CASE STUDY
REPORT

OXFORD UNIVERSITY HOSPITALS
NHS FOUNDATION TRUST

PUTTING **OPTEL CERTA**™
SOFTWARE TO THE TEST

OPTEL™
Traceability technologies for a better world

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INTRODUCTION

OPTEL GROUP, the leading global provider of traceability systems in the healthcare industry, recently partnered with the Oxford University Hospitals NHS Foundation Trust, a world-renowned centre of clinical excellence and one of the largest NHS teaching trusts in the UK, to carry out an eight-week pilot project.

This pilot tested a decommissioning solution, OPTEL Certa™ Software, which was designed and developed through stakeholder engagement. Certa's design takes into consideration ergonomics, user experience and evidence from published work[1] and allows dispensers to immediately comply with the requirements of the European Union's Falsified Medicines Directive (EU FMD).

CONTEXT

According to the World Health Organization (WHO), in 2009, the International Criminal Police Organization (Interpol) seized 34 million pills, bottles and packets of counterfeit and illegal medicines in Europe, and a further 20 million in Asia. Today, the WHO states that an estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified.[2]

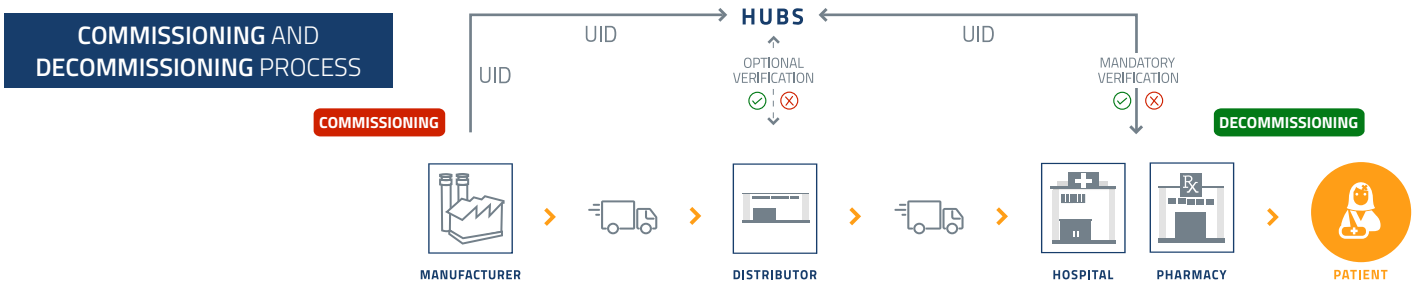
To secure the supply chain and protect public health, the EU FMD outlines mandatory safety features and the steps needed to enhance the traceability of prescription drugs distributed in EU countries.

One critical aspect of the EU FMD focuses on European healthcare providers, including retail and hospital pharmacies, which will be required to perform verification, decommissioning and recommissioning of prescription medicine using unique identifiers (UIDs). These UIDs are stored within a 2D Data Matrix barcode on each manufactured pack.

As medications move through the supply chain, the various stakeholders will be able to verify the status of the medication pack using the UIDs and compare this information against two centralised databases that are responsible for the exchange of medication data: the European Medicines Verification System (EMVS), also known as the European Hub, and the National Medicines Verification Systems (NMVS) for each European country.

Pharmacy staff will be required to verify and decommission the UID of each medication in their possession before dispensing it to patients. The decommissioning of medication results in a change of UID status, from "active" to "supplied". Dispensaries can then confirm a medication's status and receive immediate notifications if the medication is expired, or has been recalled or decommissioned elsewhere, etc., which may be a sign that the product has been falsified. If there is a reason to question the validity of a medication, it is the responsibility of the dispensary to inform the authorities and ensure that it is not administered to the patient. The EU FMD states that decommissioning should be conducted as close to the patient as possible to optimise safety and eliminate the risks of counterfeit, falsified, recalled or out-of-date medication being administered to patients.

The goal is to improve the security of the supply chain, increase visibility into operations and, ultimately, enhance patient safety.



