The Office of the National Coordinator for Health Information Technology

Application Programming Interface (API) Write-Back Workshop Summary Report

PREPARED BY

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Background and Purpose

INTRODUCTION TO WRITE-BACK APIS

Today's interoperable health data ecosystem provides improved access to a variety of rich data sets to advance clinical decision-making and scientific discovery. These data sets originate from a wide range of health care settings via electronic health records (EHRs), health information technology (IT) systems, and other large repositories of clinical data. In addition, clinicians, patients, and researchers are gaining access to a rapidly burgeoning supply of genomic data, patient-generated health data (PGHD), social determinants of health data (SDoH), medical device data, and third-party consumer data. Recently, new regulations have enabled greater access to health data through the use of open, standards-based application programming interfaces (APIs).

APIs enable providers, patients, and researchers to use third-party applications (apps) to gather external data or apply insights and analysis to EHR data in a seamless manner. With the rapid advancement and adoption of Fast Healthcare Interoperability Resources (FHIR®), health IT developers are providing access to a range of APIs for use by provider and patient-facing apps.

Provider and Researcher Use of APIs

One of the major challenges faced by health care providers and researchers in health care today is storing and delivering large amounts of data to researchers in an efficient, verifiable and compliant manner. A widely held rule of thumb is that 80% of the time spent in creating an analytic data set is allocated to cleaning, linking, and merging data, while only 20% of the effort is applied to analyzing the data for insights or applying machine learning.[1] With data residing in siloed systems across multiple platforms, researchers are exploring how APIs may be able to address the tedious work of collecting, normalizing, and analyzing large quantities of data in a standardized and logical manner.

Provider organizations have implemented APIs available from health IT developers to support the ability to create, read, update, and delete (CRUD) FHIR resource data for authorized applications. Today, provider-facing APIs have been used for risk calculators, clinical decision tools, and resource lookups based upon an individual patient's EHR data. Organizations are also starting to evaluate the use of FHIR Bulk Data Access (Flat FHIR) APIs to replace the cumbersome interfaces with population health management tools.

In addition, through the use of standards-based APIs, the health care industry has reacted quickly to the pandemic and developed innovative ways to capture patient data from inside hospitals as well as from patients at home who may have been tracking their COVID-19 symptoms in self-assessment tools.[2] APIs are what allow researchers to get fast access to large amounts of real-time data from across the country, and even the world, to report global and national COVID-19 statistics.

Patient Use of APIs

The ubiquitous use of consumer technologies has resulted in an exponential growth of PGHD, defined as health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern. These data can be used to improve clinical decision making,

shared decision making, patient safety, and information access[3] as well as decrease time and costs for clinical trials.[4] However, these data are not systematically collected and used in clinical settings or for research. Additionally, SDoH data are not typically integrated into clinical care either, though these factors account for a substantial amount of health burdens and can predict health outcomes.[5]

Patient-reported outcomes (PRO) data can also be used to understand disease and treatment burdens, but PROs are usually not collected outside of clinical trials or other research efforts.[6] The ability to collect, summarize, and integrate PGHD, SDoH, and PRO data into an EHR may result in improved clinical care and more complete data sources for research. However, a standardized way to harness these data has not been widely adopted by or integrated into health care systems.

Write-Back APIs

APIs can also facilitate the exchange of data from an external source to an EHR using "write" processes, which encompasses the create, update, and delete aspects of API CRUD functions noted above. These processes can introduce functionalities to enable the EHR to process incoming data and store that information in a database. However, read-only APIs currently dominate in the health IT realm, especially for patient-facing mobile applications.[7] A notable exception has been patient-facing write-back APIs for administrative purposes, such as appointment scheduling and payment processing.[8]

As APIs are frequently being used to exchange information, researchers have started to develop standards-based architectures to collect PGHD and PRO data and integrate them into EHRs.[9,10] In 2020, ONC's Advancing Standards for Precision Medicine project piloted the inclusion of emerging data types - health, sensor, and wearable data and SDoH data – captured and written back to an EHR through the use of an API.[11]

As consumers leverage technology, such as health related smartphone apps and wearable devices, health IT developers and app developers are striving toward greater interoperability between traditional EHRs and mobile devices. While bidirectional data exchanges through APIs have been developed and tested, it is still an emerging technology in health care. As a result, there is a need to further investigate API write capabilities to explore existing architectures and inform the future development of standardized implementation guidelines.

WORKSHOP PURPOSE

In late 2020, the American Medical Informatics Association (AMIA) and ONC partnered to invite experts from across the health care, government, research, and financial technology (Fintech) industries to gather for a one-day virtual workshop to discuss the current and future use of write-back APIs. The purpose of "A Policy and Technology Workshop on Write-Back APIs", held on March 19, 2021, was to discuss stakeholder knowledge, current usage, potential use cases, and lessons learned on "write-back" API technology. Today, most write-back API usage involves vendor-provisioned (proprietary) FHIR®-based APIs for provider-facing applications. Generally available FHIR standard APIs available to all API users in support of Cures Act requirements are "read-only", for patient access use cases. This workshop also aimed to identify policy and technology barriers and opportunities for advancing availability of write-back APIs that enable "public-facing" third-party applications (apps) to populate EHRs. The goal of the workshop was to begin collecting

insights regarding current state adoption, understand opportunities and barriers, and collect input for future policy and technology efforts that can accelerate adoption of write-back APIs.

WORKSHOP PARTICIPANTS

Workshop participants included individuals representing perspectives from government, industry (app developers, health IT developers, and integrators), health care (provider organizations), academia (clinical researchers and informatics researchers), financial technology (FinTech), and consumers. The workshop was open to invited participants only from those organizations in Table 1. The Agenda and Participant List are provided within Appendices.

Table 1: Representative Organizations

Stakeholder Groups	Organizations	
App Developers and Integrators	1upHealth Central Square Solutions The Commons Project	Open mHealth Zus Health WaveOne Associates
Academic Institutions and Informatics Researchers	Cornell University Duke University Indiana University Health Harvard University New York-Presbyterian Hospital	Oregon Health & Science University University of California at San Francisco University of Kansas Medical Center UT Health at San Antonio
Health IT Developers Technology Vendors	Apple Cerner Epic	IBM Microsoft
Financial Technologies (FinTech)	Early Warning	The University of Manchester
Consultants, Contractors, and Government Partners	Clinovations Government + Health Leavitt Partners Martin, Blanck & Associates	MITRE Stratametrics
Government	Agency for Healthcare Research and Quality Centers for Medicare and Medicaid Services Centers of Disease Control and Prevention	Food and Drug Administration National Institutes of Health Office of the National Coordinator for Health IT
Health Care – Providers and Life Sciences	Boston Children's Hospital Intermountain Healthcare MedStar Health	Pfizer Reliant Medical Group Regenstrief Institute
Non-Profits – Advocacy and Policy	AMIA Global Liver Institute	SHIEC CARIN Alliance

ONC Perspectives

NATIONAL COORDINATOR - MICKY TRIPATHI, PHD, MPP

Micky Tripathi, the National Coordinator for Health IT, provided the opening remarks and an overview of the workshop. Mr. Tripathi described his early work with FHIR® through the Argonaut Project and the trajectory of the FHIR evolution, noting that we are still laying the foundation for future advances using FHIR. He reiterated that the industry needs to build the capabilities of using FHIR in a stepwise fashion, first starting with read capabilities and then moving towards expanding the use of FHIR APIs to include write capabilities to facilitate greater data exchange for research purposes. Micky laid out the goals of the workshop and asked participants to consider: 1) the best use cases for write-back APIs; 2) which capabilities we are trying to enable through the use of write-back APIs; and 3) what is the value or benefit to clinical care or research.

