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Post-exposure Prophylaxis for HIV, HBV and HCV

INTEGRATED PROTOCOL FOR MANAGING EXPOSURES TO BLOOD AND BODY FLUIDS IN MANITOBA

MANITOBA HEALTH, SENIORS AND ACTIVE LIVING
| Active Living, Population and Public Health Branch

Manitoba

Developed by the **Post-Exposure Prophylaxis Protocol Update Working Group**

DISCLAIMER: This protocol is not meant to serve as a textbook and therefore deliberately provides little, if any, explanation or background information. It is designed as a quick reference guide in order to rapidly acquaint the intended user with post-exposure situations and how to manage them. Considerable care was taken in ensuring that recommendations accurately reflect current practice standards. Nevertheless, users of this protocol are urged to confirm that the information contained herein is correct. Manitoba Health, Seniors and Active Living accepts no responsibility for any inaccurate or misleading information, nor does it guarantee the success of any prophylactic interventions described.

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ABBREVIATIONS

3TC	Lamivudine
anti-HBs	Hepatitis B antibody
anti-HCV	Hepatitis C antibody
ARV	Antiretroviral
CPL	Cadham Provincial Laboratory
ER	Emergency room
FNIHB	First Nations Inuit Health Branch
FTC	Emtricitabine
HBIG	Hepatitis B Immunoglobulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCP	Health care provider
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HSC	Health Sciences Centre
ID	Infectious diseases
LPV/r	Ritonavir-boosted lopinavir
MHSAL	Manitoba Health, Seniors and Active Living
MSM	Men who have sex with men
NAAT	nucleic acid amplification test
nPEP	Non-occupational post-exposure prophylaxis
NRTI	Nucleoside reverse-transcriptase inhibitor
OH	Occupational health
OHS	Occupational health and safety
oPEP	Occupational post-exposure prophylaxis
PEP	Post-exposure prophylaxis

PH	Public health
POCT	Point-of-care test
RAL	Raltegravir
RHA	Regional Health Authority
RNA	Ribonucleic acid
STI	Sexually-transmitted infection
TDF	Tenofovir
UC	Urgent care
VL	Viral load
ZDV	Zidovudine

USING THIS PROTOCOL

This Protocol is primarily intended to be used as a reference for urgent care/emergency room physicians, occupational health (OH) physicians, OH nurses and other health care professionals knowledgeable in the assessment of blood or bodily fluid exposures. Health care providers (HCP) responsible for providing follow-up care, such as family physicians, should find the document useful as well.

Information contained in the Protocol will provide HCPs with basic directions for managing post-exposure incidents in Manitoba. The aim is to have a high-level, relatively succinct protocol that providers can use for a quick reference to deal expeditiously with post-exposure situations. Users of the Protocol are expected to exercise good clinical judgment as well as due diligence.

The post-exposure management algorithm described in the Protocol has four major parts: initial, non-specific management for all exposures, and subsequent management specific to each of the three bloodborne infections—human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). Each part has a process diagram presented as a swim lane flowchart. This visually groups along separate lanes, steps in the algorithm that pertain to the exposed (white background) and source (gray background) individuals. It further distinguishes responsibilities between the initial care provider (i.e., provider of initial assessment and prophylaxis) (plain foreground) and the laboratory (i.e., Cadham Provincial Laboratory) (stippled foreground). The boxes indicate the corresponding sections or tables in the document, which in the electronic (pdf) version is **hyperlinked** for ease in navigating around the document.

The flowcharts, as well as tables on HIV risk assessment and HBV management, are conveniently found altogether in a "Quick PEP Guide" at the beginning of the main body of the Protocol (i.e., immediately following this how-to-use-the-Protocol section).

Special icons:

This Protocol uses special icons along the margins to emphasize certain points, as follows:

MB These initials pertain to information specific to Manitoba. Providers in Manitoba should pay particular attention.


This icon pertains to information that may be easily overlooked or misunderstood, possibly resulting in sub-optimal care that impacts negatively on clinical outcomes.


This icon pertains to telephone numbers in Manitoba that may be contacted for more information or guidance (listed in APPENDIX C)


This icon pertains to websites that may be visited for more information (listed in APPENDIX C)

If the icon appears next to a section header, it applies to information in that section and all subsections; if it appears next to a paragraph, it applies only to information in that paragraph and any list of items or bullet points under it; if it appears next to a list item or bullet point, it applies only to information in that list item or bullet point and any sub-level list of items or bullet points under it. *The pertinent information within the section, paragraph, list item or bullet point is italicized.*

