Effective vaccine storage

With pharmaceutical companies investing heavily in extensive R&D to produce effective vaccines for existing and emerging health risks, there is a growing recognition that protecting the potency and viability of a vaccine during storage is essential.

by Dr A. Esmon

One of the most rapidly expanding pharmaceutical markets today, the vaccine therapy category protects public health globally and saves an estimated three million lives each year [1]. Vaccines are big business too, with predictions estimating that the vaccine market will reach an annual growth rate of 14% and resulting sales of €25 billion by 2012 [2]. However, incorrect refrigeration and storage of vaccines can lead to costly mistakes. In clinical practice, refrigeration problems have been cited as a major cause of the $20 million wasted each year from ruined vaccines in the U.S. Federal Vaccines for Children Program [3]. In addition, a recent UK study revealed that 40% of vaccines were kept at the incorrect temperature, which could potentially damage a vaccine's potency and effectiveness [4].

Because it is not apparent if a vaccine has become sub-standard through exposure to temperature fluctuations, incorrect storage temperatures can lead to a very real danger that patients are given a sub-standard vaccine, leaving them unprotected against dangerous diseases. Storing vaccines in controlled and constant temperature conditions is therefore the key to protecting a population at risk. Correct vaccine refrigeration also reduces expensive wastage of high-value and fragile biological samples, eliminating the need for costly revaccination programmes that may have to be initiated if the integrity of a vaccine becomes compromised.

Choosing the correct storage

There are significant differences in levels of performance and reliability across various categories of cold storage equipment. Critical cold storage applications demand a safe, stable environment; the temperature fluctuations found in household or commercial cabinets must be eliminated. Choosing the appropriate equipment with proven performance that meets all government standards is now an important business decision for research, hospital, pharmacy and clinical laboratories. Today's specialised laboratory refrigerators and freezers are well equipped to provide efficient high-value biological sample storage that maintains vaccine integrity. Improvements in design and technology ensure that advanced refrigeration can keep vaccines at the constant conditions that clinics and laboratories require.

Maintaining constant temperature

The majority of commonly administered vaccines need to be stored between 2 and 8 °C and must not be exposed to freezing temperatures, which will irreversibly reduce their titre. However, the development of the varicella vaccine in 1995 and the more recent introduction of the live attenuated influenza vaccine (LAIV) have increased the complexity of vaccine storage. These vaccines, including MMR, Varicella (Chickenpox) and Zoster (shingles), as well as LAIV must be maintained in a frozen state (-18 °C is recommended) without any freeze-thaw cycles occurring [5, 6].

Temperature fluctuations can result from sample retrieval by multiple users, unpredictable defrosting cycles or poor insulation. Accidental freezing of freeze-sensitive vaccines, which represent over 31% of the vaccines on which UNICEF spent €318 million in 2005 [7], can also irreparably damage the chemical structure of a vaccine, rendering it ineffective. In addition, certain freeze-sensitive vaccines contain an aluminum adjuvant that precipitates when frozen, resulting in a loss of efficiency and potency.

To prevent temperature deviations, modern clinical refrigeration equipment provides microprocessor-controlled in-built monitoring systems. These can include a graphic thermometer that confirms normal, high or low temperature conditions, with the optional ability to automatically record temperatures over a period of time in a chart format. Alternatively, the placement of a US National Institute of Standards and Technology (NIST)-certified thermometer in the centre of the storage unit, adjacent to the vaccine, allows the unit's temperature to be read and documented twice a day. Records are then kept for a minimum of three years, as recommended in the US CDC guidelines [5]. If temperatures are found to be outside the recommended range, action must be taken immediately.

Storage equipment that features an automatic defrost system is highly recommended, as it prevents water, ice, frost or coolant leaks that could potentially harm vaccine samples. Refrigeration units provide efficient compression technology and forced-air circulation to maintain temperature uniformity throughout the cabinet. They also provide a tight and secure door closure through the use of spring-loaded, self-closing doors and effective door seals, to offer additional vaccine protection. Some units also supply 'Door Ajar' alarms that notify users when the cabinet door is not closed properly. Blown-in insulation that conforms to the unit's shape prevents cold air escaping, as well as internal temperature fluctuations due to exposure to ambient conditions. Many modern laboratory refrigerators and freezers also supply audio and visual alarms that alert users to temperature deviations, providing a real-time warning that cannot be ignored when, for example, preventative maintenance is required. Every clinic should be prepared with a recovery plan, in case of problems, that includes a refrigerator with a back-up generator in the event of, for example, a power cut or natural disaster. Today's refrigeration equipment can provide a full alarm function in case of power failure and a low battery alarm that displays when the alarm system battery backup is low.

Administering a high volume of vaccine doses per year requires a dedicated high performance laboratory refrigerator or freezer.

Best practice vaccine protection

The storage units selected should be of a high enough quality to negate the need for frequent maintenance and repairs, which can compromise vaccine quality due to cabinet 'downtime' and the transfer of samples to another location.Temperature should be recorded twice daily and any deviations from the optimum range should be reported. Studies have demonstrated that educating at least one staff member about correct monitoring and reporting of the refrigerator temperature significantly improves the maintenance of storage conditions, with fewer deviations from optimal temperature ranges going unreported [8, 9]. It is recommended that clinics should use dedicated refrigerators and freezers to store vaccines. Although combined refrigerator/freezer units are acceptable for vaccine storage if each compartment has a separate door, inconsistencies in temperature uniformity can arise, making combined units less suitable for the storage of any temperature-critical samples [10].

Clinics need to make allowances for the largest possible batch of vaccines that they will need to store at one time. This can be problematic as pandemics, e.g., the recent H1N1 (swine flu) outbreak, are not easily predicted. However, since individual doses need to remain 5 - 8 cm away from all walls, doors, drawers and cold air vents (as these are most likely to have temperature extremes), the footprint of the freezer needs to be chosen with care [9].

Conclusion

With organisations investing much time, effort and money to screen, develop and produce potentially life-saving vaccines, it is detrimental in terms of time and cost-efficiency if these vaccines lose effectiveness through incorrect storage. Maintaining constant conditions for vaccine storage is key to improving viability and protecting a population from health risks. Selecting the most efficient clinical cold storage equipment is therefore crucial for ensuring sample protection.

The latest available refrigeration equipment enables much easier and more reliable monitoring and maintenance of ideal temperature conditions for vaccine storage, reducing the occurrence of temperature fluctuations to a minimal level. These in-built technological advances in storage units, in combination with a degree of education on quality control measures, can help to ensure that vaccines remain viable after storage, eliminating the need for costly losses and the implementation of revaccination programmes.

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