ISSN 1188-4169

Canada Communicable Disease Report

Date of Publication: June 1999

Volume 25S2

Supplement

Hepatitis C Prevention and Control: A Public Health Consensus

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Hepatitis C Prevention and Control : A Public Health Consensus

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Executive Summary

From October 14-16, 1998, the Laboratory Centre for Disease Control, Health Canada, held a national consensus conference in Ottawa: *Hepatitis C Prevention and Control: A Public Health Consensus*. The aim was to review progress in addressing the public health recommendations of a 1994 conference, examine the present state of public health knowledge and action on hepatitis C virus (HCV) infection, and update the previous public health recommendations as necessary.

Participants were assigned to one of six working groups: surveillance; public health interventions; public health laboratory issues; injection drug user issues; education; and blood supply issues. Several important recommendations were as follows.

Surveillance

- Three different approaches are recommended to fulfil surveillance objectives:
  - routine case-by-case surveillance;
  - enhanced surveillance based in sentinel health units;
  - enhanced surveillance that targets specific locations, physician practices, or populations.
- Routine case-by-case surveillance should include collection of a minimum data set on all notified cases: date of birth or age, sex, location, time of onset (of acute symptomatic cases), and information on risk factors. The case definition for routine surveillance is a confirmed anti-HCV positive test result or a positive test for HCV RNA together with negative anti-HCV.
- The objectives of the sentinel health unit surveillance system are:
  - to determine newly identified/acquired infections;
  - to document clinical data, demographic information, risk factors, and costs more fully;
  - to provide follow-up to determine the natural history of the disease;
  - to support special studies;
  - to support evaluation of preventive programs.

  In this type of surveillance, the investigation of risk factors will be more extensive than for routine case-by-case surveillance. Other data elements will depend on the objectives of the sentinel study.

- The objectives of targeted enhanced surveillance are:
  - to identify newly acquired infections;
  - to monitor the burden of disease;
  - to support special studies;
  - to identify new emerging infections (agents) or risk factors;
  - to monitor seroconversion (repeated measures);
  - to provide information to determine the natural history of the disease;
  - to support targeted and cohort studies.

Public Health Interventions

- Public health has principal responsibility in primary prevention and surveillance.
- Primary care providers general practitioners, family practitioners, nurses (especially in northern communities), street outreach programs, etc. should offer testing for HCV infection to all people with risk factors, e.g. history of injection drug use. Testing needs to be done in the context of a comprehensive assessment of the individual s health needs; such needs may include testing for other infections, such as HIV, care for addiction, counselling, consideration of therapy for HCV, and follow-up.
- People with multiple sex partners should practise safer sex, e.g. by using barrier methods.
- In general, longstanding sexual partners do not need to change sexual practices if one of them is found to be infected with hepatitis C. However, partners need to be informed that although the risk is low it is not absent, and barrier methods are available.
- Data on risk factors should be collected: specifically, public health should follow up with the physician or primary care provider to determine whether there is a history of blood donation or receipt, and if so to share this information with the Canadian Blood Service or Héma-Québec (CBS/HQ).
- There is a need for public health and CBS/HQ to share database information (e.g. names of all HCV-positive people to be checked for past history of blood donation); a legal and ethical basis for this is required.

Public Health Laboratory Issues

- Despite the high specificity of current enzyme immunoassays (EIAs) in the detection of anti-HCV, false positive reactions will occur in populations with a low prevalence of infection. Therefore, all screening algorithms must include supplemental testing. A positive anti-HCV result is defined as a repeatedly reactive EIA and a positive supplemental test result. Only this result should be reported to the treating physician and public health authorities.
- Although EIA for the detection of anti-HCV should remain the test of choice for initial assessment of specimens in both immunocompetent and immunosuppressed persons, HCV nucleic acid detection (HCV RNA) should be performed in immunosuppressed patients who have a negative anti-HCV result but in whom HCV infection is suspected.
- Qualitative HCV RNA assays are not required for all anti-HCV positive patients. However, such testing may be useful in the following situations:
  - resolution of indeterminate HCV serology;
  - detection of infection in anti-HCV negative immunocompromised patients;
  - detection of HCV infection in the infant born to an anti-HCV positive mother (the optimal timing and frequency of monitoring requires data from prospective cohort studies);
  - documentation of viremia in anti-HCV positive patients with repeatedly normal liver function tests (for anxiety relief rather than to guide clinical management);

- determination of the response to anti-viral treatment and the durability of that response.

