The Office of the National Coordinator for
Health Information Technology

Accelerating Application Programming Interfaces for Scientific Discovery: Consumer Perspectives

PREPARED BY

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Introduction

Achieving a vision of increased consumer access and use of health information through software applications (apps) requires shifting the current health care ecosystem to fully leverage open and standards-based application programming interfaces (APIs). Put simply, an API is a software intermediary that allows two applications to talk to one another, by delivering a request to the data "owner," and returning the response back to the requester of the data. The Office of the National Coordinator for Health Information Technology (ONC) Cures Act Final Rule (Cures Act Final Rule),[1] released in March 2020, seeks to accelerate this shift to enable consumers to store, aggregate, use, and share electronic health information (EHI) using APIs and apps of their choice by establishing access to health information "without special effort" and the ability to exchange EHI with third-parties, including researchers. In this report, third-party refers to an app developer or user of health data (such as patients, researchers) who is not the developer of the health IT solution that serves as the originating data source, such as an electronic health record (EHR). The categories of APIs and patient-facing, provider-facing, and other third-party health apps such as those used for population health and research will hereafter be referred to as "APIs and apps."

The ONC *National Health IT Priorities for Research: A Policy and Development Agenda*[2] (Agenda) published in February 2020, highlights the need for 1) high quality data from health IT systems to enable discovery and 2) a health IT infrastructure that can provide necessary functionality for research. In particular, the Agenda prioritizes effective engagement of consumers in research through the use of health IT and expanded use of APIs. To enable goals of the Cures Act Final Rule and the Agenda, it is important to understand the needs of relevant stakeholders; in particular how consumers can benefit from increased access to, and sharing of, their electronic health information for research and other purposes. In addition, a recently published ONC-funded study identified a range of unmet needs and opportunities for APIs and apps to meet user needs.[3]

In 2016, ONC and the National Institutes of Health (NIH), announced the launch of Sync for Science,[4] a pilot project to develop a way for consumers to access their health data and share it with researchers in support of the goals of the Precision Medicine Initiative (PMI). Through its involvement in Sync for Science, ONC initiated an effort to spur innovation regarding the use of APIs and apps for consumer-directed data exchange and increased participation in research. A key component to this effort is understanding the needs of stakeholders required to participate in the API and app ecosystem, including consumers' needs. To better understand the landscape of consumer-directed data exchange in a rapidly evolving electronic health data ecosystem, discussions were conducted with nine patient representative and consumer organizations. This report summarizes common themes, findings, challenges, and barriers for consumer use of APIs and apps in support of the Cures Act Final Rule and the Agenda.

Methodology

To better understand the needs of consumers, and barriers and challenges using APIs and apps, nine unstructured discussions were conducted with patient representative and consumer organizations to provide relevant insights based upon their expertise or roles engaging consumers in advocacy, policy, products, or research. The discussions sought perspectives on consumer use and adoption of APIs and apps to access their health information, barriers to adoption, and challenges with accessing or sharing data from EHR systems. Background information regarding the project's scope and preliminary discussion topics was distributed to the patient representative and consumer organizations prior to each discussion. Nine relevant patient representative and consumer organizations were identified to provide perspectives on:

- the broader experience and use of APIs and apps by the consumers they serve;
- an understanding of the multiple uses and benefits of APIs and apps; and
- the health IT policy and implementation issues related to API and app use.

Unstructured discussions were conducted in May and June 2020. A facilitator was joined by a notetaker who documented the discussion, organized the information collected, and assisted in the identification and analysis of key themes and findings using grounded theory techniques. The patient representative and consumer organizations and their respective discussion participants are listed in Table 1.

