

EMPOWERING INDIVIDUALS THROUGH INTEROPERABLE MEDICATION LISTS

EFFORT SUMMARY THROUGH DECEMBER 2016

Office of the National Coordinator for Health Information Technology
Office of Standards and Technology

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Overview and Effort Focus

Over the past eight years, the Office of the National Coordinator for Health Information Technology (ONC), in collaboration with federal partners and the private sector, has ushered in an era of widespread health IT adoption and use throughout the country.

As a result, nearly every hospitalization and most doctors' visits now have a digital footprint, and an extraordinary amount of electronic health data exists that simply didn't just a decade ago.

This historic advancement sets the stage to transition our focus to the seamless and secure sharing of health information to improve the health and care of individuals and communities.

Specifically, these advancements lay the groundwork for progress on a range of national health priorities, including:

- The Cancer Moonshot
- Delivery System Reform
- Combating the Opioid Epidemic
- The Precision Medicine Initiative
- Protecting and Advancing Public Health

To achieve the goal of seamless and secure flow of information, we squarely focused on:

- Promoting common, federally-recognized standards
- Building the business case for the flow of electronic health data
- Changing the culture around access to health information

In order to continue advancement of these efforts, earlier this year ONC developed a shared commitment to health information exchange through the [Interoperability Pledge](#). This pledge includes companies that provide 90% of electronic health records nationwide, as well as many of the largest health systems in the country. This partnership requires working in collaboration with federal partners, states, consumers and the private sector. Central to this pledge are three core commitments:

Consumer Access:

- Help consumers easily and securely access their electronic health information
- Direct their electronic health information to any desired location
- Provide assurance that their information will be effectively and safely used to benefit their health and that of their community

No Blocking/Ensuring Transparency:

- Help providers share individuals' health information at the their request whenever permitted by law:
 - to other providers
 - directly to the patient making the request for their information
- No blocking of electronic health information (defined as knowingly and unreasonably interfering with information sharing)

Standards:

- Implement federally recognized, national interoperability standards, policies, and guidance for electronic health information
- Adopt best practices including those related to privacy and security

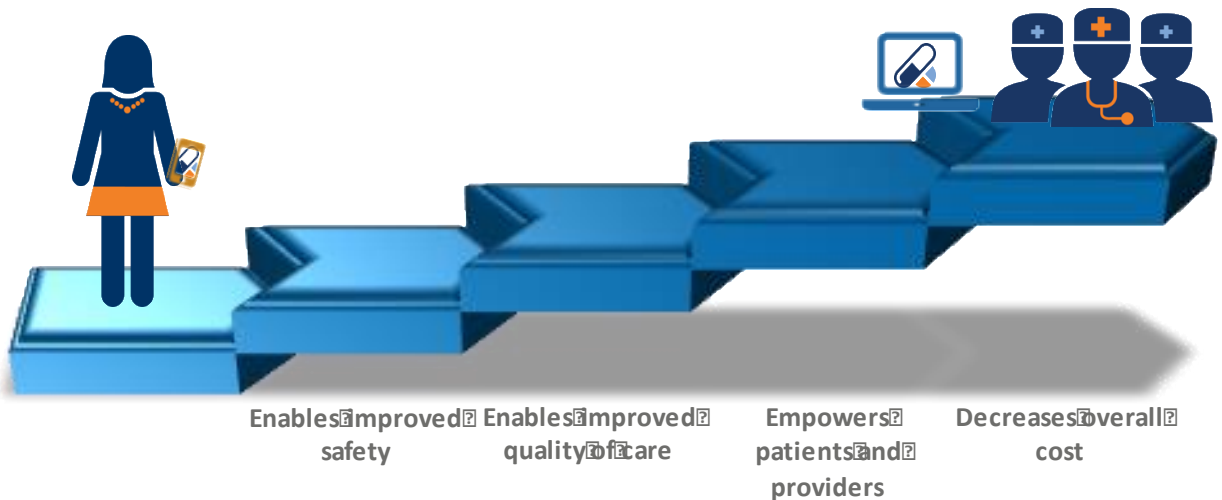
Effort Vision: The Empowering Individuals through Interoperable Medication Lists Effort focuses on making medication lists from multiple sources accessible to patients in an interoperable way. Any patient should be able to access their current medication list conveniently and comprehensively, for any purpose they choose, from any provider or health care entity that has provided care to them. Leveraging existing standards to achieve this goal is key to the effort.

