Recommendations on the Management and Postexposure Prophylaxis of Needlestick Injury or Mucosal Contact to HBV, HCV and HIV

Scientific Committee on AIDS and STI (SCAS), and Infection Control Branch, Centre for Health Protection, Department of Health

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(a) to advise the Controller of the Centre for Health Protection (CHP) on the scientific basis for the prevention, care and control of HIV/AIDS and STI in Hong Kong;
(b) to develop recommendations and guidance regarding HIV/AIDS and STI in Hong Kong; and
(c) to keep under review local and international development of HIV/AIDS and STI.

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Background

Since publication in 2007 of this set of local guidelines on postexposure management following occupational exposure to blood-borne pathogens, new data and international guidelines¹ have emerged in regard to the use of HIV postexposure prophylaxis and schedule of subsequent serological testing. Although the basic principles of management remain largely unchanged, the Scientific Committee on AIDS and STI (SCAS), and the Infection Control Branch of the Centre for Health Protection consider it necessary to add the corresponding updates to these guidelines.

Guiding principles

2. As with the previous document, this set of revised guidelines is recommended according to the following principles:

(a) An integrated approach is taken by considering collectively the most important bloodborne infections, i.e. hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) (Annex I).

(b) Risk assessment and counselling constitute the basis of postexposure management which lead to specific options of postexposure prophylaxis (PEP) when appropriate. As such, case-by-case evaluation is crucial.

(c) Local perspectives as well as scientific evidence and international developments were taken into account in putting forth the recommendations.

Blood-borne infections and their transmission risks in the health care setting

3. HBV infection is still endemic in Hong Kong, although

seroprevalence of HBV surface antigen differs widely among major segments of the population. For example, it is low at 1.1% in new blood donors, but reaches 7.4% in antenatal mothers. Up to 25% of HBsAg carriers may eventually die of chronic liver diseases, principally hepatocellular carcinoma and cirrhosis. The risk of contracting HBV infection through occupational exposure ranges from 18% to 30%, depending on the type of exposure, the body fluid involved and the infectivity of the source. Specifically, percutaneous injuries with hollow-bored, blood-filled needles from a patient positive with HBeAg carry the highest risk of infection at 37-62%.

4. Between 70 and 80% of people infected with HCV results in chronicity, and a significant proportion of chronic HCV infection results in chronic hepatitis, cirrhosis and hepatocellular carcinoma in 10 to 30 years of time. Prevalence of anti-HCV positivity in new blood donors was below 0.1% in the last decade and it was estimated that some 0.2-0.3% of the population have been infected. HCV is not transmitted as efficiently as HBV. The estimated risk of contracting hepatitis C through needlestick injury involving HCV-infected blood is 1.8% (range 0-7%). In a meta-analysis, the risk of transmission was shown to be greater if the source was HCV RNA positive.

5. HIV infection has also been reported to occur in the health care setting. By December 2010, 57 confirmed and 143 possible cases of HIV transmission via occupational exposure had been reported to the US CDC.

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The average risks of HIV transmission after percutaneous and mucocutaneous exposure to HIV-infected blood were estimated to be 0.3% and 0.09% respectively. In Hong Kong, the prevalence of HIV in the adult population is <0.1%.

6. The prevention of HBV, HCV and HIV transmission in the health care setting depends on the practice of infection control measures based on the principles of standard precautions, provision of personal protective equipment and safety devices, and implementation of safer procedure, e.g. avoidance of needle recapping and sharps disposal in designated containers. The details of infection control practice, however, fall outside the scope of this document. Management after exposure occurs involves provision of first aid, reporting, risk assessment, counselling and additional procedures specific to individual pathogens implicated (Annex I). It is important that those responsible for management should familiarise themselves with the principles and procedures involved.

First Aid

7. Immediately following any exposure, whether or not the source is known to pose a risk of infection, the wound should be washed immediately and thoroughly with soap and water. Antiseptics are not necessary as there is no evidence of their efficacy. Wounds should not be sucked. For mucosal contact, such as spillage into the conjunctivae, the exposed part should also be washed immediately and liberally with clean running water. The exposed HCW should then seek medical advice for proper wound care and post-exposure management.

