A Quality Improvement Project to Improve the Decision Making Process of High-Risk Sterile Compounded Preparations

Lyons D[1], Yoon T[1], Hennessey T[1], Mysak T[1]

[1]Pharmacy Services, Alberta Health Services

Opportunity

- High-risk sterile compounding are compounded medications for individual patients with specialized medical needs.
  - Non-sterile ingredients are used in the preparation, and the final product must be sterilized prior to use.
- Specialized knowledge and skills are required to ensure there is no contamination and the purity and potency are exact.
- There are literature reports of patient harm where proper compounding techniques have not been used and where the clinical evidence is weak.

- Regulatory standards must be complied with by July 1, 2020.

Method

- Team formation to provide oversight of site and program-level efforts
- Pharmacy professionals and managers engaged and educated

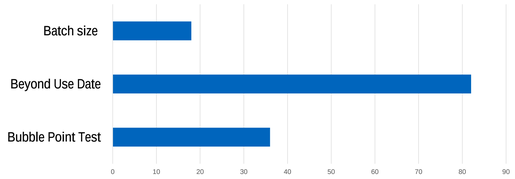
- Phase 1 focused on achieving improvements in rapid sequence to address the highest risks for non-sterility
- Quick wins implemented and previously unknown risks identified

- Phase 2 (ongoing): implementation of principles and standardized processes
- Unnecessary risks eliminated through reduction in the number of high risk compounds prepared

Phase 1

- Sites performing high risk compounding were surveyed to identify where there were gaps between compliance with standards and current practices.

Percentage of Non-Compliance



- A matrix was used to prioritize improvements based on the potential risk level to patients:

Bubble Point Testing – This test confirms the filter sterilized the product.

Beyond Use Dates (BUD) – High-risk preparations have no guarantee of sterility; therefore, BUDs should be as short as possible to reduce the potential for microbial growth.

Batch Size – Make-on demand reduces preparation risk.

Site teams used Plan-Do-Study-Act (PDSA) work packages outlining the steps to compliance and had to address the following questions:

Is the BUD applied correctly?	Are the compounding worksheets reviewed and updated on a regular basis?
Is the compounded preparation process adherent to best possible practice?	Are pharmacists involved in monitoring the patients that have been receiving high-risk preparations?
If sterile filtration occurs, is filter integrity testing being done and documented appropriately?	Are prescribers aware that the preparations in question are high-risk, and do they have the full understanding of what that means?
If heat sterilization occurs, is it by convection oven? Is the equipment used calibrated on a regular basis?	Is the media fill test used specific to high-risk preparations?
Is there an opportunity extend the BUD through sterility testing where batch sizes are greater than 25?	Are compounding personnel certified twice per year? (As opposed to the regular once per year for low and medium-risk compounding).
Is endotoxin testing occurring?	Has container integrity been verified?
Is there an opportunity to consolidate high-risk compounding, such as one site per zone?	Is appropriate PPE used for handling powders?
Is the powder being used pharmacopeia grade?	

Phase 2

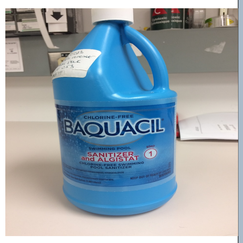
After Phase 1, four further areas for improvement were identified:

Therapeutic Necessity – Evidence exists for the efficacy of the compound, and there is a lack of commercially available therapeutic options.

Master Formula Quality & Standardization – Formulae should include proper referencing as well as standardization of strength prepared, verbiage used, and dosage form application. Quality control testing and verification in place.

Staff Safety & Storage – SDS sheets and PPE followed 100% of the time and hazard labels and storage reviewed for each chemical.

Supplies & Ingredient Quality – Documentation of all materials as being suitable for use (certificate of analysis or calibrated equipment).



Example of ungraded product identified used to prepare a high risk compound.

A provincial working group was tasked to address these areas and a standardized process was developed to include the following steps:

- **Intake process** – defined process to review new compounds
- **Therapeutic evaluation** – is there evidence?
- **Complexity evaluation** – can Pharmacy compound to follow current Standards?
- **Clinical evaluation** – does this compound have sufficient place in patient care?
- **Ethics evaluation** – for situations where the compound may not meet Standard but still fits a defined patient need.

Outcomes

- Risks to patients and staff were reduced by limiting compounds to those where no other product could meet the therapeutic needs of the patient, reducing batch sizes, implementing filter integrity testing, applying appropriate BUD and implementing safe handling procedures.
- 80% compliance with standards was achieved in Phase 1. BUDs were decreased by as much as 6 months.
- Through Phase 2 review of compounded products it is anticipated we will be able to reduce the number of high risk preparations by almost 70%.

Lessons Learned

- Complex changes require careful planning.
- Knowledge translation to front-line clinicians was necessary to facilitate and sustain changes.
- Provincial consistency is achieved with a strong centralized plan that simultaneously provides direction and empowers change to be undertaken at a local level.
- Drug backorder or orphaned drugs can lead to high-risk compounding.
- Disclose the risks to patients.

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Acknowledgements

We would like to acknowledge the following teams who contributed to the success of our efforts:

- Pharmacy Services Technical Practice Team
- Pharmacy Services Leadership Team
- Pharmacy site Aseptic Leads

Contact information

Dana Lyons– dana.lyons@ahs.ca

All Authors declare no conflicts of interest