he was not aware of his CKD status and, like the majority of patients, abruptly started (i.e., crashed) on dialysis from a hospital emergency room. The AAKP advocates for patient choice in a treatment modality, but crashing into dialysis does not provide a patient that opportunity. Mr. Knight credits his otherwise healthy state for triumphing over dialysis and continuing to manage a small business. While on dialysis, he found it challenging to negotiate processes he thought were common

sense, such as self-checking glucose levels and making use of at-home dialysis treatment. Mr. Knight then focused his sight on a transplant, applying his business strategist training. He noted that educating patients about the available treatment options is critical.

As a member of the Steering Committee for NIDDK's Kidney Precision Medicine Project (KPMP), Mr. Knight is aware of acute kidney injury, its onset, and clinical signs. His most recent experience of being hospitalized for symptoms of pneumonia revealed the disconnect in communications between health care systems and supports the need for an integrated MCC e-care plan. Mr. Knight makes a habit of requesting all documentation regarding his care, which his colleagues in the KPMP helped him to read carefully and understand. While he was in the hospital being treated for pneumonia, his health care team expressed concerns about his prostate size. After 12 years, his transplant surgeon was able to view his records electronically and confirm that his prostate size had not changed. Had this data been available to his hospital staff, this might have been known sooner. Mr. Knight emphasized that quality of life is a priority for patients and called attention to the challenges a dialysis patient faces in keeping up with the many in-person office visits.

Ms. Blackwell described her experiences as caregiver for her adult son who has autism and seizure disorders and is intellectually disabled. A staff of 10 personal care nurses and support specialists, which she supervises, is necessary to provide the level of care her son needs. Although she is a trained case manager and geriatric social worker, Ms. Blackwell remarked on the amount of work that navigating her son's care requires. The copious amounts of paperwork alone can be daunting. The disconnect between clinical care from her son's neurologist, psychiatrist, and PCP continues to be an issue. Ms. Blackwell pointed out the challenges in navigating care and insurance for a Medicare dual-eligible beneficiary like her son, especially when having to change doctors. She described the care plan currently available for her son, noting that it is 45 pages long and, as a result, unusable. She emphasized the need for a concise care plan that can be more easily digested and used.

Discussion

- A participant remarked on communication barriers on all levels—person to person, person to EHR, and provider to provider—and asked about examples of effectively documenting decision-making preferences for care, aside from directly interfacing with the clinicians. Although one of her doctors requested she communicate her symptoms via an online patient portal, Ms. Khan observed that some of these platforms are not user friendly. She also noted that responses from the clinician can be delayed. Mr. Knight explained that some patients are communicating with their PCP and making appointments via online portals, but the interoperability of systems remains an issue. Ms. Blackwell explained that because her son's care plan is a 45-page document—which is unlikely to be read by clinicians or other health care staff—she designed a 1-page summary that can be shared with hospitals or emergency medical technicians easily. Ms. Voinche noted her success with using patient portals and pointed out that the PCP must set aside time to review the information and respond. She encouraged patients to be proactive in this area.
- Dr. John Piette (University of Michigan) asked whether privacy regarding data sharing and sensitive information was a concern for patients. Ms. Blackwell explained that data privacy is different for her son, who routinely accesses social and health care services, than for others not affected by his particular health disorders. Ms. Voinche observed that some patients have heightened anxieties that their health-related information could be used negatively against them, particularly when seeking employment opportunities.
- Dr. Blackford Middleton (Apervita), an internist and chronic condition patient, thanked the panelists for sharing their experiences. He asked about input on having an MCC e-care plan with

components for managing finances and/or risk, given that patients often are affected by bankruptcies resulting from health care costs. Mr. Knight suggested that more can be done to decrease the cost of health care in America, especially in bringing to the forefront the cost of long-term dialysis versus having a transplant. The panelists agreed that inclusion of information on cost of care and insurance coverage in the care plan would be useful.

PANEL 2: Care Planning for MCC—Healthcare Provider Perspectives

Moderator: Arlene Bierman, M.D., AHRQ

Primary Care

David Dorr, M.D., M.S., Oregon Health & Science University (OHSU)

Dr. David Dorr noted his role as OHSU’s Chief Research Information Officer is to improve the ability to generate knowledge from patient care and apply that knowledge to future patient care. His experience has taught him that innovations should be designed to overcome the challenges patients face. Currently, for most patients, care is not coordinated, and care plans are complicated and not integrated. A person with five chronic conditions sees an average of 12 specialists per year, each potentially prescribing a variety of medications and lifestyle changes. Having five or more chronic conditions greatly increases the risk of hospitalization. Primary care facilities are mission-driven, focused on the holistic care of patients, and have a very high workload burden. Managing preventive and chronic illnesses for 2,500 patients in a primary care practice would require 18 hours per day from each provider. Care planning is the most time-consuming and also most crucial activity for high risk patients. Integrated e-care planning is considered an ideal goal in health care. The field has struggled toward this end, and Dr. Dorr observed that the goal is closer than ever.

OHSU’s Care Management Plus program identifies vulnerable patients and tailors care to their specific needs to minimize downstream risk and improve outcomes. Care Management Plus places a Care Manager or Care Coordinator within a primary care team, assisting and coordinating PCPs, specialists, patients, and families using health IT. Although not yet a comprehensive care plan, Dr. Dorr reported that the program has demonstrated improved outcomes, including reduced hospitalization and increased patient satisfaction with care. Incorporating patient and caregiver voices into these plans remains a challenge. OHSU is beginning to incorporate social and behavioral needs—which are important factors in treating people with MCC—into the care plans.

Dr. Dorr emphasized that gathering data only from EHRs results in incomplete and inaccurate care plans. Data from the EHR are known to be of poor quality on the individual level. Poor data quality is problematic, because conformance, completeness, and accuracy of data can dramatically alter predictions for patients with MCC. Data on functional status, health-related behavioral and social needs, and other important aspects of health are often lacking. Systems must be built robustly to account for this issue. Continuity of Care documents act as starting points; however, most are missing key information, and new information cannot easily be integrated. The U.S. Core Data Interoperability and FHIR standards may be useful. Researchers have found that analyzing and prioritizing the information can reduce the data collection demands of PCPs. However, Dr. Dorr cautioned care plan developers not to assume that PCPs will automatically begin implementing added structure into their patient charts without being told.

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Social Work

Nicole Ruggiano, Ph.D., The University of Alabama

Dr. Nicole Ruggiano explained that many providers are not aware of the positions social workers serve in health care. She provided background information on the unique role of social work in health care and the opportunities social workers have in care planning. Dr. Ruggiano advocates for the value of fully integrating social workers in care teams. Care planning in social work involves helping people navigate health systems, linking clients to health and other services, coordinating care, assisting with decision-making, addressing resource deficits, and expanding health literacy. When a patient presents with conflicting advice from two physicians, the social worker can help the patient make an informed decision.

