WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II
(BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

TOOL "D" TO ASSESS THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN), World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, Geneva 27, Switzerland 1211. Fax +41 22 791 4836. E-mail: sign@who.ch.

Intended use and proposed timeline for this document	
Preparation of draft 1 by selected consultants	February 22, 2000
Review of the draft 1 by a group of experts and preparation of draft 2	April 30th, 2000
Review of draft 2 by workshop participants to prepare draft 3	May 31st, 2000
Field testing of draft 3 in few countries to prepare draft 4	September 1st, 2000
Wider dissemination of draft 4 for broad use and ongoing feedback	2000-2002
Preparation of a final version after two years of feedback from the field	End of 2002

INTRODUCTION

Injections have been associated with adverse events, including abscesses, [1] infections with bloodborne pathogens, [2] poliovirus associated provocation paralysis, [3] oral polio vaccine-associated provocation paralysis, [4] and paralyses secondary to sciatic nerve lesions. [5] Among these adverse events, infections with bloodborne pathogens, including HBV, HCV, and HIV are associated with the heaviest burden of diseases and deaths. [6,78,9,10] However, that burden is not immediately apparent since the initial phase of infection with bloodborne pathogens is frequently asymptomatic. Thus, epidemiological studies should conducted locally to assess the association between injections and infections and to provide the evidence upon which policies for safe and appropriate use of injections can be based.

PURPOSE OF THE TOOL

The purpose of this tool is to provide suggestions regarding methods to conduct an initial assessment of the association between injections and infections.

CONDUCTING AN INITIAL ASSESSMENT OF THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS

Methods are available regarding abscesses and infections with bloodborne pathogens.

ABSCESSES

Caution is advised when using abscesses as an indicator of injection safety. First, abscesses do not represent the majority of the burden of disease associated with unsafe injection practices. Second, the breaks in infection control practices that may cause abscesses may differ from the breaks in infection control practices that may lead to transmission of bloodborne pathogens (e.g., abscesses may result from a failure to decontaminate the skin which may bear no substantial risk of cross infection with bloodborne pathogens). Finally, there is little experience regarding the feasibility and usefulness of abscess surveillance.

When abscess surveillance is conducted, it should be conducted in an exploratory way so that experience can be recovered regarding the feasibility and usefulness of such a system. If possible, abscess surveillance should be conducted in conjunction with information collection regarding the incidence of injection-associated infections with bloodborne pathogens so that the relationship between the incidence of injection-associated abscesses and the incidence of injection-associated infection with bloodborne pathogens can be assessed.

Objectives

The objectives of studies to assess the association between injections and abscesses are to:

1) Estimate the incidence of injection-associated abscesses in a population;

2) Identify the type of injections that lead to injection-associated abscesses.

Case definition

An abscess is defined as a subcutaneous collection of pus that develops within two weeks at the site of an injection, excluding other potential inoculation modes (e.g., injuries, surgery).

Study design

Stimulated passive surveillance

Population under surveillance

Because a population-based estimate of the incidence of abscesses is needed, surveillance data should be linked to a well-defined population base of known population size. This population base may be:

1) Exhaustive (e.g., all healthcare facilities to cover the population of a district or a country);

2) Sentinel (e.g., selected healthcare facilities that capture a well-defined reference population base. Taken together, these well-defined population bases constitute a sentinel group that can be used to infer what the situation may be for the total population).

Data collection

Healthcare workers can collect information on abscess report forms (Instrument 1, Sample case report form for abscess surveillance, Page 11) distributed in healthcare facilities for prospective or retrospective surveillance.

Data analysis

The number of abscesses should be added and divided by the total area population size for the calculation of a population-based annual incidence [1].

INFECTIONS WITH BLOODBORNE PATHOGENS

Objectives

For bloodborne pathogens, the objectives of studies to assess the association between infections and injections are to:

1) Determine whether infections with bloodborne pathogens are associated with injections;

2) Estimate the strength of the association between infection with bloodborne pathogens and injections;

3) Estimate the proportion of new cases of infection with bloodborne pathogens that may reasonably be attributable to unsafe injection practices (i.e., by the calculation of the population attributable risk [11]).

