

Keeping track of the COVID-19 Vaccine in the Centralised Vaccination Clinics (CVCs)



Siobhain Duggan, Director of Innovation and Healthcare, GS1 Ireland

Challenge

As COVID-19 vaccines became available, Ireland's Health Service Executive (HSE) needed an efficient and effective way of receiving, administering, tracking and reporting vaccinations across its more than 40 Centralised Vaccination Clinics (CVCs). It was important for the HSE's National Immunisation Office (NIO) that no dose was wasted and that batches of vaccine could be tracked to the point of vaccination.

Approach

The HSE in collaboration with GS1 Ireland adopted a GS1 standards-based approach for the identification and tracking of vaccines to the point of vaccination. Following an intensive design phase with the HSE project team, two software applications were developed: ScanVax and TrackVax. ScanVax was installed on over 1,000 PCs across the country to allow for the receipt of vaccines. By scanning the barcode on each of the vaccine boxes, vaccine information is then uploaded to the national vaccine administration system. This means that vaccinators can select the correct batch when administering the vaccine. TrackVax has been installed in all CVCs across the country. This allows the CVC teams to identify, label, track and report on the vaccines in their centres, allowing a much easier vaccine reconciliation process locally and nationally. Both solutions are provided by GS1 Ireland.

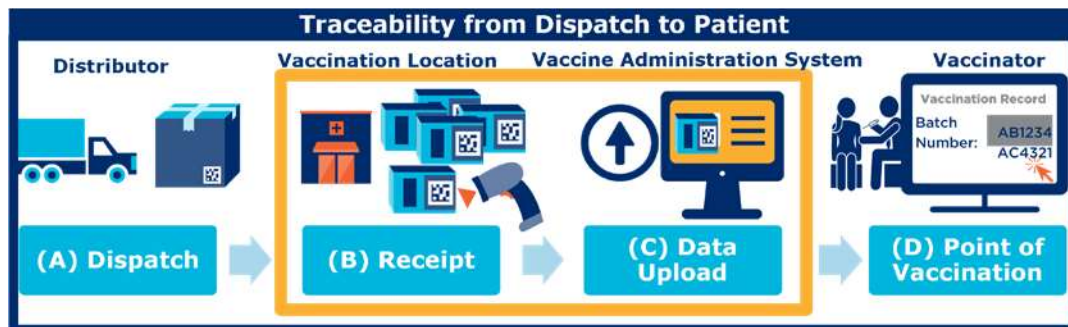


Figure 2: ScanVax is used to record receipt of COVID-19 vaccines by scanning the barcode on the box for upload to the national vaccine administration system

“The feedback on TrackVax from the Senior Management Teams and the High Level Taskforce has been really positive in terms of enabling visibility of vaccine usage and it has been recognised that TrackVax has made a significant contribution to the efficient rollout of the COVID-19 vaccinations across Ireland.”

Dr. Lucy Jessop, Director of Public Health, HSE National Immunisation Office

Background

Over the last 15 years, the HSE has worked with GS1 Ireland to implement traceability standards in areas such as National Haemophilia track and trace, National Instrument and Endoscope track and trace and the development of the Health Directory, which assigns

GS1 identifiers to locations, people, assets and more. These identifiers all played a role in the establishment of the national vaccine administration system as identifiers were required for the people being vaccinated and the locations where the vaccination clinics were operating. Additionally, GS1 identifiers were assigned to

staff using TrackVax and in some cases to boxes of vaccines to identify smaller pack sizes.

As a result of the EU's Falsified Medicines Directive (FMD), manufacturers of prescription medicines are required to assign a two-dimensional (2D) DataMatrix barcode on the secondary package of the product, which means traceability data can be captured in one scan. The barcode has four data elements: the Global Trade Item Number® (GTIN®), batch, expiry date and serial number. Although some of the vaccines didn't have a serial number due to a derogation for COVID-19 vaccines, which presented additional challenges in managing vaccines in the clinics.

Designing in traceability standards

1- Standardised labelling to manage dynamic expiry dates

In December 2020, the HSE invited GS1 Ireland to join discussions on how to manage the change in expiry date for

“It was clear from early in the CVC design stage, that the ambitious vision for the scale of vaccination in the CVCs required a comprehensive in-CVC vaccine tracking tool to support a standardised medicines management process. Identification and tracking of vaccine at vial level enabled vaccine stewardship. Articulating this need was crucial for the successful approval of the business case for the development and rollout of TrackVax.”

