

Blue Button and My HealtheVet

Progress Update — White Paper

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Introduction

On August 2nd, 2010, President Obama spoke at the Disabled American Veterans Conference in Atlanta, Georgia and introduced Veterans to the "Blue Button":

"And today – today I can announce that for the first time ever, Veterans will be able to go to the VA website, click a simple 'blue button,' and download or print your personal health records so you have them when you need them and can share them with your doctors outside of the VA."

(Watch the remarks at 24 min 13 sec.)

Later in the fall of that year on the 7th of October, the White House announced the availability of Blue Button for Veterans through My HealtheVet, the Department of Veterans Affairs' personal health record for now over two million Veterans who receive care at VA. Since then, more than one million VA patients have downloaded a summary of their health record over 6.7 million times. While initially limited to Veterans and Medicare beneficiaries, the success of Blue Button sparked a national campaign in 2012 through the Office of the National Coordinator for Health Information Technology (ONC) at the Department Health and Human Services (HHS) with the goal of making Blue Button available to all Americans. Around that same time, the first class of Presidential Innovation Fellows (PIFs) were being welcomed by White House Chief Technology Officer, Todd Park. Three fellows would work with VA and HHS to accelerate the Blue Button for America project, helping "spread the ability for millions of Americans to easily and securely download their own health information electronically." In February of 2013, the second class of innovation fellows was announced to continue this cross-disciplinary work across government to drive consensus on policy and technology, and more closely collaborate with private industry to help realize a healthcare industry where patient data is digitally accessible and shareable.

Blue Button is now a movement comprised of many dedicated public servants and stakeholders in the federal government and beyond. The challenges and opportunities that surround Blue Button can be explored from many viewpoints, however this document is primarily written from the perspective of the 2nd class of Blue Button Presidential Innovation Fellows. The goal is to provide an overview of our progress, where we've been, and what might come next as our community develops a vision and strategy for patient empowerment through access to personal health data.

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¹ See attachment [A], "Cross-Agency Blue Button Common Core Metrics for April 2014"

Blue Button at Dept. of Veterans Affairs

For Veterans, Blue Button is about freedom, the freedom to access their health information at anytime and anyplace, and to share that information with whomever they choose, whether it be a family member, caregiver, or non-VA provider or specialist. Since 2010, this ability has made a tangible difference in lives of thousands of veterans, like <u>Vietnam Veteran Randy Watson</u>. While we have made incredible strides, there is still much more we can all do to

provide Veterans with seamless access to their health information, and help empower them to live healthier and more fulfilling lives. Our Veterans deserve to benefit from the most innovative technology solutions and digital experiences our country can offer, and VA has the opportunity to lead the industry in the adoption and advancements of these innovations as the nation's largest healthcare provider.

The desire to provide Veterans with personalized, proactive, patient-driven health care is also described in the <u>Veterans Health Administration's (VHA) Strategic Plan</u>. My HealtheVet and Blue Button deliver on these goals and objectives.



The Patient in Health Information Exchange

Data is the lifeblood of healthcare, powering care decisions, clinical support, coding and billing, research and clinical trials, and care coordination. Clinical data today is primarily shared between regions and providers. A "regional information exchange," like New York's SHIN-NY or Massachusetts' Mass Hlway, is able to connect private practices, nursing homes, clinics, and hospitals to these information hubs and share patient data with other providers in the region, and perhaps between regions as well. If a Regional Health Information Organization (RHIO) doesn't exist, providers may exchange clinical data directly.



Too often in healthcare today, the patient isn't directly involved when their health information

being exchanged, or at best they are an afterthought. A "consumer information exchange" puts the patient at the center of the network with direct access to their personal health data. They may interact at the provider or regional level, but in either case, they are in control of their information.



Blue Button is all about the patient, so this type of exchange is of great interest to us. Our opportunity is to develop and coordinate the policies, standards, and technologies to enable consumer information exchange for Veterans and all Americans.

Moving Blue Button Forward

The first class of Blue Button Presidential Innovation Fellows at VA and HHS sought to take the initiative to all Americans, but also demonstrated how government can lead the way. In cooperation with ONC and other health IT stakeholders, they developed the Blue Button+ Implementation Guide using the Standards and Interoperability (S&I) Framework with input from more than 70 volunteer individuals and organizations. The implementation guide added policy and technical standards to Blue Button so data holders and receivers could take part in an emerging ecosystem of tools and applications powered by personal health data. It aligned with view, download, and transmit requirements of Meaningful Use Stage 2 (MU2), utilizing the Direct Project to achieve transmit functionality to third-party applications. The first class of fellows also outlined how VA could implement these standards to meet MU2 requirements and advance the state of Blue Button. This guidance was captured in the "VA Blue Button Direct: Process Flows and Use Cases" presentation.² My HealtheVet, VLER Health, and Humetrix collaborated through 2013 to implement the transmit use cases described in this document. The fellows also explored how this new functionality could impact the patient experience, especially when viewing their health data. They launched the Health Design <u>Challenge</u> asking designers from across the country to reimagine the patient health record. Sample patient data from VA was provided with four design objectives:

1. Improve the visual layout and style of the information from the medical record.

² See attachment [B], "VA Blue Button Direct: Process Flows and Use Cases"

- Create a human-centered design that makes it easier for patients to manage their health.
- 3. Enable health professionals to more effectively understand and use patients' health information.
- 4. Help family members and friends care for their loved ones.

Over 230 teams responded with several winners selected in the categories of best overall design, best medication design, best problem/medical history, and best lab summaries. The challenged helped VA understand the many possible ways to present health data to patients more effectively, along with demonstrating how to work with an external community of engaged healthcare innovators to generate ideas and solve collective problems. At the conclusion of the competition, fellow Ryan Panchadsaram gave a talk at TEDMED summarizing the challenge and the opportunity in empowering patients with their health data at large.

