

**MEETING SUMMARY**  
**PRESIDENT'S CANCER PANEL**  
**THE PERSONAL HEALTH DATA REVOLUTION, CONNECTED HEALTH,  
AND CANCER**

March 26, 2015  
San Francisco, California

This workshop was the second in the President's Cancer Panel's (the Panel) 2014–2015 series on connected health and cancer. The workshop brought together leaders in academia, technology, government, advocacy, and healthcare to discuss the current personal health data landscape and ways in which personal health data could be utilized for individual health management, healthcare, public health, and research. Participants were encouraged to live-tweet at [#cHealth4Cancer](#) during the workshop. This meeting summary was prepared to satisfy requirements established by the Federal Advisory Committee Act. The summary provides an overview of presentations and discussions occurring as part of the workshop and does not necessarily reflect the views of Panel members.

***President's Cancer Panel***

Barbara K. Rimer, DrPH, Chair  
Owen Witte, MD

***National Cancer Institute, National Institutes of Health***

Abby Sandler, PhD, Executive Secretary, President's Cancer Panel

***Meeting Co-Chairs***

David K. Ahern, PhD, Special Advisor, Health Communications and Informatics Research Branch,  
Division of Cancer Control and Population Sciences, National Cancer Institute  
Bradford W. Hesse, PhD, Chief, Health Communications and Informatics Research Branch, Division of  
Cancer Control and Population Sciences, National Cancer Institute

***Participants***

Christopher Boone, PhD, Executive Director, Health Data Consortium  
Janet Freeman-Daily, MS, ENG, Lung Cancer Patient, Addario Patient Advisory Board  
Stephen H. Friend, MD, PhD, President, Sage Bionetworks  
Gilles J. Frydman, Chairman, Smart Patients  
George Komatsoulis, PhD, Senior Bioinformatics Specialist, National Center for Biotechnology  
Information (NCBI)  
Blackford Middleton, MD, MPH, MSc, Professor of Biomedical Informatics and of Medicine,  
Department of Biomedical Informatics, Vanderbilt University Medical Center  
Judy Murphy, RN, FACMI, FHMSS, FAAN, Chief Nursing Officer and Director, Global Business  
Services, IBM Healthcare  
Wendy Nilsen, PhD, Program Director, Smart and Connected Health, National Science Foundation  
Kevin Patrick, MD, MS, Professor and Director, Center for Wireless and Population Health Systems, The  
Qualcomm Institute/Calit2  
Urmimala Sarkar, MD, MPH, Associate Professor, University of California, San Francisco  
Richard L. Schilsky, MD, Chief Medical Officer, American Society of Clinical Oncology

Nirav R. Shah, MD, Senior Vice President and Chief Operating Officer, Quality and Operations, Kaiser Permanente Southern California

Emily S. Van Laar, MS, Director, Oncology Medical Strategy, WebMD/Medscape

John T. Wald, MD, Medical Director for Public Affairs and Marketing, Mayo Clinic

## **WELCOME AND INTRODUCTIONS**

Dr. Rimer welcomed invited participants and other attendees to the meeting on behalf of the Panel. She introduced Panel members, provided a brief overview of the history and purpose of the Panel, and described the aims of the current series of meetings. Dr. Rimer thanked the two workshop co-chairs, Drs. David Ahern and Bradford Hesse. She also introduced workshop facilitator Robert Mittman and Panel staff members. Dr. Rimer emphasized that while the term “patients” often is used, personal health data have potential to promote health and disease prevention for all individuals, not only patients.

## **OPENING ROUNDTABLE**

The goals of the workshop were to explore the role of personal health data as a driver of change in how individuals manage their own health and how institutions deliver patient care and conduct research.

Participants introduced themselves and were asked to identify a single issue in cancer for which personal health data could make the most significant contribution. Participants discussed the potential for personal health data to empower patients and facilitate communication among stakeholders in healthcare.

Personalized health data can help generate knowledge that will allow patients to be linked to the most appropriate treatment and clinical trials. The importance of integrating different types of information from different sources was emphasized. Sources would include data ranging from genomic information to information about lifestyle and environmental factors. Data and technology can be used to accelerate knowledge to practice and improve quality of care and quality of life for patients, in part through disease prevention. These tools also have potential to reduce overall healthcare costs.

## **THE PERSONAL HEALTH DATA LANDSCAPE**

Select participants delivered short presentations to describe the current landscape of personal health data.

### **DR. KEVIN PATRICK**

#### **THE PERSONAL HEALTH DATA LANDSCAPE**

##### **Background**

Dr. Patrick is Professor of Family and Preventive Medicine at the University of California, San Diego, and Director of the Center for Wireless and Population Health Systems at the Qualcomm Institute/Calit2. He is Director of the Health Data Exploration project of the Robert Wood Johnson Foundation (RWJF). He served as Editor-in-Chief of the *American Journal of Preventive Medicine* for 20 years (1994–2013) and has served on the Secretary's Council for Health Promotion and Disease Prevention of the U.S. Department of Health and Human Services and the Armed Forces Epidemiology Board. His research, supported by the National Institutes of Health (NIH), the National Science Foundation (NSF), the Centers for Disease Control and Prevention (CDC), and RWJF, explores how to use mobile, home, and social technologies to measure and improve the health of individuals and populations.

##### **Key Points**

- There has been a dramatic increase in mobile phone and smartphone use over the past several years. The International Data Corporation forecast that more than 1 billion smartphones would be shipped in

2014. An article in *The Economist* predicted that 80 percent of adults will have supercomputers in their pockets by 2020.

- People increasingly are becoming connected to one another through their devices. Recent data indicate that 152 million people in the United States and 1.35 billion people around the world use Facebook on a daily basis. According to 2011 Cisco data, there are more connected devices than there are people in the world. It is estimated that by 2020, there will be 50 billion connected devices for a world population of 7.6 billion. Terms used to describe this connectivity include the “internet of things” and the “internet of everything.”
- An increasingly diverse and expanding ecosystem of devices, apps, and services is generating vast amounts of data, including health data. In addition, more and more patients are sharing information about their health and diseases.
- With funding from RWJF, the Center for Wireless and Population Health Systems conducted the Health Data Exploration project to learn more about opportunities and barriers to using personal health data in research. The report generated for this project, entitled [\*Personal Data for the Public Good\*](#), is now available online. The report describes the ecosystem of personal health data as having three components: (1) individuals generating the data, (2) companies capturing the data, and (3) researchers who want to use the data to gain new insights into health.
- Low-income populations often have access to connected technologies, which creates tremendous opportunity for researchers to use personal health data to address health disparities. Personal health data may also help rein in runaway healthcare costs.
- Using personal health data to improve health research and promote the public good will require new models of inquiry. There also are many ethical issues that must be considered, including privacy and informed consent. Informed consent models used for traditional research are not optimal for research using personal health data.
- The Health Data Exploration Network has been created through the Health Data Exploration project to consider issues related to personal health data. The Network—which currently comprises 75 people—brings together individuals and organizations from across the United States. Core research areas pursued by the network include the representativeness of, utility and safety of, and methods and metrics for using personal health data.
- The Health Data Exploration Network supports several Agile Research Projects. One project, entitled “When Am I At My Best?” involves using passive sensing of circadian rhythms to develop individualized models of cognitive performance. Another project involves using wearable devices to explore self-monitoring and self-experimentation among patients with multiple sclerosis. A third Agile Research Project being done in partnership with RunKeeper is exploring relationships between level and type of activity and the built environment. Arizona State University, Fitabase, Jawbone, and Google are collaborating on an Agile Research Project to explore strategies to improve acceptability and usability of just-in-time adaptive interventions using proximity sensors. Another Agile Research Project being done in partnership with FitBit is working to develop guidelines and processes that support use of wearable data in ways that satisfy user privacy preferences.