SETTING

The Oxford University Hospitals NHS Foundation Trust (OUHFT) has four main hospitals: The John Radcliffe, the Nuffield Orthopaedic Centre, the Churchill Hospital and the Horton Hospital, the latter of which was chosen as the location for the pilot project due to the mix of clinical services it offers.

The Horton Hospital is a district general hospital that includes emergency and acute general medicine, general surgery, trauma, paediatrics, critical care and a cancer centre. It has 250 beds and dispenses a wide variety of medications. Before the pilot project, pharmacy staff were already knowledgeable about the EU FMD.

THE PILOT

The OUHFT and OPTEL GROUP organised the pilot project to understand and define what must be done to efficiently verify, decommission and recommission prescription medicines, and how they could incorporate the new EU FMD requirements into the hospital's existing workflows and processes. In collaboration with the OUHFT chief pharmacist, an EU FMD expert researcher, pharmacy technicians, operational manager and IT employees, OPTEL GROUP mapped out an eight-week pilot project that included:

- Two pre-pilot visits to observe the pharmacy's existing workflows
- Installation and testing of two different models of scanning hardware, OPTEL Vertical Station and OPTEL Bi-Optic Station
- Testing connectivity to a simulated NMVS
- A 45-minute training session was conducted on how to use the solution to verify and decommission medication as well as how to recognise false or recalled drugs. Those who could not attend the session were given cascade training by their colleagues.
- Post-pilot user and management interviews

To begin the pilot, the OPTEL team created a test environment in which a substantial inventory of medication was uploaded to replicate the NMVS and the actual verification, decommissioning and recommissioning processes.

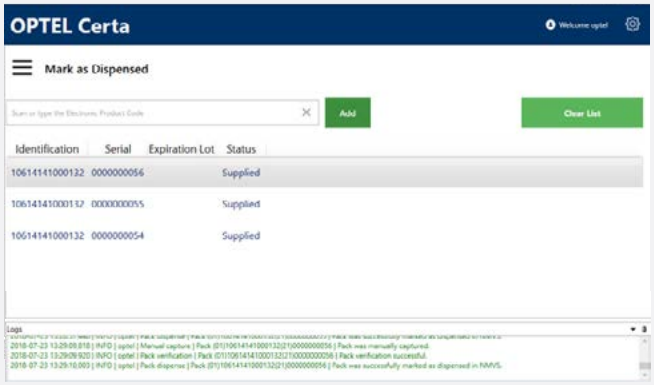
Initially, the OPTEL Vertical Station was installed in the hospital pharmacy. Installation took place in the evening to avoid any impact on day-to-day operations. The OPTEL Vertical Station was installed on the checking bench as part of the checking process. Based on previous analyses, this was identified by pharmacy staff as the ideal location to ensure that operations were not disrupted and that decommissioning could take place as close to the patient as possible[3].

Testing of the vertical scanner was conducted over a four-week period. Once this phase was completed, the team installed the OPTEL Bi-Optic Station and tested it for another four weeks in the same location. The difference between the Vertical and Bi-Optic Stations is simply that the former features one integrated and one handheld scanner, while the latter features two integrated and one handheld scanner, which was anticipated to improve medicine decommissioning efficiency.

OPTEL **CERTA** SOFTWARE WITH **BI-OPTIC** STATION

OPTEL **CERTA** SOFTWARE WITH **VERTICAL** STATION

Both devices required pharmacists and pharmacy technicians to log in to verify, decommission and recommission current medications, using the built-in, high-speed scanner to scan the 2D Data Matrix on bottles, vials and boxes, and the handheld scanner for bulkier packages. The models' software interface, OPTEL Certa™ Software, provided clear, automatic-stop and on-screen notifications as well as different sounds and lock-out modes to ensure that users could immediately address any fraudulent, counterfeit, expired or recalled medications.