Most recently, the second round of PIFs continued to push Blue Button forward by growing the national campaign, inviting industry partners to support and participate in the initiative, and add rigor to the definition of Blue Button regarding policy and technology to support viewing, downloading, sending, and connecting a personal health records to apps. We also engaged developers, providing them with open-source software tools, documentation, specifications, and other resources to help them create applications and services that use personal health data.

Defining Our Challenges

The first class of PIFs, along with their agency partners and stakeholders, left Blue Button with a solid foundation to build upon. The desire to then define and implement new digital experiences informed by the Health Design Challenge, add more robust exchange capabilities, and grow an application ecosystem introduced all-new complexities and increased demands on stakeholders.

In order to advance Blue Button where patients would have seamless access to their health information and be empowered to live healthier and more fulfilling lives, we first needed to define our challenges ahead, particularly that of building consensus. The brilliance of Blue Button has always been the leveraging of existing policies, standards, and technologies, while only resorting to creating new ones if no appropriate ones existed. While there are many advantages to that approach, the primary concern would then be consensus. For example, healthcare is polluted with dozens of standards for clinical documents; many policies exist to govern trust, but no one policy solves all concerns for every organization, public or private; technologies that permit secure transmission of health data are suitable for some use cases but not others. Even the branding and naming of these methods of exchange proved to be contentious at times. The "BB+ Priorities" document is an example of the work that was done to drive consensus on these issues.³

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³ See attachment [C], "BB+ Priorities"

Understanding how we could build consensus was a primary goal of the second class of PIFs. We wanted to more deeply understand what this new functionality meant for all involved, and what the right combination of policy, standards, and technology might be for those organizations willing to participate. We also didn't want to lose sight of the patient experience – the true indication of success would be if the user could seamlessly find and access their personal health information.

Expanding the Blue Button Community

An important strategy to resolve issues of consensus was to involve a larger community of stakeholders. Being aware that there was a risk involved to adding more voices to the conversation, we saw a big potential payoff in cooperation and collective problem solving.

At the national level, the White House Office of Science and Technology Policy organized the "My Data" initiative, part of the Administration's efforts to empower Americans with secure access to their personal data, and to increase citizens' access to private-sector applications and services that can be used to analyze their own data for a growing array of useful purposes. Blue Button at VA was the first major project as part of this initiative, where there are now other agencies like Department of Energy, Commerce, and Education who are helping citizens access their data and empower them with it.

Within Health and Human Services, we invited ONC's Federal Health Architecture (FHA) group to participate in the cross-agency Blue Button initiative. FHA was created as part of an executive order and established by the White House Office of Management and Budget as an E-Government Line of Business in 2004 with the goal of advancing the national agenda for health IT. FHA now works with over 20 federal partners in deep inter-agency collaboration resulting in effective health information exchange, enhanced interoperability among federal health IT systems, and efficient coordination of shared services. Traditionally, FHA workgroups have not directly been involved in consumer exchange, so it was a priority for us to introduce and involve them in these conversations as they shape the foundational government infrastructure to enable patients to access their health data. Implementing Blue Button-friendly policies, standards, and technologies across federal agencies is a considerable undertaking, and so FHA as a mediating body to help drive consensus and cooperation is invaluable, and a resource which should continue to be invested in.

VA and the Department of Defense (DoD) also continued to develop and implement interoperable capabilities to specifically support Blue Button, much of which is described in the attached "IPO Accelerator Task 1.4". As the DoD/VA Interagency Program Office (IPO) concluded their work on this task, the office was dissolved with no further tasks assigned. However, some uncoordinated work continues at the Defense Health Agency (DHA), part of DoD's Military Health System (MHS), as indicated by MHS Chief Technology Officer Mark Goodge at the White House My Data Biweekly Interagency Meeting on July 22nd, 2014. At

⁴ See attachment [D], "DoD Blue Button - IPO Accelerator Task 1.4"

the meeting, there was a strong desire to find new ways to collaborate between DoD and VA, and the White House was willing to host a Blue Button summit for federal partners.

The 2nd round PIFs also placed a high importance on involving the private healthcare industry to ensure Americans everywhere could benefit from these activities. In February 2014, fellow Adam Dole with U.S. Deputy Chief Technology Officer Nick Sinai announced that leading pharmacies and retailers would join the Blue Button initiative including Walgreens, Kroger, CVS, Rite Aid, Safeway, and others. Each committed to a range of activities that supported the movement, such as allowing patients to securely share their data with others, including third-party applications. This was the first public announcement of its kind involving for-profit organizations supporting patient access to health data, and sets the precedent for how government and industry can work together to support patients. There is also an opportunity to leverage existing industry partnerships – VHA is already working with Walgreens on a number of care coordination initiatives.

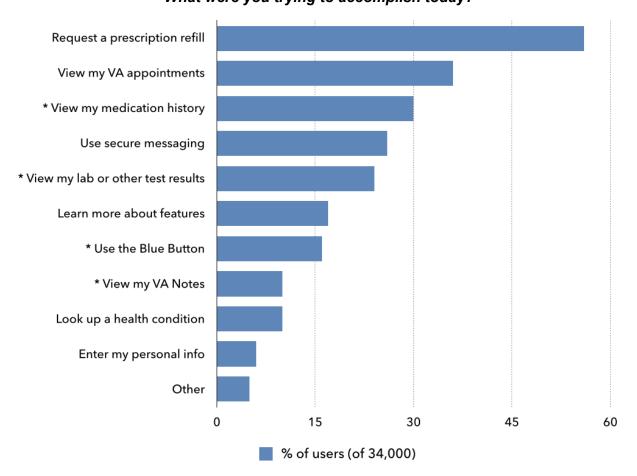
Finally, there are now a few recurring events to engage the public more broadly. ONC's Consumer Health IT Summit, an event that highlights public and private sector efforts to advance patient engagement through access to digital health data and technology, prominently brands the event with the Blue Button logo. The Health Data Consortium's Health Datapalooza, a national conference focused on liberating health data, has a growing number of workshops and talks on Blue Button, a quickly-growing topic of interest for companies, startups, academics, government agencies, and individuals who attend the event.

