

# The Drug Supply Chain Security Act and 2D Vaccine Barcodes

## **Prepared for**

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# 1 Executive Summary

The Drug Supply Chain Security Act (DSCSA), signed into law on November 27, 2013, aims to enhance the FDA's ability to protect consumers by identifying and removing counterfeit and dangerous medicines/products from the U.S. pharmaceutical supply chain. The DSCSA stipulates that by 2023, the U.S. will have an electronic, interoperable system that will be able to monitor the movement of prescription drugs from manufacturing to dispensation. To operationalize this objective, the DSCSA requires that manufacturers imprint, in human readable form, a product identifier to each package and case of a product that they intend to introduce into the supply chain. In addition, the product identifier must include the National Drug Code, Serial Number, Lot Number and Expiration date encoded within a 2D barcode.

Product serialization is a key building block and enabler of traceability; in the public health context, traceability can support improved recall capabilities and the ability to validate the authenticity of pharmaceutical products. These gains, however, are highly dependent on the integration and interoperability of information systems and processes.

# Background and Overview

## 1.1 Background

Ongoing regulatory efforts to bolster drug distribution security have promoted an enhanced focus on ways to leverage two-dimensional (2D) barcodes to improve how pharmaceutical product information is stored, distributed, managed, and used. To transcend limitations around the amount of data contained in linear barcodes, leading industry stakeholders evaluated alternative technologies. This manifested in the passing of Title II of the Drug Quality and Security Act (DQSA)—also referred to as the Drug Supply Chain Security Act (DSCSA).<sup>12</sup> The DSCSA outlines steps to build an electronic, interoperable systems to identify and trace certain prescription drugs as they are distributed in the United States.<sup>3</sup> The system is intended to enhance the FDA’s ability to: 1) protect consumers from drugs that may be counterfeit, stolen, contaminated or otherwise harmful; and 2) detect and remove potentially dangerous drugs from the drug supply chain.<sup>4</sup> This act requires the consistent traceability of pharmaceutical products from the manufacturer to the dispenser, and is one in a series of regulations intended to improve the safety of products in the U.S. pharmaceutical supply chain.<sup>5</sup>

The goal of DSCSA is to develop and use an electronic system to identify and trace pharmaceuticals throughout the U.S. supply chain by 2023.<sup>6</sup> This will facilitate information exchange at the individual package level, improve recall efficiency, and enable swifter action against products identified as illegitimate or counterfeit.<sup>7</sup> Serialization, or product identification, requires a product identifier in human readable form as well as encoded within a data carrier. The product identifier consists of the National Drug Code (NDC), Serial Number, Lot Number, and Expiration Date. Per the DSCSA, the data carrier is required to be a 2D data matrix barcode when affixed on the product package. The impact of serialization on vaccines is discussed later in this document.

There are three phases to DSCSA. Over a ten-year period, from 2013 to 2023, the implementation will cover lot- and chain-of-ownership data with a 2015 deadline (phase 1); item-level serialization and marking with a 2017 deadline (phase 2); and exchange of item-level serialization and traceability back to origin by 2023 (phase 3).<sup>8</sup>

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<sup>1</sup> Upton, Fred. “H.R.3204 - 113th Congress (2013-2014): Drug Quality and Security Act.” Webpage, November 27, 2013. <https://www.congress.gov/bill/113th-congress/house-bill/3204>.

<sup>2</sup> Center for Drug Evaluation and Research. “Drug Supply Chain Security Act (DSCSA).” *FDA*, 20 May 2019, /drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

<sup>3</sup> *Ibid*

<sup>4</sup> *Ibid*

<sup>5</sup> Coustasse, Alberto, Craig A. Kimble, Robert B. Stanton, and Mariah Naylor. “Could the Pharmaceutical Industry Benefit from Full-Scale Adoption of Radio-Frequency Identification (RFID) Technology with New Regulations?” *Perspectives in Health Information Management* 13, no. Fall (October 1, 2016). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075230/>.

