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FMD: A hospital pharmacy perspective

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Background

The Oxford University Hospitals NHS Foundation Trust has four main hospital sites at the John Radcliffe, Nuffield Orthopaedic, the Churchill and the Horton. Three have pharmacy departments and all have electronic prescribing for in-patients that links to the pharmacy system. The Trust wanted to run a pilot, in line with the requirements of the Falsified Medicines Directive (FMD), to understand what they needed to do to authenticate their medicines and the clinical value behind this.

What is the problem?

There are a number of stats that illustrate the size of the problem and the reasons behind the Falsified Medicines Directive. A few examples include:

- The World Health Organisation estimates that 1% of all medicines in the developed world are counterfeit, and that number goes up to 10% globally
- Involving nearly 2,500 cases, EU Customs seized 27.4m doses of falsified medicines at EU borders in 2011 – an almost seven-fold increase from 2007
- In May 2014, the MHRA seized £8.6m worth of falsified medicines and discovered fraudsters are infiltrating the NHS drugs supply chain and diverting medicines to street drug dealers and illegal websites
- In June 2015, 6.2m doses of counterfeit and unlicensed medicines were seized in the UK

However most chief pharmacists don't see this as is a problem that affects them. As far as they're concerned, they have a very secure supply chain and have never come across this as an issue.

How was it solved?

In 2011, the European Parliament adopted the Falsified Medicines Directive and in February 2016, the Delegated Regulation supplementing Directive 2001/83/EC and 4 Annexes was published in the Official Journal of the European Union. Pan-European implementation of the directive is expected by February 2019.

The legislation requires the serialisation of every pack of prescribed drugs with a 2D barcode matrix using GS1 or IFA/PPN standards. Every pack must include this serialisation code number with an expiry date and lot number, as well as the expiry date and lot number in human readable form. These measures mean every pack can be verified and authenticated, via a repository of the 2D barcodes, so that the supplier can be linked to the individual who receives it. If anything needs recalling, it can be identified down to the individual packet.

The process behind the legislation means that products can be checked and verified at all stages of the supply chain – by the manufacturer, the wholesaler or the pharmacist. This way, nobody else can reuse or falsify the product.

The aim of the pilot in Oxford University Hospitals NHS Foundation Trust (OUHNFT) was to:

- Look at their existing workflows and drug distribution cycle
- Identify potential stages of authentication
- Develop the protocols to go with the authentication

OUHNFT ran initial staff education training, and identified a portfolio that included a variety of medicines, to make sure they were testing everything that could go through the system. Across 8 weeks they analysed the dispensing and the checking stages and if there were any problems, these were put aside to be reviewed.

Some of the misconceptions that they encountered along the way included:

- Counterfeit medicines don't make it into the legitimate supply chain
- Staff will be opposed to scanning every drug
- The extra step will slow down the dispensing process
- Detection of unsafe medicines is rare
- Implementation will be time consuming
- The new law will waste NHS money
- There's little or no value in authentication in a developed country

In fact though, they found that when you share information and statistics about the level of the problem out there, people take it more seriously.

Key learnings

From their early experience as a UK hospital implementing FMD as a pilot project, some of the key things OUHNFT learned were:

- In terms of the actual integration it was very quick to integrate (5 days). However it took 5 months to arrange meetings and to get all the required permissions
- Physical authentication rate was approximately 70%. Further work needs to consider human factors to improve this, change suboptimal workflows and include auditory and visual triggers
- Staff adapted well and requested some additional changes to the system. 70% said it was easy to use
- All departments need to get in touch with their robot and pharmacy system supplier as soon as they can
- Educational requirement is key to overcome resistance to change
- A key decision will be where to do the verification
- Implementing your solution could make you more productive
- Don't buy pharmacy robots that do not scan 2D data matrices
- Don't do the 'dreaded calculation'. The number of packs x time for scan = number of man hours leading to a lot of full time equivalents!

OUHNFT found the FMD an enormous change for hospital pharmacy practice, but it was also a fantastic opportunity for improving safety. And, it provided many opportunities to generate cost and efficiency savings and to clinically empower pharmacists.

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