



Temperature Monitoring De-Stresses

the Already Strained COVID-19 Vaccine Distribution System



COVID-19 Vaccine Distribution System

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Delivering COVID-19 vaccines to 7.8 billion people is a daunting challenge that will stretch supply chains past their limits. Even if all the needed doses were ready today, vaccine manufacturers still must find solutions to deliver multiple doses of those vaccines to most people on the planet.

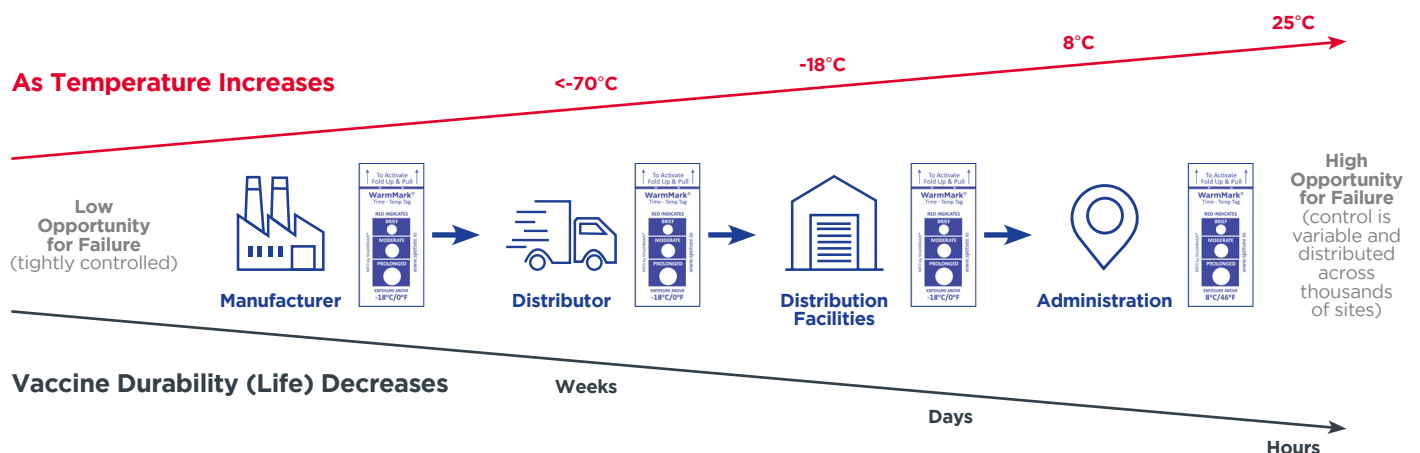
Last mile delivery is the greatest hurdle. As truckload shipments of vaccines are broken down into smaller units for shipments to hospitals, clinics, pharmacies, and physicians' offices, it becomes increasingly difficult to ensure temperature stability over time.

The "Centers for Disease Control and Prevention (CDC) requires diligent management to minimize vaccine waste, and the COVID-19 vaccines require more attention than most. At temperatures above 8°C (refrigerated), they are expected to become ineffective. Once thawed, the clock starts ticking on product shelf life.

To complicate the issue, deep-frozen vaccines like Pfizer's will be shipped and stored in special shippers. Pfizer says they may be opened no longer than one minute. Yet, the refrigerators or coolers used to temporarily store the vaccine will be repeatedly opened and closed, and coolants may not be properly recharged by healthcare professionals rushing to care for patients. This leads to unintended temperature excursions.

Indicators are designed for last-mile and point of administration use. There, they assure pharmacists or physicians that the vaccine has maintained its proper temperature during this final stage before it is injected into a patient. Alternatively, time-temperature indicators, like SpotSee®'s WarmMark®, note not only whether temperature excursions have occurred but also their duration. Along with protecting human health and ensuring vaccine effectiveness these types of monitors indicators provide, medical professionals with an effective tool to manage inventory and avoid wasting valuable vaccines doses. One should be included in each box so temperature can be monitored during the vaccine's patient administration window.

Here's how that could work. For point of administration, the cases of vaccines are separated into individual boxes. They are shipped individually and placed in a freezer upon arrival. But, freezer failures are a major source of wastage. Placing temperature indicators throughout the inventory can indicate which vaccines experienced temperature excursions and



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which are still useable. And, because temperature indicators are cost-effective – costing less than 50 cents when bought in bulk versus \$5 or more for other loggers– deploying multiple indicators is a smart solution. SpotSee's [WarmMark](#) time-temperature indication, for example, can detect a range of temperatures including -18°C (deep freeze), 8°C (refrigeration), 25°C (room temperature), and excursion times from 30 minutes to 168 hours. The indicators can also be customized to mirror vaccine specifications.

Indicators are highly visual. WarmMark indicators change color from white to red to indicate temperature excursions and duration.

Having that information can make the difference between administering or destroying precious vaccine. Ideally, a time-temperature indicator would be deployed each time a bulk shipment is broken down and shipped, all the way to last mile distribution.