<sup>6</sup> “The Drug Supply Chain Security Act (DSCSA) Working Towards Enhanced Drug Distribution Security in the U.S.” presented at the GS1 Healthcare Conference, n.d. [https://www.gs1.org/sites/default/files/docs/Bogota/Day2\\_20181104\\_Bogota\\_US%20Drug%20Supply%20Chain%20Security.pdf](https://www.gs1.org/sites/default/files/docs/Bogota/Day2_20181104_Bogota_US%20Drug%20Supply%20Chain%20Security.pdf).

<sup>7</sup> *Ibid*

<sup>8</sup> GS1 U.S., “GS1 Standards for DSCSA Suppliers Certificate Course Summary.” Webpage, August 23, 2019. <https://resources.gs1us.org/GS1-US-Store/Product-Viewer/dscsa-00614141026029>

The original deadline for drug manufacturers to comply with item-level serialization requirements was November 2017, though, in recognition of the burden of the changes on manufacturers, enforcement of the regulation was delayed to November 28, 2018.<sup>9</sup> The FDA has planned these phases to align with product serialization enforcement in 2018, product package level verification in 2019, and implementing an electronic interoperable system by 2023.<sup>10</sup>

The Centers for Disease Control and Prevention's (CDC) National Center for Immunization and Respiratory Disease (NCIRD) is monitoring the evolution of DSCSA and its effects on vaccines and immunization information systems (IIS), if any. In September 2013, the CDC published the report "Evaluation of the Impact of 2D Barcodes on Vaccine Secondary Packaging" on its website.<sup>11</sup> Since then, CDC has conducted three pilot projects designed to evaluate the effects of vaccine barcode scanning and increase the adoption of 2D barcodes on the unit of use (i.e. individual vial and syringe) in provider settings and with IIS. These pilots have demonstrated that using scanners to collect product identifier, lot number, and expiration date increases accuracy and completeness of data collection while also saving time in recording this information in the patient record.

## 1.2 Current State of DSCSA Implementation

Implementation of 2D barcodes on external packaging (known as the unit of sale, or UoS) requires manufacturers, distributors, and providers to make capital investments of infrastructure and system upgrades to create, verify, and scan 2D barcodes to collect data carried in those barcodes. As a result of this change, manufacturers have had to change their label design and testing of the 2D barcode content before products are distributed. Distributors and providers also invested in equipment (scanners) to read the 2D barcode and technology infrastructure changes to manage the data that is collected.

In May 2018, in order to evaluate industry progress towards Phase 1 and Phase 2 DSCSA implementation, AmerisourceBergen, McKesson Pharmaceutical, and Cardinal Health, in collaboration with GS1 Healthcare US<sup>12</sup>, conducted an assessment of barcode capabilities.<sup>13</sup> The assessment intended to quantify the number of packages and cases in the market with a readable barcode containing the four DSCSA-required data elements (NDC, serial number, lot number, and expiration date).<sup>14</sup> Both AmeriSourceBergen and McKesson scanned packages at distribution centers (specialty medications and prescription pharmaceuticals), while Cardinal Health assessed homogenous case-level barcodes on pharmaceutical products in its Ohio National Logistics Center. Key assessment findings include:<sup>15</sup>

- Results from the AmerisourceBergen and McKesson assessments show a year-over-year increase of approximately 14 percentage points from 2017 to 2018.

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<sup>9</sup> "FDA Issues Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy." *FDA*, February 9, 2019. /drugs/drug-supply-chain-security-act-dscsa/fda-issues-draft-guidance-product-identifier-requirements-under-drug-supply-chain-security-act.

<sup>10</sup> "The Drug Supply Chain Security Act (DSCSA) Working Towards Enhanced Drug Distribution Security in the U.S."

<sup>11</sup> <https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/secondary-packaging-evaluation.pdf>

<sup>12</sup> GS1 US is a not-for-profit information standards organization that administers the Universal Product Code (UPC) barcode as well as other information standards and data carriers.

<sup>13</sup> "Assessing Current Implementation of DSCSA Serialization Requirements." GS1. Accessed May 22, 2019.