Effort Goals

- Empower people to access a comprehensive list of their medications for any purpose, from any doctor or health care organization where they receive care in a form that is easy to view, manage, store and share.
- Use existing standards and infrastructure. Reuse rather than reinvent.
- Enable and demonstrate the ability to represent medications:
 - From multiple sources (e.g., providers, institutions, EHR vendors), and
 - From multiple types of sources (e.g. EHR orders/Rx, dispense records, patient reported medications).
- Demonstrate interoperability from at least two different source systems outside of the native EHR system.

Core Use Case

Empowers patients to access and manage their medication list collaboratively with their doctors.



Effort Approach

Engagement of Stakeholders: Participants included:

- Patients
- Consumer Advocates
- Health IT Developers
- Drug Knowledge Base Vendors
- Providers and Health Systems
- Pharmacy Systems
- E-Prescription Networks
- Payers
- Multi-Sector Alliances
- HIE Organizations
- Professional Associations
- Trade Associations
- Federal Partners

Based on interest and or expertise, participants worked collaboratively on one or more of three primary work streams. Works streams identified the use case, standards and privacy and security considerations for a patient accessible interoperable medication list. Each work stream met bi-weekly.

Usability and Workflow Work Stream:

- **Charge:** Develop the core use case and supporting workflows describing accessibility of the patient medication list in a way that is useful to the patient.

Standards and Technology Work Stream:

- **Charge:** Address the standards, APIs and design topics necessary for the requirements of the core use case. Identify and apply existing standards to meet requirements produced by the Usability and Workflow Work Stream.

Privacy and Security Work Stream:

- **Charge:** Address requirements relative to permission to release or share PHI data.

Broad Stakeholder Participation

The table below provides a listing of all the stakeholders participating in this effort.

| | | |
|---|---|---|
| American Association of Nurse Practitioners (AANP) | Dartmouth Hitchcock Health | National Community Pharmacists Association (NCPA) |
| American College of Physicians (ACP) | Duke | National Partnership for Women and Families |
| American Hospital Association (AHA) | Electronic Health Record Association (EHRA) | New York Presbyterian Health System |
| Allscripts | EOU.S. Digital Service | Oracle |
| American Medical Association (AMA) | Epic | Partners |
| American Medical Informatics Association (AMIA) | First Data Bank | Patients Like Me |
| American Nurses Association | Fresenius | Pharmacy Quality Alliance |
| Apex Data Solutions | GE Healthcare | Physicians EHR Coalition |
| Ascension Health | Geisinger Health System | Polyglot |
| American Society of Health-System Pharmacists (ASHP) | Get My Health Data | Praxify |
| athenahealth | Hackensack Meridian Health | Providence Health & Services |
| CareEvolution | Hospital Corporation of America (HCA) | PSMI Consulting |
| CARIN Alliance | Healthcare Information and Management Systems Society (HIMSS) | Qualcomm |
| Carolinas HealthCare System | Intermountain HealthCare System | Rite Aid |
| Cerner | Kaiser Permanente Managed Care Consortium | RxRevu |
| College of Healthcare Information Management Executives (CHIME) | Marathon Health | Surescripts |
| Centers for Medicare and Medicaid Services (CMS) | Marshfield Clinic | Trinity Health System |
| Clinovations Government Health | MediSafe | Walgreens |
| CommonWell Health Alliance | MEDITECH | WellSheet |
| CVS Caremark MinuteClinic | National Association of Chain Drug Stores (NACDS) | Wolters Kluwer Lexicomp/Medi-Span |

Proposed Technical Workflow

There were two alternative technical workflows proposed for consideration, primarily based on the way authorization and access control decisions are handled by the data sources.

- 1) Patient Directed
- 2) Patient Mediated

In the “Patient Directed” workflow, it is expected that technology present at the provider will be able to automatically identify the provider locations where medication information is present, while in the “Patient Mediated” workflow, the individual identifies the provider locations where medication information is present.