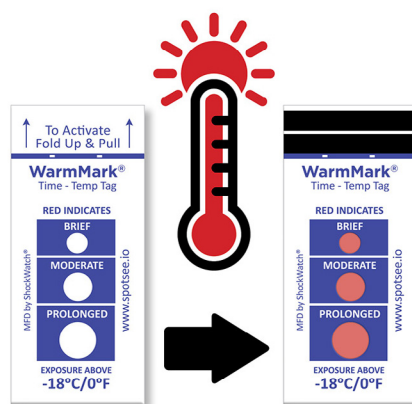
Vaccine development involves more than a few companies and research labs. Globally, approximately 260 vaccines are in development against COVID-19, according to [ClinicalTrials.gov](#). Nearly 60 of those vaccines are in Phase III trials (the final step before approval for widespread use). Some are expected to be approved for use before the end of 2020, while others are likely to be approved throughout 2021.

Monitoring vaccine storage and shipping temperatures is a global challenge, therefore, that is exacerbated by the different handling temperatures of the various vaccines.

COVID-19 vaccines come in a variety of types, such as mRNA- and DNA-based vaccines, protein subunit vaccines, replicating and non-replicating viral vectors vaccines, live attenuated virus vaccines, inactivated virus vaccines, and artificial antigen-presenting cell vaccines. Some of them are novel, with storage and temperature requirements unlike those of previous vaccines.

For example, some mRNA vaccines require deep frozen temperatures. Reports indicate that the vaccine being developed jointly by Pfizer and BioNTech must be stored at -70°C. At that temperature, it can be stored for only ten days. When refrigerated at 2° - 8°C, it lasts only [five](#) days. Pfizer has [\\$1.95 billion](#) contract with the U.S. government to supply up to 100 million doses of its vaccine, so a lot is at stake.

[Moderna's mRNA](#) vaccine, in contrast, must be stored at -20°C for as long as six months. When stored between 2°C



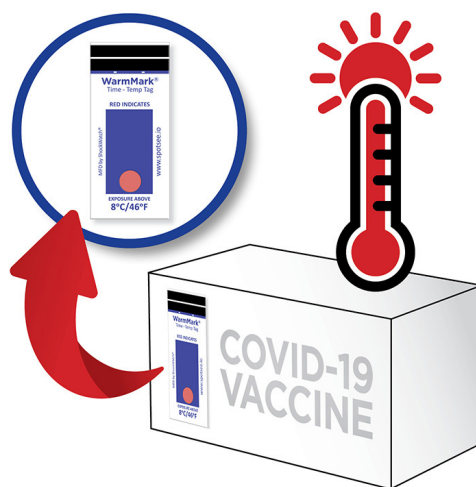
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and 8°C (refrigeration), it remains potent as long as 30 days. That said, the vaccine will be distributed in 10-dose vials that must be used within six hours of opening, thus increasing the potential for temperature excursions.

COVID-19 vaccines that use a viral vector to carry a protein subunit (typically a part of spike protein – the infective part – of the SARS-CoV-2 virus) to cells to elicit an immune response can be shipped and stored at 2° to 8°C. These include the vaccines being developed by Sanofi/Novavax and Johnson & Johnson. Yet, DNA vaccines and at least one of the mRNA vaccines in development can be stored at room temperature for at least one week. They still require temperature monitoring to ensure room temperatures were maintained.

Clearly, the time a vaccine remains at a given temperature affects its potency. With such urgent needs, minimizing wastage is vital. Therefore, using a time-temperature indicator that shows whether a vaccine has been exposed to unsafe temperatures for a period of time can signal whether it is, or is not, safe to use.

Preparing vaccines for administration also is time-temperature sensitive. Moderna's mRNA vaccine, and probably others, will be supplied in multi-dose vials. Before the vaccine can be administered to a patient, they must be thawed and prepared. During this time, they are susceptible. Before a vial is thawed, walk-in sites, such as local pharmacies, must bet that enough patients arrive in a given time window to justify opening that vial. Protecting those vials with a time-temperature indicator provides assurance that the vaccine remains safe and effective. The WarmMark three-window indicator provides that assurance, accurately and cost-effectively.



For vaccine manufacturers and carriers, distribution isn't merely a matter of arranging the extra 15,000 flights estimated by DHL and McKinsey. Most of the vaccines require special handling. Therefore manufacturers and carriers must ensure the cold chain remains intact during what, traditionally, is the peak shipping season. In response, UPS and Deutsche Lufthansa, are expanding their freezer farms at airport hubs. FedEx and DHL are adding temperature monitoring systems to make their solutions more robust to ensure the vaccines are handled properly all the way from the manufacturer to the patient.

McKesson, which agreed to deliver pandemic vaccines as part of a contract signed in 2016, delivered the H1N1 flu vaccine during that pandemic and already delivers the vast majority of America's flu shots. It is bringing several new facilities on line and adding employees to assemble the kits of needles, syringes, protective equipment that accompany each shot, as well as mixing kits.