Study population

Study population should be chosen so that the conclusions of the study can be generalized. The study population may be the general population (e.g., residents of a certain area) or subgroups of particular importance (e.g., hospitalized patients, children). Use of individuals who can be accessed and studied easily but cannot be identified as a population group should be avoided (e.g., blood samples available from a bank of serum).

Choice of a pathogen

The bloodborne pathogen(s) of interest should be chosen according to the incidence and prevalence of the various bloodborne pathogens in the study area. In most cases, the bloodborne pathogen of interest will be HBV, HCV, or HIV as injection-associated infections with other bloodborne pathogens (e.g., viral haemorrhagic fevers) usually occur as time-limited outbreaks.

Choice of a type of infection

Strengths and weaknesses of the use of recent versus past or present infections for studies assessing the association between injections and infections with bloodborne pathogens are summarized in Table 1.

Table 1: Strengths and weaknesses of use of recent versus past or present infections for epidemiological studies

	Types of infection to be studied	
	Recent (incident)	**Past or present (prevalent)**
Logistical feasibility	Difficult	Easier
Disease frequency requirement	High incidence	High prevalence
HBV infection studies	Marker of recent infection available	Marker of chronic infection available
HCV infection studies	Marker of recent infection not available	Marker of chronic infection available
HIV infection studies	Marker of recent infection available but clinical syndrome aspecific	Marker of chronic infection available
Referent exposure period	Based upon incubation of infection	Lifetime (or surrogate)
Quality of scientific evidence	Best	Approximate
Estimation of population attributable risk	Best	Approximate

Recent infections
Use of recent infections is adapted to high incidence situations. Because the exposure of interest has occurred in the recent past, studies of recent (incident) infections (in cohort or case-control studies) are methodologically more appropriate, provide better epidemiological evidence, and allow precise calculation of population attributable risks. However, they are more difficult to

conduct, and incident cases of recent infection may be difficult to identify because a non-specific clinical syndrome (e.g., acute HIV infection) or because of the absence of a serological marker of recent infection (e.g., recent HCV infection).

Past or present infections
Use of past or present infections is adapted to high prevalence situations. Because cases are easier to identify, studies of past or present (prevalent) infections (in cross-sectional and case-control studies) are easier to conduct and may provide sufficient evidence to justify a safe and appropriate use of injection policy. However, they are subject to a number of limitations and they only allow an approximate calculation of population attributable risks.

Case definitions

Case definition for infections with bloodborne pathogens should include criteria based upon clinical features and criteria based upon serological diagnosis.

HBV infection
    Recent infection
The following case definition of acute hepatitis B should be used:

- Acute illness with jaundice (and, if available, elevated aminotransferase activity, at least 5 times the upper limit of the laboratory normal value);
- Positive IgM antibody to the hepatitis B core antigen (anti-HBc IgM) test.
  Past or present infection
- Positive total anti-HBc antibody test

HCV infection
    Recent infection
Because of the absence of a serological marker of recent HCV infection, the case definition for recent HCV infection should aim at capturing cases of acute, non A, non B hepatitis that are antibody to hepatitis C virus (anti-HCV) positive:

- Acute illness with jaundice and elevated aminotransferase activity (at least 7 times the upper limit of the laboratory normal value)
- Negative IgM antibody to hepatitis A virus (anti-HAV IgM) test
- Negative anti-HBc IgM test
- Negative antibody to hepatitis E virus (anti-HEV) test *
- Positive anti-HCV EIA test
- Positive supplemental anti-HCV test (e.g., RIBA) †
  Past or present infection
- Positive anti-HCV EIA test
- Positive supplemental anti-HCV test (e.g., RIBA) †

HIV infection
    Recent infection
The non-specific characteristics of acute HIV infection makes it difficult to use acute HIV infection as an indicator.