Reporting

8. The institution should ensure that a mechanism is in place and made known to all HCW to facilitate reporting and management of sharps injury and mucosal exposure in the occupational setting. Clear documentation and investigation of the circumstances of exposure are necessary. In addition, a surveillance system of exposure events should be set up with a view to avoidance of similar incidents. In this endeavour, however, safeguard of confidentiality is of the utmost importance since such exposures often occur in the presence of co-workers.
9. Until infection is ruled out, health care staff potentially exposed to HBV, HCV, or HIV infected blood should refrain from donating blood, plasma, organs, tissue or semen. Safer sex with condom is advisable.

Management of accidental exposure to HBV

10. The management of an incident of accidental exposure to HBV involves proper risk assessment, counselling tailored to the needs of individual client, and the prescription of postexposure prophylaxis as appropriate.

11. As a rule, for the best protection, all health care staff with potential risk of exposure to blood and body fluids are advised to receive hepatitis B vaccination as soon as possible for their own safety. Subjects with anti-HBs titre ≥ 10 mIU/mL 1-4 months after vaccine completion are considered as responders. Non-responders are those with no detectable anti-HBs and hypo-responders refer to those whose anti-HBs titre are between 0-10 mIU/mL. Both non- and hypo-responders should complete a second 3-dose vaccine series and retested at the completion of the second vaccine series. Non-responders to the initial 3-dose vaccine series have a 41% chance of responding to a second 3-dose series.

12. Though antibody levels fall gradually over time, those who have mounted an initial response following the 3-dose regimen could achieve effective protection upon a subsequent challenge, regardless of the titre of anti-HBs at the time of exposure. This is referred to as the anamnestic response.

13. The efficacy of hepatitis B immunoglobulin (HBIG) and HBV vaccine for postexposure protection in occupational exposure can be referenced from the scene in perinatal transmission. A single dose of HBIG lowers the infection rate of infants born to HBsAg positive mothers from 92% to 54% at 1 year. With multiple doses, HBIG becomes 70-75% effective. The efficacy

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of protection is further increased to 85-95% by adding a standard HBV vaccination regimen to HBIG.\textsuperscript{14}

14. The need for HBIG administration and HBV vaccination depends on the exposure, and HBV status of the source and the exposed. (Annex II) Individuals who lack HBsAg and have not previously developed satisfactory immune response to the virus may be susceptible. They could be offered HBIG for immediate protection upon significant exposure to HBV. An individualised approach founded on risk assessment is recommended for the management of a health care worker with unknown response to hepatitis B vaccination, one who has been exposed to an unknown source or a source with unknown hepatitis status. In such circumstances, the HBV status of the source and/or the exposed should be determined where appropriate. The exposed person may be managed as in the case of an injury involving an HBsAg positive source person if the HBV status of the source cannot be ascertained.

Management of accidental exposure to HCV

15. One principle of HCV post-exposure management is to identify those with acute HCV infection and refer them to specialists for further evaluation. At baseline, blood specimen for HCV antibody should be obtained for both the source (with informed consent) and the exposed. The specimen from the former should be tested, while that from the latter should be kept by the laboratory and stored for at least one year. For the exposed, the test is performed on another specimen obtained at 6 months, and 12 months if the source is HIV-HCV co-infected. If positive, the baseline specimen from the exposed is retrieved for testing to diagnose seroconversion. (Annex III)

16. If the source person is known to be HCV infected or is an injecting drug user with unknown HCV status, baseline ALT should be considered for the exposed. Furthermore, HCV Ab, ALT and HCV-RNA should be determined between 6 to 8 weeks in order to capture those who develop acute hepatitis. Those who do should be promptly referred to specialists for further evaluation.