Learning about Patient Needs

While expanding the capabilities of Blue Button, ensuring the patient's needs came first was paramount. Any change to the experience should be respectful of what the patient is actually trying to accomplish. In developing public service announcements for ONC's Blue Button campaign, the PIFs were able to observe focus groups held to learn about how several patient demographic segments perceived accessing their health information and what they would find most useful. The opportunity to eavesdrop on real conversations about the experiences we were designing was invaluable.

The My HealtheVet team also learns about their customers' needs through an online feedback tool which informs their <u>American Customer Satisfaction Index (ACSI)</u>. The most interesting question for us was, "What were you trying to accomplish?" This provided an indication of whether accessing health data is useful, which kinds of data is most desirable, and how often is it being requested. Of the top ten transactions in the results below, four of them (prefixed with an asterisk) involve viewing some information contained in their medical record. This demonstrates Veterans are actively seeking out their personal health data.

My HealtheVet American Customer Satisfaction Index (ACSI)⁵ June 22 − September 8, 2013 "What were you trying to accomplish today?"



My HealtheVet's marketing materials also nicely align with what real users are doing on the site, as seen in the following brochure.

⁵ See attachment [E], "MHV ACSI"





VA's Award-Winning Personal Health Record

Anywhere, Anytime Internet Access to VA Health Care!



Veterans Health Administration

Office of Informatics and Analytics



Important features



Download My Data

Use the VA Blue Button to download, store or print the information in your My HealtheVet account.



VA Prescription Refills

Order your VA prescription refills online.



Secure Messaging*

Communicate non-emergency healthrelated information with your participating health care team through Secure Messaging.



VA Appointments*

View your scheduled VA Appointments and your appointment history for the past two years.



VA Wellness Reminders*

View your VA Wellness Reminders.



Vitals

Monitor and graph numerous health statistics online, such as blood pressure and blood sugar.



Medical Libraries

Access extensive online medical libraries.

* IPA required

Veterans Health Administration Office of Informatics and Analytics www.va.gov

Revised: 06/11 IB 10-233, P 96276

Rethinking the Blue Button Experience

Armed with years of experience serving Veterans with convenient, online access to their health information, along with more recent opportunities to learn directly from patients, designers, and developers, we set out to rethink the experience of accessing health data and sharing it with the people, organizations, applications, and services which are important to the patient. We saw as we added new capabilities to Blue Button and asked more of it than was originally intended, it became confusing not only to patients, but internally among stakeholders as well. We needed to refocus on a simpler definition of Blue Button that was patient and Veteran-centric, and not cluttered by technical jargon. The goal was to move the conversation away from the brand and its permutations, and instead toward what the patient actually wanted to do, namely view, download, send, and connect their health summary to applications and services. The Blue Button user experience hadn't yet been rigorously defined - it was ambiguous, subjective, and therefore becoming fragmented. Unabashed, ruthless simplification was needed if we wanted to achieve more functionality and capabilities while also increasing patient adoption and satisfaction. If we simplified the messaging, limited the technical variations, and ensured consistency of the user experience, we would increase the likelihood of success.

Structuring Data with CCDA

The first step necessary to achieve the above was to select a clinical data standard that could be relevant across use cases. There are many to choose from: C80, C83, C62, CCR, C32, CCDA, etc. Thankfully, https://dww.hes/cms/maningful/wes/stage-2 (MU2) has already selected the CCDA) as the standard for representing all health summaries for View, Download, and Transmit (V/D/T):

"MU2 objectives are the measurable benchmarks that EPs and EHs/CAHs must meet in adopting and using electronic health record (EHR) technology to qualify for Medicare and Medicaid incentive payments."

"CDA is a base standard which provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents."

"Before Consolidation, providers trying to implement a specific clinical document (e.g. C32) were faced with a 'rabbit hole' of cross-referenced materials creating an ever growing, complex web of documentation — Consolidation was undertaken to address this issue."

From the presentation: "Implementing Consolidated-Clinical Document Architecture for Meaningful Use Stage 2", ONC Implementation and Testing Division

In the Blue Button use cases that follow, all employ the CCDA as the canonical clinical document format for representing health summary data. Implementing a health data standard

is too often a monumental task, but if a community is rallying around a single format and working together to resolve implementation challenges, the barrier to entry is lowered dramatically, and everyone reaps the benefits. A common standard helps ensure that consistency is achieved when parsing, rendering, and transmitting data. High quality, interoperable data also directly impacts the patient experience, ensuring information is presented consistently and without errors. In many ways, the CCDA is becoming the Portable Document Format (PDF) for healthcare in its ability to present health data in a manner independent of application software, hardware, or operating system – a universal format for health information exchange.

Blue Button's Four Verbs

When all-new view, download, and transmit functionality were being proposed, new ways of identifying Blue Button also emerged: Blue Button+, Blue Button+ Push, Blue Button+ Pull, Blue Button+ REST API, Blue Button Direct. This was confusing for a number of reasons, but primarily it removed any indication of what the patient was trying to accomplish. Instead, Blue Button could simply be described by four central patient use cases, that is, *how* the patient wants to access, use, and share their data. They can **view** a health summary, **download** a summary in a variety of formats most useful to the patient, **send** a health summary to an external trusted healthcare provider or institution, and **connect** a health summary to applications and services to gain new insights derived from their personal health information. Leading with patient use cases is also consistent with Secretary McDonald's desire to view VA from the lens of the Veteran and design digital services with them at the center:

"That's why we're looking at every service we provide, every customer interaction we have, every single thing we do through the eyes of the Veteran. We want to look at everything we do through the lens of the Veteran. That perspective makes every decision, every right decision absolutely clear."

<u>Secretary McDonald Press Conference Outlining The Road To Veterans Day</u> September 8, 2014

Describing Blue Button is then no longer about identifying technical functionality, but instead what the patient can actually do with that functionality. A description of each verb follows.