- In patient management, pretreatment genotyping provides important information with respect to the risks/benefits and duration of treatment. Opportunities should be made available for accessing genotyping services in Canada.

- Pretreatment quantitative HCV RNA assays provide important information with respect to the risks/benefits of treatment and duration of therapy and should be made available.

Injection Drug User Issues

- Hepatitis C prevention programs should adhere to the harm reduction model as a health promotion strategy.

- A federal-provincial advisory committee should be created to ensure the implementation of a hepatitis C national action plan on injection drug user (IDU) issues; where there is significant overlap of issues, other bloodborne infectious diseases often found among drug users should also be addressed by the committee.

- Drug users themselves must be included at all levels of discussion and intervention. This involves the creation, provision of resources for and continuing support of drug user groups at federal/provincial/territorial and local levels.

- Since HCV infection is acquired very rapidly after initiation into injection drug use, prevention efforts should target above all (but not exclusively) new injection drug users and those who are contemplating injecting.

Education

- A federally led national awareness campaign should be developed as a priority.

- A national clearinghouse should be instituted for hepatitis C information as a central repository where information is readily available for health care providers, patients, and the general public, including a 1-800 telephone number (displayed on all information) and Internet access.

- Through discussion with universities/schools/professional organizations, case-based curricula should be developed for health care providers that take into account their knowledge and comfort when dealing with drug users and related issues.

- Educational materials should be developed with client groups and disseminated through existing networks, e.g. methadone clinics, needle exchange programs.

Blood Supply Issues

- Targeted lookbacks[a], both retrospective and prospective, should be continued. When the HCV-infected donor is identified outside the blood service, complete identifying information should be provided to the blood service to permit lookback.

- Traceback investigations[b] on HCV-infected transfusion recipients should be continued so that other HCV-infected recipients may be identified through a subsequent lookback.

- Recipient notification programs[c] should be considered in jurisdictions where they have not been carried out. The final decision should be

[a] After identification by/to the blood service of an anti-HCV positive blood donor who has made previous donations, corresponding recipients are identified and advised to consult their family physicians about anti-HCV testing.

[b] After identification of an anti-HCV positive blood recipient by/to the blood service, corresponding donors are identified and offered anti-HCV testing, and a targeted lookback is subsequently conducted for donors found to be anti-HCV positive.

[c] After identification of all recipients of blood, e.g. from a specific institution for a specific time interval, such recipients are advised to consult their family physicians about anti-HCV testing.

made on the basis of feasibility; regional, local, and provincial priorities; other methods available; and the likely yield of such activities (number of yet unidentified HCV-infected recipients).

- Enabling legislation and regulations should be enacted in all jurisdictions to allow full and free sharing of information. Such legislation must safeguard the right to privacy and confidentiality of donors and recipients.
- New mechanisms are required to ensure systematic coordination between public health and the Canadian Blood Service/Héma-Québec at three levels: federal; provincial/territorial (of high priority); and regional.

Background

Hepatitis C

Hepatitis C virus (HCV) is an enveloped RNA virus belonging to the *Flaviviridae* family and one of the five viruses that account for most cases of viral hepatitis. There are at least six genotypes of HCV and many more subtypes; genotype 1 is the commonest genotype in Canada, accounting for perhaps two-thirds of cases.

