The Best Defense Is Good Design:

Human Factors Engineering to Reduce Sharps Exposure in Injectable Medication Preparation and Delivery

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REAL PEOPLE.
REAL ENVIRONMENTS.
BETTER DEVICES.

Sharps Exposure Remains an Everyday Occupational Hazard

Needlestick injuries and sharps exposures remain a significant occupational hazard for healthcare professionals, despite decades of safety-engineered devices and standardized protocols that seek to mitigate the risk. Some sharps use is inherent to the delivery of care, including the needle required to establish vascular access. Yet a known and well-documented problem remains: preparing and delivering medication introduces additional, potentially avoidable contact with sharps. This invites a different approach to risk reduction: rather than continuing to manage the hazard through protocols and behavior, can we design it out of the workflow altogether?

2.5 million needlestick injuries occur among healthcare workers worldwide each year. Roughly three in ten are linked to needle recapping, a share that has barely moved since it was first documented in 1988, and each injury costs an estimated $750 to $4,500 to manage.

[Designer: set as numbered superscript citations with a reference line. Sources: WHO EMRO meta-analysis; Jagger et al., NEJM 1988;319:284-8; 2023 meta-analysis (recapping 30%); PMC economic review of NSI costs.]

Where Sharps Remain in the Medication Workflow

	Vascular Access Established	Vial Access	Draw & Prepare Dose	Transfer to Line or Port	Administer & Dispose
CURRENT PRACTICE	**SHARPS:** Venipuncture required	**SHARPS:** Needle pierces stopper	**SHARPS:** Exposed needle in hand	Needle already designed out: needleless connectors are standard of care	**SHARPS:** Needle requires disposal
NEEDLE-FREE ACCESS	**SHARPS:** Venipuncture required	**NO NEEDLE:** Syringe connects directly to Luer-Lock closure	**NO EXPOSED NEEDLE**	Needle already designed out: needleless connectors are standard of care	**NO SHARP TO DISCARD**

Once vascular access is established, every remaining needle in the medication preparation and delivery workflow is a source of potentially avoidable risk. Human factors analysis can do more than identify where those risks occur; it can challenge whether the sharps that create them are necessary at all. When the design carries that burden instead of the clinician, safety no longer depends on performing every step perfectly, every time.

A Safety Lens on the Workflow

Human factors engineering examines medication preparation and delivery as clinicians actually perform it. Workflow analysis and representative use scenarios help identify where sharps persist, how clinicians interact with them, and where risk may be reduced through better design. Healthcare worker observations are translated into defined design inputs, while iterative usability evaluations assess whether proposed changes improve safety without introducing new burdens or use-related risks. Throughout development, safety must be considered alongside usability, manufacturability, and regulatory requirements, creating opportunities to build protection into the product itself rather than relying solely on protocols or perfect human performance.

Human Factors in Practice: Needle-Free Vial Access

These principles are illustrated through the development of an injectable pharmaceutical packaging and delivery platform designed to eliminate the needle from vial access. The container closure incorporates a Luer-activated septum that opens when a Luer-Lock syringe is threaded onto the closure and reseals upon removal, allowing medication to be withdrawn without piercing the stopper with a needle. By redesigning the interface between syringe and vial, the system removes a sharps- handling step while maintaining compatibility with established vial formats, clinical workflows, and fill-finish infrastructure.

Lessons Learned

Human factors evaluation is an opportunity to challenge the status quo rather than merely refine it, revealing possibilities for improvement that extend beyond how clinicians interact with an existing workflow. When insights from this broader lens are incorporated early in the design process, engineering teams have greater opportunity to reduce risk at its source while preserving the familiar workflows clinicians rely on. Although illustrated here through a single platform, the principle applies broadly across medical device and combination product development: thoughtful design can support safer practice by reducing the number of hazards clinicians are asked to manage.

Design out the needle

Not every sharp in healthcare can be eliminated. But when a workflow step no longer requires one, thoughtful design can remove the hazard rather than ask the clinician to manage it. **The safest needle will always be the one that isn't used.**

Learning Objectives

- Identify opportunities to reduce sharps exposure through human factors engineering.
- Translate clinical workflows and healthcare worker observations into actionable design inputs.
- Apply human-centered design and iterative evaluation to reduce use-related risk.
- Recognize opportunities to reduce reliance on clinician behavior by addressing hazards through design.

Scan for more on the Klim-Loc needle-free vial container closure system.

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