



**衛生防護中心**  
Centre for Health Protection

**Recommendations on the Postexposure  
Management and 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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**September 2007**

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***has the following terms of reference :***

- (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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**Correspondence**

Address : 5/F, Yaumatei Jockey Club Clinic  
145 Battery Street, Yaumatei, Kowloon, Hong Kong  
Tel : (852) 2304 6100  
Fax : (852) 2337 0897  
E-mail : [aca@dh.gov.hk](mailto:aca@dh.gov.hk)

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

## Background

Occupational exposure to blood-borne pathogens is a well-recognised hazard to health care workers (HCW). Adherence to standard infection control practices is the best way to prevent blood-borne infections in the health care setting. However, accidental exposure still happens. In 2005, the Centre for Health Protection (CHP) conducted a survey to examine the local incidence of sharps injury or mucocutaneous exposure to blood or body fluids in the health care setting. Of 3,090 HCWs who participated in the survey, 151 (4.89%) had sustained occupational injuries in the preceding 12 months [unpublished data].

2. On the prevention side, recommendations have been made on the infection control practice for HIV transmission in health care settings.<sup>1</sup> Local recommendations on post-exposure management were also made in 2003.<sup>2</sup> A two-tier approach was adopted where lesser exposures would be managed by a double-nucleoside regimen. However, as new and less toxic agents became available and experience with them has grown, the Committee now favours standard highly active antiretroviral therapy if chemoprophylaxis were indicated.

3. At the same time, there is tendency toward more active management of acute hepatitis C after accidental exposure, although what constitutes the most appropriate treatment remains controversial. Nevertheless, consensus has been achieved that acute hepatitis C should be referred to experts in the field in a timely manner.

4. Against these backgrounds, the Scientific Committee on AIDS and STI, and the Infection Control Branch of CHP have revised the local guidelines on postexposure management.

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<sup>1</sup> Scientific Committee on AIDS and STI, Centre for Health Protection, Dept of Health. Recommendations on infection control practice for HIV transmission in health care settings, Jan 2005. (Available at <http://www.aids.gov.hk>. Accessed 2 Jan, 2007).

<sup>2</sup> Scientific Committee on AIDS, Scientific Working Group on Viral Hepatitis Prevention. Recommendations on the management and postexposure prophylaxis of needlestick injury or mucosal contact to HBV, HCV and HIV, Mar 2003. (Available at <http://www.aids.gov.hk>. Accessed 2 Jan, 2007).

## Guiding principles

5. 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

6. HBV infection is endemic in Hong Kong. About half of the adult population above 40 years of age have been infected. Eight percent of the population are carriers, of whom up to 25% may eventually die of chronic liver diseases, principally hepatocellular carcinoma and cirrhosis.<sup>3</sup> 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.<sup>4</sup> Specifically, percutaneous injuries with hollow-bored, blood-filled needles from a patient positive with HBeAg carry the highest risk of infection at 37-62%.<sup>5</sup>

7. 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.<sup>6</sup> 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

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<sup>3</sup> Chu CM. Natural history of chronic hepatitis B virus infection in adults with emphasis on the occurrence of cirrhosis and hepatocellular carcinoma. *J Gastroenterol Hepatol* 2000;15(Suppl):e25-30.

<sup>4</sup> Pruss-Ustun A, Raptiti E, Hutin Y. Sharps injuries: global burden of disease from sharps injuries to health-care workers. Geneva, World Health Organisation 2003 (WHO Environmental Burden of Disease Series, No 3). (Available at: [http://www.who.int/quantifying\\_ehimpacts/publications/en/sharps.pdf](http://www.who.int/quantifying_ehimpacts/publications/en/sharps.pdf). Accessed 4 July, 2007)

<sup>5</sup> Werner BG, Grady GF. Accidental hepatitis-B-surface-antigen-positive inoculations: use of e antigen to estimate infectivity. *Ann Intern Med* 1982;97:367-9.

<sup>6</sup> Yatshhashi H, Yano M. Natural history of chronic hepatitis C. *J Gastroenterol Hepato* 2000;15(Suppl):E111-6.

have been infected.<sup>7</sup> 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%).<sup>8</sup> In a meta-analysis, the risk of transmission was shown to be greater if the source was HCV RNA positive.<sup>9</sup>

8. HIV infection has also been reported to occur in the health care setting. By June 2000, 57 confirmed and 138 possible cases of HIV transmission via occupational exposure had been reported to the US CDC.<sup>10</sup> 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%.

9. 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

10. 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.

