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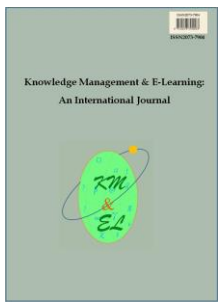

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A description of rapid design and implementation of new features in an electronic health record in the United States Department of Veterans Affairs, Veterans Health Administration response to the Covid-19 pandemic

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Abstract: The onset of the COVID-19 global pandemic called for the implementation of new functionality to the Electronic Health Record (EHR) system for the United States Department of Veterans Affairs (VA), and VA responded rapidly. VA's EHR-related COVID-19 response can be grouped into two categories: 1) a new banner to provide a rapid way to view a patient's COVID-19 status and 2) EHR templates for addressing COVID-19 screening and patient care during the COVID-19 pandemic. COVID-19 clinical reminder dialog templates were rapidly implemented to meet provider and patient needs for scenarios involving the care of patients suspected of COVID-19 infection and for treating and monitoring patients who tested positive. Semi-structured interviews were conducted with solution developers and users to elicit feedback on the design process as well as overall usability and utility. The new functionality in the EHR was developed, evaluated, and delivered at record speed in real time as the pandemic unfolded. This paper presents the process used for the rapid delivery of the new functionality and describes how VA was able to maintain a high standard of usability while creating this enhanced functionality in the face of an unprecedented challenge.

Keywords: Covid-19; Patient safety; Decision support; Electronic health records; Health informatics

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1. Introduction

The novel coronavirus disease 2019 (COVID-19) was initially identified in December 2019 in Wuhan, China, as a case of pneumonia and later emerged as a global pandemic, affecting more than 150 countries around the world (He et al., 2020; Johns Hopkins University Center for Systems and Science Engineering, 2021; World Health Organization, 2020; Wu et al., 2020; Wu & McGoogan, 2020; Zhu et al., 2020). By January 2020, the virus had reached the United States and quickly spread nationwide (Holshue et al., 2020). By March 13th, 2020, the Executive Office of the President of the United States declared the pandemic a national emergency (The White House Archive, 2020).

In response to the pandemic, the Veterans Health Administration (VHA), a branch of the United States Department of Veterans Affairs (VA), promptly adapted to meet dynamic and emergent healthcare needs (Luo et al., 2021). In addition, VA's mission statement includes a "Fourth Mission," to improve the Nation's preparedness for response to war, terrorism, national emergencies, and natural disasters by supporting national, state, and local emergency management, public health, safety, and homeland security efforts (Department of Veterans Affairs, 2021). During the COVID-19 response, this included provision of Personal Protective Equipment (PPE), other equipment, and COVID-19 testing capability as well as deployment of personnel to support state and community nursing homes and admission of 488 United States non-Veteran citizens for care at VA Medical Centers (VAMCs) (Veterans Health Administration, 2021).

To accommodate the surge of new clinical cases of COVID-19, VA leveraged current informatics capabilities, a strategy pursued by other health systems (Grange et al., 2020; Kannampallil et al., 2020; Reeves et al., 2020; Turer et al., 2020). More specifically, the COVID-19 Initiative Workgroup was formed to augment the functionality of VA's Electronic Health Record (EHR) system, the Computerized Patient Record System (CPRS).

In this paper, we detail VA's rapid and integrated health information technology (HIT) response to COVID-19, specifically highlighting development, dissemination, and implementation of new CPRS COVID-19 templates and a COVID-19 Banner that provides COVID-19 status on every patient's health record. We include a discussion of the formation of the design groups, creation of work products, evaluation and iteration of designs, and dissemination of information throughout the organization. It is important to note that work was iterative, and there was feedback throughout the process of design, testing, distribution, and implementation. The non-research status of this VHA operations

activity was not in question and therefore did not need review or approval by an Internal Review Board or other review committee.

2. Methods

Early in the COVID-19 pandemic, VA stood up the national Clinical Coordination Cell (CCC) to coordinate VA's response to the COVID-19 pandemic. The CCC is a clinical group that includes decision makers and clinicians from specialties such as emergency medicine and infectious disease. As the need for clinical coordination with COVID-19 expanded, the group dedicated an individual with workload capacity to be able to quickly approve informatics solutions to reduce bottlenecks. This person was the default decision-maker and was invited to all working meetings where informatics tool development occurred.

