Needlestick Injury and Blood/Bodily Fluid Exposure Policy Statement and HIV PEP Kit Dispensing Guideline

Providing certain services in a pharmacy, especially injections, carries a risk for the pharmacist and pharmacy personnel of being exposed to the blood and bodily fluids of patients, particularly via needlestick injury. Exposure to the blood/bodily fluids of another person can result in the transmission of diseases like HIV, hepatitis B and hepatitis C. This policy is designed to be an overview of what to do in the event of an exposure incident or needlestick injury and was developed using the "Guidelines for the Management of Exposures to Blood and Bodily Fluids[1]" (October, 2013) by the Government of Saskatchewan. For more detailed information on the risks associated with exposure to blood/bodily fluids as well as needlestick injuries and procedures for handling them, please review **Appendix 1 and 2 of this document.**

Pharmacists and pharmacy personnel responsible for handling blood/bodily fluids or providing injections should be vaccinated for hepatitis B. Post-immunization titre testing is recommended for anyone who receives the hepatitis B vaccine. There is no vaccine for HIV or hepatitis C.

Immediate Management of a Needlestick Injury:

Allow the wound to bleed freely, "milking" the wound if possible;

- Wash the wound liberally with soap & water;
- Cover wounded area with bandaging; and
- Immediately report to a hospital or emergency health care facility HIV PEP kit provider. **This step should be taken within 2 hours OR as soon as possible.**

  PEP kit sites: https://www.ehealthsask.ca/services/manuals/Documents/hiv-guidelines-appendix2.pdf.

Prevention of an Exposure Incident/Needlestick Injury

Most exposure incidents and needlestick injuries can be prevented by taking the appropriate precautions. Where there is even a small risk of an exposure incident or needlestick injury, it is advisable to take the following precautions:

1. In the event that an exposure incident or needlestick injury occurs the source patient's information will need to be shared with health care providers. It is recommended to receive consent to share the patient's contact information as well as pertinent health and vaccine status with health care providers before an injection is administered or an exposure incident occurs.

[1] http://www.ehealthsask.ca/services/manuals/Documents/hiv-provider-guidelines.pdf

a) Note: a patient may not provide consent to share his/her information. Consent must "verbal, informed, voluntary, and documented.[2]"

2. Wash hands for 15 – 30 seconds using sufficient soap to lather on all surfaces of the hands and fingers. Rinse with running water.

3. Ensure you have adequate lighting and an adequate surface upon which to place needles, sharps, or other contaminated items.

4. Do not carry uncapped needles or sharps from one area to another. Have everything you will need to perform injections within arm's reach.

5. Assess the patient's readiness and ability to cooperate to allow the injection. Request that the patient remain calm and avoid sudden movements. Request assistance if necessary.

6. Uncap the needle only immediately prior to administering the injection.

7. Ensure others working in the area are aware when you are working with an uncapped needle or a sharp.

8. Avoid re-capping a used needle. Simply dispose of the whole needle and syringe in a designated sharps container. Never dispose of a needle or sharp in an undesignated container such as a trash can.

9. Dispose of any items that have been contaminated with blood or bodily fluid in an impervious receptacle that can be sealed and follow the guidelines as outlined in the "Saskatchewan Biomedical Waste Management Guidelines," February 2008:

    a) "Segregated solids **that are saturated and dripping with human blood or body fluids** must be labelled as hazardous. They can be incinerated, or they can undergo biomedical waste treatment followed by disposal at a waste disposal ground…Solid items that are saturated or dripping with blood (e.g. surgical drapes, surgical gowns, sponges, closed drainage tubes and dressings, etc.) should be packaged within yellow containers or plastic bags, which are sturdy enough to withstand the transportation processes." [3]

    b) "Items that have had contact with blood, exudates or secretions, **but are <u>not</u> saturated or dripping with blood**, do not require segregation, labelling or special transport and disposal procedures. The following items fall into this category (i.e. not considered biomedical waste) if they are dry: soiled dressings,

[2] "Appendix 16: Consent for Source Patient Testing Following a Blood/Bodily Fluid Exposure", pp. 110-111; Government of Saskatchewan – Ministry of Health: "Guidelines for the Management of Exposures to Blood and Body Fluids," October, 2013.
[3] Government of Saskatchewan, "Saskatchewan Biomedical Waste Management Guidelines," February 2008, p. 17.

sponges, surgery drapes, lavage tubes, casts, catheters, disposable pads, disposable gloves, specimen containers, lab coats and aprons."[4]

10. Seal and dispose of sharps containers when they are no more than ¾ full. Sealed sharps containers should be disposed of in a designated receptacle.

