View Abstract

Title: TOGETHER for PPE Readiness

Abstract Body:

Project abstract (1000 Characters): Strains on the healthcare ecosystem by the 2009 H1N1 and 2014 Ebola outbreaks highlighted gaps in Personal Protective Equipment (PPE) inventory management and reallocation capabilities across the country, largely stemming from a lack of trust between stakeholders and of automation for exchanging PPE data. Addressing these gaps is especially critical during the COVID-19 pandemic.

The Center for Medical Interoperability (C4MI) entered a public-private partnership with the Centers for Disease Control and Prevention (CDC) to develop FHIR services deployed on a trusted platform that supports near-real-time monitoring of personal protective equipment.

FHIR clients deployed in stakeholder networks ingest data from inventory systems and other local data sources, reporting PPE data to a custom FHIR API and other data services deployed on C4MI's Healthcare Trust Platform (HTP). This has been deployed as a pilot, and the resulting ecosystem spans 78 hospitals across 17 states and 7 HHS regions.

Project rationale, impact and innovation (3500 Characters): In the event of a public health emergency response, the need to protect 18M healthcare workers results in an abrupt increase in demand for PPE. Additionally, U.S. healthcare does not have a standardized system for monitoring PPE inventories, which further exacerbates PPE demand as pandemic situations often result in panic purchasing, such as those seen in COVID-19, SARS, H1N1, and Ebola. To meet this elevated demand, manufacturers need upwards of three months to increase production, resulting in PPE shortages. In response, hospitals acquire PPE products not typically used by their staff. This requires the redirection of critical resources to provide just-in-time training. Although emergency PPE stockpiles exist throughout the country at local, state, and federal levels, the exact PPE products being used by major hospital networks are unknown, making alignment of stockpile inventories within a region challenging. Furthermore, the quantity of stockpiled PPE has proven insufficient to meet the entirety of demand for large-scale events, implying additional emergency preparedness strategies are needed.

One of the largest gaps in this area is the lack of trust between and among various stakeholders, particularly with respect to the exchange of inventory data. On behalf of its members, C4MI had previously defined the Healthcare Trust Platform (HTP), a business and technology platform designed to enhance interoperability, data liquidity, and trust among devices, systems, applications, and stakeholders in the healthcare industry. The HTP includes a technical architecture and a governance model embodied in common participation and data use agreements. The alignment of strategic objectives between C4MI and its health system members has created a strong partnership for the application of a clinical use case on the Healthcare Trust Platform.

The TOGETHER for PPE Readiness project aims to use the HTP to establish an ecosystem of hospitals, coalitions, stockpiles, and other stakeholders to share PPE inventory data in a trusted and automated way, to create a near-real-time PPE monitoring system that provides insights into the ecosystem's readiness to respond to outbreaks and other disaster scenarios. This project builds on the use-case agnostic HTP technical architecture and governance model. PPE-specific FHIR applications deployed within participants' networks integrate with existing inventory systems and securely communicate up-to-date PPE data via a FHIR API deployed on the HTP. Generic HTP data use and participation policies are amended to include provisions specific to PPE data.

Use of this near-real-time PPE monitoring system by major hospital networks and emergency stockpiles will allow decision makers to have accurate information about PPE inventories during emergencies and to closely monitor PPE use during regular clinical care. Data gathered by this system will enable emergency planners to prepare for surge demands by (1) informing optimal PPE inventories based on hospital characteristics (e.g., major metropolitan area with large immigrant population) and rates of PPE use during previous emergencies;

(2) allowing hospital networks and coalitions to standardize PPE for sharing; (3) empowering federal, state, and local government stockpiles to align inventories with that of major medical centers; and (4) enabling PPE inventory comparisons among hospitals, coalitions, and networks with similar characteristics to self-assess preparedness levels.

Project design and implementation (7000 characters): To demonstrate the approach and feasibility of a PPE monitoring system, C4MI engaged with several of its hospital and health system members to participate in a pilot, resulting in near-real-time PPE data reported from 78 hospitals from 3 health systems across 17 states and 7 HHS regions. In this pilot, technology was developed and deployed to automatically extract and report PPE data from the participant's information systems for analysis and blinded reporting to the CDC.
Participating hospitals engaged in the following ways:
1. Steering Committee – clinical leadership from participating hospitals provided primary points of contact for general oversight, project prioritization, feedback, and logistics
2. Technical Input Contacts – participants' architecture, data, and security teams provided technical input to inform the design and development of all technical components
3. Legal Teams – the C4MI legal and policy team engaged with the participants' counterparts to ensure legal documents and frameworks were in place for data exchange

The components developed and deployed for this pilot include custom FHIR clients ("PPE Importers") that are locally deployed in hospital IT networks to integrate with information systems, extract PPE inventory and purchase order data, and automatically report the data to a custom FHIR API ("PPE FHIR API"). A report generator queries the API to automatically generate supply and demand analysis reports. All components are deployed on a use-case agnostic platform for trusted data exchange. Key components are described below.