[https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical/dscsa-barcode-assessment?mkt\\_tok=eyJpjoit0dnm1phvm1omkzqtmndyisinqioijhswkwdzhovjvob0fuulzttkcyoflvuuq5d2zgexdzsvj5umpcuhp6umhvmvj2ttvnlvzvw4bkfpxc9uumjpaityeencvnmvlwvk0plx9hmvh0c0ria2vuc](https://www.gs1us.org/industries/healthcare/standards-in-use/pharmaceutical/dscsa-barcode-assessment?mkt_tok=eyJpjoit0dnm1phvm1omkzqtmndyisinqioijhswkwdzhovjvob0fuulzttkcyoflvuuq5d2zgexdzsvj5umpcuhp6umhvmvj2ttvnlvzvw4bkfpxc9uumjpaityeencvnmvlwvk0plx9hmvh0c0ria2vuc).

<sup>14</sup> *Ibid*

<sup>15</sup> *Ibid*

- Overall, approximately 15-21% of packages scanned at all three providers had a readable barcode with all four DSCSA-required elements—which is substantially lower than the expected 30-40%.
- The placing of the barcodes remains an issue on product cases; insufficient white space between barcodes and wrapping barcodes around the case often render them unreadable.
- Serialization remains a challenge and AmerisourceBergen found that only 77% of the 2D barcodes included serial numbers. Low serialization figures are largely driven by the fact that serialization processes require additional technology (to create, capture, and send serial numbers) that suppliers may lack.
- The FDA published the “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier” guidelines in 2018.<sup>16</sup> These guidelines allowed unexpired pharmaceuticals (manufactured and repackaged) that were packaged and in inventory before the November 2018 deadline to remain in the supply chain. The bulk of pharmaceutical products have a multi-year life cycle and realization of full DCSA serialization will likely take until late 2021.<sup>17</sup>

Since the initiation of the CDC’s efforts to encourage 2D barcodes on vaccine units of use (UoU) products in 2011, NCIRD has maintained quarterly communication with vaccine manufacturers. During this outreach, NCIRD requests information for vaccines that use the 2D barcode data carrier for either the UoS or UoU, or both. This outreach is an opportunity to keep the list of vaccine presentations with 2D barcoded UoU current. As providers move to use 2D barcode scanning for inventory management and data collection at the point-of-administration of vaccines, mappings tables for vaccines that are 2D barcoded have become necessary. As of February 2019, four of seven U.S. vaccine manufacturer self-reported that all of their new vaccine products are affixed with 2D barcodes on UoS.<sup>18</sup>

In interviews conducted with two leading electronic health record (EHR) vendors and one U.S. vaccine manufacturers in July 2019, very few challenges persist for Phase 1 and Phase 2 of DSCSA implementation. The EHR vendors interviewed did not report any issues stemming from the implementation. They reported that the cost of equipment is a barrier to 2D barcode scanning for their customers and not the functionality of the system to scan 2D barcodes. One EHR vendor reported that the benefit of having the 2D barcode on the UoU was the ability to more easily capture important information (like NDC, lot number, and expiration date) into inventory, further stating that he “wished the drug manufacturers included lot number and expiration date on all units of use, too; it would make things so much easier.”

In our interview with one U.S. vaccine manufacturer, they reported that there were no current challenges with complying with the DSCSA implementation and that most of their products were compliant for the original deadline of November 2017. There are still products in inventory at pharmacies and provider sites that may not have the 2D barcode on the UoS, but as these are used, or reach their expiration dates, will become fewer and fewer.

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<sup>16</sup> “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier Guidance for Industry.” FDA, n.d. <https://www.fda.gov/media/109591/download>.

<sup>17</sup> “Assessing Current Implementation of DSCSA Serialization Requirements”

<sup>18</sup> GSK, Sanofi Pasteur, Dynavax, Wyeth, Merck, Seqiris, Medimmune representatives, email messages to author, February 2019.

## 2 Traceability and Applications of DSCSA to Vaccine Products

The International Organization for Standardization (ISO)<sup>19</sup> 9000:2000 guidelines define traceability as the “ability to trace the history, application or location of an object;” when considering products or services, traceability can relate to the origin of materials or parts, processing history, and the distribution and location of the product or service after delivery.<sup>20</sup> Traceability systems can be adapted to sectoral and organizational objectives, and vary along metrics of the breadth,<sup>21</sup> depth,<sup>22</sup> and precision.<sup>23</sup> These systems alone cannot improve patient safety, but they provide the ability to more quickly determine the source of a problem.

