Pocket PEP: Development of a clinical tool to promote best practice

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Disclosures

• Abbott Virology
Introduction

- St. Michael’s Hospital
  - tertiary care centre
  - policy to minimize transmission of blood borne pathogens after a potential exposure

- Complete assessment of exposure risk required for appropriate management
  - Type of injury/exposure
  - Body fluid
  - Inoculum size
  - characteristics of the source person

- Published Guidelines available

- No published protocol found containing both management of occupational and non-occupational exposures for distribution in Ontario
  - What to evaluate, what tests to order, what medications should be given
Objectives

• To review and update the post-exposure prophylaxis (PEP) protocol at SMH to align with current guidelines and best practices

• To create a convenient pocket reference for clinicians to assist with managing both occupational or non-occupational exposures to hepatitis B, hepatitis C and/or HIV

• To promote safe and appropriate prescribing of PEP medications
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Methods

• Literature retrieval through Cochrane Library and PubMed
  • “Post-exposure prophylaxis”, “human immunodeficiency virus”, “hepatitis C virus” and “hepatitis B virus”

• Local and international guidelines were reviewed

• Internet search for pocket guides or quick references
Results

- Developed an evidence-based protocol for “The clinical management of non-occupational and occupational exposures to hepatitis B, hepatitis C, and/or HIV at St. Michael’s Hospital”

- A pocket reference, “Pocket PEP” was created from the protocol to provide users with a convenient tool for use in clinical practice

- The pocket reference has been distributed to key stakeholders at St. Michael’s hospital including staff in the Emergency Department, Corporate Health and Safety Services (“Employee Health Unit”), primary care physicians, and medical house staff
5 step process

1. Treat exposure site & report for assessment
2. Assess the exposure risk
3. Assess the source & perform baseline Testing
4. PEP Management
   a. HBV
   b. HCV
   c. HIV
5. Follow-up
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**STEP 1**
TREAT EXPOSURE SITE & REPORT FOR ASSESSMENT

An individual who experiences an occupational or non-occupational exposure to blood borne pathogens needs to have immediate first aid treatment for any wound and a risk assessment for the likelihood of transmission of a pathogen.

**SMH staff with occupational exposures should immediately:**
- Remove any contaminated clothing
- Allow wound to bleed freely
- Wash the area thoroughly with soap and water
- If exposed area involves the eyes, nose or mouth, thoroughly flush well with water
- Report the incident to his/her immediate supervisor and complete the Blood Borne Pathogen Exposure Report. If the source patient is known, it is important to record the source patient’s full name and hospital number in the exposure report.
- Proceed immediately for risk assessment:
  - During Business Hours (Monday to Friday, 0700-1600h)
  - Corporate Health and Safety Services (O Shuter, Ext 5013)
  - After hours, weekends, holidays:
    - Emergency Department

**STEP 2**
ASSESS THE EXPOSURE RISK

Many factors contribute to a significant exposure and a higher risk of transmission of a blood borne pathogen, including the type of body fluid involved, the type of injury that occurred, the size of the inoculum, and the attributes of the source patient. All of the following information should be obtained and recorded.

a. **Body fluids**: Body fluids considered potentially infectious include:
   - blood
   - vaginal secretions
   - pleural fluid
   - amniotic fluid
   - plasma
   - cerebrospinal fluid
   - peritoneal fluid
   - semen
   - synovial fluid
   - pericardial fluid

   Body fluids NOT considered potentially infectious unless visibly bloody include:
   (However: HBsAg is found in feces, nasopharyngeal washings, saliva and sweat)
   - Feces
   - sputum
   - urine
   - nasal secretions
   - sweat
   - saliva
   - tears
   - vomitus

b. **Type of Injury/Exposure**
   - cutaneous - skin puncture or laceration by needle or sharp object
   - mucosal - splash to mucous membranes (eg. eyes, nose, mouth)
   - cutaneous - contact through nonintact skin (eg. cuts, dermatitis)

   c. **Inoculum size**
   - volume of infectious fluid involved (eg. hollow bore vs. solid needle; large volume vs small volume splash)
   - viral titre in the infectious fluid if known (eg. well controlled disease vs. poorly controlled)

   d. **Source patient**
   - unknown HBV, HCV or HIV status
   - positive for HBV, HCV, and/or HIV
   - negative with risk factors (eg. men who have sex with men, multiple sexual partners, injection drug use, tattoo/body piercing, recipient of blood transfusion before 1986 for HIV or 1990 for HCV in Canada)
   - negative with no risk factors

**Estimated risk of transmission:**

Following percutaneous exposure to blood or potentially infectious fluid:
- hepatitis B: 6-30%
- hepatitis C: 3-10%
- HIV: 0.3% (0.09% for mucous membrane exposure)

