USP COVID-19 Vaccine Handling Toolkit: Operational Considerations to Support Confidence, Trust, and Quality

Thursday, March 25, 2021
www.nabp.pharmacy/webinar

COVID-19 Vaccine Handling and Operational Best Practices

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March 2021
Disclosures

- Melody Ryan and Farah Towfic report they have no actual or potential conflicts of interest associated with this presentation.
- Off-label use of medication will be discussed during this presentation.
  - COVID-19 vaccines have emergency use authorization (EUA), which is not Food and Drug Administration approval.

Learning Objectives

- Describe the USP COVID-19 Vaccine Handling Toolkit
- Explain how to accelerate delivery of COVID-19 vaccines
- Support the safe handling of COVID-19 vaccines while maintaining quality and trust
Self-Assessment Questions

- The beyond use date for COVID-19 vaccines are best assessed through:
  a. Application of USP<797> to all vaccines
  b. Following manufacturer labeling in the Emergency Use Authorization
  c. None of the above

- The transport of prepared COVID-19 vaccine product may take place under which of the following conditions?
  a. Vaccine in frozen state in vials
  b. Vaccine in refrigerated state in vials
  c. Pre-drawn syringes in refrigerated state
  d. COVID-19 vaccines should not be transported once delivered to provider site
  e. A, B, and C

Overview

- Who is USP?
- Building trust in COVID-19 vaccines through quality
- USP COVID-19 Vaccine Handling Toolkit
  - Preparation and labeling
  - Storing, handling, and transporting
  - Waste minimization and ancillary supply disposal
- Facilitated Q & A
USP COVID-19 Vaccine Handling Toolkit: Operational Considerations to Support Confidence, Trust, and Quality

1. Who Is USP?

USP Mission

To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.
Collaborating to Achieve Our Mission

Partnering with our expert volunteers

Partnering with global regulators, including the United States FDA and WHO

Partnering with stakeholders, including industry, practitioners, and academia

Access to quality medicines

Our People – USP’s Global Staff and Volunteers

1200+ Staff

United States 29%
Indonesia 6%
China 6%
India 4%
Brazil 4%
Other global sites: Ethiopia, Europe, Ghana, Indonesia, Nigeria, Singapore 58%

981 Scientific Experts

426 EC Members 20%
362 EP-Only Members 37%
191 Government Liaisons 43%

NABP Webinar – March 25, 2021
Responding to Today’s Public Health Challenges Through Coordinated Standards, Advocacy, and Capability Building

- **Standards**: To be a definitive source of standards for the supply of quality medicines

- **Advocacy**: To be the global institutional leader advancing the supply of quality medicines

- **Capability Building**: To be a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients

More Than 9,000 USP Standards Provide Quality Benchmarks Across the Supply Chain

- Standards for medicines, excipients, and APIs in *USP-NF*
  - 350 General Chapters
  - 4,900 product-specific monographs
  - 3,500 physical reference standards

- More than 1,200 standards for dietary supplements in the *Dietary Supplements Compendium (DSC)*

- Nearly 1300 standards for Food Ingredients in *Food Chemicals Codex (FCC)*

- More than 500 standards for biologics

- About 300 Healthcare Quality & Safety Standards, including compounding, nomenclature and labeling, safety, etc
USP Standards Along the Supply Chain

USP Standards Are Utilized in Over **150** Countries

USP Reference Standards were shipped to over **22,000** entities in FY19

Units of USP Reference Standards shipped globally (Top 10 countries labeled, 2015-2019)
Advocating for the Supply of Quality Medicines Worldwide

- Generating data to inform policy making through the USP Quality Institute (e.g., AMR, excipient quality, and procurement policies)
- Engaging in public dialogues to provide USP’s expertise and perspective in the interest of better policy and outcomes
- Collaboration with stakeholders and USP Convention members to help inform and drive change
- Supporting the supply of and public trust in vaccines and treatments to address COVID-19
- Longstanding regulatory engagement with pharmacopoeias and governments worldwide

Our Global Engagement and Advocacy Is Powered By More Than 490 USP Convention Organizations

FAST FACTS

490+ Total members | 42 Countries represented
Example: There Is a Need for Greater Upstream Supply Chain Transparency

Information listed on US-approved human prescription drug labels (N=40,178)

- While approval information is known, we don’t know how many are manufacturing the medicine/API.
- All labels specify the ANDA filer, an entity responsible for the drug’s quality. However, manufacturing is often done by a different entity than the filer.
- While manufacturers are required and do report suppliers to US FDA, also sharing supply chain information publicly could help providers proactively safeguard patient health. (eg, when a safety issue is identified with an API manufacturer, providers will have on-hand information about impacted brands.)