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QUICK PEP GUIDE

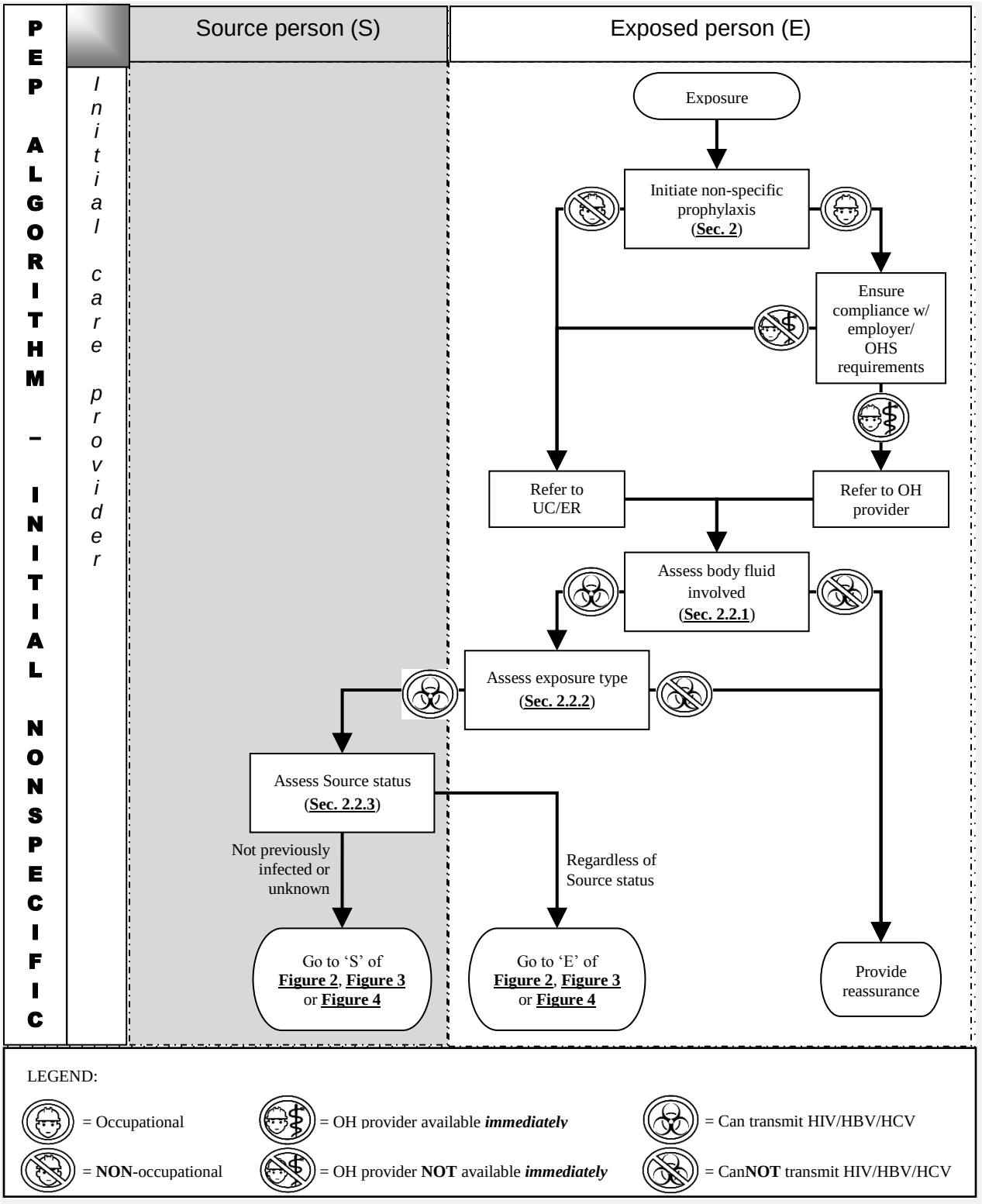

Figure 1 – Diagram of initial, non-specific portion of the PEP algorithm

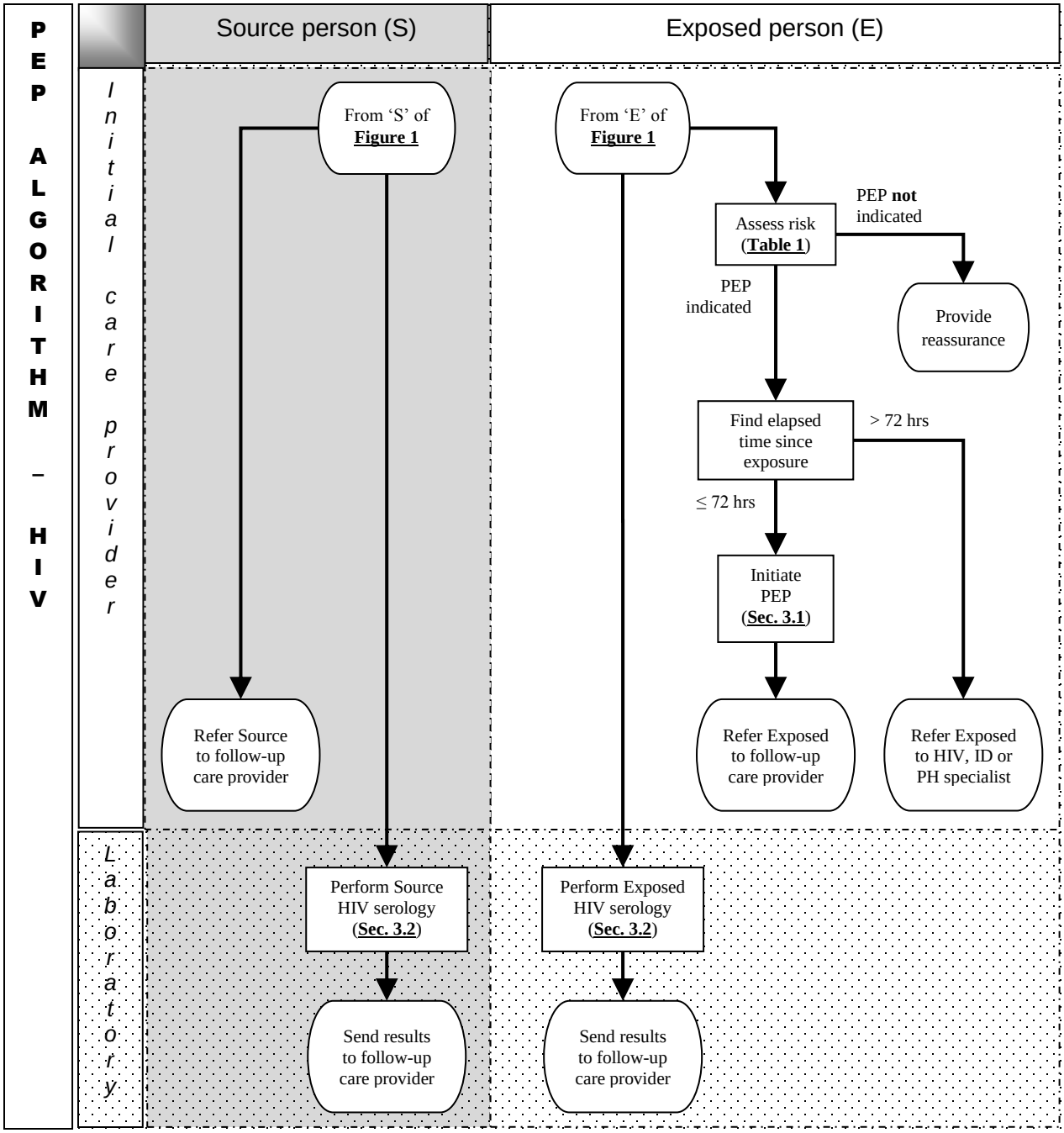

Figure 2 – Diagram of HIV portion of the PEP algorithm

Table 1 – HIV risk assessment for PEP initiation			
Risk from the exposure type	Likelihood that source person has transmissible HIV		
	Substantial[1]	Low[2]	Negligible or none[3]
High[4, 6] / Moderate[5, 6]	Initiate PEP	Consider PEP	Consider PEP[8] / PEP not required
Low[7]	PEP not required	PEP not required	PEP not required

[1]HIV+ and viremic (i.e., VL >40 copies/mL) OR HIV status unknown but source from a priority population with high HIV prevalence compared to the general population

[2]HIV+ believed to be VL<40 with concomitant STI present at the time of exposure

[3]Confirmed HIV negative OR HIV+ with confirmed VL<40 and no known STI present at time of exposure OR HIV status unknown, general population

[4]Anal (receptive), needle sharing

[5]Anal (insertive), vaginal (receptive, insertive)

[6]The average risk for HIV transmission after a percutaneous or mucous membrane exposure or mother-to-child transmission is within what would be considered moderate to high.(1, 2)

[7]Oral sex (giving, receiving), oral-anal contact, sharing sex toys, blood on compromised skin

[8]Consider PEP **if occupational setting**, unless source person is confirmed HIV negative;(1)
PEP not required **if NON-occupational setting**

N.B. Adapted to be applicable to both nPEP and oPEP from Tables 1, 2 and 4 of the Canadian Guideline on HIV PrEP and nPEP 2017(3)