## **DR. CHRISTOPHER BOONE**

### **PERSONAL HEALTH DATA IN HEALTHCARE**

#### **Background**

Dr. Boone is Executive Director of the Health Data Consortium. He is a recognized expert in health systems, health informatics, health information technology (IT) policy, and the use of electronic clinical data to generate clinical and scientific evidence for public policy, quality improvement, and patient-

centered outcomes research efforts. He merges his knowledge of electronic clinical systems in provider settings with his knowledge of health IT policy to construct systems that generate relevant real-world evidence. Dr. Boone is a sitting member on the advisory board of the American Society of Clinical Oncology (ASCO) CancerLinQ, the Board of Directors for the National Patient Advocate Foundation and the Patient Advocate Foundation, and the Board of Directors for SHARE for Cures. In addition, he is a former sitting member on the Office of the National Coordinator for Health Information Technology's Policy Committee. Dr. Boone holds a BS in management information systems, an MS in healthcare administration, and a PhD in public affairs and health policy from The University of Texas at Dallas. His doctoral thesis focused on addressing informatics barriers to conducting observational comparative effectiveness research. In addition, he is a fellow of the American College of Healthcare Executives, a certified professional of healthcare information and management systems, and a project management professional.

## Key Points

- The Health Data Consortium is a public-private partnership focused on accelerating the availability and innovative use of health data, specifically open health data. The Consortium works at the intersection of health data innovation and public policy.
- Dr. Boone designed electronic health record (EHR) systems and also worked with the American Heart Association on clinical data registries and quality improvement initiatives.
- Approximately 71 percent of the 300 million people in the United States own smartphones.
- A recent IBM study entitled *[The Future of Connected Health Devices: Liberating the Information Seeker](#)* posits that two groups—the extremely health conscious and the chronically ill—have historically been the primary users of health devices. A large proportion of the population often is neglected by developers in this field. Strategies are needed to engage the entire population.
- Healthcare has traditionally been more paternalistic than collaborative. This needs to change. Healthcare can be democratized through liberation of health data and increased engagement of patients in shared decision making. Efforts are needed to bridge the gaps between different stakeholder groups in medicine. Appropriate incentives are needed to promote data sharing by providers and others.
- Healthcare reform is driving the need for connected health. There have been several initiatives aimed at increasing value and quality in healthcare, including the recent establishment of the Health Care Payment Learning and Action Network. There is also discussion related to value demonstration, precision medicine, healthcare delivery reform, and interoperability.
- The patient perspective must be considered in efforts to achieve open data. The Health Data Consortium created the Consumer Circle, which is focused on integrating patients' voices into discussions about health data.
- One drawback of the Apple ResearchKit is that it cannot integrate with patient medical records for purposes of validation and verification. Effective integration is key to the success of connected health.
- Effective high-level data governance models are needed.
- Data should be made available to consumers so that they can make healthier choices. Data should also be available to others, such as city planners, so that healthier and safer communities can be developed.
- Discussions related to health data should be guided by a few principles. First, multistakeholder involvement is critical. Government involvement is important because there are regulatory issues that must be addressed. Private and patient perspectives also are important. Second, “open” approaches (e.g., open source, open science, open innovation, open collaboration) must be embraced. Finally, it is important to maintain a systems perspective.

## DISCUSSION

Participants started the discussion session by providing examples of personal health data. These included electronic health records, self-tracking apps that relate to one or more cancer risk factors, a Vanderbilt app that provides patients with information about their genetic profiles, Bluetooth-connected sensors (e.g., FitBit, blood pressure sensors, blood sugar monitors), patient conversations on social media, disease-/condition-focused social media networks, information on environmental factors (e.g., how many fast-food restaurants are in the area), data generated through loyalty card use, stress-monitoring apps, individual healthcare institute apps, the Apple Health app, the Apple ResearchKit, data provided by nonprovider caregivers, smart home data, and terms used in Internet searches. Participants then discussed healthcare trends, technology trends, and digital media trends and the role of personal health data in these domains. Policy and regulatory issues related to personal health data also were discussed.

### Health Care Trends

- One trend in healthcare delivery is the shift from payment for service/volume to payment for value. Personal health data can assist in assessment of value by providing information on patient wellness and satisfaction with clinical experiences.
- Patients are increasingly seeing different types of providers in different venues. This trend makes connectivity and communication even more important than in the past. It also is important to ensure that patients are seeing the right providers at the right point in their illness. Lack of coordination among providers leads to fragmentation of care.
- Personal health data can play an important role in the shift toward precision medicine, which requires extensive data to inform personalization of treatments.
- There is increasing transparency about encounter-level prices for medical care in some areas in the United States. This type of information can inform discussions of quality and cost.
- There is a trend toward increasing integration of existing EHR systems.
- A trend toward different types of patient-provider interactions is illustrated by efforts such as Flip the Clinic. Patients are educating themselves ahead of time and coming to their appointments ready to engage with their providers and make empowered decisions. Patients also are learning more about how the healthcare system works and becoming informed consumers of healthcare services.
- Development of tools capable of compiling and interpreting patient data would allow providers to spend less time collecting information and more time communicating with patients during appointments.
- The Medicare penalty for rehospitalization of a patient within 30 days has created a strong incentive to avoid rehospitalization.
- Technological advancements have made telemedicine a feasible option for many patients. An additional incentive for telemedicine use was created in January when the Centers for Medicare & Medicaid Services (CMS) expanded reimbursement for telemedicine and telehealth services beyond rural settings. Telemedicine use is growing exponentially within the Kaiser system.
- Clinical trials often focus on traditional clinical outcomes (e.g., overall survival, progression-free survival). Many factors important to patients are not considered in clinical trials. Most existing quality-of-life instruments do not capture information in clinically useful and/or meaningful ways. This makes it difficult to determine the value of new therapies from the patient perspective.
- It can be difficult to have discussions about value because the term can be defined differently by different people.

- Alexandra Drane uses the term “the unmentionables” to describe factors unrelated to health care—such as relationships, sex life, community, and financial status—that can have a big impact on health outcomes.

## Digital Media Trends

- There has been a shift toward mobile Internet access and, more recently, toward immersive digital experiences (e.g., Apple watch). There also has been an increase in location-based personal use of digital media. For example, half of Walgreens app usage takes place within Walgreens stores.
- Videos have emerged as an important type of media, in part because of YouTube. Videos can be produced cheaply and easily. Videos related to virtually any topic are available to everyone.
- Digital media allow patients to learn from and communicate with each other and doctors, which helps them make decisions about their treatment. For example, doctors sometimes post videos about how they are treating certain types of patients, such as patients with specific acquired mutations. Patients can use this information to start discussions with their own providers. Patients also can help each other find clinical trials, which is often easier than navigating the clinicaltrials.gov website.
- Disease-focused chat rooms have helped bring patients together, particularly those with rare conditions.
- Healthcare stakeholders—including patients, caregivers, providers, and institutions—participate in Twitter chats on various topics. There was a Twitter chat about the current Panel workshop.
- Social media and health-monitoring platforms are being increasingly integrated. For example, MyFitnessPal communicates with Facebook.
- Digital media tools directed at providers are changing the way providers think about evidence. The HealthTap app allows doctors to give opinions about the efficacy of a drug for a particular condition. If a certain number of doctors indicate they think a drug is efficacious, this is viewed as evidence.
- Massive open online courses (MOOCs) are making knowledge freely available to large audiences, redefining the notion of who is in control of learning. The level of disruption created by MOOCs is on par with what was created by the invention of the printing press.
- Sentiment analysis of digital media (e.g., analysis of user comments) can be a public health tool for early detection of health problems.
- One downside of the widespread availability of information is that patients may acquire information that is confusing, irrelevant, or of low quality. They may ask providers to help them sift through this information during already time-constrained appointments. However, one participant pointed out that there are more reliable sources available now than in the past (e.g., ASCO, Mayo Clinic websites).
- When the Internet first became widely accessible, there were concerns that patients would look for information on the Internet instead of talking to their doctors, which was referred to as disintermediation. This did not happen on a large scale. Now people refer to “apomediation,” which means that both patients and providers are surrounded by large amounts of data and must make sense of it together.
- One important trend in digital media is the growth of companies like Buzzfeed that rapidly collect and select content for users.
- Gaming represents a way to reach and educate people about disease- and health-related issues, including cancer.