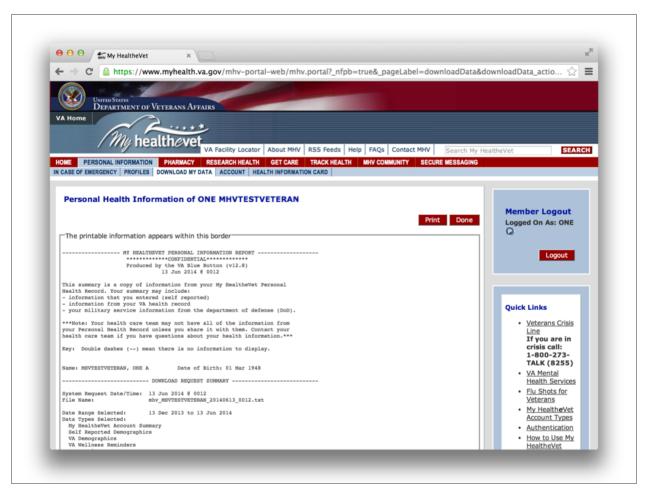
View

A patient can <u>view</u> their health summary at any time, on any device.

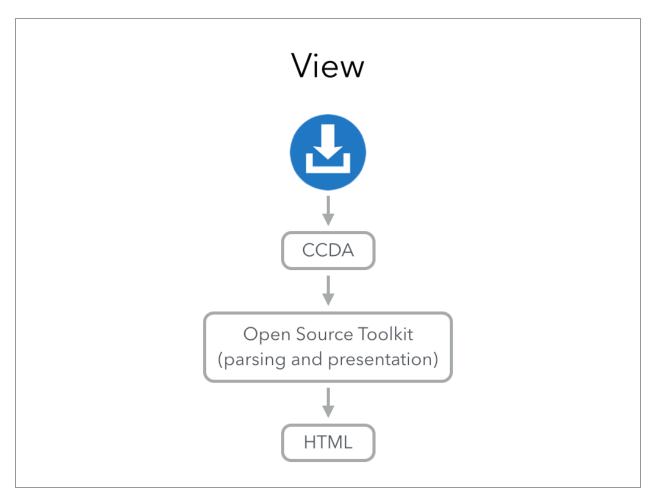
<u>Use cases</u>: The primary use case for "view" is for a patient to quickly check information in their medical record, whether it be a lab or test result, their medication list, or something else in their medical history. They don't have a need to store the information, but would like to see it on any device they find convenient, such as a personal computer, tablet, phone, or perhaps even a kiosk at a VA medical center. They also have the ability to print the summary just as they see it on the screen.

Improvements over current functionality: Today, "view" is satisfied simply by showing the patient any information in their medical record in any format or presentation style. Without a recommended style guide or human-interface guidelines (HIG), a common practice of leading software companies (see Apple's iOS HIG), examples of viewing health record information varies greatly among healthcare portals. We propose rendering the contents of a CCDA in a web page that is able to respond to various screen sizes, ensuring consistency across devices. Health information could be styled to take advantage of the designs presented in the Health Design Challenge mentioned previously. By also keeping data separate from the presentation layer, different designs and layouts can easily be swapped, so as we learn about how Veterans want to see and interact with their health data and which is most important to them, the presentation of the health summary can adapt to best serve their needs. Since data is also presented as web content, interactivity and dynamic visuals are possible to make the patient's health data more accessible and easier to understand. This is not possible when data is presented as plain text or as an embedded PDF, as My HealtheVet and many other health portals do today.

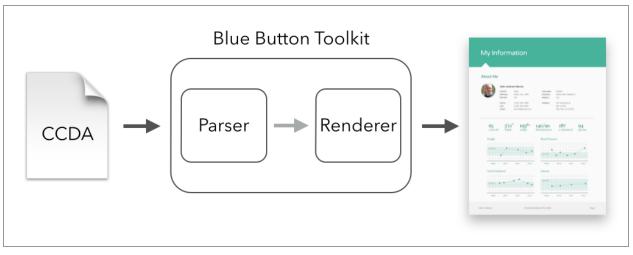
<u>Technical details</u>: When the user chooses to view their health summary, their health data is retrieved as a CCDA health summary document. The XML data contained in the CCDA is parsed using an open-source toolkit (more info about the toolkit below in the "Developer Resources" section) and HTML is generated. Presentation styles written in CSS are applied to the HTML web content, which is then embedded on the portal web site. To accommodate the greatest range of users and limit development resources needed to implement "view," building dedicated applications is not recommended (<u>read the UK government's position on mobile apps</u>), although it seems VHA is already investing in a <u>Blue Button mobile app</u>. Instead, health portals should make web content mobile first, where health data would look outstanding in any browser, on any device.



Current view of a health summary in My HealtheVet.



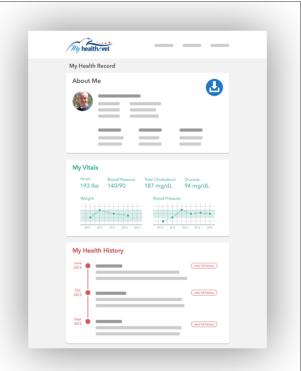
The improved "view" process flow.



Process showing how a health summary is parsed, then rendered. The Blue Button Feasibility
Report discusses this process in more detail.⁶

⁶ See attachment [F], "Blue Button Feasibility Report"





A mockup of My HealtheVet before clicking the "Blue Button" to view the health summary (left), and after where the summary has been rendered in the portal content area (right). Details about how this functionality could be implemented is documented in the Blue Button Presentation Framework, My HealtheVet Integration Plan.⁷

⁷ See attachment [G], "bbClear MHV Integration Plan"

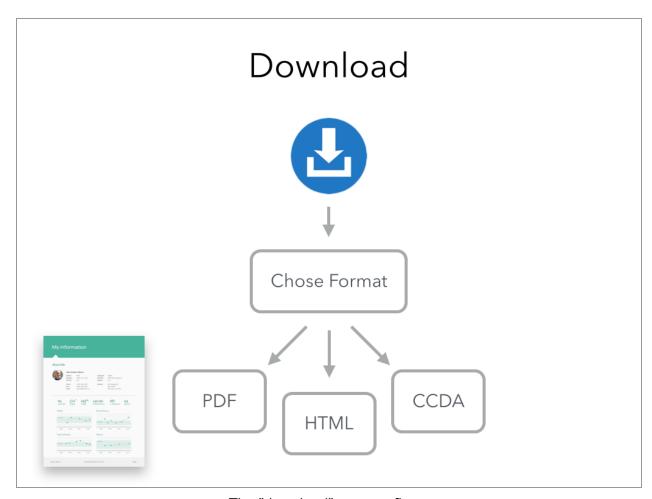
Download

A patient can <u>download</u> and save a copy of their health summary in the format of their choosing.

