



COVID-19

Year 1 Update: Strengthening the Supply of Vaccines, Treatments, and Preventatives

Just ahead of the 2020–2025 USP Convention Governance Meeting in May 2020, the global healthcare landscape changed considerably. Responding to the COVID-19 pandemic became a critical USP priority. We rapidly mobilized to leverage the expertise of staff and Expert Volunteers to help strengthen the supply of trusted, quality-assured COVID-19 vaccines, treatments, and preventatives.

Year 1 Update

USP developed a suite of tools and resources to address quality challenges and potential efficiency gaps in the delivery of COVID-19 vaccines, treatments, and preventatives. Today, they are helping to build capacity, support trust, get more shots in arms, and save lives. These resources include:

Vaccine Handling Toolkit – USP’s COVID-19 Vaccine Handling Toolkit outlines operational considerations for vaccine administrators and other stakeholders to address potential efficiency gaps in vaccine handling. Toolkit strategies are designed to help maximize shots in arms and minimize waste while maintaining safety and quality.

The toolkit includes vaccine-specific guides and a video on maximizing doses per vial, a factsheet on beyond-use dates, guides on vaccine transportation and visual inspections, and FAQs. An international version of the toolkit was created for use outside the U.S. and has been translated into multiple languages.

Substandard & Falsified Product Tools –

USP’s resources for preventing, detecting, and responding to the threat of substandard and falsified (SF) vaccines, particularly in low- and middle-income countries, include a white paper with practical guidance on quality assurance, toolkits for vaccine quality assessments, and a visual inspection guide to help ensure trust in quality-assured vaccines. Additional USP resources addressing the potential for SF COVID-19 treatments include 1) a toolkit for determining the identity and purity of remdesivir and 2) a white paper on responding to SF health products.

Hand Sanitizer Toolkit – USP’s Hand Sanitizer Toolkit addresses quality challenges for production and use of alcohol-based hand sanitizers intended to reduce the risk of COVID-19 transmission. The toolkit includes free access to standards, information, and education on producing quality hand sanitizers and addressing the potential for potency issues and methanol contamination.

Training & Education – USP held a webinar in conjunction with the World Health Organization and Sabin Vaccine Institute that offered a forum for immunization expert dialog on delivering COVID-19 vaccines globally. Additional trainings held include:

- ▶ Webinars on USP’s toolkits for vaccine quality assessments targeting regulators in low- and middle-income countries in collaboration with USP’s Promoting the Quality of Medicines Plus (PQM+) program.
- ▶ A USP seminar focused on helping stakeholders ensure quality alcohol-based hand sanitizer production and supporting safe use of the products.
- ▶ A separate forum addressed regulatory and quality issues for the manufacturing of alcohol used in drug products more broadly, including hand sanitizers used to combat the public health emergency.

Awareness & Outreach Efforts –

Throughout the year, USP worked in concert with allied organizations, including Convention Members, to promote awareness of our COVID-19 resources among healthcare practitioners, manufacturers, regulators, educators, government officials, immunization professionals, and other key stakeholders. These efforts have had a quantifiable impact. Over 50 million additional COVID-19 vaccine doses were made available in the U.S. as of July 2021 with the help of strategies outlined in the USP COVID-19 Vaccine Handling Toolkit, which was received by over 76,000 U.S. vaccine network providers. The international version of the toolkit has reached over 50 countries. Meanwhile, we reached 4 million people globally with our Hand Sanitizer Toolkit to

increase the world’s supply of safe, effective hand sanitizer.

Planned for Year 2

- ▶ USP will update toolkits and resources as new vaccines and treatments achieve regulatory approval and new information becomes available.
- ▶ USP will continue to translate select resources to further facilitate dissemination around the globe and help end the pandemic.
- ▶ USP will continue to promote stakeholder awareness of our COVID-19 resources and related training and educational outreach. This includes plans for 1) a webinar series supporting responses to COVID-19 and future health crises in low- and middle-income countries, in collaboration with PQM+, with a focus on the international version of the Vaccine Handling Toolkit and 2) a shorter webinar on USP toolkits for vaccine quality assessments.
- ▶ USP will continue capability building efforts with a particular focus on low- and middle-income countries to 1) help diversify manufacturing and regulatory quality capabilities across geographies and manufacturers and 2) support a more resilient global pharmaceutical supply chain.
- ▶ USP will continue to collaborate with other public health leaders and influencers to advance best practices to shorten the pandemic and help prepare for future public health emergencies.

Contact

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