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<sup>7</sup> Special Preventive Programme, Centre for Health Protection, Department of Health. Surveillance of viral hepatitis in Hong Kong – 2005 update report. (Available <http://www.hepatitis.gov.hk>. Accessed 2 Jan, 2007).

<sup>8</sup> US CDC. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR 1998;47(RR19):1-39.

<sup>9</sup> Dore GJ, Kaldor JM, McCaughan GW. Systematic review of role of polymerase chain reaction in defining infectiousness among people infected with hepatitis C virus. BMJ 1997;315:333-7.

<sup>10</sup> US CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. MMWR 2001;50(RR-11).

## Reporting

11. 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.

## Counselling

12. 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

13. 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.

14. 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  $\geq 10$  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.<sup>11</sup>

15. 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.

16. The efficacy of hepatitis B immunoglobulin (HBIG) and HBV

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<sup>11</sup> Scientific Working Group on Viral Hepatitis Prevention, Dept of Health. Recommendations on hepatitis B vaccination regimens in Hong Kong. Mar 2004. (Available at <http://www.hepatitis.gov.hk>. Accessed 3 Jan, 2007)

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.<sup>12</sup> With multiple doses, HBIG becomes 70-75% effective.<sup>13</sup> The efficacy of protection is further increased to 85-95% by adding a standard HBV vaccination regimen to HBIG.<sup>14</sup>

17. 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**

18. 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, HCV antibody should be tested for both the source (with informed consent) and the exposed. Sera should also be stored for at least one year. For the exposed, testing should be repeated at 6 months, and 12 months if the source is HIV-HCV co-infected. (Annex III)

19. 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 in addition to HCV Ab. 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.

20. Currently, there is no effective vaccine or chemoprophylactic

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<sup>12</sup> Beasley RP, Hwang LY, Lee GC, et al. Efficacy of hepatitis B immune globulin for prevention of perinatal transmission of the hepatitis B virus carrier state: final report of a randomized double-blind, placebo-controlled trial. *Hepatology* 1983;3:135-41.

<sup>13</sup> US CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the US through universal childhood vaccination: recommendation of the Immunization Practices Advisory Committee (ACIP). *MMWR* 1991;40(RR-13):1-25.

<sup>14</sup> Wong VCW, Ip HMM, 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. Data from the literature, however, suggest that therapy (interferon or pegylated interferon, with or without ribavirin) may prevent chronic HCV infection when administered to patients with acute hepatitis.<sup>15</sup> The sustained virological response may be up to 94-100% when treatment is started within 24 weeks of symptom onset.<sup>16,17,18,19</sup> Nevertheless, it should be borne in mind that some 26% of patients with acute HCV infection would have spontaneous resolution without treatment.<sup>20</sup> As of now, the optimal regimen, dose and time to initiate therapy remain undefined.<sup>21</sup> Therefore, patients who have acute hepatitis C should be promptly evaluated by experts in this field.

## Management of accidental exposure to HIV

21. 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.

22. 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.

23. 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.

24. It has been shown that some features of the accident were associated with a higher potential of seroconversion after percutaneous

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<sup>15</sup>Puro V, Carli D, Cicalini S, et al. European recommendations for the management of healthcare workers occupationally exposed to hepatitis B virus and hepatitis C virus. *Eurosurveillance* 2005;10:10-12.

<sup>16</sup>Kamal SM, Moustafa KN, Chen J, et al. Duration of peginterferon therapy in acute hepatitis C: a randomized trial. *Hepatology* 2006;43:923-31.

<sup>17</sup>Snatantonio T, Fasano M, Sinisi E, et al. Efficacy of a 24-week course of PEG-interferon  $\alpha$ -2b monotherapy in patients with acute hepatitis C after failure of spontaneous clearance. *J Hepatol* 2005;42:329-33.

<sup>18</sup>Ogata K, Ide T, Kumashiro R, et al. Timing of therapy and sources of infection in patients with acute hepatitis C. *Hepatology Res* 2006;34:35-40.

<sup>19</sup>Nomura H, Sou S, Tanimoto H, et al. Short-term interferon- $\alpha$  therapy for acute hepatitis C: a randomized controlled trial. *Hepatology* 2004;39:1213-9.

<sup>20</sup>Micallef JM, Kaldor JM and Dore GJ. Spontaneous viral clearance following acute hepatitis C infection: a systemic review of longitudinal studies. *J Viral Hep* 2006;13:24-41.

<sup>21</sup>Alberti A, Boccardo S, Vario A and Benvegnù L. Therapy of acute hepatitis C. *Hepatology* 2002;36(Suppl 1):S195-S200.

exposure to HIV-infected blood. These included: (a) injury with a device 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.<sup>22</sup>

25. 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.