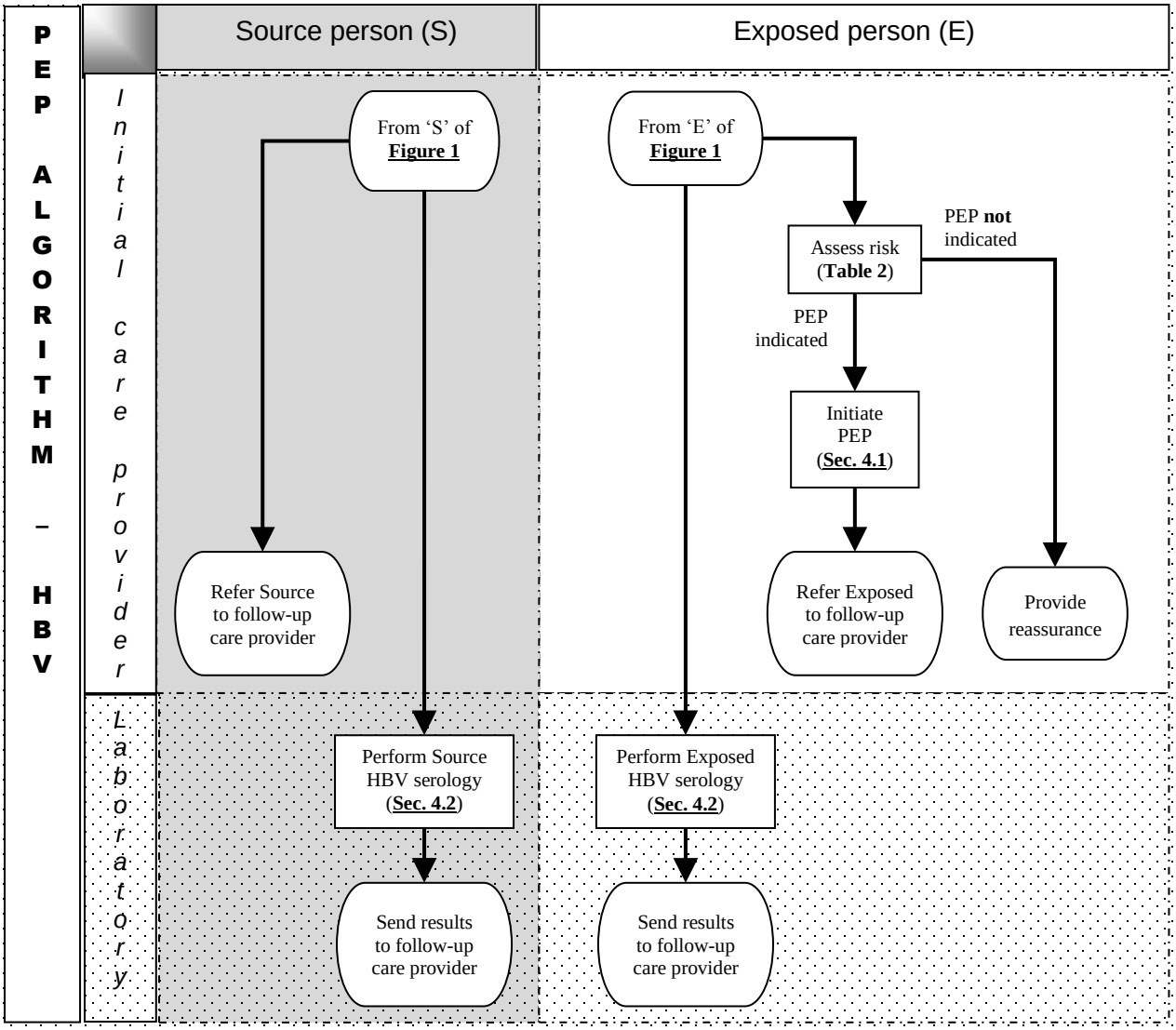

Figure 3 – Diagram of HBV portion of the PEP algorithm

Table 2 – Management of HBV post-exposure

Vaccination status of exposed	Recommended action		
A. Completely vaccinated[1], responder[2]	**Regardless of Source status**		
	No action needed, consider immune		
B. Completely vaccinated[1], unknown response[2]	**Source is infected or high-risk[3]**		
	Test for anti-HBs[4]	≥10 IU/L	No action needed, consider immune[6]
		<10 IU/L	1. Give HBIG x 1 dose 2. HB vaccine booster x 1 dose 3. Re-test for anti-HBs after 4–6 mos. If still <10 IU/L, complete 2nd HB vaccine series[7]
	Source is uninfected or low-risk		
	Test for anti-HBs	≥10 IU/L	No action needed, consider immune[6]
		<10 IU/L	1. HB vaccine booster x 1 dose 2. Re-test for anti-HBs after 1–2 mos. If still <10 IU/L, complete 2nd HB vaccine series[7]
C. Completely vaccinated[1], non-responder[2]	**Source is infected or high-risk[3]**		
	1. Give HBIG x 1 dose 2. Give HB vaccine 2nd series[7]		
	Source is uninfected or low-risk		
	Complete 2nd HB vaccine series[7]		
D. Completely vaccinated[1] x 2 courses, non-responder[2]	**Source is infected or high-risk[3]**		
	Give HBIG x 2 doses (4 weeks apart)		
	Source is uninfected or low-risk		
	No action needed		
E. Incompletely vaccinated[1], unknown response[2]	**Source is infected or high-risk[3]**		
	1. Test for anti-HBs[5] 2. Complete vaccination	≥10 IU/L	No action needed, consider immune[6]
		<10 IU/L	1. Give HBIG x 1 dose 2. Re-test for anti-HBs after 4–6 mos. If still <10 IU/L, complete 2nd HB vaccine course[7]
	Source is uninfected or low-risk		
	Complete vaccination[7]		
F. Unvaccinated	**Source is infected or high-risk[3]**		
	1. Test for anti-HBs 2. Give HBIG x 1 dose 3. Complete vaccination[7, 8]		
	Source is uninfected or low-risk		
	Complete vaccination[7]		

[1]Number of doses of a completed course varies according to provincial and territorial immunization schedule and to the recommended product-specific dose.(4) Vaccination according to various approved schedule for routine vaccination for specific ages and vaccine formulations elicits similar final rates of seroprotection.(5) Thus, PRE-exposure vaccination based on the two-dose schedule of Manitoba's school-based immunization program is equivalent to the three-dose adult schedule and is therefore deemed complete for purposes of assessing vaccination status.

[2]Responder is one with protective concentration of anti-HBs (≥10 IU/L) on prior testing.

[3]See Sec. 2.2.3

[4]If result is unavailable within 48 hrs, give HB vaccine booster x 1 dose. Once result known, individuals with titre ≥10 IU/L require no further action; individuals with titre <10 IU/L should receive HBIG and be retested after 4–6 mos. If titre remains below 10 IU/L, a second series of vaccination is called for.

[5]If result unknown after 48 hrs, give HBIG x 1 dose. Once result known, individuals with titre ≥10 IU/L require no further action; individuals with titre <10 IU/L should be retested for anti-HBs after 4–6 months. If titre remains below 10 IU/L, a second series of vaccination is called for.

[6]Individuals who are immunocompromised, have chronic renal failure or are on dialysis cannot be considered to have lifetime immunity and require serologic testing in case of subsequent exposure to HB.

[7]Re-test anti-HBs 1 to 6 months after completion of the HB vaccine series.

[8]Complete the vaccine series regardless of the anti-HBs titre. The anti-HBs test may reassure the exposed individual about the immediate risk of becoming infected.

N.B. Adapted from Figures 1 and 2 of the Hepatitis B vaccine chapter of the Canadian Immunization Guide 2017(4)