In the U.S. food sector, traceability systems are largely motivated by economic incentives rather than stringent government traceability regulation.<sup>24</sup> In this industry, private firms build traceability systems in order to improve supply-side management, increase safety and quality control, and to market foods with credence attributes/enhance brand reputation. The benefits associated with pursuit of these objectives include lower-cost distribution systems, reduced recall expenses, and increased sales of high-value products. Traceability, however, must be paired with other management, inventory, and safety/quality control tools to meaningfully make progress toward these objectives. For example, simply knowing where a product is in the supply chain does not improve supply chain management unless the traceability system is paired with a real-time delivery system or another inventory control system. Similarly, tracking food at different stages of the production process does not improve consumer safety unless linked to recall and safety control mechanisms.

Take the traceability systems developed by the food industry in Japan, in particular the beef supply chain. In 2003, foodborne diseases like bovine spongiform encephalitis (BSE) led the Japanese government to pass the Cattle Traceability Law. To ensure the safety of Japanese beef, the law established stringent measures concerning the management and relay of information for individual identification of cattle.<sup>25</sup> Each cow is uniquely identified and tracked from “farm to fork”.<sup>26</sup> In Japan, beef supply chain traceability has four levels of depth. “First, an ear-tag uniquely identifies each living animal. Then, a 10-digit code corresponding to the ear-tag and the animal’s DNA is kept in a national database.”<sup>27</sup> As the animal progresses through the supply chain, all feed and health information is associated with that serial number in the database. Finally, all meat derived and processed must be retained and identified with the animal’s serial number. Notably, consumers have direct access to this information: using an online or in-

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<sup>19</sup> The ISO is a worldwide federation of national standards bodies that promotes the development of standardization and international standards for a wide range of products. ISO 9000 guidelines are quality management system standards.

<sup>20</sup> “ISO 9000:2015 Quality Management Systems — Fundamentals and Vocabulary.” Accessed May 23, 2019.

<https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-4:v1:en>.

<sup>21</sup> Breadth refers to the amount of information the traceability system records.

<sup>22</sup> Depth of a traceability system refers to how far back or forward the system tracks.

<sup>23</sup> Precision reflects the degree of assurance with which the traceability system can pinpoint a product’s movement or characteristics. Precision is determined by the unit of analysis used in the system and the acceptable error rate.

<sup>24</sup> Golan, Elise H. & Krissoff, Barry & Kuchler, Fred & Calvin, Linda & Nelson, Kenneth E. & Price, Gregory K., 2004. “Traceability In The U.S. Food Supply: Economic Theory And Industry Studies,” Agricultural Economics Reports 33939, United States Department of Agriculture, Economic Research Service.

<sup>25</sup> Schroeder, Ted C., and Glynn T. Tonsor. “International Cattle ID and Traceability: Competitive Implications for the US.” *Food Policy* 37, no. 1 (February 2012): 31–40. <https://doi.org/10.1016/j.foodpol.2011.10.005>.

<sup>26</sup> *Ibid*

<sup>27</sup> Souza Monteiro, Diogo M., & Julie A. Caswell. *The economics of implementing traceability in beef supply chains: Trends in major producing and trading countries*. No. 1669-2016-136420. 2004.

store lookup of the animal's 10-digit number (found on each package of beef), a consumer can quickly find all relevant details tracked from birth to slaughter date.<sup>28</sup>

The Japanese beef supply chain example exhibits all three attributes of a traceability system. Breadth indicates the amount of information collected for each unique product. In this case, the animal's location, DNA, feed and health information are maintained in the national database. Depth indicates the backward and forward traceability of the system, not only "farm to fork" but also "fork to farm." The Japanese system starts when the animal is alive and living on the farm and the serial number follows the processed products to consumers. Precision indicates how well the system allows the identification of any one product and is usually increased by the creation of unique identifiers.

DSCSA aims to create traceability of drugs and vaccines in the pharmaceutical supply chain. Traceability allows for the validation of the product via confirmation of the product identifiers, the lot numbers, and expiration dates as pharmaceuticals move from the manufacturers to product re-labelers to healthcare providers and pharmacies. Traceability systems with breadth, depth, and precision can further enhance patient safety by identifying and removing counterfeit drugs from the supply chain.