Table 1. Participating Patient Representative and Consumer Organizations

Organization	Discussion Participant
Ciitizen	Deven McGraw, JD, MPH
e-Patient Dave	Dave deBronkhart
Evidation Health	Bray Patrick-Lake, MFS
FasterCures	Hadly Clark, MHSA
FORCE	Sue Friedman, DVM
Institute for eHealth Equity	Silas Buchanan
LeadingAge	Majd Alwan, MS, PhD
	Scott Code, MS, MBA
National Partnership for Women & Families	Sinsi Hernández-Cancio, JD
	Dani Gillespie
	Erin Mackay, MPH
National Patient Advocate Foundation	Gwen Darien

Findings

MOTIVATORS FOR ADOPTION AND USE

Define and Focus Priority Audience

Discussion participants were asked to describe characteristics of consumers likely to use and benefit from APIs and apps that access, use, or share their health data. The consensus across discussion participants was that the use of APIs and/or apps is driven by a compelling need or desire for information. Discussion participants identified three common motivators:

- A health condition or status involving a **large amount or critical type of health data** to manage the condition;
- A **rare, hereditary, terminal, or other health condition** involving data that could contribute to research on treatment and cures; or
- A **need or strong interest in using technology** to organize and apply health information to ease the burden on the consumer or the consumer's caregivers.

Discussion participants described five categories of individuals with a strong desire and need to use APIs and apps to access, use, and share their health data:

1) Patients managing **rare or terminal diseases**;
2) Patients managing **chronic or hereditary diseases**;
3) Patients and caregivers managing **age-related conditions**;
4) Parents managing **pediatric** patients; and
5) Patients and caregivers managing **behavioral and mental health conditions**.

Discussion participants consistently indicated that healthy individuals outside the categories noted above generally do not access, use, or share their health data through APIs and apps because they do not have a compelling driver. They suggested that low use of these technologies can be partially attributed to a lack of perceived need among this large, healthy segment of the population.

Discussion participants from patient representative and consumer organizations commented on the unintended consequences of the Promoting Interoperability[5] program measures and incentives. Providers and health organizations earn incentives by directing consumers to access their health information via portals or apps. Although discussion participants supported the need for standards-based access to interoperable health information, they felt that a focus on use of apps that drive defined use cases and value for the consumer would best serve the intent of the Cures Act Final Rule.

Increase Value and Utility

Health data can be complex and managing large or frequent quantities of data is time-consuming and tedious. For the five categories of consumers mentioned above, as well as healthy individuals, discussion

participants felt that APIs and apps have not widely served as meaningful tools to obtain, organize, and use health data. Although apps that use open Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard APIs allow consumers to aggregate and consolidate their health information, most consumers may have no need to do so, unless they are motivated. Healthy consumers may access their health information to initiate medication refills, message their provider, or pay their bills - functionality often available through their patient portals and health IT developer-specific apps rather than through third-party APIs and apps.

At the time the discussions were conducted, most APIs and apps that connect to EHRs did not include clinical notes, as that information is not structured or standardized and is not required under the 2015 Edition Health IT Certification Criteria. Data elements included in the Common Clinical Data Set (CCDS) include a subset of the health information that patient representative and consumer organizations reported finding useful when managing chronic conditions or for other use cases.[6, 7] Discussion participants cited clinical notes as critical missing data for consumers seeking their health information. However, discussion participants shared examples of emerging uses where APIs and apps supported value-added purposes and roles for specific consumer groups.

Remote Monitoring: Several discussion participants described the utility of health data gathered from wearables and other tracking devices to assist remote monitoring by a health care professional or caregiver. Data sent to a clinician or other care team member can be used to identify risks or trends requiring intervention. Electronic transfer greatly assists in situations where the consumer and the person or device monitoring the health data do not share the same physical location.

- A discussion participant described the value for predicting falls-risk in geriatric consumers of devices that monitor upper body sway, balance, and average walking velocity and also shared examples of devices that collected data on the number of awakenings at night, disturbances, and sleep quality for early detection of conditions such as cognitive decline.
- As researchers and clinicians gain understanding of COVID-19 symptoms and treatment, a number of other discussion participants described the critical role of devices that enable remote monitoring of oxygen saturation, blood pressure, temperature, and pulse rate. Several discussion participants commented on observations from researchers, providers, and consumers that the national public health emergency has revealed gaps in remote consumer monitoring capabilities and a need for technology solutions that enable providers to collect data from consumers.

Chronic Condition Management and Care Plan Monitoring: When discussion participants spoke about supporting consumers and caregivers as they manage care plans, they often noted the utility of APIs and apps containing key health data and instructions on achieving a desired status or improvement. For consumers with multiple providers and conditions that require monitoring of a substantial quantity of information, APIs and apps have already alleviated the challenge of managing multiple portals tethered to each provider's EHR. Such apps obtain the relevant data from each of the consumer's provider EHRs for the consumer, store it in a central location, and present it in a format that enables the consumer to view the data across providers.