DATA MODEL
A standard data model for PPE inventory and purchase order data supports consistent monitoring and analysis across all participating hospitals. This data model was designed by analyzing participating hospital's information systems. It was developed as a logical model and manifests in the hospital information system data extraction (a CSV file), the PPE FHIR API, and the database backing the PPE API. The resulting FHIR resources are
- Product: a PPE item (such as an N95 or surgical mask), identifiable by a manufacturer, model number, possibly a Global Trade Identification Number (GTIN), and a category conveyed by a custom nomenclature
- Inventory: represents an on-hand quantity (at some point in time) for a specific product, organization, and internal location (e.g. supply closet #1)
- Order: represents the state (at some point in time) of a purchase order for a specific product, organization, and internal location, including status (open/pending/closed) and received quantities

Key challenges with this data model design include:
- Supporting supply chain variation across participating hospitals (e.g. standardizing purchase order status codes)
- Handling purchase order edge cases (e.g. partially filled orders)
- Existing equipment category vocabularies (e.g. UNSPC) are not uniformly adopted by hospitals
- FHIR API design. After consulting with the HL7 Orders and Observations working group on the initial API design and performing a gap analysis with existing FHIR R4 resources, it was determined future iterations should profile DeviceDefinition for products, profile SupplyRequest for orders, and align with existing IHE efforts for inventory data.

PPE FHIR CLIENTS
Custom FHIR clients ("PPE Importers") are locally deployed in hospital IT networks. These applications (written in Java using HAPI FHIR) consume PPE data as C4MI-specified CSV files that hospitals generate as scheduled exports or reports from their local inventory and supply management systems. This data is validated and cached locally before being converted to FHIR requests and sent to the C4MI-hosted PPE Data Services. Inventory systems may also write FHIR requests directly, if supported.

One challenge here was the architectural review, security assessment, and business impact analyses required for deployment at all participating hospitals. Developing legal arrangements and data use agreements also represented a significant challenge.

PPE DATA SERVICES
The PPE Data Service (also written in Java using HAPI FHIR) supports the PPE FHIR resources, allowing it to

receive reported PPE data from participating hospitals, normalize against a C4MI-curated PPE product catalog, and support queries for supply and demand analysis.

Performance of these data services was carefully considered to ensure the PPE Data Services could handle a growing number of participants and data. Once an organization is onboarded and reporting daily, data volume and product management are relatively stable, but the onboarding itself represents significant spikes in data volume and new PPE products. This needs careful consideration, especially since some hospitals report several orders of magnitude more data than others.

The PPE Product Catalog also represents a significant maintenance effort and requires careful consideration to scale.

PPE REPORT GENERATOR

To demonstrate the feasibility of supply and demand analysis of the raw PPE data reported by participating hospitals, a FHIR app was developed (the “PPE Report Generator”) to automatically query the PPE FHIR API and generate reports that show raw data and trends for states and individual hospitals (organizationally blinded to remove easily identifiable information). These reports are based on daily data delivered from participating hospitals and are delivered weekly to CDC sponsors.

Each PPE report contains raw PPE data, including daily trending on-hand inventory and received quantities at model and category levels. Each report also contains burn rate estimates derived from the raw data. This estimate considers on-hand quantities from a given day, on-hand quantities for the previous day, and received quantities to approximate the number of items used that day (a “daily burn”). Warning indicators are based on configurable fixed thresholds (e.g. “if on-hand quantities of N95 respirators drops below 5000, display a warning”) and on large fluctuations over time (i.e. large deviations from a moving average).

Some data quality issues were encountered when developing the report generator. Specifically, if hospitals report order data for some items or internal locations but are not able to report corresponding on-hand quantities, then calculated burn rates will be overestimated, because it appears that orders are coming in and being used. (Similarly, if order data is underreported, burn rates will be underestimated.)