Dr. Ruggiano detailed the basic principles of social work relevant to this issue. Person-in-Environment Theory is the biopsychosocial perspective that health and choices are heavily influenced by the constraints in a person's environment. She remarked that although the concept of social determinants of health (SDOH) is a new consideration in the medical field, social work has incorporated this understanding for many decades. The Strengths-Based Approach emphasizes that patients have knowledge, skills, and abilities they should leverage when addressing their problems. This approach conflicts with the medical model of the physician as the leader. Self-determination means that the people served should make the decisions about their own lives. Self-determination does not mean that a provider gives a patient two choices without further input. Social workers provide in-home services, which can include visiting patients in assisted care or rehabilitation facilities. In-home and community-based services sometimes have their own care plans that are not incorporated into patients' medical care plans. Some home health care agencies have been excluded in federal legislation from receiving financial incentives to developing EHRs.

Dr. Ruggiano closed by emphasizing that social workers observe the realities of a patient's experience, which are more complex than a care plan might indicate. Social workers address barriers that might make the care plan untenable, help patients solve problems, and advocate for patients. In her work, Dr. Ruggiano has observed that patients may be hesitant to talk to their doctors about concerns with following medication or lifestyle regimens.

Long-term Services and Support (LTSS)

Nancy Kusmaul, Ph.D., LMSW, University of Maryland, Baltimore County

Dr. Nancy Kusmaul explained that LTSS comprise the non-medical side of caregiving, including both informal (e.g., friends and family) and formal (e.g., nursing homes, adult day care, assisted living, and others) caregiving services. LTSS are provided to people who require assistance to perform daily activities over an extended time period because of disability or chronic illness. LTSS goals include maintaining health, improving functional capacity, maximizing autonomy, and enhancing physical, social, and emotional well-being. LTSS address the activities of daily living (ADL), including basic functional tasks—such as bathing, dressing, and feeding—as well as instrumental activities of daily living (IADL), including complex tasks required for independent living, such as shopping, housekeeping, and food preparation. Research indicates that about one-third of people age 65 or older and two-thirds of people age 85 or older require functional assistance. Dr. Kusmaul conveyed that the number of family caregivers is decreasing because of social trends. Medicaid is the primary payer for LTSS, encompassing 51 percent of all LTSS spending in 2013. Dr. Kusmaul emphasized that many older adults are unaware of, and hence have not planned for, the fact that Medicare does not cover LTSS.

Home- and community-based services (HCBS) can include case management, home health services, personal care, adult day services, or respite care. Respite care provides relief to a caregiver on a temporary or periodic basis, either by adult day care or in-home services. Dr. Kusmaul expressed that

respite care is a cost-effective and culturally responsive form of care. Adult day care centers provide a variety of services, the specifics of which depend on their classification as either medical or social adult day centers.

Assisted living is a congregate residential setting that provides or coordinates personal and health-related services, which can include 24-hour assistance. Assisted living accommodates residents' changing needs; maximizes their dignity, autonomy, and independence; and encourages family and community involvement. Currently, more than 700,000 residents live in 22,000 assisted living residences in the United States. Most residents pay significant out-of-pocket expenses. About one-fourth of residents have at least four chronic health conditions. Dr. Kusmaul noted that assisted living centers are not always connected with patient medical care plans.

Continuing care retirement communities (CCRCs) are residential communities containing multiple levels of care—independent living, assisted living, and skilled nursing—within one complex. Residents can move between care levels based on need. About 2,240 CCRCs house more than 745,000 older adults in the United States. Four percent of people age 65 or older live in nursing homes; however, about one-fourth of older adults stay in nursing homes at least temporarily for rehabilitation purposes.

In closing, Dr. Kusmaul conveyed that a care plan needs the grounding information of the patient's life and care goals, so providers know how to give the best care. Social workers provide many services to people with MCC that affect these goals. Comprehensive care plans should be written in language that all stakeholders can understand and must include details about the LTSS that patients receive.

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Shared Care Plans: Nurses, Physicians, and Patients

Patricia Dykes, D.N.Sc., R.N., FACMI, Brigham and Women's Hospital and Harvard University

Dr. Patricia Dykes described her research using health IT to improve patient engagement, team communication, and patient outcomes using shared care plans and shared communication tools. She emphasized that ineffective communication and lack of patient engagement are leading root causes of medical error, which is the third leading cause of death in the United States behind heart disease and cancer. To address this problem, the Promoting Respect and Ongoing Safety through Patient-centeredness, Engagement, Communication, and Technology (PROSPECT) program, led by Brigham and Women's Hospital, aims to optimize intensive care unit (ICU) experiences by implementing patient-centered interventions while minimizing preventable harms. The goals include increasing patient and family engagement and satisfaction, improving care plan concordance, and promoting dignity and respect.

The PROSPECT team developed tools for both providers and patients to facilitate communication among care team members. Provider-facing tools include a safety checklist integrated with EHRs, a multidisciplinary plan-of-care platform accessible by all team members, and an electronic nursing plan-of-care workspace. Parts of the nursing plan workspace are accessible only to hospital staff. A patient-centered microblog enables patients and families to ask questions; any of the patient's providers can view the questions and respond. The microblog contains a provider-only thread enabling clinicians to discuss among themselves before responding to the patient. Patients also have access to the plan-of-care platform,

enabling them to actively input their personal care goals and rate the quality of care they receive. The patient platform features safety information, medication schedules, test results, diet information, and a discharge checklist.

The data indicate a decrease in preventable harms and an increase in overall satisfaction of patients and care partners after PROSPECT was implemented. Dr. Dykes conveyed that this initiative's success has been driven by the clinical workflow integration and problem-solving by care team members, as well as the technological developments. Challenges include providing additional support for patients who are less technology-savvy, incapacitated, or do not speak English and helping more providers understand the value of patient-generated information.

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Discussion

- Dr. Boustani observed that the main barriers to improving health care systems are shortages of time and space. He emphasized the need to assess more deeply the solutions proposed by care plan developers, especially regarding the decision-making processes, as well as the perception-based and group-based decisions. Dr. Bierman commented that care plan implementation requires a culture change to take care of people as a whole, in contrast to current disease-specific approaches to care.
- Ms. Sharon McDaniel (Effective Management of Pain and Opioid-Free Ways to Enhance Relief [commonly called EMPOWER] Study participant) reported that, as a patient, she had at no time been asked to list her goals after any of her 22 surgeries; she was asked about her goals when staying at rehabilitation clinics. Ms. McDaniel appreciated the inclusion of patient goals in the presentations of this meeting.
- Dr. Kusmaul noted that if a patient's goals do not align with the best treatment options or certain standards of care, clinicians often view these goals as not rational. She advocated for viewing patient goals with respect.
- Dr. Dykes commented that administering rounds in an ICU takes 4 hours; adding 1 minute per patient translates to an additional 30 minutes overall. Planning for PROSPECT analyzed which components added value to care and creatively integrated the new tools and procedures into existing ICU rounds.
- Dr. Ruggiano commented on her prior work on health self-management for older adults with chronic conditions. This study was informed by bounded rationality theory, which holds that people use all information available to make the best decisions possible. She found that many older adults have information withheld from them because providers do not think they will understand it or do not value patient education. Dr. Ruggiano advocated asking patients about their preferences in terms that the patients understand. The health care field needs to reconfigure how it informs and provides resources to patients so patients can make better choices toward their care preferences.
- Mr. Knight emphasized that the roles of social workers, nurses, and nutritionists are very valuable. In dialysis situations, for example, the nephrologist usually only spends a few minutes with each patient. He expressed that physicians' communicating with patients in terms understandable by laypeople helps to build patient-provider trust.