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* In countries where HEV is endemic or when patients have travelled to HEV endemic countries

† May be avoided if a second or third generation test was used and if the prevalence of HCV infection in the population was high (exceeds 5%)

Past or present infection (in adults, adolescents, or children >= 18 months
Laboratory criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay), followed by a positive results on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test) *

Or

- Positive result or report of a detectable quantity on any of the following HIV virologic (non-antibody) tests:
  - HIV nucleic acid detection
  - HIV P 24 test
  - HIV isolation (viral culture)

Or clinical or other criteria

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician

Or

- Conditions that meet criteria included in the case definition for AIDS.

Study designs

<u>Analytic cross-sectional studies</u>
   Principle
Cross sectional studies (surveys) may be used to assess the association between past or present infection with bloodborne pathogens and injections if:

1) Serum samples were collected for the diagnosis of past or present infection with bloodborne pathogens;

2) Relevant epidemiological information was collected regarding potential exposures, including use of injections;

3) Sampling methods used for the survey ensure that the study sample is representative from the study population (e.g., cluster sampling [**Error! Bookmark not defined.**]).

Because past or present infection with bloodborne pathogen in a study participant may have been caused by any exposure that occurred during lifetime, information regarding lifetime exposure histories should theoretically be collected. However, different surrogate referent exposure period may de defined as judged appropriate (e.g., past year, past 5 years, past 10 years) [12].

The prevalence of the serological markers of past or present infection with bloodborne pathogen may be studied according to the distribution of various exposures for the calculation of prevalence ratios. Such studies have been conducted to evaluate the association between the lifetime history of injections and the presence of serological indicators of present or past infection with HBV [13], HCV [12], or HIV [14,15].

   Advantages
Cross sectional studies are the least complicated to conduct and are useful to obtain the evidence of an association between past or present infection with bloodborne pathogens and injections. Cross sectional studies are also useful when symptoms of initial infection are rare and non-specific (e.g., HIV infection) or when serological makers of recent infection are not available (e.g.,

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* New saliva-based or urine-based test are now available for the diagnosis of HIV infection.

HCV infection). Cross sectional studies are particularly relevant for young children since 1) information regarding lifetime exposure histories may be easier to collect and 2) the much narrower time window of exposure decreases the probability of misclassification of the appropriate time period. However, for studies conducted among young children, a serological assessment of the status of the mother might be needed to sort out perinatal transmission.

Limitations

Cross sectional studies are limited because past or present infection with bloodborne pathogen in a study participant may have been caused by an exposure that occurred at any moment during lifetime. Use of lifetime as the referent exposure period may lead to imprecision in the recall of exposure and in the estimation of the strength of the association. In addition, cross sectional studies can only provide prevalence ratio estimates. Calculation of risk ratios and of population attributable risks is not directly possible but may be attempted through the use of advanced epidemiological methods.

Overall, caution is advised when planing, conducting, or analysing cross sectional studies to study the association between infections and injections. While these studies are not demanding in terms of time and resources, they require substantial expertise not to be misinterpreted. The multiple criteria that are needed to conclude in favour of a causal relationship between an exposure and an outcome should be checked, including:

- The strength of the association;

- The presence of a dose-response relationship;

- The consistency among results of different studies;

- The biological plausibility.

Case-control studies

Principle

In case-control studies, cases of infection with bloodborne pathogens and unaffected controls are compared for the frequency of various exposures, including injections. When recruited cases are recent, incident cases, such studies [4] can provide rapid estimates of the relative risk of infection with bloodborne pathogens for persons exposed to injections. Relative risks can then be used to calculate population attributable risks. The following issues that are practical consequences of the principles of case-control studies [16] should be given consideration:

1) When possible (see Table 1), cases of adverse events should be recent, incident cases (as opposed to past or present, prevalent cases);

2) When recent, incident cases are used, information should be collected regarding potential exposures, including injections, during a referent exposure period that should be compatible with the incubation period or the natural history of infection (e.g.; two to six months before illness in the case of recent hepatitis B or C virus infection);

3) Control-subjects should be susceptible to the adverse event studied (e.g., control-subjects should be anti-HBc negative in the case of acute hepatitis B and anti-HCV negative in the case of acute hepatitis C);

4) Appropriate information collection and analysis should control confounding factors[*] that might confound the association between an adverse event and injections (e.g., age, blood transfusions, other healthcare related exposures, and sexual practices).