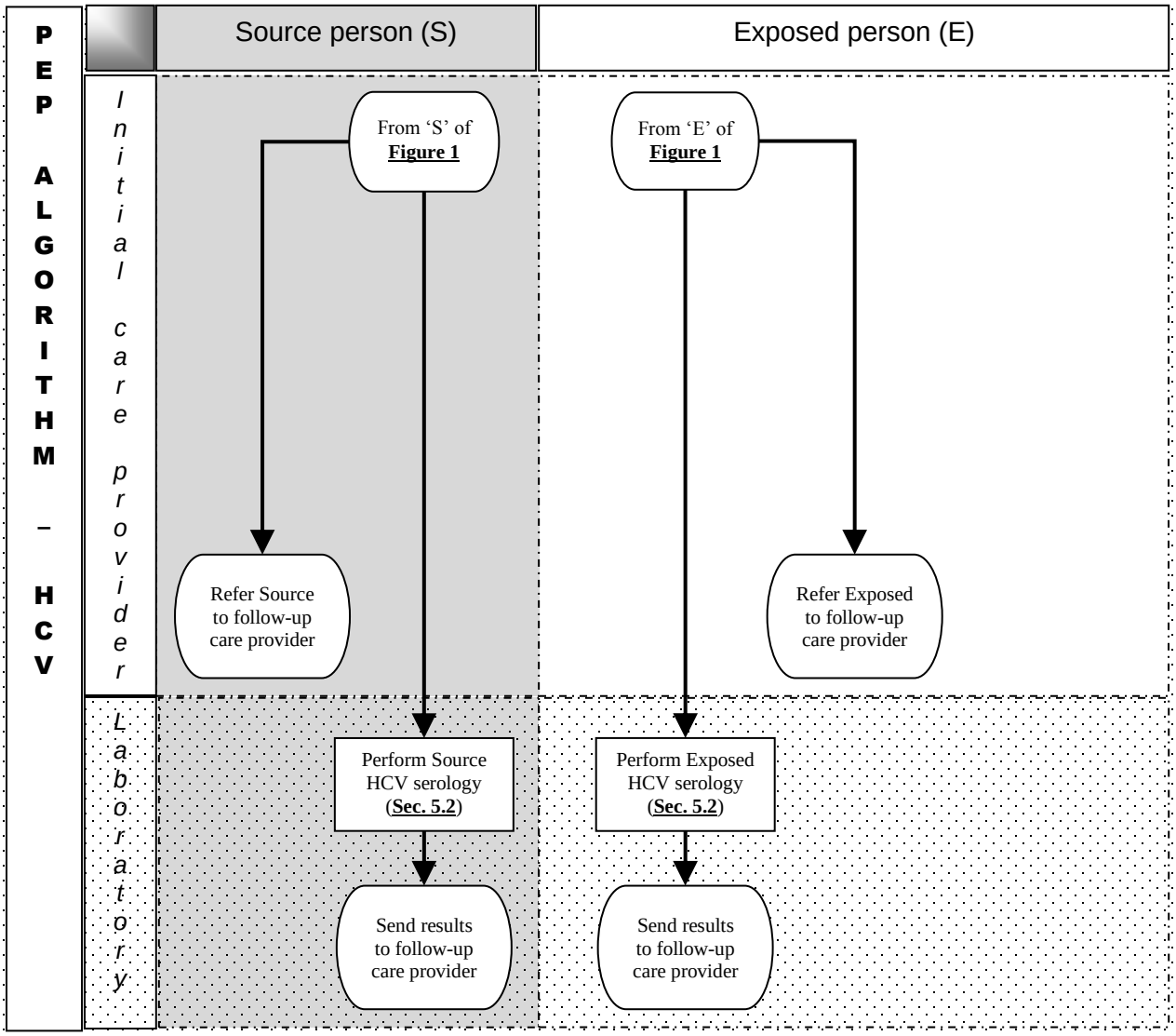

Figure 4 – Diagram of HCV portion of the PEP algorithm

1. OVERVIEW

Post-exposure prophylaxis (PEP) is preventive management to avoid infection subsequent to exposure to human blood and body fluids that may transmit human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV).

Management of such exposures is disease-specific.

- PEP for HIV involves antiretroviral (ARV) therapy
- PEP for HBV may involve both passive and active immunization against HBV
- Post-exposure management for HCV may include testing and follow up only. There is currently no approved PEP regimen for this virus.

This integrated protocol outlines the PEP management for HIV, HBV and HCV, in occupational as well as non-occupational settings.

2. INITIAL NON-SPECIFIC PROPHYLACTIC MEASURES AND RISK ASSESSMENT

See diagram on p. 1.

The following actions are recommended immediately following any exposure to blood or other body fluids regardless of whether the source person is known to pose a risk of infection for HIV, HBV and/or HCV(6):

- Thoroughly rinse the site of a percutaneous injury with running water, and gently clean any wound with soap and water.
- Flush mucous membranes of the eyes, nose or mouth with running water if contaminated with blood, body fluids, secretions or excretions.
- Thoroughly rinse non-intact skin with running water if contaminated with blood, body fluids, secretions or excretions.
- Although the use of antiseptics is not contraindicated, injection into the wound is **not** recommended.(5)

Any additional facility-specific instructions for post-exposure management should also be followed.

2.1. Initial Assessment and Reporting of Exposure Incident

Initial assessment of an exposure is performed in a timely manner. Depending on the exposure situation (i.e., occupational or non-occupational), the initial assessment is performed by an urgent care (UC) physician, an emergency room (ER) physician, an occupational health (OH) physician, an OH nurse or another health care professional knowledgeable in the assessment of blood or bodily fluid exposures. Follow-up care should be overseen by the appropriate health care provider (HCP), usually the relevant specialist physician or nurse practitioner, perhaps in collaboration with the family physician or OH physician.

2.1.1. Occupational Exposures

Occupational exposures are accidental exposures occurring in work contexts (e.g., healthcare).(3) Workers need to comply with any employer and/or occupational health and safety (OHS) requirements in their workplace. Requirements may vary depending on the facility/organization and the occupation of the exposed person.

The exposure incident must be reported immediately to the appropriate administrative personnel with appropriate OH notification as per institutional/facility policy and protocols.

If the facility's OH unit or equivalent is not immediately available, the exposed person must go to UC primarily or an ER as a secondary option. Assessment and, if indicated, prophylaxis must then be initiated at the UC/ER.

2.1.2. Non-occupational Exposures

Non-occupational (or community) exposures occur in the community, usually in relation to sexual exposure or injection drug use.(3)

The service designated to provide the initial assessment may vary among different provincial Regional Health Authorities (RHA) and First Nations Inuit Health Branch (FNIHB) jurisdictions. Generally, initial assessment for non-occupational exposures is performed in UC primarily or an ER as a secondary option. *Depending on prevailing policies by the relevant RHA/FNIHB (e.g., specialized clinics on weekdays, UC/ER on weekends and holidays), the client may be triaged to the appropriate facility. Check with the relevant RHA/FNIHB (for contact numbers, see APPENDIX C).*

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2.2. Risk Assessment of Exposure Incident for Consideration of PEP

If the source person is infected, the risk of transmission to the exposed person will depend on the body fluid involved, the type of exposure and the status (e.g., viral load) of the infected source person.

2.2.1. Body Fluid Involved

Body fluids capable of transmitting HIV, HBV or HCV include the following(3, 4, 7-10):

- Blood, serum, plasma or other biological fluids visibly contaminated with blood
- Pleural, amniotic, pericardial, peritoneal, synovial, cerebrospinal fluids
- Semen, vaginal secretions
- Breast milk
- Organ and tissue transplants
- Donated blood and manufactured blood products (minimal risk in Canada)

Saliva, urine, vomitus, feces, nasal secretions, sputum, sweat or tears (unless visibly contaminated with blood), do **not** transmit HIV, HBV or HCV. Further risk assessment after exposure to these body fluids is not necessary, and PEP is **not** indicated.

2.2.2. Type of Exposure

Exposure types of concern for possible transmission of HIV(3), HBV(4) or HCV(10) include the following:

- Sexual contact (anal or vaginal)
  - HCV is not efficiently transmitted through sex, unless there is concomitant HIV infection
- Needle sharing (e.g., injection drug use)
- Percutaneous injury (i.e., puncture or laceration of the skin that penetrates into or below the dermis)
- Mucous membrane exposure
- Mother-to-child transmission

Further risk assessment (including evaluation of the source person) is necessary only where the exposure incident (body fluid involved and exposure type) is deemed to be of concern for possible transmission of HIV, HBV or HCV.

Sexual Assault

HIV seroconversion may occur in persons whose only known risk factor was sexual assault or sexual abuse, but the frequency of this occurrence likely is low.(10) Although sexually assaulted persons are sometimes at risk for HIV transmission, they often decline non-occupational PEP (nPEP), and many who do take it do not complete the 28-day course.(11) HCPs who undertake initial assessment for nPEP should distinguish between consensual and non-consensual exposures and should provide or refer to sexual assault services accordingly. Screening for non-consensual sex is advised in order to ensure patients are offered access to sexual assault services *(e.g., see APPENDIX C)* where appropriate, and because sexual assault is a recognized risk factor for challenges with nPEP adherence that may warrant additional support.(3)

2.2.3. Status of Source

Wherever possible, the source person should be tested. In the case of an unknown source, background circumstances may provide limited indication of the degree of risk.(4)

Source persons having one or more of the following risk factors are more likely to have transmissible HIV(3), HBV(4) or HCV(10):

- Known infection (HIV, HBV, HCV)
  - For HIV, has to be HIV+ and either viremic (i.e., VL >40 copies/mL) or with concomitant sexually transmitted infection (STI)
- Unknown infection status but belonging to a population with high HIV, HBV or HCV prevalence compared to the general population:
  - Has a sexual partner with known infection or high risk of infection (HIV, HBV, HCV)
  - Men who have sex with men (MSM) (HIV, HCV)
  - Has history of multiple sex partners (HBV, HCV)
    - For HCV, risk increases commensurate with increasing numbers of sex partners among heterosexual persons with HIV infection and MSM
  - Engages in group sex (HCV)
  - People who inject drugs (HIV, HBV, HCV)
  - Has history of intranasal drug use (HCV)
  - Has tattoo obtained in unregulated setting (HCV)
  - Born to a mother with known infection (HCV)
  - In close family contact with an HBV-infected person (HBV)
  - Received blood products prior to 1985 (HIV), 1970 (HBV) or April 1992 (HCV).
  - Has history of residence in a country or area with a high prevalence of infection (HBV) *(for web link, see APPENDIX C)*

3. HIV PEP

See diagram on p. 2.