## **Technology Trends**

- Ubiquitous computing—including access through smartphones and smart watches—is an important technology trend.
- Extensive computing power is needed to analyze the large data sets being generated and integrate multiple large data sets. However, there are concerns that predicted limits to computing power will be reached within the next five to seven years (i.e., computing power will not continue to increase at rates that have occurred over the past several decades).
- A strong pipeline of data scientists with STEM expertise (science, technology, engineering, and math) is needed to handle the large volume of data being produced.
- The availability of personal genomic data is changing the way people are thinking about disease and disease risk.
- Point-of-care diagnostics that can be used in patients' homes or other convenient locations are being developed. XPRIZE recently sponsored two competitions for consumer-focused diagnostics.
- Consumers want access to the data being collected by their devices. Some consumers hack their own devices to access these data.
- Many sensor developers are working with designers so that their products are useable and attractive.
- Nanotechnologies and other implantable devices can be used to monitor physiological processes.
- Artificially intelligent computer systems, similar to IBM's Watson, could be used to achieve evidence-based medicine and match patients with appropriate clinical trials.
- Other technological advancements include the ability to identify circulating tumor cells for cancer detection and/or monitoring of response to treatment and increased understanding of the microbiome.

## **Policy and Regulatory Issues**

- There must be transparency surrounding who is using data and for what purpose. Patients should own and control their own data, as well as their biospecimens. Other issues that must be addressed are data standards, interoperability, terms of use, informed consent, privacy, information security policies and practices, and open data systems.
- Three waves of Meaningful Use criteria have been developed, but it is unclear whether these standards will be implemented or enforced.
- Regulation of and reimbursement for molecular and genomic testing for cancer and cancer risk should be considered.
- Broader collection of health data will facilitate postmarket evaluation of drugs and devices. This has potential to transform the regulatory landscape.
- Cross-state licensing of providers must be addressed in order for telemedicine and telehealth to be widely adopted.

## **PERSONAL HEALTH DATA FOR INDIVIDUALS AND PATIENTS: DESIRED FUTURE STATE FOR INDIVIDUAL HEALTH MANAGEMENT**

Select participants delivered short presentations to describe the desired future state of personal health data for individual health management.

## **DR. JOHN WALD**

### **PERSONAL HEALTH DATA FOR INDIVIDUAL HEALTH MANAGEMENT: TECHNOLOGY, DATA, AND CARE PERSPECTIVES**

#### **Background**

Dr. Wald is a member of the Department of Radiology at Mayo Clinic, Rochester, with subspecialty training in neuroradiology. He has filled numerous leadership positions within the organization, including leading Mayo Clinic's Manage to Reimbursement initiatives, and was the physician lead during development and implementation of Mayo Clinic's Knowledge Content Management System. He currently serves as Mayo Clinic's Medical Director for Marketing and Public Affairs.

#### **Key Points**

- The role of personal health data in individual health management should be considered from the technology perspective, the data perspective, and the care perspective.
- Technology is constantly changing. New technologies emerge and replace older technologies. Apps that are popular today may not exist in a few years. Because it is difficult to predict the future of technology, it makes sense to focus discussion on data and care.
- It is important to think about how care teams will interact with the increasing amounts of data being generated. Within intensive care units, nurses and physicians are now overwhelmed by all the data that are available. The Mayo Clinic has implemented a system called AWARE (Ambient Warning and Response Evaluation) that allows critical pieces of information to be identified and brought to the attention of providers so that the neediest patients can get attention as early as possible.
- Consumers are accumulating health data through Apple Health and other products. It is challenging to integrate these data into electronic medical records and the healthcare setting in a meaningful ways. Data are only helpful if they are actionable. Algorithms are needed to allow providers to interact with data in ways that will allow them to help patients and consumers. Strategies are needed to identify patients at risk of emergency room admission or other adverse events.
- The healthcare paradigm is changing. It is about delivering information, guidance, and, ultimately, care to both patients and consumers. Information and guidance can be embedded in activities outside of the traditional provider appointment.
- In the future, most healthcare will be delivered by registered nurses, advanced practice nurses, and teams of medical professionals. There must be communication and coordination among everyone involved in patient care.
- Although it is important to treat each patient as an individual, providers should attempt to deliver standardized care for many conditions. This will result in more standardized outcomes data and care pathways.

## **DISCUSSION**

Participants were asked to consider how personal health data could be used to improve cancer prevention and management of care for cancer patients. Potential recommendations were suggested for consideration by Panel members.

#### **Cancer Prevention**

- About 50 percent of cancers are caused by lifestyle factors such as tobacco use, human papillomavirus (HPV) infection, lack of exercise, and poor diets. It should be possible to prevent many of these cancers, but this has proven very difficult. More effective strategies are needed to

promote behavior change. Data must be made personal and actionable, and interventions must be cost-effective.

- Progress in behavioral science and behavioral medicine has yielded a large evidence base for individualized tobacco cessation programs based on personal health data. Tools based on this evidence are being developed, and some are already commercially available. These tools can be very effective if they are tailored to the user and delivered at the right time. Harnessing the potential of these interventions would reduce tobacco use and benefit the population as a whole.
- Simple text messages can help reduce smoking if they are delivered at the right time. Evidence also is accumulating that this approach will work to increase physical activity.
- Researchers are developing complex approaches for using personal health data to promote healthy behaviors. One example is the Mobile Sensor Data-to-Knowledge initiative. One tobacco cessation project funded through this initiative is using a combination of eye tracking, gesture tracking, and other sensors to understand where people might be exposed to cigarette advertisements or other people who are smoking. These types of projects bring together computer scientists, geographers, and pattern recognition scientists to develop just-in-time adaptive interventions, which also are referred to as ecological momentary interventions. Many of these interventions are designed to sense when users are at risk for a certain behavior (e.g., tobacco use, alcohol use) and intervene before the behavior takes place.
- Personal health data could carry stigma if they are not used in productive ways. For example, individuals could be stigmatized for past smoking behavior, even if they quit smoking at a young age. Not all cancers can be prevented through lifestyle change, and people should not be stigmatized if they are diagnosed with a cancer that is sometimes associated with lifestyle factors.
- Utility modeling of patient preferences should be done to determine what patients need to know to make informed decisions. Incentives for wellness and health maintenance also should be established. Some organizations are offering monetary incentives to their employees, but, in at least some cases, these incentives are too modest to substantially influence behavior.
- It would be helpful to develop a reliable personal risk assessment app for cancer. When Angelina Jolie had her breasts and ovaries removed to reduce her cancer risk, many women became overly anxious about their own risk and some underwent inappropriate procedures. A useful app would build on the awareness created by celebrities such as Angelina Jolie but also would help individuals reliably assess whether they have similar risk factors and/or should talk to their doctors.
- Consideration must be given to the types of data that are collected in healthcare settings. In many cases, providers are not collecting the information that patients want to share. Conversations between patients and providers are often very different from conversations between patients and peers and/or caregivers. Healthcare professionals should ensure that the perspectives of patients and the public are taken into account when building programs and defining data sets so that patient-reported data include information important to consumers.

## **Cancer Patients**

- Some patients are highly engaged and motivated to collect and share their personal health data with their providers. However, consideration should be given to how to help patients who are not and/or do not want to be highly engaged. One study conducted by Kaiser found that the average diabetes patient wanted to spend between 90 seconds and 3 minutes preparing for a primary care appointment.
- Many cancer patients are not ready to be engaged in their care immediately after diagnosis. However, most patients reach a transition point at which they are ready to learn more about their disease and treatment options. Ideally, the healthcare system would use personal health data to be aware of when this transition takes place and have resources available to help patients become engaged when they

are ready. This could be in the form of a social network that connects patients with others taking the same drug.