- Both workflows are based on the [FHIR API Standards](#) and [OAuth authorization workflow](#) adopted by the [Argonaut Project](#), which is also being used by participants in other initiatives including [Sync for Science](#). The “Patient Directed” workflow provides additional enhancements by requiring support for key capabilities such as Single Sign-On using [OpenID Connect Framework](#) and cross-organization exchange using the [Cross-Organization Data Access Profile](#) which are on the roadmap of the health IT developer community.

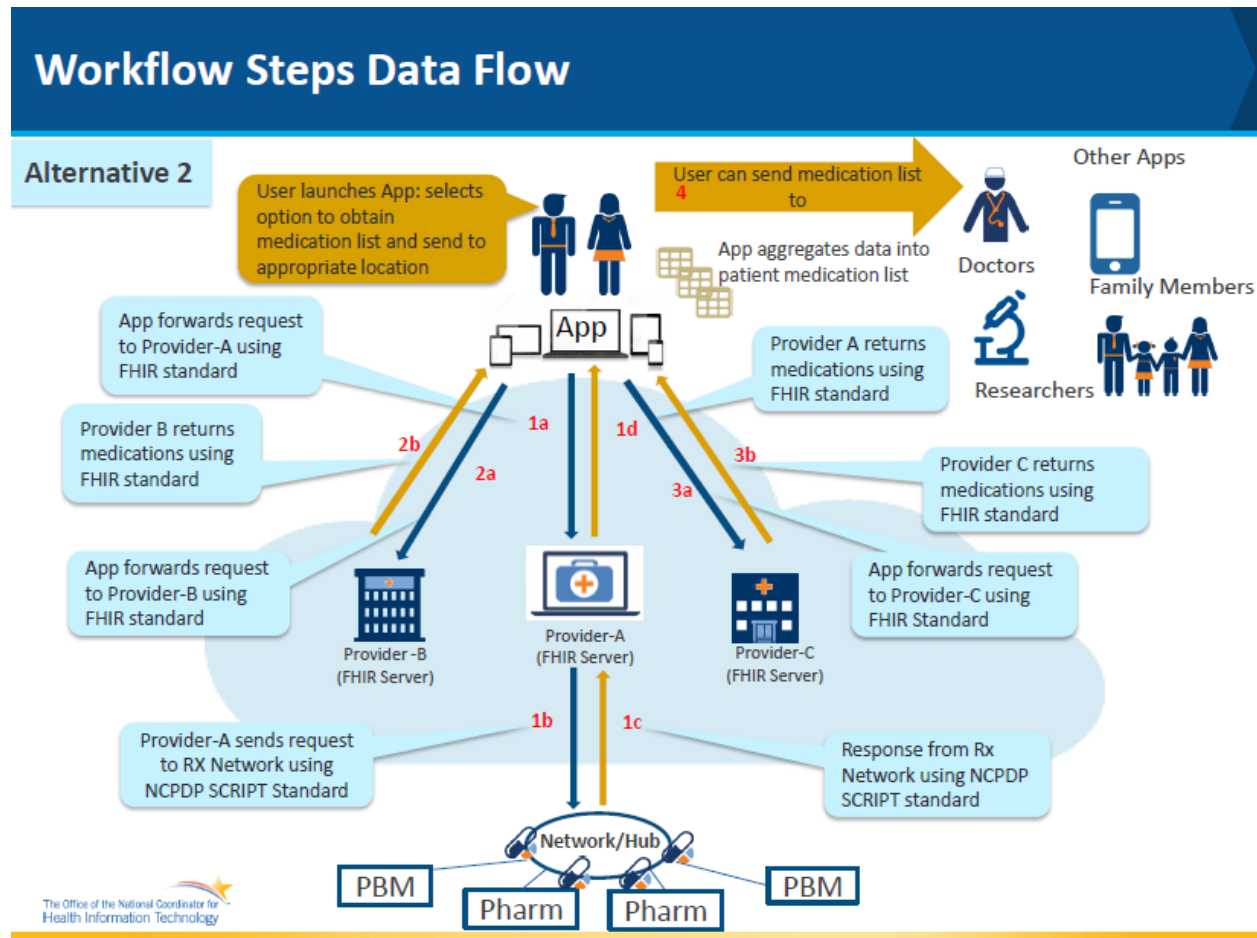
Additionally, a “hybrid” workflow is possible. The Hybrid workflow presents an ecosystem of co-existing functionality where participants develop the “Patient Directed” approach with some partner systems, while possibly still using the “Patient Mediated” approach for other systems.

