UNISAFE™: A PATIENT-CENTRIC APPROACH TO OPTIMISE CONFIDENCE IN MEDICAL DEVICE DESIGN

Here, Alex Fong, MBA, Research and Insights Manager at Owen Mumford, provides an overview and update on needlestick injury, its prevention and the market for needle safety devices, and introduces Unisafe™, Owen Mumford's springless, passive safety device designed to work with existing prefillable syringes.

The global healthcare system is experiencing growing pressure, affecting every segment from costings and financial requirements, through to the quality and safety of treatments made available. The world's population is expected to rise to 9.7 billion by 2050, according to the United Nations Department of Economic and Social Affairs,[1] with an impending demand for medical services and treatment higher than ever before. With the requirement for treatment at an all-time high, it is imperative to empower patients with the correct tools and awareness that will enable them to execute their treatment correctly.

A GROWING POPULATION, DEMANDING SAFETY

Injections have become one of the most common healthcare procedures across the world, with over 16 billion treatments via injection taking place each year.[2] Injections come in a variety of forms, but self-injection of medication (into subcutaneous or intramuscular layers) is one of the more frequently used methods.

Due to the invasive nature of the treatment, injections are not universally safe. Needlestick injuries (NSIs) can arise from the injection process itself and can occur during the use, dissembling of or disposal of needles. For healthcare workers, the risk of cross contamination or transmission of blood or bodily fluid from patients infected with HIV, or hepatitis B or C, for instance, also remains a concern. In 2003, the WHO estimated that each year up to three million needlestick injuries occur in healthcare workers,[3] whilst up to a half of all occupational needlestick injuries remain unreported.[4]

Today, the risk of injury to both end-user and healthcare worker has escalated in line with the market demand for treatments via injection. The severity of the issue has been recognised in the US, and more recently Europe through the European Health and Safety (Sharps Instruments in Healthcare) Regulations 2013, an EU directive with a framework agreement on the prevention of sharps injuries.[5]

Patients and workers alike who access this method of treatment must be protected against the risks of using and disposing of needles. According to The Premier Safety Institute (Charlotte, NC, US), 40% of injuries occur during treatment, whilst another 40% occur after use and before disposal of the needle.[6] Injuries of this kind remain one of the most serious hazards faced by healthcare workers. Most needlestick injuries can be avoided with the use of a safety-engineered device which may protract

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a needle before and after use, ensuring that the end-user remains protected.

Compared with traditional devices, safety injection devices reduce the risk of needlestick injuries by offering optimal protection to the healthcare provider or patient. These safety-oriented devices have emerged as one of the most popular and preferred delivery methods for injections. The US CDC estimates that using safer medical devices could indeed prevent anywhere between 60-80% of sharps injuries in hospitals.[7] Safety injection devices including safety syringes and safety needles are designed to enhance the safety of drug administration and reduce risk of injury.

For prefilled safety devices, the market is set to triple by 2020, from US$250 billion (£205 billion) to $797 billion, and between 2017 and 2018 alone the sales forecast is set to see its largest increase of 34% annual growth.[8]

Pharmaceutical companies and healthcare providers alike are facing a great change in market demand, with patient safety and confidence at the heart of effective treatment delivery. Regulations in recent years have also demanded this and safety injection devices have emerged as one of the key focus areas for device solutions. Not only do these enhance the patient experience and promote wider adoption of treatment (due to a safer and more effective experience) but they also encourage long-term economic benefits to an already overloaded healthcare system by allowing the patient to treat themselves effectively.

There are huge advances in innovation and technology in relation to the design of safety devices with government regulations and end-user demand contributing two strong driving factors behind device development amongst medical device teams.

RESPONDING TO MARKET DEMANDS

Owen Mumford, has responded to the increasing requirement for a safer, more effective syringe device. A thorough understanding of long-term treatment and injecting, partnered with world class research, design expertise and engineering capabilities has led Owen Mumford to a strong and close working relationship with pharmaceutical partners.

The current market place is largely composed of retractable and non-retractable safety syringes which are activated through a spring component. This has previously led to challenges, including accidental activation where a device may activate in transit or accidental under-dosing, where it may be challenging for the user to visually confirm the full dose has been delivered (for instance, if a spring is placed at the front of the syringe barrel, obstructing the view.)