The COVID-19 Initiative Workgroup and associated design groups for the VA HIT COVID-19 response are multidisciplinary groups composed of subject matter experts (SMEs), technical experts, and domain experts. The composition of each team varied based on the topic of the issue being addressed. For example, HIT solutions related to screening included SMEs with infectious disease experience, while solutions for scarce resource allocation included ethics SMEs. Early in the pandemic response, many of the SMEs were infectious disease and intensive care clinicians from medical centers in New York City and New Orleans, which were treating high rates of COVID-19 in the spring of 2020.

At the beginning of the iterative design process for each HIT solution, the CCC identified a need, sometimes based on requests from the field, and a specified reason for the need. For example, an identified need might be screening for COVID-19 to identify patients or staff who may be contagious. From there, the SMEs from the design group drafted a solution set with design input from human factors engineers on the team. The team worked to match the solution to information available from the Centers for Disease Control and Prevention (CDC), which sometimes changed in real time as the design progressed.

This methodology followed the same process that the VA National Clinical Templates Workgroup developed for creation of clinical templates during normal times. A template must be sponsored by a program office, which brings requirements specification and a skeleton of a template with proposed content to the group. For COVID-related templates, the COVID-19 Initiative Workgroup looked at how to organize template information to best support care that also supported the unified COVID-19 package. They also considered sensible batching of templates for release, balancing urgency with efficiency of response, and addressing flexibility needed by local sites.

After a design was developed, the design groups conducted rapid usability evaluations. A key component to this method was the inclusion of the full team—including SMEs, IT representatives, clinicians, informaticians, medical terminologists, patient safety personnel, and human factors engineers—on each call to offer input throughout the design cycle. At identified test sites, the new design was put into a test environment so that any unintended consequences of installation could be evaluated. Health Informatics Specialists and recruited clinicians then provided feedback that included safety and usability of the design and indicated their intention to use it. Following evaluation, the design was pushed to all sites.

Implementation of the COVID-19 HIT solutions occurred on a national level, with installation mandated for all but a few templates, which were designated as a best practice but not required. Facilities could request an exemption, and these were reviewed for workflow compatibility. Indeed, not all templates were appropriate for all sites due to local variability and context of use. The enterprise worked to allow local flexibility and balance the need for national reporting with the local requirements for providing the best clinical care.

Carefully coordinated communication, utilizing a multipronged approach, was a critical component of the VA HIT COVID-19 response. All communications about the COVID-19 HIT solutions were issued through the Health Informatics Community of Practice (HI CoP), which offered mechanisms for announcing innovations through emails as well as filing the information in a single location for future reference and distributing links to the VHA community. This standardized method of communication funnelled the information to the field to prevent possible confusion from receiving information from multiple sources as well as resolve any conflict in information before it reached end users. Communications, which contained instructions as well as points of contact, were sent to all relevant users in the health informatics community, including Clinical Applications Coordinators, Clinical Reminders Users, Chief Health Information Officers (CHIOs), the Field Health Informatics Council, and the Nursing Informatics Field Alliance. HI CoP also supported office hours for field informaticians. These were collaboratively led by IT representatives and clinicians and offered an opportunity for users to ask questions and receive support for problem solving. In addition, the meeting platform, Microsoft Teams, allowed for a continued rolling discussion of issues in real-time and as a historical reference.

3. Output

The tools in the VA HIT COVID-19 response can be grouped into two main categories according to how the user interacts with the tools. The first category includes a single tool, the CPRS COVID-19 Status Indicator Banner ("Banner"), which displays on every CPRS tab of a patient's record for both inpatients and outpatients. The second category includes COVID-19 specific templates, which may be used for COVID-related healthcare activity within the EHR.

3.1. Covid-19 banner

The Banner indicates a patient's COVID-19 status. It is located directly below the CPRS Header Bar (Fig. 1, 2, 3) and is intended to give VA clinicians a quick way to view a patient's COVID-19 status. It is informational and does not override any infection control processes that might be in place. The Banner is yellow to call attention to it and to differentiate its text from surrounding information. It also taps into a mental model common in the U.S. that yellow can mean caution. Additionally, local medical center leadership can choose to turn off the yellow color, which will turn the banner light gray. Initial Banner capabilities launched in March 2020 contained six possible statuses: 1) Positive, 2) Clinically Positive, 3) Pending, 4) Recovered (now called Prior Positive), 5) Negative, and 6) Not Tested. The status message displayed depends on the conditions detected in the patient's chart. For any status related to a COVID-19 test, the ordered/completed date of the test is also displayed. As information about the disease process evolved, so did the role of diagnostic testing when evaluating and managing patients with COVID-19. This evolving understanding included details about sensitivity

