Vaccination Documentation: International Data Standards as an Essential Foundation

18 February 2021
10:30-12:00 EST/16:30-18:00 CET
Agenda

• Introduction
• Urgency and Goals of the Proposed Project
• International Consensus Towards Vaccination Documentation
  o Current Landscape and Scope of Project
  o CDISC Initial DRAFT of Core Elements for Vaccine Administration Record Information
• Questions
• Breakout Groups for Discussion
• Comments from Breakout Groups
• Actions and Next Steps
Issues Encountered in Managing Covid-19 Data

New York Times (13 July 2020)

• “Before public health officials can manage the pandemic, they must deal with a broken data system that sends incomplete results in formats they can’t easily use…..Health departments track the virus’s spread with a distinctly American patchwork: a reporting system in which some test results arrive via smooth data feeds but others come by phone, email, physical mail or fax… These reports often come in duplicate, go to the wrong health department, or are missing crucial information…”

Resolve to Save Lives - Report (21 July 2020)

• “The report found critical gaps in the availability of information necessary to track and control COVID-19: across the 50 states, only 40% of essential data points are being monitored and reported publicly. More than half the essential information—strategic intelligence that leaders need to turn the tide against COVID-19—is not reported at all.”

(See also http://preventepidemics.org )

Protocol (7 July 2020)

• “The COVID-19 crisis laid bare all the ways that EHRs have fallen short—and what needs to be done….as with any systemic problem, there are endless root causes. One of them it the lack of uniform standards for how data is entered into EHRs to begin with.”

Situation in Spain, Italy and the United States During the Pandemic

• The U.S. has over 56 different public health systems that all function differently; responsibility was distributed.
• Spain has 17 different regions; a national approach was in place for 3 months; there is now regional responsibility.
• Italy has different regions, however, during the pandemic, a national approach was instituted.
Proposed Project

Goal: widely adopted and internationally implemented data standards documenting vaccine administration

Use Cases: travel, education, business safety, learning → knowledge

Scope: minimum set of core elements and metadata (including terminology/codelists) of key data related to vaccine administration

Not for Discussion Today:
• Safety Information (pharmacovigilance, adverse event tracking)
• Credentialing information (security, confidentiality, privacy)
• Application development and technology solutions
International Air Transport Association (IATA)

IATA Website: “The fragmented and diverse set of COVID-19 testing requirements for entry and exit as well as the range of different types of tests (PCR, LAMP, antigen and spectroscopic) required by governments have created a challenging and complex environment for immigration authorities, passengers and airlines to navigate.”
The Case an International Data Standard

Public Health/Private Vaccine Documentation
Various Paper Records (Pharmacies, Gyms, Clinics, etc.)

Public Health
-> Databases within Various Regions, States and/or Countries

Hospitals/Clinics

Electronic Health Records

Various Apps in Development

Border Requirements for Vaccine Administration Data

= Vaccine Administration Data Content

= Other data, e.g. testing, Tx
For vaccine documentation apps to be successful, the underlying data upon which they are based must be:

- Accurate and meaningful
  - Accessible
  - Consistently defined
- Represented in a standard data format

To encourage adoption of a common international standard for vaccine administration data to support apps and the desired use cases, the standard must be simple and understandable, supporting data inputs from healthcare, research, public health, including:

- Paper Forms (data entered later)
  - eCase Report Forms
- Public Health Databases, Registries
  - Electronic Health Records
**Relevant Standards Initiatives**

**Vaccine Credentialing Initiative (VCI)**  
VCI Coalition = CARIN Alliance, Cerner, Change Healthcare, The Commons Project Foundation, Epic, Evernorth, Mayo Clinic, Microsoft, MITRE, Oracle, Safe Health, Salesforce

- HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (406 pages)
- SMART Health Cards specification, based on W3C Verifiable Credential and HL7 FHIR standards

**Clinical Data Interchange Standards Consortium (CDISC)**  
Developed international therapeutic area standards for clinical research data to support regulatory decisions, including one for Covid-19 vaccines and therapies  
Released May 2020

