



SAFE | SUSTAINABLE | SMART



A smart sustainable way to make injections safer

A RONCADELLE OPERATIONS WHITE PAPER

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Executive Overview

A global crisis in needlestick injuries (NSIs) has been recognized by both the US and the EU authorities. The US Occupational Safety and Health Administration (OSHA) was concerned enough to bring in the US Needlestick Safety and Prevention Act of 2000, endorsing the use of safe needles or needleless devices in medical settings. Then in 2013, the European Commission passed the Health and Safety (Sharps Instruments in Healthcare) Regulations, making specific, detailed recommendations to strengthen their existing safety laws about the duties of healthcare employers.

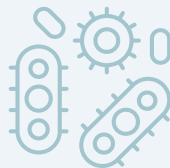
16 billion

injections administered annually worldwide.



23 million

result in infections - more than double the populations of Paris, London or New York every year.¹



In Italy alone, there are 100,000 NSIs every year, but estimates put the number of unreported incidents at 45%. In the USA, an estimated 385,000 NSIs occur annually, of which 60% go unreported.¹ And across the EU, the COVID-19 pandemic, has led to a recent explosion of infections. The European Biosafety Network (EBN) commissioned an IPSOS MORI survey, which revealed an estimated 276,000 increase in sharps injuries to healthcare workers in 2020. What's more, 98% of respondents blamed the rise on increased pressure and stress due to COVID-19.³

This clearly adds up to a huge global risk. The administration of injections carries substantial dangers for healthcare workers due to potential cross-contamination from patients infected with HIV, hepatitis B or hepatitis C, or potentially "every pathogen present in human blood".² And as the global demand for injection-based treatment grows, this risk of injury continues to increase.³

However, such injuries are largely, if not wholly, avoidable since the majority are caused by bad injection practices and poor syringe design. The adoption of Safety Injection Devices (SIDs) in hospitals could cut the risk of sharps injuries by 70-80% or more. This would have the added benefits of reducing the cost of these injuries to health organizations, improving the healthcare worker and patient experience and increasing take-up of injections by making it safe and simple enough for patients to treat themselves.⁴

Needlestick injuries - a worldwide crisis set to escalate

Injections are among the most-used health care procedures. Roughly 90% occur in therapeutic care, 5% in immunization and the rest through transfusion of blood/blood products and intravenous drug, fluid and contraceptive usage has burgeoned since 2019 with the boom in Covid-19 cases and the increased number of syringes required for its vaccines.

This situation naturally demands renewed focus on high safety standards to prevent needlestick injuries and the consequent risk of bloodborne infections. Unfortunately, however, studies in many countries have shown that safety precautions are often not followed over the last decade.

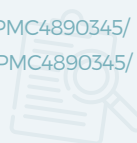


¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4890345/>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4890345/>

³ World Health Organization Guidelines PDF

⁴ World Health Organization Guidelines PDF



The impact on healthcare

In addition to the direct health risk to patients and healthcare workers, NSIs have financial repercussions across the healthcare industry. Gaining an accurate cost is complex, but a systematic review of 6 of 11 studies that assessed direct costs (such as laboratory testing, post-exposure management) and indirect costs (e.g., counselling NSI victims, lost productivity, treatment, and compensation), put the median of the mean of these combined costs at \$747 per incident.

These costs, and the attendant risks, are set to escalate in line with the increasing demand for syringes.

The growing burden of chronic diseases like diabetes, cancer, hormonal diseases, etc. and the increasing need for self-care devices are now driving growth in the Prefillable Syringe market. For example, the international journal Clinical Practice and Diabetes Research stated in 2019 that the global prevalence of diabetes had reached 9.3% (463 million people), a figure they say is likely to keep growing to 25% in 2030 and to 51% by 2045.

By which time, with one in two people living with diabetes, the safety of self-injection by the patient will have become absolutely paramount.

As for the safety of healthcare workers, the US OSHA Standard 1910.1030 has already stated that employees must have a say in what devices are used and that instruments must be chosen for appropriateness and effectiveness in preventing infection. Failure to take this into account could have consequences for organizations in the future.⁷



The unsafe practices are linked to NSIs.

The World Health Organization has identified the four critical practices largely to blame for NSIs.

1. Unsafe sharps waste management

Poor practices that increase risks from infected sharps include: not incinerating properly, disposing in open pits or dumping sites and discarding used syringes in hospital laundry. There is also a risk of scavenging used injection equipment from rubbish dumps, then washing and repackaging them and reselling them as new.

2. Re-use of injection equipment

Equipment re-use leads to the transmission of bloodborne viruses such as HIV, HBV and HCV from one patient to another. A WHO literature review on the worldwide use of injections in health care settings estimated that up to 75% of injections were administered with unsterilized re-used equipment.