and specificity of tests, persistence of COVID-19 positive test results in recovered patients, the resolution and recovery process, and changes to antibody testing. In response, Version 5 of the Banner became clickable to open a pop-up window with clinical and diagnostic testing results for the patient that provide additional details. The window includes the condition that set the Banner status, the definition of the status, any VA and non-VA lab results, clinical information captured as health factors from the COVID-19 templates, a COVID-19 Problem List, and immunization information (Fig. 4).

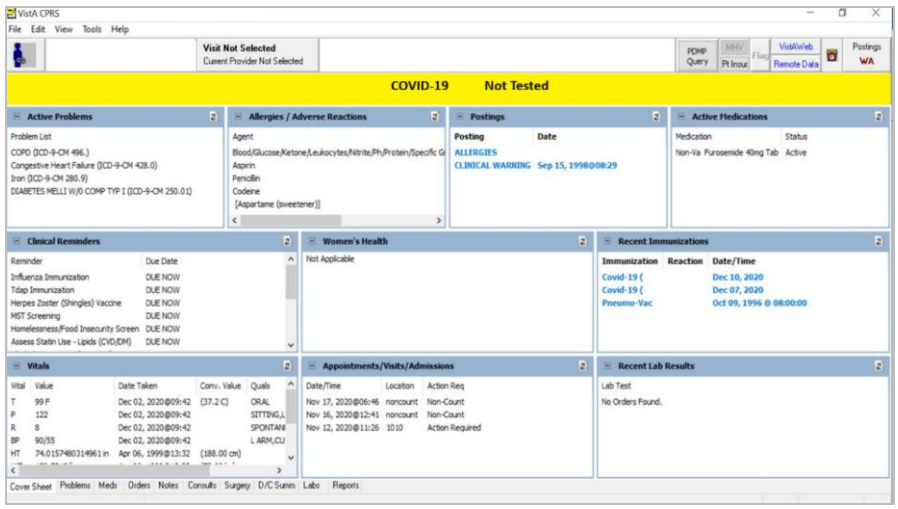

Fig. 1. CPRS coversheet for simulated patient with no Covid-19 test

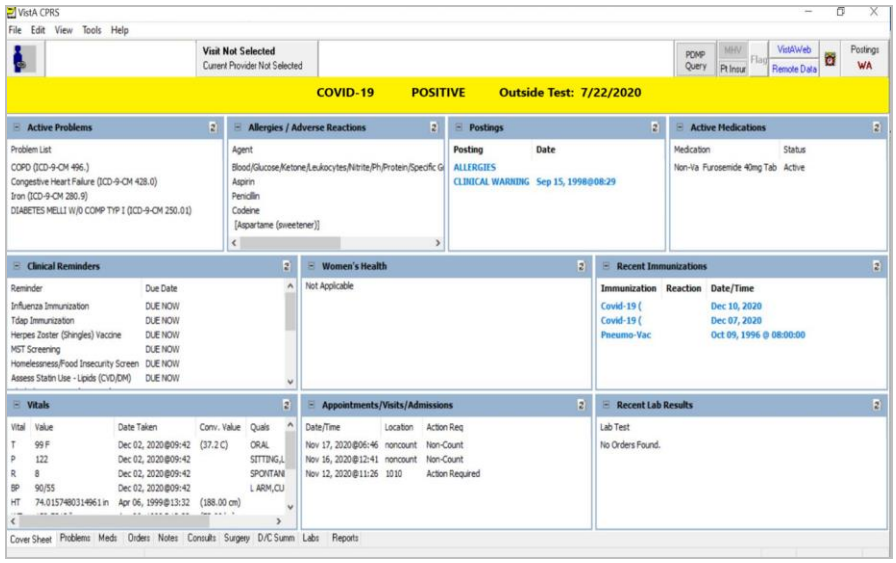

Fig. 2. CPRS coversheet for simulated patient with a positive Covid-19 test result