<u>Use cases</u>: The primary use case for "download" is for a patient to save a copy of their health summary for offline use. They may be traveling and want to carry their health summary with them where Internet access may not be available; they may just want to keep a copy as a backup they can refer to at any time, like other important documents they may archive. Given the limited ability to send health records between providers, downloading and sending the health summary to a care provider or specialist may be their only option.

Improvements over current functionality: Today in My HealtheVet, downloading a health summary is the most popular Blue Button feature. Of the 6.7 million health summaries downloaded, 42% were PDFs, 40% were plain-text files, and 19% were "Blue Button" files (also plain-text with additional information not present in other formats). Veterans like the ability to take their health data with them, wherever they go, and while there are more sophisticated and secure methods of accessing and sharing health data on the horizon, "downloading" may still be valuable as a simple method of access and ownership of their data. There are opportunities, however, to both enhance this functionality and ease the burden for implementers. First, patients will have the ability to download the exact health summary they see in the "view" use case. The web content (as an ".html" file) can be saved on their computer and opened in any web browser, even while disconnected from the Internet – all interactivity and visual styles will be preserved. There should also be other formats and file types made available that are most useful to the patient, for example plain text, PDF, or even the raw CCDA data file intended to be read directly by another health IT system.

Technical details: When the user chooses to download their health summary, they are presented with a number of formats, ranked by popularity determined by user feedback. Descriptions of each format and when they are most often useful should also be presented. When the user chooses a format and clicks to download their health summary, the file is generated by the same open-source toolkit leveraged in the "view" use case, where the source health data is also the CCDA. If they download an HTML file, the exact same web content in "view" is packaged in an ".html" file capable of being opened offline. The HTML file actually contains the original CCDA embedded in the file, and when opened by a web browser, the health data is parsed and rendered dynamically. The user may also extract and save the CCDA file from the ".html" file if they choose to do so. If they download a PDF, the same toolkit parses the CCDA and renders a PDF file similar to the styles chosen for "view." The same process takes place for plain text as well, where the toolkit parses the CCDA and generates text only, formatted so that it is still readable and able to be navigated by the user. In fact, converting CCDA data to any format and file type can easily be accomplished by the toolkit, meaning data holders can quickly respond to patients needs.



The "download" process flow.

Send

A patient can <u>send</u> their health summary to a trusted non-VA care provider.

<u>Use cases</u>: The primary use case for "send" is for a patient to transmit their health summary to a non-VA provider or specialist, in fact, any health professional who is not in the VA network. This is important because "research suggests that up to 70% of Veteran patients use both VHA and non-VHA providers for health care," according to a VA memo from the Director of the Office of Rural Health.⁸ The memo further states: "To achieve the best possible coordination of care, reduce or eliminate therapeutic or diagnostic duplication, and ensure patient safety, health information exchange between providers is necessary." Dr. Henry Wei, PIF in the first class at VA, also contributed a detailed "send" use case (see attachment titled "Veteran User Story - Send").⁹

New functionality: This new functionality will allow veterans to "send," or "transmit" in MU2 V/D/T parlance, their health summary as a CCDA continuity of care document to any trusted non-VA provider using the Direct protocol. To the patient, this experience is much like sending an email where the content and health summary attachment is automatically chosen.

<u>Technical details</u>: When the user chooses to "send" their health summary, they must enter (or perhaps search for) the Direct address of the recipient. This address is formatted just like a standard email address, although "direct" is usually chosen as the subdomain by convention, as in: "provider@direct.va.gov". Further technical guidance is available in the Blue Button+Implementation Guide in the section <u>Transmitting Data Using the Direct Protocol</u>. The document being transmitted is the CCDA, so it is intended to be processed by a receiving health IT system as raw patient data. The recipient may then choose to render the patient's data using a similar toolkit mentioned in "view" and "download" in a way that is most useful to the provider or specialist.

<u>Pilots and progress to date</u>: VA is already implementing this use case to satisfy MU2's V/D/T requirements. Since June 2013, <u>VHA's Office of Rural Health</u> in partnership with the <u>HHS/ONC Rural Healthcare Initiative</u> and <u>White House Rural Council</u> have participated in the VICTOR-HIE pilot with the goal of improving quality and care coordination for rural Veterans by using VA's Blue Button capability through My HealtheVet to facilitate health information exchange when veterans use both VHA and non-VHA providers for health care. ¹⁰ ONC has also published a series of blog posts concerning rural Veterans sending their health record:

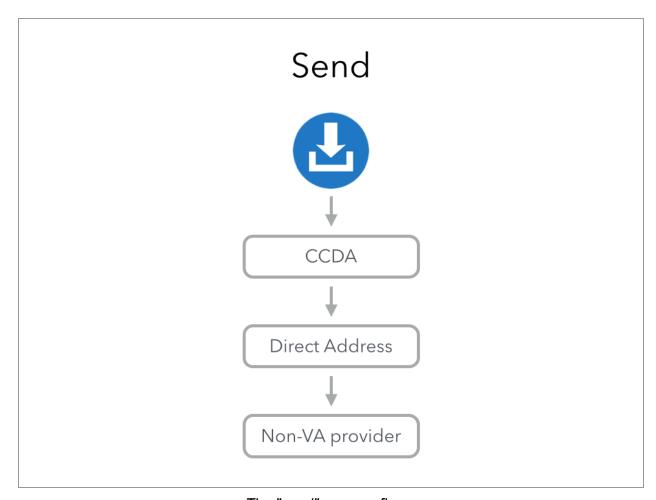
- ONC and ORHP: Working to help rural health providers leverage health IT to improve guality and fuel economic development
- Transforming Veterans' Care in Rural Practices Using Health IT
- Using Health IT to Connect Rural Vets With Their Data