- Patients must be made aware of their rights. Many patients are accustomed to the paternalistic model of medicine and do not know that they have the right to engage and ask questions. Patients will not feel empowered unless they have access to information. Patients must be given the information they need to decide how engaged they want to be in their care.
- Cancer patients need help navigating the healthcare system, preferably from a human navigator. It is important that patients be linked to navigators that are matched to their individual needs. Patients have different personality types, as well as different cultural, social, and economic backgrounds. Patients' needs also vary depending on where they are in their treatment. The organization Navigating Cancer is working to match patients to the resources they need.
- Mental health and cognitive factors should be part of the personal health data collected for cancer patients. Ginger.io is doing work in the area of mental health tracking.
- Mayo Clinic providers have found that patient access to medical records has enhanced provider-patient interactions. There was concern that patients would have many questions about test results and that providers would have to spend a lot of time addressing these questions. However, in practice, patients often are able to get their questions answered before their visits through secure messaging with providers. Face-to-face conversations during appointments can then be more focused and productive. The secure messaging system works well for both patients and providers.
- Perspectives of diverse patients must be taken into account when designing tools and interfaces for collecting personal health data. Although the input of highly connected patients is important, it also is important to talk to patients who are not highly connected, as well as patients who are diverse with respect to racial/ethnic background, language, educational attainment, and health literacy.
- Healthcare providers are diverse with respect to their knowledge and engagement with technology. Not all healthcare providers are aware of the most up-to-date information. Motivated patients with access to information can help educate providers.
- Caregivers know things about patients that providers do not know. Some less engaged patients have highly engaged caregivers who would benefit from having access to patient health data. If given access, these caregivers could help more effectively manage patient care. Caregivers also can be a rich source of data about cancer patients, particularly late-stage cancer patients. Caregivers know how patients are reacting to treatment and what adverse events patients are experiencing. Caregiver involvement raises questions related to data ownership that must be considered.
- Caregivers need information to help effectively care for patients at home. They need to understand the side effects patients likely will experience, when they should call the doctor, and which provider they should contact for what problems.
- Data experts can help identify important information in aggregated patient data. They can help determine when individual anecdotes collectively create a signal that could be missed by providers interacting with individual patients.
- Patients should be able to decide what data they want to share and what data they want to keep private. This will become increasingly important as wearables generate continuous data.
- Physician reimbursement models must be reformed to incentivize and accommodate the types of provider-patient-caregiver interactions that have been discussed. Currently, providers are reimbursed only for office visits or administering treatments in an office setting. They are not reimbursed for time spent communicating with patients via email or collaborating with other healthcare providers or data scientists.

## Potential Recommendations

- Providers could use potential clinical trial participation as a starting point for discussions with patients about patient needs and the best ways to use patient data even outside the context of a clinical trial.
- Tools based on personal health data should be designed with a user-centric approach.
- A large cohort study focused on a cancer-related issue should be conducted. Participants would be those willing to share a variety of personal health data (e.g., collected by wearables, social media conversations, genomic data). Many of these data could be passively collected. The resulting large data set could provide insight into what factors influence various disease-related outcomes. This would help consumers understand that collective sharing of health-related data can help them and others.
- Navigators and/or navigation tools should be developed to help link patients to appropriate clinical trials and other resources. Navigation services should be tailored to individual patient characteristics and needs. Algorithms should be developed to identify patient needs. Past studies of patient navigation should be considered as these services are developed.
- An education campaign should be conducted to increase consumer awareness of connected health resources and tools.
- Incentives should be created to promote provider adoption of technologies and other tools that can utilize personal health data.
- Healthcare providers should be educated about the tools and technologies being used by patients.

## PERSONAL HEALTH DATA FOR CANCER DETECTION AND CARE: DESIRED FUTURE STATE FOR HEALTHCARE

Select participants delivered short presentations to describe the desired future state of personal health data for cancer detection and care.

### DR. STEPHEN H. FRIEND

#### PERSONAL HEALTH DATA FOR CANCER DETECTION AND CARE: HOW TO EXIT THE AGE OF “MEDICAL ALCHEMY”

##### Background

Dr. Friend was on the faculty at Harvard Medical School from 1987–1995, Massachusetts General Hospital from 1990–1995, and University of Washington before becoming a full member at the Fred Hutchinson Cancer Research Center in 1995. He and Dr. Leland Hartwell founded and co-led the Seattle Project, an institute linking genetics and drug discovery that developed a method for examining large patterns of genes and provided detailed functional snapshots linking yeast and man. This allowed researchers to intuit cellular activity directly from data versus using hypothesis-driven, narrative approaches to biology. By 1997, the Seattle Project evolved into Rosetta Inpharmatics, where Dr. Friend was Chief Executive Officer and President. Rosetta developed cutting-edge tools to generate and analyze high-dimensional functional genomics data, matching genetic variation and function to drug response. Merck & Company acquired Rosetta in 2001 and integrated its approach across the global pharmaceutical enterprise with Dr. Friend as Senior Vice President and Franchise Head for Oncology Research. In 2009, Dr. Friend and Dr. Eric Schadt co-founded Sage Bionetworks, a nonprofit organization with a goal of creating a global integrative bionetwork community where researchers and the public are rewarded for collaborating and sharing their data, knowledge, and insights. Dr. Friend is actively engaging the

community to crowd-source solutions to complex biomedical questions through targeted open DREAM analysis challenges and working on projects such as The Resilience Project.

## Key Points

- It is important to appreciate the complexity of biological systems and diseases. Most people learned about, and are comfortable thinking about, linear signaling pathways, but most of these pathways are very complex, with numerous interrelated factors. Other examples of complexity include heterogeneity among different patients' genomic variants and the various pressures of the microenvironment on tumor cell growth and evolution. In many ways, modern medicine operates in the realm of medical alchemy because there is not a clear understanding of the complex rules that regulate biological processes and disease states, including cancer. As a result, it is important to appreciate the wobbly nature of data when it comes to a specific person. Until there is a more complete understanding of the rules that govern biology and disease, it is not possible to truly do precision medicine.
- There is discontinuity between the state of technology and the way institutions are established. Traditional ways of collecting information are not compatible with new technologies.
- Sage Bionetworks focuses on a world in which biomedical research is about to fundamentally shift toward an open, collaborative model that includes teams of teams. These teams will include expertise beyond the current guilds of experts and contribute to making better, faster, and more relevant discoveries.
- Synapse is a tool that facilitates transparency in data management and analysis. It allows researchers to see who has done what with the data. Traditionally, biomedical researchers have not been fully transparent with their methods. A group of researchers used Synapse to facilitate large-scale collaborative analysis of TCGA (The Cancer Genome Atlas) data. The effort resulted in 18 Nature Publishing Group publications within nine months.
- The researcher who collects data may not be the best or only person who should analyze the data. Sage Bionetworks hosts large genetic clinical data sets and allows open access to various collaborators in over 30 countries. The data sets include comparative arm data from industry clinical trials. One recently launched project focuses on prostate cancer.
- The public must be engaged as partners in research. Currently, more genotypic data than phenotypic data have been amassed for cancer. The public can help address this asymmetry. Investigators must acknowledge that patients are equal experts and engage them in research accordingly.
- Regulators and clinicians use composite scores to make decisions. However, in order to understand disease, it is often necessary to unpack the various dimensions that contribute to diseases and patient outcomes.
- The Parkinson's Voice Initiative is using voice information collected through anonymous phone calls to generate a screen for Parkinson's disease. The resulting tool is able to use voice characteristics to determine with 97 percent specificity and 95 percent accuracy whether an individual has Parkinson's.
- The BRIDGE initiative, which is funded by RWJF, is collecting data from large cohorts of patients in an effort to turn anecdotes into signals and find windows for intervention. BRIDGE uses validated anchors in combination with structured tasks and passively collected data.
- Apple has introduced a mobile platform for biomedical research. One smartphone-based project is allowing women to explore what makes their post-breast cancer therapy symptoms better or worse. By including large numbers of participants, this type of approach can turn anecdotes into signals.
- Synapse gives research participants a choice about how broadly they want to share their data. Two-thirds to three-quarters of participants elect to make their data openly available. This suggests that privacy is not a major concern for many research participants.

