Vaccine Preparation — Process Improvements

Scores of SEL employees have devoted work hours to the mass vaccination clinics the company continues to host in collaboration with local public health departments, hospitals, and healthcare providers. We are proud to be able to help with the efforts to vaccinate community members and bring an end to this pandemic.

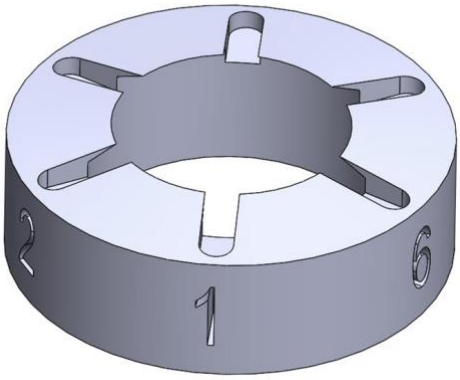
As part of these efforts, SEL recruited a group of its engineers to identify ways to streamline the process for preparing doses of the Pfizer COVID-19 vaccine with the goal of vaccinating as many people as possible at vaccination clinics and optimizing the use of the vaccine constituents.

After observing and analyzing draw events with experienced nurses, pharmacists, and physicians volunteering to prepare syringes, tabulating the time per preparation step for each person—the average time to prepare a single 6 dose vial is upwards of 15 minutes, depending on the skill of the preparer—the group shared the following observations, bottlenecks, and surprise challenges associated with the vaccine preparation process along with suggested methods to address them. Careful implementation can result in a significant reduction in vaccine preparation times.

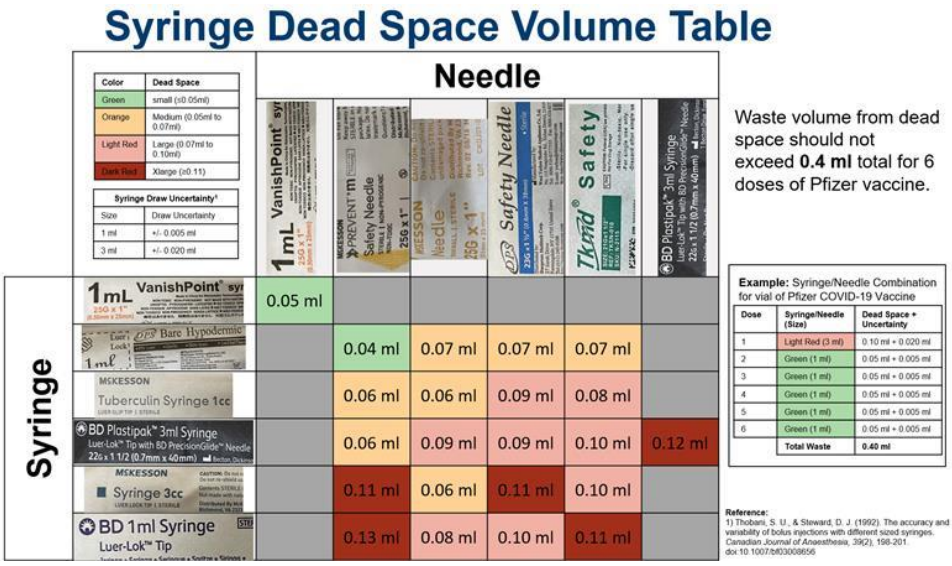
1. Preparing Pfizer COVID vaccine involves dozens of steps. However, the process can be optimized by doing the following:
    - Save a few steps and materials by ordering prefilled diluent syringes, if available.
    - Avoid "Assembly Line Theory." Assembly lines are proven to achieve maximum throughput and minimum cycle time. However, best practices associated with a medical professional's responsibility to manage start-to-finish preparation and handling of medicine they administer to patients themselves prevents confident use of assembly line methods.
    - Embrace flexible preparation habits. Every trained medical professional has their own technique for handling and preparing syringes, which they will be reluctant to change. Granting syringe preparation volunteers the freedom to perform work the way they always do is important. Instead of controlling the preparation method, focus on creating an environment that makes the preparation easier.
    - Improve the comfort of those preparing syringes by lining up plenty of confirmed volunteers to reduce timeline pressure. Have volunteers wear comfortable shoes and bring their corrective lenses. Keep the room at a comfortable temperature, provide elevated seating options, "shut the door" to eliminate distractions, play music to pass the time, and provide snacks and beverages for break times.
    - Maintain a clean and organized work area. Tape off individual workstations, use shadow boxes to identify incoming and outgoing material locations at each station, provide trash cans and syringe disposal containers near each workstation.