⁸ See attachment [H], "Rural Health Information Exchange Pilot Program MOU"

⁹ See attachment [I], "Veteran User Story - Send"

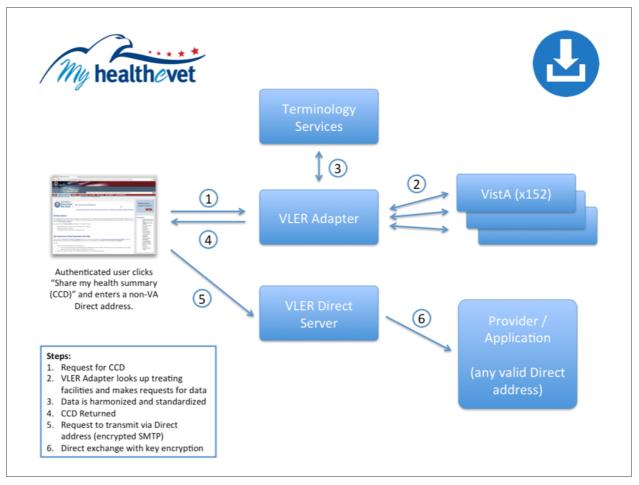
¹⁰ See attachment [J], "The VICTOR-HIE Project"

For a technical description of the CCD Direct project at VA, see attachment "VA Blue Button Continuity of Care Document (CCD)" and the diagram that follows. 11 While implementation is still ongoing, much progress has been made to date in order to implement this functionality, and VA could be poised to be the first healthcare provider in the country allowing patients to electronically transmit their machine-readable health summary to any trusted external provider or organization.



The "send" process flow.

¹¹ See attachment [K], "VA Blue Button Continuity of Care Document (CCD)"



A diagram showing how a CCD is retrieved from the VistA electronic medical record and VLER, and sent to a non-VA provider at the request of a user through My HealtheVet.

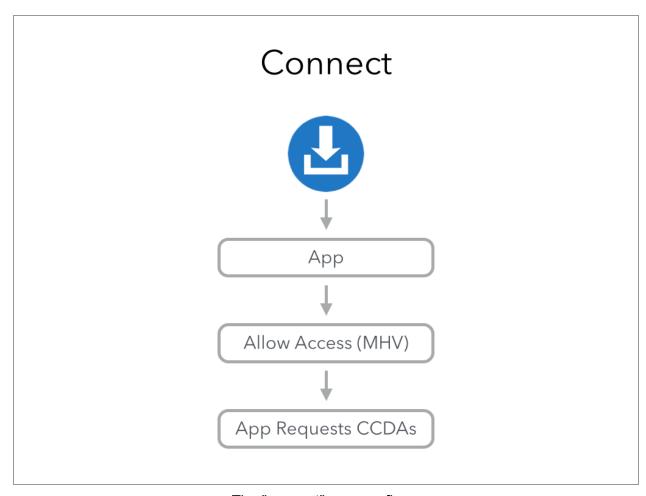
Connect

A patient can <u>connect</u> their health summary to applications or services of their choosing.

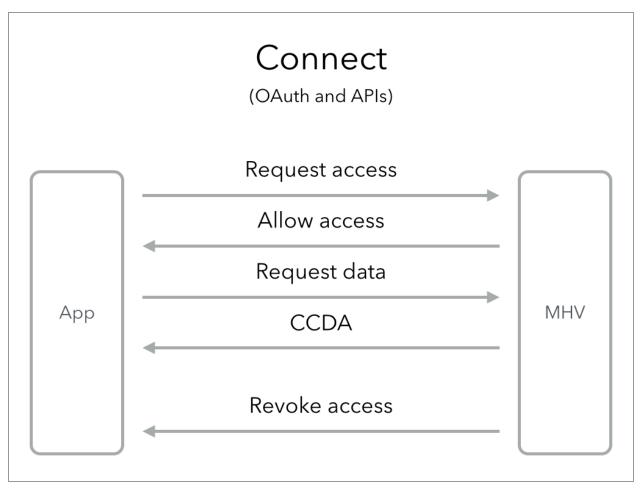
<u>Use cases</u>: The primary use case for "connect" is for a patient to authorize an application or service (web, mobile app, etc.) to automatically request a health summary so the patient may conveniently gain new insights about their health or more effectively manage their health data.

New functionality: In the spirit of giving patients the right to use their health as they see fit, "connect" is a modern, safe, and secure method of sharing health data with applications and services. Patients may have an application they trust and want to take advantage of its innovative functionality, something that the patient's current health system may not offer. The "connect" use case lets them accomplish this by authorizing an application or service to seamlessly access their health summary. Patients are in complete control over which applications are authorized and can revoke them at any time. Furthermore, a health system may want to recommend applications they trust as an additional precaution. Applications developed by health systems, such as VHA, can also use this functionality just as any external application would. This method of sharing health data is the most natural, intuitive experience for the patient – they simply select an application, authorize it, and they're done. Utilizing health data outside the confines of a health portal holds great potential, and "connect" gives patients the ability to accomplish just that.