The most robust traceability mechanisms provide the individual identification of each product and its characteristics along all points of the supply chain. In the Japanese beef market, the unique 10-digit identifier (that links an animal's individual ear tag with enciphered DNA) is a key building block and contributor to traceability. In the example above, cattle in Japan were each given a 10-digit serial number that linked their individual ear tag with an enciphered DNA code. Similarly, within the U.S. pharmaceutical supply chain, the identifying information in each 2D barcode (NDC, serial number, lot number, expiration date) is crucial to enhancing traceability throughout. With enhanced traceability, there are opportunities to improve data and inventory management of vaccines and emergency response efforts related to vaccines.

## 2.1 Data and Inventory Management

### Deduplication

The deduplication of immunization records encompasses both the deduplication at the demographic/patient level (e.g. two records describe the same patient) and deduplication at the vaccination level (e.g. two records describe the same immunization).<sup>29</sup>

The use of 2D barcode scanning, in conjunction with an Electronic Health Record (EHR) system, have several notable benefits for patients, providers, and the wider health community.<sup>30</sup> Employing 2D barcode scanning supports the increased accuracy of immunization records by limiting errors introduced via manual entry and improving the completeness of that data in the patient's record. The time spent on data entry is also diminished when 2D barcode scanning is employed at the point-of-administration.<sup>31</sup>

While no published studies could be found describing how serialization of the vaccine UoS improves deduplication of vaccination level records, one can extrapolate that deduplication could be enhanced with serialized data. In addition to using data element indicators such as the product identifier and lot number to identify potentially duplicative records, registries could also use the serial number of the

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<sup>28</sup> *Ibid*

<sup>29</sup> "IIS | Deduplication Toolkit | Vaccines | CDC," May 6, 2019. <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/deduplication.html>.

<sup>30</sup> "Immunization Information Technology: A Guide for Pediatricians on Immunization Information Systems and Two-Dimensional Barcoding." The American Academy of Pediatrics, 2019.

<sup>31</sup> *Ibid*

vaccine package to identify vaccine level duplicates. However, for this to be possible, the EHR system would need to map the vaccine's UoU to the UoS and include the UoS serial number in the vaccination level record. To enable the use of serial numbers to further aid in deduplication, functional capability guidance could be published describing the need for such mapping tables, and for the documentation of the serial number in the patient's record. However plausible, it remains to be investigated whether the addition of the UoS serial number improves deduplication of vaccination level records.

## **Provider Inventory Management**

It is recommended that providers store vaccine in original packaging in order to protect vaccine from light exposure, which can negatively impact vaccine potency.<sup>32</sup> Despite this recommendation, however, following inventory receipt process, a portion of providers discard secondary packaging upon receipt of a product and instead store the vaccine in its primary container (i.e. vial or syringe) to maximize refrigerator storage space. Once a vaccine is administered to a patient, providers are legally required to record key vaccine product information including lot number, product ID, expiration date, manufacturer, and product name. Most providers enter this information into the patient medical record based on the UoU, and not the UoS. This occurs primarily due to the risk of incorrect data entry of information such as lot number or expiration date on the secondary packaging. This information can be entered manually, selected from preloaded drop-down lists, or scanned from the vial or syringe.

Providers handle and administer both privately purchased and publicly subsidized vaccines. Certain public vaccine stocks require additional inventory reporting on data elements such as quantities, lot number, and expiration dates; most of which is entered manually into online inventory tracking databases. IIS reporting requirements vary by state; however, CDC publishes recommended core data elements that they endorse on their website.

Aside from certain hospitals and large provider practices, ambulatory providers may not have 2D scanning capabilities for inventory management purposes; some may not yet have linear scanning for inventory purposes. Again, the reported main barrier to adopting scanning for inventory management purposes is the cost of equipment. Two EHR vendors with large market shares reported that many outpatient customers are considering using 2D barcode scanners, but the cost of scanners and related equipment is a limiting factor.<sup>33</sup>

Outpatient healthcare providers have thus far made limited technology upgrades to accommodate 2D barcode scanning. DSCSA requires providers to have lot-level traceability by November 2019, however, it does not require that providers use 2D barcode scanning to achieve this level of traceability. Based on the experience of providers using 2D barcode scanning, it is evident that scanning will be faster and more accurate than other methods of inventory tracking.