2. **Material handling and tracking can be confusing** – Vaccine ancillary supply kits arrive as a pile of disorganized materials. Finding and assembling the kit ingredients required to prepare the vaccine during an event is a challenge, as is keeping track of what is waste and what is not. Prepared for handling material by doing the following:
    - Pause for a brief stand up meeting with all volunteers before the event starts to help establish roles and responsibilities and give focus to important areas and organizational patterns.
    - Allow those preparing the vaccine to focus on their job. Everything needed to do their job should be kept within arm's reach.
    - Create pre-prepped material kits (1 kit per vaccine vial).
    - Deliver materials to the same spot at each prep station every time.
    - CREATE OWNERSHIP - Establish a dedicated "runner" role to handle material inventory and manage retrieval of filled syringes. The volunteer to fill this role does not need to be medically trained. Along with the above-mentioned items, the runner delivers fresh materials to each syringe prepper and retrieves completed syringes for delivery to the vaccination location.
3. **Significant amounts of vaccine can be lost during the draw process –** Vaccine may be wasted due to unbalanced vial pressure, leaks at previous needle insertion points, and unknown syringe dead space volumes, which reduces the number of available doses at vaccination events. Improve these situations by doing the following:
    - Maintaining a vacuum on the vial is important. This is achieved after diluent is inserted in the vaccine vial by drawing air into the empty diluent syringe, and by drawing air into the vaccination syringes prior to needle insertion. These preparation steps must not be skipped. (View the Drawing Pfizer COVID-19 Vaccine video)
    - Avoid inserting needles into the same vial membrane location more than once by creating separate target insertion points on the membrane using a marker. Alternatively, SEL has created a reusable 3d printed vial cap with needle insertion targets, available for download here. Note that numerous online 3d printing services are

available. Local schools and libraries also typically provide publicly accessible 3d printers.



- Due to lack of availability, use of low dead space syringes is not a reliable way to conserve vaccine. SEL has tabulated dead space volume measurements for possible combinations of common needles and syringes. When kitting materials, consider including combinations of needles and syringes with a total dead space volume that maximizes the chance for a 6-dose extraction. Table (shown below) is also available for download on the SEL Vaccine Clinic Resources webpage (https://selinc.com/company/vaccine-clinic-resources/).



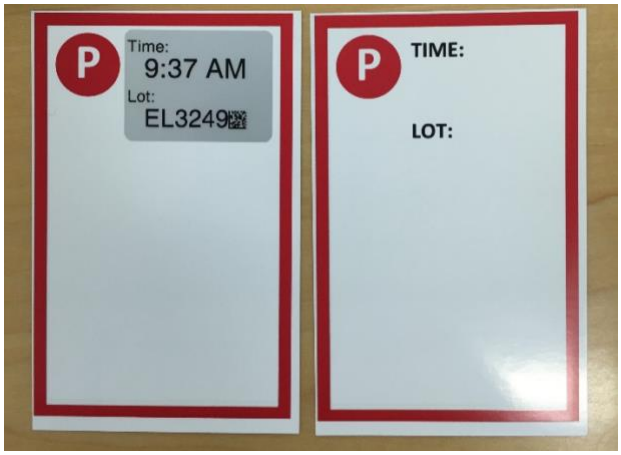
4. **Syringe bubble extraction is time consuming and tiring** – The typical method to remove bubbles is to inflict a sharp tap to a syringe using the flick of a finger or utensil. Bubbles are hard to see and the prepper must keep their arms in the air for the entire extraction process. The vaccine vial is typically dangling on the tip of the syringe needle which increases the chance of vial being dropped, which requires disposal. Make this process easier by doing the following:
    - Reduce fatigue and implement a station rotation plan that allows volunteers to rest and take frequent breaks without impacting the flow of filled syringes.

- Find the best tapping tool and make it available. A resin chopstick works well. These are appropriately weighted, readily available, and easy to sanitize. A chopstick allows for a more focused tap than a finger or ballpoint pen and reduces the number of taps required to dislodge bubbles. Purchase a dozen on Amazon here.
- Improve lighting to make it easier to see bubbles. Back lighting with adjustable illumination is ideal. Numerous portable videography style LED soft light panels are available on Amazon. These lights are typically dimmable and easy to mount on a table or tripod.

5. **Vaccine vials must be handled with care before and during vaccination events** – Frozen vaccine must be stored upright, but it is delivered in open trays that allow the vials to jumble. The vials are small and easy to mishandle or drop. Reduce storage and handling fallout by doing the following:
   - The Pfizer COVID vaccine must be stored at ultra-low temperatures per the manufacturer's storage requirements. Temperature monitoring is a critical component of vaccine storage. SEL's 2411TM is ideal for temperature monitoring applications. Purchase the 2411TM here.
   - Create a carriage to keep vials upright during ultra-cold storage. An example is shown below:


   - Create foam trays for handling multiple vaccine vials at a time outside of ultra-cold storage. An example is shown below:

6. **Total count, lot and expiration tracking is challenging and inconsistent** – The entire event centers around three questions: How many vaccines have been administered? How many unprepared vaccines remain? How many prepared vaccines are ready? Inconsistent tracking methods allow prepared vaccine to leave the room without being tracked and increases the likelihood of prepared vaccine expiring before use. This creates chaos, especially near the end of a vaccination event, which can be improved by doing the following:
    - Create printable color-coded FIFO (first in, first out) cards. SEL uses blue cards for boosters and red cards for first doses. These cards are placed in baskets with completed vaccine syringes to make identification easy.



    - CREATE OWNERSHIP - Assign a dedicated "counter" role. The volunteer for this role does not need to be medically trained. This person is responsible for tallying the number of delivered vaccine syringes and remaining vaccine vials. They are also responsible for staging the oldest prepared vaccine syringes for delivery to the vaccination area before other newer syringes. This role can be combined with the "runner" role mentioned previously.
    - More foam trays, like those mentioned previously, can be used to identify dose counts that are achieved when drawing from vials. Simply place vials into the appropriate container as a secondary means to identify how many doses have been prepared.