DEPUTY NATIONAL COORDIANTOR - STEVE POSNACK, MS, MHS

Steve Posnack, Deputy National Coordinator for Health IT, welcomed the participants and provided an overview from his perspective of the value that the group will bring towards understanding the issues surrounding the use of write-back APIs and future health care industry. Mr. Posnack described the history of ONC's regulatory work regarding APIs, beginning with the 2015 Edition certification criteria and through the passage of the Cures Act Final Rule which codifies the use of FHIR R4 as the standard for FHIR-based APIs to be used for gathering individual data for patient access, and the FHIR Bulk Data Access API standards for population health and research purposes. Steve echoed the sentiments from Micky regarding the future expansion and use of FHIR as the primary means to advance the use of APIs in the health care industry. Steve acknowledged that there are challenges and barriers to the adoption of write-back APIs and cautioned the group to consider those issues as they discussed use cases during the workshop. However, he was optimistic as we learn and discover new ways to build APIs into clinical workflows to benefit consumers, clinicians, and researchers in the future.

SCIENTIFIC ADVANCEMENT BRANCH - KEVIN CHANEY, MGS

Kevin Chaney, Senior Program Manager, described the work of the Scientific Advancement Breach and its role in supporting scientific initiatives that help accelerate the health IT infrastructure, which is at the intersection of both research and care delivery. Mr. Chaney introduced the concept of APIs and reviewed the standards required by the Cures Act Final Rule, and described the current state of the adoption and use of APIs including proprietary and public (open, standards-based) APIs. Kevin also described recently completed and ongoing efforts at ONC to pursue advances using APIs including the following projects: Sync for Science, API Privacy and Security Considerations, and Accelerating APIs for Scientific Discovery. He reviewed the two most recent reports published on ONC's website under the 'Accelerating APIs for Scientific Discovery' project from the Consumer Perspective and the Researcher Perspective. These reports can be found on the project website at: https://www.healthit.gov/topic/scientific-initiatives/accelerating-apis-scientific-discovery. Kevin then reviewed the agenda for the day and introduced the five speakers that would offer remarks and varying stakeholder perspectives and then engage in related discussion with the workshop participants.

Stakeholder Perspectives

RESEARCH - PATTI BRENNAN, PHD

Dr. Patti Brennan, Director of the National Library of Medicine, presented the Researcher perspectives related to patient-generated health data (PGHD) and the use of write-back APIs to gather this valuable, rich data set from patients. Dr. Brennan presented several patient use cases where the use of technology tools may benefit both patient and care team by capturing important data before or after an episode of care.

In considering patients providing data for research, PGHD often means that a professional has asked the patient to provide information. Therefore, the patient is the data provider, but not the data generator. Professionals and patients don't always define terms in the same way. Lots of PGHD actually requires the patient to define what that are telling us.

Dr. Brennan also articulated several critical questions to answer before we may advance using write-back APIs:

- Who is writing to whom? (e.g., Is it the patient writing to a physician, a care coordinator, or another specialist?)
  - Affects workload of patients and clinicians
  - Creates context for interpretation
  - Requires expectations management for clinicians to not "drown in data"
- Who decides what is written back to the record?
  - Is it patient-generated health data or patient-defined health data?
  - What other operations are needed (e.g., visualization, AI-driven NLP, alerts/warnings)
- What happens with the written data?
  - Where does the information go when it is "written" back to a patient record?
  - Who will review that information and ensure it is going to the correct place?
  - What is the expectation of a response to the patient and in what timeframe?
- How can we ensure that these technologies do not accelerate health disparities?

Dr. Brennan also stressed the importance of ensuring that information is interpreted accurately so patients and clinicians are communicating effectively, and highlighted several research programs that the National Library of Medicine at NIH has funded in support of write-back APIs:

- Data Science Research: Personal Health Libraries for Consumers and Patients – Designed to bring data science into the hands of patients.[12]
- **Notice of Special Interest (NOSI): Computational and Statistical Methods to Enhance Discovery from Health Data** – Designed to work on de-biasing data as sparse sets of data are hard to interpret so that clinicians or patients don't have to sort it.[13]

- **Computational Approaches to Curation at Scale for Biomedical Research Assets** – Researches ways to annotate and curate in stream at the point of communication, not simply at the point of recording.[14]
- **Post-Acute Sequalae of SARS-CoV-2 Infection** – Provides opportunities for PGHD and patient-defined data to understand the near-term and long-term sequalae of the COVID-19 infection. We do not know how long we have to monitor people and we need to think about light touches and technologies to support research and may be a great place to think about write-back APIs.[15]
- **Bridge2AI** – Generates AI-ready datasets to make large datasets available for use and modeling to begin to learn how to better work with data gathered for the purpose for advanced analytics, not retrofitted.[16]

Finally, Dr. Brennan initiated her closing remarks by noting near-term considerations for an integrated research approach to write-back APIs:

- Defining the information to convey (write-back)
- Care delivery impact of the information written-back
- Patient self-management impact of data written-back
- Standards and technology needed to address these areas

She highlighted additional future areas for research and consideration related to write-back APIs:

- Human factors:
  - Mental models and psycho-motor skills needed.
  - How to approach individuals who lack sensory capabilities to engage in generating the desired PGHD.
- Artificial Intelligence and synthesis tools:
  - Computer vision to understand the dynamics in a family structure, such as when a child with a behavioral problem starts to have a serious event that can have an automatic understanding and interpretation in the learning system.
  - Computer vision to help better understand gait and mobility in elders.
  - Robotics to assist in understanding range of motion following a stroke to supply patient outcomes information.
  - For professionals or patients, there is too much data to physically view and the development of synthesis tools is needed.
- Infrastructure needs, privacy and security:
  - Need to establish privacy preserving communication analytics and interactions to ensure a person does not have to worry about data security or hacking.
- Regulatory and policy environment:
  - Incentives for better engagement of patients in health and healthcare.

> ***"We know it's important to go to where the care happens and to bring technologies there. As I think about write-back APIs, I started thinking about when [write-back API data exchange] would occur…the care between the care."***
>
> ***"Anything [data] that assist a person and taking better care of themselves can be of significant value if we can provide the privacy to it."***
>
> ***"If we could get 25% of the people engaged in the way that made their health care more efficient, we might actually make the whole system more efficient."***

Participant Discussion

Guided by Dr. Brennan's remarks, workshop participants engaged in a ten-minute discussion on the following topics:

- **PGHD**: There has been work on defining what patient-generated data is, but more needs to be done to define "patient-defined" data and standards that can support it.
- **Natural Language Processing (NLP) tools**: Dr. Brennan noted future benefits from NLP tools that can help understand the person in context. The information retrieval community, largely focused on fixed text, could start to think about gestures and vocals to provide improved context.
- **Data aggregators**: The group discussed how data aggregators for derived intelligence can be used to additional context, such as public health data. Public health monitoring data, water quality information, air quality population trends, can provide 80% of the information and the patient can provide the 20% of information that is relevant to them.
- **Public health data/reporting**: There are still policy issues to consider regarding how to use public health data – such as data collected in the course of a public health emergency – and understanding the ability to reuse that data.
- **Patient consent and clinical research**: While there's been a good understanding of patient consent, participant consent, and research data privacy. As we move into clinical research data, we start to understand the complex interplay between a participant agreeing to data sharing for the purpose of care, and how that feeds – or does not feed – into the individual being willing to have their data used for the purposes of research.
- **Research models**: We can apply models from operations research, particularly from manufacturing that would characterize the performance of a system in its steady state and look at deviations from that performance that can be computed mathematically, or algorithmically, to make recommendations or predict a future state.

TECHNOLOGY - JOSH MANDEL, MD

Dr. Josh Mandel, Chief Architect for Microsoft Healthcare and Researcher at Microsoft, presented from the technology perspective of advancing the adoption and use of write-back APIs.

- First, Dr. Mandel encouraged the workshop participants to focus on identifying use cases for that are worth investing in, and to think about how those use cases could be grouped together in ways that one common piece of functionality can serve many different needs. One example of such a use case may be a clinician-defined form that requests specific information from a patient.
- Second, he asked the group to consider workflows that could be useful, not just in the research context, but also for clinical care. Dr. Mandel stressed that workflows that support both clinical and research purposes may be easier to get buy-in for implementations at scale, with different EHR systems and inside may different clinical provider organizations.
- Third, Dr. Mandel discussed another opportunity for write-back APIs in generating risk assessments, by gathering data coming from tools and consumer apps and aggregating that data into predictions and risk scores. Then those risk scores can be written back to the [EHR or other clinical] system of record to make clinical decisions.