17. Currently, there is no effective vaccine or chemoprophylactic

\textsuperscript{14} Wong VCW, Ip HMH, Reesink HW, et al. Prevention of the HBsAg carrier state in newborn infants of mother who are chronic carriers of HBsAg and HBeAg by administration of hepatitis B vaccine and hepatitis immunoglobulin: double blind randomised placebo-controlled study. Lancet 1984;1:921-6.
agent for preventing HCV infection after accidental occupational exposure. However, treatment of acute infection (interferon or pegylated interferon, with or without ribavirin) may prevent progression to chronic HCV infection. The sustained virological response may be up to 90% or higher when treatment is started within 12 weeks of symptom onset. Nevertheless, it should be borne in mind that some 26% of patients with acute HCV infection would have spontaneous resolution without treatment. As of now, the optimal regimen, dose and time to initiate therapy remain undefined. Therefore, patients who have acute hepatitis C should be promptly evaluated by experts in this field.

Management of accidental exposure to HIV

18. The issue of PEP should be considered after an exposure that has the potential risk of HIV infection. Initial assessment should include the type of body fluid or substance involved, the route and severity of the exposure and the likelihood of HIV infection in the source patient.

19. Occupational injuries may be divided into: (a) percutaneous exposure (from needles, instruments, bone fragments, human bite with breach of skin, etc); (b) exposure via broken skin (abrasions, cuts, eczema etc); and (c) exposure via mucous membranes including the eye.

20. In addition to blood and visibly bloody body fluids, potentially infectious fluids include cerebrospinal fluid, synovial fluid, pleural, peritoneal fluid, pericardial fluid, and amniotic fluid. Although semen and vaginal secretions are also potentially infectious, these are not normally implicated in the health care setting. Faeces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus are not considered infectious unless they are visibly bloody.

21. It has been shown that some features of the accident were associated with a higher potential of seroconversion after percutaneous exposure to HIV-infected blood. These included: (a) injury with a device

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visibly contaminated with the patient’s blood; (b) a procedure involving a
needle which has been placed in a vein or artery; (c) deep injury; and (d)
exposure from source patients with AIDS or high plasma viral burden.19

22. A person infected with HIV may not be aware of his or her own
HIV serostatus. Therefore, the exposed person should always be encouraged to
have baseline blood taken for HIV antibody after receiving pre-test counselling
and giving consent.

23. If possible and with informed consent, the HIV status of the
source person should be assessed. A validated HIV rapid test, such as the
OraQuick® test, followed by Western blot for confirmation if positive may be
considered. Its role in reducing anxiety of the exposed and avoiding
unnecessary antiretroviral prophylaxis has been shown.20

24. Nevertheless, the HIV status of source person is not always
obtainable. Therefore, the likelihood of HIV infection has to be estimated
based on clinical clues in the setting: (a) HIV prevalence of the community
group which the source belongs to (b) HIV-related risk behaviours, e.g.
unprotected sex, multiple sex partners, needle-sharing for drug injection; (c)
HIV-related illnesses, e.g. Pneumocystis jiroveci pneumonia, oral thrush etc.

25. If the source person is HIV-infected and the exposure event
constitutes a significant risk of HIV transmission, antiretroviral
chemoprophylaxis should be considered. Findings from animal studies
suggested that antiretroviral drugs would not be effective if begun more than 72
hours after exposure.21 Therefore it should be initiated as soon as possible,
preferably within 1-2 hours of exposure, and continued for 4 weeks. Delayed
initiation after 72 hours may be considered only on an exceptional basis if the
likelihood of benefit clearly outweighs the risks inherent in taking antiretroviral
medications and the possibility of antiretroviral resistance should transmission
occur.

19 Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health-
20 Kallenborn JC, Price TG, Carrico R, Davidson AB. Emergency department management of
93.
21 Tsai CC, Emau P, Follis KE, et al. Effectiveness of post-inoculation. (R)-9-(2-
phosphonylmethoxypropyl)adenine treatment for prevention of persistent simian immunodeficiency
virus SIVmac infection depends critically on timing of initiation and duration of treatment. J Virol
26. A combination of at least three drugs should be used for PEP if indicated. No comparative trial data on efficacy are available for different PEP regimens. As far as nucleoside reverse transcriptase inhibitor (NRTI) is concerned, zidovudine may be the antiretroviral with the most extensive evidence on risk reduction of HIV transmission following occupational exposure. However, recent studies have also supported the use of other NRTIs, such as tenofovir and emtricitabine, as a component of PEP, demonstrating good tolerability and safety.  