- Ms. Voinche expressed that provider attitudes will not shift unless they are encouraged to give data to patients and consider the patient’s biopsychosocial factors. Therapists or social workers can provide the biopsychosocial bridge between provider and patient. She doubted that meaningful data could be collected, or trust established in a 15-minute doctor visit. She mentioned that at the Stanford University Pain Management Center, psychologists are involved in helping patients identify their goals. Dr. Kusmaul added that a disconnect exists between the physical health system and the mental health system.

Background on Key Data and Knowledge Standards

Clem McDonald, M.D., National Library of Medicine (NLM)

Dr. Clem McDonald explained that most people view data as a flat structure: a spreadsheet with one row per person or visit, one column for each variable. This contrasts with a “stacked” structure—many records per patient, one record per observation—which is used by many health IT systems, including EHRs. While flat structures may work for one-time data sets, they do not catalogue variables into a master file. Flat structures often do not contain consistent field headers or category names between visits, requiring patient data to be synthesized manually. Clinical observations comprise 90 percent of all structured data in EHRs and research databases. Stacked structures allow use of a master file to catalog variables so that observations can be tracked between visits and across patients. The Health Level Seven International (HL7[®]) Version 2 (V2) and FHIR standards use stacked structure.

The HL7 V2 message structure of logging data is currently used in most hospitals. Dr. McDonald conveyed that HL7 V2 has worked fairly well within institutions but fails across institutions, because each site uses its own codes to identify variables. A universal coding system for observation types is needed to maximize data interoperability. Dr. McDonald explained that the Logical Observation Identifiers Names and Codes (LOINC) international coding system is free to use and contains standardized codes for most clinical observations. Several regulations and standards, including some issued by the U.S. Food and Drug Administration, require LOINC codes to be used for clinical data beginning in March 2020. Several other coding systems (e.g., Unified Code for Units of Measure (UCUM), Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT), U.S. standardized nomenclature for clinical drugs [RxNorm], U.S. codes for genetic variants [ClinVar], and International Classification of Diseases) are in use for particular applications; some are required by federal regulations for meaningful use data.

Dr. McDonald detailed HL7 FHIR, the new apex health care data interchange standard that will replace HL7 V2. Often described as an application program interface (API), FHIR is a health care interchange standards based on modern internet technology. It is designed to be elegant, flexible, and consistent. FHIR includes specifications for data structures and behaviors needed to support all health care activities, including administration and research. FHIR’s special features include a specification for input forms and tools for decision support. FHIR contains resources to house data on individual patients, providers, clinical observations, medications, research studies, research subjects, and many more categories still in development. Each resource is similarly constructed for ease of user learning. Details about resource documentation can be reached through a single click. FHIR encourages or requires the use of specific coding systems, such as LOINC and UCUM for observations, RxNorm for drugs, and the SNOMED for conditions and other fields. Common standards for each kind of data ensure interoperability between users at other institutions. FHIR’s most important attribute is its extensive and growing popularity, which facilitates its interoperability as the new common standard. Several major technology companies, most health-related federal agencies, major health insurance companies, and big pharmaceutical companies have adopted FHIR. The U.S. 21st Century Cures Act enacted December 2016 requires the use of an API, a standard met by FHIR.

The HHS ONC and CMS have proposed rules to require support for 15 of the most-developed FHIR resources, which use NLM-supported coding systems. The proposed rules forbid blocking information from patients or their designees and would require payers to give patients and providers access to claims data and clinical data. ONC's draft Trusted Exchange Framework and Common Agreement (TEFCA) would enable nationwide exchange of electronic health information across disparate networks. Dr. McDonald pointed out that implementation of TEFCA would facilitate longitudinal tracking of patient data at low cost.

Discussion

- Ms. Norton noted that despite meaningful use requirements for clinical coding standards, uptake has been slow. Dr. McDonald indicated that some institutions that have adopted LOINC have yet to fully implement the standards.
- In response to a comment from pharmaceutical company representatives suggesting that integration of EHRs with FHIR would be challenging, Dr. McDonald noted that many pharmaceutical companies still use an outdated computer system for logging data, but he is optimistic for their future uptake of newer systems.
- When asked to speculate on future development of e-care plan logic specifications, Dr. McDonald replied that Clinical Quality Language might be adopted; he expressed support for the implementation of a JavaScript logic.
- Dr. Shelly Spiro (Pharmacy Health Information Technology [HIT] Collaborative) asked how registries that collect pharmacological or immunological data can facilitate the transition from HL7 V2 to FHIR. Dr. McDonald explained that laboratories are unlikely to change from HL7 V2. Registries include data that often do not exist in medical records. He also noted that computer scientists are seeking ways to convert V2 to FHIR.
- Ms. Kelly Cronin (HHS) observed that the social services field is far behind other health care fields in adopting clinical informatics. Dr. McDonald pointed out that planners should be cognizant of the time required by staff to fill in codes for the data standards. Having patients fill out codes can help save time, but some patients need assistance from providers or caregivers to enter data.

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PANEL 3: Data Standards in Action

Moderator: Chun-Ju (Janey) Hsiao, Ph.D., AHRQ

Ms. Evelyn Gallego remarked that care planning is a defined process that requires input data and results in a care plan with the ultimate goal of improving outcomes, including experience and quality of care, population health, and cost. Care plans must contain five basic components: information about all care team members, including caregivers and the patient; health concerns and needs; goals and objectives of the patient and provider; interventions and activities; and progress made toward the goal outcomes. Care plans have evolved from a 1980s concept of static structures to a dynamic model in which each component informs the data of the other components. Technologies are emerging to support the dynamic behavior required for comprehensive care planning. Ms. Gallego conveyed that health IT standards provide the fundamental definitions and structures for data across many health care use cases.

Interoperable care planning involves standardization across three layers: data transport, syntax, and semantics. Syntax refers to the data's structure and format, whereas semantics conveys the information's meaning.