11. When required to re-cap a needle or remove a needle from a syringe, use the following techniques:

    a) One-Handed Needle Recapping Method[5]:

        i. Step 1: Place the cap on a flat surface like the table or counter with something firm to "push" the needle cap against

        ii. Step 2: Holding the syringe with the needle attached in one hand, slip the needle into the cap without using the other hand

        iii. Step 3: Push the capped needle against a firm object to "seat" the cap onto the needle firmly using only one hand.

    b) Use specifically designed needle clippers to clip the needle off the syringe safely.

12. Do not lose sight of an uncapped needle or sharp (i.e. place it under gauze or other objects).

13. Do not pass an uncapped needle or sharp to another person by hand – utilize a pre-determined location/tray in which the other person may collect it.

14. Ensure your needles, sharps or other contaminated items are accounted for and disposed of appropriately before leaving the area.

If an Exposure Incident Occurs

1. If exposure is:

    a. via the skin (broken or otherwise), wash liberally with soap and water;

    b. via the eyes, irrigate with sterile saline or eye wash;

    c. via the mouth, rinse out thoroughly with water and DO NOT BRUSH TEETH;

2. Report the incident to the Pharmacy Manager or immediate supervisor;

3. Cover a wounded area with bandaging;

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[4] Government of Saskatchewan, "Saskatchewan Biomedical Waste Management Guidelines," February 2008, p. 18.
[5] US Food and Drug Administration: "What to Do if You Can't Find a Sharps Disposal Container", 01/27/2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm263259.htm

4. Immediately report to a hospital or emergency health care facility. *This step should be taken within 2 hours OR as soon as possible* of exposure to the blood or bodily fluids of another person;

5. Report the source patient's contact information, vaccination status, and other pertinent health information to health care providers. This should be collected prior to administering an injection. If it was not collected prior to the injection then it is recommended that the Pharmacy Manager or another pharmacist who is not the recipient of the injury be the one to collect it.

6. Receive testing for HIV, hepatitis B and hepatitis C;

7. Health care providers will determine if the use of an HIV PEP kit is necessary;

    a. Post-exposure prophylaxis (PEP) is short-term antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure, either occupationally or through sexual intercourse.

8. An Exposure Incident Report Form[6] should be completed by the healthcare provider;

9. Report the injury to the Saskatchewan Workers Compensation Board;

10. Receive follow-up testing, counseling, and monitoring.

If a Needlestick Injury Occurs

1. Allow the wound to bleed freely, "milking" the wound if possible;

2. Wash the wound and the surrounding area liberally (but do not scrub) with soap under running water;

3. Report the incident to the Pharmacy Manager or immediate supervisor;

4. Cover the wounded area with bandaging;

5. Immediately report to a hospital or emergency health care facility. *This step should be taken within 2 hours OR as soon as possible (depending upon location)* of exposure to the blood or bodily fluids of another person;

6. Report the source patient's contact information, vaccination status, and other pertinent health information to health care providers. This should be collected prior to administering an injection. If it was not collected prior to the injection then it is recommended that the Pharmacy Manager or another pharmacist who is not the recipient of the injury be the one to collect it;

7. Receive testing for HIV, hepatitis B and hepatitis C;

[6] "Appendix 3: Exposure Incident Report Form", p. 71; Government of Saskatchewan – Ministry of Health: "Guidelines for the Management of Exposures to Blood and Body Fluids," October, 2013.

8. Health care providers will determine if the use of an HIV PEP kit is necessary;

    a. Post-exposure prophylaxis (PEP) is short-term antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure, either occupationally or through sexual intercourse.

9. An Exposure Incident Report Form should be completed by the healthcare provider;

10. Report the injury to the Saskatchewan Workers Compensation Board;

11. Receive follow-up testing, counseling, and monitoring.

HIV PEP Kit Dispensing Guideline

The human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) starter kits are provided by the Saskatchewan Ministry of Health. HIV PEP starter kits are located in a variety of health care facilities throughout Saskatchewan (see Appendix 2, pp. 60-69 of the "Guidelines for the Management of Exposures…" document).