Figure 1: Unisafe™, the springless, passive safety device designed to work with existing, prefillable syringes, avoids disruption to an end-user's treatment routine whilst ensuring that there is no need to change any existing injection components.

Scenarios such as these can impact the efficacy of the treatment – the patient may not receive the correct dosage, the device may be under-populated and there may be discomfort experienced in using the device, alongside the risk of injury. All of these factors create a barrier to continued treatment.

Owen Mumford focused on designing a passive safety device that would overcome these issues. The first option was to start with an existing and proven prefilled syringe and build a spring driven safety mechanism around it, but this could introduce other compromises to device performance. A second was to design a completely new safety syringe to make a brand new solution. However, this would necessitate the use of an unproven primary container that was considered unattractive in the industry. Owen Mumford needed to create a device which would remain effective whilst reducing potential barriers to treatment (painful administration, bulky design, uncomfortable use) whilst also offering suitability for ISO prefilled vendors.

PATIENT-CENTRIC DESIGN IMPACT

The device had to respond to the need of the patient first, whilst allowing for a greater patient responsibility and accountability. By following a patient-centric approach, the device design had to be both intuitive and easy to use for patients and offer additional safety for healthcare workers.

Owen Mumford thus developed a springless, passive safety device designed to work with existing, prefillable syringes. Unisafe™ (see Figure 1) is designed to increase patient confidence when injecting, eliminating the possible risks and challenges of traditional sprung syringes whilst also reducing potential barriers to sustained treatment. The device works just like a normal syringe, ensuring a lack of disruption to an end-user's treatment routine. Change, and the unknown, can both be barriers to treatment, and so Unisafe™ has been developed to ensure there is no need to change any existing injection components. For healthcare providers, the device can be used across an array of injectable formulations which require a syringe, reducing the financial implications of having to purchase multiple devices.

After conducting early formative studies on the design, Owen Mumford continued to develop the concept and further enhance usability. The finger flanges are now smoother, creating a more integrated look and feel, and the plunger head has been made larger for easier handling.

The design and usability of Unisafe™ has recently been the focus of a study conducted with an independent research house.[9] The study comprised nurses (50) and patients (57), accessing and administering injections across various rheumatology, oncology, respiratory, cardiology and gastroenterology indications. In traditional safety syringes, a lack of visibility or confidence that a treatment has been executed fully and correctly can cause anxiety for the end-user.

In response to this, Unisafe™ provides an unobscured prefilled syringe barrel allowing the user to view the drug and labelling

without having to spin the barrel, reducing the risk of under-dosing. In the study, 94% of nurses agreed it was easy to view medication in UniSafe™ before delivering the dose, whilst 89% of patients stated UniSafe™ made it is easy to know that the entire dose had been delivered.

Intuitiveness and ease of use are essential components of patient-centric product design. Working in the same way as a normal syringe and thus preventing any complication, Unisafe™ only requires the end-user to: remove the needle shield, inject the needle into the injection site, then depress the plunger. Needlestick injuries can happen in the first few moments after needle withdrawal and so Owen Mumford responded to this by ensuring the needle is shielded right away.

The device has a passive needle-retraction mechanism, meaning the user does not need to take any additional steps to shield the needle after use. This in turn reduces the risks associated with needle reuse and contamination. In addition, the device has been built with a strong grip, promoting confidence that the end-user or healthcare provider can administer the treatment safety. For 88% of nurses questioned and more than 75% of patients, grip was a key factor in the design of Unisafe™, particularly in raising confidence that the device would not slip during administration.

Some patients with chronic diseases can suffer from impaired dexterity, making it difficult to perform an injection. Mindful that this could produce a barrier to treatment, Unisafe™, has been designed with a larger, ergonomic plunger head and a smoother, more integrated finger flange for a more comfortable and integrated look and feel. This ensures the end-user can use the device confidently and intuitively, regardless of hand size, dexterity or condition. The device is thus suitable for all patient types and, in the study, 82% of nurses agreed their patients would find Unisafe™ intuitive to use, whilst 83% of patients agreed they would feel more confident using the device.

CHANGING MARKET NEEDS REQUIRE CONSTANT REVIEW

Patient-centric design is always changing and Owen Mumford is working closely with pharmaceutical partners to adapt products to meet the growing demand for injectable treatments.