It is estimated that up to 3% of the world s population is infected with HCV, i.e. up to 170 million chronic carriers. The majority of those newly or chronically infected have no symptoms and are, therefore, often unaware of their infection; however, they serve as a source of transmission of infection and are at risk for chronic liver disease, cirrhosis, and liver cancer. Unpublished population-based studies in the United States indicate that 40% of chronic liver disease may be attributable to HCV infection.

In Canada, national reporting of HCV infection was started in 1992, and it is expected that infection will soon be reportable in all provinces and territories[d]. The number of cases reported has increased dramatically from 1992 (1,321 cases) to 1997 (19,571 [provisional]), mainly because of increased recognition of previously acquired infection. Although there are no direct measurements, it is reasonably estimated that the prevalence of HCV infection in Canada is about 0.8% (240,000 persons), and of these people probably only about 30% are aware of their infection[(1)]. Since most newly acquired cases are clinically silent and there is no laboratory test to distinguish such cases from chronic cases, it is difficult to measure incidence; while cautious interpretation is prudent, applying U.S. projections to the Canadian situation[e] predicts approximately 2,200 new cases per year in Canada at this time.

Injection drug use (IDU) is the most important exposure for HCV infection in Canada, accounting for perhaps 70% of all prevalent infections. Among IDU cohorts in Vancouver and Montreal, the prevalence of HCV is reported as 85% and

[d] As of January 01, 1999, HCV infection was reportable in all Canadian provinces and territories.

[e] In the United States there are an estimated 36,000 incident cases per year at this time arising from 3.9 million prevalent cases. Applying the proportion 36,000/3,900,000 to the estimated 240,000 prevalent cases in Canada predicts 2,200 incident cases per year in Canada. The United States reports a marked decrease in incidence over the last decade; however, it is not clear that this has occurred in Canada.

70% respectively, and the annual incidence is reported as 26% and 27% respectively. On the basis of studies in other countries, the highest risk period for HCV acquisition through IDU is early after initatiting the behaviour. The overall control of HCV infection in Canada depends primarily on interventions for IDU.

Therapeutic blood exposure accounted for perhaps 10-15% of incident infections in the past, but the current risk is quite low, perhaps 1 in 103,000 donations.

In about 85% of newly acquired HCV infection, the infection becomes chronic. However, the progression of chronic hepatitis C disease is usually slow and may not be manifest during the first two decades following infection. However, given that many cases of chronic HCV infection in Canada were acquired in the remote past, perhaps 15-25 years ago, it is expected that there will be substantial increases, of the order of a doubling or tripling (or more), in disease sequelae of HCV infection in Canada over the next decade, e.g. cirrhosis, liver failure, deaths due to liver disease and the need for liver transplants.

LCDC National Conferences

In December 1994, the Laboratory Centre for Disease Control (LCDC) held a national meeting on the prevention and control of hepatitis C; the results and recommendations of the conference were published in July 1995[2]. Given that four years have passed since then, a second conference, *Hepatitis C: Prevention and Control A Public Health Consensus*, was held from October 14-16, 1998, in order to review the present state of knowledge and action with regard to public health aspects of hepatitis C and to update the recommendations accordingly. Participants were assigned to one of six working groups, covering the fields of surveillance, public health interventions, public health laboratory issues, injection drug user issues, education and blood supply issues. The recommendations of these groups are presented in the next section.

Recommendations

1. Surveillance Working Group

Public health surveillance was defined as the systematic, ongoing and timely collection, collation, analysis, and dissemination of information necessary for the planning, implementation, and evaluation of public health action. Such action can be either routine responses to well-understood situations or adaptations to new problems.

Public health must provide a coordinated approach to surveillance across jurisdictions and program interests to identify gaps in surveillance activities, recommend areas for further surveillance, research or action, and identify the need for appropriate resources.