- Patient advocacy organizations can help engage patients in research. A Parkinson's advocacy group helped recruit a significant number of patients to the Parkinson's Voice Initiative.
- Researchers, including investigators from pharmaceutical companies, are interested in using apps to engage participants and conduct research. Apps and open data could fundamentally change the way research is conducted.

## DR. BLACKFORD MIDDLETON

### PERSONAL HEALTH DATA FOR CANCER DETECTION AND CARE: DESIRED FUTURE STATE FOR HEALTHCARE

#### Background

Dr. Middleton is Assistant Vice Chancellor for Health Affairs and Professor of Biomedical Informatics and of Medicine at Vanderbilt University and adjunct faculty at the Technische Universität München, Graduate School of Information Science in Health, Munich, Germany, and the Clinical Excellence Research Center at Stanford University. He provides oversight and guidance for the informatics and information technology infrastructure to support the Vanderbilt University Health System, related education, and research activities, and conducts clinical informatics research. He has over 400 publications and invited national and international presentations on electronic and personal health records, clinical decision support, and related policy and technical issues. Dr. Middleton is a member of the Board of Directors of the American Medical Informatics Association and is Chairman for 2014–2015. He serves on the National Advisory Committee of the Robert Wood Johnson Foundation Aligning Forces for Quality program and on several editorial boards. He was a co-founder of the Institute for Decision Systems Research in Palo Alto, CA and the Center for Information Technology Leadership at Partners, and led the Center's research in value-based technology assessment until 2010. Dr. Middleton was recognized by *Modern Physician* as one of the top 50 most powerful U.S. physician executives in 2005 and by *Modern Healthcare* as one of the top 300 influential people in healthcare in 2008 and the top 25 clinical informaticists in 2010. He is a fellow of the American College of Physicians, the American College of Medical Informatics, and the Healthcare Information Management & Systems Society.

#### Key Points

- The desired future state for healthcare should adhere to the five Cs: continuous, collaborative, coordinated, conscientious, and patient centered. Conscientious care refers to evidence-based medicine and data-driven care.
- The National Committee on Vital and Health Statistics generated a report on the different dimensions of data that influence healthcare and wellness. These include the healthcare provider dimension, the personal health dimension, and the population health dimension. This model could be expanded to include the environmental dimension and the behavioral dimension.
- The Patient Access to Advanced Care Technologies experiments, which were carried out in Boston and funded by the Agency for Healthcare Research and Quality (AHRQ), provided patients with tools for collecting social history, family history, and medication history, as well as a tool for diabetes co-management. Patients liked using these tools to provide data and engage with providers. The information exchange facilitated more efficient and, hopefully, more appropriate clinical encounters. Increased patient engagement led to increased provider engagement and activation. For example, providers of patients using the diabetes tool were more likely to modify patient medications.
- It takes a long time for new evidence to be translated into guidelines and clinical practice. This process is fraught with inefficiency. The Clinical Decision Support Consortium was created to improve this process through a national knowledge-sharing service. Information from the Harvard

decision support system was compiled and made available to remote institutions via the cloud. There were challenges to overcome, including those related to data governance, legal issues, and data sharing. Technical issues related to development of cloud-based web services also needed to be addressed. Once the system was built, users across the country felt like they had Harvard embedded in their EHR systems.

- Effective decision support tools must incorporate cognitive and behavioral models, identify and use relevant patient-centered data abstractions for knowledge engineering, include reference standards and architecture, and allow effective use of patient-centered cognitive services in health IT. Additional research is needed in each of these areas to develop a true learning healthcare system that has built-in feedback loops and continuous adaptive responsiveness.
- The ultimate goal is a nationwide health information network through which health information and other knowledge relevant to patients' care can be shared seamlessly among providers and other stakeholders.

## DISCUSSION

Participants were asked to consider how personal health data could be used to improve cancer control and care from the perspective of providers and the healthcare system. Potential recommendations were suggested for consideration by Panel members.

- Ideally, patients would not need to collect their records on paper or CD in order to share them with other providers.
- User-centered design principles often are ignored in healthcare. Health system tools and apps should have interfaces that are easy to navigate and use for both patients and providers.
- ASCO is building a rapid learning system for oncology. One of the challenges is determining when enough knowledge has accumulated to justify a change in physician behavior. For rapid learning systems to be effective, it is important that inferences, observations, and conclusions are sufficiently robust so that physician behavior is altered at the right time and in the right ways.
- Medical practice is based on evidence gained through traditional clinical trials as well as practice-based evidence, which is based on retrospective analysis of observations made during the course of practice.
- National Comprehensive Cancer Network (NCCN) guidelines for oligometastatic disease were updated recently based on input from patients who collected and distilled information from 21 journal articles.
- One benefit of having clinical guidelines publicly available is that patients are able to review the guidelines and compare them to their physicians' recommendations. This can spur discussions between patients and providers about treatment options and the risks patients are willing to undertake. In some cases, patients may want to undergo more aggressive treatment approaches than those suggested by their providers.
- As more cancer-related biomarkers are identified and used to classify cancers, an increasing number of cancers will be considered rare cancers. Online communities of patients with these rare cancers will be able to make important contributions.
- There should be a cultural shift away from the paternalistic model of medicine toward a more consumer-centric approach.
- Clinical guidelines have several limitations. Most guidelines are consensus driven. For those guidelines that are evidence based, they are usually based on clinical trials, the results of which may not be generally applicable to most patients. In addition, there are no guidelines for many decisions that must be made in medicine.

- A learning healthcare system based on real-world medical practice and patient experiences can address many of the limitations of guidelines. The Federal Aviation Agency (FAA) provides a model for how massive amounts of population-level data can be processed on a daily basis to influence decision making. Data scientists with a solid understanding of data quality and error must be involved in analysis of large population-based data sets. Many physicians and scientists do not have a strong understanding of statistics and the limitations of large data sets.
- Learning health systems need to continue to monitor and assess whether changes have led to improved outcomes. If improved outcomes are not observed, the reasons for this should be investigated.
- Unlike the FAA, healthcare systems are not closed-loop systems. Personal health data should be used to build closed-loop systems.
- Interoperability of data systems is key to achieving the desired future state of cancer care. However, vendors with proprietary systems lack incentives to work toward interoperability.
- Ideally, information could be gathered from patients during appointments without requiring providers to spend most of the appointment time looking at a computer.
- Patient preferences change over time. Learning health systems should take this into account using responsive tools and resources.
- Patients need life-sensitive records that accumulate over time to capture the changes that occur over time.
- Many patients would be willing to share their data if they knew it would be deidentified. The risk of reidentification sometimes precludes data sharing. Current approaches to informed consent also can make it difficult to share data.
- Metadata associated with data are important for providing contextual information.

### **Potential Recommendations**

- Patients should be able to access, control, and share their data. In addition, data should be accessible to providers regardless of the data source or location. Interoperability is necessary to achieve this level of accessibility, as are effective data governance models and data standards. Consideration must be given to the fact that new kinds of personal health data are being collected via new tools (not just EHRs). A public-private committee should be created to facilitate discussion of these issues and the policies and regulations needed to achieve data accessibility. The Institute of Medicine (IOM) or AHRQ could be tasked with creating a panel to establish the taxonomy and framework for patient-derived data, as well as data standards.
- EHRs are designed for documentation and billing, not for optimization of clinical care. EHR systems should be redesigned to better serve the needs of patients. EHR vendors and the government should be involved in discussions regarding how to achieve this. Meaningful Use requirements may need to be modified.
- Investigators for existing cohort studies should be encouraged to incorporate collection of additional personal health data (e.g., through wearable technologies or other sensors). This would contribute to validation of these types of data and data collection tools.

### **PUBLIC COMMENT**

- Patients should be informed about the resources available to them through cancer care and advocacy groups, such as transportation and emotional support.
- Cancer registries are enduring and rich locally based data sources, although they generally remain silos. It is interesting that registries were not mentioned during the discussion sessions.

## **PERSONAL HEALTH DATA FOR CANCER POPULATION HEALTH: DESIRED FUTURE STATE FOR PUBLIC HEALTH**

Select participants delivered short presentations on the potential of personal health data to promote population health.