Technical details: This use case employs the Blue Button Application Programming Interface (API) specification, which was developed within ONC's Standards and Interoperability (S&I) Framework under the Blue Button+ Pull Workgroup. The specification uses the most modern, secure, and widely adopted industry standard for accessing data from applications over the web. It uses OAuth, an open protocol allowing secure authorizations in a simple, standard method from web, mobile and desktop applications used by most software companies who offer access to their platforms, like <u>Twitter</u> and <u>Google</u>. Once authorized, applications request data using RESTful principles, which are based on the fundamental architecture of the World Wide Web, and not a specific protocol like Direct, meaning the specification is easier for developers to understand and implement. Compared to how applications often get access to patient health data today, this method is far safer and more secure. Applications like Humetrix's iBlueButton take the Veteran's username and password to log them into My HealtheVet on their behalf, and then "scrapes" the contents inside the portal to collect their health information. Patients can't revoke access to their account, unless they change their password. This is also requires much more development work for Humetrix, since scraping is a very error-prone process. Other services, like WellnessFX, require patients to download a Blue Button file from My HealtheVet, then manually upload it to their website, a very inconvenient process. The data format being exposed to trusted, authorized applications through "connect" is a CCDA, like all other previous use cases. Currently, the API specification states the entire health summary should be made available to applications, but in the future more granular controls could be added to specify what specific health data categories (results, medications, etc.) should only be shared with applications.



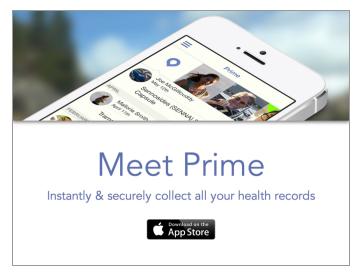
The "connect" process flow.



The simplified "connect" request / revoke process. First, a health application requests access to My HealtheVet and the patient's data. The patient chooses to give the application access. The application can then request a CCDA containing the patient's health summary. Once authorized, the application can make as many requests for health data as desired, unless there are specific limits imposed by My HealtheVet. At any time, the patient can revoke the application through My HealtheVet, prohibiting access to their health data.

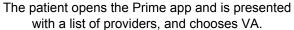
An Example Application using Connect

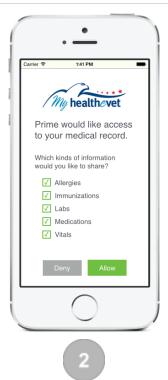
Prime is an application for iPhone available in the Apple App Store. It allows patients to instantly and automatically get their health records from any doctor, and take them anywhere. The app works with over 400 providers, covering 100 million patients, where Veterans make up the largest customer segment. Prime has implemented the Blue Button API specification, although no providers have yet done the same. They see it as a quantum leap compared to how they currently have to retrieve personal health data: through painstaking manual



processes which are laborious and error prone. The "connect" use case means they can forget about the old, challenging method of collecting health data, and instead focus on creating the best possible, secure experience for Veterans who want to see all their health records in one place. The images below tell the story of how Prime could one day "connect" with My HealtheVet to request a CCDA on behalf of the patient.







Then, an authorization screen appears from My HealtheVet stating Prime would like to access the patient's medical record.



If the patient chooses to allow Prime access to their record, the app then requests a CCDA and imports their health data. In this image, the patient's medication list is shown.



In this image, the patient has chosen to share their VA health data with their family – their comments are shown below the details of the encounter.

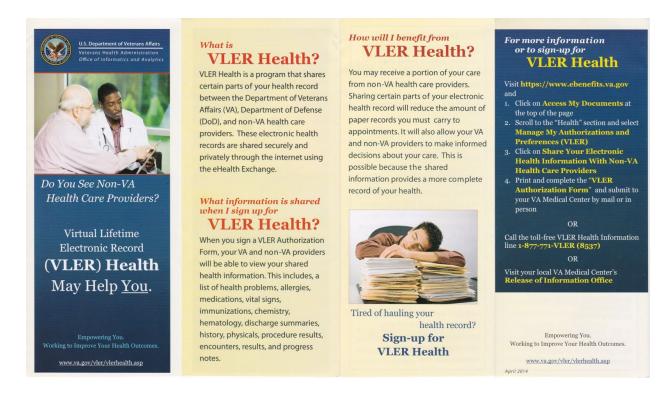
Implementing Blue Button at VA

The table below summarizes the four use cases above, what has been currently implemented at VA, and what functionality is desired.

	Currently Implemented	Desired
View	Embedded within a web page: Text file (as a ".txt" and ".bluebutton") PDF	CCDA embedded in the web page which is parsed and rendered by an open-source toolkit (separating data from presentation), enabling layouts from the Health Design Challenge
Download	Formats available: • Text file (as a ".txt" and ".bluebutton") • PDF • C32	Desired formats: HTML (same experience as "view") PDF generated from the CCDA, which is parsed by an open-source toolkit and rendered by the browser or on the server CCDA, for uploading to another system (application or electronic health record)
Send	In progress	Send a CCDA via Direct to trusted non-VA care providers
Connect	Not available	Applications which can connect to the health record via the Blue Button REST/Oauth API, providing health data as a CCDA

Implementing the four use cases above will have a profound impact on Veterans, empowering them with new ways to access their personal health data so that they may lead healthier, more productive lives. However, completing this is a considerable task for any healthcare system. The challenge may be more difficult at VA, which runs the nation's largest integrated healthcare system. With this challenge comes opportunity – VA's size and influence means their innovations can significantly impact the healthcare industry at large. While standards bodies are important, implementers hold the power in determining what gets adopted nationwide. As an actual implementer of Blue Button, My HealtheVet is in a unique position to shape the patient experience, how they access, use, and share their personal health data. This is why the ability to rapidly drive consensus and implement new software features is so important for Veterans, and ultimately all Americans.

While My HealtheVet was still in the process of implementing changes needed for Veterans to send their health summary to non-VA care providers, the <u>Virtual Lifetime Electronic Record</u> (<u>VLER</u>) <u>Health</u> program released this functionality separately through <u>eBenefits</u> and began marketing directly to Veterans:



Developer Resources

To implement the four use cases, there are a wealth of resources available for data holders and application developer alike. For the second round of PIFs, growing the developer ecosystem was a top priority, as they hold they key to creating the applications and services that make health data useful for patients. We held two Blue Button developer meetups, one in San Francisco and another in New York City, to answer technical and policy questions, demo applications, and provide assistance with implementation. We also helped organize Boston's first ever Blue Button Innovation Challenge in partnership with Tufts University MedStart and MIT H@cking Medicine (more info can be found in this article on MedTech Boston). We also presented at Health 2.0's HxRefactored on the subject of conquering complex health data. These events provided the opportunity to rally and inspire the next generation of healthcare developers who will create the innovative applications and services that will empower patients and help them live better lives.

