Achieving Pharmacy Compliance with Regulatory Standards for Medication Sterile Compounding

Ian Creurer, Dana Lyons, Jody Read, Tana Yoon, Jim Wan
Pharmacy Services, Alberta Health Services

Context

Standardization for safety

The first ever national Standards for Sterile Preparations set requirements necessitating re-engineering of long standing practices.

Timelines by the regulatory College mandate these changes within three years.

Scope of change

Sterile compound preparation by Pharmacy Services in Alberta hospitals…
… more than 50 hospital pharmacies in Alberta
… more than 1.5 million doses every year
... prepared in accordance with previously available standards, but new standards introduced hundreds of changes, some small and others very large.

With no precedent for this scale of change and no additional resources available, a systematic and well supported plan is needed.

Reasons for Regulatory standards

- …to keep patients and health care professionals safe
- …because 'sterile compound' medications are necessary and also involve some risk.

What this involves

Compounded medications…
…individual ingredients mixed together in the exact strength and dosage form, to customize a medication to meet the patient's specific needs.

Sterile Compounded Preparations…
…are those medications that must be sterile to avoid introducing infection (examples –those given by injection, into a vein, a muscle, an eye, etc.)
…safe preparation requires specialized training, techniques, equipment, and environments.

Journey

To achieve compliance, required a robust method to:

- Ensure understanding of effort required
- Refocus resources

Multiple approaches have been undertaken together:

Sterile Compounding Framework

Developed to bring together:

- Standards
- Best practices
- Change tools
- Coordination of site-specific plans
- Align plans for critical tasks with timelines.

Gap Analysis + Framework = Action Plan

… for each site
… action plan 'chunks' a complex, multi-faceted issue into manageable pieces of work.

Core Compounding Working Group

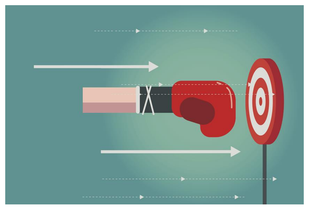
Established, with front line membership from all business units, to support coordinated oversight of both site- and program-level efforts to achieve compliance with standards.

High Risk Procedures – Rapid Improvement Process

…done in addition to the overall 'long game' of the total Framework.

…identified significant gaps in knowledge, requiring a standardized improvement method
…used a Plan-Do-Study-Act (PDSA) cycle and minimum compliance requirements.

Impact



Comprehensiveness

The Framework captures all elements of the standards, aligned with timelines.

Continual Framework updates provide local teams with tools and current information to progress toward compliance.

Accountability

…compliance with sterile compounding standards added to the Pharmacy Services strategic plan

…tracking via a standardized tool, with a Tableau® dashboard to monitor provincial implementation.

High Risk Rapid Improvements

… quickly achieved baseline compliance for high risk preparations in five zones
…developed site-specific action plans for ongoing improvement
… Improvement Team-led projects translated knowledge to the front-line.

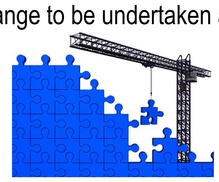
Lessons Learned

Complex issue needs complex plan

Achieving widespread consistency over a large area in a short time requires a strong centralized plan

The plan must simultaneously:

- provide direction, and
- empower change to be undertaken at a local level.



Gaining support and awareness

Requires thorough and timely communication

Purpose:

- Manage constraints
- Achieve clarity
- Obtain support for the challenges

Multiple target audiences:

- Executive level
- Stakeholders such as the regulatory College and Capital Planning programs
- Pharmacy managers and front line staff.

Interpretation and clarity

National standards are carefully written. Despite this, they are not fully self-evident.

Interpretation is required before implementation can occur. This involves internal expertise, as well as dialogue and negotiation with the regulatory College.

Contact information

Ian Creurer
Director, Operational Excellence
Pharmacy Services
Alberta Health Services
ian.creurer@ahs.ca