Received: 16 March 2020 | Revised: 11 July 2020 | Accepted: 21 September 2020

DOI: 10.1002/pds.5142

COMMENTARY

WILEY

Preparing for COVID-19 vaccine safety surveillance: A United States perspective

Kevin Haynes

HealthCore, Inc, Wilmington, Delaware

Correspondence
Kevin Haynes, HealthCore, Inc. Wilmington, Delaware 19801.
Email: khaynes@healthcore.com

The availability of a vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus which causes the respiratory illness coronavirus disease 2019 (COVID-19), may be over 10 months away with many potential products in development.[1] However, just as important as the development of the vaccine, we need to create a robust system to evaluate the real-world evidence of safety and effectiveness in parallel. One component of this system must be an electronic exposure registry that can track vaccine administrations. Similar to other mass vaccination campaigns,[2] public health authorities will need to control distribution and roll out a nationwide campaign. Since the 2009 to 2010 H1N1 pandemic, many models have utilized pharmacies to administer influenza vaccine.[3,4] Developing this infrastructure and model for vaccination delivery will allow for orderly distribution of the product which must be linked to efficient billing process through multiple channels to create a much needed active surveillance system.

Vaccine administration has been at the forefront of innovative public health delivery. Part of this innovation has led to the development of organized record keeping systems to document the administration. In 1955, Congress passed the Polio Vaccination Assistance Act at the time private physicians were urged by the American Medical Association to make records on vaccinations they performed consisting of the name and age of the individual, the site of injection, and source and lot number of the vaccine.[5] In 1962, Congress extended the Centers for Disease Control and Prevention's (CDC) Public Health Service Section 317 Immunization Grants Program to establish the Vaccination Assistance Act to assist in purchasing vaccine doses. In addition to direct public vaccine provision, the act developed immunization registries and promoted the conduct of vaccine-preventable disease surveillance and population needs assessments.[6] In 1986, the National Childhood Vaccine Injury Act was enacted and afforded the Department of Health and Human Services the opportunity to establish the Vaccine Adverse Event Reporting System (VAERS), co-administered by the US Food and Drug Administration (FDA) and CDC.[7] VAERS is charged to accept all reports of suspected adverse events. The advent of a COVID-19 vaccine presents an urgent need to further advance these prior initiatives into the 21st century through digitalization of documented of vaccine administrations. A robust system will afford database documentation with linkage to conduct real-world active safety surveillance across multiple points of community vaccine delivery (eg, pharmacies, doctors' offices, schools, and workplaces).

The FDA Sentinel System is a distributed data network with a common data model (CDM) of curated real-world data and distributed analytic tools to generate real-world evidence for FDA decision-making,[8] and offers a unique ability to conduct active medical product surveillance as has been shown before for influenza.[9] However, the Sentinel System lacks the electronic documentation of community and workplace vaccine administrations and is delayed in physician and health system medical record claims documentation of vaccine administration. In order to maximize the utility of such surveillance systems, administrations of a COVID-19 vaccine should be broadly available with an ability to integrate data into a CDM such as Sentinel. One way to facilitate broad availability is to consider use of pharmacy distribution systems given the robust ability of pharmacy claims adjudication to provision a near real-time registry. There are three reasons distribution and physical administration should be conducted through retail pharmacies or utilize the retail pharmacy distribution and adjudication systems. (1) Controlled distribution of product through existing supply chain processes; (2) Established electronic claims adjudication conducted at the time of physical administration; (3) Reduced burden on health systems and providers who will be providing care for those with COVID-19. Health systems that wish to administer the vaccine to either hospital or home bound patients could utilize retail pharmacies owned by those health systems or local pharmacy distribution for documentation. While the current infrastructure in place serves as an excellent foundation, community pharmacies will need additional nursing and public health staff trained in immunization delivery to aid in increased physical administrations. In addition, local pharmacies will need to be staffed with additional pharmacy technicians to process the electronic documentation of vaccine administrations. This process can be modeled after the seasonal influenza vaccine programs most