The specific objectives with regard to public health surveillance of hepatitis C virus (HCV) infection are as follows:

- to monitor the prevalence of HCV infection over time
- to determine the incidence of infection in the Canadian population and selected high-risk populations, and to monitor incidence over time
- to determine risk factors for infection and disease transmission patterns
- to evaluate public health programs
- to characterize the natural history of the disease
- to assess the burden of HCV infection
- to identify infected persons for counselling and intervention
- to identify new opportunities for prevention

Surveillance of hepatitis C is complicated by the proportion of patients with acute and chronic disease who do not have symptoms, the long latent period between infection and the sequelae of chronic disease, and the limitations of the diagnostic tests available. Therefore, several approaches will be required to meet the objectives outlined.

Three surveillance systems were proposed: routine case-by-case surveillance, enhanced surveillance based in sentinel health units, and enhanced targeted surveillance. The objectives, case definitions, and data to be collected will vary for each system.

Recommendations

1.1 Information should be collected over time on risk behaviours and factors in the general population to allow modelling of hepatitis C infection.

1.2 Three different approaches are recommended to fulfil surveillance objectives:

- routine case-by-case surveillance
- enhanced surveillance based in sentinel health units
- enhanced surveillance that targets specific locations, physician practices or populations

Routine case-by-case surveillance

1.3 The objectives of routine case-by-case surveillance are

- to determine the magnitude/extent of identified HCV infection in the population, recognizing that not all cases of infection will be identified
- to identify cases for public health action, for example, immunization against hepatitis A or hepatitis B
- to identify risk factors among notified cases

1.4 Routine case-by-case surveillance should include the collection of a minimum data set on all notified cases:

- date of birth or age, sex
- location, time of onset (of acute symptomatic cases)
- other information (likely date of exposure to risk factor or behaviour to be included for each)
  - blood donor
  - blood, blood product, tissue or organ recipient
  - injection drug user
  - hemodialysis patient
  - other identified risk (e.g. HCV positive sex partner or HCV positive mother)
  - notation that no data are available or information was not sought

1.5 Caution should be used in the interpretation of the category no risk factor , since only the principal risk factors may have been included in questioning.

1.6 The resources available will determine the methodology and extent of determination of risk factors; who does this will depend on the jurisdiction. For each case, a determination should be made as to whether the case has been a blood donor or recipient.

1.7 Analysis and dissemination of information should be done in a timely fashion to all those who need to know.

1.8 The case definition for routine surveillance is a confirmed anti-HCV positive test result; or a positive test result for HCV RNA (e.g. polymerase chain reaction [PCR]) together with negative anti-HCV.

- This case definition relies on laboratory data.
- HCV-infected persons and not blood samples are counted.
- Acute cases usually cannot be distinguished from chronic cases; this will only be possible with the development of the appropriate laboratory test.
- Infected persons (donors and recipients) identified by the Canadian Blood Service or Héma-Québec will be included.

Enhanced surveillance based in sentinel public health units

This approach will provide valid, comprehensive data and at least a representative national picture, including trends. Representativeness at a provincial level is an option. Repeated measures and a consistent approach over time will be possible.

1.9 The objectives of the sentinel health unit surveillance system are

- to determine newly identified/acquired infections
- to document clinical data, demographic information, risk factors and costs more fully

- to provide follow-up to determine the natural history of the disease
- to support special studies
- to help evaluate preventive programs

1.10 The investigation of risk factors will be more extensive than for routine surveillance. Other data elements will depend on the objectives set for the sentinel study.

1.11 Data and information resulting from analysis must be provided to participating health units and the provinces in a timely fashion.

1.12 Sentinel study investigators may develop case definitions specific to their objectives. A suggested case definition for newly acquired infection is:

An acute illness with a discrete onset of symptoms and either jaundice or elevated serum aminotransferase levels;
plus serum aminotransferase level > 2.5 times the upper limit of normal
plus IgM anti-HAV negative, IgM anti-HBc negative or HBsAg negative
plus confirmed anti-HCV positive;

or

seroconversion with a confirmed anti-HCV positive test result in the presence or absence of symptoms.

Enhanced surveillance targeting specific locations, physician practices or populations

This surveillance approach should be implemented through sentinel physicians, hospitals or clinics.