27. Other than the 2-NRTI backbone, a ‘third’ drug is needed to constitute a PEP regimen. Based on the experience in management of established HIV infection and the relative rarity of primary resistance in Hong Kong, ritonavir-boosted protease inhibitor (PI) is generally preferred. The newly available ritonavir tablet and PI such as darunavir make this option more tolerable and convenient than before.

28. The ‘third’ drug may theoretically be a non-nucleoside reverse transcriptase inhibitor (NNRTI). However, nevirapine is contraindicated for PEP due to an unacceptably high risk of hepatotoxicity in HIV negative subjects. Efavirenz, another commonly used NNRTI in established HIV infection, is also associated with neuropsychiatric effects and with potential teratogenicity in pregnant women. Recently available, the newer NNRTIs including etravirine and rilpivirine are more tolerable. They may be considered as alternatives if available.

29. Recently, the use of integrase inhibitor (II) together with two NRTI has also gained acceptance because of remarkable tolerance and the hitherto low prevalence of primary II resistance.

30. Fixed-dose combination antiretrovirals are more expensive but preferred if available. Table 1 summarises information on the commonly used antiretrovirals. It is noted that antiretroviral therapy is a rapidly changing field and the most updated information should be obtained before prescription. Experts in HIV medicine should be consulted if the source person is suspected

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to have antiretroviral resistance.

31. Timely assessment and treatment are keys to success of PEP. The Emergency Department is often the first place where an HCW presents after occupational exposure. It is advisable that the Department make a decision on the appropriate starter PEP regimen(s) to stock and devise its own management protocol. Treatment should be started as soon as possible if indicated by a rapid assessment. Early referral is then made for follow up by physicians with more expertise in antiretroviral therapy.

32. Many HCWs who take PEP experience adverse effects and a substantial proportion could not complete the full 4-week course of treatment. Therefore, they should be carefully followed. Baseline and serial blood tests are indicated, adverse effects of antiretrovirals are expectantly managed, and counselling and support given to enhance adherence.

33. Follow-up HIV antibody tests should normally be performed at 3 to 6 months. Additional, earlier testing may also be needed to alleviate anxiety or to evaluate possible acute retroviral syndrome. Testing at a longer interval may also be considered, such as to detect delayed HIV seroconversion in those who have become infected with HCV after exposure to a source co-infected with HIV and HCV.

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Annex I

**Flow chart: General algorithm of management of occupational exposure to HBV, HCV and HIV**

1. **Occupational exposure**
2. **First aid**
3. **Reporting**
4. **Risk assessment**
5. **Exposure evaluation**
6. **Source & exposed evaluation**
   - If risk is established, perform baseline blood testing for HBV#, HCV* (see Annex III) and HIV for exposed and source
7. **Choice of postexposure prophylaxis regimen**
8. **Follow-up for laboratory testing & clinical assessment**

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# Testing for HBsAg/Anti-HBs may be omitted if the exposed is known to be a responder to the HBV vaccine or have natural immunity against HBV

* Baseline specimens of exposed are often initially stored, and retrieved for testing when a subsequent specimen tests positive
Annex II

Postexposure prophylaxis against HBV infection

<table>
<thead>
<tr>
<th></th>
<th>POSTEXPOSURE PROPHYLAXIS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Previously Vaccinated</td>
<td>Unvaccinated</td>
</tr>
<tr>
<td></td>
<td>Known Responders</td>
<td>Known Hypo-/ Non-responders</td>
</tr>
<tr>
<td>I. SOURCE KNOWN</td>
<td>(a) HBsAg + ve</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>(b) HBsAg – ve</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>(c) HBsAg unknown</td>
<td>Nil</td>
</tr>
<tr>
<td>II. SOURCE UNKNOWN</td>
<td>Nil</td>
<td>as in I(a)</td>
</tr>
</tbody>
</table>

N.B.

