# EHI Live 2014: UK unsure about smart medical devices

## Lack of familiarity about the legal and regulatory framework

This year's EHI Live conference, held at the Birmingham NEC on 4-5 November, brought together much of the UK's eHealth sector to mull over the latest initiatives, opportunities and hurdles faced by the sector. Based on the talks and technology demonstrations on show, much of the UK's eHealth sector seems preoccupied with the transition to paperless, 'big data'-related privacy fears, and tentative experiments with social media. More advanced technology, such as clinical decision support software, smart medical devices, cloud computing, and even the classic example of eHealth's promise, telemedicine, were less prominent. There are many possible reasons for why this might be. One of those might be regulatory uncertainty; some IT providers and their potential customers (both in the NHS and private sector) seemed to suffer from significant discomfort and lack of familiarity around the legal and regulatory framework within which they were operating. It is possible that fear and uncertainty may be stunting conversations and causing many potential users to needlessly shy away from exploring the value of these technologies.

### Technology focus: connected care

Much of the technology being exhibited related to electronic healthcare records ('EHRs'), digital data capture, system interoperability engineering (needed to enable dozens of hospital IT systems to 'talk' to one another), and other infrastructure needed for paperless practice.

Those familiar with the history of eHealth in the UK will no doubt remember the failure of the UK Department of Health's £11.4 billion project to implement a single EHR system for use throughout England. The Department of Health has now switched to a decentralised strategy that lets the myriad of federated components of the NHS source their own solutions.

One panellist estimated that at least 30 EHR solutions may be in use, and many bemoaned the lack of standardisation and interoperability between different systems. NHS England has said that it expects to reach agreement on EHR standards sometime in April 2015. Whilst England stumbles, representatives from the NHS Health and Social Care Board in Northern Ireland vaunted that nearly every Northern Irish citizen now has an EHR. Interestingly, citizens were opted-in automatically; their consent was assumed if they didn't opt-out. To safeguard their privacy, however, they must expressly consent to medical staff accessing the records, except in an emergency.

### Uncertainty about regulatory framework

To an outsider, much of this data seems like fairly rudimentary 'plumbing'; even 'cloud' solutions to data handling and processing, so readily embraced by much of Britain's private and public sector these days, were largely absent from the show-floor.

Those expecting more in the way of 'smart' IT, playing an active role in diagnosis and therapy, would have been especially disappointed. Whilst we heard about interesting pilot projects, and saw a few demonstrations of clever technology, these are not yet mainstream features of modern UK healthcare. It could be that uncertainty around the regulatory framework is holding UK eHealth back; even some of the suppliers showed a surprising degree of unfamiliarity with the legal environment in which they operate.

Whilst information governance (data protection and professional confidentiality) was a recurring topic, attitudes varied widely over issues such as implicit/explicit consent, the legality of international data transfers, and restrictions on data sharing across NHS units or with the private sector; much of the NHS may still be getting to grips with the recommendations made by the 'Caldicott2' review. Surprisingly, many attendees seemed unaware of the EU's ongoing efforts to reform data protection laws, despite the potential impact those reforms could have.

To many, medical device regulation was an even greater mystery. Some attendees were simply not aware that the UK's medical device regulations could potentially apply to software intended for medical purposes; others were only slightly more alive to the issue. One exhibitor stated that they were convinced that their software - which compares patient vital statistics against normal values, and alerts nurses if it spots a possible need to call a doctor - fell outside the medical device rules, because humans ultimately made all the decisions. The Medicines and Healthcare Products Regulatory Authority ('MHRA') might disagree; its recent guidance makes it clear that even software used for dose calculations, symptom tracking or clinician guides can be a medical device, even more so if the output affects the treatment of an individual.

Regulators in the UK are rapidly getting up to speed on 'smart' medical devices. The MHRA recently set up an expert advisory group on medical devices, and has published guidance on 'software as a medical device' ('SaMD'). Meanwhile, the Information Commissioner's Office ('ICO') launched a study that will look at medical device usage and data protection. Developments at the international level also continue apace. Industry (and the NHS) perhaps has some catching up to do. Once there, not only will it be less likely to trip up over various rules, but the various participants in the eHealth economy will be able to have more confident discussions about the possible use of these advanced technologies. We can look forward to future EHI Live conferences where the focus has evolved from 'connected care,' to 'smarter care.'

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