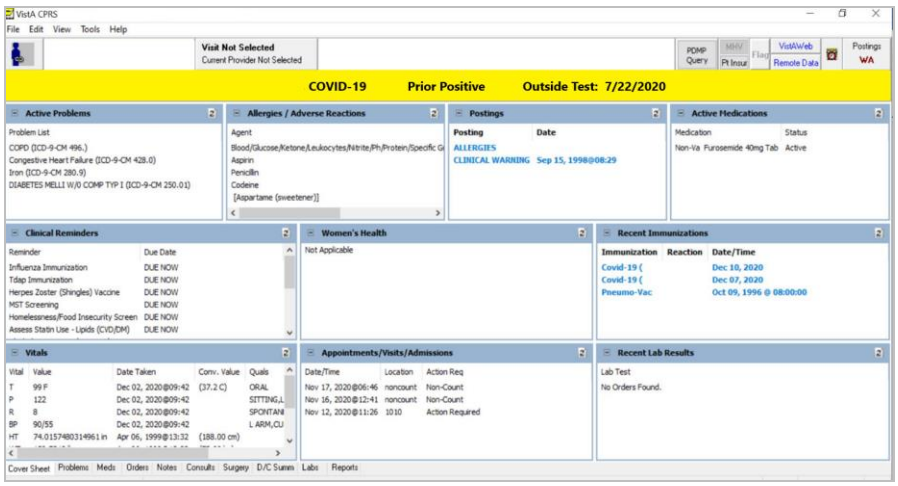

Fig. 3. CPRS coversheet for simulated patient with positive lab test over 14 days old

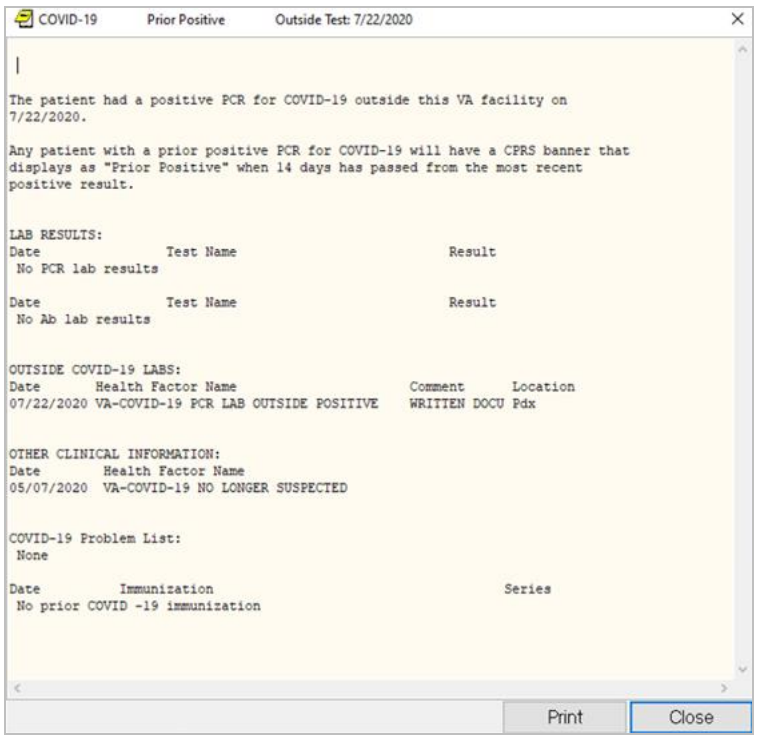

Fig. 4. Banner pop-up window that appears when users click the Banner

3.2. Covid-19 templates

The COVID-19 templates were designed to be used by clinicians to provide care related to COVID-19 or care changed substantially by COVID-19 in the VHA system. Table 1

describes the deployed COVID-19 templates. It includes the template name, purpose, and category of use. “Screening/testing” refers to the systematic method or documentation of the process to identify a COVID-19 case. “COVID care” refers to any procedure or documentation used to attend to a patient with COVID-19. “Non-COVID care” refers to any procedure or documentation not directly associated with patient care related to COVID-19. This table does not include information on template updates.