Dr. Mandel described the early work with the Argonaut Project, and stressed that this ecosystem must be viewed in terms of incremental progress and is often slow. He said that the aim is to standardize these processes so they don't have to constantly be reinvented, and then standards can layer in over time. While the government can assist in identifying the areas where advances are needed, those functional requirements will lead to industry development. Once technologies are developed, lessons learned can be shared and early standards and definitions may be developed and tested. Once the standards are actually working consistently across multiple systems, then government may think about developing regulations to impose requirements for certification/implementation, such as with the consumer-access API. For example, with consumer APIs, this process took five to seven years between identifying some functional areas and having hard requirements in the regulation to being rolled out and reported.

Workshop participants added comments and questions related to the tremendous value of questionnaires and surveys even as they compare to validated research instruments, and how some organizations struggle with how to implement because they are asking providers to add data from PGHD to their current workloads.

In closing the interactive discussion, Dr. Mandel posed separating write-back to an EHR database from write-back into a clinical workflow, which may involve an EHR, other systems, SMART-on-FHIR® apps, etc. Participants concurred that there isn't a good understanding (in terms of standards, guarantees, and eventual testable requirements) what writing to a "clinical workflow" means. Important policy considerations to implement write-back raised included how to have clinicians agree to receiving data, and confirm that they have the technology and workflows to handle receiving write-back data from patients and other sources.

Participants noted that certain use cases may not involve write-back to an EHR, and could involve writing-back to a shared care collaboration or third-party coordination app that is patient-centric, not EHR-centric.

An example provided was a scenario to for wearable data transmitted to a SMART-on-FHIR® app that a clinician uses during an encounter, or reviews from an EHR inbox message. In this scenario, the information is sent to the provider, but the data doesn't have to be written back into the EHR database. There are reasons to write into the EHR database, but we should be intentional about when and why it's needed, and understand the cost implications and challenges.

> ***"What are the use cases that are worth investing in? How do we think about grouping or lumping those use cases together so that one common piece of information may serve many different needs?"***
>
> ***"It's a mind shift to say to researchers, 'Here's a pile of data – a common core data set – for free from many different systems. You may not have all the data you want or be able to answer every different question, but thinking of it as a booster pack that's going to get you started, without deep custom integration.'"***
>
> ***"What are the places it makes sense to have external app writing directly into a health record system and what are the other paradigms to consider? If data lands into a holding tank instead of directly into a system, what is the expectation for review of those data over time?"***
>
> ***"We learned a lot from doing one-off efforts that don't scale - one institution and one use case at a time. The aim is to standardize these processes so that we don't have to keep reinventing."***

Participant Discussion

Guided by Dr. Mandel's remarks about use cases, workflows, and sequencing of standards efforts, he invited reactions and engaged in discussion with the audience on the following topics:

- Research Questionnaires:
  - How can we bring together the measurement and conceptual integrity community with the FHIR questionnaire community? There is a broad spectrum for questionnaires and surveys from SurveyMonkey – where anyone can write questions and execute the data collection – to validated research questionnaire instruments with inter-rater reliability.
  - FHIR can support the entire space by providing a set of data models for any type of interaction across this spectrum.
  - If you're using this technology in the context of a research study, participants discussed the notion that researchers could also publish a standardized FHIR questionnaire to accompany a research study or journal publication that defines the concepts and the choices.
  - In the near term, activities such as mapping 10 or 20 questionnaires of interest in standard way could be of value.

- Potential use cases:
  - Strongly typed observations, questionnaire responses, risk assessment/scoring, symptom surveillance, care plan adherence, family caregiver support, medication reconciliation and use cases for care coordination in between care.
  - A provider participant shared potential candidates for "low hanging" passive external data write-back that is supported within his organization: From hospitals – everything; From State Immunization registry - Immunizations, From Consumer Health Devices – blood pressure, heart rate, weight, pulse oximetry data. Activity has been tested, but not implemented it because outside of the frail elderly it offers less value.
- Risk Calculators:
  - A participant asked, "For predictions/risk scores, a participant inquired how sending apps can share the details that allow receiving providers to appropriately interpret and act on them?"
  - In the context of delivery of risk scores, an info card or something that explains "the input that was considered, here's how it's processed, and here's where you can go to learn more" could be helpful as context.
  - Another participant noted, "There are added legal/risk/compliance issues with write-backs for risk prediction scores. Without interpretation, scores auto populated into the EHR, healthcare systems are very concerned about the legal liability implications."
- PGHD:
  - For patient-generated health data, the industry could consider thinking through two different processes: one with health data from sensors and other modalities that may be collected passively once permitted; and the other being active patient reporting through a survey or survey-like methodologies and apps.
- Medication reconciliation:
  - Participants engaged both in live and online conversations regarding the opportunities for write-back APIs in supporting medication reconciliation.
  - Reconcilable data (data that is recorded in duplicate across different systems like medications, allergies, problems), uniquely patient authored data (patient device observations) that could file without reconciliation, and patient mediated data (data authored not by a patient but another Covered Entity institution).
- Incentives:
  - Participants called for more thinking about how to change the incentive paradigm again around patient-facing surveys that may be written-back to records. The value proposition for providers is challenging due to limited resources, needs to address regulatory and payor needs, etc.

Notable comments from participants during the accompanying online chat include:

- "Why do we have to spend so much time at every visit due to not trusting what we see on the 'current' medication list?"

- "Research-quality surveys with strong measurement characteristics are almost the opposite of patient-defined health data, and are often not patient-friendly, not useful to patients themselves, and hard to get patients to complete. There's a new science we need to build on how to use new inputs of subjective states."
- "Can you imagine how powerful simple, human-readable questionnaires (in multiple languages) that capture data in FHIR and write-back to public health could be in helping to address our next pandemic?"

Links shared by participants using the online chat during this session included:

- Forms to consider review for mapping and standardizing using FHIR – have existing LOINC panels and questionnaires that were created for MDS, OASIS, public health. Could use the L-forms approach with an output that is the questionnaire response with structured FHIR-based data: https://loinc.org/lhc-forms/
- NIH Common Data Elements (CDE) Repository: https://cde.nlm.nih.gov/home
- Google resource on "model cards" as an approach to develop a shared understanding of AI models: https://modelcards.withgoogle.com/about
- HL7® Patient Empowerment is writing a white paper on Patient Contributed Data (PGHD) to help understand the definition, the current standards landscape, and identify where gaps and opportunities are from the standards perspective. https://confluence.hl7.org/display/PE/Patient+Empowerment+Home
- Links to certified health IT developer FHIR capabilities for write-back were shared (Appendix C)

PROVIDER - BEN ORWOLL, MD, MS

Dr. Ben Orwoll, a practicing pediatric critical care physician and Assistant Professor of Pediatrics, Medical Informatics at the Oregon Health & Sciences University, presented from the provider perspective on the use of write-back APIs, using his own experiences as a provider. Dr. Orwoll highlighted that providers are a heterogeneous group, practicing at any number and type of location(s) such as hospitals, clinics, mobile health clinics and telemedicine sites. In addition, providers themselves come from a variety of educational backgrounds, experiences, and specialization.

Dr. Orwoll provided an overview of the current inputs to the electronic health record and how PGHD may provide additional data that could be useful to a provider. He questioned whether we need write-back APIs to gather some of this information, even such as PGHD as some of the goals may be accomplished using read requests that do not write-back. He offered the example of wanting to see his patients home blood pressure readings where he can simply launch a FHIR app that reads from the home blood pressure monitoring database and might also read from his local database at the same time to present blood pressure trends without having to write anything into his EHR system from the outside.