Specifications

There were two primary specifications we shared:

- For the "send" use case, the Blue Button+ Implementation Guide contains the canonical transmit information needed:
 - http://bluebuttonplus.org/transmit-using-direct.html
- For the "connect" use case, the Blue Button API specification: http://bluebuttontoolkit.healthit.gov/blue-button-plus-pull/

Josh Mandel of Boston Children's Hospital and Harvard Medical School also created a tutorial for an application that used both use cases and specifications: https://github.com/jmandel/bb-tutorial-growthtastic/wiki

Testing

There are several resources and tools available for testing both transmit functionality, as well as CCDA implementation:

- Testing Direct: http://bluebuttonplus.org/direct-sandbox.html
- Resources to test the "send" use case: http://bluebuttonplus.org/toolkit.html
- Sample CCDAs:
 - SMART Platforms: https://github.com/chb/sample_ccdas
 - EMERGE's synthetic samples: https://github.com/chb/sample_ccdas/tree/master/EMERGE
- Validating CCDA quality, SMART Platforms' CCDA Scorecard: http://ccda-scorecard.smartplatforms.org/
- ONC's Standards Implementation & Testing Environment (SITE): http://sitenv.org/

Open Source Software

The Blue Button community has always had a strong open-source ethos – all the work we produce is <u>available on our GitHub page</u>, and we encourage developers to do the same. As part of the "open-source toolkit" mentioned previously, two projects are at the center:

- <u>BlueButton.js</u>: An open-source JavaScript library to parse, validate, reconcile, and render health documents and data.
- <u>bbClear</u>: An open-source framework for rendering more usable health records. It enables developers of electronic health record systems to output a printed health record that is more helpful for patients, their families, and caregivers.

Outreach

Spreading the word about what Blue Button is, how it empowers patients, and how others can get involved in the moment is critical to our success. During the second PIF class, we engaged with <u>Blue Button Pledge</u> members and encouraged more to <u>make the commitment</u>. We helped organize focus groups with ONC, which led to the creation of the <u>Blue Button Public Service Announcement (PSA) Campaign</u> that will appear on partnering websites beginning at the start of <u>Health IT Week</u> in September 2014. As PIFs, we also built the <u>Blue Button Connector</u> to help patients find and request their personal health data from insurers, hospitals, clinics, pharmacies, labs, and immunization registries. For example, Veterans can now quickly see what <u>Blue Button features My HealtheVet offers</u>.

Training and Education

My HealtheVet already provides a wealth of educational materials on how to use Blue Button today, such as the <u>VA Blue Button User Guide</u> and the <u>VA CCD User Guide</u>, along with a simplified "getting started" guide on the VA website. When new functionality such as the "send" and "connect" use cases are added, all new patient and provider education materials will need to be produced. Since sending a health summary is part of the existing MU2 V/D/T requirement, ONC will be the authoritative source for those training materials – they've already begun authoring content. Since "connect" is so new and final user experience is not yet known, it does not currently have any educational materials for patients or providers. When it is time to train VHA staff and patients, My HealtheVet has an incredible team of coordinators at every medical center who can distribute materials and hold in-person training. They also can provide feedback from the front lines to help directly improve the digital experience.

Looking into the Future

Despite the complexity and challenges in establishing the first consumer information exchange, Blue Button has a bright future ahead of it, thanks to the dedication of talented public servants and increasing private sector participation. While the four enhanced use cases are our best guesses today regarding how patients want to access, share, and use their health data, there is much more to learn about their preferences and concerns. There are potential use cases that are not covered by those described here, such as sending new health data *from* a non-VA care provider back into the VA's electronic medical record system, known as "bi-direction." Patients are also increasingly tracking their health outside of the hospital or clinic. This "patient-generated data" could be useful to VA healthcare providers, even a pillar of telehealth in the future. Patients may also want access to data that is not or cannot

¹² Patient-generated health data (PGHD) are health-related data created, recorded, or gathered by or from patients, family members, or other caregivers to help address a health concern or promote health. PGHD

currently be captured in the CCDA, such as imaging (like an MRI or CT scan) or doctor's notes. How patients will use this new data, especially imaging, and if it will drive better health outcomes is not well known. One thing is clear, if we listen to Veterans, understand their needs, and "look at everything we do through the lens of the Veteran," as Secretary McDonald stated, "that perspective makes every decision, every right decision absolutely clear." That is to say, Blue Button and access to personal health data should not be shaped by what VA or the health administration wants, but by what Veterans need, and what helps them achieve better health outcomes and lead healthier, more productive lives.

From a technical perspective, improvements on how clinical data is structured and represented might be possible. In addition to providing applications a CCDA through the "connect" use case, My HealtheVet might also be able to return the actual entire patient medical record stored in VistA, represented as a simple key-value structure in <u>JSON</u>, which is the most widely used format for data exchange on the web.

Policy will also affect the way forward. New stages of Meaningful Use will be introduced, and current specifications, such as Blue Button Direct and the Blue Button API could be written into future stages. The <u>Clinical Laboratory Improvement Amendments (CLIA)</u> will also impact how test result data will be made available to patients, something developers will need to consider when attempting to provide seamless access to health data across different silos.

This document attempted to present what the future of Blue Button at VA could look like, but it is not a perfect vision, and building consensus is a task that must continue. Going forward, future Presidential Innovation Fellows, VHA, and ONC will help decide this future, continue to refine the patient experience, evangelize the movement among industry influencers, encourage more Americans to demand electronic access to their health records, and help grow the developer ecosystem so that new innovative applications are created and able to flourish.

include, but are not limited to: health history, treatment history, biometric data, symptoms and experiences, patient reported outcomes, and device data.