Ms. Gallego described two fundamental data standards that facilitate the sharing of care plans—HL7's Clinical Document Architecture (CDA[®]) and FHIR. CDA contains a set of maturely developed document templates, whereas FHIR consists of still-evolving resources. CDA imports data from full documents and exists independent of system integration; FHIR exports granular data from both APIs and full documents and is tightly integrated with IT and business systems. Both CDA and FHIR standards share common syntax and semantics and also support point-of-care-based document exchange. New data standards that support dynamic exchange, based on the FHIR framework, are currently being developed by the nonprofit organization Integrating the Healthcare Enterprise.

Ms. Gallego acknowledged several relevant standards initiatives: the CMS Post-Acute Care Interoperability (PACIO) Project, the FHIR at Scale Taskforce (FAST) Initiative's shared care planning use case, the HL7 Da Vinci Project (provider to payer data interoperability), the HL7 Creating Access to Real-time Information Now (CARIN) Alliance (consumer-directed data interoperability), the HL7 Care Plan Domain Analysis Model (DAM), and the HL7 Gravity Project (social determinants of health data interoperability). She highlighted two initiatives as particularly important—HL7's DAM 2.0 and the Gravity Project. DAMs are not standards for implementation, but represent the static or dynamic semantics of a subject area in a manner that enables the harmonization of the various perspectives of the stakeholders in the domain. The Gravity Project is identifying terminology codes to represent SDOH data in the EHR across screening, diagnosis, goals, and interventions.

Several challenges remain in adopting these data standards. Ms. Gallego indicated that health care organizations should work with vendors to implement robust standards for care plans and EHRs. Methods for nonclinical systems, which do not use EHRs, need to be developed and incorporated into the new standards. Semantic standards need further development. Policy barriers include additional planning among provider groups and individuals, the acceptance and incorporation of person-generated clinical and nonclinical information, and the inclusion of SDOH data. Consensus is needed on processes, procedures, and workflow to support longitudinal and dynamic care planning. Mechanisms should enable the consolidation and reconciliation of care plans. Operational and cultural barriers include coordinating the roles of care team members and agreeing on plan components. These plans require significant resources to build, maintain, and share, and care planning needs to be valued over cost.

Ms. Gallego concluded that despite the current slow uptake of standardized care planning, progress can be made by increasing awareness and bringing stakeholder groups together. Health IT-enabled care planning capabilities are essential for advancing the transition to value-based payment models. Care plans should be used and shared by all care team members across diverse settings.

Data Standards for Social Determinants

Sarah DeSilvey, APRN-C, Northwestern Medical Center

Ms. Sarah DeSilvey addressed the importance of SDOH in clinical settings. Published literature documents the detrimental health effects of food insecurity, housing insecurity, transportation barriers, and adverse childhood experiences. Many health associations have comprehensive initiatives addressing these SDOH, and industry interest is growing. Ms. DeSilvey pointed out that because social factors clearly affect patient health, SDOH should be included on clinical documentation, referrals, orders, risk analysis, and research. The medical field needs to expand its terminology for social needs to better care for patients and populations, share care among clinical and community partners, study interventions and their effect on health outcomes, and better allocate resources toward social risk.

Ms. DeSilvey enumerated challenges to incorporating SDOH into interoperable data standards. Some systems possess either too many or too few codes, and some institutions are still refining concepts needed to inform the codes. A review by the SIREN at the University of California, San Francisco, documented 1,095 existing SDOH codes. Ms. DeSilvey explained that researchers in SIREN's Gravity Project are examining whether existing codes accurately reflect the breadth of social needs care in clinical and community settings.

The Gravity Project is a public collaborative with more than 700 current members. Its mission is to create and maintain consensus to expand SDOH core data and accelerate interoperable standards-based exchange of information through HL7 FHIR. Ms. DeSilvey emphasized that Gravity includes the perspective of community stakeholders who care for patients' social needs beyond the clinical space. Gravity's Phase 1 deliverables include agreeing upon common data elements and associated concepts and the capture and grouping of coded data elements for three use cases—documenting SDOH data from patient encounters, documenting SDOH-related interventions and their outcomes, and aggregating SDOH data for such uses as population health management, quality reporting, and risk analysis. These efforts are specifically tailored to food insecurity, housing instability and quality, and transportation access.

Ms. DeSilvey described Gravity's process. Ms. DeSilvey and colleagues have integrated existing data from SIREN, health organizations, and published literature into a master list. Gravity members provide input and suggest additions. Gravity's core team adjudicates these suggestions to continue refining the list. Through this process, the Gravity team is developing core definitions and building a logical syntax to incorporate into FHIR. The team has generated a structure that delineates core activities and interventions in social needs care. Specific programs and roles are built upon this basic syntax structure. The team revised the intervention structure to address engagement, enable roles beyond the patient, differentiate counsel from education, and describe goal assessment more fully. Deliberate semantic adjustments were made to use terminology appropriately for each case. Regarding definitions to drive the value set logic, the Gravity team found that, existing food insecurity definitions are population-based and do not allow for computable logic. Ms. DeSilvey and her colleagues are performing research to decide upon a person-level definition for food insecurity that can inform computable logic.

Ms. DeSilvey highlighted remaining opportunities for the Gravity Project. The team can develop LOINC Panel questionnaires for program eligibility and program enrollment, develop provider taxonomies to encompass emerging clinical and community roles, and work with vendors to address patient privacy concerns. Health care provider taxonomies are needed to address interventions for social needs. The data standards community will continue coordinating SDOH terminology across initiatives.

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Data Standards for CKD

Theresa Cullen, M.D., M.S., FAMIA, Regenstrief Institute, Inc.

Dr. Theresa Cullen explained that NIDDK's NKDEP formed a CKD e-Care Plan Working Group to create an e-care plan for CKD, which Ms. Norton described earlier in the meeting. The care plan aims to enable patients, clinicians, and caregivers to input, change, access, and retrieve key patient information, goals, and preferences across settings. A key step toward development of the care plan included identifying key elements of clinical, social, and contextual data and standards relevant to comprehensive care for people with CKD. The Working Group used an ONC care plan standard from 2015 as a framework and agile software methodology to identify and prioritize data elements. They captured patient voices, developed personas and scenarios to understand various perspectives, gathered input from stakeholders, and settled upon standards for key data elements.

The Working Group compiled existing structured data standards and identified additional data needed, consulting nephrologists, patients, and nutritionists. The group compiled a list of data elements using a Delphi process. The elements included CKD-specific items, complications and comorbidities, social factors, patient goals and preferences, interventions, and health status evaluations toward desired outcomes. The working group found multiple significant health factors that currently lack data standards, including modalities for patient choice during end-stage renal failure, kidney failure risk prediction, CKD patient education, and patient goals. The team developed LOINC codes for these elements. Dr. Cullen expressed appreciation for the ongoing volunteer work performed by the CKD e-Care Plan Working Group members.