- Although the everyday importance of electronic access to care plans was noted by one discussion participant, the participant was skeptical about APIs and apps having a widespread impact in the near term. The participant felt that adoption of APIs and apps by healthy consumers would be spurred only by the need to coordinate a care plan for a child, spouse, or parent.

- Progress made by the OpenNotes[8] initiative, which encourages providers to share progress notes with patients, was outlined by a discussion participant who emphasized the potential for APIs and apps that facilitate access to clinical notes. The data provided by APIs and apps may deepen a consumer's understanding of their clinician's approach to their treatment.

Social Isolation and Engagement: For some consumers using long-term and post-acute care (LTPAC) services, discussion participants saw APIs and apps serving a key role in assisting and managing data, but also addressing social isolation.

- One discussion participant noted a dramatic increase in demand for and deployment of apps and devices among LTPAC providers. These apps help address issues of social isolation and improve client health by engaging consumers in activities of daily living (ADL). This participant noted that the threshold app is one that monitors medical conditions such as blood pressure, and then other apps are added.

Research Participation: Patients with rare, hereditary, or terminal diseases are motivated to access and exchange their health information because they want to support and accelerate research exploring promising or new treatments. Discussion participants from patient representative and consumer organizations representing groups of consumers with rare and terminal conditions spoke clearly about their members' desire to share their data with researchers to accelerate treatments and experiment with new cures.

> " **There is an explosion of apps and devices that are being deployed and demanded by aging-services providers and senior living communities** that are used primarily to fill the gap on social isolation and engaging clients in activities that have implications for health. You get 'in the door' with monitoring blood pressure, and then offer shared yoga classes and social interaction and improve balance. "

- One discussion participant observed that patients with hereditary cancers and other hereditary diseases are generally more willing to share data and participate in research than patients with non-hereditary conditions. The discussion participant explained that findings from organizational surveys indicated that, for some patients, helping relatives was a motivating factor that was as strong or stronger than helping themselves.

Health Maintenance: Discussion participants frequently mentioned the low utility of APIs and apps and portals for healthy consumers who are not motivated by the drivers mentioned above. They emphasized that, absent an app that makes healthy people want to regularly access their health data, they are likely to remain a population that does not seek access to apps or drive further API and app development. Based on input from discussion participants, technologies supporting health maintenance, such as step counts,

weight monitoring, and laboratory results, could motivate this healthy population and consumers seeking to maintain a specific health status to use APIs and apps.

Although the examples provided by discussion participants provide current and potential opportunities for using APIs and apps, they agreed that the electronic ecosystem will continue to develop quickly and support new and emerging use cases. When asked what use cases could drive increased use, a number of discussion participants emphasized the importance of app development in response to the health objectives of motivated people and encouraging creative and flexible app development in response to consumer-driven objectives.

As illustrated in the COVID-19 examples below, the scale of the national public health emergency has prompted efforts to gather wearables' data from healthy consumers to contribute to better understanding of symptoms. These efforts may lead to a greater willingness and comfort-level in widespread data sharing. In addition, and, more importantly, these efforts may help drive the innovation, infrastructure, and progress needed to leverage this technology for other use cases.

COVID-19 and the Need for API-Enabled Health Data Sharing

- A Washington Post article[9] published on May 28, 2020 described patients sharing heart rate, breathing, and temperature data from wearables with researchers to understand COVID-19 symptoms. Researchers value the real-world data from wearables that can detect the baseline for an individual and identify variations that deviate from the baseline as potential indicators of illness.

- The University of California, San Francisco (UCSF) and OURA, the maker of a wearable technology called the Oura Ring, partnered to conduct a study called TemPredict[10] to determine if physiological data collected by the Oura Ring, along with responses to daily symptom surveys, can predict symptoms of COVID-19. Researchers will use this data to identify patterns that may predict future cases of COVID-19 onset, progression, and recovery.

- Fitbit, Scripps Research Translational Institute, and the Stanford Medicine Healthcare Innovation Lab launched the DETECT (Digital Engagement & Tracking for Early Control, & Treatment) Study[11] to build an algorithm to detect symptoms of COVID-19 and the flu before their onset. Researchers will utilize a participant survey and Fitbit data indicators to determine early signs of COVID-19 and flu. Fitbit states that participation is voluntary and participants may withdraw at any time.