If HIV PEP is indicated, it is recommended the antiretroviral therapy (ART) medications be initiated as soon as possible.

Before dispensing the HIV PEP Kit, the current list of medications the exposed person is on must be reviewed to determine if there are any contraindications. It is ideal to view the prescription history in the Saskatchewan Drug Plan's electronic Pharmaceutical Information Program (PIP).

The HIV PEP Kit includes 3 days of medication[7]. These starter kits contain Kaletra® and Combivir®. The Pharmacist doing the initial assessment is required to have a timely phone consultation (within 24 hours) with an ID Specialist so authorization for ongoing HIV PEP can occur. If the initial or ongoing risk assessment indicates that HIV PEP should be continued, the full treatment period is 28 days.

Initiation of all medications in the HIV PEP 'starter kit' should not be delayed:*

1. HIV PEP should start as soon as possible, preferably within 2 hours of the exposure and is unlikely to be of benefit if more than 72 hours post-exposure.
2. Adherence to HIV PEP medications is critical for prevention of infection.

An HIV PEP 'starter kit' contains the following medications:

1. Kaletra® (lopinavir/ritonavir, LPV/RTV) supplied as:
    a. tablets – lopinavir 200mg/ritonavir 50 mg or lopinavir 100mg/ritonavir 25mg
    b. oral solution – lopinavir 80mg/ritonavir 20mg per ml (contains 42.4% alcohol)
2. Combivir® (zidovudine/lamivudine) supplied as:
    a. tablets – zidovudine 300mg/lamivudine 150mg
    b. dosing of individual components of Combivir®:

[7] PEP Kits located in sites north of Prince Albert contains 5 days of medications.

i. zidovudine (ZDV AZT) – Retrovir® as capsules 100mg or oral solution 10mg/ml (240ml) plus;
ii. lamivudine – 3TC® supplied as tablets 150 mg or 300 mg or oral solution 10mg/ml (240ml)

HIV PEP Kit Provider Sites
http://www.ehealthsask.ca/services/manuals/Documents/hiv-guidelines-appendix2.pdf

Reporting Requirements

Once the injury has been attended to by health care professionals the injury will need to be reported to several different agencies/individuals. See the following in the "Guidelines for the Management of Exposures…" document:

1. Reporting Requirements (Appendix 12, p. 104).

2. Ensure the Exposure Incident Report Form is completed and submitted to the Regional Public Health Office (the MHO or Communicable Disease Coordinator) who will submit necessary reporting elements to the Ministry (Appendix 3, pp. 71-75).

3. The HIV PEP Kit Replacement Form must be completed and Page 1 must be sent to Ministry of Health. Page 2 must be sent to Royal University Hospital (RUH) Pharmacy to have another kit dispensed to the HIV PEP Kit location (Appendix 4, pp. 77-78).

4. In occupational exposure, Saskatchewan Workers Compensation Board forms that must be completed include:

   a) the Worker's Initial Report of Injury (W1)
   https://myaccount.wcbsask.com/WCBPortalPage/page_forms_file_a_w1.html

   b) the Employer's Initial Report of Injury (E1)
   http://www.wcbsask.com/wp-content/uploads/2013/11/E1-EmpFrm.pdf

   c) the physician's report to WCB

5. In occupational exposure, employees should follow their employing agencies incident reporting protocols.

The ongoing HIV PEP medications will be provided free of charge[8]:

1. Saskatchewan Drug Plan: The Saskatchewan Drug Plan authorizes Exception Drug Status (EDS) for the client when the physician or pharmacist requests it. The pharmacist needs to know the EDS criteria requested is 'HIV PEP' and the name of the ID Specialist authorizing ongoing HIV PEP to inform the Drug Plan.

[8] "Antiretroviral Therapy (ART) for HIV Post-Exposure Prophylaxis (HIV PEP)", pp. 21-23; Government of Saskatchewan – Ministry of Health: "Guidelines for the Management of Exposures to Blood and Body Fluids," October, 2013.

2. Non-Insured Health Benefits (NIHB) recipients. If prior approval is required, the pharmacist will call the Drug Exception Centre at 1-800-580-0950 to initiate the exception process. The prescriber will be faxed a form to complete so a decision can be made.

