Minimising Vaccine Wastage with Advanced Refrigerator and Freezer Technologies

A leading cause of vaccine wastage is exposure to inappropriate temperatures during cold chain storage. A new international standard will help healthcare providers to select high-performance refrigerators and freezers with the precise temperature control necessary to protect the quality and integrity of the vaccines stored inside.

Introduction

The COVID-19 pandemic has catalysed an unprecedented acceleration in vaccine research and development. In less than a year from the identification of the novel viral pathogen, the first vaccines against SARS-CoV-2 gained emergency approval from regulators in several countries after demonstrating high efficacy in clinical trials. The use of innovative vaccine platforms, such as novel mRNA technologies, has played a huge part in this remarkable success story.

While the development of COVID-19 vaccines brings hope of a way out of this global crisis, success also hinges on their efficient and rapid rollout to the world's population. The new vaccine technologies bring new challenges to this already daunting task, not least with managing the vaccine cold chain. Comprised of cold rooms, freezers, refrigerators and transportation boxes, the complex global network contains many components that must keep products at an appropriate temperature on their journey from the manufacturing line to the patient.

Despite intense global efforts to ramp up COVID-19 vaccine production and distribution, many of these doses are still not reaching people's arms, with hundreds of thousands of vaccines being wasted. The US' Centers for Disease Control (CDC) alone recorded 182,874 wasted COVID-19 vaccine doses as of late March 2021. More broadly, the World Health Organisation (WHO) estimates up to 50% of all vaccine doses are wasted each year.[1] A leading cause of vaccine wastage is exposure to inappropriate temperatures during the cold chain.

Establishing the proper cold storage infrastructure needed to help mitigate vaccine wastage will be an important part of tackling the current pandemic, as well as facilitating the rapid and efficient delivery of future vaccination programmes. Recently, NSF International (formerly the National Sanitation Foundation) introduced a new international standard, which will make it easier for healthcare providers to choose high-performance vaccine storage units that are certified to stay within required temperature ranges to reduce the risk of vaccine wastage.

The challenges of managing the vaccine cold chain

All vaccines are biological products, and many will need to be kept at carefully controlled temperatures from the moment they are produced until administered. Any deviations from validated temperature ranges can lead to the degradation of a vaccine's active ingredients and a loss of effectiveness. Each vaccine will have specific cold storage requirements that must be adhered to on its journey to patients.

Traditional vaccines contain a disease-specific antigen or weakened forms of the pathogen designed to trigger an immune response. But the first-ever RNA vaccines, which work by introducing an mRNA sequence encoding a specific disease antigen into the body wrapped in fat droplets, were among the first COVID-19 vaccines to receive regulatory approval. Once inside cells, our bodies make the viral antigen – it is this foreign protein that triggers the immune response.

While these next-generation RNA vaccines offer game-changing advantages over traditional vaccines, including a good safety profile and their ease of manufacturing, they also bring new challenges, such as the need for long-term storage at low temperatures. For example, Moderna's RNA vaccine must be kept in a freezer at around -20°C, while the Pfizer-BioNTech vaccine requires storage at ultra-low temperatures of around -70°C.

Exposure to an incorrect temperature – either too hot or too cold – at any point in the cold chain can render a vaccine ineffective. The entire batch must be discarded, resulting in loss of time, resources and potentially public confidence. This also creates avoidable delays in getting effective vaccines to people, which is of critical importance as the world tries to overcome the effects of the current pandemic. Even worse, any undetected exposures run the risk of unknowingly delivering ineffective vaccines to patients – inadvertently putting lives at risk.

While there are many different elements involved in managing the integrity of the vaccine cold chain, healthcare providers need to know which refrigerators and freezer equipment are suitable for vaccine storage, providing peace of mind for the quality and effectiveness of the precious products inside.

The clear need for high-quality vaccine storage equipment, which has been heightened due to the additional pressure from the current pandemic, has led to the development of a unique class of specialised, high-performance refrigerators and freezers with more precise and sophisticated temperature control features than their typical household or commercial-grade counterparts.

Inadequate standards for vaccine storage equipment

Not only has the COVID-19 pandemic thrust the vaccine cold chain into the spotlight, but it has also exposed some potential insufficiencies.

Until now, few official standards existed for vaccine storage equipment in clinics, pharmacies and other vaccination sites. For instance, the US CDC provides annual guidelines – the Vaccine Handling and Storage Toolkit – that highlights best practice for measuring cabinet temperature and handling vaccines.[2] However, it stops short of detailing temperature performance, design and documentation requirements for a vaccine refrigerator and freezer to prevent product loss.