HIGH-VALUE CHARACTERISTICS

Once a consumer is motivated to seek an app to access, use, or share health data, discussion participants reported that the interface and utility, as well as the user's overall experience with the app, may influence sustained use. Conversations with discussion participants revealed two main requisites: **(1) the apps must reduce the burden of manually accessing health data and using it for the intended purpose**, and **(2) the data must be of value**.

Discussion participants spoke clearly about the need for APIs and apps to reduce the time consumers spend obtaining their health data from multiple sources, manage their health or condition, and – if desired – share the information. Discussion participants defined four characteristics of valuable data within an app:

1) **Interoperable**
2) **Detailed**
3) **Accurate**
4) **Timely**

> " [A user will be] someone who has a busy life of their own, and **it helps if apps can just go get the data**. "

These characteristics, described in Table 2, are relevant to any use or presentation of health data for consumer consumption, such as via a patient portal.

Table 2. Defining Value for Health Data Within APIs and Apps

CHARACTERISTICS OF DATA WITHIN HIGH-VALUE APIs and APPS

Interoperable	
• Gather and combine comprehensive data from consumers, EHRs, claims, and other sources using national vocabulary standards • Contain sufficient metadata that enables different types and sources of data to be integrated, de-duplicated, and presented for different purposes across APIs and apps (rather than confined to a static format)	*"The less data that is in there, the less people will care. Here is your measly patient portal with three pieces of measly data."* *"In the future, participants can be the conduit [for all data sources] and there will be one comprehensive record."*
Detailed	
• Include rich, unstructured data from progress notes and care-plan instructions to further inform and provide context to structured data • Present data with trends over time and provide information that enables consumers to understand normal and abnormal information ranges	*"The information in your patient portal is like a 'connect-the-dots,' where you don't know what it is. Notes fill in the context and promote trust and deepen relationships with providers."*
Accurate	
• Sustain consumer trust in the organization collecting and storing the data by being consistently free from errors and omissions • Capture "real-world" data that take into account environmental conditions outside of a research lab and differentiate them from the data representing a health status or condition • Present data personalized to a consumer's "normal" or target from a baseline of data (or trends) specific to the consumer	*"In a lab, the microphone is 90% predictive of Parkinson's, but in the real world, your dog is barking. For a thermometer reading of 101 degrees, it's not the value but the trend that can matter."*
Timely	
• Collect data available at a frequency that is meaningful and actionable for the consumer's intended use (i.e., support monitoring, alerting, or display of detailed trends) • Real-time or near-real-time patient-generated health data (PGHD) or remote monitoring data may offer greater value than less frequently collected data in health care settings	*"I looked at Apple Health, and I can see my weight and blood pressure, but I have more access to blood pressure from my home health devices, as compared to the readings from my twice-a-year doctor's appointments."*

As the Cures Act Final Rule takes effect in the near-term for information blocking, and in the longer-term for consumer access to EHI, APIs built using the FHIR® standard will be capable of accessing, presenting, and exchanging data consistent with the United States Core Data for Interoperability (USCDI) standard. The first version of the USCDI standard (USCDI v1) is adopted as the standard in the Cures Act Final Rule and sets a foundation for broader sharing of EHI to support patient care and includes crucial clinical notes data requested by discussion participants.

However, one discussion participant pointed out that, according to the regulations set forth by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the information included in USCDI v1 is still a small subset of protected health information (PHI) that consumers have a right to access. Information needed by consumers with chronic or serious medical conditions, such as chemotherapy flowsheets and information typically stored within pathology systems, would not be included in the USCDI and are not formatted and standardized for capture and transmission through health IT. The discussion participant noted that until this information can be captured and exchanged in a computer consumable format, its utility for APIs and apps will remain limited.

CONSUMER AWARENESS AND TRUST

Discussion participants consistently described low levels of consumer awareness that APIs and apps exist and are useful for accessing, using, and sharing their data. This finding applied to consumers who rely on health data to effectively manage conditions and those with rare conditions seeking to share information for research, clinical trials or treatment purposes. One discussion participant observed that unless providers disseminate information about appropriate apps and registries, desperate consumers rely on the broader information available on the internet and may share inaccurate information with others in similar situations.