At the start of the WHO Injection Safety Program and the Safe Injection Global Network (SIGN), WHO also estimated that 40% of the 16 billion injections were given with re-used injection equipment in health care settings, leading to 21 million new HBV cases (32% of all new cases), 2 million new HCV cases (40% of all new cases) and around 260 000 HIV cases (5% of all new HIV cases). Other diseases can also be transmitted in this way, including viral hemorrhagic fevers, e.g., Ebola and Marburg viruses, malaria and other diseases.

The background What makes an injection unsafe?

The WHO definition of a “safe injection” is one that does not:

- Harm the recipient.
- Expose the injection giver to avoidable risk.
- Cause waste that is dangerous for the community.

⁵ World Health Organization Guidelines PDF

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4890345/>

⁷ Saia et al. (2010)



3. Accidental needle-stick injuries (NSIs) through providing health care

These can occur during or after the injection (before, during or after disposal). Recapping contaminated needles is a common cause of NSIs, according to surveys on injection practices using the WHO Injection Safety Assessment Tool.¹⁰

In 2003, a WHO study on the burden of diseases from NSIs in healthcare workers (HCWs) pointed to 3 million accidental NSIs, leading to 37% of all new HBV cases in HCWs and 39% of new HCV and around 5.5% of new HIV cases.¹¹

4. Over-use of injections

Multiple surveys have demonstrated the overuse of injections in administering medications when an oral formulation would be equally or more appropriate.

The view from the WHO

Since 2000, the WHO has increased endeavors to tackle unsafe injection practices (in tandem with the Safe Injection Global Network (SIGN) and other key international health players). Together, they have helped countries implement a three-pillar strategy:

01. Encouraging behavior change among patients and HCWs;
02. Improving the availability of high quality (safer) injection devices; and
03. Implementing a safer sharps waste management system.

To support these strategies, WHO guidance includes, among other recommendations:

WHO-UNICEF-UNFPA Joint Policy Statement¹³ - recommending AD syringes exclusively for all immunization injections

“Guiding principles to ensure injection device security”¹⁴ - stating “syringes with a re-use prevention feature offer the highest level of safety for injection recipients. They should be considered for use for therapeutic injections where local data indicate that unsafe practices are prevalent.”

WHO best practices for injections and related procedures toolkit¹⁵ - points out the importance of maintaining a sufficient supply of quality-assured syringes and a corresponding supply of safety disposal bins prevalent.”

In particular, the WHO made these specific recommendations:

“We recommend the use of syringes with a sharp’s injury protection feature (SIP devices), as opposed to syringes without a sharps injury protection feature, by health care workers (HCWs) delivering intramuscular, subcutaneous or intradermal injectable medications to patients (conditional recommendation, moderate-quality evidence).”

Their rationale noted that although the evidence of effectiveness was of moderate quality, the “balance of benefit to harm is judged as probably favorable, with benefits outweighing harm.” It was also noted that benefits could be expected to increase in settings with a higher prevalence of HIV, HBV and HCV disease or frequency of sharps injuries.

“We recommend the use of syringes with a re-use prevention feature (RUP devices), as opposed to devices without, by HCWs delivering intramuscular, subcutaneous or intradermal injectable medications to patients (conditional recommendation, very low-quality evidence).”

Again, allowances were made for low-quality evidence, but “the balance of benefit-to-harm is judged as probably favorable, with benefits outweighing harm.” They further noted a decrease in the rate of re-use of syringes where RUP devices were used in therapeutic injections or immunizations, which in turn led to a fall in NSI-related disease transmission with “no expected harms”.

¹⁰Hutin Y, Hauri A, Armstrong G. Use of injections in healthcare settings worldwide, 2000: literature review and regional estimates. *BMJ* Volume 327. 8 November 2003.

¹¹Hauri A, Armstrong G, Hutin Y. The global burden of disease attributable to contaminated injections given in health care settings. *Int J STD AIDS*. 2004; 15(1):7-16. Hutin Y, Hauri A, Armstrong G. Use of injections in healthcare settings worldwide, 2000: literature review and regional estimates. *BMJ* Volume 327. 8 November 2003.

¹²(http://www.who.int/injection_safety/toolbox/techttools/en/).

¹³Pruss-Ustun A, Rapiti E, Hutin Y. Sharps injuries: global burden of disease from sharps injuries to health care workers. *Environmental burden of disease series N° 3*, WHO 2003.

¹⁴Quick JD, Rankin JR, Laing RO et al. (Editors). *Managing drug supply*, 1st edn 1997; pp430-49. West Hartford: Kumarian Press, Hutin Y, Hauri A, Armstrong G. Use of injections in healthcare settings worldwide, 2000: literature review and regional estimates. *BMJ* Volume 327. 8 November 2003.