Use of viral hepatitis surveillance data

When acute viral hepatitis B or C is used as an indicator, acute hepatitis cases reported through surveillance may be used to nest case-control studies [16] where reported hepatitis A cases are used as a control group for reported acute hepatitis B and or C cases. The calculation of this odd ratio should be adjusted for potential confounding factors including age and socio-economic status. In addition, routine use of hepatitis A cases as controls should be validated through the initial recruitment of a second population-based control group. If conducted appropriately, this method allows evaluating the association between acute hepatitis B and or C and injections and calculating a population attributable risk (Table 2). In addition, because surveillance is based upon ongoing information collection systems, this method allows monitoring the strength of this association over time, which can be used to evaluate prevention programs (See evaluation, page **Error! Bookmark not defined.**).

While exhaustive surveillance may be difficult to conduct and expensive in a whole country, sentinel surveillance in a limited number of districts or hospitals selected to represent the country may be sufficient to obtain information for action.

Similarly, if ongoing collection of information through viral hepatitis surveillance cannot be maintained, surveillance may be conducted intermittently at regular time interval to conduct nested case control analysis where cases of recent hepatitis B or C virus infections are compared to cases of non B-non C acute hepatitis.

Table 2: Association between acute hepatitis B and injections among unvaccinated children reported with acute hepatitis, Romania, 1997-1998 [10].

	Reported, serologically confirmed acute hepatitis cases		Odds ratio	95% confidence interval
	Hepatitis B cases	Hepatitis A controls		
Received an injection	15/32 (47%)	33/288 (11%)	6.8	1.8-16

In addition to the basic attributes of a surveillance system [17], surveillance systems need to meet certain requirements to be used to assess or evaluate the association between viral hepatitis and injections, including:

1) The surveillance system should base diagnosis of acute viral hepatitis A and B upon serological markers of recent infection (IgM anti-HAV and IgM anti-HBc);

2) Reliable information regarding potential risk factors for infection during the referent exposure period (e.g., receiving injections) and the vaccination status against hepatitis B, should be routinely collected on case report forms;

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[*] Confounding factors (e.g., hospitalization) distort the association between the exposure and the outcome because they are associated with the exposure (e.g., injections) and the outcome of interest (e.g., hepatitis). An apparent association between injections and hepatitis could be explained by hospitalisation: hospitalisation can cause infections through nosocomial transmission and hospitalised patients are more likely to have received injections.

3) Investigators who collect information regarding exposures for reported cases should not be aware of the serological diagnosis of the hepatitis patients.

Advantages

Case control studies are easy to conduct. When conducted using recent, incident cases, they allow estimations of relative risks and population attributable risks.

Limitations

Case control studies are subject to recruitment and information bias and should be conducted according to the general principles of case control studies [16].

Cohort studies

Principle

In cohort studies, the incidence of infections is compared for subjects followed over time who are exposed or unexposed to selected exposures, including injections. In addition to the occurrence of an acute illness meeting the case definition for recent HBV, HCV, or HIV infection, evidence of seroconversion among participants identified as susceptible on a previous serological test represents evidence of recent infection.

Advantages

Cohort studies are less sensitive to bias than cross sectional or case-control studies. They provide the best estimate of the strength of the association between injections and infections through estimation of the relative risk and of the population attributable risk. They may be easy to conduct in specific settings where the risk of infection is high and the information is readily available for well-defined populations [7] (e.g., patients who will be exposed to a high number of injections or infusions in hospitals).

Limitations

Obstacles to conducting cohort studies include duration of follow up, low incidence of infection with bloodborne pathogens, and costs of follow up that includes repeated serological testing. Thus, in many developing country settings, cohort studies would require too much time and resources and would delay interventions if they were the only source of evidence upon which prevention activities can be decided.