Table 1
Covid-19 templates created in the EHR

Template Name	Template Purpose	Category of Use
Screen, ED triage note	Assess for symptoms	Screening/testing
CLC screen	Assess for symptoms in Community Living Center residents	Screening/testing
Cancelled appointment follow-up	Ensure appropriate follow-up on appointments cancelled due to the pandemic	Non-COVID-19 care
Immunization reminder	Support administration, tracking, and reporting of vaccine administration	Non-COVID-19 care
NSG admission and shift assessment notes	Simplify required documentation to minimal data directly influencing care	COVID-19 care
Telephone follow-up	Provide next steps follow-up from nursing	COVID-19 care
Provider follow-up	Provide structure for further evaluation after initial screening	Screening/testing
Outside lab results	Capture information from outside the VA and update the COVID-19 Status Banner	Screening/testing
Inpatient admission H&P	Provide evaluation questions, assessment, and a next steps plan	COVID-19 care
Suicide risk management follow-up	Provide structure and guidance for conducting outreach calls	Non- COVID-19 care
Discharge instructions	Can be used in conjunction with existing discharge instructions from all sites of care	COVID-19 care
Radiology clinical review	Request to review and reassess the clinical urgency of a patient's imaging exam	Non- COVID-19 care
Antibody/PCR panel	Order testing	Screening/testing
Spinal cord injuries note	Assess and screen patients specifically with spinal cord injuries	Screening/testing
Status adjustments note	Manage the COVID-19 Status Banner independent of other templates	Screening/testing
Return to work	Provide a templated letter for patients seeking to return to work	COVID-19 care
Inpatient provider	Provide a draft note template for inpatients	COVID-19 care
Scarce resource allocation	Provide guidance to facilities on the management of ethical challenges	COVID-19 care

Fig. 5 shows the number of times each template was used and total number of unique patients as of February 2021.

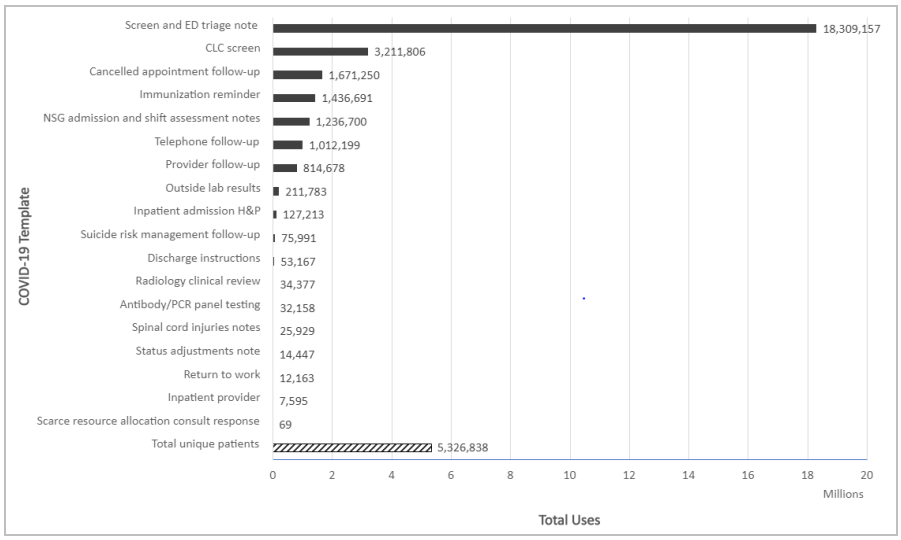

Fig. 5. The number of totals uses for each Covid-19 template and the total number of unique patients for whom the templates have been used as of February 2021

4. Covid-19 banner and template feedback from developers and users

Semi-structured audio interviews with clinicians and leaders in critical support functions such as information technology (IT), training, and scheduling elicited information about the COVID-19 HIT solutions and purposes behind design decisions.

4.1. Banner development process

One informaticist provided information about Banner development and use:

> *I think people have gotten accustomed to [using] the Banner, and they understand it more. In the beginning, I do not think people had a clear understanding of it, even though we kept giving information and we kept reinforcing it. In the beginning they wanted everything and the kitchen sink in the Banner. And it was just way too complex.*

The process of determining the precise content for the COVID-19 Banner involved negotiation and careful deliberation. The challenges related to determining what to include and what to exclude from the Banner were described:

> *Sites continually want us to add other things to the Banner, I think so they do not have to go look through the rest of the chart. They want another vaccine status, and they want to know their isolation precautions. We can keep coming back to the point of the Banner was that you would know…positive or negative status as accurately as possible at a glance. Go look in the rest of your chart just as you would for any other patient on their isolation status or their vaccination status because of the coding of that. It's quite complicated.*