Dr. Orwoll provided an overview of his research project, "MammoScreen, Evidence-Based Shared Decision-Making for Breast Cancer Screening", funded through the Agency for Healthcare Research and Quality (AHRQ), where patients answer questions on a brief survey, that generates a risk assessment and

is written back into the EHR and generates an alert and clinical decision support workflow from the provider to do some shared decision making with the patient. In this workflow, the results of the survey are generated and stored on the app servers; however, the EHR and the provider have no way to know when the patient has completed a survey except through the receipt of a result, through a write-back API. The receipt of particular data within the patient's chart can then trigger internal workflows or messages that can prompt providers or their staff to reach out to the patient and initiate further shared decision-making activity. Dr. Orwoll is not currently able to use a FHIR Questionnaire resource or a FHIR Questionnaire Response workflow because the write-back API is not yet supported in his EHR. He is having to use other workarounds to get the data back into the EHR. This type of workflow provides an example where write-back functionality is needed.

Dr. Orwoll questioned whether these workflows need write-back APIs, and concluded that these situations may greatly benefit from write-back functionality because they involve incoming data from outside sources that is unsolicited or asynchronous with provider EHR activity. Currently, these workflows are supported with non-standardized methods and APIs for lab results or other device integrations.

Dr. Orwoll provided several examples of where write-back APIs could assist in performing common administrative and clinical documentation functions that are already part of a full-featured EHRs:

- Schedule Appointments
- Nursing Documentation
- Record Vaccinations
- Send Messages
- Decision Support
- Dictate Notes
- Population Management
- Place Orders

Dr. Orwoll then discussed two of the concerns that providers have when discussing write-back APIs: providers must be confident in the security and provenance of data in their electronic records. With most EHRs, you can look at an audit record to determine where, when, and by whom any action or point of data was recorded. The same level of metadata would need to be provided along with data that is integrated into the EHR using write-back. FHIR already includes a provenance resource type, and in most cases, this information may be rarely reviewed, but there needs to be trust that the provenance trail exists. Providers want to be sure that they don't expose their organizations or their patients to intolerable risk through use of write-back technology.

"Without the ability to write-back, most applications are more like reference materials; you can look at them, but you can't really do anything, and you have to go back to the EHR to take the appropriate actions."

"One of the promises of standardized and web-enabled APIs like FHIR, is that they might allow for opportunities for the re-emergence of best-of-breed or specialized applications that provide more functional, useful, pleasing experiences for the user, while maintaining the stability and the system-wide integration of the underlying EHR as far as the data are concerned."

"I would like to have all the information I can, but I don't want to necessarily be expected to look at it all the time, I want to look at it when I want or if it's flagged or if it's requested."

"Expecting providers to proactively look at all of the data coming in from external sites, like home health agencies or research databases is probably too much to ask, but there needs to be some sort of consensus [across the community]."

"How do we create the right incentives to make this process good and work for providers?"

Participant Discussion

Guided by Dr. Orwoll's clinical and operational examples, participants engaged in discussions regarding workflow implications of write-back technology:

- What kind of expectation-setting needs to be applied to the process on both the clinician side and patient side? If a patient sends some data that could require immediate action, how should this be handled without a portal message or alert to notify of important results?
  - It is going to be tough to come up with paradigms that solve every potential situation. We have to take a relatively cautious approach to implementing any type of write-back into a system that could produce critical data.
  - How can we take data from the outside and allow it to trigger or initiate some sort of messaging or decision support workflow to alert providers or staff that something needs to be done? This is not easy.
  - Dr. Orwoll referenced earlier online workshop discussions noting that data may need to be manually reconciled before it can be incorporated into the EHR for decision support. However, someone needs to know about the data before reconciling so there could be this period of unreconcilable limbo where the patient thinks they have submitted something, but nothing has happened with it.

- Since every workflow is different, how do we try to standardize this type of write-back? Is it through a technical implementation guide or is it simply through a set of principles that needs to be followed and adhered to? This is the broader question for the workshop participants in considering "what is the process that we need to have in place to define those principles so that there is some consistency across the board?" Some perspectives from the past that could be applied here included:
    - In the past, there was similar concern regarding patient-provider email – there was concern that critical time-sensitive information would be conveyed using a mechanism that wasn't reviewed instantaneously.
    - This was also a concern in opening up portals to patients at the time the data is available to providers. Essentially this proved to be a non-issue at the organizations that were concerned about it.
    - After a patient was discharged and lab results were resulted post-discharge a process was implemented to follow-upon "late arrival" lab results – this was an example where a workflow was necessary to support asynchronous, unexpected communication.
- Write-back APIs from a provider perspective are not necessarily limited to patient-based inflow of data – you can have data from any number of different organizations and outside agencies (e.g., social determinants of health) and we will still need expectations to be set on how this data will be handled.
    - Most institutions don't want data from other EHRs from other organizations in their system for a lot of these reasons and also due to concerns regarding duplication.
- Clinically relevant data could come from clinical research – how can this relevant data come from multititle different pharmaceutical companies without being burdensome to the clinician? How do we ensure this data is considered trusted data for the clinician?
    - We really need to start developing expectations as a community around how much data and where the data comes from that you can realistically be expected to act upon.
    - Possible data to consider acting upon could include data flagged for review and data provided in response to a specific order or request.
- Writing data back to an EHR doesn't have to be outside data. We need to be able to layer something on top of the EHR that's sharable, such as the result of machine learning.
- Distinguishing between "write" vs. "write-back" could be helpful. There are passive apps versus apps "that do things" such as having a FHIR app onto an EHR that performs an action through a write operation – either they are writing an order or writing data back into an EHR based upon an algorithm. Applications are having a two-way communication between two systems – they are reading some data and they are authenticating back and forth.
    - Write: There is some data that the user does not know about, and it is shared, whether it's from the patient or another source.

    - Write-back: Assumes that a party is reflecting on data that exists, and the data provider is annotating, correcting, or updating existing data. This is more challenging to govern and address.
- Another potential framework to consider for handling of write-back data could include and consider metadata that represents:
    - App writes something to a chart, and it will be reviewed when the chart is looked at.
    - App writes something to the chart and periodically, a digest of this information will be sent to a care team
    - For a population that is actively managed, the app writes something that is reviewed by a care manager
    - The app writes something that is a cause for concern that needs to be escalated internally through a care process
- Participants discussed the need to invest in research to determine the best way to implement write-back with APIs. In addition to research and reporting on how write-back can be implemented and work, funding may be needed to investigate the idea of whether the write-back data is usable, and understanding the provider response to it, and whether the expectation comprises an acceptable workflow.

PATIENT - DONNA CRYER, JD

Donna Cryer, CEO and President of the Global Liver Institute, presented from the patient/consumer perspective of the needs and issues facing them in the health care system today, and how write-back APIs could assist in the delivery, coordination communication, and efficiency of care. Ms. Cryer reminded the group that contrary to some of the comments earlier in the day, patients are not most concerned with billing and administrative functions in the EHR system. She expressed that as a person with a chronic and an especially complex medical history and treatment plan, what is needed most is accuracy in the medical record. Therefore, her view was that write-back APIs should instead focus on allowing patients to review and amend records when necessary, and facilitate provider communications and patient engagement.

Ms. Cryer provided multiple examples of how patients often have a better understanding of their own care than their providers, and how personally she struggles with the accuracy and timeliness of the data because her course of treatment changes so frequently and is dependent upon her patient-reported outcomes. She also stressed the importance of being able to prioritize data stored in the EHR, to update it based on conditions and treatments that are no longer relevant.

As a patient advocate, Ms. Cryer strongly believes that patients need to be included in the development and implementation of write-back APIs because they are the ones that have a better sense of their own care rather than providers. Five reasons she described patients making their data of better is through:

1. *Accuracy* – Patients are often the best source of accuracy of data, with information that takes place outside the confines of the provider's facility
2. *Currency* – Patients know the most current status of medications, conditions, and problems

3. *Prioritization* – Patients can help to prioritize information in the record, especially for complex patients in order to help providers focus on the issues at hand
4. *Completeness* – Patients are able to provide complete data from multiple sources of care
5. *Coordination* – Patients are highly motivated to have all of their care coordinated and data shared between multiple providers can reduce duplication of tests and coordinated treatment plans

In addition, Ms. Cryer emphasized that having complete, accurate data from patients is important for five key reasons: patient safety, quality, efficiency, research, and ethics. Write-back APIs can facilitate this process.