Data collection

Sample templates that may be used to formulate data collection instruments are shown in the appendix. These sample include a template for cross sectional surveys (Instrument 2, Page 12), a template for incident case control studies (Instrument 3, Page 15), and a template for a hepatitis case report form that can be used to nest case control studies within surveillance data (Instrument 4, Page 17). Questionnaires for cohort studies can be constructed on the basis of these templates according to the frequency and length of follow up.

Data analysis

Data analysis should aim at the calculation of measures of association, including prevalence ratios (cross sectional studies), odds ratios (case-control studies), and risk ratios (cohort studies). Confounding factors should be controlled through adjustment, restriction, matching, and logistic regression as appropriate. Population attributable risk calculation should be attempted, although they are theoretically limited to studies involving recent, incident cases.

HUMAN SUBJECTS

Depending on local institutions, final study design, objectives, and data collection, studies conducted on the basis of this tool:

- May or may not be considered as research;

- May or may not be subject to an Institutional Review. Board (IRB) approval.

Institutions taking responsibility for these studies should check locally to determine whether any ethical counsel or approval is needed or not before conducting the study.

INSTRUMENT 1: SAMPLE CASE REPORT FORM FOR ABSCESS SURVEILLANCE

For the purpose of surveillance, an abscess is defined as a subcutaneous collection of pus that develop within two weeks at the site of an injection

District::   City / village:

Healthcare facility identification: Recall period: From: / / to / /

Estimated population for the catchment area: Date of completion of the report

Type of surveillance: 1- Prospective   2- Retrospective

ID	Date of onset (dd/mm/yy)	Place of residence	Age (years)	Gender (M/F)	Suspected cause (Tick as appropriate)			Referral	Comments (specify if aseptic)
					Injection by healthcare workers	Injection by informal providers	Other causes		
					Quinine	Others				

INSTRUMENT 2: SAMPLE QUESTIONNAIRE FOR ANALYTICAL CROSS SECTIONAL STUDIES

SUGGESTED WORD OF INTRODUCTION *

[Greetings] My name is _____, and I work with [Institution]. [Institution] is doing a study about diseases that may be caused by unsafe injections. To do this survey, we are asking a series of questions any injections you may have received and about diseases that you may or may not have presented. You have been chosen at random to take part in this study. The questions will take about 10 minutes to complete. There is no risk to taking part in this study, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part or if you want to skip a question, you will not lose any of the healthcare benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.

(Please note that an additional consent form may be needed if blood is taken for the purpose of the study)

QUESTIONS FOR ALL STUDY PARTICIPANTS

Status:		1- Case	2- Control
1. Date of birth:	Day ___	Month ___	Year ___
2. Gender:		1- Male	2- Female
3. District of residence:			
4. How many persons live in this household?	____ >= 15 y	___ < 15 y	
5. What is the monthly income of this household?	____	(Currency)	
6. Do you receive daily insulin injections for diabetes?	1- Yes	2- No	3- Don't kw
7. Do you have any clotting factor disease such as hemophilia?	1- Yes	2- No	3- Don't kw
8. Do you receive hemodialysis for renal disease?	1- Yes	2- No	3- Don't kw
9. Is someone in your household chronically infected with hepatitis B?	1- Yes	2- No	3- Don't kw
10. Were you vaccinated against hepatitis B?	1- Yes	2- No	3- Don't kw
11. If yes, how many doses have you received?	____	Doses	

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* This note should be adapted to each country and subject to ethical committee review or approval.

