

Covid-19 Vaccines: Applying healthcare traceability learnings to ensure safe global distribution

Grant Courtney

We face significant challenges ensuring the safe, global distribution of a legitimate Covid-19 vaccine. Grant Courtney looks to our learnings throughout twenty-plus years of developing healthcare traceability to highlight the key lessons we must apply.

The first results of Covid-19 seroprevalence surveys indicate sufficient levels of herd immunity are a long way off. Given the uncertainty about the duration of such immunity, it is becoming increasingly clear that a vaccine will be key to mitigating the impact of the pandemic on society and the economy. However, the development and manufacture of a vaccine is just the start of the process. There are further significant challenges in the safe global distribution of this most precious commodity.

The vaccine development is going to take some time and this gives us a short but vital window to plan for its manufacture and distribution. The global distribution of a Covid-19 vaccine will pose challenges, not least the issue of supply chain security and product verification. Without factoring in these considerations, we open the door to fake vaccines, theft, hijacking and illegal product diversion. For this reason, in 2009, tight security measures surrounded large shipments of H1N1 vaccines and the FDA set up a task force to investigate counterfeit H1N1 treatments.

We have seen a significant upsurge in criminal activity since the start of the Covid-19 outbreak with fake masks and therapeutics, among other counterfeit medical products. In March and April, Homeland Security in the US identified 19 000 suspect Covid-19-related domain names and seized more than \$3.2m linked to 494 shipments of "mislabelled, fraudulent, unauthorised or prohibited COVID-19 test kits, treatment kits, homeopathic remedies, purported anti-viral products and...PPE," leading to 11 arrests. More than 6.5m "products with inaccurate claims" have been flagged by online retail giant Amazon.

Without intervention, we have every reason to expect these same illegal activities to significantly impact the safe distribution of a vaccine. Counterfeit medication is not exclusive to the dark web and underground marketplaces, falsified product has found its way into all corners of the healthcare supply chain, and unknowingly been distributed by legitimate healthcare providers. At best, a fake vaccine can cause a false belief in an individual's protection from the virus, at worst falsified medication can cause death. There are further wider-reaching impacts of false-vaccination on the community, creating new outbreaks in areas assumed to be vaccinated and resulting repercussions on social and economic welfare. The impact of this on a global scale serves to further highlight that our ability to guarantee that a Covid-19 vaccine is legitimate and from a controlled supply chain, will be crucial to tackling this virus.



Grant Courtney is a leading healthcare industry consultant and industry-recognised expert advisor on digital brand protection and product traceability.

Through his twenty-four year career working for GlaxoSmithKline in manufacturing, supply chain and commercial positions, Grant held multiple global roles in strategy and advocacy management, working on a number of large strategic initiatives, including product coding, serialisation, traceability and pack management.

Grant has been a trusted advisor to EFPIA in defining the industry's advocacy and strategic approach to anti-counterfeiting and product traceability in Europe. He was an elected member of the GS1 global healthcare leadership team for ten years, developing the organisation's strategy for driving adoption of standards to increase patient safety and lower healthcare costs globally. He held the role of co-chair of the GS1 healthcare public policy group and currently co-chairs the GS1 digital link working group.

Grant has been recognised through several industry awards including the Institute for Safe Medication Practices Award for preventing the spread of counterfeits in Nigeria and the Best Pharmacy Initiative - Falsified Medicines Directive anti-counterfeiting model. He has a degree in Business Studies, a Lean Sigma Green Belt and is accredited by the Chartered Institute of Marketing. Grant is based in the UK.

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The worth of a successful vaccine reaches far beyond its financial value. It has the potential to protect people from the virus, which is literally a matter of life or death for some. Yet, to deliver its full and most effective potential, the vaccine will need to reach every corner of the world.

Distribution of the vaccine globally presents a further challenge. The fewer the number of producers, the greater this challenge. Some of the current trials use RNA based vaccines, which have a potential for more regionalised manufacture compared to the more traditional vaccines. Irrespective of the type of vaccine technology used, cross border and regional distribution will be necessary. What we need to keep in mind is that the greater the number of countries involved in the supply chain, the more complex the management and the greater the risks.