### **DR. NIRAV R. SHAH**

#### **SUPPORTING POPULATION HEALTH THROUGH INTEGRATED HEALTHCARE SYSTEMS, PATIENT ENGAGEMENT, AND TRANSPARENCY**

##### **Background**

Dr. Shah is Senior Vice President and Chief Operating Officer for Clinical Operations for Kaiser Permanente's Southern California region, a \$20B health system with 14 hospitals, 168 medical offices, and over 3.7 million members. He oversees health plan and hospital quality, service, accreditation, regulatory compliance, and licensure, as well as nursing, the continuum of care, and the effective use of technology, data, and analytics to produce better patient health outcomes. He also serves as a key liaison with the Southern California Permanente Medical Group for medical education, graduate medical education, and research. Dr. Shah is board-certified in internal medicine and is a graduate of Harvard College and Yale School of Medicine. He has been a Robert Wood Johnson Clinical Scholar at the University of California, Los Angeles; an attending physician at Bellevue Hospital in Manhattan; an associate investigator at Geisinger Health in central Pennsylvania; and on the faculty of New York University Medical Center in the section of value and comparative effectiveness. Most recently, he served as Commissioner of the New York State Department of Health. Dr. Shah is an elected member of the Institute of Medicine of the National Academy of Sciences. He has served as a director for dozens of public and private institutions, as chairman of NIH grant review panels, and on the editorial boards of medical journals. He has received numerous NIH grants and published over 100 peer-reviewed articles. He is a nationally recognized thought leader in patient safety and quality, health information technology, population health, and strategies required to transition to lower-cost, patient-centered healthcare.

##### **Key Points**

- Most cancer research investigates questions at the cellular and molecular levels. However, approximately two-thirds of cancers are caused by lifestyle factors such as smoking, diet, and physical activity. To address these factors, more efforts are needed at the macro level, focused on policy, population health, and public health.
- Three important areas must be considered as public policies related to personal health data are crafted: integration, engagement, and transparency.
- Most accountable care organizations (ACOs) are teams brought together for convenience (i.e., “shotgun wedding”), but these ACOs fail because they are not fully integrated. To be effective, integration must extend beyond the surface. Teams must have the physiology of integration, not just the anatomy of integration.
- In 2004, Kaiser redesigned its systems to focus on collecting data for quality improvement instead of collecting data for reporting (e.g., Healthcare Effectiveness Data and Information Set [HEDIS]). The new information system integrated decision support, workflow, self-management support, and other features. The mantra of the effort is “standardization is innovation.”
- A [study](#) published by Stanford researchers in the January 2015 *Journal of Clinical Oncology* found that racial and ethnic disparities in colorectal cancer survival were absent within Kaiser's integrated system. Kaiser patients in Southern California underwent 300,000 prostate-specific antigen (PSA)

tests in 2014, and there was follow-up for every abnormal result. Reliably excellent care was delivered every time.

- Kaiser's integrated system facilitates generation of practice-based evidence. Kaiser found that although the average participant in a breast cancer clinical trial is 48 years old and has a 2 percent risk of febrile neutropenia, the average Kaiser breast cancer patient is 72 years old and has an 18 to 20 percent risk of febrile neutropenia. This knowledge allows providers to proactively address this potential problem.
- In a *JAMA Oncology* article, Dr. Don Berwick describes several care design principles he thinks are needed to make progress toward the triple aim of improving the experience of care, improving the health of populations, and reducing per capita costs of healthcare. One of these principles is to move knowledge, not people. Kaiser has embraced this philosophy. Among eligible Kaiser members, 69 percent are registered at kp.org. Last year, Kaiser patients sent 20 million emails to their providers. In addition, about two-thirds of prescription refills are done online. Online personal action plans have also reduced gaps in care. This system has resulted in a sixfold increase in mammogram completion, a sixfold increase in Pap smear completion, and a tenfold increase in completion of appropriate colorectal cancer screening within 90 days.
- Transparency is key to progress. Kaiser created a patient health data portal in New York that published statistics on things like inpatient infections and costs. Simply publishing data on inappropriate elective catheterizations done by cardiologists resulted in a dramatic decrease in the number of inappropriate catheterizations, from 23 percent to 8 percent.
- New York has invested \$60 million in a statewide health information network. This investment is a fraction of New York's \$125 billion healthcare delivery system budget. The network links all of the Regional Health Information Organizations. It includes all clinical and claims data. The data are Blue Button-accessible and available through a patient portal.
- Data should not provide a competitive advantage to health systems or vendors.
- Maureen Bisognano of the Institute for Healthcare Improvement says that healthcare needs to reframe its question to patients from, "What is the matter with you?" to "What matters to you?" Personal health data will allow the healthcare system to learn the answers to the latter question.

## DISCUSSION

Participants were asked to discuss how personal health data could support population health and public health. Potential recommendations were suggested for consideration by Panel members.

- Very few healthcare systems are truly integrated in the same way as Kaiser. However, integration is possible. Simply democratizing data—as was done with the statewide database in New York—helps drive progress. People in New York are building apps to allow consumers to use the data to determine where they should go for various kinds of care.
- Kaiser's integrated system is an example of a population health effort directed at Kaiser patients. While population health is important, it is equally important to consider the public health perspective, which includes consumers who are not necessarily patients within a healthcare system. Public health encompasses a variety of issues, including environmental and lifestyle factors.
- The distinction between population health and public health is becoming blurred in light of broad availability of personal health data and other types of data. One example of this is that Medicaid is funding water fluoridation in New York. Ideally, information on all of the factors that influence health would be available to clinicians.
- Information technology can traverse the divide between population and public health. CDC now integrates information from several complementary databases. This is sometimes referred to as "situational awareness" rather than surveillance.

- Many organizations recognize the value in pooling data from a variety of sources and initiatives into data commons. The Patient-Centered Outcomes Research Institute (PCORI) and the Observational Medical Outcomes Partnership are examples of organizations that are pooling data. PCORI is creating a network of networks that includes six formerly competing hospitals and healthcare systems. The network members realized that combining their data allowed them to develop a better understanding of their patients' journeys, which then allows them to address healthcare costs and quality.
- Data commons make data more accessible and findable, but there are challenges to integrating data, including absence of appropriate metadata and other issues stemming from the fact that the data come from different sources.
- Secure, scalable, and sustainable infrastructure is needed for data commons. Issues of security, privacy, user access, and controlled use must be considered. Many data aggregators may be hesitant about contributing data because they are concerned about liability. There should be discussion about who is liable for data misuse (i.e., contributing aggregators or those who maliciously use data).
- For cancer, personal health data can help improve patients' quality of life and support cost savings. They can help with treatment adherence, management of side effects, and screening for secondary malignancies. Many of these issues are particularly relevant to cancer survivors. Patients must be educated about the importance of the various components of their care, but they also must be tracked long term so that they receive care when they need it.
- Integration of environmental data with personal health data could help identify environmental causes of cancer, which could create opportunities for prevention. A recent World Health Organization report estimated that as many as 20 percent of lung cancers are due to air pollution. Many cancer registries are organized by county, which may not be granular enough for identifying cancer hot spots. Personal health data from other sources may allow analysis of smaller geographic areas.
- All data sources have strengths and weaknesses. One limitation of cancer registries is that they include only predefined data elements. Registry data also are often incomplete because of limited resources. However, registry data can be very useful. ASCO is discussing linking CancerLinQ data with Surveillance, Epidemiology, and End Results (SEER) data because they are generally from different sources. SEER data are primarily derived from hospital admissions while CancerLinQ data are primarily derived from outpatient encounters.
- Data collection and consent vary depending on the intended use of data. For example, data may be collected differently for quality improvement compared with research.
- One participant suggested that permissions move with data as part of the metadata. However, there are challenges to this, in part because of the way data are aggregated. Reasonable bounds of privacy, access, and control should be explained to individuals who contribute data.
- Metadata associated with Apple HealthKit data indicate whether contributors would like to be contacted if interesting discoveries are made using their data.
- It may be possible to create more granular informed consent that allows people to more clearly delineate how they want their data to be used (i.e., segmented opt-in and opt-out). Patient participants in the Healthcare Leader TweetChat held prior to the workshop generally indicated they would be willing to share their data if they could have control over how they would be used.
- The nature of open data makes it a practical impossibility for individuals to withdraw consent for use of their data. Once data are aggregated and shared, it becomes very difficult to disaggregate them.
- Participants discussed whether the Health Insurance Portability and Accountability Act (HIPAA) should be revisited or modernized. There have been changes in the technological landscape since HIPAA was written. In particular, methods for data reidentification have expanded. In addition, there are differences between how HIPAA is written and how it is enforced.

