Patient Safety Alert: Urgent Alert Regarding Medication Vial Coring and Fragmentation Risks

March 30, 2025

Issued by: Anesthesia Patient Safety Foundation (APSF) and ECRI/Institute for Safe Medication Practices (ISMP)

APSF and ECRI/ISMP have received several reports recently of medication vial **coring** incidents. Coring occurs when a piece of the flexible stopper on a medication vial detaches during needle insertion which may lead to contaminating the medication and the risk of injecting stopper fragments into patients. While coring has been shown to occur with any needles used to access a flexible vial stopper, the highest risk seems to be related to using blunt needles.[1] While coring has been known to be a problem for some time, the data supporting best practices for accessing vials is limited.[2,3] Nevertheless, given the recent surge in reports, APSF and ECRI/ISMP believe the potential risk to patients warrants careful consideration of practices for accessing medication to minimize the occurrence of coring.

APSF and ECRI/ISMP are actively working to develop well documented, evidence-based, recommendations. Based upon the data available at this time, these are the interim recommendations.

Interim Practice Recommendations to Minimize the Risk of Coring When using Needles to Access Medication Vials

1. Consult and follow the manufacturer's package insert of the intended product for specific recommendations on accessing the vial. If instructions are not provided, avoid the use of blunt needles. Use sharp needles, ideally with needle guard protection.[1]
2. Smaller gauge needles are preferred. Consider using 21-gauge rather than 18-gauge needles when possible.[2]
3. The angle at which the vial is entered may help to reduce the risk but recommendations for the optimal angle (45-60 degrees) are inconsistent and not supported by objective data.[3,4] When using a sharp needle, an angle that creates the least resistance to puncture seems desirable.
4. Puncture the vial stopper only one time.[2]
5. Inspect the vial for macroscopic coring and if present:
    - Do not administer the medication to the patient if coring is suspected or visible
    - Secure the affected vial and drawn up medication.[1]

    - Contact pharmacy for assistance with reporting and returning affected vials to the manufacturer.
- Report any instances of coring directly to ISMP: https://home.ecri.org/pages/ecri-ismp-error-reporting-system. Useful information to include in the report includes the medication, manufacturer, vial lot number, needle type (sharp or blunt) and gauge used to access the vial. Photos of the visual evidence of coring are also helpful.

While no documented cases of patient harm have been reported to date, APSF and ECRI/ISMP believe there is a potential for significant risk if these fragments are inadvertently injected into patients. These recommendations only apply to the use of needles for accessing medication vials with flexible stoppers. Other transfer devices are available, but there are no data to inform the risk of coring when using these devices. APSF and ECRI/ISMP do not offer any guidance on the use of alternate transfer devices.

These guidelines are intended to be the best practices we can recommend at this time to minimize the risk of coring. More thorough investigation is planned and the results will be published as soon as possible along with any updates to the guidelines.

References:

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2. https://www.westpharma.com/blog/2014/june/causes-of-coring-and-fragmentation-in-the-field
3. American Society of Health-System Pharmacists. Practical Training in Compounding Sterile Preparations Certificate. May 31, 2023. Accessed on March 24, 2025 at https://elearning.ashp.org/products/10734/practical-training-in-compounding-sterile-preparations-certificate
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