All workflows require access to the e-prescription networks, to ensure that the individual receives a complete list of medication information. The workflows assume that the individual’s medication information will be limited to the organizations that are participating in the proof of concept.

Although, participants acknowledged the benefits and efficiency that a Patient Directed workflow (“Alternative 1”) could offer, the Patient Mediated workflow (“Alternative 2”) was selected for implementation due to limitations of current technical capability and existing privacy/security access frameworks. We present the Patient Mediated, Alternative 2, below.

Workflow Actors

- User: Patient wanting her medication list
- App: Application making request on behalf of user
- Provider-A: FHIR based Health IT system to which the App makes the request. Provider A has established trust relationship with the App (E.g. App is native on the provider A’s health IT system)
- Provider-B: FHIR based Health IT system that enables users and trusted partners to access individual’s medication data
- Provider-C: FHIR based Health IT system that enables users and trusted partners to access individual’s medication data
- Network/Hub: e-prescription network that is connected to Pharmacy Benefit Managers and Pharmacies



Patient Perspective Roundtable

ONC convened a patient perspective listening session to gain a better understanding of the information patients and caregivers want to see and how they would like to use a medication list. Key feedback from the patient perspective roundtable are listed below:

1. Use a simple, usable format with language and terms that can be easily understood.
2. Provide a centralized, master medication list for management.
3. Allow for an interactive medication list, so that the patient may add/provide feedback.
4. Include alerts as part of the functional features of medication list management for drug-drug interactions, contraindication warnings, and dose warnings.
5. Allow for communication between users including the patient, primary care provider, pharmacist, and all other providers (i.e. specialists) to aid in the medication reconciliation process.
6. Provide clarity on dosing and instructions.
7. Support multiple levels of views for the medication list that allows for drill-down specificity (i.e. patients should be able to control the view to filter as needed such as viewing medications by the required date and time for dosages).

8. Remove barriers to allow caregiver access to the medication lists.
9. Educate physicians on the use of the medication list and the importance of incorporating the medication information into the patient's health records.
10. Provide a method for visualization that supports the patient to more easily identify the medications.
11. Include pharmacy records and pharmacy information so that patients and providers can identify and trace medications, as needed.
12. Use medication data to improve medication management approaches, research, and allow for community sharing and learning.
13. Include provider contact information (pharmacist, PCP, etc.) to discuss any issues and concerns (dosing, problems, etc.) .
14. Include patient goals within the medication list
15. Privacy Issue: Allow patients the ability to provide permissions for access to providers and caregivers. Ease the process and allow for more transparency across the healthcare continuum.
16. Privacy Issue: Provide balance between permissions for patients to restrict access to certain types of medications (e.g. mental health-related medications) and the associated safety issues/concerns by restricting access to this information.
17. Privacy Issue: Provide health plans access to medication lists for purposes of care coordination and care management.
18. Educate patients and providers on the effective and efficient use of the medication lists.
19. Understand and educate on the practicality of the medication list and provide a longitudinal view of what historically worked and what does not work.
20. Simplify the too complex HIPAA / regulatory process regarding privacy and security as it frequently poses unreasonable barriers.

Recommendations

As part of Final Recommendations, the ONC recognizes:

The following enhancements are part of the final recommendations for the future phases of the Empowering Individuals through Interoperable Medication Lists Effort. These recommendations are a result of unified efforts between the three effort work streams.

Workflow Enhancements

1. Implement workflows for real patients in a production environment preferably using workflow Alternative 1, but if necessary as an intermediate milestone using Alternative 2.
2. Implement Medication Dispense FHIR Resource to incorporate pharmacy dispense records.
3. Bidirectional updating/reconciliation workflow with provider (Patient Perspective Roundtable feedback).