> ***"The arrogance of accuracy that [what] happens in a doctor's office is more accurate and higher quality data than the patient's data, I think that is one that we need to get over."***
>
> ***"Patient portals have lovely design, but every condition I've ever had – every code and diagnosis – from over 30 years as an active patient is overwhelming for any provider, and not really helpful to the conversation I hope to have with my provider during that visit."***
>
> ***"Patients can have a role – and should have a role – in setting personalized values of importance and pulling out the relevant data fields."***
>
> ***"No one is more interested in having all of my care coordinating and information in one place as I am…. I have connected my Johns Hopkins and Mayo Clinic and other records into one sot that my providers can coordinate my care and not order duplicate tests."***

Participant Discussion

Guided by Ms. Cryer's comments regarding the value of write-back APIs for patients, the participants discussed additional considerations to ensure this capability addresses the needs of patients:

- Not everyone has been every level of patient – complex patients with eight different portals that needs to interact with their health information regularly versus healthy patients that occasionally need to review their records. We need to think about the needs for different levels of patient and caregiver needs.
- If this was as simple as a tiny data set, it would be solved, but there is not a single API or a single piece that is going to the translation to do what we need. As we are on the cusp of making some changes to support Cures Act compliance, it's being led by people in informatics and IT, but these changes require being linked in arms with physicians that understand and teach the art of medicine successfully so that we can learn to talk about data.

- How do we get the time and design input we need from patients to actually develop the tools they need? How do we make sure we use a user centered design model to reach what each type or level of patient needs?
    - In addition to the patient questionnaires discussed earlier, we should add a way to collect how the patient feels or have the patient be able to document what is important to them. We need a group document to highlight the most useful points in the conversation with providers for the patient.
- From the technical side, we could focus efforts on a common set of standards for classifying incoming messages whether it is patient reported or machine generated or from a device. There could be agreement on the types of data coming in and then each organization can make decisions on what to do with the data coming in. Could start with sending the data to a SMART-on-FHIR app because the EHR may not worry about it yet – patient reported outcomes could go to a third-party app first and then hospitals could have the controls to determine when and how to accept the data.

FINTECH - MARKOS ZACHARIADIS, PHD, MSC

Dr. Markos Zachariadis, Professor of Financial Technology and Information Systems at the University of Manchester, presented on the topic of APIs from the financial services and financial technology (FinTech) industry perspective. Dr. Zachariadis highlighted the comparison between the data sharing issues facing healthcare currently, and those historically faced by the financial services and FinTech industries. He provided an overview of the use of APIs including “external” (proprietary, tailored) APIs such as those used by card networks VISA and MasterCard, and third-party applications such as PayPal and Amazon Payment to check out and support payment processing.

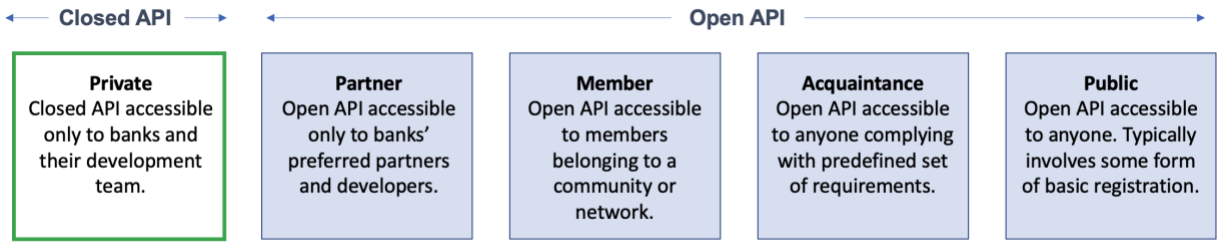
Dr. Zachariadis explained that another technology method often used to access and capture data stored in closed systems is “terminal emulation”, or “screen scraping”, where unstructured data residing in web sites is captured by the web-scraping software and stored in a structured way that can be analyzed or re-used. He discussed the many technical and regulatory challenges with this method, including the lack of governance, oversight and privacy concerns. A major technical challenge was that when companies changed their websites and user interfaces, web-scraping software had to be reengineered to capture data in their new formats. In addition, the software required users to share their login credentials in order to allow third parties to access their bank records, which had obvious privacy concerns. From the regulatory perspective, initially third parties writing this software were unregulated and consumers had no guarantees of data privacy. There was also a lack of oversight and governance to support how these technologies were deployed across the industry, which created perceived market forces towards a lack of competition.

As Dr. Zachariadis described, increased demand for data led to the creation of a niche market of data brokers or intermediaries who specialized in extracting data from banks (on behalf of the customer) and would sell access to third parties (e.g., FinTechs) who would then reuse the information to provide new and innovative services to customers. Firms such as Yodlee (founded in 1999 and acquired by Envestment in 2015) and Plaid (almost acquired by VISA) became very influential and profitable in the FinTech industry.

As data openness evolved in the European Union (EU) and United Kingdom (UK) financial services industry, regulators questioned the matter of competition and security risks, and whether more regulation

was needed. Due to higher prices, less quality, bigger switching costs, and higher barriers to entry, regulators and competition authorities saw data openness as the remedy to battle the monopolistic behavior within financial services. Dr. Zachariadis then provided an overview of the various regulations that emerged in the EU and UK. Once regulations were enacted, the EU and UK realized they needed a new technology that was consistent and standardized. Currently, the UK created a standardized, regulated framework for data sharing in financial services using APIs.

As Dr. Zachariadis shared, the API framework that is used by the European Banking Association moves from closed/private APIs to an increasingly more open API environment along the following spectrum:



Source: ABE-EBA (2016)

Dr. Zachariadis further highlighted the movement of the financial services industry into new business models including the "unbundling" of banks, banking services as a platform, and "re-bundling" of banking services. Another development was the emergence of API aggregator platforms when there was a lack of standards in the API market. The move to more openness of data sharing also created several benefits to consumers in the financial industry including opportunities for more personalized products, better cash and financial management, less "red-tape", more secure communications with third-party apps (compared to screen-scraping technologies), more automation, and faster interactions with service providers (e.g., loans).

Dr. Zachariadis closed with his perspectives on developing an open data sharing framework in financial services, describing three themes that industry practitioners and regulators need to think about when opening up data:

1. What are the objectives and approach? Policy-mandated vs. market driven?
2. Need to solve for accountability issues, as when data gets lots or mistreated (e.g., wrong payment, fintech collapses), there's a lot of data hanging with parties that we don't know (who they are). What decisions are needed regarding liability issues? What are the relevant data privacy laws?
3. How to create and implement a data-sharing infrastructure? There are different decisions that are needed regarding:
    - *Data openness and competition* – How open should the data be? What types of data access rights and permissions are required?
    - *Digital identity and identification of third parties* – How do you ensure that information can be accessed securely and identified properly? How did the third-party identify themselves? Are they licensed or is a license required?
    - *API adoption and standards* – Who sets the standards? When are they updated?

- *Security* – Are there authorization and authentication standards as well as standardized permission frameworks?
- *Data standards* – Are the data standards established?

"Data openness and also particularly the use of open APIs led to the entire industry opening up and becoming more modular….now we are moving into an ecosystem of different providers that can be linked because of data openness and the use of open APIs."

"Lack of access to data, drove higher prices, less quality, higher switching costs, and higher barriers to entry. Regulators and competition authorities saw data openness as the way to treat or remedy monopolistic behavior within financial services…. And that's ow we saw the emergence of data sharing frameworks in financial services."

"We envision in the near-future, a way where you have full control of your data, what you have consented for to share with third-parties, and how you can revoke access from third-parties."