3. Workers' Compensation Board (WCB): In the instance of occupational exposures where WCB provides coverage, the usual WCB process should be followed. If the claim is not yet set up through WCB, options for payment include:

    a. The employer may pay for the prescription and submit the bill to WCB for coverage once the claim is set up.

    b. The employee can pay for the prescription and submit the bill to WCB for coverage once the claim is set up.

    c. The employee can request the prescription be filled for one week at a time to reduce upfront costs and to allow time for WCB to set the claim up.

4. Should WCB deny coverage, but the ID Specialist determines the exposure requires HIV PEP, the medications would be covered by the Ministry of Health. To facilitate coverage:

    a. The Saskatchewan Drug Plan will approve the EDS for the HIV PEP medications.

    b. The pharmacy will submit a manual pharmacy claim to the Drug Plan for the medications if there is a patient co-pay portion.

    c. The Drug Plan will pay the pharmacy for the full cost of the prescription.

Potential Adverse Effects of One Month of Antiretroviral Therapy

The following provides a rough estimate of frequency of adverse effects to assist discussion between the physician and the exposed person in deciding about use of HIV PEP.

1. Minor Reactions – nausea, fatigue, etc. (70% of patients).

2. Serious Reactions – are rare. Due to the frequency of minor reactions, individuals may be unable to work for the month of therapy (30 – 60% of patients); however, this risk is probably lower with the newer regimens.

3. Long Term Effects – are poorly defined: ≈1:5,000.

4. Risk of Death – is unknown, but estimated to be 1:15,000 to 1:150,000 (BC Centre for Excellence in HIV/AIDS, 2009).

Special Considerations

PREGNANT/BREASTFEEDING CLIENTS

The antiretroviral medications contained in the provincial HIV PEP kit are 1st line choices for treating pregnant HIV patients and as such may be used if HIV prophylaxis required. **Do not**

deny HIV PEP solely on the basis of pregnancy. As with all HIV exposures where HIV PEP is initiated, expert consultation with an ID Specialist should be sought as soon as possible. HIV PEP is indicated at any time during pregnancy when a significant exposure to HIV has occurred. Before administering to a pregnant woman, the clinician should discuss the potential benefits and risks to her and the fetus. It should be noted there has been no evidence of human teratogenicity for Combivir®or Kaletra® (i.e. well-tolerated, short-term safety demonstrated in Phase I/II studies; both rated FDA pregnancy category C [Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission, 2011]).

Avoid breastfeeding while on HIV PEP and for 3 months after the exposure or once HIV transmission has been ruled out. The risk of breastfeeding is related to the risk of transmission of the virus through the breastmilk, not because of risks from the medications.

CHILDREN

The antiretroviral medications contained in the provincial HIV PEP kit are also 1st line choices for treating HIV positive children, though oral solution formulations should be obtained as soon as possible to ensure optimal doses of each agent and avoid the need to split tablets. Additional considerations include individuals with renal insufficiency and those on other medications. Significant drug interactions and dosing adjustments are highlighted in Appendix 5 – Antiretrovirals in HIV PEP Kits.

References

1. American Nurses Association “7 Things to do in Response to Needlestick Injury”, 2010; http://www.nursingworld.org/DocumentVault/OccupationalEnvironment/Needles/7-Responses.pdf, retrieved June 11, 2015.
2. American Nurses Association “Preventing Needlestick Injuries Healthcare Workers Checklist,” 2010; http://www.nursingworld.org/DocumentVault/OccupationalEnvironment/Needles/Checklist.pdf, retrieved June 11, 2015.
3. College of Pharmacists of Manitoba: “Needlestick Injury Guidelines”, June 30, 2015; http://mpha.in1touch.org/uploaded/web/Guidelines/Needle%20Stick%20Guidelines%20%28June%202015%29%20FINAL.pdf, retrieved July 8, 2015.
4. Government of Saskatchewan: “Saskatchewan Biomedical Waste Management Guidelines,” February 2008; http://www.environment.gov.sk.ca/adx/aspx/adxGetMedia.aspx?DocID=217,216,104,81,1,Documents&MediaID=1099&Filename=Biomedical+Waste+Management.pdf, retrieved July 22, 2015.
5. Government of Saskatchewan – Ministry of Health: “Guidelines for the Management of Exposures to Blood and Body Fluids,” October, 2013; http://www.ehealthsask.ca/services/manuals/Documents/hiv-provider-guidelines.pdf, retrieved July 21, 2015.