## **Vaccines for Children Inventory Management**

The Vaccines for Children (VFC) program is a federally funded initiative that strives to protect children by providing public-purchased vaccines for children and adolescents who otherwise would be unable to afford them.

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<sup>32</sup> "Vaccine Storage and Handling Toolkit," CDC, last modified January 2019, accessed November 2019, <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

<sup>33</sup> EHR vendor, interviews with author, May 2019 & July 2019

There are currently approximately 38,000 provider sites nationwide registered as VFC providers. Children are eligible for vaccinations from the VFC program if they are under the age of 19, and are either uninsured, Medicaid-eligible, American Indian or Alaskan Natives, or underinsured with respect to vaccination when served in Federally Qualified Health Centers / Rural Health Clinics (FQHCs/RHCs). The VFC program currently offers vaccines against 16 vaccine preventable diseases to protect children, all recommended by the Advisory Committee on Immunization Practices (ACIP).

The VFC program purchases vaccines at negotiating discounted prices with manufacturers and provides CDC's immunization awardees with access to a centralized vaccine ordering system. Orders placed by providers through immunization program awardees are then shipped to providers using a centralized vaccine distribution mechanism. Enrollment of individual providers is managed by immunization program awardees, typically state health department immunization programs. These awardees are also responsible for receiving immunization information from providers and projecting annual demand for planning purposes.

The VFC program is aware of the industry movement toward 2D barcodes on secondary packaging and is cognizant of the fact that the industry may be impacted by this transition.

## 2.2 Emergency Response

### Pandemic Response

A pandemic<sup>34</sup> occurs as infectious disease spreads throughout a wide region. Pandemic response requires the swift mobilization of international and national scientific, public health, public policy, and security communities to identify the virus, develop an effective vaccine, and mitigate the impact on citizenry.<sup>35</sup> The quick progression of a pandemic overburdens healthcare resources at the local, regional, and national level while disseminating concern in the public. Lessons learned from a review of pandemic response literature suggest that the addition of 2D barcodes to the vaccine UoS will support improved security, effectiveness, and efficiency of pandemic response in the United States.

The inherent chaos of a pandemic event may prompt criminal elements to view them as opportunities for unlawful gain. The ability to leverage serialized 2D barcodes to verify the authenticity of a vaccine product will work to deter the introduction of illegitimate vaccine products into the vaccine supply chain during pandemic events. An additional benefit is the increased confidence of vaccinators that they have received and are administering the vaccine they ordered.

Furthermore, the use of 2D barcodes promotes efficient and responsive inventory processes that support the effectiveness and efficiency of a response. These processes can be leveraged to understand the volume and location of vaccines in the healthcare system while providing important data on uptake rate across geographic locations. A review of the H1N1 pandemic response in the United States highlights the critical importance of a robust and visible vaccine supply chain to: 1) ensure vaccines are deployed effectively to reduce the burden of disease; 2) provide reliable data on vaccination rates; and 3) decrease costs associated with unused and disposed vaccines.

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<sup>34</sup> The World Health Organization (WHO) defines a pandemic as “the worldwide spread of a new disease.”

<sup>35</sup> *The Domestic and International Impacts of the 2009-H1N1 Influenza A Pandemic: Global Challenges, Global Solutions: Workshop Summary*. Washington, D.C.: National Academies Press, 2010. <https://doi.org/10.17226/12799>