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Electronic LTSS (eLTSS) Initiative Overview

Elizabeth Palena Hall, M.S., M.B.A., B.S.N., HRSA

Ms. Elizabeth Palena Hall discussed the eLTSS initiative, a joint project of the CMS, ONC, several state Medicaid agencies, and community participants. She began by emphasizing that the health care system and the human services system need to integrate. Disparate eligibility and payment systems, particularly through Medicare and Medicaid, can lead to disconnected care settings, treatment goals, and desired outcomes. Interoperable systems have the potential to improve care coordination in LTSS.

The eLTSS Initiative began in 2014 with the CMS Testing Experience and Functional Tools (TEFT) grant. Initiative researchers aimed to develop a human-readable data set that would provide value for all care team members. The team began by analyzing states' current individual service plans to generate a harmonized data set with those elements considered the most valuable toward providing LTSS. After pilot-testing the data set with TEFT grantee states and vendors, the researchers produced a revised and validated eLTSS data set containing 56 elements. Ms. Palena Hall conveyed that mapping this data set to the FHIR structure required a joint learning effort by HL7 staff and members of the HCBS field.

The data element categories include beneficiary demographics, patient goals and strengths, person-centered planning, risk identification and management, service information, service provider information, and plan signatures. Ms. Palena Hall conveyed that the eLTSS core data set is the output of a process to achieve person-centered care planning. She remarked that future work might add or customize data elements to support input data, such as assessments and screenings and additional patient preferences.

The eLTSS FHIR implementation guide was approved by HL7 in May 2019 and was published in September 2019. The implementation guide was tested at an HL7 FHIR Connect-a-thon, in which an eLTSS data set was generated and transmitted for a use case using the FHIR resource. Ms. Palena Hall explained that the eLTSS Initiative team is interested in developing relationships with organizations to explore future pilot-testing opportunities.

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Discussion

- Ms. Norton asked about progress in connecting eLTSS systems with health IT systems. Ms. Palena Hall pointed out that community-based organizations have traditionally collected SDOH data. The eLTSS data set will facilitate the flow of information between the community organizations and clinicians. Ms. Gallego added that FHIR enables anyone with access to the API to query a patient's information.
- Dr. Bierman called attention to an AHRQ request for applications (RFA) funding announcement (RFA-HS-19-002) on population health, which will bring together data on chronic diseases, SDOH, and social services for primary care practices to manage population health and identify high risk individuals. The awardees will be announced in October 2019.
- Ms. Palena Hall commented that the post-acute care field has standardized the domains of information that they collect for interoperability. Elements for functional status have been standardized and mapped to LOINC; cognitive status is forthcoming.
- Noting that the progress made in health care data standardization in the past several years has occurred disparately, Dr. Bierman suggested producing a compendium to chart the efforts of various groups.
- Participants discussed care plan needs in general, suggesting that the value proposition in care planning for mutual benefit to patients, caregivers, and providers should be emphasized. The patient's voice only is emphasized in the goals section of care plans; language to inform the patient about prescriptions and interventions should be included. Care plans should guide parents regarding care practices for children with chronic conditions. The eLTSS care plans are meant to be shared with patients' families and caregivers. The clinical terms should be translated to language understandable to families and caregivers. The Gravity Project is ensuring that the standards are intelligible to all care plan stakeholders, expressed in the simplest possible language.
- Dr. Jennifer Wolff (Johns Hopkins Bloomberg School of Public Health) mentioned the importance of the family's roles for people who have significant long-term care needs. She asked whether the platforms being developed recognize the roles of families in working with formal service providers and in making decisions about care plans. Panelists explained that services include informal support, such as from a neighbor, and that some care plan models were built to

enable input from family caregivers. In some cases, the specified taxonomy codes for a pediatric use case.

- Dr. Boustani commented that major health insurance companies have begun working directly with community-based SDOH providers. Research has demonstrated that community-based organizations provide needed transitional care. He expressed that to generate an MVP, the user needs to be well understood. He mentioned the possibility of generating multiple MVP care plans for each type of care team member (e.g., patient, clinician, and insurer) and choosing one plan to implement first. He advocated for protecting the SDOH language and semantics from the medical part as much as possible by not causing confusion for the different users, a problem that has occurred in EHRs.
- Ms. DeSilvey expressed that the HL7 model's openness is one of its best attributes and noted that most of the Gravity Project members who submit input on coding are non-clinical personnel. Ms. Palena Hall added that social isolation is a recently added data element in the upcoming post-acute assessments.
- When asked by Dr. Tiffany Washington (University of Georgia) whether the perspective of the renal social worker was incorporated into the CKD e-Care Plan Working Group, Dr. Cullen explained that nephrology groups provided significant input. Dr. Cullen and Ms. Norton indicated that the project can be improved by expanding to reflect additional perspectives.
- Dr. Stanley Huff (Intermountain Healthcare) commented that LOINC is nondenominational and intends to make codes accurately to support both medical and non-medical users. LOINC is a common language, and FHIR is a utility that can support many diverse stakeholders.
- Dr. Spiro explained that NCCARE360 in North Carolina is a new platform allowing social agencies, nonprofit organizations, and health care systems to communicate with one another. NCCARE360 will share patient outcomes and SDOH data.

PANEL 4: Care Plans in Action

Moderator: Steve Bernstein, AHRQ

HL7 FHIR Care Plan Connect-a-thons

Dave Carlson, Ph.D., M.B.A., Clinical Cloud Solutions, LLC

Dr. Dave Carlson, who has 12 years of experience in HL7 standards development, discussed his work with HL7 FHIR Connect-a-thons. He stated that his goal for health care planning is to create an e-care plan that will enable patients and clinicians to record, change, access, create, and receive key patient information, goals, and preferences across settings. Dr. Carlson discussed dynamic care plans enabled by SMART on FHIR applications that could support interactive care management. The dynamic care plans are guided by care pathways, real-time access to current care plans, and the supporting clinical data. He noted the relationship between care plan and clinical practice guidelines (CPG), highlighting the new HL7 CPG on FHIR project which aims to expand use of Clinical Quality Language (CQL) for guideline rules. He also described how care plans can support care team management, enabling invitation of new care team members and notification of care plan changes or gaps in care. Dr. Carlson conveyed the importance of direct engagement among patients, clinicians, and caregivers.

The HL7 FHIR Connect-a-thon is a 2-day event providing hands-on FHIR development and testing. Dr. Carlson explained that the event supports more than 30 tracks regarding specialized subjects; care planning and management is the focus of one of these tracks. Participants work to test an implementation guide. Dr. Carlson explained that at the start of the meeting, he challenges each participant to consider,

Betsy Johnson, the MCC patient persona developed by the NKDEP CKD e-Care Plan Working Group. He outlines her medical history and current situation, asking participants to determine how to meet Betsy’s health care needs by considering her story holistically. He conveyed that the care plan is an evolving dynamic process that includes providers across the continuum of care.