The safety syringe market is set to expand at 9.7% CAGR following a rise in health and safety awareness[10] in 2013-2019. Manufacturers utilising a patient-centric design are responding to this, changing in line with market evolution and customer demand. The demand and development of injectable devices is a constant feedback loop between end-user and manufacturer, and development is vital to both encourage adherence to treatment regimes and help patients effectively self-manage their condition.

With up to 16 billion injections occurring every year, there is a demand for manufacturers to provide devices that are intuitive, safe and easy to use, for both patients and healthcare providers.

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ABOUT THE COMPANY

Owen Mumford is a major medical device manufacturer that develops pioneering products for its own Owen Mumford brand and custom device solutions for the world's major pharmaceutical and diagnostic companies. Owen Mumford's goal is to improve quality of life, encourage adherence to treatment and reduce healthcare costs. Making a world of difference, to a world of people.

With a history of world firsts in device solutions, Owen Mumford offers proven design, development and delivery services from a broad base of proven self-injection and blood sampling platform devices and intellectual property.

In business for over 60 years, Owen Mumford remains privately owned with a focus on long-term investment to deliver sustainable business growth. With a strong internal research and development capability, Owen Mumford's goal is to develop solutions that address today's healthcare demands. Through advanced research involving end users and healthcare professionals, and extensive design and manufacturing capabilities, Owen Mumford produces class-leading medical devices that are used globally, exporting over 85% of its products to more than 60 countries worldwide.

Selected as one of The World Economic Forum's Global Growth Companies, Owen Mumford is a trusted partner to many of the world's biggest medical device, diagnostic and pharmaceutical companies and works with international organisations to support customers at a local level and provide consistent and dedicated support.

THE AUTHOR

Alex Fong is a Research and Insights Manager at Owen Mumford. He holds an MBA and has worked in the market research industry for ten years, on both client and agency side. His current role manages market analyses, understanding the consumer and the end-user.

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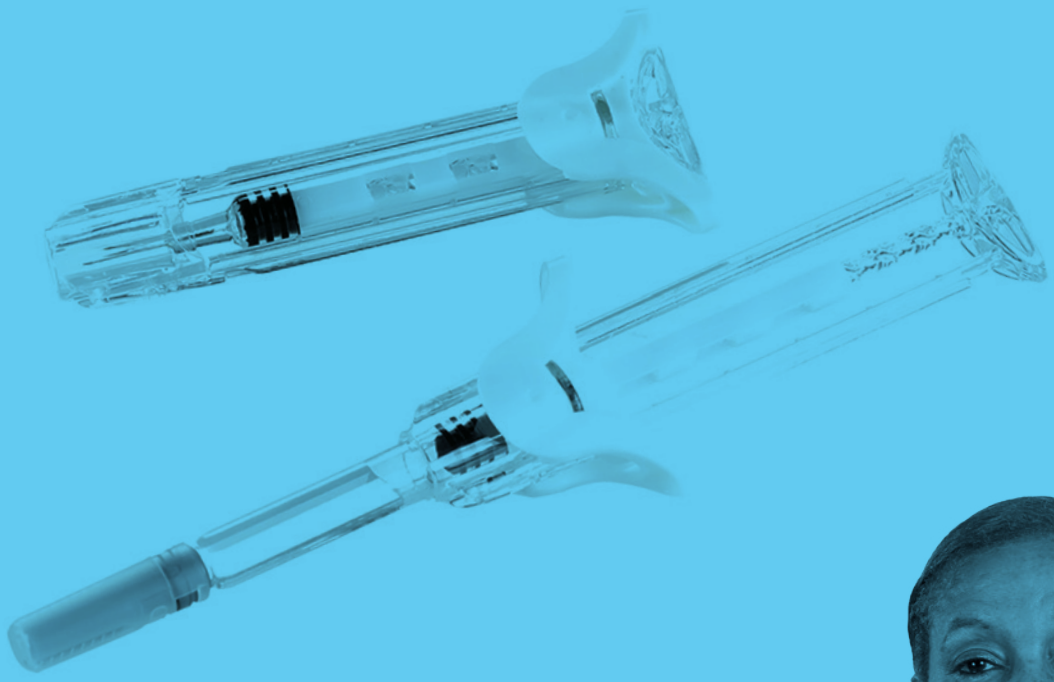

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