**European eHealth Network**  
Guidelines on proof of vaccination for medical purposes - basic interoperability elements
Harmonized Vaccine Administration Standard

- Harmonized set of core elements
  - European eHealth Network
  - CDISC
  - OMOP
  - HL7 CCD, USCORE (FHIR)
- Discussion today in breakout groups
- Rapidly publish/disseminate core data elements for broad international comment
- With sufficient interest, develop further and finalize standard through a robust, accredited, standards development process
- Produce a readily understandable Implementation Guide
- Ensure there is a Communication Plan
Proposed Core Data Elements

• **Vaccination Information**
  • Disease or agent targeted
  • Vaccine/Prophylaxis Medicinal Product & Trade Name
  • Marketing Authorization Holder
  • Manufacturer
  • Expected number of doses (property)
  • Vaccine Administered
  • Batch/lot number
  • Dose, Dose Unit
  • Route of Administration
  • Date of 1st dose
  • Date of 2nd dose
  • Booster, if applicable
  • Administering center
  • Administered by
  • Country of vaccination
  • Next vaccination date (optional)

• **Patient Identification Information**
  • Name: First and last. Mother’s maiden name
  • Date of Birth, Month of Birth, Year of Birth
  • Gender
  • Address, City, County, State, Country, Post code
  • Informed consent date - Day, month, year

• **Certificate Metadata**
  • Certificate issuer
  • Certificate Identifier
  • Certificate Valid from (optional)
  • Certificate Valid until (optional)
  • Certificate Schema Version - Version of minimum dataset definition (E.g. 1.0)

Note - some fields will repeat (ex. dates, dose and dose unit)
**Controlled Terminology**

**EXAMPLE: Constrained List for ‘Route of Vaccine Administration’**

- **Route of Administration**
  - Intermuscular
  - Nasal
  - Oral
  - Percutaneous
  - Sublingual
  - Topical

The Case for an International Data Standard

Public Health/Private Vaccine Documentation
Various Paper Records (Pharmacies, Gyms, Clinics, etc.)

Public Health
-> Databases within Various Regions, States and/or Countries

Hospitals/Clinics

= Vaccine Administration Data Content

Various Apps in Development

Border Requirements for Vaccine Administration Data

Electronic Health Records
Potential Benefits of this Project

• International, interoperable, fit-for-use mappable record of vaccinations
• Easy to understand and implement for paper forms, electronic forms, EHRs
• Can be shared among a variety of providers (public health, hospitals, pharmacies, governmental agencies)
• Enable app developers to be successful in accessing the data they need so that they can innovate around user interfaces vs. contending with disparate data sources
• Allow travelers to have internationally acceptable proof of vaccination
• Allow educational institutions to track vaccinations to ensure safety of instructors and students
• Allow businesses to open more safely
• Enable learning from a wider variety of data sources with access to a more trustworthy and understandable data
• Enable secondary use in the future
  • De-identified patient level data
  • Standard testing data
• Supports regulatory missions related to pharmacovigilance, public health and welfare
• Is the proposed minimum core set of data elements missing anything essential?

• Is there anything in the proposed minimum core set of data elements that is unnecessary?

• Does the group have other recommendations with respect to the core set of data elements proposed?

• What other stakeholders should be engaged and how?
Breakout Group Reports
Actions and Next Steps

Facilitated by Dr. Charles Friedman

• For Slides, Participant Bios, References, Notes from Today
  • www.learninghealth.org (Initiatives Tab)

• For the organizers’ publication
  • Learning Health Systems Journal Vol.5, Issue 1, January 2021

Addressing the Covid-19 pandemic and future public health challenges through global collaboration and a data-driven systems approach (wiley.com)

• Questions…e-mail: rkush@catalysisresearch.com

• For further information on CDISC and the Covid-19 Therapeutic Area Standard
  • www.cdisc.org
  • www.cdisc.org/standards/therapeutic-areas/covid-19

Thank You All for Participating!