Appendix 1 – Exposure Incident Flow Chart[9]

Guidelines for the Management of Exposures to Blood and Body Fluids

MOST EXPOSURES DO NOT WARRANT HIV PEP, HOWEVER, IT IS STILL RECOMMENDED TO PROVIDE THE INDIVIDUAL WITH BASELINE TESTING AND FOLLOW-UP

This includes:

BASELINE TESTING:
- HIV antibodies (pre-test counselling required)
- Hepatitis B & C serology (anti-HBs, HBsAg, anti-HCV)

EDUCATION
- Supportive counselling
- Safer sex education
  - ➢ Patients should have protected sex with partners until their results of final HIV antibody testing is known to be negative
- Blood and Body Fluid Precaution Education (to take precautions until final HIV test result is known). See Section 6 – Counselling and Follow-Up

FOLLOW-UP
- HBV post-exposure prophylaxis (vaccination and HBIg if indicated)
- For Health Region Employee, refer to Regional Occupational/Employee Health Department
- Refer the exposed person to their Family physician
- If source is known positive for HIV, HBV or HCV or their status is unknown complete follow-up testing as per table below
- Send completed Exposure Incident Report Form to MHO

SKIN & MUCOUS MEMBRANE EXPOSURE

FIRST AID
- Skin – wash site liberally with soap and water
- Eyes – irrigate gently with sterile saline
- Mouth – rinse with water
  - ➢ Tooth brushing is NOT recommended

Exposed individuals should be assessed URGENTLY

If indicated, HIV PEP should commence as soon as possible, preferably within 2 hours of an exposure

RISK ASSESSMENT
- When did exposure occur
- Nature of exposure (type of fluid and amount)
- Duration of exposure

CONSIDER HIV PEP IF THE FOLLOWING CONDITIONS ARE MET:

If there is exposure of NON-INTACT skin or mucous membrane by blood or other body fluids (excluding urine, saliva & faeces)
AND
The source is KNOWN to be HIV positive
OR
The source is at HIGH RISK for HIV
AND
The patient consents to PEP
AND
The time from exposure to HIV PEP is < 72 hours

Consider HIV PEP NO

Consider HIV PEP YES

Follow-up Testing	Month 1	Month 3	Month 6
HIV	√	√	
HBsAg		√	
Anti-HCV	√	√	√
Hep C PCR	* - See App 10		

The HIV PEP Kit may be started if there is a delay in obtaining source information

SOURCE DETAILS
HIV STATUS OF SOURCE UNKNOWN
If available and consents:
- Test for HIV, HBV & HCV
  - ➢ Consider possibility of source window period

HIV STATUS OF SOURCE KNOWN TO BE POSITIVE
Information that is helpful for the ID Specialist:
- HIV viral load
- Current and past anti-HIV drug therapy AND reasons for stopping/changing regimen
- HBV & HCV status

If HIV positive source, administer 1st dose of HIV PEP regimen to the exposed person (if not already given)

EXPOSED PERSON'S DETAILS
- Medical history including all drugs
- Review for drug interactions on PIP
- Vaccination history for HBV
- Previous HIV test results
- In women, ask about pregnancy or breast feeding