Dr. Carlson presented an overview of the components of a health care plan, along with their corresponding FHIR standards. He described the Care Plan DAM, which provides an information model to consistently define elements included in a care plan and supports the need and use of static versus dynamic care plans. He stressed the importance of a patient-centered goals, contrasting patient-expressed goals (e.g., playing with a grandchild) and clinical goals with target date and value (e.g., weight less than 140 pounds by November 30, 2019). He explained that FHIR observations enable the capture and exchange of laboratory and vital sign data, including vital signs taken at home. FHIR questionnaires—which can be assigned to a patient as needed—enable capture of patient-reported outcomes, including social risk factors, and those responses can be captured as FHIR observations. He demonstrated implementation of the LOINC “Challenges for treatment plan maintenance” and “CKD management personal goals” panels, developed by the NKDEP CKD e-Care Plan Working Group, into the FHIR questionnaire format in the iPhone operating system (iOS).

Dr. Carlson discussed the concept of a standards-based integration platform that spans multiple providers. This model, he explained, would allow applications to maintain an integrative view of multiple care plans that have been reconciled. He highlighted four opportunities in care plan development: (1) Empower patients with smartphone applications that provide patients with their data, engaging them in the care process and allowing them to share their voice with the rest of the health care team. (2) Identify gaps in guidelines-based care. (3) Leverage HL7 FHIR standards using APIs for real-time data access, despite lagging support from EHR vendors. (4) Employ FHIR Clinical Reasoning using clinical decision support (CDS) standards, such as CDS Hooks.

Primary Care Plan

Shelly Spiro, Pharm.D., Pharmacy HIT Collaborative

Dr. Spiro provided an overview of the Pharmacy HIT Collaborative and stated that the organization’s goal is to improve standards-based interoperability, health IT workflow integration and usability, and quality measurement for pharmacists. She explained the Joint Commission of Pharmacy Practitioners’ Pharmacists’ Patient Care Process provides her organization with a model of a standardized patient-centered collaborative care process for pharmacists providing medication therapy management (MTM) services. The model has been a framework for the organization’s efforts to work with vendors to standardize documentation of medication-related information. These efforts have helped pharmacists move into the care planning process. Dr. Spiro provided an overview of the National Council for Prescription Drug Programs-HL7 harmonization, which began in 2015. She highlighted a recently balloted joint e-care plan project that will be released by the end of fall 2019.

Through the pharmacists’ e-care plan, pharmacists can provide comprehensive medical reviews of patients. Dr. Spiro explained that this procedure is consistent with chronic care management, which pharmacists are trained to perform. She spoke on the need to document clinical terms, highlighting the importance of codified information and recent efforts by Pharmacy HIT Collaborative to create coded sets of information, which currently are held in the NLM Value Set Authority Center.

In 2016, Dr. Spiro helped launch a pilot study in partnership with Community Care of North Carolina and its pharmacy to implement the use of e-care plans. She highlighted the success of this study, noting at least 26 vendors currently use the care plan for value-based payment models. The National Community Pharmacists Association is now working to apply the pilot model across the United States. They have

documented approximately 21,000 care plans that were created under this system. Dr. Spiro also described efforts to connect plans with ambulatory EHRs, which she said is challenging. She stated the need for other disciplines to begin using care planning. She concluded by reiterating the congruence between health care plans and pharmacy; pharmacists desire to share and receive health care information. Because the pilot study was successful, she believes the system will be implemented extensively.

Nursing Care Plans

Laura Langford, Ph.D., M.S.N., B.S.N., Healthcare Services Platform Consortium

Dr. Laura Langford discussed health care plans from a nursing perspective. She explained that the nursing community drove the initial development of care plans, and the system constitutes an integral part of nursing care. Dr. Langford stated that contribution of the nursing field is reflected in the DAM; many of the authors, including herself, are nurses. Dr. Langford outlined the key features of care planning, stating that care plans must be viewed as an interdisciplinary tool with integrative function. She noted that having multiple care plans is unhelpful to the patient for determining goals and outcomes, because different plans are likely to provide conflicting information.

Dr. Langford discussed ongoing improvements to DAM, which include updates to clarify issues and missing topics. She stressed the importance of discussing definitions, recognizing key building blocks, and addressing key aspects of the health care plan. Topics requiring deeper exploration include protocols, advanced directive, and coordination. She acknowledged other care plan standards briefly, including the consolidated clinical document architecture (C-CDA) and FHIR, and described the Integrating the Healthcare Enterprise (IHE) Dynamic Care Plan, which provides the structures and transactions for care planning within the Patient Care Coordination Technical Framework to allow dynamic updating of the care plan as the patient interacts with the health care system, but it does not assume a single care plan for each patient. Dr. Langford discussed how the system could report consequences for patients if goals are not met.

Dr. Langford described the role of the American Nurses Association in care plan development, which has slowed because of changes in leadership. She spoke also on Nursing Knowledge Big Data, which she stated is an incredible resource for identifying essential care coordination data elements and for transitioning across settings. These efforts, she affirmed, contribute to the nursing voice of the HL7 work.

Discussion

- Dr. Middleton expressed concern about the development of a dashboard of multiple care plans that primary care doctors would not know how to integrate well. He asked panelists how the field would arrive at a common knowledge construct. Dr. Spiro replied that integration depends on workflow and usability, emphasizing the role for clinicians to become involved in the process. Dr. Carlson affirmed that reconciliation of care plans is a top priority, stating the need for an integration platform to facilitate this concern across multiple provider systems.
- In response to a question from Dr. Bierman, Dr. Spiro affirmed the expertise of pharmacists in gathering health information from patients. She emphasized also the importance of open conversations between patients and providers. In response to an attendee's comment that providers often are unable to determine which medications their patients actually are taking; Dr. Spiro reiterated the importance of a model to share the valuable information acquired by pharmacists.

Charge to Breakout Groups

Saadia Miran, M.S., NIDDK

Ms. Saadia Miran charged the breakout groups to focus on identifying crosscutting data elements and issues in health care. The specified topics were SDOH, patient preferences and goals, data privacy and security, patient-reported outcomes, and identification of high-priority issues. Participants attended one of five breakout groups.

