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How Can COVID-19 Vaccine Manufacturers Minimize Vaccine Wastage?

Ümit Kartoğlu

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Today, the world is experiencing the biggest vaccination effort in its history. As of August 16, more than 35.5 million doses of COVID-19 vaccines were being administered daily. Although this corresponds to 31.4 percent of the world's population being vaccinated with at least one dose, almost all low-income countries are still struggling to access vaccines and to immunize their health workers first. As of August 16, only 1.3 percent of people in low-income countries had received at least one dose.

This comes on the heels of new spikes in cases in countries such as the United Kingdom and the United States due to the Delta variant.

New variants don't stop at borders, and all these new surges remind us that we will not be safe unless everyone is safe. There will not be a secured country like an island in the middle of the pandemic. With the world passing the tragic milestone of four million

recorded deaths in early July, World Health Organization (WHO) Director-General Dr. Tedros reminded us that vaccine inequity persists and continues to be a threat to all nations.

While equitable distribution of vaccines and vaccine technology are rightly in the spotlight, another significant issue needs to be addressed: vaccine wastage.

What do we know about wasting COVID-19 vaccines, and what can we do to minimize it?

Why Are Vaccines Wasted?

Vaccine wastage is a reality in all immunization programs. It is never possible to immunize one million people with one million doses of a vaccine; vaccine wastage must be factored in when ordering vaccines. Vaccine wastage occurs at all legs of the supply system—during storage, transport, and administration. Vaccines can be affected by temperatures outside of their recommended storage and transport temperatures. Occasionally, accidents such as dropping a box of vaccines during transport or handling may result in breakage and loss of vaccines. And not being able to use the vaccines before they expire may happen in routine programs, although this is very unlikely in a mass immunization program; however, when demand dwindles, loss due to expiry becomes inevitable.

Vaccine wastage can also occur during administration with opened multi-dose vials; although this could be minimized, it is expected. Vaccines come in either mono or multi-dose vials. Multi-dose vials are the preferred presentation, especially for mass immunization programs such as COVID-19, because they are more economical compared to their mono-dose presentations and naturally require less storage and transport space.

Today, we have 6-, 10-, and 15-dose vials of COVID-19 vaccines. In general, some multi-dose vials can be used in subsequent immunization sessions once they are opened (for example, routine childhood vaccines) in accordance with the WHO's multi-dose vial policy. Some vaccines, once opened, need to be discarded in six hours or at the end of an immunization session, whichever comes first. All opened multi-dose COVID-19 vaccines should also be used within six hours; at the end of this period, remaining doses must be discarded.

In mass immunization programs, wastage in opened vials can be minimized through pooling recipients. This is mainly done by opening the vial once the equal number of people to doses in the vial are available for vaccination. However, if this is not possible, the vial still must be opened and used for those available. Otherwise, sending people back and advising them to come again another day may result in missed opportunities. The rule in vaccination programs is to open a multi-dose vial even if one person is available for vaccination.

The goal is to minimize vaccine wastage, so the program does not suffer from these losses logistically, economically, and morally. While some wastage is acceptable, some can and should be prevented. One cause of wastage that deserves urgent attention is temperature abuses.

The Importance Of Stability Budgets

All vaccines are time- and temperature-sensitive. All vaccines are sensitive to heat, some to freezing, and some to light. When developed, all vaccines are tested for their

stability/durability against temperatures beyond the recommended range. Through these studies, a stability budget is established.

The stability budget tells users which temperature excursions would be allowable without having a negative impact on the quality of the vaccine. For example, the hepatitis B vaccine can withstand constant 37oC (98.6oF) temperature excursions for at least 30 days, while the most heat-sensitive oral poliomyelitis vaccine would survive for two days at the same temperature. That means vaccines do not go bad instantly when they are exposed to temperatures above or below the recommended range.

The same is true with perishable food items; the milk will not go bad if you forget it on the kitchen table for some time. But it is easy to tell when perishables go bad; they do not look fresh, they change color, and most of the time there is an odor. But it is not possible to differentiate a temperature-abused vaccine from another vaccine that is kept at optimum temperature just by looking at it.

What Can Be Done To Minimize Unacceptable Vaccine Wastage?

The very first rule to minimize unacceptable wastage due to temperature excursions beyond the recommended range is to know that vaccines are abused. The only way to know this is to monitor temperature in a continuous manner, which is the standard current good practice.

The next rule is to make informed decisions based on the stability budgets. WHO prequalified vaccines come with a special unit-level cumulative time and temperature indicator (vaccine vial monitor, or VVM) that mimics vaccine degradation by heat. The combined effects of time and temperature cause VVM to change color irreversibly; by comparing the color of the active surface to the reference ring, health workers can make informed decisions about whether to use the vaccine or not. VVM is based on the stability budget information of the product. When there is no VVM, and the vaccine insert does not have any information on the stability budget, generally vaccines are discarded once they fall outside the recommended temperature range.

In some countries (such as the US), when a vaccine has experienced a temperature excursion beyond the recommended range, the practice is to reach the manufacturer, explain the temperature excursion, and wait for advice about whether to use it or not. This is very impractical; it takes too much staff time and puts the immunization program on hold until the response is given. I know, through my experience working as a scientist at the WHO headquarters for 17 years, that vaccines are much more stable than they are claimed on the product labels.

When stability budget information cannot be used, good vaccines are wasted, many at a time. Stability data are therefore an extremely critical piece of information for countries to manage their COVID-19 vaccine logistics. Let's take the Pfizer/BioNTech COVID-19 vaccine as an example. When the vaccine received the emergency use authorization, unopened vials were recommended to be kept and transported at -90°C to -60°C (-130°F to -76°F) and were allowed to be at 2°C to 8°C (35°F to 46°F) only for five days. This naturally limited wide distribution of the vaccine to all clinics in many countries. Continued stability studies brought good news, easing the logistics with the possibility of transport at -25°C to -15°C (-13°F to 5°F) for up to two weeks and extended life at 2°C to 8°C (35°F to 46°F) for up to 31 days. This new information was a game changer for many countries. Now, it was possible to distribute vaccines more widely.

However, this new information is not helpful to countries when they experience excursions beyond 8°C (46°F). They have no information available to make informed decisions about whether to use the vaccines or not. In the absence of such information, vaccines are discarded, and we know that the majority of these brief periods of such exposures would not affect the quality of the vaccine. We need to know the results of accelerated stability studies, which are conducted on all vaccines before licensing, to tell us how long they can withstand the exposure to temperatures above the recommended ranges.

Making vaccines available to the masses as an exit strategy out of this pandemic is the right course of action, but it is not enough. Now, following development of the vaccines, vaccine manufacturers ought to release the stability budgets of their products and continue to make public updates as further studies are done. This will be remembered and valued as the biggest contribution to public health to minimize unacceptable vaccine wastage.

Author's Note

Dr. Kartoğlu has worked with the WHO as a consultant on authoring the guidelines on the international packaging and shipping of vaccines, including the requirements for candidate COVID-19 vaccines, as well as revising specifications and verification protocols for temperature monitoring devices. He also worked as a consultant for Temptime Corporation, Insite Enterprises Inc., Sensitech Inc., and UNICEF on vaccine-quality related issues. The author declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this post.