1. Blood should be taken from the source and the exposed person whenever possible and indicated, particularly if the latter has not received hepatitis B vaccination before.
2. Where indicated, one dose of HBIG (dosage as recommended by the manufacturer) should be given within 7 days, preferably within 24 hours of exposure. Attention is drawn to the need of blood taking before administering HBIG.
3. Hepatitis B vaccination (HB Vac) is offered for (a) health care workers (HCW) who have not received HB vaccination before, and (b) HCW who are hypo-/non-responder to one previous course of HB vaccine. HB Vac is given IM into the deltoid at a dose of 10ug (B-Hepavac II) or 20ug (Engerix-B). The second and the third doses are to be given one and six months afterwards.
4. HBIG and HBV vaccine can be given together but at different sites. If HBIG has been given, the first dose of vaccine can be delayed for up to 1 week after exposure, pending results of serological test. If HB Vac is started, the second dose of HBIG can be omitted unless the HCW is a known hypo-/non-responder.

* For a previously vaccinated person with unknown response, he/she should be tested for anti-HBs
  • no treatment is required if anti-HBs is positive
  • HBIG ± HBV vaccine is offered if anti-HBs is negative
Flow chart: management of accidental exposure to hepatitis C

Annex III

Risk established for exposure

Source is known HCV positive, or known IDU with unknown HCV status

Baseline HCV Ab*

Baseline HCV Ab* + ALT

6-8 wk: HCV RNA, ALT, HCV Ab

-ve

6 months: HCV Ab

-ve but if source is HIV +ve

Consider 12 months: HCV Ab

Referral to specialist for further evaluation ± treatment

-ve, negative
+ve, positive

* Baseline specimens are often initially stored and retrieved for testing when a subsequent specimen tests positive
Table 1: Some commonly used first-line antiretrovirals for HIV PEP

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Antiretrovirals</th>
<th>Dosage</th>
<th>Major adverse effects and precautions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRTI</td>
<td>Combivir (fixed dose combination of zidovudine 300mg + lamivudine 150mg)</td>
<td>1 tab bd</td>
<td>bone marrow suppression (anaemia, neutropaenia); GI intolerance; headache; insomnia; myopathy; lactic acidosis &amp; hepatic steatosis</td>
</tr>
<tr>
<td></td>
<td>Truvada (fixed dose combination of tenofovir 300mg + emtricitabine 200mg)</td>
<td>1 tab qd</td>
<td>GI intolerance; headache; rarely renal insufficiency and Fanconi syndrome; rarely lactic acidosis &amp; hepatic steatosis</td>
</tr>
<tr>
<td>PI</td>
<td>Kaletra® (lopinavir 200 mg + ritonavir 50 mg)</td>
<td>2 tablets bd</td>
<td>GI upset, especially diarrhoea, elevated transaminases; hyperglycaemia; lipid abnormalities, arrhythmia, prolonged QT, risk of drug-drug interaction</td>
</tr>
<tr>
<td>Ritonavir-boosted</td>
<td>Ritonavir 100mg qd + Atazanavir 300mg qd</td>
<td></td>
<td>Indirect hyperbilirubinaemia; nephrolithiasis; hyperglycaemia; GI intolerance; prolonged QT; risk of drug-drug interaction; administer with food; antacid, H2 blockers, and proton pump inhibitors may reduce absorption</td>
</tr>
<tr>
<td>Ritonavir-boosted</td>
<td>Ritonavir 100mg qd + Darunavir 800mg qd</td>
<td></td>
<td>GI intolerance; headache; hepatitis; rash; prolonged QT; risk of drug-drug interaction</td>
</tr>
<tr>
<td>II</td>
<td>Raltegravir</td>
<td>400mg bid</td>
<td>Well tolerated; mild GI intolerance; headache; myositis; rash; affected by UGT1A1 inducers such as rifampicin.</td>
</tr>
</tbody>
</table>

General composition of PEP: 2 NRTI + PI or II
NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI protease inhibitor; II, integrase inhibitor
*Please also refer to full prescribing information