Some of the most knowledgeable experts in the field are already stressing the challenge of distributing a vaccine globally. "The resulting distribution will be truly global in scale, requiring a monumental logistical effort if all countries are to benefit from the vaccines," wrote Lee Hampton, the head of vaccine safety and vaccine preventable disease surveillance at the Gavi Alliance. Meredith Wadman, a reporter at Science Magazine and published author of *The Vaccine Race*, described the challenges of global distribution of a Covid-19 vaccine, in an interview with book publisher Penguin. "It's not going to be simple to get this vaccine distributed. You look at developing countries that just scarcely have the infrastructure to get our existing vaccines to their population.

And you just have to know that this highly infectious disease, if it (the vaccine) doesn't reach them, will continue to circulate."

Vaccinating the population of low-to-middle income countries (LMICs) could be further complicated by illegal diversion of vaccine shipments back to countries in the developed world. The ability to identify and track the path of a Covid-19 vaccine will be of great importance. This will make supply chain security a significant and vital aspect to address as we plan how to distribute the product.

Tracing the vaccine

Traceability has been utilised in many countries to address supply chain security and help tackle the issue of counterfeit products. In Europe last year, the Falsified Medicines Directive (FMD) triggered an obligation to validate each pack of medicines sold in the European Union's 28 member states against national and European databases. Similar traceability systems have also been successfully established in Turkey, Argentina and South Korea. Healthcare traceability using serialisation first started over 25 years ago, when regulators put labels on packs to facilitate payment and reimbursement. Track and Trace in Healthcare started to emerge around 15 years ago with the FDA looking at which technologies should be used and a number of countries starting to develop legislation. Healthcare is therefore widely acknowledged as a key industry in traceability, with its finely honed techniques being replicated across other high-value goods markets such as food and wine.

What are the lessons we can learn from existing traceability implementations in Healthcare?

Given the challenge of distribution, we already know that products will be shared across countries within a region, therefore **solutions must be global**. The way to achieve this is to base traceability solutions on international global standards. Proven methodologies already exist, allowing harmonisation of the traceability features, as well as data sharing.

The other approach is to **implement a traceability system which can operate across different countries**.

Most current Healthcare traceability systems are specific to an individual country, which will not work for the distribution of products across regions such as Africa. We must break the dependency on having to know where a product is going to be consumed at the point of manufacture and instead allow traceability data to be published to a temporary location and drawn down when needed by regional or national systems.

Whichever solution is chosen, **solutions which are operable with mobile technology** will be central to a Covid-19 vaccine traceability. This will allow deployment where physical infrastructure is not available. Countries not yet incorporated in a traceability system will need a mobile and cloud-based infrastructure. Private actors can be relied on to provide technological solutions to adapt mobile phone technology to scanning, for instance.

In any case, **we must avoid proprietary closed** solutions. Our focus must be on open, universal, collaborative solutions.

In addition to product security, traceability can also be used to provide information on the physical flow of products, product condition monitoring and real time demand information amongst others. This is all critical data when managing temperature sensitive products on a global scale.

Apps which facilitate services like contact tracing, pharmacovigilance and vaccination certification could use the barcode on the vaccine pack to capture the product code, serial number, as well as batch and expiry data. This way there is a record that an individual has actually been vaccinated with a verified pack, and the batch and expiry data is available for aspects such as recall management and pharmacovigilance reporting.

Several serialisation pilot projects have been launched in LMICs by international aid agencies, notably through USAID's DELIVER Project in Nigeria, Egypt, Rwanda and Ethiopia. LMICs now need further support to ensure effective traceability solutions can be put in place to support the distribution of a Covid-19 vaccine. We have the opportunity to use this as a piloting and learning experience, to develop solutions which we could then leverage.

As discussed, we have a limited window of probably some months to fully assess and action a traceability solution, prior to starting the manufacture of the vaccine.

Pharmaceutical serialisation has made huge steps in the last two decades, now is the time for the rest of the world to use these learnings and adopt pharmaceutical serialisation to this crucial global effort. If successful, a global Covid-19 vaccine traceability system would leave a foundation for future pharmaceutical solutions and a positive legacy from the Covid-19 crisis.