BREAKOUT DISCUSSIONS: Identification of Crosscutting Data Elements and Issues

Social Determinants of Health

Moderators: Sarah DeSilvey, APRN-C, Northwestern University

Jenna Norton, M.P.H., NIDDK

Patient Preferences and Goals

Moderators: Jennifer Wolfe, Ph.D., Johns Hopkins Bloomberg School of Medicine

Nicole Ruggiano, Ph.D., The University of Alabama

Data Privacy and Security

Moderators: Douglas Fridsma, M.D., Ph.D., FACP, FACMI, American Medical Informatics Association

Steve Bernstein, AHRQ

Patient-reported Outcomes

Moderators: Ashley Wilder Smith, Ph.D., M.P.H., National Cancer Institute

Chun-Ju (Janey) Hsiao, Ph.D., AHRQ

Identification of High-priority Issues

Moderators: David Dorr, M.D., OHSU

Arlene Bierman, M.D., AHRQ

THURSDAY, October 3, 2019

Reports from Breakout Sessions

Moderator: Arlene Bierman, M.D., AHRQ

Dr. Bierman invited the breakout group moderators to report the results of their discussions, touching on the crosscutting data elements and issues.

Breakout Group 1: Social Determinants of Health

Ms. DeSilvey reported that the group discussed challenges and barriers in capturing SDOH in the e-care plan. She noted an emerging nomenclature regarding SDOH, which affect everyone and may be positive or negative—for example, **social risks**, which contribute to poor outcomes but might not be a priority focus area for the patient, and **social needs**, which are social risks prioritized by the patient. She explained that the Gravity Project currently is working to determine SDOH data elements and standards that should be included in the EHR, which the AHRQ-NIDDK project can leverage. Ms. Norton added that the Gravity Project is open and welcomes participation from anyone interested in conversations on these issues.

The group divided challenges relating to incorporating SDOH in e-care plans into three categories: ethical, practical, and data/privacy. Ethical challenges include the potential for increasing demand for support from community-based organizations (CBOs) when sufficient resources might not exist to meet this demand; sharing of sensitive data that may put people at risk of punitive action, particularly for the criminal justice-involved population; and the potential that clinicians might be biased by SDOH information. In addition, an ongoing debate in the field questions whether it is appropriate to collect SDOH data if the underlying social risk cannot be addressed; however, Ms. DeSilvey suggested that just because you cannot “fix” the social risk/need does not mean that you cannot provide care relevant to that risk/need. Ms. DeSilvey noted that value-based care, resource shifting, policy changes and advocacy, social work, and compassion-based care may help address some of these ethical challenges.

Practical challenges include the frequent lack of access to care or technology among the highest-need populations, the dynamic nature of SDOH and that maintenance of up-to-date information will be important, and the need to distinguish risks from needs and incorporate patient preferences regarding their SDOH data. In addition, support of bidirectional communication between the traditional health care system and CBOs will be important, both to “close the loop” on referrals to CBOs and because SDOH information gathered by CBOs could be useful in care. Proposed solutions include the involvement of CBOs in this and other projects, inclusion of a referral tracking system, provider- and patient-ranked problems lists, and improved data visualization. The primary privacy challenge centers on the issue that many people are uncomfortable with having social risk listed among their problems and then shared publicly. A proposed solution for data/privacy challenges includes a platform in which data are accessible for analysis and interpretation but restricted as appropriate.

Breakout Group 2: Patient Preferences and Goals

Dr. Ruggiano reported that the group’s discussion centered on three themes: the dynamics of preferences and goals based on context; the ways in which goals and preferences are linked to outcomes; and interventions that support goals, preferences, and quality of life. The group discussed the definition and measurement of preferences and goals in daily life, noting that these definitions are critical to the identified themes. Interventions in particular cannot be performed effectively without the guidance of clear definitions. Dr. Ruggiano stated that the field cannot reach a paradigm shift if it relies on a health care system that considers interventions to be something performed on patients rather than with patients. She stressed the importance of maintaining an open dialogue to explore issues of preferences, goals, and quality of life. Other topics of discussion included reconciliation of data, the role of new technologies, and reducing burden for patients.

Breakout Group 3: Data Privacy and Security

Mr. Steve Bernstein reported that the group discussed issues related to data privacy, which constitute a shared responsibility between the patient and the organization. Ultimately, decisions regarding data sharing are made by the patient. Some patients, notably members of American Indian/Alaska Native tribes, prefer that their data be kept fully private. The group discussed the need for coding of patient preferences, noting that the preferences should migrate with the data but may change over time. They discussed also the issue of compromised security, data misuse and data violation, noting that some patients may not understand fully the risks of sharing their data. The group raised concerns about data standardization, explaining that some organizations may be unequipped to deal with this issue fully. New legislation will be critical to address data privacy fully. Mr. Bernstein concluded by stating that although major issues exist in the current framework for patient privacy, the issues should be resolvable with proper attention.

Discussion

- Dr. Bierman asked whether the group discussed data sharing for research. Mr. Bernstein stated that the existing framework, the Common Rule, is insufficient for handling all the data in an expanded and integrated care plan. Ms. Norton added that the NIH *All of Us* Research Program may provide a model for the movement of data from clinical to research settings.

Breakout Group 4: Patient-reported Outcomes

Dr. Ashley Wilder Smith reported that the group discussed the role of patients in capturing and sharing patient-reported outcomes data. She explained that data relevance is dependent on both the patient and context. She emphasized that patient-reported outcomes represent a perspective on health states, a notion that she said was implicit in the group's discussion. Identified challenges included time constraints and workflow design. Participants discussed the possibility of data capture prior to visits. Important components of remote collection included time frame, location, interoperability, centralization, and standardization. They discussed adherence and compliance issues related to remote collection, including usability and access for patients. Integration of data is also critical to communication between the provider and patient. Dr. Smith conveyed also the role of computer adaptive testing in generating questionnaires that are both standardized and tailored to the patient's needs.

Discussion

- Ms. Norton noted that the terms “adherence” and “compliance” place blame on the patient. Dr. Smith agreed that this terminology should not be used in discussions with patients. She suggested the field work to identify ways in which barriers to patient participation might be reduced.
- Dr. Bierman commented that she was struck by the connection between patient goals/outcomes and the generation of actionable data that can be used to help patients achieve those goals.
- A participant raised the issue of identification in remote reporting, noting that patients often are assisted by caregivers.
- Dr. Dykes commented on data visualization, stating the importance of reporting data that is meaningful to patients and their families.

Breakout Group 5: Identification of High-priority Issues

Dr. Dorr reported that the group first asked which purpose of care planning was being discussed, because the context can vary dramatically. They discussed how care planning varies for different patients. Interoperability, existing historical data, granularity, understandability, grouping language, and inaccuracies were identified as potential issues. Dr. Dorr stressed the importance of reconciliation between data sources, independent validation, and integration.

Dr. Bierman added that participants discussed the purposes of care planning, noting that patients can be overwhelmed by multiple plans. She explained that multiple people will use the same plan for different purposes; thus, flexibility in data visualization is important. She stressed the importance of a user-centered design.