- Once data are deidentified, it is often difficult to track who is doing what with it.
- There are very few oncology-specific EHRs. In most health systems, oncologists use multidimensional EHRs and record nuanced information in the clinician notes field. It is a formidable challenge to map unstructured information in the notes field into structured data. Much of the information that patients and clinicians would like to be included in an oncology health record is not present in a useful format; for example, pathology reports and imaging files may be housed in separate EHR systems, and genomic data often are attached as Portable Document Format (PDF) files. In addition, any information collected through a clinical trial generally is not linked to a patient's clinical EHR.
- In addition to discussing data elements and technical issues, it is important to think about specific ways in which personal health data can help improve health at a population level.

### **Potential Recommendations**

- Further research is needed on informed consent to identify models that are aligned with patient preferences. Ethicists and qualitative researchers should be part of these discussions.
- A panel should be assembled to develop consensus-based standards for data sharing. Research networks like PCORI provide a model for this type of effort.
- Distributed cloud computing should be explored as a model for data accessibility. Application program interfaces (APIs) are another model to consider.
- Existing public policies and regulatory frameworks that have an impact on data sharing should be clarified (i.e., state of play). This is needed for all data, not only health- or cancer-related data; however, it may be possible to make progress more quickly if there is a more narrow focus on specific types of cancer-related data or issues. It may be possible to benefit from the fact that cancer patients are more willing than the average consumer to share data. Lessons learned in the cancer realm likely would be applicable in other domains.
- A more concrete vision of the desired future state should be developed. A marketing campaign also is needed to inform consumers and others about the benefits of sharing and integrating personal health data. An op-ed piece published in *JAMA* by Dr. Ken Mandl described the potential for personal health data enabled through technology, mobile devices, and mobile apps to address the Ebola crisis and other infectious diseases.
- Improved oncology EHR systems should be developed. This will facilitate data integration and yield higher quality data, which will allow for population-level and public health research. In addition, clinicians should capture more information about patients' lifestyles and other factors that provide context to patients' medical problems. For example, Moffitt Cancer Center's total cancer care protocol includes collection of comprehensive diet and lifestyle information. This type of information should be incorporated into medical records as a matter of routine.
- All health systems, even those serving disadvantaged populations, should have a certain level of technological infrastructure to facilitate system and data integration.
- Positive educational feedback loops could be used to inform individual decision making and, ultimately, improve public health.

### **PERSONAL HEALTH DATA FOR CANCER RESEARCH: DESIRED FUTURE STATE FOR RESEARCH**

Select participants delivered short presentations on the potential of personal health data to support cancer research.

## DR. RICHARD L. SCHILSKY

### CANCERLINQ: THE FUTURE OF QUALITY CANCER CARE

#### Background

Dr. Schilsky earned his MD at the University of Chicago Pritzker School of Medicine in 1975. Following a residency in internal medicine at The University of Texas Southwestern Medical Center and Parkland Memorial Hospital, he received training in medical oncology and clinical pharmacology at the National Cancer Institute (NCI) from 1977 to 1981. He then served as Assistant Professor of Medicine at the University of Missouri-Columbia School of Medicine from 1981 to 1984 when he returned to the University of Chicago. At the University of Chicago, Dr. Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991–1999), Associate Dean for Clinical Research (1999–2007), and Chief of the Section of Hematology-Oncology (2009–2012). From 1995 to 2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group. An international expert in gastrointestinal malignancies and cancer pharmacology, Dr. Schilsky has published more than 320 scientific articles, reviews, and commentaries. He has served on a number of peer review and advisory committees for NCI, including as a member and Chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and Chair of the Oncologic Drugs Advisory Committee of the Food and Drug Administration (FDA). He presently serves as a member of the Board of Directors of the Reagan-Udall Foundation for the FDA, the Board of Directors of Friends of Cancer Research, and the National Cancer Policy Forum of the Institute of Medicine. He has served as a member of the ASCO Board of Directors and the ASCO Conquer Cancer Foundation and as ASCO President in 2008–2009.

#### Key Points

- ASCO is building what it hopes will be a rapid learning system for oncology. CancerLinQ is a data informatics system designed by oncologists for oncologists to meet the need for effective, adaptable, and comprehensive quality improvement tools in cancer care. It will collect, aggregate, and analyze structured and unstructured EHR data from every oncology patient and every oncology practice in the United States that chooses to participate.
- The primary goals of CancerLinQ are to improve quality of care and outcomes for patients. Other benefits for patients include clinical trial matching, safety monitoring, real-time side effect management, and collection of patient-reported outcomes. Benefits for providers include real-time second opinions, observational and guideline-driven clinical decision support, real-time access to resources at the point of care, and quality reporting and benchmarking. CancerLinQ also has potential research applications, including mining “big data” correlations, facilitating comparative effectiveness research, generating hypotheses based on data exploration, and identifying early signals for adverse effects and effectiveness in off-label use.
- Off-label use of oncology drugs is increasing as more targeted drugs are available to practitioners and more patients are having genomic profiles created for their tumors. There currently is no mechanism for capturing information about these off-label uses.
- Clinical trial patients tend to be younger, healthier, and less diverse than most oncology patients. Only 25 percent of clinical trial patients are over 65 years of age, compared with 61 percent of real-world cancer patients. Among kidney cancer patients in a large cancer registry, 40 percent would not have been healthy enough to qualify for the clinical trials that supported approval of their treatments. Only 10 percent of clinical trial participants are non-white compared with 23 percent of the U.S. population.

- Once a drug is licensed by the FDA, the vast majority of patients receiving the drug undergo no active surveillance. Only small numbers of patients participate in postmarketing studies. This is concerning given that drugs with the new breakthrough designation can be approved based on smaller and smaller studies. The information included on FDA drug labels is based on small numbers of relatively homogeneous patients. There is great opportunity to learn more about breakthrough drugs and other drugs through increased postmarketing data collection using a resource like CancerLinQ.
- CancerLinQ could help provide data for risk stratification. For example, it could provide insight into how drugs work in older populations that have more comorbidities than younger, healthier clinical trial populations.
- CancerLinQ also could assist with cohort identification for clinical trials. For example, it could help researchers identify patients with specific molecular subtypes of cancer. It also could generate a list of trials for which a given patient may be eligible.
- Dr. Dawn Hershman from Columbia University conducted an analysis of erythropoietin use over time using SEER-Medicare data. The label for erythropoietin drugs was changed due to safety issues, which resulted in a decrease in use. A CancerLinQ prototype with deidentified data for 170,000 breast cancer patients was able to quickly generate similar data. Because CancerLinQ had more granular data than are available in Medicare claims databases, the hemoglobin levels of patients receiving erythropoietin also could be calculated. This revealed that erythropoietin was not only being prescribed less often but was being prescribed more appropriately (i.e., to patients with lower hemoglobin levels).
- It is possible to embed a randomized clinical trial into a clinical registry or data system. A group of cardiologists conducted such a trial to investigate differences between cannulating the radial artery or femoral artery. Data from an existing registry on all catheterizations were used to autopopulate case report forms for the trial, and these forms formed the analytical database for the study. Embedding a randomized clinical trial into a clinical registry requires informed consent, real-time randomization at the point of care, and clinical endpoints that are readily available in clinical data. In addition, the trial must compare standard treatments (i.e., not include an investigational treatment).
- Oncology is facing several challenges in the era of targeted therapy. There are increasing numbers of rare cancers as common cancers are subtyped based on molecular markers. There also are more drugs and drug combinations being used and more complex clinical trial designs. There are not enough patients, money, or time to learn everything that remains to be learned in oncology using traditional clinical trials. Learning from real-world clinical data will greatly facilitate cancer care and research.