Some discussion participants reported a small, but growing interest in APIs and apps and the use of this technology, based on conversations with the LTPAC service providers they support. They mentioned that there was little interest and utilization of the portal capabilities offered by health IT developers, but identified consumer outliers among a small subset of consumers and provider organizations that are interested in and actively using health IT and APIs and apps to access, use, and share their health data.

Although awareness of APIs and apps was characterized as the initial challenge to broader use, discussion participants also emphasized that consumers who are willing to use APIs and apps struggle to find reputable sources that have vetted and presented them in an intuitive, useful manner. One approach cited as a method to avoid was the clinical trial "laundry list," where consumers receive the names of clinical trials, but are left to explore purpose, timelines, relevance to their condition, and

> **Patients just do not know about apps and registries that are available.** If a provider is aware, that is one way. But otherwise, patients rely mostly on the internet. People are desperate, they go to the internet and they share it all so they can help others and others don't become desperate to find it. Otherwise, they just hear it through the grapevine.

other details without guidance or input from the organization that created or delivered the list. Discussion participants recommended "hubs" of apps related to particular conditions that are provided and shared by patient representative and consumer organizations with credibility, as discussed in the next section.

Although participants articulated a strong desire from consumers with rare diseases to share their data for research, they cautioned that burdensome and confusing processes can overwhelm and deter consumers. One respondent said that "No one has created an app that is useful enough to download it and use it. There is no utility. Appealing to a person's altruistic sense to donate their data to research does not cut it with the misery of the experience."

Several respondents described APIs and apps for health data as a still emerging and nascent market because of the prevalence of inconsistent and unmonitored behavior, especially in terms of regulatory oversight. Until there is more established infrastructure, adoption, and regulatory guidance for app developers and their products, there may continue to be a reluctance to invest time and trust in APIs and apps that lack a wide user base or established performance record for safely storing and protecting consumer data. In describing a patient advocacy organization's exploration of app developers with whom to partner, one discussion participant noted that there are many start-ups, and time and resources are required to evaluate not only a product's quality and utility, but an app developer's data management, security processes, and stability.

By contrast, when a clinician or a well-established research or academic institution offers tools to consumers, such as a portal or an app, the recommendation conveys trust because of confidence in the provider, or an organization's credentials, to properly manage health data.

> **The problem [with promoting apps] is they are [developed by] start-ups.** We don't have the ability to vet if they have the staying power, and there are so many of them. Which horse do you go with? When a company is collecting data and a company dissolves, what happens to your data? How do you know it's secure? …We've been reluctant to put any of those in front of our community or partner with any of those apps and say here's who you should be working with."

AWARENESS AND ADOPTION STRATEGIES

To address low levels of consumer awareness about APIs and apps to access, use, and share data, discussion participants described outreach and education methods and discussed their effectiveness. They encouraged using trusted information sources, taking a marketing and advertising approach, and conducting information dissemination with particular attention to cultural sensitivity.

Two discussion participants underscored the critical importance of conducting education and outreach in culturally and linguistically appropriate ways and in partnership with trusted intermediaries, such as pastors and leaders from community-based organizations. They also spoke about the importance of designing the process of collecting consumer data and configuring the technical functionality in health IT in a way that prioritized: **(1) trust; (2) consent; (3) mechanisms to share de-identified, aggregated data; and (4) participation in solutions based on the data.** The pipeline of data from communities currently underrepresented in research would increase, they suggested, by creating equitable relationships across community members, payers, providers, researchers, and academics, rather than offering small tokens of remuneration in exchange for data.

A lack of deliberate effort to share results and a failure to play a role in improving the health conditions and environmental factors that contribute to poor health were viewed by discussion participants as key barriers to greater motivation to adopt APIs and apps and share data. One participant articulated concern around funding

APIs and apps that do not construct and implement specific plans to share data with community members and patient representative and consumer organizations. Participants warned against repeating historical misuse of consumers and their health information, which has resulted in ongoing mistrust of providers in communities that have been harmed. One participant noted that, unlike the trust extended to a clinician, a researcher's request for data or participation might be viewed with suspicion based on tragic historical events.