Discussion

- Ms. Norton stated that the care plan should be considered a dynamic data set tailored to the user's needs, rather than a static document. A participant suggested that excessive tailoring may prevent providers from considering the larger picture, thereby working against the goal of coordinating care. Ms. Norton agreed that the visualization should reflect a balance between broad and specialized information.
- Dr. Dorr stated his concern that the scope of the proposed project is too broad. He suggested that the use of existing health records would be more effective. Ms. Norton agreed and explained that the intention of the project is to leverage data already in the EHR using standards for interoperability and data mobility.
- Dr. Christine Everett (Duke University) asked how the system would handle the issue of timeliness, because a patient's condition can change quickly. Ms. Norton agreed that time presents a major challenge but noted that many people are considering how to best address the issue. Ms. DeSilvey added that sharing data across multiple sources results in more efficient processing.
- Ms. Lindsey Hoggle (IRIS Health Solutions) stated the need, in an age of information overload, for the team to "start small" and "think big." Although the dynamics of health care are changing, patients and providers may be overwhelmed with rapid changes. Dr. Bierman agreed and proposed the inclusion of an executive summary to accompany data in the health care plan.

Charge to the TEPs

Jenna Norton, M.P.H., NIDDK

Ms. Norton explained that participants were each assigned to a disease-based TEP prior to the meeting. She charged the TEPs to consider, from the perspective of each of the assigned conditions (type 2 diabetes, cardiovascular diseases, and pain and opioid use), specific challenges related to data collection and reporting. TEP members also were asked to identify important data elements for the assigned condition.

TEP BREAKOUT DISCUSSIONS: Condition-specific

Type 2 Diabetes

Moderators: John Piette, Ph.D., University of Michigan

Christine Everett, Ph.D., M.P.H., PA-C, Duke University

Cardiovascular Diseases

Moderators: George (Holt) Oliver, M.D., Parkland Center for Clinical Innovation

Melissa Wei, M.D., M.P.H., University of Michigan

Pain and Opioid Use

Moderators: David Thomas, Ph.D., Office of Research on Women's Health

Mary Lynn McPherson, M.D., M.P.H., University of Maryland School of Pharmacy

Reports from Breakout Sessions

Moderator: Jenna Norton, M.P.H., NIDDK

Ms. Norton invited the TEP breakout group moderators to report the results of their discussions, touching on specific challenges related to data collection and reporting.

Breakout Group 1: Type 2 Diabetes

Dr. Everett reported that the group discussed the importance of having data on start dates and diagnosis dates for diabetes and related conditions. She also stated the importance of oral health data. More broadly, she suggested the inclusion of patient capacity to self-manage and measures of patient activation (e.g., self-advocacy, social network, food insecurity). She stressed the importance of a feedback loop in which information could be shared among community service providers. The group also identified larger barriers to development. She conveyed the importance of data transport from the system, the capacity to use algorithms, and the ability to incorporate other pieces of information provided by the patient (e.g., complications from prior treatments, glucose monitoring, personal attitudes and beliefs) to inform strategies for treatment. Finally, the group highlighted the need to capture patient instructions and stories.

Breakout Group 2: Cardiovascular Diseases

Dr. George Oliver reported that the group made efforts to categorize data into different groups, noting that the care plan is context- and user-dependent. The group raised questions about how the data would be curated and how users would incorporate additional input. Using the sample care plan as a model, the group placed the plan in the context of existing drivers for action. Dr. Oliver acknowledged the roles of decision support and patient interaction to augment the physician's data, but identified physician effort as a potential barrier.

Dr. Melissa Wei conveyed that the group identified relevant components (e.g., lifestyle, goals, care planning), as well as those specific to cardiovascular disease. Potential challenges include the sharing of sensitive data, as well as data synthesis and efficiency. Dr. Wei identified the possible role of a technology company in the system, but acknowledged concerns about interoperability. She emphasized the need for open-source data with a common underlying framework and standards for consistency.

Breakout Group 3: Pain and Opioid Use

Dr. David Thomas reported discussions by the group about the balance between opioid access and pain control, noting that risks of opioid use must be balanced against the need for pain control. For patients with certain conditions (e.g., kidney disease), non-steroidal anti-inflammatory drugs are contraindicated, limiting pain control options. Cannabis and complementary medicine (e.g., acupuncture or cognitive behavioral therapy) were discussed as alternatives for pain management. The group discussed that the care plan cannot track pain and pain treatment alone, but should also assess the many factors that accompany pain and affect the ability to cope, including biopsychosocial factors, gene-drug interactions, adverse childhood experiences, functional status, cognitive status, medication side effects, triggering events, and resilience. The Collaborative Health Outcomes Information Registry (commonly called CHOIR) health care learning system developed by Stanford University informaticists was discussed as a potential model for data elements. Providing patients with context about the benefits of collecting these data will be important, as well as demonstrating respect toward the patient in capturing this information.

The group acknowledged that many existing measures of pain are subjective, but objective measures are being researched and may be included in the future.

The group also discussed the role of smartphones in measuring pain, both objectively and subjectively. Dr. Thomas stated the need for communication between patients and providers, noting that patient priorities may be a way to narrow clinician focus in the busy clinical workflow. The work of the Camden Coalition of Healthcare Providers (Camden, New Jersey) in identifying patient priorities was highlighted. Ms. Norton noted that issues of care coordination could be addressed within the care plan. Dr. Thomas emphasized that information from the health care system feeds back to research that can inform treatment, leading to better-informed care. Other topics of discussion included the stigma around pain and addiction, racial and gender discrimination, and issues surrounding the costs of treatment.

Discussion

- Ms. Voinche emphasized the importance of encouraging patient involvement by providing the tools to help patients understand their condition and be proactive in their health care, and Ms. McDaniel commented that patients must serve as their own advocates.
- Participants discussed clinician time and cost regarding a care plan. The need for clinicians to track their time and allocation for developing care plans will be critical. Patient consent to billing poses a greater barrier to development of health care plans. A team-based approach will be important to ensure that the payment model is meaningful to small practices.

Synthesis—How We Move Forward

Arlene Bierman, M.D., AHRQ

Jenna Norton, M.P.H., NIDDK

Ms. Norton and Dr. Bierman thanked the presenters and participants for their hard work and excellent thinking. They affirmed that they would be considering the feedback and discussion generated at this meeting as they move the AHRQ-NIDDK e-Care Plan Project forward. They reminded participants that the data elements and standards identified by this group will feed into an e-care plan application that will be tested in a health care system through this project.

Discussion

- When asked about the app's development cycle, Dr. Bierman replied that the team has established a structure supporting communication between users and developers. Test results will be provided to developers to incorporate in the final model.
- In response to a question about representation among app users in prototype testing, Dr. Bierman stated that they are testing across multiple practices. She clarified the importance of testing in health systems and practices that have data system capacity. A follow-up study would allow testing in more diverse settings and communities.

Adjournment

Ms. Norton and Dr. Bierman thanked the participants for their ideas and input for the e-Care Plan Project. Ms. Norton adjourned the meeting.