retail pharmacies provide with documented ability to increase vaccine distribution reach and capacity.[10] Through secure smart phone technology, pharmacy claims adjudication using bar code scanning via secure pharmacy claims processing could be established virtually anywhere, including physician offices, hospital entrances, airports, places of worship, community centers, or mobile clinics. Smart phone technology has been used in Syria to document vaccine administrations.[11] Similarly, the Handheld Automated Notification for Drugs and Immunizations (HANDI) system has captured influenza vaccination data during Denver Health's annual employee influenza campaign.[12] Engaging state boards of pharmacy to permit this mobilization of the pharmacy distribution network would help expand the availability to all corners of health care delivery and community engagement while maintaining the ability to create the digital registry. The utilization of administrative pharmacy claims to conduct high quality comparative effectiveness vaccine studies of influenza vaccine have shown the utility of this real world data to support evidence generation.[13] Physician billing processes through procedure claims documentation of HCPHCs and CPT codes is slow and prevents real time utilization in safety surveillance systems a radical shift would be to have providers bill through NDC pharmacy claims systems for more real time electronic data capture. The rapid adjudication of pharmacy claims within the FDA Sentinel System has been proven to provide an active product surveillance framework for vaccine safety.[14]

The traditional pharmacy transactional claims processing can provide a robust mechanism to electronically update a registry of the population vaccinated and through technology enabled solutions provide this registry securely to providers to update patient's electronic health records (EHR). This integration of retail pharmacy data with EHRs would greatly enhance the immunization information systems (IIS) developed at the state level to track immunization histories as many are in desperate need for modernization.[15] A patchwork of state laws limits the utility of these vital information systems in how the data are collected and transmitted.[16] A transactional pharmacy claims-based system can provide a nationwide solution including for those not covered under insurance as an adjudication process and can be performed for those obtaining the vaccine through public assistance programs. Medicaid pharmacy record systems could be included in the FDA Sentinel System with state approval as these claim systems are identical to those utilized among commercial insurance systems. Any vaccine distributions conducted through regional distribution for the uninsured could have similar provisions to populate a nationwide information vaccine surveillance system. This nationwide registry could either push or have systems pull records to individual health system EHRs, thus automating the electronic documentation across health systems and potentially preventing repeat vaccination. Medication and vaccine list portability has been achieved utilizing HL-7 Fast Healthcare Interoperability Resources (FHIR)-based data transfer.[17] This active monitoring system would generate a nationwide patient safety resource to protect the public health. The investment in interoperability across pharmacy adjudicated claims, state IIS, and vendor EHR systems would greatly enhance public health. Given how rapid the integration of clinical information systems to support the COVID-19 pandemic in collaboration between the Office of the National Coordinator and the CDC, it is feasible now to put in place the mechanisms to improve vaccine safety surveillance.[18]

Although given the public health reporting purpose, which allows for direct use of personally identifiable information (PII), secure privacy preserving record linkage could be implemented to further protect PII in a Health Insurance Portability and Accountability Act (HIPAA) compliant manner, similar to other public health exposure record systems such as state prescription drug monitoring programs for the opioid epidemic. The generation of a nationwide COVID-19 registry and safety surveillance system would become a model for a nationwide learning health system and create the infrastructure necessary to interoperate across health care delivery, medical product safety surveillance, and patient-centered comparative effectiveness research. The patient-centered comparative effectiveness research could be extended through the use of the FDA MyStudies app,[19] or other suitable digital health enabled applications. Mobile applications and web-based portals could engage patients to participate in patient reported outcome studies and obtain authorization for additional data linkage with clinical data systems.

As our nation contends with the current COVID-19, we must also prepare the vigilance systems necessary to digitally track the physical administration of a future available vaccine and ensure that public safety surveillance monitoring will be in place to protect public health. Our nation has an opportunity to build the necessary digital infrastructure to support the public health safety surveillance to counter emerging threats.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ORCID

Kevin Haynes https://orcid.org/0000-0002-7087-9159

REFERENCES

1. World Health Organization. DRAFT landscape of COVID-19 candidate vaccines. 2020. https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf. Accessed March 10, 2020.
2. Institute of Medicine. *The 2009 H1N1 Influenza Vaccination Campaign: Summary of a Workshop Series*. Washington, DC: The National Academies Press; 2010.
3. Fitzgerald TJ, Kang Y, Bridges CB, et al. Integrating pharmacies into public health program planning for pandemic influenza vaccine response. *Vaccine*. 2016;34(46):5643-5648. https://doi.org/10.1016/j.vaccine.2016.09.020.
4. Schwerzmann J, Graitcer SB, Jester B, et al. Evaluating the impact of pharmacies on pandemic influenza vaccine administration. *Disaster Med Public Health Prep*. 2017;11(5):587-593. https://doi.org/10.1017/dmp.2017.1.
5. Anderson OL. The polio vaccine assistance act of 1955. *Am J Public Health Nations Health*. 1955;45(10):1349-1350. https://doi.org/10.2105/ajph.45.10.1349.
6. Brink E, Koops G, Brusuelas K, Hicks T. Immunization Program Operations Manual (IPOM). Atlanta, GA: Centers for Disease Control and Prevention, National Immunization Program; 2000.