Fionnuala King, Chief Pharmacist, Acute Hospitals Drug Management Programme, HSE Acute Operations

Figure 1: Example of label specification for the Pfizer-BioNTech vaccine

the Pfizer-BioNTech vaccine on removal from the Ultra-Low Temperature (ULT) freezer prior to distribution. GS1 Ireland provided a label design for the distributor and subsequently worked very closely with the HSE and system implementation partners to advise on how to “design-in” traceability standards for the national COVID-19 vaccination programme.

2- ScanVax to capture vaccine details in one scan

The next challenge was how to capture the batch details of the vaccines on receipt in the vaccination clinics across Ireland. There was

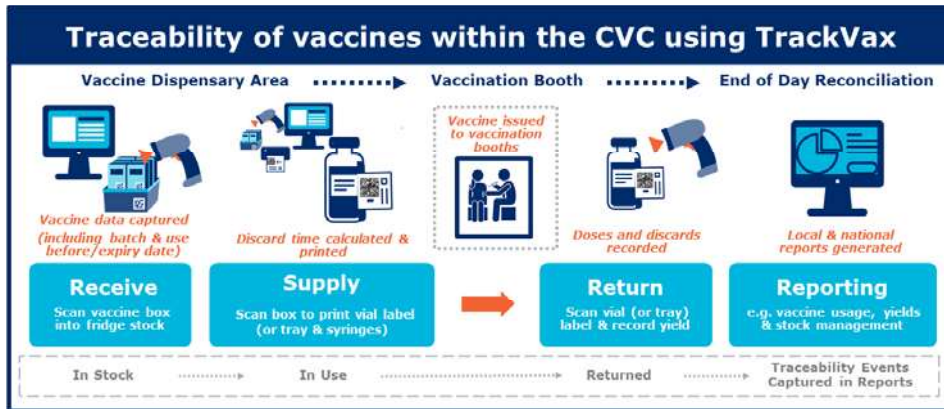
COVID-19 vaccines: Gaining efficiencies in special handling processes

The COVID-19 vaccines, based on the mRNA technology, are fragile and require special handling to ensure they maintain their effectiveness. For the Pfizer-BioNTech vaccine, on removal from the ULT freezer to storage between +2°C and +8°C, the expiry date must change and a “use before” date and time of 120 hours needed to be assigned to the product prior to distribution. This now has been increased to 31 days. For the Moderna vaccine, the expiry date changes on arrival at the vaccination centres and requires a new label “use before” for storage between +2°C and +8°C, which is assigned on receipt into TrackVax.

Consider the process for the Pfizer-BioNTech vaccine. There is one distributor that delivers the National Cold Chain Service (NCCS) for the entire country. All vaccines arriving in Ireland are brought to a central warehouse in Dublin. Each package or box of Pfizer-BioNTech vaccines, containing 195 vials or 1,170 doses, is marked with a 2D DataMatrix barcode as part of the requirements for the EU’s FMD regulation. The boxes are stored in freezers at the designated temperature.

To prepare the vials for distribution to vaccination sites, the vials are repackaged in smaller pack sizes with the exact number needed for these sites (e.g., nursing homes). From the distribution site, the packaged vials of vaccines are transported in refrigerated vans to more than 600 locations throughout Ireland. One of the first recommendations by the GS1 Ireland team was the design of a standardised, full box and break-pack label—for the secondary packages that contain the vaccine’s unique identifier—the GTIN, its batch/lot number, and the revised expiry date and time based on the re-packaging activity—encoded in a 2D DataMatrix barcode. The “use before” date and time information was needed for the Pfizer-BioNTech and Moderna vaccines as their remaining shelf life reduced once stored between +2°C and +8°C.

a backlog of vaccine data that needed to be transferred, so barcode scanning was the obvious choice. One scan can automatically capture the vaccine type, batch and expiry date details related to the COVID-19 vaccines. By early January 2021, GS1 Ireland had developed ScanVax, an app that enables the receipt of vaccines by scanning the barcode



on the vaccine boxes. The details from the barcode are then uploaded to the national vaccine administration system. This means that vaccinators can select the correct batch when administering the vaccine, thus minimising human error and greatly reducing the time required to record the vaccine details. ScanVax has been installed on more than 1,000 PCs and is used to record receipt of vaccines and upload vaccine information to the national vaccine administration system in locations across the country.