1.13 The objectives of targeted enhanced surveillance are

- to identify newly acquired infections
- to monitor the burden of disease
- to support special studies
- to identify new emerging infections (agents) or risk factors
- to monitor seroconversion (repeated measures)
- to provide information to determine the natural history of the disease
- to support targeted and cohort studies

1.14 The case definition will depend on the purposes of surveillance.

1.15 There may be a role for banked sera or registries of chronic or fulminant hepatitis.

1.16 Data and information from analysis must be provided to participating practices or agencies and to the provinces in a timely fashion.

Research

1.17 There should be research into the following areas:

- laboratory tests to differentiate acute asymptomatic from chronic infection
- valid surrogate markers for chronic liver disease surveillance
- longitudinal studies, as these are the best means of characterizing the natural history of the disease. Examples of such studies are as follows:
  - case follow-up of a representative sample of incident cases
  - case follow-up of a representative sample of prevalent cases
  - case follow-up of infants of infected mothers
  - prospective studies of cohorts with defined risks, for example, transfusion recipients, injection drug users, etc.
- given evolving science (e.g. new organisms, new laboratory tests), there may be a need to retain negative or untested sera in a planned fashion for later use in special studies
- cross-sectional seroprevalence studies and longitudinal incidence studies among special populations to determine the true extent of HCV in the population

2. Public Health Interventions Working Group

Public health has a major contribution to make in ensuring that primary and secondary prevention strategies against hepatitis C are in place and comprehensive care programs are available as well as in facilitating the actions of others in the areas of prevention, education and advocacy. Public health has principal responsiblity in primary prevention and surveillance.

Approaches to the control of hepatitis C should recognize that it must be dealt with in the context of other bloodborne pathogens and by means of coordinated programs dealing with substance abuse.

Case finding for hepatitis C is considered to benefit primarily the individual rather than to protect the public through disease control. Public health benefits may result from the prevention of secondary cases, but the number of such cases may be small.

Although there is no rationale for systematic, organized HCV screening programs from the public health perspective (i.e. for disease control) such programs may be undertaken for the benefit of individuals and for ethical reasons, for example, the testing of recipients of blood before 1992.

Primary care providers general practitioners, family practitioners, nurses (especially in northern communities), street outreach programs, IDU care programs etc. should offer testing for HCV infection to all people with risk factors. Testing needs to be done in the context of a comprehensive assessment of the individual s health needs; such needs may include testing for other infections (e.g. HIV), care for addiction, counselling, consideration of therapy for HCV, and follow-up.

There are certain groups for whom routine testing is *not* recommended, and groups for whom there is inadequate evidence (of risk) to recommend routine testing. Because of the uncertainty, directions for counselling this latter group (e.g. sexual partners of HCV-infected individuals) are of necessity tentative.

Recommendations

Routine Testing

2.1 Routine testing should be offered by the primary care provider to the following groups:

- people who have ever injected drugs that were not medically recommended
- people who have undergone or are undergoing hemodialysis on a long-term basis
- people with persistently abnormal alanine aminotransferase levels
- recipients of clotting factor concentrates before 1988
- recipients of blood, blood components or solid organs before 1992
- recipients of blood, blood components or solid organs from an HCV-positive donor
- people with significant exposure to the blood of HCV-infected individuals or to the blood of those at high risk of infection with hepatitis C
- prisoners in correctional institutions
- infants of HCV-infected mothers (as per the Canadian Paediatric Society recommendations[3])
- older children of HCV-infected mothers if there is reason to believe that vertical transmission may have occurred

2.2 Routine testing is *not* recommended for the following groups:

- pregnant women
- health care workers and students in the health care professions[f]

[f] Concern was raised about certain occupational groups, e.g. health care workers in hemodialysis units. However, there is a paucity of data on which to base a recommendation at this time.