HEALTHCARE TRUST PLATFORM

All components are deployed on the Healthcare Trust Platform - a use-case agnostic platform for trusted data exchange. This platform is a distributed network requiring digital identities (issued under a C4MI-managed PKI), secure communications, and auditable transaction logs, all supporting a trusted ecosystem of actors such as FHIR clients and APIs. Governance aspects, including participation and common data use agreements, are critical to maintain the trust, accuracy, and availability of HTP components and transactions.

Project evaluation and sustainability (3500 characters): Success for the pilot near-real-time PPE monitoring system was defined as meeting a specific deployment footprint, with participating hospitals reporting daily data, and blinded summary reports being automatically generated and sent weekly to the CDC.

DEPLOYMENT FOOTPRINT

The goal deployment footprint was 100 hospitals across 7 HHS regions and 18 states. By the end of the pilot period, the deployment footprint had reached 78 hospitals across 7 HHS regions and 17 states. While this fell slightly short quantitatively, the participants represented an excellent cross-section of hospitals, including community, academic, and large health system participants.

PPE DATA

Daily PPE data reporting by participants was also successful. The only requirement here was daily reporting, which was met, but the quantity of data is worth noting. By the end of the pilot 10,126 on-hand inventory quantities and 4,844 order statuses were reported daily, and the product catalog represented 2089 unique products from 186 unique manufacturers and 128 distributors.

GENERATED REPORTS

Automatically generated weekly reports were also a success. These reports contained daily blinded data from all participating hospitals, along with burn rate estimates and summary data. They were sent weekly to the National Personal Protective Technology Laboratory (NPPTL) within the CDC’s National Institute of Occupational Safety and Health (NIOSH), resulting in 15 weeks of successfully delivered automated reports.

TRUST

Trust between stakeholders was determined to be a major gap in supporting inventory management and equipment reallocation capabilities across the country. Deploying the PPE components on the Healthcare Trust Platform supports this trust by providing a secure infrastructure for data exchange and a governance framework amenable to all participants. Onboarding participating organizations to this trust platform requires executed data use agreements from all participants, the request and issuance of digital identities from C4MI's PKI, and the deployment of Trust Platform Gateways and PPE applications within participants' networks. All these tasks were considered qualitative measures of success and were achieved within the pilot.

SUSTAINABILITY

The team has explored project sustainability from multiple perspectives. C4MI's membership model, in which hospitals and health systems contribute membership dues, allowed C4MI to establish the Trust Platform, while the CDC's need to respond to project PPE shortages during pandemics brought federal dollars to enable its implementation and PPE-specific application development.

The platform approach allows the distribution of costs for the trusted data exchange infrastructure, so as the number of users increases, the cost falls significantly across the network. A cooperative model (present in other industries), in which the infrastructure's users also have an opportunity to own it, is one possibility for long-term sustainability of the core platform.

Regarding PPE data exchange, the PPE monitoring system alone likely does not hold enough market demand to sustain itself, even in the age of COVID-19. One possibility is for federal, state, and local entities who might benefit from its existence to support or mandate it. Another possibility is a market-based solution, where the PPE API could be packaged as a base offering in the cooperative organization that offers the core platform.

Twitter project summary (140 characters): Using FHIR to deploy a near-real-time PPE monitoring ecosystem for health system PPE readiness during the COVID-19 pandemic

How is FHIR used in the App being demonstrated (500 characters)? : FHIR is used as a machine-to-machine interface. A FHIR API using custom resources for PPE data is the primary means of data exchange. FHIR clients deployed in hospital IT networks consume data from local information systems and send data to the FHIR API; a report generator queries the API for supply and demand analysis and automatically generates summary supply and demand analysis reports containing raw data and burn rate estimates.

1. What FHIR release does your application use? (500 characters)?: The PPE FHIR API is based on FHIR R4. Resources are all custom (profiles of Basic), except for a profile of the Organization resource. Details on these resources, their initial development, consultation with HL7, and their future development is in the "Implementation" section above.

What is the data source for the FHIR resources and how are the FHIR resources accessed? (500 characters): Custom FHIR clients deployed in hospital IT networks integrate with local information systems, extract PPE inventory and purchase order data, convert the data to FHIR requests, and automatically report the data to a custom FHIR API. The resources are accessible by authorized systems on the Healthcare Trust Platform, including a report generator that queries the API to automatically generate supply and demand analysis reports.

Customers: No

Solution Date: 09/01/19

Implementation Date: 06/01/20

How many users does your solution have or how many patients have been impacted by it (please indicate time frame)?: Deployment footprint includes 78 hospitals from 3 health systems across 17 states and 7 HHS regions

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