Participant Discussion

Dr. Zachariadis participated in an active discussion with the participants, who posed a number of questions in applying FinTech lessons to healthcare:

- How has the journey to distributed models shifted the value proposition and infrastructure for the FinTech industry?
  - The financial institutions who were traditionally the brokers of money are now becoming the brokers of data. For example, you may be consuming mortgages from a bank, but the bank may be more so the marketplace that provides access to the services and gatekeeper of information more than the provider of the money. It has fundamentally challenged some of the value chains we have in financial services, but has also changed the nature of a lot of the financial institutions we have right now in the financial services industry.
  - In a decade from now, with data sharing in banking and finance – if it catches on dramatically, we'll definitely have a huge paradigm shift that we haven't seen for centuries.
- There's been a lot of progress in the financial sector in identity verification, which is the starting point of a future building on top of that. Financial services can contribute to healthcare, lessons in identity verification and establishing it in a trusted way.

- There are a lot of laws that the financial sector must operate under that protect financial information and govern sharing and data security practices. Part of the analogy from financial services for healthcare, is that we are creating a consumer permissioned way to share your financial information. This would allow a customer of a third-party (e.g., applicant for health insurance, patient on a health portal) to log into their financial institution to prove their identity, without sharing any credentials with the healthcare provider or even with us (as an intermediary) – they are only sharing data with their own financial institution. With the step-up authentication, facial recognition, touch recognition that individuals already use with their financial institution – and allow visibility of data an individual has requested to share – name, birth date, SSN verification, payment credentials (e.g., credit card number, token, Zelle alias). It's a brand-new initiative with a customer permissioned way to authenticate themselves with highly regulated data as well as provide permissions for sharing – with dashboards that indicate the status of who you're sharing data with.
- Another use case financial services is considering in healthcare is in retail pharmacy where you can use this type of customer consented identify proofing service to sign up for vaccinations or procedures or other types of things you are getting through your pharmacy today.
    - The issue is the liability model – banks are not making money on this; they are doing this for the convenience of their customer. They don't want to take a lot of related risk, particularly in high-risk areas like healthcare, but there are still potential collaborations to explore.

BREAKOUT SESSIONS

Workshop participants were divided into five breakout groups, comprised of an even distribution of stakeholder perspectives (e.g., technology, provider, researcher) within each group. Each breakout session included a facilitator and note taker, with the group identifying a workshop participant to report out to the broader group.

The group was instructed to discuss workflows, clinical/operational scenarios, or other functions that could benefit from write-back APIs. The groups were tasked with the goal of defining potential use cases and identifying considerations and factors to consider for each potential use case, such as:

- What data is being requested by the third-party application, and what is written back to the EHR?
- Does this use case aim to "create" new data, "update" existing data, or "delete" existing data within the EHR or other health IT system?
- Who will be supplying the "write-back" data? (e.g., patient, provider, care team member, analyzed data, third-party data source)
- What technology barriers or challenges need to be considered?
- What policy, preference, or data use concerns are there around ingesting this kind of data?

Key Takeaways

Workshop participants developed general recommendations and considerations for advancing write-back APIs at a broader level applicable to multiple potential use cases. Key takeaways from these discussions are summarized in this section.

Potential Use Cases for API Write/Write-Back:

- Device data, wearable data, remote patient monitoring data from devices
- Patient questionnaires and other data being used for care coordination, management, or research from the patient and EHR
- Assessment risk scores, risk calculators
- Patient input for symptom data, medication reconciliation, and medication compliance
- Patient input for subjective and functional data such as patient reported outcomes
- Provider decision support such as medication reconciliation support, insulin ordering/management, pain medication management/ordering, and assisting in writing or amending notes based upon data within the chart
- Communications between patient and providers between appointments (e.g., new symptoms that occur between appointments, patient messages to provider)
- Machine learning/artificial intelligence (AI)-created data to assist in diagnosis and treatments available
- Transitions of care and inter-organization write-back from other health care providers caring for the patient

- Community resources and social care data regarding social determinants of health from Community Based Organizations

Technology Barriers or Challenges:

- Maturity of FHIR standard – there are still gaps in standards that allow information to be written back, as standard definitions may exist, but are interpreted differently.
- Reliability, accuracy, and integrity of data written back into the system
  - How is inaccurate information validated and rolled-back?
- Security of information being written into the record from third party apps and devices
- Data mapping/coding issues remain a significant barrier to broader acceptance and use:
  - What is the data to be written-back?
  - Where does the data go within the EHR or receiving system?
  - What types of data go into what types of resources and how are they coded?
  - How to manage local code or code set variation across organizations?
- Patient matching capabilities needed to write-back patient-provided or external data with the right patient record – typical EHR-based patient matching may not be sufficient.
  - Need for some manual workflow or reconciliation process before storing in the record.
- Need tools and functionality to manage new incoming data and analytics to support data management
  - What is the needed action by the organization or clinician based upon data written back?
  - What data is written-back as-is and what data requires review and interpretation?

Policy, Preference, or Data Use Concerns:

- Data ownership requires processes and policies for clearly defining patient and provider expectations concerning data provenance and information flows in the EHR
- Compliance with HIPAA Privacy Rule and considerations for written-back data
  - How to implement the “right to amendment” construct in a write-back scenario?
  - Does patient-provided or third-party data need to be part of the designated record set or legal medical record?
- Volume of data from multiple sources needs to be balanced with value and trust
- Regulatory and policy efforts are needed to support open APIs and adoption
  - Can a certification or validation process consider real world testing?
  - Should future health IT policy require write-back capabilities?
  - Are additional regulations required for patients, providers, developers or others?

FinTech Modular Approaches for Healthcare Data:

Data may not always need to be written back to the EHR. Participants asked how healthcare could support a modular approach, as discussed in the workshop’s FinTech session. Participants posed that some data

may not need to be written back to the EHR or other health IT system and could instead reside within the third-party app. The app could store the data and make the data available for presentation within the user-interface (e.g., EHR) to the end-user. As the third-party app may best understand the data that is collected outside of the EHR, it may also be best suited to present or visualize the data. A group posed whether this approach could be sufficient and recommended considering and identifying the scenarios where third-party storage of the data is not enough and true "write-back" to the EHR is needed.

The group proposed that the EHR could be considered as a single component of a modular platform, as suggested in the FinTech discussion. Just as the financial status of an individual may change over time, patients can be healthy at one point, but become sick over time. The group recommended thinking about health data in a way that does not use the EHR as the central component to a hub and spoke model. The group posed for consideration how to use the workshop's deep thinking about write and write-back to move towards a more modular system as presented during the FinTech discussion. With emerging healthcare APIs opening the EHR and shifting the system, with the use of third-party apps, a more modular approach is possible.

Considerations for Research vs. Clinical Care

Workshop participants highlighted differences between clinical and research operations. The data sources for decentralized clinical trials (e.g., sensors, wearables, apps, direct data capture) are not interoperable, and none of the systems in use have the ability to write back, although some will pull data from the EHR.

In research, the organization who controls the data flow and implementing controls for custody of the data can be very complicated. Managing this is "the opposite of low hanging fruit". Decentralized clinical trial data involves data that is collected by clinicians (who may be research investigators), clinical research coordinators, or home health care aides. In these scenarios, data is collected for research, not clinical purposes, and is typically not contained within the EHR, but in systems designed for the research study. However, there is clinically relevant data in these datasets. As the industry seeks improved access to patient data, there is an interest in bridging the research and clinical datasets.

Research tends to be more diverse in how information is represented. The path to obtain and store the data is currently unclear. There is interest in understanding how FHIR resources can be used to advance clinical research, to determine the types of standards that can be represented. For example, there are standards they may be in place for research that cannot be used within clinical systems. There are also unique challenges regarding rights to access or view the data as some trials are blinded and others are unblinded.

Potential Use Cases

Participants utilized the breakout discussion framework to initiate a list of recommended use cases to consider in advancing write-back APIs.

