

THE AUSTRALIAN

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THE SAFETY ISSUE

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SAFETY

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LEADERSHIP

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Strength in unity

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Traceability of both medication and medical devices is essential to patient safety. Otherwise we risk another patient being given the wrong medication, counterfeit medication entering the system and untraceable faulty medical devices. Australia needs a unified approach if we are to achieve best practice standards.

"Imagine a world where a patient's records capture the brand, dosage, and lot number of each drug and medical device she uses, along with the name of the physician who ordered the product and the nurse who administered it;

where bedside scanning confirms that she gets the right product in the right dosage at the right time; where hospitals and pharmacies know the exact location of short-supply medical devices and drugs and when they can be delivered;

where regulators can recall adulterated products with accuracy and speed from every point in the supply chain; and where manufacturers can monitor real-time demand changes and shift their production schedules accordingly."

McKinsey Healthcare Report, Strength in Unity, 2012

This powerful statement opened the executive summary of this 2012 McKinsey report. It still resonates today across the health sector the world over. Regulatory bodies, manufacturers, health system operators, clinicians and health providers of all types as well as the most important healthcare stakeholder, consumers, all agree that this is what we need within our health systems.

But have we addressed the underlying challenges related to traceability that impact our ability to deliver this future? Do we really understand how important data standards and the utilisation of unique identification are to ensure we can deliver an interoperable, patient-centric and safer health system?

Image credit: ©GS1

Traceability is essential

Ensuring traceability of the products used within health care is incredibly important in the pursuit of patient safety. Investigations such as those documented by journalist Katherine Eban in *Dangerous Doses* and within government investigations such as the Lindsay Inquiry in Ireland have highlighted where patients have been put at risk due to traceability not existing within the system that supports pharmaceuticals.

In the aftermath of the worldwide scandal related to Poly Implant Prosthese (PIP) breast implants, many countries discovered that they were unable to identify and contact all affected patients to communicate the potential risk (or not). This issue, and others like it, highlighted that without consistent identification and processes to capture data all the way through to the patient record, traceability of the devices is not possible. The challenge is made greater by our increasingly mobile populations where patients have relocated or where they are no longer in contact with the original implanting physician, and there are no centralised records recording the implant.

Using data to protect patients

We often think that traceability is only for the 'supply chain' and many do not see the risk to the patient or consumer without it, or the benefits to patients with it. We have also not always understood that the data related to the actual pharmaceuticals and medical devices that we are providing to patients and consumers is some of the 'data' we need to ensure their safety.

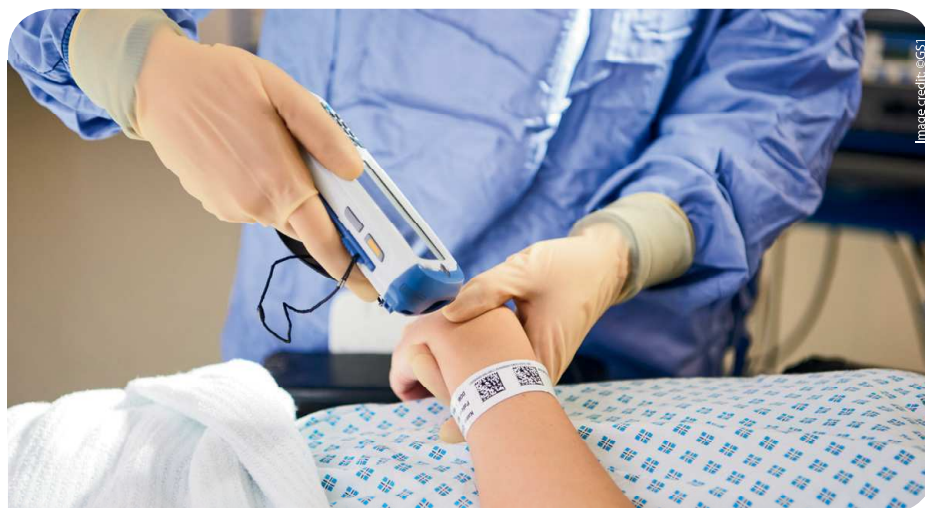
The issues documented above, and others like them, have really highlighted that addressing traceability is critical to safety in many instances. It is evident that changes need to be made across the entire process from the origination of a product, where the products are used by clinicians and when they reach the patient or consumer.

Since the McKinsey report, and the release of these other publications, what has changed to resolve the challenges of traceability within health care? The answer to this question is a lot; however, given the issues documented in the Grattan Institute's latest study of Australian Hospitals (*All complications count: Using our data to make hospitals safer*, Feb 2018), there is still more to be done.

Global trends

Globally there has been a significant shift in focus within the manufacturing communities of both pharmaceuticals and medical devices. They now understand the necessity for a harmonised global approach to traceability, as it removes manufacturing complexity and simplifies internal quality assurance processes. Representative organisations, such as the European Federation of Pharmaceutical Industries and Associations, have helped by strongly supporting a harmonised approach.

Within the regulatory environment there has also been a substantial number of new or revised regulations that require 'unique identification' of products based on recognised global standards. The Unique Device Identification Guidance from the International Medical Device Regulators



Forum laid out the need for a globally harmonised system to increase patient safety by supporting traceability through distribution, use and corrective action.

It also identified that such a system will assist with documenting and longitudinal data capture related to medical devices. This guidance has since provided the foundations for regulations in the USA, European Union and an increasing number of other countries globally.

Similarly, in pharmaceuticals there have been even more comprehensive regulations and traceability frameworks put in place in many countries. These address the need for secure supply chains as well as the requirement for improved accuracy in recording pharmaceutical information within the processes of prescribing, dispensing and administration.

Some of the most notable regulations globally include the Falsified Medicines Directive in Europe and the Drug Supply Chain Securities Act (USA). At a local level in Australia there have also been requirements emerging such as the identification and barcoding requirements of the National Blood Authority, which mandates globally unique identification and serialisation for all products they fund.

Leveraging technology

Despite these advancements, there remains a fundamental lack of understanding of the need for technology to ensure we can achieve traceability for our patients and fulfil the dream articulated by McKinsey. Unlike the United Kingdom, where they have reinforced the need to ensure all products, places and people are identified using unique identification, and that there is also the means to physically capture data this data within interactions or events, many others have focused less on this area.

Standards frameworks, such as the one in development and implementation by ACT Health, start to address this by outlining the standards that are needed, articulating how they will be captured and defining what future technology investments must support. The emphasis on global standards means that solution providers can now develop and implement scalable solutions that meet not only Australian but also international market needs.

If being able to capture and analyse data is accepted as one of the keys to creating safer health care in our hospitals and communities for our patients as suggested in so many studies, then this approach is a step in the right direction and one worth considering by others.

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