3.1. Provision of HIV Prophylaxis

*HIV PEP should be initiated as soon as possible (maximum of **72 hours**) after the exposure incident,*(11) if indicated based on the nature of the exposure incident (see **Table 1**), and even while awaiting testing results for the source person. *No laboratory evaluation is required prior to initiation of HIV PEP.*

PEP medication regimen should contain three ARVs and may be prescribed to complete a 28-day (four-week) course (1, 3, 8). *To help ensure prompt initiation of PEP, MHSAL provides starter kits free of charge. If the HCP determines that PEP is to be continued for the full 28-day course, the additional drug supply over those provided in the starter kit shall be prescribed (may use for this purpose the preprinted form available in APPENDIX* B*) – MHSAL does not assume the cost of these additional drugs. For a description of the PEP regimen currently included in the kits, see APPENDIX A.*

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HIV PEP is indicated if the exposure type is moderate to high risk and the source person has a substantial risk of having transmissible HIV infection. *If the source person is of unknown HIV status but at high epidemiologic risk, or is HIV-positive and unavailable or does not provide consent for additional viral load (VL) testing (or verification of undetectable status), an assumption of a substantial risk for transmissible HIV infection must be made.(3)*

PEP may be considered for individuals who have had an exposure that is moderate- or high-risk with a source person who has a low but non-negligible risk of having transmissible HIV. *Following moderate/high risk **occupational** exposure with a source person who has negligible risk, a case by case assessment needs to be performed to determine if the risk of transmission warrants the use of PEP. PEP should still be considered if the source is a known HIV patient with an undetectable viral load.(1)*

Prophylaxis is not recommended for individuals **in non-occupational setting** who have had a low-risk exposure, regardless of HIV status of source person.(3) On the other hand, because the great majority of **occupational** HIV exposures do not result in transmission of HIV whereas the agents administered for PEP (even those with relatively favorable safety profiles) can be associated with severe side effects, PEP may not be justified either for exposures that pose a low risk for transmission.

*HIV PEP is **not** indicated if the exposed person is already HIV-infected. Individuals found to already be HIV-infected should be referred to appropriate services for eligibility assessment for ARV therapy according to national guidelines.* However, assessment of HIV status of the exposed person should not be a barrier to initiating PEP. In emergency situations where HIV testing and counseling is not readily available but the potential HIV risk is high, or if the exposed person refuses initial testing, PEP should be initiated and HIV testing and counseling undertaken as soon as possible.

Consultation with a specialist in HIV medicine, public health or infectious diseases is recommended for the situations listed below(1):

- Delayed (i.e., later than 72 hours) exposure report
  - Interval after which benefits from PEP are undefined
  - Significant risk of exposure may warrant PEP initiation despite the time lapse
- Unknown source person (e.g., needle in sharps disposal container or laundry)
  - Use of PEP to be decided on a case-by-case basis
  - Consider severity of exposure and epidemiologic likelihood of HIV exposure
  - Do not test needles or other sharp instruments for HIV
- Known or suspected pregnancy in the exposed person
  - The risk of HIV transmission poses a threat not only to the mother but also to the fetus and infant, as the risk of mother-to-child HIV transmission is markedly increased during acute HIV infection during pregnancy and breast-feeding.
  - Do not delay initiation of PEP while awaiting expert consultation
- Breast-feeding in the exposed person
  - Do not delay initiation of PEP while awaiting expert consultation
- Known or suspected resistance of the source virus to ARV agents
  - Resistance should be suspected in a source person who experiences clinical progression of disease, a persistently increasing VL, or a decline in CD4+ T cell count despite therapy and in instances in which a virologic response to therapy fails to occur.
  - If source person's virus is known or suspected to be resistant to one or more of the drugs considered for PEP, selection of drugs to which the source person's virus is unlikely to be resistant is recommended.
  - Do not delay initiation of PEP while awaiting any results of resistance testing of the source person's virus.
- Toxicity of the initial PEP regimen (for some examples, see **Table 6**)
  - Side effects (e.g., nausea, vomiting) are often manageable without changing PEP regimen by prescribing the appropriate medications (e.g., antimotility or antiemetic drugs)
  - Side effects are often exacerbated by anxiety
  - Counselling and support can help mitigate the side effects and promote adherence
- Serious medical illness in the exposed person
  - Significant underlying illness (e.g., renal disease) or already taking of multiple medications may increase the risk of drug toxicity
- Drug-drug interactions

Any exposed and source persons diagnosed with HIV as a result of testing should be referred by the health professional receiving the test results to *the Manitoba HIV Program (204-940-6089, 1-866-449-0165)* for appropriate counseling and treatment.

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Early HIV PEP Discontinuation

If the exposed person has begun an HIV PEP regimen and it is later determined either that the exposed person has HIV infection already or the source person is HIV-negative, HIV PEP should be discontinued,(1, 11) regardless of the number of days of prophylaxis completed. Exception to the latter situation (HIV-negative source) is if the source person is strongly suspected to have acute HIV infection based on evaluation for signs or symptoms and results of additional laboratory testing, that is, HIV ribonucleic acid (RNA) nucleic acid amplification test (NAAT), are pending(3), or there is increased risk that the source person is in the window period of infection (seroconversion phase). For example, persons whose sexual(12) or injection-related(13) exposures result in concurrent acquisition of HCV and HIV infection might have delayed HIV seroconversion. Continuation of nPEP may be considered despite negative testing result in source person.

Other situations in which nPEP may be stopped early:

- If the source is HIV positive and is found to have had a viral load below the limit of detection (< 40 copies/mL) for ≥ 6 months with no evidence of concurrent STI at the time of the exposure
- If ≥ 72 consecutive hours of nPEP have been missed, stopping nPEP should be considered

In cases that do not require PEP, the exposed person should be provided reassurance and counselled about limiting future exposure risk.(8, 9)

3.2. HIV Laboratory Testing

Baseline testing of both exposed and source individuals is necessary where the exposure incident (see Sec. 2.2) is deemed to be of concern for possible transmission of HIV. Initial positive enzyme-linked immunosorbent assay test result undergo confirmatory testing.

Where available, testing of the exposed and source persons can also include a point-of-care test (POCT), which is conducted at or near the site at which care is being provided, but this should not replace the standard serology test. The value of the POCT is that results are usually returned rapidly so that clinical decisions can be made in a timely and cost-effective manner.(8)

Testing of the source person is recommended even when the source person was previously tested negative. Procedures should be followed for testing known source persons, including obtaining informed consent, in accordance with applicable laws. *Manitoba's Testing of Bodily Fluids and Disclosure Act enables a person who has come into contact with a bodily fluid of another person to apply for a court order requiring the other person to provide a blood sample, which will be tested to determine if that person is infected with HIV (for web links, see APPENDIX C).*

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In Manitoba, all diagnostic tests for HIV are performed at Cadham Provincial Laboratory (CPL). Please contact CPL (see APPENDIX C) for sample collection/submission instructions, testing schedule and result waiting time, as well as any request for urgent or "STAT" testing.