Use Case/Scenario Short Description	Data "Sent" to App	App Data to "Write-Back" to EHR	Technology Barriers or Challenges	Policy, Preference, or Data Use Concerns
Clinical: CHF patients that use Bluetooth-technology home monitoring, such as blood pressure monitors, weight, pulse oximeters – written back into the EHR, only signify abnormalities (structured, passive)	• N/A	• Only abnormalities go back to nurses and then doctor reviews • Care managers review • Data flows through Epic once the patient authenticates • Phone call from nurse or nurse practitioner (not everyone has patient portal) • API needs the parameters for priority	• Submits order in EMR - one for weight, blood pressure, and pulse-ox - generates a code, patient needs to put that code into a website with their last 4-SSN • Using open mHealth schema (software called Shimmer), GoogleFit, Granola • Georgia Tech wrote Open mHealth to FHIR • Combination of custom development (FHIR client) in Epic, use Epic's flowsheet row • Is this scalable to other orgs? • Standard needs to be for high value workflows • Barrier that not all patients have email or patient portal	• Care team reviews - needs guidelines, policies, procedures • Monitors are Wi-Fi - don't require phone • Need the context for the data to know how to trust it - provenance of data

Use Case/Scenario Short Description	Data "Sent" to App	App Data to "Write-Back" to EHR	Technology Barriers or Challenges	Policy, Preference, or Data Use Concerns
Clinical: Manually entered data (medication and reconciliation)	• Medication lists • Demographics for authentication • Fill history from Surescripts/ pharmacy data	• Correct medications, dosages, dates started/stopped to EHR	• Need a provenance "tag" • "Shared" list? • Multiple layers of metadata	• Double reconciliation from provider • Issues around integrity and truth of the data • Need the context for the data to know how to trust it - provenance of data • How to validate the information - who does this? • How do we know whether the person took it?
Clinical: "Shared Care Plan" for patients and providers to edit and communicate	• Providers / Clinical team • Encounter data	• N/A	• UCSDI has read only care plan resources	• Gives patient a stronger voice • Not every provider uses it • Workflows need to be updated so clinicians will use it • Multiple care plans for patients with chronic/complex conditions • Transparency and accountability
Clinical: Third party decision support application (e.g., supported by CDS Hooks) documenting its reasoning and recommendation or a machine-learning app involved in a decision	• Major changes in condition; life information	• N/A	• N/A	• Major changes in condition • Life information

Use Case/Scenario Short Description	Data "Sent" to App	App Data to "Write-Back" to EHR	Technology Barriers or Challenges	Policy, Preference, or Data Use Concerns
Patient: Consumer-Write Back (e.g., SDOH screening)	• Patient-generated • School/ workplace-generated • Care coordinator/MSW data	• N/A	• Patient write-back might be easier, may or may not be stored in a certain place of the EHR	• Patients are in the best position to describe their SDOH factors and important to reduce health disparities (applicable to patient visit app, as well). • Two challenges with SDOH: 1) Data is in the FTE space (incentivized to keep the data) and Data sharing between health and health care. 2) Low-hanging fruit: Present data in the EHR and verify it is correct with the patient instead of asking the questions again.
Patient: Visit app (issues to discuss)	• Medication data and symptoms severity	• Could catch this data for review in EHR (reviewed by care management team)	• Data is often unstructured • Unstructured data may be helpful for medication compliance (side effects, brain fog, etc.)	• N/A
Patient: Message your Provider and Scheduling app	• Unstructured Message: general message with what you want your provider to know prior to your visit	• N/A	• Existing APIs may not be useful for those with guardians or with caregivers acting on their behalf (data sharing via password sharing) • Questionnaire and Task resources (may not be standardized in EHRs yet)	• Can be done in portal • Low-hanging fruit • Already exists in portals but it isn't in APIs • Could be tied to the scheduling app

Use Case/Scenario Short Description	Data "Sent" to App	App Data to "Write-Back" to EHR	Technology Barriers or Challenges	Policy, Preference, or Data Use Concerns
Devices: Patient Remote Monitoring	• Blood pressure, glucose monitoring • Data directly from a device	• Vitals • Glucose	• Decision support might see a new weight – could cause challenges • Accept metadata associated with the data being written in	• Who is the receiver of the data? That will set expectations for the patient • Separate the data from the workflow
Research, Patient: COVID "long-haulers" use case (Patients share symptoms to the system of record or to/from research)	• N/A	• Vaccination status • Testing lifecycle • Data sitting in the "holding tank"	• Healthcare system resistance to manage the record • Provenance & liability for the health system because it's coming from an "unconfirmed" source (What is my liability for receiving this data? (Failure to act, etc.)) if data is automatically filed • Accuracy and quality of data • Data definition, mapping to field in EHR, change management	• Patient aggregated and mediated data • Policy to address the provenance and liability issues • Setting expectations via an accountability framework (how will the data be used, when will it be used, etc.)

Use Case/Scenario Short Description	Data "Sent" to App	App Data to "Write-Back" to EHR	Technology Barriers or Challenges	Policy, Preference, or Data Use Concerns
Research: Data collected via "Research" activity, but is deemed relevant to the clinical record and should therefore be written into the record	• Through a portal (additional / derived data that makes its way back into the record) - at level of patient • Through a portal (additional / derived data that makes its way back into the record) - at aggregate level • How about genomics/genetic data? Including data coming from sources such as 23andMe, ancestry, etc. • Sync4Science/ Sync4Genes work	• Clinical trial management data system (many being developed) • PRO type solutions managed by patients/ participants	• Discrete field does not exist (or it can't be matched) so where does it get filed	• Flexibility should be coming from the patient level • Standardization of fields that need to be more fixed (concept of extensions to accommodate those that don't fit into the standard)

CONCLUSIONS

This workshop collected perspectives and lessons learned from over 70 individuals across technology developers, researchers, health IT developers, industry SMEs, providers, life sciences, industry experts, and government. Experiences in widespread adoption of write-back APIs outside of health care, such as the financial services industry, provide useful insights for the health care industry to consider in its policy and technology advancement activities for write-back APIs.

Future considerations:

- Engagement and principles development from experts to participate in TEP activities;
- Additional workshops to further investigate and identify use cases and the related standards, policy, and regulatory factors that could provide a useful foundation for expansion efforts;
- Coordination with Standards Development Organizations (SDOs) such as HL7®;
- Analysis of write-back privacy, security, policy, and regulatory considerations;
- Expanding outreach and engagement of FinTech to conduct a TEP, workshop, and/or develop a policy and technology recommendations report; and
- API advancement projects including funded LEAP pilots, development of implementation guides, and addressing standards gaps.

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Appendices

APPENDIX A – WORKSHOP AGENDA

11:00 am – 11:05 am	**WELCOME AND INTRODUCTIONS**	**Kevin Chaney**, *MGS,* Senior Program Manager, *ONC*
11:05 am – 11:15 am	**OPENING REMARKS**	**Micky Tripathi**, *PhD, MPP, National Coordinator for Health IT, ONC*
11:15 am – 11:30 am	**API CURRENT STATE FROM ONC PERSPECTIVE**	**Steve Posnack,** *MS, MHS, Deputy National Coordinator,* and **Kevin Chaney**, *MGS, Senior Program Manager, ONC*
11:30 am – 11:55 am	**PGHD / RESEARCH PERSPECTIVES**	**Patricia Flatley Brennan**, *PhD, Director, National Library of Medicine*
11:55 am – 12:20 pm	**TECHNOLOGY PERSPECTIVES**	**Josh Mandel**, *MD, Chief Architect, SMART Health IT / Microsoft Health*
12:20 pm – 12:45 pm	**PROVIDER PERSPECTIVES**	**Ben Orwoll,** *MD, MS, FAAP, FAMIA, Assistant Professor, Oregon Health & Science University*
12:45 pm – 1:15 pm	**BREAK**	*ALL*
1:15 pm – 1:40 pm	**PATIENT PERSPECTIVES**	**Donna Cryer,** *JD, President and CEO, Global Liver Institute*
1:40 pm – 2:05 pm	**FINTECH PERSPECTIVES**	**Markos Zachariadis,** *PhD***,** *Professor, FinTech & Information Systems, University of Manchester*
2:05 pm – 2:10 pm	**BREAKOUT INSTRUCTIONS**	*ALL*
2:10 pm – 2:30 pm	**BREAK**	*ALL*
2:30 pm – 3:30 pm	**POLICY AND TECHNICAL BREAKOUT SESSIONS**	*ALL*
3:30 pm – 4:00 pm	**BREAK**	*ALL*
4:00 pm – 4:45 pm	**FACILITATED REPORT OUTS FROM BREAKOUT SESSIONS & DISCUSSION**	**Anita Samarth**, *Clinovations GovHealth*
4:45 pm – 5:00 pm	**WRAP-UP AND CLOSING**	**Kevin Chaney / Steve Posnack**, *ONC*

APPENDIX B – PARTICIPANT LIST

Workshop Attendees

Lou Anne Alexander, MBA, Chief Product Officer, Early Warning

Brian Babb, MBA, Senior Business Development Executive of Open Platforms, Cerner Corporation

Dixie Baker PhD, MS, MS, FHIMSS, Senior Partner, Martin, Blanck, & Associates

Lisa Bari, MBA, MPH, Interim CEO, SHIEC

Ricky Bloomfield, MD, Clinical and Health Informatics Lead, Apple Inc.