¹⁵http://www.who.int/injection_safety/toolbox/resources/en/

¹⁶Guiding principles to ensure injection device security. WHO 2003

¹⁷WHO best practices for injections and related procedures toolkit. WHO 2010. Available under the following link: http://www.who.int/injection_safety/toolbox/9789241599252/en/

What solutions are available?

ACTIVE (manual)

A Single-use Active Safety syringe can prevent re-use but depend on the user remembering to cap the needle, which (by adding an extra step) adds risk.

PASSIVE (automatic)

A Single-use Passive Safety syringe retracts the needle automatically, preventing re-use without the need for any extra action from the user (hence the word “passive”).

These passive, fully-automatic safety devices have been shown in studies (Linuma et al. (2005) and Bausone-Gazda et al. (2010)) to be the most effective in preventing needlestick injuries since they can easily be used with one hand, and the passive safety mechanism protects against injury. They also don't require learning any special new technique to engage the safety mechanism. For this reason, they are being used more and more in medical environments worldwide (Cooke & Stephens, 2017; Feng & Liu, 2009; Handiyani et al., 2018; Pham & Neustein, 2009).

Barriers against usage

Some products have deterred usage by being too bulky, uncomfortable to use or painful in administration. Others have been felt to be too expensive. And some can cause concern in the user if it is not clear that the medication has been fully dispensed.



When a standardized solution is not a solution

Solutions should ideally be standardized on the basis that they are the safest and best-performing method or device for the specific application and, if necessary, a range of products should be matched to their different purposes. Some syringes deemed “safety” devices by their manufacturers offer limited degrees of protection against needle-stick injuries in practice, if any and can therefore increase risk, disruption and consequent cost.

Standardizations adopted on the grounds of cost, logistical convenience, streamlining supply chains or compatibility with current apparatus rather than safety can naturally increase risk. This risk can be increased if further training is required, as no training can be guaranteed to be 100% effective.

So, it makes sense that standardization must be rooted firmly in performance and safety for each specific application, even if this means specifying different products for different purposes. Factors such as cost and streamlining supply chains must be considered secondary to patient and staff safety concerns.

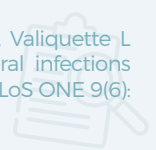
Towards a more effective solution

Safer healthcare practices must depend upon the global availability (and affordability) of intuitive, passive safety syringes with a needle retraction mechanism designed to eliminate needle-stick injuries, such as those produced by the med-tech innovations company Roncadelle Operations.

Such devices typically require very little or no training to use, are usable with one hand and are 100% safe right through to disposal. It is also desirable that they come in a range of needle/syringe sizes so that their use can be standardized.

While the single-use operation is ideal, in the real world, multiple injection attempts can blunt needles, so it is expedient to design a device to allow the needle to be changed.

¹⁶Pépin J, Abou Chakra CN, Pépin E, Naultv, Valiquette L (2014) Evolution of the global burden of viral infections from unsafe medical injections, 2000-2010. PLoS ONE 9(6): e99677. Doi: 10.1371/journal.pone.0099677.



Making safety syringes affordable

The fewer the components, the better is the watchword in producing the ideal safety syringe to minimize manufacturing costs and increase reliability, encouraging healthcare organizations to evangelize their use. Ideally, they should also be versatile and work for prefilled and cartridge configurations, with or without the needle.

Gathering global support for safety syringes

Governments in more and more countries are beginning to call for syringes that cut maintenance costs (e.g., cleaning and sharpening) and make injections easier and safer. However, education is still needed in regions with a less developed healthcare system where there is still a preference for reusable syringes.

Nevertheless, this mindset is set to spread as global vaccination efforts and raised awareness of risks increase demand for safer injection practices. In addition, as competitive technologies age and healthcare networks seek safety at an affordable price, enthusiasm is already growing for such solutions.



SAFER® SYRINGE

Passive safety syringe with retractable needle



Conclusion

Given the risks identified by the WHO and the above-identified disruption and cost to healthcare organizations from needlestick injuries, it is strongly recommended that passive retractable safety devices (such as the SafeR® range produced by Roncadelle Operations) be adopted as an effective solution.

Such devices will entirely eliminate the risk of re-use and, therefore, the possibility of cross-contamination between users. In addition, they will remove the NSI risk to health workers, eradicate the problem of scavenging and resale, and dispel the risk of poor waste management. Furthermore, they would meet all the WHO's criteria for safe injection.

They are likely to encourage behavior change through their affordability, ensuring wider availability and creating an ecosystem of safer sharps waste management, thus supporting the WHO's Three Pillar System. And of course, their expense will be offset by the savings on the cost of NSIs to each healthcare organization.





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