26. 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.<sup>23</sup>

27. 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.

28. 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.<sup>24</sup> 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.

29. To date, zidovudine is the only drug for which there is evidence of a reduction in risk of HIV transmission following occupational exposure and it continues to be a reasonable choice as a component of PEP. However, experience with treatment of established HIV infection and prevention of

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<sup>22</sup> Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health-care workers after percutaneous exposure. *N Engl J Med* 1997;337:1485-90.

<sup>23</sup> Kallenborn JC, Price TG, Carrico R, Davidson AB. Emergency department management of occupational exposures: cost analysis of rapid HIV test. *Infect Control Hosp Epidemiol* 2001;22:289-93.

<sup>24</sup> 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 SIV<sub>mne</sub> infection depends critically on timing of initiation and duration of treatment. *J Virol* 1998;72:4265-73.

mother-to-child transmission strongly suggested that highly active antiretroviral treatment (HAART) comprising at least three drugs would be more efficacious for PEP than single drugs or double combination. Therefore, it is recommended that HAART should be used for PEP if indicated.

30. The antiretroviral composition for PEP should be dictated by toxicity profile and the possibility of drug resistance. Nevirapine, for example, is contraindicated for PEP due to an unacceptably high risk of hepatotoxicity in HIV negative subjects.<sup>25</sup> The other non-nucleoside reverse transcriptase inhibitor, efavirenz, is not favoured either, because of generally poor tolerability and potential teratogenicity in pregnant women.

31. Based on the experience in management of chronic HIV infection, ritonavir-boosted lopinavir (co-formulated as Kaletra®) combined with 2 nucleoside reverse transcriptase inhibitors such as ZDV and lamivudine is currently preferred because of potent antiretroviral activity and the relative rarity of resistance emergence. Nevertheless, other protease inhibitors that have been used in HIV infection with success, such as indinavir, with or without ritonavir, may also be selected. Nevertheless, indinavir is generally difficult to tolerate. Table 1 summarises information on the two commonly used regimens. It is noted that antiretroviral therapy is a rapidly changing field and the most update information should be obtained before prescription. Experts in HIV medicine should be consulted if the source person is suspected to have antiretroviral resistance.

32. Timely assessment and treatment are the keys to success of PEP. The Emergency Department is often the first place where an HCW presents after occupational exposure. It is advisable that a starter pack of antiretrovirals be stocked for immediate use. The physician in the Emergency Department may initiate antiretroviral chemoprophylaxis and then refer to physicians with more expertise in antiretroviral therapy for follow up of therapy.

33. Many HCWs who take PEP experience adverse effects and a substantial proportion could not complete the full 4-week course of treatment.<sup>26</sup> 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.

34. Follow-up HIV antibody tests should normally be performed at 6 months. A test earlier at 3 months is optional. Additional testing at 12 months may be considered to detect delayed HIV seroconversion for those who (1) have taken PEP; or (2) have become infected with HCV after exposure to a

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<sup>25</sup> US CDC. Serious adverse events attributed to nevirapine regimens for postexposure prophylaxis after HIV exposure – worldwide, 1997-2000 MMWR 2001;49:1153-7.