During the last year:

12. How many injections have you received for vaccinations? ____ Injections

13. How many other injections have you received from healthcare workers for any other reason? ____ Injections

14. How many injections for other reasons by informal injection providers and traditional healthcare workers? ____ Injections

Calculate total number of injections and report to the patient

What you tell me means that, in the last year, you have received ____ Injections

15. Consider the five years preceding this year, did you receive more injections, less injections, or the same number of injections on average per year in that period than in the past year?   1- More   2- Less   3- The same

16. Ignoring the last year and considering the preceding five years, how many injections do you think you received, on average, per year: ____ Injections

17. Ignoring the last year and considering the preceding ten years, how many injections do you think you received, on average, per year: ____ Injections

During your whole life:

18. How many times have you ever had a blood test? ____ Times

19. How many times have you ever been in the hospital? ____ Times

20. How many times have you ever received a blood transfusion? ____ Times

21. How many times have you ever been put to sleep for surgery? ____ Times

22. How many times have you ever had surgery without being put to sleep? ____ Times

23. How many times have you ever been to the dentist? ____ Times

24. How many times have you ever had acupuncture? ____ Times

25. How many times have you ever had tuberculosis skin tests? ____ Times

26. How many times have you ever had ear or body piercing? ____ Times

27. How many times have you ever had tattoos? ____ Times

28. How many times have you ever had you head shaved? ____ Times

29. Have you ever been circumcised?   1- Yes   2- No

ADDITIONAL QUESTIONS FOR CHILDREN UNDER 15 YEARS OF AGE

The three next questions should be asked to the mother of the child:

30. Do you have chronic hepatitis B?	1- Yes	2- No	3- Don't kw
31. Do you have chronic hepatitis C?	1- Yes	2- No	3- Don't kw
32. Are you infected with the HIV/AIDS virus?	1- Yes	2- No	3- Don't kw

ADDITIONAL QUESTIONS FOR ADULTS (15 YEARS OF AGE OR OLDER)

<u>During your whole life:</u>

33. Have you ever injected illicit drugs?	1- Yes	2- No	3- Don't kw
34. Did you ever come in contact with syringes and needles during in your workplace?	1- Yes	2- No	3- Don't kw
35. How many times have you ever donated blood or plasma?	____	Times	
36. How many sexual partners of the opposite sex have you ever had?	____	Partners	
37. How many sexual partners of the same sex have you ever had?	____	Partners	

INSTRUMENT 3: SAMPLE QUESTIONNAIRE FOR CASE CONTROL STUDIES

SUGGESTED WORD OF INTRODUCTION *

[Greetings] My name is _____, and I work with [Institution]. [Institution] is doing a study about diseases that may be caused by unsafe injections. To do this survey, we are asking a series of questions any injections you may have received and about diseases that you may or may not have presented. You have been chosen at random to take part in this study. The questions will take about 10 minutes to complete. There is no risk to taking part in this study, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part or if you want to skip a question, you will not lose any of the healthcare benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.

**(Please note that an additional consent form may be needed
if blood is taken for the purpose of the study)**

QUESTIONS FOR ALL STUDY PARTICIPANTS

Status:		1- Case	2- Control
1. Date of birth:	Day ___	Month ___	Year ___
2. Gender:		1- Male	2- Female
3. District of residence:			
4. Date of onset (cases)/ recruitment (controls)	Day ___	Month ___	Year ___
5. How many persons live in this household?	____ >= 15 y	___ < 15 y	
6. What is the monthly income of this household?	____	(Currency)	
7. Do you receive daily insulin injections for diabetes?	1- Yes	2- No	3- Don't kw
8. Do you have any clotting factor disease such as hemophilia?	1- Yes	2- No	3- Don't kw
9. Do you receive hemodialysis for renal disease?	1- Yes	2- No	3- Don't kw
10. Is someone in your household chronically infected with hepatitis B?	1- Yes	2- No	3- Don't kw
11. Were you vaccinated against hepatitis B?	1- Yes	2- No	3- Don't kw
12. If yes, how many doses have you received?	____	Doses	

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* This note should be adapted to each country and subject to ethical committee review or approval.