3- TrackVax for safer medication management and more efficient vaccine reconciliation

The evolving situation with the pandemic meant it was a race to get people vaccinated. The HSE COVID-19 vaccination planning teams worked intensively on the design of the purpose-built CVCs. As part of this design phase, it was agreed that a standardised vial label was required, and GS1 Ireland was asked to provide the software to print these labels. This software ultimately evolved to become TrackVax, a full track and trace software to identify, label, track and report on the COVID-19 vaccines in the vaccination centres. This proved invaluable for pharmacy staff as the CVCs were extremely busy during their peak when averaging 8 clients vaccinated per minute.

The COVID-19 vaccines are received into stock in the CVC so that a full record is available for stock management. When a vial is required by vaccinators, the staff scans the box and the required number of vials are entered. TrackVax then prints a label for each vial with the key data, including a GTIN, batch and discard time, printed and encoded in a 2D DataMatrix barcode.

“We had approximately 20,000 vaccine deliveries, 4 vaccine types and 20 complicated data fields for each vaccine type. ScanVax standardised everything and meant we could capture records both accurately and quickly. Vaccine data is now seamlessly reportable for the first time in a vaccine programme in Ireland.”

Kerry Ryder, ICT General Manager, HSE National Immunisation Office

Figure 3: Traceability of vaccines within the CVC using TrackVax

There is also the option to print syringe labels depending on the requirements of the CVC. The syringe mode is particularly helpful when approaching the end of the day to minimise the number of open vials and avoid wastage.

The vials or syringes are given to the vaccinators in the booths. There is also the option to assign a vial to a vaccination bay. Some sites used this option when they didn’t have as many staff since it was easier to locate a vial when needed. The vaccinators like the standardised label as they can easily read the batch information and the discard time. When the vaccinator is finished administering the vaccine, the number of doses drawn from the vial is written on the vial label and is then returned to the pharmacy so that the vial yield can be recorded in TrackVax. When in syringe mode, the tray is returned so the yield can be recorded. Each vaccine has different levels of yield. For example, for AstraZeneca the yield is typically between 11 and 12 vaccinations. For Pfizer-BioNTech the yield is between 6 and 7. Based on this wide range, TrackVax needed to be flexible to manage the yields.

TrackVax also allows for discarded vaccines to be accounted for. The system was designed so a discard code can be assigned. This is an important reporting requirement for the NIO in relation to vaccine usage and to detect any trends related to quality issues, or if additional training is required in sites.

The system provides a live dashboard for staff so that vaccine usage can be tracked throughout the day and oversight can be kept if a vial is close to expiration.

Reconciliation of vaccines

One of the challenges for staff in the early days was the reconciliation of the vaccine when using a paper-based process. CVCs use the data from TrackVax to keep a very close track of opened vials particularly as the end of the day approaches which enables an accurate forecast of the number of additional vials that will be required for the remainder of the clinic. It is the combination of vial information or doses in open vials and remaining appointments that helps them manage this process.

TrackVax has made the vaccine reconciliation process much easier to manage since a full audit trail is available and an end-of-day report is automatically generated. This report is used to complete the vaccine reconciliation and

“The success of the implementation of TrackVax has demonstrated the importance of traceability, not just for the COVID-19 vaccine, but for all vaccines.

It is truly exciting times for immunisation programmes which are ever changing and TrackVax will be integral to successful rollouts in the future.”

Cliona Kiersey, Chief Pharmacist, HSE National Immunisation Office

confirm that the doses dispensed match the doses administered in the national vaccine administration system. The report also summarises the vaccine usage information and includes any discarded doses. This reporting was previously done manually by staff at the end of a busy day.

As all of the CVCs started to use TrackVax, the information related to vial yield was visible at local and national levels. The HSE can follow the yields by site and by vaccine type. And, because the vials are scanned and tracked as they are used in the CVC, the accuracy and timeliness of the data enables HSE and the individual CVC to make quick decisions.

TrackVax is giving the CVCs and HSE visibility of vaccine usage and stock management:

- What are current inventory levels of vaccines?
- What are the expiry dates?
- How many boxes and how many vials by vaccine type are in stock?
- How many doses have been administered in a given timeframe?
- What is the yield per vial? Are there any discarded doses?