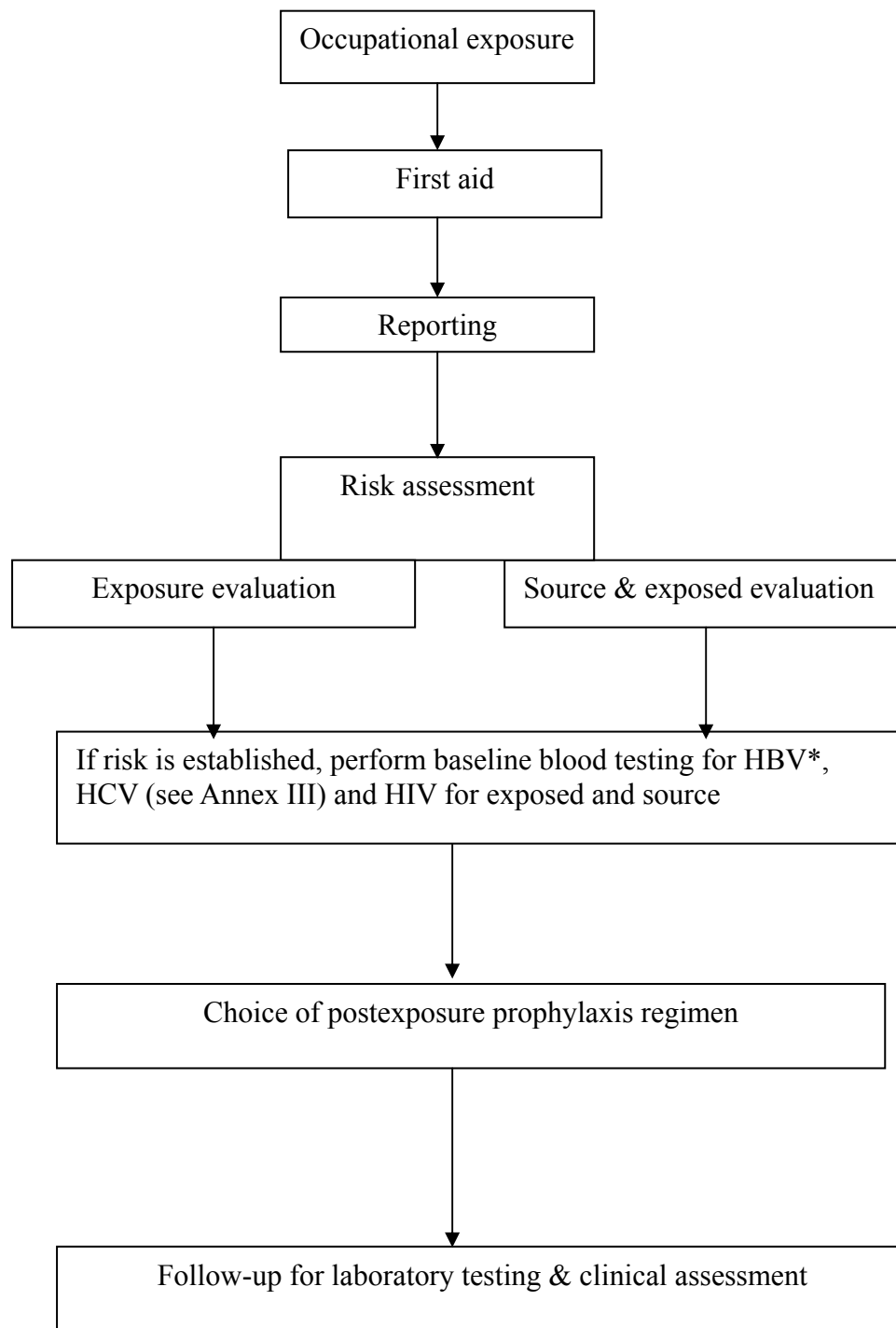
<sup>26</sup> Parkin JM, Murphy M, Anderson J et al. Tolerability and side-effects of post-exposure prophylaxis for HIV infection. Lancet 2000;335:722-23.

source co-infected with HIV and HCV.