Source: USP analysis of DailyMed
2 ‘Label, Relabel, Pack, Repack’

We Are Generating Proactive Insights on Risk in the Upstream Supply Chain

- We created the USP Medicine Supply Map as an early warning system to identify, characterize, and quantify risk in the upstream pharmaceutical supply chain.
- Data model links across 10+ datasets and dozens of data elements, including USP’s proprietary insights.
- “In-the-field” data gathering, including through USP’s subject matter expert network.
- More than 1 million medicines globally included.
- Graph-based data model is capable of tracking quality issues up the supply chain.
Education, Training, and Verification Services to Build Stakeholder Capabilities in Advancing Medicines Quality

- Helping global regulators and manufacturers acquire the required skills, knowledge, tools or enabling environment to advance access to quality medicines and medical products
- Verification services for industry (eg, dietary supplements, excipients)
- Facilitating the adoption of new manufacturing technologies (eg, continuous manufacturing)
- Custom tailored standards and tools for analytical research & development (eg, impurities)
- Donor-funded work to support regulatory and industry capability building in LMICs

Being a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients

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Building Trust in COVID-19 Vaccines Through Quality
COVID-19 Vaccine – Learning About Trust and Confidence

- Reagan-Udall Foundation for the FDA conducted the COVID-19 Vaccine Confident Project in 2020 to identify gaps in trust and patient confidence in vaccines
- Communities interviewed
  - Frontline workers in service, retail, and health care
  - Under-represented communities who experience health disparities and are at increased risk of COVID-19 (e.g., Black or African American, Hispanic/Latinx, and Native/Indigenous communities)

Areas of Identified Gaps That Impact Public Trust and Confidence

- Lack of equity and access to vaccines
- Speed of EUA process
- Distrust of government
- Distrust of health care system
- Need for education and communication to bridge the knowledge gap with new vaccine platforms and assurance of quality
- Perceptions of prioritizing economics over science
- Concern the vaccine will not work for certain communities

Source: Reagan-Udall Foundation for the FDA; CDC Equity Task Force
Addressing Trust in COVID-19 Vaccines

- 83% of individuals rely on health care practitioners as trusted sources of information related to vaccines (e.g., pharmacists, physicians, nurses, physician assistants)\(^1\)
- 60% rely on family and friends to deliver information\(^1\)
- Messages that work aim to personalize the message, explain the process, and never shame:
  - Protecting your loved ones
  - Return to normal
  - Acknowledge and address people’s fears based on culture (e.g., historic injustices such as the Tuskegee Experiment)

From the Frontlines: Building Confidence in COVID-19 Vaccines

- Need to address misinformation that is spreading (e.g., vaccine ingredient base like polyethylene glycol versus ethylene glycol)
- Example patient interactions
USP Engagement in COVID-19 Vaccine Preparation and Handling

We asked – What are other organizations doing? How can USP help fill gaps using our expertise?

Our focus:

- **Communities** – supporting our convention stakeholders with their work (e.g., vaccine platform technology, convention roundtable with US FDA, advocacy to build trust in quality of vaccines)

- **Scientific expertise** – creating operational considerations driven by USP’s public quality standards for compounding, microbiology, containers, labeling, distribution, stability, and storage
USP Created the “COVID-19 Vaccine Handling Toolkit”

Content will be evolving
- Quickly developed by over 40 independent expert volunteers led by USP’s Healthcare Safety and Quality Expert Committee with representation from several other Expert Committees including government representatives from the Centers for Disease Control and Prevention (CDC) and the US Food & Drug Administration (FDA)
- USP is engaging with manufacturers that are anticipated to enter the marketplace to update our toolkit to launch new versions in tandem with regulatory approval

Reaching our stakeholders
- USP will push content out through convention membership, government representatives, including CDC website, HQS listserv, and media
- Initial engagement numbers (version 3 launched 3/12)
  - > 38,000 page views (average time spent = 7:43 minutes)
  - > 15,000 downloads

COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners

Empowers practitioners with critical information that facilitates operational efficiencies during the handling of COVID-19 vaccines while preserving quality and safety

Includes operational strategies in three key areas:
- Preparation and labeling
- Storing, handling, and transporting vaccine
- Waste minimization and ancillary supply disposal

https://www.usp.org/covid-19/vaccine-handling-toolkit
Preparation and Labeling

- Driving consistency across states in preparation
- Enabling pre-draw of syringes (detailed BUD in syringe)
- Supporting different practitioners preparing and administering vaccines and critical labeling examples
- Operational efficiencies that drive more vaccines in arms at an accelerated rate while ensuring quality, safety, and public trust

USP COVID-19 Vaccine Fact Sheets

Beyond-Use Date in Vial and Syringe for COVID-19 Vaccines
Storing, Handling, and Transporting COVID-19 Vaccines

- Vaccines will need to be transported to mass vaccination clinics, nursing and long-term care facilities, and more.
- Vaccines need to reach more than 300 million individuals in the United States and billions of people around the world.
- Utilization of mobile clinics, practitioners who have not been involved in vaccination in the past, and other considerations will drive creativity in how vaccines are delivered to the patients who need them most.
- As more vaccines enter the marketplace, challenges and disparities in storage, handling, and transport become more pronounced and potential safety concerns.

USP COVID-19 Vaccine Fact Sheets

Transporting COVID-19 Vaccines Off-Site
Waste Minimization and Ancillary Supply Disposal

**Goal:** Support settings in preventing vaccine waste and addressing gaps for vaccine administrators in proper disposal of ancillary supplies

- Special considerations to optimize vial pressure to maximize number of doses per vial become critical
- Correct needle and syringe combination
- Vial septum rotation during needle insertion
- Disposal of unfamiliar ancillary supplies such as dry ice
- Ensuring safe disposal of empty vials to prevent diversion

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USP COVID-19 Vaccine Fact Sheets

**Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine**
Self-Assessment Questions

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Facilitated Q & A
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7. Click the claim button

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