Although community-based approaches may effectively sustain interest and participation, a discussion participant warned that they take time to evolve and are difficult to scale. Academic and not-for-profit organizations that serve specific groups of consumers based on their health status and condition have an important role in leveraging their

> " A researcher can ask me to [share my data or participate in a study], but I'm thinking about Tuskegee. It's different if my doctor asks me. "

trust to share information about apps with consumers. Several participants recommended professionally operated information campaigns around apps that target consumers with specific conditions or potential app users with a certain need.

When asked about sources that could best share information regarding API and app capabilities and features in a manner that would motivate consumers to try and continue use, participants emphasized the trustworthiness of the source. Three trustworthy sources of information emerged**: (1) the consumer's clinician, (2) academic and not-for-profit organizations representing a group of consumers or conducting research or other work that promotes treatment**, **and (3) community-based organizations and leaders**. Conversations with discussion participants revealed benefits and disadvantages of these information sources, presented in Table 2.

Table 2. Benefits and Challenges of Consumer Information Sources

Information Source	Benefits	Challenges
Clinicians and Provider Organizations	• Trusted as a key information source with the consumer's best interests in mind • Well-positioned to serve as a conduit for educating consumers about research studies	• Focused on consumer care and less focused on technology solutions for consumers to manage health • Inclined to express fatigue with requirements related to unreimbursed consumer engagement via health IT solutions
Academic and Not-for-Profit Organizations	• Generally trusted to conduct work that promotes health and treatment for groups of consumers • Equipped with mechanisms to disseminate information to engaged groups of consumers	• Often focused on specific populations related to mission or funding • Can face constraints related to industry funding or government grants
Community-Based Organizations and Leaders	• Well-regarded as having a local community's best interest in mind with a powerful platform to influence groups of consumers	• Often, not well-informed about APIs and apps for information sharing and access • In communities that have been marginalized or harmed by clinical research, may have skepticism and mistrust for outside seeking data of community members

PRIVACY AND SECURITY FACTORS

Discussion participants were adamant that current consent and user agreement methods are insufficient to adequately inform consumers of the responsibility they assume for their health data's privacy and security after it is electronically transferred from an entity covered under HIPAA to their phone or to another device. Discussion participants also consistently reported that consumers are unaware of the extent to which their health data is de-identified, sold, and otherwise reused without their consent. Participants remarked on the individuality of consumers where perceived risks and life experiences are concerned. They emphasized the importance of obtaining consumers' consent for reuse of data and enabling them to withdraw that consent if they later decide that the risk of downstream use of their data outweighs the benefit of immediate access.

In addition to well-established concerns about long consent forms in language that is difficult to understand,[12] a participant expressed concern for consumers with rare diseases and with a health condition or status that makes them more willing to tolerate higher degrees of risk in exchange for the opportunity to share health data that could contribute to treatment advances through research.

Discussion participants explained that provider organizations are seeking to increase consumer access to health data in a manner that prioritizes consumer privacy, trust, ease of access to data, and motivation to use and share data. One participant emphasized the importance of providers implementing consent processes that explain the information collected and how it will and will not be used. In addition, consumers should understand how the provider will screen third-parties with access to data for matching purposes, what security practices are followed, and if there are user-friendly methods to opt-out of communications (e.g., SMS text messages).

> " There is no monolithic patient. Everyone has their own privacy and security preferences, and they can change every time the perceived risks and experience[s] are different. Patients need to be able to change their mind[s] when their situation changes, and the risks of the downstream use of that data outweigh the benefit of immediate access. "

Another participant encouraged building trust via methods that: 1) Are **simple and straightforward**; 2) Inform consumers of what **specific health data is sought, the research partner(s) involved, and the purpose and use** of the data; 3) Follow **consumer consent** of data for each time their data is released to third-parties (such as researchers); 4) Establish **strict protocols for privacy and security** protections, and; 5) Assign the **monetary value** of data to the consumer providing it.

Comments made by discussion participants reinforced the acknowledged importance of simple and clear consent processes that explain to consumers their rights, the use and potential reuse of their data, options for making their data unavailable for reuse, and opportunities for opting-out of data sharing. Several participants encouraged the use of resources such as the CARIN Alliance Code of Conduct[13] and the HHS Model Notices of Privacy Practices[14] to help consumers and providers understand selection criteria for APIs and apps. They shared additional insight aimed at shifting the consent ecosystem toward:

1) Models that acknowledge consumer ownership of data in a manner that positions consumers to participate in its monetary value and prompts researchers and other potential users to motivate consumers to share their data through incentives; and

2) Use of technologies such as APIs and apps to facilitate the process of obtaining and sharing data in a manner that places the consumer in control.