During the two to six months before symptoms (cases) or recruitment (controls):

13. How many injections have you received for vaccinations?	____	Injections
14. How many other injections have you received from healthcare workers for any other reason?	____	Injections
15. How many injections for other reasons by informal injection providers and traditional healthcare workers?	____	Injections
16. How many times have you ever had a blood test?	____	Times
17. How many nights have you ever been in the hospital?	____	Times
18. How many times have you ever received a blood transfusion?	____	Times
19. How many times have you ever been put to sleep for surgery?	____	Times
20. How many times have you ever had surgery without being put to sleep?	____	Times
21. How many times have you ever been to the dentist?	____	Times
22. How many times have you ever had acupuncture?	____	Times
23. How many times have you ever had tuberculosis skin tests?	____	Times
24. How many times have you had ear or body piercing?	____	Times
25. How many times have you had tattoos?	____	Times
26. How many times have you had your head shaved?	____	Times
27. Have you been circumcised?	1- Yes	2- No

ADDITIONAL QUESTIONS FOR CHILDREN UNDER 15 YEARS OF AGE

The three next questions should be asked to the mother of the child:

28. Do you have chronic hepatitis B?	1- Yes	2- No	3- Don't kw
29. Do you have chronic hepatitis C?	1- Yes	2- No	3- Don't kw
30. Are you infected with the HIV/AIDS virus?	1- Yes	2- No	3- Don't kw

ADDITIONAL QUESTIONS FOR ADULTS (15 YEARS OF AGE OR OLDER)

During the two to six months before symptoms (cases) or recruitment (controls):

31. Have you injected illicit drugs?	1- Yes	2- No	3- Don't kw
32. Did you come in contact with syringes and needles during in your workplace?	1- Yes	2- No	3- Don't kw
33. How many times have you donated blood or plasma?	____	Times
34. How many sexual partners of the opposite sex have you had?	____	Partners
35. How many sexual partners of the same sex have you had?	____	Partners

INSTRUMENT 4: SAMPLE CASE REPORT FORM FOR VIRAL HEPATITIS SURVEILLANCE

General characteristics – Identification

Date of reporting: / /		ID:	District:
Last name:		First name:	
Date of birth: / /		Gender: 1- Male 2- Female	
Case patient's education years: ___ yrs		Number of children in the households: ___	
Prison: 1- Yes 2- No		Number of adults in the household: ___	

Clinical characteristics

Onset date: / /			**Serological testing**			
Hospitalization:	1- Yes	2- No	HAV IgM	1- Pos	2- Neg	3- Unk
Jaundice:	1- Yes	2- No	HBc IgM	1- Pos	2- Neg	3- Unk
Death:	1- Yes	2- No	Anti HCV	1- Pos	2- Neg	3- Unk
ALAT:		IU/ litre	Anti HEV	1- Pos	2- Neg	3- Unk

Exposures in the two to six weeks before onset

Involved in a common source outbreak:	1- Yes	2- No	3- Unknown
Attendance or work in a day-care:	1- Yes	2- No	3- Unknown
Contact with a case of hepatitis A:	1- Yes	2- No	3- Unknown
Raw shellfish consumption:	1- Yes	2- No	3- Unknown
Consumption of untreated surface water:	1- Yes	2- No	3- Unknown
Consumption of untreated well water:	1- Yes	2- No	3- Unknown

Exposures in the two to six months before onset

Number of injections / infusions:	Vaccination: _____	Others: _____	
Injections by informal / traditional providers :	1- Yes	2- No	3- Unknown
Hospitalization:	1- Yes	2- No	3- Unknown
Surgery:	1- Yes	2- No	3- Unknown
Blood transfusion:	1- Yes	2- No	3- Unknown
Haemodialysis:	1- Yes	2- No	3- Unknown
Dentist visit:	1- Yes	2- No	3- Unknown
Injection drug use:	1- Yes	2- No	3- Unknown
Occupational exposure to blood:	1- Yes	2- No	3- Unknown
Skin piercing / barber / circumcision:	1- Yes	2- No	3- Unknown
Tattoos or acupuncture:	1- Yes	2- No	3- Unknown
Number of sexual partners:	Opposite sex _____	Same sex _____	
Dates of hepatitis B vaccine doses:	1:	2:	3:
Mother known to be HBsAg positive:	1- Yes	2- No	3- Unknown

Comments:

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