A simple but important metric used to assess refrigeration performance is temperature uniformity, which involves measuring the maximum temperature difference within a unit at any specific moment in time. This can provide valuable

information about temperature performance in all parts of the useable spaces within the cabinets. Current CDC guidelines stipulate measuring cabinet temperature using a single data logger with a weighted probe. However, these measurements will depend on the location of the probe and frequency of readings – meaning temperature fluctuations may be missed, putting vaccines at risk.

It is also important to consider how a refrigeration storage unit will typically be used in a vaccine clinic, hospital or pharmacy. There are many other factors, such as how often, and how long, the doors are opened, which might impact on performance. Additional tests that mirror typical real-world usage are also needed to assess how these might affect the performance of the storage unit, and inevitably the vaccines stored inside it.

A new international standard to minimise vaccine wastage

These additional considerations, coupled with challenges faced by vaccine providers in selecting the right vaccine storage equipment, led NSF International (formerly the National Sanitation Foundation) to create a new standard. It aims to minimise wastage by keeping the cold chain within the validated range of a specific vaccine to ensure its effectiveness, and ultimately protect the public.

The NSF brought together a multi-institution committee, including re-presentatives from the CDC, state health department immunisation programmes, non-profit organisations and vaccine storage equipment manufacturers, to define a set of performance standards for specialised vaccine refrigerators and freezers. The group created the new standard, NSF 456-Vaccine Storage, based on the analysis of data from real-life usage within clinics, pharmacies and vaccination sites.[3]

The new NSF standard details requirements for the performance and safety, as well as labelling of vaccine storage units. For example, it dictates the use of weighted probes that more accurately simulate vaccine vials to evaluate the performance of a unit using a test method designed to mirror typical usage. This assessment includes long and short door-opening sessions as well as closed-door sessions, empty and loaded cabinets, and provides information about where to place the probes. While the standard is currently voluntary, collecting these additional data will help evaluate how the typical use of vaccines in a clinic, hospital or pharmacy will impact the performance of a storage unit, and inevitability the effectiveness of the vaccines within.

The NSF standard also details specific requirements around the design of units intended for vaccine storage and accompanying documentation. For example, these must be labelled to indicate the usable internal space where vaccines can be stored.

Choosing high-performance vaccine storage equipment

Even within the specialist vaccine class of refrigerators and freezers that are available from manufacturers today, there are huge variations in product performance, functionality and design intent. Many of these products may not meet the new standard recently developed by the NSF.

Previously, specialised vaccine storage refrigerators and freezers were assessed against applicable safety standards used to evaluate and mitigate the risk of electrical shock, casualty or fire hazards. While these are all important points to consider for helping ensure a higher level of safety, such tests do not examine performance, functionality or design intent. Of these, product performance is the most important aspect for protecting vaccines from critical temperature fluctuations that might render them ineffective.

The new NSF standard supports providers to identify a unique class of advanced, high-performance refrigerator and freezer designed with the priority of protecting critical products sensitive to temperature variation. These units offer precise temperature controls to ensure uninterrupted storage conditions throughout the internal chambers; helping to reduce the risk of product wastage and ensure the effectiveness of the products stored inside.

While the world currently focuses on the rapid deployment of COVID-19 vaccines to mitigate the immediate effects of the current pandemic, the introduction of this new NSF standard will also support longer-term public health goals. Creating a sustainable and efficient cold chain will bring benefits for future vaccination programmes by reducing product wastage; saving costs for healthcare providers and potentially improving access to life-saving vaccines.

Creating a sustainable vaccine cold chain

The COVID-19 pandemic has catalysed a transformation in the field of vaccines. Huge advances in technologies offer the promise of a new era of vaccines for controlling, eliminating and potentially eradicating a host of diseases.

But these vaccines will only be effective if they are able to reach the people who need protection. The current global crisis has highlighted some of the challenges around the rapid and efficient delivery of a large-scale vaccination programme; ensuring the integrity of the cold chain is a key step to mitigate the risk of product wastage through unintended exposure to freezing or incorrect temperatures.

Many specialist refrigeration or freezer products currently on the market for vaccine storage may not meet the new NSF standard. Choosing certified, fit for purpose cold-storage equipment is crucial for ensuring vaccines are stored within their correct temperature ranges.

The new NSF standard is a welcome step forward and will help providers differentiate cold storage equipment that is truly suitable for vaccine storage. This will help reduce product wastage and ensure the effectiveness of vaccines – ultimately protecting the public.

REFERENCES

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