RESULTS

Over the course of the eight-week pilot project, up to 370 medicines were scanned. Decommissioning data generated from the OPTEL Dashboard identified 4 p.m. as being the busiest time for medication decommissioning, due to hospital discharge activity. An OPTEL station was installed at "goods in" to load the database for the study and to allow staff to compare medicines received by the hospital to those decommissioned. After verifying the goods received, staff would put the medications on the shelf and later decommission them at "goods out". This would allow them to better control their inventory and ensure that substandard medicines were detected as close to the patient as possible.

Post-pilot interviews were conducted with all users and the following key learning points were identified:

- Pharmacy staff greatly appreciated the OPTEL stations, which freed up limited counter space and allowed staff to perform verification and decommissioning without using a keyboard or mouse.
- Integration of the OPTEL stations into the hospital's existing workflows was easy, taking less than three hours.
- Implementation required minimal resources. Employees were autonomous from the moment the hands-on practice session was complete, regardless of their computer skills.
- The training sessions were quick and hands-on. They were very beneficial in debunking the myth that "adding a decommissioning step would bog down the pharmacy's dispensing process and reduce operational performance".
- Thanks to the solution's ease of use, the overall dispensing process was not slowed down, even though a decommissioning step was added to the workflow.
- The workflow dashboard was useful to both pharmacy staff and management for the following reasons:
    - It indicated at what times decommissioning was most often performed, on a monthly, hourly and even per-minute basis.
    - It allowed users to quickly identify if expired or nearly expired products were being received from manufacturers.
    - It identified the type of work being carried out on the station (verifying, dispensing, reintroducing medication, destroying medicine or samples, etc.).
    - It enabled users to easily compare usage trends over time or across all stations.

STAKEHOLDER IMPROVEMENTS

Stakeholders suggested several improvements, which were implemented as part of Certa 2.0. These included:

Problem: Regular login was not suitable in a busy environment and had regular knock-on effects.

Solution: The ability to log in using a barcode badge was identified as a quick and easy way to facilitate seamless login.

USER TESTIMONIALS

At the end of the pilot project, a survey was sent to all participants. Here are some of their comments:

"For organisations with little time to comply with the EU FMD regulations, the solution has demonstrated the potential for EU FMD compliance within a relatively short time."

"I liked it; it was quick, just like scanning in a supermarket."

"The OPTEL Bi-Optic Station is very fast thanks to the double-scan feature."

"Really nice project. Everyone feels heard. It is nice to have our feedback valued and actioned. It is going to be a lot easier when everything needs to be scanned."

CONCLUSION

This pilot project has demonstrated the importance of innovating responsibly, by gathering stakeholder opinion and implementing stakeholder change to create a solution that is suitable for its intended context. The pilot clearly demonstrated that with the right decommissioning solutions, as well as minimal training and IT intervention, a hospital pharmacy can quickly adapt—not necessarily completely change—their current processes to efficiently meet EU FMD requirements. Overall, this opportunity helped to prove that pharmacies do not need to compromise on operational efficiency to improve patient safety and secure the healthcare supply chain.

References

1. Naughton B, Roberts L, Dopson S, Brindley D, Chapman S. Medicine authentication technology as a counterfeit medicine-detection tool: a Delphi method study to establish expert opinion on manual medicine authentication technology in secondary care. BMJ Open. 2017 May 6;7(5):e013838.

2. WHO. A study on the public health and socioeconomic impact of substandard and falsified medical products. [Internet]. 2017. Available from: http://www.who.int/medicines/regulation/ssffc/publications/Layout-SEstudy-WEB.pdf

3. Naughton B, Roberts L, Dopson S, Chapman S, Brindley D. Effectiveness of medicines authentication technology to detect counterfeit, recalled and expired medicines: a two-stage quantitative secondary care study. BMJ Open. 2016 Dec 1;6(12):e013837.

RELATED LINKS

For more information on the EU FMD, OPTEL Certa™ Software or OPTEL's other healthcare solutions, visit:

- optelhealthcare.com
- optelhealthcare.com/expertise
- optelhealthcare.com/products

optelgroup.com

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