Lapsing into Consciousness: Learning From IPAC lapses

Presentation to IPAC - SWO
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Objectives

• A brief overview of PHO’s role in IPAC Lapses
• To discuss the collaboration and partnership between Public Health Ontario (PHO) and the local public health unit (PHU)
• Work through an IPAC lapse
• Share and review PHO resources
Anatomy of a Complaint Investigation

- Local Public Health Unit
- MOHITC
- PHU investigation
- Advice, tools and resources
- Partner involvement for advice and for action
- CPSO
- CNO
- OCP

Partners

- Public Health Ontario (PHO)
- Local Public Health Units (PHU)
- Ministry of Health and Long-Term Care (MOHLTC)
- Regulatory colleges

PIDAC Best Practice Documents
Expert Guidance Provided

- General IPAC practices
- Cleaning, disinfection and sterilization of medical equipment and devices
- Safe medication administration
- Environmental cleaning

Working with the PHU

PHO supports the PHU with:

- IPAC Risk Assessment
  - Review information and analyze audit results
  - Qualitative/quantitative risk assessment helps inform the local MOH’s decision for patient look-back
  - Determine the risk of exposure to blood-borne pathogens
  - Identify issues with improper reprocessing of medical equipment/devices or improper medication administration practices
  - Complete literature search
  - Access to IPAC Resources – checklists and IPAC training
  - Access to laboratory/epidemiology support

Risk Assessment

Takes into consideration:

- The nature of the IPAC lapse
- The setting
- The potential for BBI transmission – type of body fluid and type of exposure
- In some cases, the local epidemiology of BBI in the region
- The disease prevalence of BBI in the population potentially exposed to the poor practice
Risk Assessment

Consider the persistence of these BBIs in the environment:

- HBV in dried blood on environmental surface at room temp – up to 7 days
- HCV under similar conditions - 16 hours to 4 days
- In contrast, HIV does not persist in the environment, though it has been noted in lab conditions to persist for up to 7 days +

CDC cautions against using the results from laboratory studies for individual risk assessment

LLDs and HLDs can kill enveloped viruses (HIV, HCV, HBV)

Let’s look at some IPAC Lapses

Cleaning, Disinfection and Sterilization Lapse #1

- Physician using improperly reprocessed critical instruments to perform minor procedures such as removal of cutaneous warts, skin tags and sutures
  - No pre-clean or cleaning of instruments
  - Instruments being placed directly in enzymatic cleaner
  - Soaked for an undetermined period of time (may be up to one week)
  - Instruments removed from solution when needed, rinsed and pat dry
- Not compliant with established CSR practices
- Improper reprocessing practice stopped
- Follow-up inspection completed by the PHU
Lapse #1 (cont...)

Issues:
- Minor procedures were considered high risk (excessive bleeding)
- Instruments classified as critical requiring sterilization
- No pre-cleaning done and cleaning was questionable
  - No monitoring of enzymatic soaking solution
- Increased risk of exposure to blood-borne pathogens
- Carrying out these procedures for decades
- Large caseload and difficult to track patients having had a high risk procedure done
- Literature search did not reveal any relevant information

Lapse #1 - Decision

- Physician's practice could have resulted in the risk of transmission of BBP (HBV, HCV & HIV)
- Those patients verified as having one or more of the minor procedures of concern to be notified and offered testing for HBV, HCV & HIV

Lapse #1 - Outcome

- 580 patients were sent letters with testing recommendations
  - 150 patients initially identified but because record keeping was an issue, PHU went public
    - Revealed additional patients
    - Practice then came forward with additional 400 patients
  - As of mid-February 2016, 360 tested but additional results trickle in (2-3 per week)
- BBP identified but not definitively attributable to the practice:
  - 1 HIV; 2 HBV; 4 HCV
Cleaning, Disinfection and Sterilization Lapse #2

- Improper use of single patient-use glucometers and lancing device holders during blood-glucose monitoring on multiple patients at walk-in clinics.
- Non-disposable, pen-like lancing devices that holds the lancet that may become contaminated with blood.
- Reprocessing (cleaning and disinfection) of these devices between each patient use was not done.
- Involved multiple walk-in clinics in multiple jurisdictions (within and beyond Ontario).
- MOHLTC was involved.

Lapse #2 (cont...)

- Issues:
  - Use of these lancing devices by multiple persons could potentially result in exposures to blood borne infections (i.e., hepatitis B, hepatitis C and HIV).
  - Hepatitis B transmission has been epidemiologically linked to the shared use of lancing devices intended for single patient-use in multiple instances in the US and the UK long-term care facility settings.
  - In addition, an increased risk of hepatitis C transmission has been associated with shared lancing device use for blood glucose monitoring in a hospital setting.

Lapse #2 - Decision

- Taking the observations and risk estimates into account, it was the unanimous consensus of PHO that the risk of transmission of blood borne viruses was extremely low.
- We recommended that those patients verified as having received glucose monitoring using single patient-use glucometers and lancing device holders be notified of these exposures.
- Affected patients were encouraged to discuss the situation with their primary care provider and, if concerned, could be considered for HBV, HCV and HIV testing.
Medication Administration
Lapse #3

• Previous poor practice stopped
• Clinic considering pre-loading 7 equal doses of reconstituted medication.
• Clinic would draw from original vial and inject into a sterile vial to be given to the client for home use.
• Instructions would be given to the patient on how to draw up a dose in an insulin syringe for injection.
• The withdrawal of the drug and placement into a sterile vial was performed using aseptic technique on a clean surface in a medication preparation area in the office.

Lapse #3 (cont...)

Issues

• Once any drug is reconstituted according to manufacturer’s instructions, any further reconstitution or dilution of a conventionally manufactured sterile product is considered compounding.
• Repackaging of a conventionally manufactured sterile product from its original primary container into another primary container must be performed in accordance with USP 797 standards for CSPs, including preparation in an ISO 5 environment.

Lapse #3 - Decision

• Clinic was advised that:
  • This proposed practice is not recommended
  • Medication was to be prepared at a compounding pharmacy and handled accordingly
  • No patient notification was required due to previous practice
PHO Resources - Checklists

- Three checklists available on PHO website:
  - Core
  - Reprocessing of medical equipment/devices
  - Endoscopy

- Based on IPAC best practices (Provincial Infectious Diseases Advisory Committee (PIDAC) and Canadian Standards Association (CSA) documents)

- Useful audit tools

PHO Resources – Online Training Programs

Reprocessing in Community Health Care Settings
Summary

- Each IPAC lapse has unique characteristics and must be handled on a case-by-case basis
- Importance of open communication with the local PHU is key
- A standardized approach and the use of tools and resources is important
References


• Rutala W and Weber D. How to assess risk of disease transmission to patients with there is a failure to follow recommended disinfection and sterilization guidelines. Infect Control Hosp Epidemiol 2007; 28: 146-155