The amount of information on the Banner was deliberately limited due to the difficulty of representing complex information in the small area available as well as the reduced utility for a clinician who is attempting to rapidly gain important information about the patient. An informaticist described this challenge:

> *So as an example, the point-of-care antigen testing…I have to say: it's not binary. So, a positive doesn't always mean the patient's positive and negative doesn't always mean a patient's negative. And there are other steps that must be taken based on if they were symptomatic or if you were doing screening. And so, we've made the decision that point of care antigen testing will not inform the Banner. Instead, if you clicked on the Banner, you could see that the point of care testing had been done and what the result was, but we are going to make them use a template that takes into account that whole algorithm of what's considered positive, what's considered negative and what is not, and you need additional testing. That will be the way that the Banner gets updated.*

As knowledge about COVID-19 has increased and technology evolved, so too has the Banner received updates. For example, there is now a plan for the Banner to include positive antigen tests from external sources to provide additional information to support clinicians in their workflows.

Support for the idea of carefully considering the scope of the Banner and limiting the content to encourage appropriate use was verified by a clinical SME:

> *They did not want this banner to dictate PPE. They did not want it to dictate clinical practice—it is meant to just save you the time of having to click to the labs and scroll through, or click through the notes and scroll through, or click through the problem list. It was just meant as a snapshot. It was not meant to guide clinical practice, and they were always pretty adamant about that.*

4.2. Template development process

While the development of the COVID-19 templates moved at an unprecedented pace, user interviews with SMEs verified that all existing processes were followed:

> *We already have a clearly defined, written process for creating all national templates, like from step one through release. We just did it in a very expedited format. So, we might have had a one-day [Human Factors Engineering] HFE evaluation. We had daily test site calls, we released things very quickly, but we followed all the steps. We had work group approval, we had HFE review, we had Knowledge-Based Systems review. We have pilot site testing and release, and we may have done that for some of these things in like a seven-day period, as opposed to a seven-month period. But I think it is important to note that we still followed the process and I think we have kind of proved that the defined process works really well because we were able to adapt it quickly. So, with the COVID templates, by having a defined process, but kind of expediting every step, it made the expectations clear, and it allowed us to get quality content out in a very fast way, by still following all of the guidelines that are in place.*

The expedient development of the COVID-19 templates offered a critical response to an emergent clinical need:

> *One of the things that I have learned, and that I think we all need to learn …. You cannot wait forever to get this stuff out because the local VISN clinician is going to go ahead and create "what I need for my facility." … It is a waste of resources.*

4.3. Standardization

There were challenges to implementing standardization related to COVID-19 across the VA network, but resilience at the local level allowed the organization to continue to meet its core mission of patient care:

> *The national program office is a lovely concept. Like everything is standardized and we know exactly what the field is doing and we're going to give them exactly what they want and that's true at the national office. And then what people do in the field, boots on the ground, is they get that work done… and that is where standardization takes a beating.*

5. Discussion

Several factors worked together to make possible the rapid cycles that occurred during the development and deployment of the VA COVID-19 response HIT products. The careful composition of teams and focused engagement meant that the right voices were present at all development meetings and bottlenecks were removed so it was possible to have rapid approval of products. The mandate to install COVID-19 tools reduced barriers to use. Though the typical timeline for development, testing, approval, and implementation was compressed, no corners were cut. Program offices actively supported template development, and SMEs were made available to provide input on clinical information. Rapid evaluations identified any needs for redesign or supporting education, such as due to technical limitations. After approval by test sites, deployment throughout the enterprise rapidly occurred, accompanied by support for implementation.

A significant challenge of these projects was maintaining congruence with the clinical information, such as asymptomatic spread, which continued to evolve as designs were created, necessitating modification throughout the process and occasionally redesigns after deployment. The tool developers strove to match the guidance from the CDC, both in terms of content and order of presentation. In some instances, however, information was coming to the developers from clinicians in the organization more rapidly than the CDC could respond and issue new guidance, so VA tool development occasionally outpaced the CDC information. For example, early in the pandemic, clinicians were reporting concerns with the accuracy of COVID-19 test results, so VA made the decision to screen based on symptoms and label patients as "clinically positive" rather than simply relying on a positive test. This decision was made based on the relative risk of improperly assigning a COVID-positive patient to a COVID-negative group while accounting for clinician experiences of test inaccuracy and patients who first tested positive for COVID-19 much later in the disease progression than expected. The CDC later issued confirmatory guidance. In addition, clinicians on the front line in the early days of the pandemic in New York City observed indications such as loss of smell and taste and gastrointestinal symptoms that were later added to the VA screening tools.