During a pandemic, the supply of influenza vaccine is often limited, and allocation thereof can significantly impact the burden of disease.<sup>36</sup> In response to the 2009-2010 H1N1 Influenza pandemic, CDC coordinated an emergency vaccine distribution campaign utilizing the population-based or pro-rata allocation.<sup>37</sup> According to this method, the CDC allocated vaccines to each state in proportion to the state's population; after receiving vaccine inventory from CDC, states used CDC's centralized vaccine distribution system to direct vaccine shipments to providers. CDC provided state and local planners with H1N1 Vaccination Campaign Planning guidelines that stressed the importance of collecting data and tracking vaccine usage to ensure supply was adequately directed where needed.<sup>38</sup> In practice, however, few states collected and tracked this information, and overall there was limited reliable data on uptake rates and vaccine inventory by geographic location. The lack of an efficient inventory process contributed to the inability to deploy sufficient inventory to areas with high uptake rates, whilst approximately 40 million doses of the vaccine (worth an estimated US\$260 million) were unused and eventually discarded.<sup>39</sup>

## Recall

With regard to biological products<sup>40</sup> approved by the FDA, a recall is defined as a “firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency could initiate legal action, e.g., seizure.”<sup>41</sup> Recalls can be conducted on a firm's own initiative, by FDA request, or by FDA under statutory authority.<sup>42</sup> Vaccine recalls or withdrawals are primarily initiated by the vaccine manufacturer, and the FDA rarely issues a recall.<sup>43</sup> When the manufacturer issues a recall, the manufacturer directly contacts vaccine distributors and healthcare facilities who might have purchased the vaccine to notify them of the suspected problem.<sup>44</sup> In turn, the individual healthcare provider informs the patient/parents of the patient that the vaccine has been recalled.

In the healthcare supply chain, product recall has been historically challenging due to the dearth of product traceability and loose integration of information systems.<sup>45</sup> However, because of vaccine administration documentation requirements, driven by voluntary and mandated data exchange with jurisdictional immunization registries, vaccine product recall is much easier. Once a recall is initiated, providers can quickly identify patients who have received the recalled vaccine by tracing the product and the specific lot number to the patient. Serialization of the vaccine UoS does not appear to have any

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<sup>36</sup> Li, Zihao, Julie L. Swann, and Pinar Keskinocak. “Value of Inventory Information in Allocating a Limited Supply of Influenza Vaccine during a Pandemic.” Edited by Jeffrey Shaman. *PLOS ONE*13, no. 10 (October 25, 2018): e0206293. <https://doi.org/10.1371/journal.pone.0206293>.

<sup>37</sup> *Ibid*

<sup>38</sup> “CDC H1N1 Flu | State & Local Vaccination Guidance | CDC 2009 H1N1 Vaccination Campaign Planning Checklist.” Accessed May 17, 2019. [https://www.cdc.gov/h1n1flu/vaccination/statelocal/planning\\_checklist.htm](https://www.cdc.gov/h1n1flu/vaccination/statelocal/planning_checklist.htm).

<sup>39</sup> “Expired Swine Flu Vaccine Headed For Incineration.” NPR.org. Accessed May 17, 2019. <https://www.npr.org/sections/health-shots/2010/07/01/128248906/happy-trails-swine-flu-vaccine>.

<sup>40</sup> The FDA defines a biological product, or biologic, as “a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.”

<sup>41</sup> Research, Center for Drug Evaluation and. “Drug Supply Chain Security Act (DSCSA).” *FDA*, 22 May 2019, /drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

<sup>42</sup> *Ibid*

<sup>43</sup> “Vaccine Recalls.” *CDC*, 24 Jan. 2019, <https://www.cdc.gov/vaccinesafety/concerns/recalls.html>.

<sup>44</sup> *Ibid*

<sup>45</sup> Jayaraman, Raja, Fatima AlHammadi, and Mecit Can Emre Simsekler. “Managing Product Recalls in Healthcare Supply Chain.” In *2018 IEEE International Conference on Industrial Engineering and Engineering Management (IEEM)*, 293–97. Bangkok: IEEE, 2018. <https://doi.org/10.1109/IEEM.2018.8607403>.

benefits for provider-level vaccine recall. Vaccine manufacturers interviewed were not able to comment on the impact of serialization on recall.