Ensuring the cold chain can be challenging in even the best of circumstances. The Wall Street Journal reported pharma executives saying that between 5% and 20% of other vaccines spoil during transportation because of poor temperature control. In the midst of this global pandemic, such a spoilage rate could mean that between 1 billion and 4 billion doses of COVID-19 vaccine could be destroyed because of cold chain failures. For COVID-19 vaccines, the supply chain will

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be taxed more than ever before. For it, the key to the efficient, effective distribution and administration of COVID-19 vaccines is to ensure the cold chain remains intact.

Clearly, the temperature requirements vary dramatically, but each of the vaccines will need proof that safe temperatures were maintained throughout storage and shipping. Even the best vaccine procedures can fail. As distribution gets farther and farther from sources of reliable power and refrigeration, the risk mounts that vaccines will experience temperatures that degrade their potency.

Think of it this way. Major transportation hubs have the facilities to ensure temperature stability, but as the vaccines move out into the country, packages become smaller so thermal mass decreases. The vaccines can warm more quickly in a small container than as part of a much larger one. Also, refrigeration facilities may become smaller and less reliable as the vaccine moves from a distribution warehouse to an individual pharmacy or physician's office.

From 2014 to 2019, [Australia lost nearly AUS \\$26 million worth of vaccines](#) from 12,000 cold chain breaches. As a result, some 747,000 vaccines were destroyed – 1.65% of all vaccines distributed in Australia.

In 2019, [Nova Scotia](#) faced the prospect of destroying 2,600 doses of influenza vaccine after refrigerators failed.

In West Yorkshire, in the UK, healthcare providers recorded [31 cold chain incidents](#) between 2016 and 2017. Refrigeration failures were the most often cited reason, but some occurred because vaccines were stored on the lowest shelf – typically the coldest part of the refrigerator.

A study of [German physicians](#) indicated that 16% had experienced cold chain breaches and a review of 21 refrigerators showed they were out of their set temperature ranges more than 10% of the time. If it can happen in Germany, Australia, and the UK, it can happen in the U.S.

The cost extends beyond unvaccinated people and the cost of the vaccine itself. Companies must destroy wasted vaccines as medical waste – whether they spoil in transit or at the point of administration.

For manufacturers and healthcare providers, that means lost revenue. For manufacturers, that also means the additional costs of manufacturing, packaging, storing, and shipping those vaccines. It's simpler – and safer – to monitor the vaccine to reduce the risk of temperature excursions.

Monitoring is an early warning system. It won't prevent a temperature excursion, but it can alert you to excursions in time to minimize their impacts. Vaccine packaging should be chosen with delays in mind, as packages may sit in customs awaiting clearance or inadvertently arrive during weekends or holidays. Likewise, changes in weather between northern and southern hemispheres also may stress the cold chain. When the distribution point is every healthcare facility or major pharmacy in the nation – or the world – the cost/benefit ratio changes.

For those situations, the safest and most cost-effective solution is to use an electronic monitor for the shipment to a major distribution point, with time-temperature indicators placed strategically within the cargo. Strategic placement enables those receiving the vaccine to determine whether products at the center of the cargo maintained temperature even if those on the outer edges experienced excursions.

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Then when the bulk package is broken into small quantities for shipment to individual clinics and pharmacies, time-temperature indicators are the best, most cost-effective option.

Knowing the length of an excursion – which time-temperature indicators show – allows the manufacturer to more accurately determine the safety and potency of the vaccine. Because even deep frozen vaccines are thawed before administration, a temperature excursion may mean simply that a particular shipment is not impaired, but that it should be used within a certain time frame, typically measured in hours.

COVID-19 vaccines are too important not to safeguard.

SpotSee® has a long history of protecting the pharmaceutical cold chain. Our temperature indicators are tuned to the ranges most needed for vaccines.



When cold is an issue, as it may be for some of the COVID-19 vaccines, SpotSee has another solution. There is no public information regarding whether specific COVID-19 vaccines are susceptible to cold, but vaccines using inactivated viruses (one approach used for some COVID-19 vaccines) can be damaged by freezing. Some existing vaccines lose all potency when frozen, according to the Centers for Disease Control & Prevention (CDC). Brief heat excursions, in contrast, may reduce potency but still allow those vaccines to be used. Temperature indicators like SpotSee's Cold Chain Complete provide a safeguard by indicating when the vaccine becomes either too warm or too cold.

Carriers are going to great lengths to protect the cold chain for what will likely be the largest-scale inoculation in history. But, sometimes, plans go awry. Refrigerated units may not be plugged in between off-loading and hand-offs, compressors fail, transportation delays occur, and passive packaging may reach its limits. Even built-in thermometers and alarms sometimes fail.

All vaccines are valuable, but COVID-19 vaccines, in particular, are too precious to risk by relying on packaging alone. Separate temperature monitors provide the assurance that correct temperatures were maintained, or warning that excursions occurred, so only safe, effective COVID-19 vaccines are administered to the world.

SpotSee is a reliable partner in the global vaccination effort. It has developed a wide range of temperature indicators and monitoring solutions, and is creating more that can be customized to your specific needs.

Contact Spotsee about ways to monitor the
temperature of your COVID-19 vaccines.

www.spotsee.io/contact