Functional Features Enhancements

Implement priorities that were deferred during first phase:

1. Enhanced presentation features for the patient such as the ability to review dispense records (e.g., pharmacy records, claims, OTC and prescription).
2. Medication list should include contact information for who to discuss medication issues with (pharmacist, PCP, etc.) (Patient Perspective Roundtable feedback).

3. Enhanced patient input into their own medication list such as the ability to group medications, identify outcomes, adherence to medications, etc.
4. Contraindications (drug-drug, drug –disease, past side effects/reactions)
5. Receive notifications such as FDA warnings about a medication. Medication info accessibility at an understandable, useful level (Patient Perspective Roundtable feedback).
6. Reason for medication
 - a. How long it should be taken
 - b. How long it was taken
 - c. Ability to discontinue
 - d. Ability to record feedback on medication

Privacy and Security Enhancements

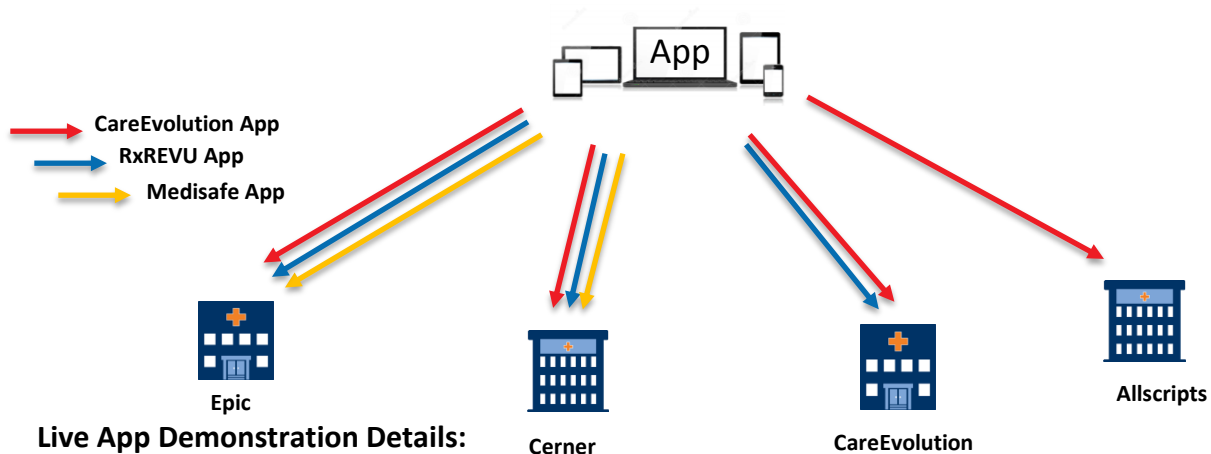
1. Establish a cross organization framework to support patient single sign-on workflows from third party applications.
2. Allow individuals to more easily provide permission to providers and caregivers (Patient Perspective Roundtable feedback)
3. Health plan accessibility to medication lists where it will be used for care coordination and care management

Demonstration December 2016

Live Proof-of-Concept App Demonstration: Bringing Interoperable Medication List to Consumers

On December 13th, 2016, at the Connected Health Conference hosted by the Personal Connected Health Alliance (PCHA), ONC, together with key stakeholders, conducted a live app demonstration. The demonstration showcased the ability to pull data from EHRs and allow an individual to access a consolidated medication list from multiple locations. FHIR-based solutions from EHR vendors Allscripts, CareEvolution, Cerner and Epic together with third party application vendors Medisafe, CareEvolution and RxRevu were used to demonstrate this functionality in vendor test environments.

Connecting to Sandboxes from Epic, Cerner, Allscripts, CareEvolution



The case of a hypothetical patient, Mary A, was used to demonstrate the functionality during the live event. In the scenario, Mary A is 78 years old, has had Epilepsy for over 20 years, hypertension, severe arthritis in both knees, asthma since childhood and mild depression that her daughter gives her St John’s Wort for. Mary is seen by three different physicians in three different clinics: Her primary care doctor, Dr. Prikar, her respiratory specialist, Dr. Respa, at DHH Respiratory Clinic , and her neurologist, Dr Synapz, at University Neurology Clinic.