7. Chen RT, Rastogi SC, Mullen JR, et al. The vaccine adverse event reporting system (VAERS). *Vaccine*. 1994;12(6):542-550. https://doi.org/10.1016/0264-410x(94)90315-8.
8. Brown JS, Maro JC, Nguyen M, Ball R. Using and improving distributed data networks to generate actionable evidence: the case of real-world outcomes in the Food and Drug Administration's sentinel system. *J Am Med Inform Assoc*. 2020;27(5):793-797. https://doi.org/10.1093/jamia/ocaa028.
9. Yih WK, Kulldorff M, Sandhu SK, et al. Prospective influenza vaccine safety surveillance using fresh data in the sentinel system. *Pharmacoepidemiol Drug Saf*. 2016;25(5):481-492. https://doi.org/10.1002/pds.3908.
10. Bartsch SM, Taitel MS, DePasse JV, et al. Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. *Vaccine*. 2018;36(46):7054-7063. https://doi.org/10.1016/j.vaccine.2018.09.040.
11. Khader YS, Laflamme L, Schmid D, et al. Children immunization app (CImA) among Syrian refugees in Zaatari camp, Jordan: protocol for a cluster randomized controlled pilot trial intervention study. *JMIR Res Protoc*. 2019;8(10):e13557. https://doi.org/10.2196/13557.
12. McClung MW, Gumm SA, Bisek ME, Miller AL, Knepper BC, Davidson AJ. Managing public health data: mobile applications and mass vaccination campaigns. *J Am Med Inform Assoc*. 2018;25(4):435-439.
13. Izurieta HS, Thadani N, Shay DK, et al. Comparative effectiveness of high-dose versus standard-dose influenza vaccines in US residents aged 65 years and older from 2012 to 2013 using Medicare data: a retrospective cohort analysis [published correction appears in Lancet Infect Dis. 2015 Apr;15(4):373] [published correction appears in Lancet Infect Dis. 2015 Mar;15(3):263]. *Lancet Infect Dis*. 2015;15(3):293-300. https://doi.org/10.1016/S1473-3099(14)71087-4.
14. Nelson JC, Wellman R, Yu O, et al. A synthesis of current surveillance planning methods for the sequential monitoring of drug and vaccine adverse effects using electronic health care data. *EGEMS (Wash DC)*. 2016;4(1):1219. https://doi.org/10.13063/2327-9214.1219.
15. Popovich M, Watkins T, Baker BA. Model for sustaining and investing in immunization information systems. *Online J Public Health Inform*. 2019;11(2):e20. https://doi.org/10.5210/ojphi.v11i2.10243.
16. Martin DW, Lowery NE, Brand B, Gold R, Horlick G. Immunization information systems: a decade of progress in law and policy. *J Public Health Manag Pract*. 2015;21(3):296-303. https://doi.org/10.1097/PHH.0000000000000040.
17. Coons JC, Patel R, Coley KC, Empey PE. Design and testing of Medivate, a mobile app to achieve medication list portability via fast healthcare interoperability resources. *J Am Pharm Assoc* (2003). 2019;59(2S):S78–S85.e2. doi:https://doi.org/10.1016/j.japh.2019.01.001
18. Health IT.gov. COVID-19 response: tools and resources for the health IT and clinical community. https://www.healthit.gov/coronavirus. Accessed April 27, 2020.
19. US Food and Drug Administration. FDA's MyStudies Application (App). https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app. Accessed March 10, 2020.

How to cite this article: Haynes K. Preparing for COVID-19 vaccine safety surveillance: A United States perspective. *Pharmacoepidemiol Drug Saf*. 2020;29:1529–1531. https://doi.org/10.1002/pds.5142