More Laboratory Testing

Baseline

Aside from for documentation purposes, laboratory testing is required for the following reasons(3, 11):

- Identify and clinically manage any other conditions potentially resulting from sexual- or injection-related exposure to potentially infected body fluids
- Identify any conditions that would affect the PEP medication regimen
- Monitor for safety or toxicities related to the regimen prescribed

For both the exposed and source persons, baseline tests include the following:

- HIV testing
  - Those with signs or symptoms of acute HIV should also undergo HIV RNA NAAT.
- Hepatitis B surface antigen, surface antibody, core antibody
- Hepatitis C antibody
- Screening for gonorrhea and chlamydia
- Syphilis serology
- Pregnancy testing

For the Exposed taking tenofovir + emtricitabine, additional tests include the following:

- Serum creatinine (for calculating estimated creatinine clearance)
- Alanine aminotransaminase, aspartate aminotransferase
- Complete blood count

Do not delay initiation of PEP while awaiting any test results.

Follow-up

For nPEP, final follow-up HIV serology should be performed at 12 weeks after exposure (i.e., eight weeks after completion of PEP). Consider repeating HIV serology at six months after exposure if HCV infection was acquired from the exposure.(3) For occupational PEP (oPEP), follow-up HIV serology should be performed at six weeks and four months.(1)

Ongoing laboratory monitoring of biochemistry and hematology during PEP is advised only for those with baseline laboratory abnormalities or in those who develop signs or symptoms of organ dysfunction or medication-related adverse effects during therapy.(3)

4. HBV PEP

See diagram on p. 4.

4.1. Provision of HBV Prophylaxis

The management of potential exposure to HBV should be based on the immunization and antibody status of the exposed person and the infection status (if known) of the source person (see **Table 2**).

HBV vaccine is the most important intervention, providing 90% of the protection from HBV(4). Hepatitis B immunoglobulin (HBIG), through immediate short-term passive immunity, may provide additional protection. HBIG and HBV vaccine can be administered simultaneously at separate injection sites using separate needles and syringes.(5)

MHSAL provides HBV vaccine and HBIG free of charge for PEP to hospitals and other sites of first contact for immediate administration for patients with potential HBV exposure throughout Manitoba using the appropriate order form (for web links, see APPENDIX C).

*If the results of the exposed and source persons are not available within **48 hours**, management of the exposed person should assume possible exposure.* If indicated, HBIG should be administered to susceptible individuals within 48 hours after exposure. The efficacy of HBIG decreases significantly after 48 hours, but may be given *up to **seven days** (for sexual contacts, up to 14 days)* after exposure.(4) The effectiveness of HBIG when administered after percutaneous, mucosal, or non-intact skin exposures beyond this timeframe is unknown.

Administration of HBIG should be omitted if the source person is tested within 48 hours and the result is negative.

The exposed person should be counselled on the use of risk reduction measures until the vaccine series has been completed and protective concentrations of hepatitis B surface antibody (anti-HBs) demonstrated.(4)

Expert consultation should be sought if the exposed person is immunocompromised.

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Any exposed and source persons diagnosed with HBV as a result of testing, that is, found to be hepatitis B surface antigen (HBsAg) positive, should be referred by the health professional receiving the test results to *the Viral Hepatitis Investigative Unit (for contact numbers, see APPENDIX C)* for appropriate counseling and treatment.

Early HBV PEP Discontinuation

Immunoprophylaxis may be discontinued if the exposed person tests anti-HBs positive or HBsAg positive or the Source tests HBsAg negative.

4.2. HBV Laboratory Testing

HBV testing includes assays for anti-HBs for the exposed person and HBsAg for both the exposed and source persons.

Baseline testing of both exposed and source individuals is necessary where the exposure incident (see Sec. 2.2) is deemed to be of concern for possible transmission of HBV. *The blood for testing of the exposed person should be drawn **before** the first dose of HBV vaccine and/or HBIG is given.*(5)

Baseline testing for the exposed person is not required if there is documented immunity to HBV (i.e., has documentation of a completed HBV vaccine series with subsequent immunity demonstrated via titre testing) or if a previous test for HBsAg is positive. In both cases, the exposed person does not require prophylaxis.

Post-vaccination serologic testing should be performed one to two months after the last dose of the HBV vaccine. If HBIG was administered, testing should be delayed until four to six months after administration of HBIG to avoid detection of passively administered anti-HBs.(5)

Testing of the source person is recommended even where the source person previously tested negative. Procedures should be followed for testing known source persons, including obtaining informed consent, in accordance with applicable laws. *Manitoba's Testing of Bodily Fluids and Disclosure Act enables*

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a person who has come into contact with a bodily fluid of another person to apply for a court order requiring the other person to provide a blood sample, which will be tested to determine if that person is infected with HBV (for web links, see APPENDIX C).

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In Manitoba, all diagnostic tests for HBV are performed at CPL. Please contact CPL (see APPENDIX C) for sample collection/submission instructions, testing schedule and result waiting time, as well as any request for urgent or "STAT" testing.

5. HCV PEP

See diagram on p. 6.

5.1. No Available HCV Prophylaxis

No PEP has been demonstrated to be effective against HCV.(10) Also, the marked genetic diversity and multiple mechanisms of persistence of HCV, combined with the relatively poor immune response of the infected host against the virus, are major barriers to development of a vaccine.(14) Close follow-up, post-exposure testing and early treatment with direct-acting antiviral combination therapy in the event that HCV transmission occurs are recommended for HCV post-exposure care.(15)

Any exposed and source persons diagnosed with HCV as a result of testing should be referred by the health professional receiving the test results to *the Viral Hepatitis Investigative Unit (for contact numbers, see APPENDIX C)* for appropriate counseling and treatment.

5.2 HCV Laboratory Testing

Baseline testing for HCV antibody (anti-HCV) of both exposed and source persons is necessary where the exposure incident (see Sec. 2.2) is deemed to be of concern for possible transmission of HCV.

Baseline testing is not necessary if the exposed person is known (documented) to be HCV-positive prior to exposure.

If baseline testing of the exposed person is negative and source person is positive, follow-up VL testing of exposed person is done at three months and anti-HCV testing at six months post-exposure. If baseline testing of exposed person is negative and source person status is unknown, follow-up testing of the exposed person should only include anti-HCV at six months.

Testing of the source person is recommended even when the source person has previously tested negative. Procedures should be followed for testing known source persons, including obtaining informed consent, in accordance with applicable laws. *Manitoba's Testing of Bodily Fluids and Disclosure Act enables a person who has come into contact with a bodily fluid of another person to apply for a court order requiring the other person to provide a blood sample, which will be tested to determine if that person is infected with HCV (for web links, see APPENDIX C).*

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In Manitoba, all diagnostic tests for HCV are performed at CPL. Please contact CPL (see APPENDIX C) for sample collection/submission instructions, testing schedule and result waiting time, as well as any request for urgent or "STAT" testing.

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APPENDIX A
HIV Post-exposure Prophylaxis Starter Kits

A preferred recommendation in Canada(3) and the United States(1, 11) for adults and adolescents 13 years and older, and children two to 13 years of age, is a regimen consisting of a nucleoside reverse-transcriptase inhibitor (NRTI) backbone of tenofovir (TDF) plus emtricitabine (FTC), with a third drug, usually raltegravir, an integrase strand transfer inhibitor. A suggested alternative NRTI backbone regimen includes zidovudine (ZDV) plus lamivudine (3TC), combined with ritonavir-boosted lopinavir (LPV/r), a protease inhibitor.

In the US(11), ZDV + 3TC is recommended as the preferred backbone regimen with LPV/r as the preferred third drug for children four weeks to under two years of age. The World Health Organization(7) recommends this same regimen for children younger than 10 years of age.

