Integrating Regulatory Requirements in the IP Program

Waleed Javaid, MD, FACP, FIDSA, FSHEA
Associate Professor

Hospital epidemiologist
Director Infection Prevention
Mount Sinai Downtown Network
Mount Sinai Beth Israel
New York Eye and Ear at Mount Sinai
Mount Sinai Union Square
The Blavatnik Family – Chelsea Medical Center at Mount Sinai
Mount Sinai Brooklyn
Objectives

1. IP will be able to implement regulatory requirements
2. IP will be able to provide expected oversight
3. IP Program will be able to measure and sustain success
Process

Who  What  When  Where  Why

How
Everyone

For this conversation we will focus on

• Infection Prevention and collaborators
What Regulatory Requirements

Federal
• CMS / CDC / FDA
  • Joint Commission
  • DNV

State / City DOH

National Standards
• AORN
• ASHRE
• AAMI
• USP
• FGI
• Others
Where

Infection Prevention oversight

Roof top / Basement

OR

ICU

Pharmacy

Patient Care floors

Staff offices

Kitchen
Oversight

Physical Environment

- Isolation
- Operating Rooms
- Pharmacy
- Construction
- Water
- HVAC
Oversight

Processes

• Instrument Reprocessing
• Medication Compounding
• Environmental cleaning
• Hand hygiene
• Personal protective equipment (PPE) use
• Surveillance, HAI prevention
• Injection Safety
• Food Handling
Oversight

Preparedness
- Outbreaks
- Disasters
- Drills
Why

Because it is required
Because it makes patient care safe
Because it makes patients safe
Because it minimizes risk
Because it standardizes care
It takes a Village ..... How
Implementation Science

PUBMED SEARCH ON ARTICLES PUBLISHED ON IMPLEMENTATION SCIENCE

- Implementation with Infection mentioned
- Others
Implementation

• Top arrow points from pre-implementation to process of implementation.
• Overlapping circles show process of implementation, and depict circular relationships between strategies, evaluations and factors.
• They surround concentric circles labeled context domains, and a box labeled innovations.
• Arrows show all components work together to comprise the process of implementation.
• Final arrow point left to post-implementation.
Implementation

- Top intervention box includes organizational (leaders, managers, staff) and patient perspective.
- Intervention flows into and out of recipients box, which contains organizational (leaders, managers, staff) and patient characteristics.
- Recipients affected by implementation and sustainability structure, and external environment, which impact and are affected by the recipients.
- Below, adoption, implementation, and maintenance flow out of relationships between recipients, implementation and sustainability infrastructure, and external environment; and interact with reach and effectiveness.

Strategy for translating evidence into practice.

1. Summarise the evidence
   - Identify interventions associated with improved outcomes
   - Select interventions with the largest benefit and lowest barriers to use
   - Convert interventions to behaviours

2. Identify local barriers to implementation
   - Observe staff performing the interventions
   - “Walk the process” to identify defects in each step of implementation
   - Enlist all stakeholders to share concerns and identify potential gains and losses associated with implementation

3. Measure performance
   - Select measures (process or outcome)
   - Develop and pilot test measures
   - Measure baseline performance

4. Ensure all patients receive the interventions
   - Implement the “four Es” targeting key stakeholders from front line staff to executives
   - Engage
     - Explain why the interventions are important
   - Evaluate
     - Regularly assess for performance measures and unintended consequences
   - Execute
     - Design an intervention “toolkit” targeted at barriers, standardisation, independent checks, reminders, and learning from mistakes
   - Educate
     - Share the evidence supporting the interventions

Overall concepts
- Envision the problem within the larger healthcare system
- Engage collaborative multidisciplinary teams centrally (stages 1-3) and locally (stage 4)

Peter J Pronovost et al. BMJ 2008;337:bmj.a1714
Recognize an opportunity and plan a change.

Test the change. Carry out a small-scale study.

Review the test, analyze the results, and identify what you’ve learned.

Take action based on what you learned in the study step.
If the change did not work, go through the cycle again with a different plan.
If you were successful, incorporate what you learned from the test into wider changes.
Use what you learned to plan new improvements, beginning the cycle again.
Implementation Process

Planning
- Conducting a needs assessment

Educating
- Hosting educational sessions

Financing
- Offering incentives

Restructuring
- Revising professional roles

Managing quality
- Audit and feedback

Attending to policy context
- Changing licensure requirements

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from:

- Microbial contamination (nonsterility)
- Excessive bacterial endotoxins
- Variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see “official” and “article” in the General Notices and Requirements) or 10% for nonofficial articles,
- Unintended chemical and physical contaminants
- Ingredients of inappropriate quality in compounded sterile preparations (CSPs)
Planning

What is the Standard
• Joint commission
• Pharmacy

Who is involved in implementation
• Joint commission
• Pharmacy

Who is providing oversight
• Infection prevention
• Internal team
Education and Learning

Know
- Understanding standard requirements pertaining to Infection prevention

Disinfection
- Which surfaces and with what

Cultures
- When, what and how often

Cleaning
- With what standards and how often
Financing

Report:ing
• Process may already be in place but not reported out

Implementation
• If no process in place, it is critical to implement to sustain pharmacy practice

FTE requirements
• If pharmacy program is extensive, may require additional IP FTE % allocation
Restructuring

Need for improvement

• Working with pharmacy leadership to find areas including:
  • Cleaning / Disinfection
  • Culturing
  • Recordkeeping

Need for reporting

• Having ASP pharmacist report 797 standard compliance during ICC
Managing Quality

Audit

• Regular review of pharmacy processes
  • Cleaning
  • Competency
  • Culture results

Feedback

• During rounds
• During ICC
• During Pharmacy meetings
Attending to policy context

Changing licensure requirements
- Other Pharmacy standards (chapters including 800, 795 etc)

Joint commission
- In 2018, The Joint Commission enhanced its process for evaluating sterile compounding
Sustainability

- Training and Competency
- Checklists
- IP skill enhancement
- Rounding
- Reporting
Training and Competency

How are the staff trained
- Educators or Certifications

How often are they retrained
- Yearly, Quarterly or never?

What signifies competency
- Once and done, or have to perform 3 times?

Who ensures competency
- Nursing Education? Managers? Infection Prevention
Checklists

Tool
• Helpful to ensure standard review occurs every time

Scalability
• Can be implemented at unit level, department level or during IP review

Status
• Need to make sure checklists are relevant and up-to-date
Infection prevention staff knowledge regarding standards

Any additional training required?

Are they able to understand, review, overview, educate as needed?
Rounding and Reporting

**Regularity**
- IP should develop a regular rounding schedule to review the physical environment.

**Reports**
- Reporting strategy for pharmacy compliance to 797 standards.
  - The pharmacy can report out during the infection control committee meeting to share compliance and culture results.

**Urgency**
- An urgent Infection prevention report and consult is required if there is any breach in compliance or positive cultures.
To Recap

**Oversight**
- Important and expected

**Implementation strategy**
- Needs to be simple and effective

**Sustainability**
- Needs to be planned from the beginning
Questions?