Unfortunately, Mary’s longtime primary care physician is retiring and closing the office. Mary requested her medication lists from each of her current doctors. Mary wants to review them with her new primary care doctor, Dr. Aiker, tomorrow afternoon when she goes in for her first visit.

App developers successfully logged the patient into their application

App developers successfully connected to vendor test servers

App developers successfully consolidated the patient’s medication list into a single patient friendly view
 Each app developer showed additional features that a patient may like to use to assist in managing their care, such as adherence tools, appointment reminders or ability to search for coupons.

A list of the participating speakers and developers is provided below.

| Category | Organization | Panelist |
|------------|---------------|---|
| Speaker | ONC | Vindell Washington, MD, MHCM, FACEP National Coordinator ONC |
| EHR Vendor | Allscripts | Tina Joros , General Manager, Open Business Jeff Danford , Principal Software Engineer |
| EHR Vendor | CareEvolution | Vik Kheterpal, MD , Principal |
| EHR Vendor | Cerner | Tate Gilchrist , Senior Business Developer |
| EHR Vendor | Epic | Janet Campbell , VP Patient Experience |
| App Vendor | CareEvolution | Vik Kheterpal, MD , Principal |
| App Vendor | Medisafe | Omri Shor , Founder and CEO |
| App Vendor | RxRevu | Peregrin Marshall , CTO |

Patient-Provider Perspective Panel Discussion:

As part of the demo, a panel of providers, payers and patients discussed how FHIR-based solutions could be deployed as early as 2017 to enable individuals to access their medication information. A list of the participating panelists is provided below.

| Category | Organization | Panelist |
|-----------------|----------------|--|
| Moderator | ONC | Vindell Washington, MD, MHCM, FACEP National Coordinator for HIT |
| Payer | Anthem | Ashok Chennuru Staff Vice President |
| Provider/Health | Trinity Health | Taha Kass-Hout |

| | | |
|-------------------------------|---|--|
| System | | SVP and Chief Digital Intelligence Officer |
| Provider/Health System | New York Presbyterian Hospital | Victoria Tiase, MSN, RN-BC Director Informatics Strategy |
| Consumer Advocate | National Partnership for Women and Families | Mark Savage Director Health IT Policy and Programs |

Press Highlights and Media Clips

The live proof-of-concept app demonstration generated positive national media coverage. The press highlights, media clips and links are provided below.

Photos from the Medication List demonstration at the PCHA Connected Health Conference are posted on [Flickr](#).

“Health IT companies prove commitment to interoperability” (The Hill Extra). A group of healthcare services and IT vendors said they kept a pledge made to the government earlier this year to improve patient access to information by allowing their systems talk to each other. Allscripts, CareEvolution, Cerner Corp. and Epic Systems — which represent the largest electronic health record (EHR) vendors in the country — worked together to create applications to allow consumers to manage multiple medications from different providers. Applications created by CareEvolution, Medisafe and RxRevu, which were demonstrated at the Connected Health Conference, allow patients to amend their drug list and set up reminder alerts; signal potential conflicts; flag providers that may not know the patient is on a drug; share medication information with outside caregivers; and find lower cost alternatives. The Office of the National Coordinator for Health Information Technology (ONC) heralded the applications as evidence of the benefit of common data standards, namely the Fast Healthcare Interoperability Resources (FHIR). ONC has been encouraging the use of FHIR, which are a set of technical standards that developers can use to ensure health IT products communicate with each other. Earlier this year, the companies and others pledged to implement three core commitments toward advancing interoperability, one of which was to help patients easily and securely access their health information, and direct it to any location.

“Cerner, chief competitor calls truce for integrated medication app” (Kansas City Business Journal). Cerner Corp. and its competitor, Epic Systems, both will be compatible with a new medication management app, which will make it easier for patients to keep track of their medications and help doctors make sure prescriptions are followed. Boston-based Medisafe serves 3.5 million patients through its existing application. The app already can pull patients' medication information from CVS and Walgreens, but it soon will be able to connect with participating electronic health record (EHR) systems, including those from Cerner and Epic. [Read Full Article Here](#) (Elise Reuter 12/15/2016)