It is no longer recommended that the severity of exposure be used to determine the number of drugs to be offered in an HIV PEP regimen.(1) Recommending a three-drug regimen for all patients who receive PEP will increase the likelihood of successful prophylaxis in light of potential exposure to virus with resistance mutation(s). Additionally, if infection occurs despite PEP, a three-drug regimen will more likely limit emergence of resistance than will a two-drug regimen. *A two-drug regimen (e.g., two NRTIs) may be considered in consultation with an expert when there are concerns about medication availability as well as potential adherence and toxicity.*(1, 11)

To help ensure timely initiation of PEP, MHSAL currently publicly funds three days of HIV PEP medications, referred to as 'starter kits' (see **Table 3***). Providers provide the appropriate kit based on client's age and weight as well as whether renal function is normal (see* **Table 4** *and* **Table 5***). Two kits may be provided, but ONLY when circumstances of the client warrant it.*[1] **MB**

Regimens other than those included in the starter kits might be considered because of patient-specific variables (e.g., contraindications in the exposed person, known drug-resistance with the source person). In this case, HCPs are encouraged to seek consultation with other HCPs knowledgeable or experienced in using ARV medications for similar clients,(11) for example, at Manitoba HIV Program (204-940-6089, 1-866-449-0165) or Nine Circles Community Health Centre (204-940-6001).

In addition to ensuring timely access to medication, the starter kits also provide a multi-day period of time for the exposed persons to have their exposure assessed by an HIV specialist.

If the HCP determines that PEP is to be continued for the full 28-day course, the additional drug supply over those provided in the starter kit shall be prescribed (may use for this purpose the preprinted form available in APPENDIX B) – MHSAL Active Living, Population and Public Health Branch does not assume the cost of these additional drugs. The individual may be eligible for coverage through the Pharmacare program. **MB**

[1]For example, long weekends, or the client lives in a remote community and there's good reason to believe three days will not be enough time either for the necessary lab results to become available or for the client to get to the follow-up care provider to obtain a prescription for more meds if needed

These starter kits are provided to hospitals and other sites of first contact throughout Manitoba, for immediate administration for patients with potential HIV exposure, at no cost (including delivery), using the appropriate order form (for web links, see APPENDIX C).

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Table 3 – HIV PEP starter kit types and drug contents

Drugs	Formulation	Quantity
A – Standard ≥ 13 yr (any weight), ≥ 6 yr (≥ 35 kg)		
Tenofovir (TDF)/Emtricitabine (FTC) (Truvada®*)	300/200 mg tablet	3 tablets
Raltegravir (RAL) (Isentress®)	400 mg tablet	6 tablets
B – Renal ≥ 16 yr (any weight), 6 to < 16 yr (≥ 35 kg)		
Zidovudine (ZDV)/Lamivudine (3TC) (Combivir®)	300/150 mg tablet	6 tablets
Raltegravir (RAL) (Isentress®)	400 mg tablet	6 tablets
C – 13 to < 16 yr (< 35 kg), 6 to < 13 yr (25 to < 35 kg)		
Zidovudine (ZDV) (Retrovir®)	100 mg capsule	18 capsules
Lamivudine (3TC®)	150 mg tablet	6 tablets
Raltegravir (RAL) (Isentress®)	400 mg tablet	6 tablets
D – 6 to < 13 yr (< 25 kg), 2 to < 6 yr (< 35 kg)		
Zidovudine (ZDV) (Retrovir®)	100 mg capsule	18 capsules
Lamivudine (3TC®)	150 mg tablet	6 tablets
Lopinavir/ritonavir (LPV/r) (Kaletra®)	100/25 mg tablet	24 tablets

*Or generic equivalent

Table 4 – HIV PEP starter kit recommendations for adults and adolescents aged ≥ 13 years				
Age group	**Weight (Kg)**	**Kit**	**Drug content**	**Dosage**
With normal renal function				
Adults and adolescents aged ≥ 13 yrs		A	TDF/FTC 300/200 mg tablet	One tablet once daily
			RAL 400 mg tablet	One tablet twice daily
With renal dysfunction*				
Adults and adolescents aged ≥ 16 yrs		B	ZDV/3TC 300/150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
Adolescents aged 13 to < 16 year	≥ 35	B	ZDV/3TC 300/150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
	25 to < 35	C	ZDV 100 mg capsule	9 mg/kg (up to 300 mg) twice daily
			3TC 150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
	20 to < 25	C	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one tablet in PM
			RAL 400 mg tablet	One tablet twice daily
	15 to < 20	C	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one-half tablet in PM
			RAL 400 mg tablet	One tablet twice daily

*Renal dysfunction is creatinine clearance ≤ 59 ml/min.
Abbreviations: 3TC = Lamivudine, FTC = Emtricitabine, RAL = Raltegravir, TDF = Tenofovir, ZDV = Zidovudine

Table 5 – HIV PEP starter kit recommendations for children aged < 13 years				
Age group	**Weight (Kg)**	**Kit**	**Drug content**	**Dosage**
With normal renal function				
Children aged 6 to < 13 yrs	≥ 35	A	TDF/FTC 300/200 mg tablet	One tablet once daily
			RAL 400 mg tablet	One tablet twice daily
	25 to < 35	C	ZDV 100 mg capsule	9 mg/kg (up to 300 mg) twice daily
			3TC 150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
	20 to < 25	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one tablet in PM
			LPV/r 100/25 mg tablet	Two tablets twice daily
	15 to < 20	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one-half tablet in PM
			LPV/r 100/25 mg tablets	Two tablets twice daily
Children aged 2 to < 6 yrs†	25 to < 35	D	ZDV 100 mg capsule	9 mg/kg (up to 300 mg) twice daily
			3TC 150 mg tablet	One tablet twice daily
			LPV/r 100/25 mg tablets	Three tablets twice daily
	20 to < 25	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one tablet in PM
			LPV/r 100/25 mg tablets	Two tablets twice daily
	15 to < 20	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one-half tablet in PM
			LPV/r 100/25 mg tablets	Two tablets twice daily

Table 5 – HIV PEP starter kit recommendations for children aged < 13 years				
Age group	**Weight (Kg)**	**Kit**	**Drug content**	**Dosage**
With renal dysfunction*				
Children aged 6 to < 13 years	≥ 35	B	ZDV/3TC 300/150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
	25 to < 35	C	ZDV 100 mg capsule	9 mg/kg (up to 300 mg) twice daily
			3TC 150 mg tablet	One tablet twice daily
			RAL 400 mg tablet	One tablet twice daily
	20 to < 25	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one tablet in PM
			LPV/r 100/25 mg tablet	Two tablets twice daily
	15 to < 20	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one-half tablet in PM
			LPV/r 100/25 mg tablet	Two tablets twice daily
Children aged 2 to < 6 yrs†	25 to < 35	D	ZDV 100 mg capsule	9 mg/kg (up to 300 mg) twice daily
			3TC 150 mg tablet	One tablet twice daily
			LPV/r 100/25 mg tablets	Three tablets twice daily
	20 to < 25	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one tablet in PM
			LPV/r 100/25 mg tablets	Two tablets twice daily
	15 to < 20	D	ZDV 100 mg capsule	9 mg/kg twice daily
			3TC 150 mg tablet	One-half tablet in AM, one-half tablet in PM
			LPV/r 100/25 mg tablets	Two tablets twice daily

*Renal dysfunction is creatinine clearance ≤ 59 ml/min.
†If child is unable to take tablet/capsule, consult HIV and/or pediatric pharmacy for administration suggestions
Abbreviations: 3TC = Lamivudine, FTC = Emtricitabine, LPV = Lopinavir, r = Ritonavir, RAL = Raltegravir, TDF = Tenofovir, ZDV = Zidovudine
Note: For children aged < 2 years, children weighing < 15 kgs or children < 6 years but weighing ≥ 35 kgs, consult an HIV or pediatric ID specialist.