DISCUSS WITH ID SPECIALIST AT TIME OF INCIDENT TO DETERMINE THE NEED FOR ONGOING HIV PEP AND FOLLOW-UP

HBV PEP
- Assess and manage as per Canadian Immunization Guide See Appendix 8

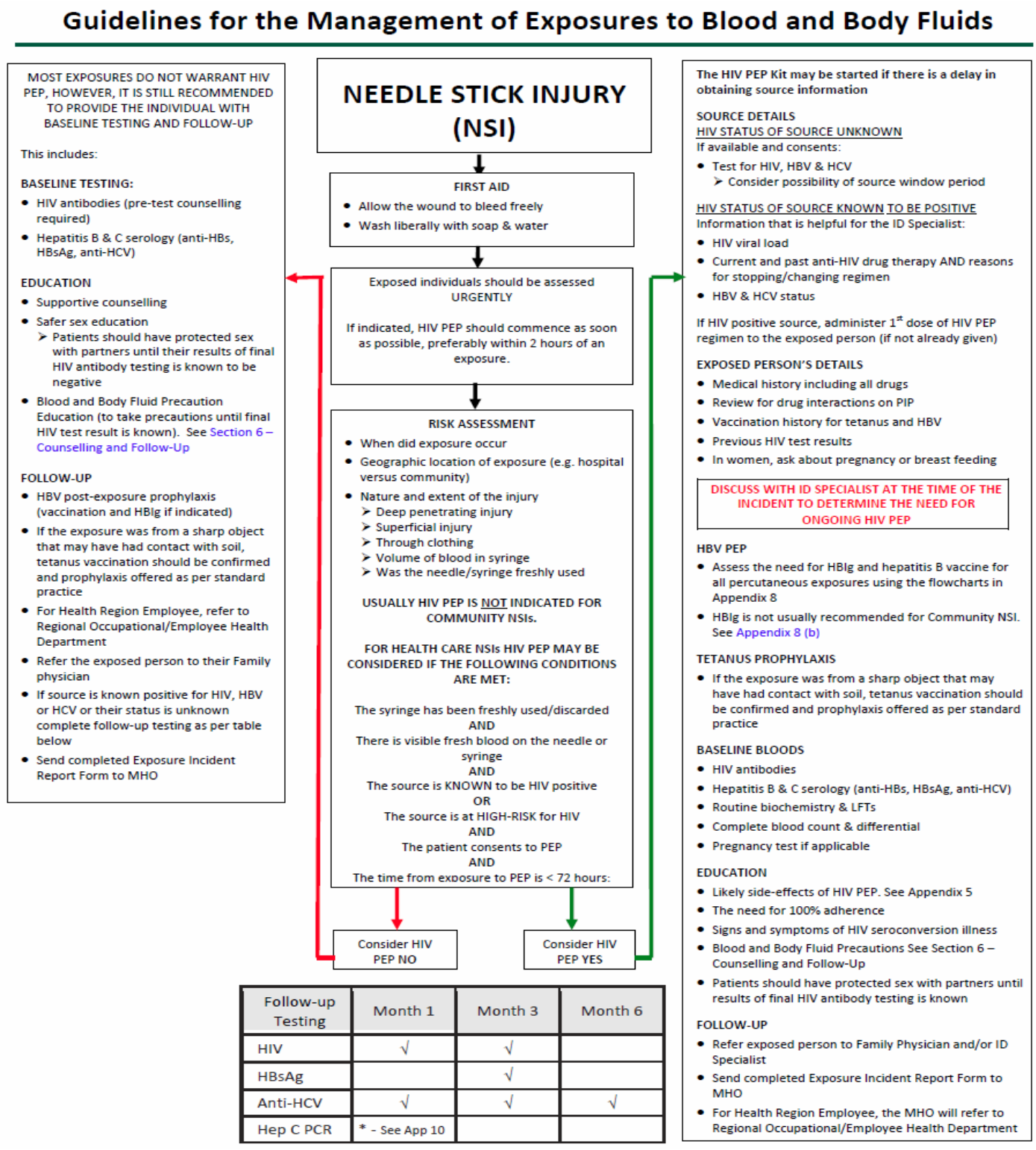
BASELINE BLOODS
- HIV antibodies
- Hepatitis B & C serology (anti-HBs, HBsAg, anti-HCV)
- Routine biochemistry & LFTs
- Complete blood count & differential
- Pregnancy test if applicable

EDUCATION
- Likely side-effects of HIV PEP. See Appendix 5
- The need for 100% adherence
- Signs and symptoms of HIV seroconversion illness
- Blood and Body Fluid Precautions See Section 6 – Counselling and Follow-Up
- Patients should have protected sex with partners until results of final HIV antibody testing is known

FOLLOW-UP
- Refer exposed person to Family Physician and/or ID Specialist
- Send completed Exposure Incident Report Form to MHO
- For Health Region Employee, the MHO will refer to Regional Occupational/Employee Health Department

[9] "Appendix 17: Decision Making", p. 113; Government of Saskatchewan – Ministry of Health: "Guidelines for the Management of Exposures to Blood and Body Fluids," October, 2013.

Appendix 2 – Needlestick Injury Flow Chart[10]



Follow-up Testing	Month 1	Month 3	Month 6
HIV	√	√	
HBsAg		√	
Anti-HCV	√	√	√
Hep C PCR	* - See App 10		

[10] "Appendix 17: Decision Making", p. 114; Government of Saskatchewan – Ministry of Health: "Guidelines for the Management of Exposures to Blood and Body Fluids," October, 2013.