Consider that one large CVC was experiencing a decrease in yield for the Pfizer-BioNTech vaccine. They immediately alerted the HSE's NIO. Using TrackVax, the team was able to check the yields for other sites and quickly identified that this decline was also happening in other CVCs. Upon closer examination, the HSE deduced very quickly that it was due to the type of syringes being used. Because the HSE had this data readily available, it immediately contacted the procurement team and arranged for the appropriate syringes to be provided to the sites to optimise the yield per vial. The data from TrackVax facilitated quick decision making.

The data wouldn't have been available using a paper-based system, and it is estimated that about 75,000 doses were saved due to this one change.

“From a medication safety perspective, the use of Trackvax across our vaccination centres really helps to standardise our workflow, ensuring vaccines are labelled clearly with all relevant details, which is so important when delivering a programme on such a big scale.

The data from Trackvax is also informing evidence-based decisions to ensure we achieve optimum yield from vaccine vials as it allows us to act quickly if any issues arise.”

Muriel Pate, Medication Safety Specialist Pharmacist, HSE Quality and Patient Safety Directorate

Throughout the roll out of the mass vaccination effort, the GS1 Ireland team has acted as an advisor to the HSE, helping to develop and put processes in place to sustain the support model. The team has also delivered onsite training as well as online training sessions as new versions of the software were rolled out and for new staff joining the CVCs. There are over 40 CVCs in Ireland and as these sites worked at full capacity, the GS1 Ireland team was busy supporting the teams on the ground.

The feedback from the CVCs is very positive, and the traceability system is making their work easier. Reconciliation of the vials at the end of the day is a very time-consuming process when working with a manual process. The excellent data quality means that the NIO has oversight of vaccine usage and accurate stock level data. This means vaccines can be managed closely and wastage is kept to a minimum.

Looking forward

The pandemic and urgent need for mass vaccinations helped to drive the call for

“Traceability is a key part of managing the vaccine process. The use of barcodes has been very beneficial and it is evident that while it has saved time and resources, more importantly it is giving time back to clinicians while providing accurate information for decisions. Patient safety is key and TrackVax has been a real enabler in this case.”

John Swords, National Director of Procurement, HSE

standardisation in how the vaccines were identified, scanned, administered and tracked. By “designing in” GS1 standards from the start, HSE and GS1 Ireland were able to act quickly and then monitor progress over time.

TrackVax has been operational since 3 March 2021. The software has enabled the tracking and management of over 3 million vaccine doses, as of September 2021, or nearly 50% of Ireland's vaccination programme. TrackVax has been widely accepted across CVCs and has delivered value to the HSE through medicine safety, vaccine tracking, operational efficiency and programme integrity.

The TrackVax governance team recognises TrackVax using barcode scanning right to the point of vaccination as an important foundation for the future management of vaccines across all vaccination centres, both large and small. The use of GS1 Traceability standards enable the tracking of vaccine type, batch and expiry date in one scan. This forms a working model for how traceability can be applied to many areas of care across the HSE.

While the benefits accrue during mass vaccination sites, further investigation is required to find ways to bring these benefits to smaller sites, such as nursing homes and general practitioners to enable end-to-end vaccine tracking and efficient, safe vaccine record creation through scanning barcodes at point of care. The next step is the development of a mobile app to facilitate the tracking of vaccines in the community based on a simpler version of TrackVax. To view the full case study and video please go to <https://www.gs1ie.org/healthcare/resources/case-studies/>

“History tells us that pandemics can last up to four years, and Ireland is now reopening society after 18 months. In order to do this, it has been critical that we have a safe and efficient vaccination programme.

TrackVax has been instrumental in enabling a high level of quality assurance and traceability of the vaccine to every citizen. At our peak we were vaccinating 8 clients per minute, we couldn't have done that without TrackVax.”

Joan Peppard, Pharmacy Vaccination lead Dublin Mid-Leinster, HSE

Thank you

GS1 Ireland would like to extend a special note of thanks to all the pharmacists who were involved in the design, testing and rollout of the ScanVax and TrackVax applications. The involvement of the pharmacists and other CVC staff was pivotal to the success of this project. Particular mention goes to Brian Cleary, Gavin Horan, Joan Peppard, Donal Hayes, Fionnuala King, Paul Gilvarry, Muriel Pate, Cliona Kiersey and Mariangela Toma.