## **DR. URMIMALA SARKAR**

### **USING SOCIAL MEDIA IN HEALTH RESEARCH**

#### **Background**

Dr. Sarkar is an Associate Professor of Medicine in Residence at the University of California, San Francisco, in the Division of General Internal Medicine and a primary care physician at San Francisco General Hospital's General Medicine Clinic. She is committed to enhancing health IT approaches to improve primary care and ameliorate disparities in vulnerable populations through health-literacy-sensitive, patient-centered approaches such as co-development and usability testing in partnership with technology development experts. She has conducted studies exploring the impact of health communication (health literacy, English proficiency) and health IT on patient safety. Her prior studies on Internet-based patient portals demonstrated digital disparities by race/ethnicity and health literacy. Her social media studies use mixed-methods approaches to understand cancer screening behaviors and patient perspectives on physician quality. Her ongoing work employs varied health information technologies to

detect and ameliorate adverse events among outpatient chronic disease populations. Other current work includes an effort to analyze how cancer-screening messages propagate on social media.

## **Key Points**

- Health research extends beyond traditional clinical trials. It includes research on cancer prevention, behavior change, communities, environmental exposures, food deserts, and other social conditions that contribute to the burden of disease. Research also includes using data, including personal health data, to study how health systems do or do not support optimal cancer care and prevention.
- All research, including traditional research on drugs, should be participatory. Patient-reported outcomes as well as patient-generated outcomes should be included. Patients often have valuable information to report that clinicians may not have considered.
- Digital technology has potential to lower barriers to accessing the healthcare system. Patients often are overwhelmed by having to navigate the healthcare system. Resources such as simultaneous translation, audio, video, repetition, and between-visit access to providers and information can lower barriers and increase patient engagement.
- Uneven deployment of technology could worsen health disparities. There are differences among population subgroups in adoption of technologies such as health system patient portals. Targeted enrollment strategies and training programs are needed to address these disparities.
- Consideration must be given early in drug development about how new treatments are developed and what populations should be recruited for trials. In general, clinical trial participants do not reflect real-world patients. In many cases, treatments that are successful in trials are not as successful in real-world practice.
- Many treatments proven to be effective in trials are not implemented in clinical practice for a long time. The National Institutes of Health and others are emphasizing implementation science to find ways to ensure that effective interventions are quickly and efficiently implemented. One implementation model is RE-AIM, which stands for reach, effectiveness, adoption, implementation, and maintenance. Large data registries, including those that contain personal health data, provide a tool for assessment of implementation science outcomes.
- Traditional health services research begins with the assumption that there are limited data and data are expensive to collect. Studies are generally designed to collect the minimum amount of data possible to answer the question of interest. In the digital era, there is a surplus of data, albeit of variable quality. A new host of statistical methods is needed to conduct research in this new environment.
- Institutional Review Board (IRB) reform is needed to align the role of the IRB with the types of research being done. Newer types of informed consent (e.g., open-ended consent, consents that allow recontact) often make IRBs very nervous despite the fact that most patients are comfortable with these approaches.
- Health researchers need new types of partners to use personal health data to effectively do research. These include sociologists and those with expertise in human factors engineering, natural language processing, and network science.

## **DISCUSSION**

Participants were asked to consider how personal health data could facilitate cancer research. Potential recommendations were suggested for consideration by Panel members.

- The role of traditional randomized clinical trials (RCTs) in modern biomedical research was discussed. Some participants felt that traditional clinical trials no longer have a place in research. Others emphasized that randomized trials are one of many types of tools available for research. No

one tool should be considered the gold standard. RCTs are used to answer specific types of questions. They are not needed to identify breakthroughs, but they are useful for identifying relatively small effects and minimizing the impact of bias.

- As it becomes more feasible to capture continuous, longitudinal data, there is less need for randomization, and it will take fewer patients to answer research questions than with traditional clinical trials. New research tools are needed that allow integration and analysis of all data collected for oncology patients. All oncology practice should be considered to be a huge ongoing clinical trial. Data should be collected with the goal of continual improvement. Current practice should be considered “living in beta” because there is always room for improvement. This is the goal of learning health systems.
- Different research strategies are needed depending on whether the research question relates to a new drug or new applications of an existing drug.
- Agile clinical trials, which are modified based on data as they are conducted, incorporate rapid learning. One example of an agile trial is the I-SPY 2 trial.
- As research is conducted using various mechanisms, it is important to consider the quality of the evidence accumulated and the distinction between correlation and causality.
- Personal health data can be used to support simulation-based clinical trials.
- Mechanisms and policies should be put in place to allow collection of data about treatments along the continuum of their development, from early testing through postmarket analysis. This collection of data would facilitate use of these treatments in the situations and populations in which they are most likely to be beneficial.
- Regardless of the trial design, it is critical to obtain patient input during the design, conduct, and analysis phases of the trial. Pharmaceutical companies will be more likely to engage patients in clinical trial design if the FDA encourages it.
- During the Phase II clinical trial for Gleevec, participants interacted with each other via social media and decided to change the way they took the pill. Instead of taking one pill every day, they split the pill in half and took one half in the morning and one half in the evening. They also kept track of their dosing, and when patients on a higher dose began responding, those still on a lower dose demanded their dose be increased. This is an example of how social feedback during a trial changed the trial. It also led to accelerated approval for Gleevec.
- Feedback from patient networks can improve clinical research. Patient feedback may have helped researchers realize earlier that patients would be less sick when taking crizotinib if they took the drug with food. There is no way to prevent trial participants from engaging in online discussions. Researchers should learn to benefit from these activities.
- The general public is confused about and skeptical of biomedical research. Strategies are needed to attract patients to be part of research. The scientific community should acknowledge gaps in knowledge. It also may be helpful to reframe the “learning health system” as a “knowing health system.” Patients may not be comfortable being part of a system that is still learning.
- Patients should be considered investigators and have access to research tools. PatientsLikeMe has generated interesting insights into various diseases.
- A new paradigm is needed for linking cancer patients with clinical trials. Clinicians cannot keep up with the numerous trials available. Patients can help each other find trials and decide on the appropriate sequence of trials if the disease progresses.
- The desired future state for cancer research includes the availability of several robust models of inquiry, including new methodologies and analytic approaches, and participation of the broader population.

## Potential Recommendations

- The role of patient groups in hypothesis generation and research design should be increased. FDA should promote and create mechanisms for engaging patients in the design and conduct of clinical trials.
- Advisors who are capable of researching clinical trials and finding the best fit for a given patient based on disease type (e.g., biomarkers) are needed. Current trial-matching services generally perform database searches and do not base their recommendations on a strong understanding of the patient's disease or the trials.
- The cancer community should partner with other disciplines to learn about how large data sets are being created and used.
- Incentives should be created for data sharing among academic researchers. Current tenure and promotion systems generally do not reward data sharing.
- Personal health data should be integrated into precision medicine efforts for cancer. The utility of "test bed" research strategies that track a broad set of information (e.g., social, environmental, medical) about groups of people over time should be explored. This type of approach would provide insight into various factors that influence health.
- Privacy issues associated with open-source databases must be considered. This is particularly important because future advancements may make it possible to learn new things from these data sets.

## PUBLIC COMMENT

- Office of the National Coordinator for Health Information Technology Chief Privacy Officer Lucia Savage refers to computable privacy permissions, which are constructs for privacy that are attached to data.
- Some data always will need to be private, but innovative systems should be developed to ensure that data can be shared as much as possible.

## CLOSING REMARKS

Panel members thanked participants for their contributions. They expressed hope that participants would be willing to provide additional input throughout the remainder of the series and report development process.

## CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *The Personal Health Data Revolution, Connected Health, and Cancer*, held March 26, 2015, is accurate and complete.

Certified by:

Date: June 12, 2015

---

Barbara K. Rimer, DrPH  
Chair  
President's Cancer Panel