Covid-19 as a catalyst for traceability

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The global rollout of the Covid-19 vaccines has presented significant and unique challenges, testing supply chain security. Grant Courtney examines the current state of play with vaccine security and the effect of unsecured supply chains on vaccine hesitancy. With serialisation as a recognised method of enhancing supply chain security, why have the benefits not been leveraged for the current vaccine rollout? And looking to the future, how can the adoption of even a partial traceability model to the vaccine distribution, leave a lasting legacy for the future of healthcare serialisation?

The perfect storm

Where demand for a highly desirable product outstrips supply, it creates the perfect conditions for opportunist profiteers to move in. The falsified product activity we have seen blighting the bottlenecked PPE and Covid-19 test kit supply chains since the start of the pandemic has now, as predicted, started to impact vaccines with instances of falsified vaccine activity reported in Mexico, US, China, Ecuador, Italy, and South Africa so far.

In December 2020 falsified vaccine activity prompted Interpol to issue an orange warning[1] regarding the threat that fake vaccines pose to public safety. An individual was arrested in Washington in January for vaccinating as many as 30 people with fake coronavirus vaccines, charging up to $1,000 per dose[2]. Six were arrested in Mexico for trafficking fraudulent vaccines at a profit of around $2,000 per dose[3].

After publicly criticising the lack of supply, an Italian official was dubiously offered 27 million doses of Pfizer shots for purchase outside of the European Union procurement system[4]. Chinese authorities seized over 3,000 fake vaccines from a criminal ring involving up to 80 individuals believed to have been operating and distributing saline-filled vials since September 2019 and in the first cross-continental incident reported, over 2,400 doses of fake vaccine were found to have travelled from China to South Africa, before being intercepted by Interpol[5]. As more variations of the vaccine appear, the falsification opportunities increase. Echoing Interpol's concerns, in February the EU's anti-fraud agency OLAF issued a statement[6] urging members to be vigilant against scammers attempting to defraud the purchasing European authorities. Such is the desire to join the 'vaccinated' population, and enjoy the anticipated freedoms therein, we have seen instances of theft and falsification of ID for vaccination, proof of vaccination as well as falsification of the vaccines themselves.

There are many reasons why people will look outside of the legitimate supply chain to procure a vaccine. It could be born of a fear that due to a lack of supply the vaccine will not reach them or reach them too late. It could be due to a reluctance to engage with the authorities and healthcare systems, or a simple case of queue jumping. In a previous article I examined some of the measures adopted to help tackle Covid-19 vaccine related cybercrime, one of which is the education of the general public regarding the safe acquisition of the vaccine and the avoidance of illegitimate supply.

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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.

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The high profile of the Covid-19 vaccines has certainly helped the cause here. It has been highly publicised that global supplies are limited. The resounding message from global authorities is that, unless a vaccine is administered by an authorised body, it is not legitimate. There are no legitimate vaccines for sale, there is also no 'spare' vaccine, and all illegitimately sourced vaccines will likely be fake. Yet equally it is these headlines that can fuel the fear and drive consumers to seek the vaccine illegitimately. With instances of theft, diversion and hijack of the genuine vaccine being reported, it is still considered plausible that real vaccines can be sourced illegitimately, despite the very real chance these vaccines have been spoiled or rendered ineffective through improper handling or administration.

It is possible that falsified or stolen product may enter both the illegitimate and legitimate open vaccine supply chains. This has many dangerous consequences including patients and consumers falsely believing they are vaccinated, and therefore not taking the necessary preventative measures of the consciously unvaccinated. Another damaging consequence of an unsecured vaccine supply chain is the erosion of consumer trust and confidence, a contributory factor in vaccine hesitancy. A deterioration in levels of trust in the safety and efficacy of various vaccines has dominated the headlines recently. It is imperative that people trust the vaccines they are offered both in terms of legitimacy as well as safety and efficacy and therefore anything that erodes trust, including discussions around falsification of vaccines, can further contribute to hesitancy and further hamper the efforts of the global rollout.

Falsification is by no means a new issue for the healthcare industry and there are many bodies, businesses, and processes in place to reduce the impact of these crimes.

The Covid-19 vaccines however present us with a rather unique situation, one that in some way helps us in the falsification battle over and above other therapeutics. The fact that there are so few variations of the vaccine, an unusually low number of SKUs and that those that do exist are rolling out through highly visible and scrutinised supply chains, are all factors that help us keep tighter control over the supply chain.

Traceability as a solution

A proven technique for reducing the opportunity for falsification is serialisation of product, mandated by the likes of the DSCSA in US and EU FMD in Europe. Serialisation offers high level visibility and traceability to primary pack level, 360-degree supply chain transparency providing the ability to trace a product back to its source, ensuring authenticity. It requires common identification of an item, standard barcodes, accurate product master data and supply chain partners who are able to share data and transact through common processes. The benefits are far reaching, going beyond just efficiency and security of the supply chain, to providing valuable data for example, for the management of product recalls. A significant enabler in this space is GS1, who has developed common standards for serialisation with a view to enhance patient safety and drive supply chain efficiency within healthcare.