Paula Braun, MS, Entrepreneur in Residence, Centers for Disease Control and Prevention

Tres Brown, Clinical Systems Integration Engineer, Duke University Health System

Scott Cannon, Senior IT Consultant, Duke University Health System

Amy Cramer, MMCi, RN, BSN, CPHQ, Global Product Development Strategic Partnerships - Pfizer; Co-Chair, Vulcan

Donna Cryer, JD, CEO and President, Global Liver Institute

Lorraine Doo, MPH, Senior Policy Advisor, CMS

Peter Embi, MD, MS, President / CEO, Regenstrief Institute

Patricia Flatley Brennan, PhD, Director, National Library of Medicine

Larry Garber, MD, Medical Director for Informatics, Reliant Medical Group

G. Scott Gordon, PhD, Senior Health Informatics Officer, FDA

Dan Gottlieb, MPA, Clinical Informaticist and Software Architect, Central Square Solutions / Boston Children's Hospital / Harvard Medical School

Laura Heermann, PhD, RN, Intermountain Healthcare

Ryan Howells, MHA, Principal, Leavitt Partners and the CARIN Alliance

Sabrina Hsueh, PhD, Data Science Lead, IBM Watson Research

Susan Hull, MSN, RN-BC, NEA, FAMIA, AMIA Public Policy Committee

Brendan Keeler, Product Manager, Zus Health

Edwin Lomotan, MD, Physician and Chief of Clinical Informatics, Agency for Health care Research and Quality

Virginia Lorenzi, MS, CPHIMS, Senior Technical Architect, NewYork-Presbyterian Hospital

Josh Mandel, MD, Chief Architect, SMART Health IT / Microsoft Health

Kenneth Mandl, MD, MPH, Physician, Director, Computational Health Informatics Program, Boston Children's Hospital; Professor, Harvard University

Brett Marquard, President, WaveOne Associates

Kristen Miller, MSL, MSPH, DrPH, CPPS, Scientific Director, MedStar Health

Alexandra Mugge, MPH, Deputy Chief Health Informatics Officer, CMS

Milind Nagnur, MBA, Chief Technology Officer, Early Warning

Viet Nguyen, MD, Founder, Stratametrics

Benjamin Orwoll, MD, MS, FAAP, FAMIA, Assistant Professor, Oregon Health & Science University

JP Pollak, PhD, Co-Founder and Chief Architect, the Commons Project; Senior Researcher in Residence, Cornell Tech

Amelie Ramirez, DrPH, MPH, Professor and Chair, Department of Population Health Sciences, University of Texas Health Science Center, San Antonio

Sumit Rana, Senior Vice President, Epic

Kathryn Sheridan, MS, Health Systems Analyst, MITRE

Kristina Sheridan, MS, Department Manager, VA Health, MITRE

Ida Sim MD, PhD, Physician, Professor of Medicine / Co-Founder, UCSF / Open mHealth

Victoria Tiase, PhD, RN-BC, FAMIA, FAAN, Director, Research Science, New York – Presbyterian Hospital

Emily Webber, MD, FAAP, FAMIA, Chief Medical Information Officer, Indiana University Health and Riley Children's Health

Scott Weinberg, MPP, Public Policy Specialist, AMIA

Ken Wiley, PhD, Program Director, National Human Genome Research Institute

Doug Williams, MBA, Chief Product Officer, 1upHealth

Tamara Winden, PhD, MBA, FAMIA, FHIMSS, Chief Research Informatics Officer, Assistant Professor, University of Kansas Medical Center

Markos Zachariadis, PhD, Professor, FinTech & Information Systems, University of Manchester

Office of the National Coordinator for Health Information Technology Participants

Elise Sweeney Anthony, JD, Executive Director, ONC

Wesley Barker, MS, Program Analyst, ONC

Kevin Chaney, MGS, Senior Program Manager, ONC

Allison Dennis, PhD, AAAS Science and Technology Policy Fellow, ONC

Mera Choi, JD, MPP, MPM, Division Director, ONC

Kyle Cobb, MS, Branch Chief, ONC

Andrew Gettinger, MD, Chief Clinical Officer, ONC

Christian Johnson, MPH, Public Health Analyst, ONC

Stephen Konya, Senior Advisor, ONC

Michelle Kost, Senior Advisor, ONC

Steven Posnack, MS, MHS, Deputy National Coordinator, ONC

Renee Rookwood, MS, RN, ONC Coordination Lead, MITRE

Talisha Searcy, MPA, MA, Deputy Director, ONC

Avinash Shanbhag, MS, MS, Acting Director, ONC

Micky Tripathi, PhD, MPP, National Coordinator, ONC

Clinovations GovHealth Participants (Contractor Staff)

Moha Desai, MBA

Crystal Kallem, RHIA, CPHQ

Nicole Kemper, MPH

Kim Klein, CPHIMS, SHIMSS, CCSFP

Rocio Payne, RN, MHA

Anita Samarth

Casey Thompson, MSN, RN-BC

APPENDIX C – AVAILABLE API FUNCTIONS BY FHIR RESOURCE

Resource Name	athenahealth (DSTU2)				Allscripts (DSTU2)				Cerner (R4)				eCW (STU3)		Epic (R4)				NextGen (R4)	
AllergyIntolerance	Read	Search			Read	Search			Create	Read	Update	Search	Search		Create	Read	Search		Read	Search
Appointment	Create	Read	Update	Delete					Create	Read	Search	Patch								
CarePlan	Read	Search			Read	Search			Read	Search			Search						Read	Search
Condition	Read	Search			Read	Search			Create	Read	Update	Search	Search		Create	Read	Search		Read	Search
Device	Read	Search			Read	Search			Read	Search			Search		Read	Search			Read	Search
DiagnosticReport	Read	Search			Read	Search							Search		Read	Search			Read	Search
DocumentReference	Read	Search			Create	Read	Search		Read	Search			Search						Read	Search
Encounter	Create	Read	Update	Delete	Create	Read	Delete	Search	Create	Read	Search	Patch	Read		Read	Search			Read	Search
Goal	Read	Search			Read	Search							Search		Read	Search			Read	Search
Immunization	Read	Search			Read	Search			Create	Read	Update	Search	Search						Read	Search
Medication	Search				Read	Search									Read					
MedicationOrder	Read	Search			Read	Search														
MedicationRequest					Read	Search			Create	Read	Search		Search		Read	Search			Read	Search
MedicationStatement	Read	Search			Read	Search							Search						Read	Search
Observation	Read	Search			Read	Search			Create	Read	Search		Read	Search	Create	Read	Update	Search	Read	Search
Organization	Search				Read	Search			Create	Read	Search				Read				Read	Search
Patient	Read	Search			Read	Search			Create	Read	Search	Patch	Read		Create	Read	Search		Read	Search
Practitioner	Search				Read	Search			Create	Read	Search		Read		Read	Search			Read	Search
Procedure	Read	Search			Read	Search	Update		Create	Read	Search		Search		Read	Search			Read	Search
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