**Estimated Per-Act Risk for Acquisition of HIV**

<table>
<thead>
<tr>
<th>Exposure route</th>
<th>Risk per 10,000 exposures to an infected source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion</td>
<td>9,000 (90%)</td>
</tr>
<tr>
<td>Needle-sharing injection-drug use</td>
<td>67 (0.67%)</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>50 (0.5%)</td>
</tr>
<tr>
<td>Percutaneous needle stick</td>
<td>330 (0.3%)</td>
</tr>
<tr>
<td>Receptive penile-vaginal intercourse</td>
<td>10 (0.1%)</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>6.5 (0.065%)</td>
</tr>
<tr>
<td>Insertive penile-vaginal intercourse</td>
<td>5 (0.05%)</td>
</tr>
<tr>
<td>Receptive oral intercourse</td>
<td>1 (0.01%)</td>
</tr>
<tr>
<td>Insertive oral intercourse</td>
<td>0.5 (0.005%)</td>
</tr>
</tbody>
</table>

Algorthim for Presentation Following Exposure to a Blood Borne Pathogen

**SMH staff OCCUPATIONAL EXPOSURE**
- CHSS (Monday-Friday, 0700-1600h)
- Emergency Dept (after hours, weekends, holidays)

**Non-SMH staff OCCUPATIONAL OR NON- OCCUPATIONAL**
- Emergency Department

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STEP 4c  PEP MANAGEMENT - HIV EXPOSURE

Management of a potential HIV exposure is dependent on the nature and risk of the exposure. PEP is not needed for exposure to stool, urine, tears, saliva, nasal secretions, vomitus, or blood. PEP may be needed (depending on type of exposure) if the source material is:
- blood, bloody fluid, semen or vaginal secretions,
- cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids
- tissue
- an instrument contaminated with one of the above substances

Management of HIV Exposure Based on Occupational Exposure and Source

<table>
<thead>
<tr>
<th>TYPE OF EXPOSURE</th>
<th>SOURCE INDIVIDUAL</th>
<th>HIV Posture</th>
<th>HIV Status Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>negligible exposure (e.g., accidental HIV infection in needlestick injuries, etc.)</td>
<td>PEP is not needed</td>
<td>PEP is not needed</td>
<td>PEP is not needed</td>
</tr>
<tr>
<td>substantial exposure (e.g., contact with blood or other body fluid of an infected person)</td>
<td>PEP is needed</td>
<td>PEP is needed</td>
<td>PEP is needed</td>
</tr>
</tbody>
</table>

HIV Post Exposure Prophylaxis (PEP) Regimens

PEP is a combination of antiretroviral drugs that are given to people who have been exposed to HIV. The regimen may vary depending on the type of exposure.

Management of HIV Exposure Based on Non-Occupational Exposure and Source

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>HIV POSITIVE</th>
<th>HIV Status Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible Exposure</td>
<td>No PEP</td>
<td>No PEP</td>
</tr>
<tr>
<td>Substantial Exposure</td>
<td>Case-by-case determination</td>
<td>Case-by-case determination</td>
</tr>
</tbody>
</table>

Contraindications

- Patients with severe renal insufficiency (creatinine clearance <30mL/min, including patients requiring hemodialysis)
- Patients with renal insufficiency (dose adjustment required)

Truvada

- Emtricitabine and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion. Since emtricitabine and tenofovir are primarily eliminated by the kidneys, coadministration of Truvada with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of emtricitabine, tenofovir, and/or other renally eliminated drugs.

Cautions, Contraindications and Drug Interactions with Truvada

- Contraindicated
  - Use with Caution
    - Patients with severe renal insufficiency
    - Patients with renal insufficiency (dose adjustment required)

Kalera

- Kalera is a substrate and potent inhibitor of the P450 isomorph CYP3A4. Caution should be used when co-administering Kalera and CYP3A4 enzyme inducers, inhibitors, or substrates with narrow therapeutic indices. If uncertain, please contact an ID/HP specialist or pharmacist. The chart below lists some of the major drug interactions identified; other drug interactions may exist.

Cautions, Contraindications and Drug Interactions with Kalera

- Contraindicated
  - Use with Caution
    - Patients with severe hepatic impairment

St. Michael's

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Next Steps…

- share this tool with key partners external to St. Michael’s hospital to promote appropriate management of potential exposures

- obtain feedback from users of “Pocket PEP” to improve usability

- evaluate the impact of this tool on the appropriate management of potential exposures including the appropriate prescribing of PEP medications
Acknowledgements

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