Table 6 – ARV medication side effects	
Drugs	**Side effects, contraindications and cautions(11)**
Emtricitabine	**Side effects:** Hyperpigmented rash or skin discoloration **Contraindications:** Do not administer with 3TC **Cautions:** FTC can be used in PEP regimens for patients with chronic HBV infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug might cause an acute hepatitis exacerbation.
Lamivudine	**Side effects:** Headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough **Contraindications:** Do not administer with FTC **Cautions:** 3TC may be used in PEP regimens for patients with chronic HBV infection, but hepatic function tests should be closely monitored when regimen is stopped since withdrawal of this drug may cause an acute hepatitis exacerbation.
Lopinavir/ritonavir	**Side effects:** Nausea, vomiting, diarrhea **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Do not administer to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks and a postnatal age of ≥ 14 days. **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life-threatening adverse events.
Raltegravir	**Side effects:** Insomnia, nausea, fatigue, headache; severe skin and hypersensitivity reactions have been reported **Contraindications:** None **Cautions:** Dosage adjustment required if co-administered with rifampin (800 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and certain oral multivitamins can reduce absorption of RAL. RAL should be administered ≥ 2 hours before or ≥ 6 hours after administration of cation-containing medications or products, however, RAL can be co-administered with calcium carbonate-containing antacids.
Tenofovir	**Side effects:** Asthenia, headache, diarrhea, nausea, vomiting **Contraindications:** Nephrotoxicity; for PEP, should not be administered to persons with acute or chronic kidney injury or those with eCrCl < 60 mL/min **Cautions:** TDF can be used in PEP regimens for patients with chronic HBV infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug may cause an acute hepatitis exacerbation.
Zidovudine	**Side effects:** Nausea, vomiting, headache, insomnia, and fatigue **Cautions:** Can cause anemia and neutropenia

APPENDIX B

HIV Post-exposure Prophylaxis Pre-printed Prescription Form[2]

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Human Immunodeficiency Virus
Post-Exposure Prophylaxis Prescription Form

Manitoba
Health, Seniors and Active Living

℞

Patient Name: ..... Date: .....

Date of birth: ..... PHIN: ..... Gender: M / F

Address: .....

*** Prescriber to tick the checkbox of the applicable drug/s below. Use separate prescription for drug/s not shown.***

☐ **Tenofovir/Emtricitabine (Truvada®) 300/200 mg tablet** *Sig:* __1__ tablet by mouth once daily (Substitutions allowed)	**QTY:** ..... tablet/s **Refill/s:** ..... QTY in starter kit/s*: ..... tablets
☐ **Zidovudine/Lamivudine (Combivir®) 300/150 mg tablet** *Sig:* __1__ tablet by mouth twice daily (Substitutions allowed)	**QTY:** ..... tablet/s **Refill/s:** ..... QTY in starter kit/s*: ..... tablets
☐ **Zidovudine (Retrovir®) 100 mg capsule** *Sig:* ____ capsule/s by mouth twice daily (Substitutions allowed)	**QTY:** ..... capsule/s **Refill/s:** ..... QTY in starter kit/s*: ..... capsules
☐ **Lamivudine (3TC®) 150 mg tablet** *Sig:* (Substitutions allowed)	**QTY:** ..... tablet/s **Refill/s:** ..... QTY in starter kit/s*: ..... tablets
☐ **Raltegravir (Isentress®) 400 mg tablet** *Sig:* __1__ tablet by mouth twice daily (Substitutions allowed)	**QTY:** ..... tablet/s **Refill/s:** ..... QTY in starter kit/s*: ..... tablets
☐ **Lopinavir/Ritonavir (Kaletra®) 100/25 mg tablet** *Sig:* ____ tablet/s by mouth twice daily (Substitutions allowed)	**QTY:** ..... tablet/s **Refill/s:** ..... QTY in starter kit/s*: ..... tablets

Drug use: For post-exposure prophylaxis (PEP) to prevent infection subsequent to exposure to human blood and body fluids that may transmit human immunodeficiency virus (HIV)

FOR PHARMACY USE ONLY

This prescription is:

- ○ New prescription
- ○ Addition to previous prescription
- ○ Replace previous prescription
- ○ Begin after previous prescription complete

Additional dispensing information:

*Prescription VOID if total number of days equivalent of quantity taken or expected to be taken from any and all starter kits/s provided PLUS quantity prescribed (including any refills) exceed 28 days.

Prescriber Signature: .....

Prescriber Name: ..... M.D.

License No.: .....

Address: .....

.....

Tel.: ..... Fax: .....

[2]Not to be confused with the **HIV Post-exposure Prophylaxis Drug Order Form** (see APPENDIX C for link), which is used by providers for ordering the starter kits

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APPENDIX C

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Important Contact Numbers and Useful Web Links in Manitoba

<u>Important phone/fax numbers</u> (phone unless otherwise indicated)

Cadham Provincial Laboratory
204-945-6123 (phone); 204-786-4770 (fax)

Note on STAT testing(16)
Monday through Friday:

- STAT testing must be arranged through the appropriate Section of CPL prior to shipment.
- A requisition with the appropriate information and clearly marked STAT (a colored sticker is optimum) must accompany the specimen.
- Prior approval from CPL's on-call medical staff must be obtained for STAT viral testing.
- Prior approval must be obtained from CPL's medical staff for all remaining STAT testing, except for organ donor emergencies.

After 4:30 p.m., and on Weekends and Holidays (call back):

- Call Health Sciences Centre (HSC) paging at 204-787-2071.

Health Canada
First Nations Inuit Health Branch
204-918-5428 (Nursing Manager on call)

Health Links-Info Santé
204-788-8200 or Toll-free 1-888-315-9257

Health Sciences Centre
Pediatric Infectious Diseases

- Call HSC paging at 204-787-2071.

Interlake-Eastern Health

For occupational exposures (general public – non-regional staff and partners)
& all non-occupational exposures:
204-467-4781 (STI Coordinator)

For regional staff & partners:
Occupational Safety and Health Department
(204) 785-4717

Klinic Community Health Sexual Assault Crisis Line
204-786-8631 (in Winnipeg); 1-888-292-7565 (Toll Free in Manitoba); 204-784-4097 (TTY)

Manitoba Health, Seniors and Active Living
Communicable Disease Control
204-788-6737 (phone); 204-948-2190 (fax); after-hours: 204-788-8666 (MOH on call)

Manitoba HIV Program
204-940-6089 or 1-866-449-0165

Nine Circles Community Health Centre
204-940-6001

Northern Health

For community exposures:
204-679-2074 (Admin on call)

For occupational exposures:
204-623-9279 (IPC Manager)

Prairie Mountain Health

For community exposures:
204-622-2995

For occupational exposures:
204-578-2101

Southern Health
204-346-6260 (CD/Immunization Coordinator)

Viral Hepatitis Investigative Unit
204-787-3630

Winnipeg Regional Health Authority

For occupational exposures (general public – non-regional staff and partners)
& all non-occupational exposures:
204-940-3607 (MOH daytime on call);
after-hours (after 4 pm): 204-788-8666 (MOH evening on call)

For regional staff & partners:
Occupational and Environmental Safety & Health
204-926-8060

Useful web links

Cadham Provincial Laboratory Guide to Services 2015
https://www.gov.mb.ca/health/publichealth/cpl/docs/guide.pdf

Hepatitis B Endemic List
(From the Alberta Immunization Policy)
https://open.alberta.ca/dataset/aip/resource/121de497-de68-42f1-a1b9-868696932615/download/AIP-BP-Hepatitis-B-Endemic.pdf

HIV Post-exposure Prophylaxis Drug Order Form
(Form to use for ordering HIV PEP starter kits)
http://www.gov.mb.ca/health/publichealth/diseases/hiv.html (look under ***Forms***)

HIV Post-exposure Prophylaxis Pre-printed Prescription Form
(Form to use for prescribing additional drug supply over those provided in the starter kits)
http://www.gov.mb.ca/health/publichealth/diseases/hiv.html (look under ***Forms***)

Testing of Bodily Fluids and Disclosure Act
https://www.gov.mb.ca/health/publichealth/tbfd.html

Vaccines and Biologics Order Form
(Form to use for ordering HBV vaccines and/or HBIG)
http://www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf

NOTE: If clicking the link does not open the website, try copy-pasting the url to your browser.