Discussion participant perspectives suggest that improved consent models and advanced API and app technologies could play a significant role in increasing the amount of consumer data available for research and other uses.

> **"** **The advantage in the API enabled app world is the patients have their data,** then they decide if they want it to be used for research or other purposes they may want, as opposed to finding an efficient way for patients to consent for data to be used by researchers. **"**

Summary of Key Findings

Discussion participants representing consumer views provided insight into the real-world experience and potential of using APIs and apps that enable consumers to access, use, and share their health information. All discussion participants reported that consumers have little awareness of available APIs and apps as tools for obtaining and managing health data. This finding was true even when discussion participants described consumers with strong motivators to obtain and manage their information, including those with rare, hereditary, terminal, or chronic diseases.

Moreover, many discussion participants emphasized that APIs and apps are unlikely to generate strong appeal to consumers who, because they are healthy, may not be motivated to actively use health data to manage care or participate in research. Suggested methods for increasing awareness and use of APIs and apps among this population included targeted marketing approaches, outreach from well-established patient representative and consumer organizations representing or supporting consumers, and communication from trusted intermediaries. APIs and apps focused on maintaining health and wellness may present an opportunity to encourage broader use and participation in research.

When describing the consumer experience with health IT, including portals and apps, discussion participants identified the core components necessary to sustain interest and use: **(1) the data must be interoperable, detailed, accurate, and timely; and (2) the app must reduce the amount of time consumers spend obtaining their data and achieving their specific objectives.**

Discussion participants noted exponential growth in API and app development. Although they spoke positively about the potential of APIs and apps to expand consumer control over health data, they expressed strong privacy concerns about APIs and apps and devices that reuse and sell data, and the lack of clarity about how those data are used. Consistent with findings from a recent Pew Charitable Trusts study,[15] participants noted there may be a general lack of awareness regarding regulatory oversight of APIs and apps. Discussion participants strongly emphasized the importance of transparent consent processes and data use agreements. Tools from reputable research and advocacy organizations were perceived as more trustworthy than those from less well-known apps developers with unproven sustainability models and little evidence of providing value back to the consumers and communities supplying their personal data.

Conclusion

This project and analysis explored the landscape of consumer-directed data sharing in a rapidly evolving electronic health data ecosystem. Although many stakeholders benefit from consumer-directed sharing of health data, this report focused on how consumer data sharing could expand the set of data available for researchers and clinicians, thereby improving the scientific process and, ultimately, enhancing clinical care through better evidence.

The findings establish considerations for making APIs and apps work for consumers. The findings also underscore the vulnerable and often secondary role that consumers find themselves in as they negotiate a health system that does not prioritize consumer preferences and privacy, and, in some cases, continues a historical legacy of harm and discrimination for groups of consumers. Although this report's findings are specific to consumer-directed data sharing, they can also support efforts aimed at amplifying the consumer's voice and role in the health system.

Some limitations of the findings include the small sample size; however, the participating consumer representative and consumer organizations reflect perspectives of a broad group of stakeholders. Several discussion participants had limited insight into the broader goals of ONC beyond the outreach materials provided prior to the discussion, and their viewpoints focused on consumers served by their specific organizations.

The priorities and needs that emerged support the strategies that ONC established in the Agenda and considerations in realizing the vision of the Cures Act Final Rule. In particular, participants underscored the importance of increasing the use of data generated by consumers in research and clinical decision making, while:

- Urging security safeguards and consent management approaches to protect consumer privacy;
- Emphasizing the need for educating consumers about the benefits and risks of capturing and sharing their data through APIs and apps; and
- Positioning consumers to be in control of how and when their data is used and shared to avoid "missed opportunities" for consumer engagement.

Continuing to seek and support the perspectives of consumers, their caregivers, and their advocates as an important component of the Agenda is critical to ensuring APIs and apps can be effectively used to engage consumers in using their health information to manage their health and participate in research.

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