Huge steps have been taken in recent years by countries such as Turkey, South Korea, and Argentina to leverage the many benefits of traceability. However, such is the uniqueness of the Covid-19 vaccine global distribution effort, that even where existing traceability systems were in place, they were initially given dispensation from serialisation in favour of speed of delivery to market, an understandable compromise due to the urgency of distribution. In some cases, partial track and trace has been applied to the vaccines with, for example, barcoding to secondary packaging.

In the US, the Center for Disease Control (CDC) has retrospectively implemented a tracking tool to help people locate suppliers and stock of the vaccine in their local area[7]. This is a rudimentary solution, far surpassed by full traceability and as recent falsification incidents have demonstrated, the lack of full serialisation of this most precious of commodities has effectively left the vaccines more open and vulnerable than a readily available and cheap, serialised pack of paracetamol.

There is a tendency for serialisation to be undertaken only under the pressure of approaching legislative deadlines and only a few countries in the world have currently implemented traceability systems across their end-to-end supply chain. Turkey was the first and perhaps remains the most comprehensive system currently in operation. Their system tracks the product from the point of manufacture through to the point of dispense and is used to prevent falsified products, reimbursement fraud, product diversion and promote the safer use of drugs. UNICEF has requested serialisation as a preferred requirement for Covid-19 vaccines[8], but it is not yet mandated. This has been the situation for the launch of the vaccines, we could yet see a level of serialisation applied to future rollouts, once the pressure on the supply chain has eased.

Again, the uniqueness of the Covid-19 vaccine supply chain has seen new manufacture and distribution parties coming together and having to devise new working systems. A serialisation system requires considerable investment both in terms of finance and time and therefore where a system was not already in place, in the case of these vaccines there was no time to implement one. Visibility in the Turkish system was achieved through the implementation of a central traceability system financed by the Turkish Medicines and Medical Devices Agency (TİTCK), which is affiliated to the Turkish Ministry of Health. This project took four years to achieve, starting in 2008 and completed in 2012, costing significant time as well as money.

The steppingstone to full traceability

There exists a spectrum of serialisation models from, for example, point of dispense in Europe, to full track and trace in Turkey, Argentina, and others. The gold standard is full traceability across the supply chain, in a closed environment. This is where every product is identifiable to the individual pack and all product is checked into a closed environment, tracked through that supply chain, and checked out of the environment at the point of administration. This type of system is seen where serialisation is mandated and legislated and is currently in play in places such as Turkey, Argentina, South Korea, and the EU. These stand as beacon examples of closed and controlled supply chains.

Some traceability models can exist within an open environment. This is where partial serialisation is utilised in an optional or voluntary capacity, offering some level of supply chain visibility and the associated benefits. A successful example of this was implemented by Danone for its baby milk powder[9], whereby manufacturers applied mobile phone scannable QR codes to the packaging, enabling the consumer to verify the quality and authenticity of the product. Two codes exist on the inner and outer packaging providing data on place of manufacture and product legitimacy but also supplementary health and nutrition information and parenting guides and support. In the healthcare industry GSK made strides in the partial serialisation space as far back as 2014, when they applied SMS technology to their antibiotic in the Nigerian market[10], allowing pharmacists and consumers to verify the authenticity of Ampiclox by texting a unique code on the blister pack to a central number, which in turn confirmed product legitimacy via a return text. This pilot led to the Nigerian medicines regulatory authorities mandating the verification process for all antimalarial and antibiotic drugs[11].

These flexible and fast models of verification have also been seen in FMCG and apparel markets. They do not offer the myriad of benefits of a full track and trace system, but without the significant investment required for such systems, they do offer significant benefits beyond the enhanced consumer experience such as being able to detect missing batches and illegal product diversion whilst allowing the sharing of data with customs and other authorities.

A closed environment with full traceability is undoubtedly more secure than an open environment with partial traceability, yet there are significant benefits to these models, since some level of supply chain visibility is better than no visibility. These partial models also stand as foundations and steppingstones to full traceability. They start the process, introducing the necessary systems, equipment and methods and enable the realisation of the benefits of full track and trace, potentially paving the way to a closed environment model. Applying such models to the many supply chain issues surrounding the Covid-19 vaccines could potentially see the pandemic leaving a legacy of significant new developments in the traceability space, as yet unseen in the healthcare industry and of huge benefit to societies and economies worldwide. This complex and ground-breaking global vaccine rollout could act as an enabler to the development of traceability, as a catalyst for discussion to build upon the foundations which already exist. It could prompt governments and stakeholders to consider and implement traceability solutions faster, making a significant acceleration in the global serialisation journey.

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