“Demo shows FHIR can enable exchange of patient med information” (Health Data Management). Four health information technology vendors on December 13 successfully demonstrated use of the Fast Healthcare Interoperability Resources (FHIR) data exchange standard to import data into electronic health records systems, then enable healthcare consumers to access a consolidated list of their medications. The vendors included Allscripts, CareEvolution, Cerner and Epic. They transmitted third-party applications for consumers created by CareEvolution, Medisafe and RxRevu. Through discussions

that originated this past June, these vendors and others discussed ways to use patient apps to enable consumers to request their medication information from their providers, says Tricia Lee Wilkins, pharmacy advisor and health IT specialist in the Office of the National Coordinator for Health Information Technology, which coordinated the demonstration. [Read Full Article Here](#) (Joseph Goedert 12/14/2016)

“ONC Celebrates FHIR-Powered Interoperability Demonstration” (Health IT Interoperability). The Connected Health Conference at National Harbor in Maryland was the site of a recent demonstration of Fast Healthcare Interoperability Resources and its ability to enable health data liquidity. The Office of the National Coordinator for Health Information Technology along with EHR vendors Allscripts, Cerner Corporation, and Epic Systems took part in a live demonstration of consumer applications that import data from health IT systems using the set of technical specifications and application programming interface that make up FHIR. “We are incredibly encouraged by the advances our private sector partners have made to unlock data and empower individuals when it comes to accessing their medication information,” National Coordinator Vindell Washington, MD, MHCM, said in a public statement. “This is just the latest example of the health IT progress and infrastructure that has resulted from public-private collaboration over the past eight years to improve the health and care of individuals and communities.” [Read Full Article Here](#) (Kyle Murphy 12/14/2016)

“ONC partners demonstrate FHIR in action” (Mobihealthnews). National Coordinator Dr. Vindell Washington may have been dealt a relatively short stint in the role, but he’s set on doing as much as he can in the time he has to advance to ONC’s interests of data sharing and interoperability. Washington was on hand at the Connected Health Conference this week in National Harbor, Maryland to show off a demonstration of the FHIR (Fast Healthcare Interoperability Resources) protocol in action. In a Tuesday afternoon session with Epic, Allscripts, and Cerner, startups Medisafe, RxRevu, and CareEvolution all showed off their own FHIR-based apps that pulled data from EHRs to deliver an updating, de-duplicated medication list to a patient. The demonstrations were the culmination of a project begun at the HIMSS Annual Conference in February. [Read Full Article Here](#) (Jonah Comstock 12/14/2016).

“App Demonstration of Connected Health Conference Shows Promise of FHIR” (Healthcare Informatics). At the annual Connected Health Conference this week, the Office of the National Coordinator for Health Information Technology (ONC), in partnership with leaders in the private sector, as well as patient and consumer advocates, coordinated a live demonstration of apps that import health IT vendor data to allow individuals to access a consolidated list of their medications from a variety of sources in one place. According to officials, the demonstration illustrated the promise of Fast Healthcare Interoperability Resources (FHIR)—a set of private sector technical standards developed with the strong support of ONC. The live demonstration at National Harbor in Maryland illustrated how data from Allscripts, CareEvolution, Cerner Corporation, and Epic—which represent the largest electronic health record (EHR) vendors in the country—could be transmitted to user-friendly, third-party applications, created by CareEvolution, Medisafe and RxRevu using FHIR. [Read Full Article Here](#) (Rajiv Leventhal 12/15/2016)

“Feds recognize innovative new consumer and provider apps”: Having challenged software developers to design apps to help consumers easily collect and integrate their health data from disparate providers and IT systems, and offer apps to physicians that expand use of electronic health records, the Office of the National Coordinator for Health Information Technology now has picked the winners. “We are thrilled to recognize new tools that make it easier for individuals and clinicians to access health

information and put it to use,” Vindell Washington, MD, who just resigned as national coordinator for health information technology, said in a statement. [1/18/2017] [Read Full Article Here](#) (Joe Goedert 01/18/2017)

Future Planning

ONC looks forward to working with stakeholders in 2017 to build upon the success of this effort.

Key Staff

Vindell Washington, National Coordinator and Executive Sponsor
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Anastasia Perchem, Standards and Technology
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Tricia Lee Wilkins, Standards and Technology