During the COVID-19 pandemic, there were multiple and sometimes competing challenges of providing COVID-related care to patients with COVID-19, providing non-COVID-related care to patients with COVID-19, and maintaining care in a significantly altered care environment for patients without COVID-19. Different components of the VA HIT COVID-19 response targeted specific areas, while overall the tools worked to address these challenges. While accounting for each of these scenarios, VA balanced efficiency, quality of care, and patient safety to arrive at solutions that would best meet patient, provider, and family needs during the pandemic.

This new, rapid approach to HIT development in a large healthcare system promoted balancing of enterprise goals with local needs and requirements while permitting the collection of data nationally to support enterprise analytics. The design groups for the VA HIT COVID-19 response endeavored to meet the needs of local facilities, which were creating tools on their own to satisfy the goal of providing clinical care, but in the process were duplicating work and utilizing resources in a less efficient way. The design teams needed to move quickly to help the field while also building in features such as structured data in the form of national health factors that would allow the enterprise to track information nationally while monitoring its response to the COVID-19 pandemic. Where possible, the design teams adapted early local responses to increase development efficiency, understand and meet local needs, and encourage adoption of national solutions.

In its HIT response to the COVID-19 pandemic, VA demonstrated some key characteristics of a resilient system that helped it continue to meet evolving patient needs. Resilience has been defined as a property of systems that allows them to remain intact and functional despite the presence of threats (Hollnagel et al., 2013). An important component to system success related to resilience is understanding work-as-done in a system as opposed to work-as-imagined. The multidisciplinary group assembled as part of the VA HIT COVID-19 response was vital due to its ability to accurately describe needs of the field, understand the current state of patient care and HIT systems, and determine how to implement solutions given the existing tools and context of use. The iterative nature of the VA HIT COVID-19 response also allowed the team to evaluate the effects of changes and incorporate this knowledge into subsequent solution development and design efforts.

Next steps for understanding the VA HIT COVID-19 response include post-implementation surveillance to continue to track use of templates, identify metrics to support value, and search for any adverse unintended consequences. For example, preventative health will be a VA priority going forward due to deferred and delayed care in 2020. Though user feedback was collected throughout the development and evaluation cycle, additional systematic collection of user feedback from sites that were not involved during the development stage may yield important information about template utility and how the templates fit with user workflow in a variety of settings.

6. Conclusion

This project demonstrated the ability of a large healthcare system to respond in an agile fashion to a significant new challenge, demonstrating resilience at both the local and the national level. Development for the VA HIT COVID-19 response moved at an unprecedented rate. Prior to the COVID-19 pandemic, many might have thought this ability to adapt so swiftly was not possible.

While the rapid nature demanded by the COVID-19 pandemic required many adaptations to typical usability work, the VA HIT COVID-19 response still addressed important human factors considerations. Additional human factors and usability efforts such as usability tests, conceptual modelling, and journey mapping would be beneficial in future development efforts (e.g., Russ & Saleem, 2018; Campbell, 2020; Joseph et al., 2020). However, the nature of the COVID-19 pandemic has meant that a rapid development pace was always required in response to surges, so more rapid alternatives to traditional usability methods may be needed (e.g., Medlock et al., 2002; Russ et al., 2010).

Through its extraordinary response to the COVID-19 pandemic, VA met its mission of continuing to provide high level healthcare while simultaneously pivoting to address the new challenge. In addition, a centralized system facilitated the distribution of resources—including materials and personnel—to other VA facilities as needed. Finally, VA was able to fulfill its Fourth Mission of supporting non-Veteran healthcare and other emergency response needs.

In its COVID-19 response, VA channeled the full capability of its diverse healthcare systems into an "all hands-on deck" response. Individuals contributed significantly, working nonstop for months to provide care as well as new tooling to meet patient needs. The COVID-19 Initiative Workgroup brought over 300 years of institutional knowledge and expertise to bear on tool creation. Vitally to the success of the response, resources were dedicated, personnel were made available, and barriers were removed to accomplish the work that was needed.

Author Statement

The authors declare that there is no conflict of interest.

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