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



**\*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**

**Postexposure prophylaxis against HBV infection**

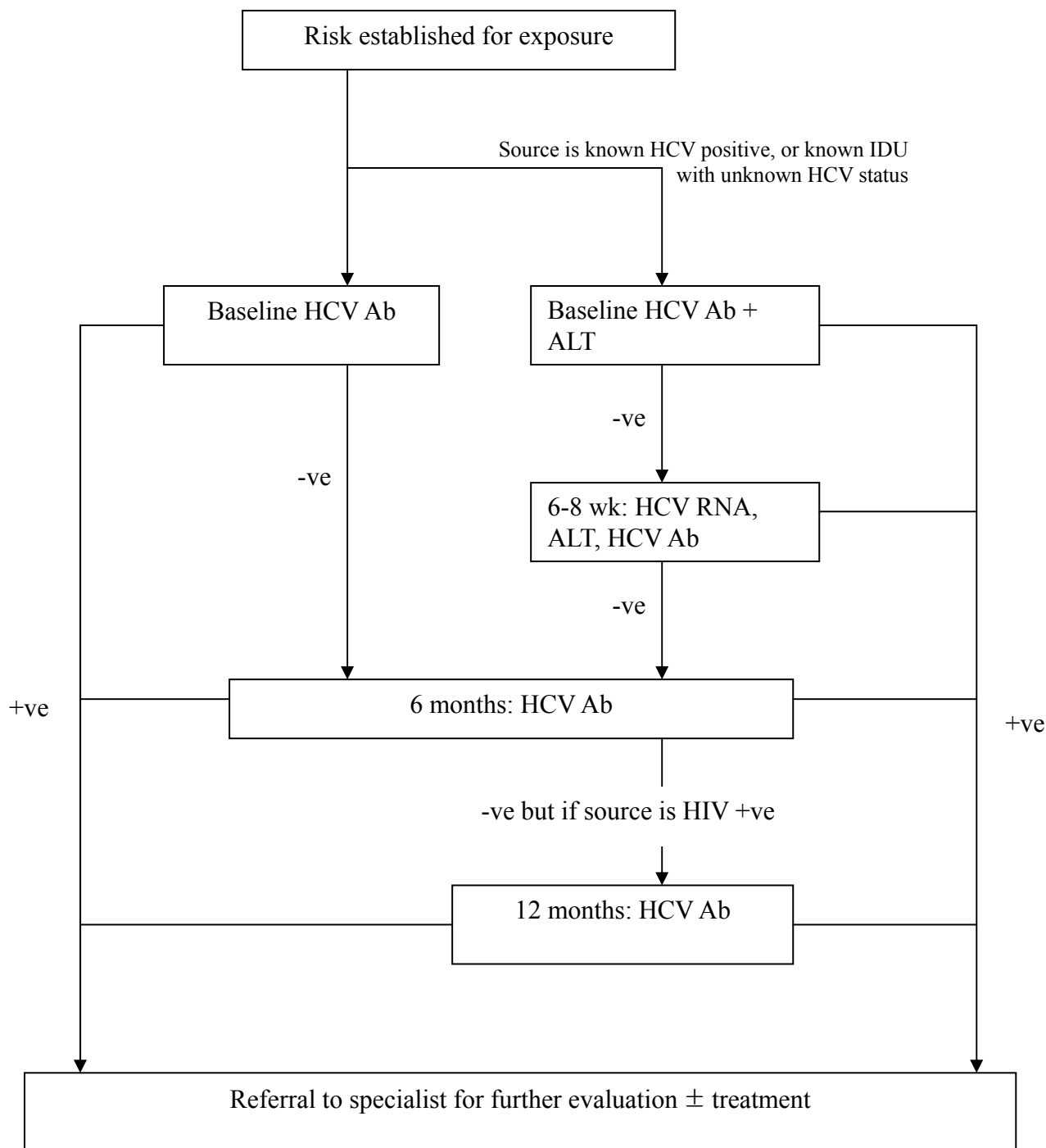
	POSTEXPOSURE PROPHYLAXIS				
	Previously Vaccinated			Unvaccinated	
	<i>Known Responders</i>	<i>Known Hypo-/Non-responders</i>	<i>Unknown Response</i>	<i>HBsAg -ve AND anti-HBs -ve</i>	<i>HBsAg +ve OR anti-HBs +ve</i>
<b>I. SOURCE KNOWN</b>					
(a) HBsAg + ve	Nil	HBIG within 24 hours; repeat after 1 month	Dependent on anti-HBs* status of exposed person	HBIG + HB Vac	Nil
(b) HBsAg – ve	Nil	Nil	Nil	HB Vac	Nil
(c) HBsAg unknown	Nil	Dependent on source HBsAg status	Dependent on anti-HBs* status of exposed person	HBIG + HB Vac, or HB Vac; depending on HBsAg status of source	Nil
<b>II. SOURCE UNKNOWN</b>	Nil	as in I(a)	as in I(a)	as in I(a)	Nil

**N.B.**

- 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.
- 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.
- 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.
- 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**

-ve, negative  
+ve, positive

**Table 1: Common first-line antiretroviral regimens**

<b>Regimens</b>	<b>Dosage</b>	<b>Major adverse effects</b>
Combivir®* and Kaletra®	<ul style="list-style-type: none"> <li>• Combivir 1 tab bid</li> <li>• Kaletra 2 tablets bid, or 3 capsules bid with food</li> </ul>	<ul style="list-style-type: none"> <li>• zidovudine → bone marrow suppression (anaemia, neutropaenia); GI intolerance, headache; insomnia; myopathy; rarely lactic acidosis &amp; hepatic steatosis</li> <li>• lamivudine → minimal toxicity; rarely pancreatitis, lactic acidosis &amp; hepatic steatosis</li> <li>• Kaletra → GI upset, elevated transaminases; hyperglycaemia; lipid abnormalities</li> </ul>
Combivir and indinavir	<ul style="list-style-type: none"> <li>• Combivir 1 tab bid</li> <li>• Indinavir 800mg q8h on empty stomach, OR (indinavir 800 mg + ritonavir 100mg) bid</li> </ul>	<ul style="list-style-type: none"> <li>• Indinavir → GI intolerance; nephrolithiasis; hyperglycaemia; joint pain; alopecia; lipid abnormalities. Fluid intake of ≥ 1.5L/d is recommended.</li> </ul>

\* Combivir tablet is a fixed dose combination of zidovudine 300mg + lamivudine 150mg and may be replaced by prescribing its individual components