During an interview with one of the top four EHR vendors in the U.S., it was explained that their pharmaceutical inventory management functionality includes warning pop-ups to indicate if the vaccine being ordered or about to be administered is part of an active recall.<sup>46</sup> To the extent that 2D barcode scanning supports product traceability and accurate documentation of immunization, it can positively contribute to recall efforts. However, potential gains are predicated upon integration of scanning into current systems and the interoperability of these information systems across the supply chain.<sup>47</sup>

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<sup>46</sup> EHR vendor, interviews with author, July 2019

<sup>47</sup>N. Haque, Saira, Suzanne West, and Alan O'Connor. "Mapping of Standards to Facilitate Immunization Information Exchange through Two-Dimensional Bar Coding of Vaccine Products." *Perspectives in Health Information Management* 14, no. Fall (October 1, 2017). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5653951/>.

# 3 Findings and Future Opportunities

DSCSA requires product serialization on UoS packaging for pharmaceuticals manufactured by November 2018. The additional data will be carried on 2D barcodes to enable better traceability through the drug supply chain. By 2023, DSCSA aims to implement an electronic interoperable system to facilitate information exchange throughout the pharmaceutical manufacturing and distribution process.

For vaccines, 2D barcode scanning, made possible by the DSCSA, allows medical record and inventory management systems to accurately record NDC, serial number, lot number, and expiration date of each vaccine UoS product, however, the improved accuracy and completeness is dependent on the use of scanning to capture data via the 2D barcode. As described above, one of the largest EHR system vendors in the U.S. reported that they have inventory functionality at no additional cost, but not all customers have enabled this functionality. Their customers cite that equipment costs for scanners are a barrier to adoption. There is an opportunity to show the return on investment from the upfront equipment costs to implementing 2D barcode scanning adoption within medical practices.

This same vendor has included a safety feature to trigger a warning pop-up when there is an issue or inconsistency between the order and the vaccine such as when recalled or expired pharmaceutical are ordered or taken from inventory for administration, or when the order and vaccine do not match. The warning, however, is independent from 2D barcode scanning and will pop-up even when orders and vaccine information are manually entered into the record. The drawback of not scanning vaccines at the point-of-use (when product is taken from inventory) is the ineffectiveness of warnings. If the warning pops-up after administration, it was not effective in preventing the administration of an incorrect, expired, or recalled vaccine. This is more of a clinical workflow and adherence issue than it is a 2D barcode scanning issue. There is continued opportunity to provide resources to promote 2D scanning workflow good practices and behavioral adherence strategies to support adoption efforts.

EHR system vendors are creating inventory modules that utilize 2D barcode scanning to dynamically track the number of vaccines in inventory and the movement of these vaccines from storage, to medication cabinets, and to patients. For a traceability system, this depth of information can be helpful to ensuring safety of patients. However, the breadth of this adoption across ambulatory healthcare settings is unclear, again, due to the limited adoption of 2D scanning as reported by some EHR system vendors.

There is yet to be industry-level consensus on best practices or lessons learned related to DSCSA implementation; however, this report will be updated as best practices and lessons learned are published.

Today, under Section 201.25 of the Code of Federal Regulations, Title 21, pharmaceutical products are required by the FDA to have at a minimum a barcode that contains “the appropriate NDC number in a linear barcode that meets European Article Number/Uniform Code Council (EAN/UCC) or Health Industry Business Communications Council (HIBCC) standards or another standard or format that has been approved by the relevant FDA Center Director.”<sup>48</sup> Typically, if a UoU includes a linear barcode, then it will only include the product’s NDC. Because of physical size, expiration date, lot number, and serial number cannot be contained in a 1-dimensional, linear barcode. Since recalls are typically managed at the lot-level, scanning a linear barcode is of limited usefulness. Mapping the UoS serial number to the

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<sup>48</sup> US Food and Drug Administration. "CFR-code of federal regulations title 21." General labeling provisions Part 201 (2018).

UoU lot numbers may prove more helpful to home in on recalled products and limiting waste of viable vaccines. This assumption requires further investigation.

The research base on the benefits of serialization for vaccine recall in the United States is limited. Several assumptions about serialization's benefits for improved data accuracy, reduced vaccine deduplication, and increasingly robust and accurate immunization documentation within state registries can be made from the improved ability to uniquely identify a vaccine package. The dearth of existing evidence creates future opportunities for research to test whether and to what extent these assumptions hold true, and whether serialization efforts support patient safety regarding recalls.

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