- other occupational groups (e.g. emergency workers, including first responders)
- nonsexual household contacts

2.3 There is **inadequate evidence** on the need to routinely test the following groups:

- long-term or regular sexual partners of HCV-infected people
- people from countries where hepatitis C is endemic
- people with a history of tattooing or body piercing
- people with a history of intranasal or inhaled drug use

Public health responsibilities

2.4 The public must have access to information about hepatitis C.

2.5 Ensure that a consistent standard of care and counselling guidelines on hepatitis C are available to health care workers.

2.6 Ensure that pre- and post-test counselling are performed.

2.7 Data on risk factors should be collected (surveillance activity).

2.8 Specifically, public health should follow up with the physician or primary care provider to determine whether there is a history of blood donation or receipt, and if so to share this information with the Canadian Blood Service or Héma-Québec (CBS/HQ).

There is a need for public health and CBS/HQ to share database information (names of HCV-positive people to be checked for past history of blood donation); a legal and ethical basis for this is required.

2.9 Access to recommended vaccines[g] should be facilitated.

2.10 Systematic public health contact tracing is not recommended for sexual partners or IDU contacts of HCV-infected people.

2.11 Hepatitis B vaccination is recommended for people with HCV infection who are also at increased risk of HBV infection, e.g. IDU.

Counselling child-bearing

2.12 Counselling HCV-infected women against becoming pregnant is not recommended.

2.13 HCV-infected women of child-bearing age should be informed that there is a risk of transmission to any infants born, that the risk increases if the women are infected with HIV and HCV, and that the infants should be tested for infection.

2.14 Breast feeding is recommended in general because of its proven health benefits and because the risk of HCV transmission by this means is only theoretical. Women who wish to take no risk may choose to use alternative feeding methods. If the nipples are bleeding or cracked, it is recommended that breastfeeding be suspended until they are healed.

Counselling household contacts and other settings

2.15 Household contacts of HCV-infected people should not share their personal hygiene items.

2.16 Household contacts should take common sense measures to protect themselves from exposure to the blood of an infected person.

2.17 Other than as mentioned in sections 2.1, 2.2 and 2.3, routine screening of household contacts is not required.

2.18 There is no need to disclose HCV status in day care or other settings. (For a discussion of disclosure by health care workers, see the

[g] The conference debated the issue of whether to recommend hepatitis A vaccine for all persons infected with HCV; however, the final consensus did not recommend such routine use.

report of the Consensus Conference on Infected Health Care Workers[4])

Counselling sexual activity

There is limited evidence that, in the absence of other risk factors, individuals with many sexual partners may be at higher risk of becoming infected with hepatitis C than those in a more longstanding, monogamous sexual relationship.

2.19 People with multiple sexual partners should practise safer sex, i.e. by using barrier methods.

2.20 In general, longstanding sexual partners do not need to change sexual practices if one of them is found to be infected with hepatitis C. However, partners need to be informed that although the risk of transmission is low it is not absent, and barrier methods are available.

2.21 Sexual partners should know that the risk of transmission during sexual activity may be increased when there are open lesions and during menses; barrier methods may be used in these situations.

Postexposure considerations for health care workers (including emergency responders)

2.22 Postexposure prophylaxis guidelines need to be developed in the context of overall risk assessment for bloodborne pathogens.

2.23 Appropriate testing is recommended for those with needle stick, sharps or mucosal exposure to HCV-positive blood[5].

2.24 At this time, there is no recognized postexposure prophylactic intervention that will decrease the risk of infection.

Research

2.25 Research is needed into the following areas:

- the extent to which the knowledge of their positive HCV status modifies the behaviour of injection drug users
- the frequency of perinatal transmission of HCV in Canada
- the prevalence of HCV infection among hemodialysis workers and other occupational groups
- the role of interferon and other potentially effective agents in postexposure prophylaxis

3. Public Health Laboratory Issues Working Group

There is a mixture of laboratories carrying out anti-HCV screening and supplementary testing across the country: public health, hospital, and private laboratories. Further, even among public health laboratories a variety of HCV diagnostic algorithms are being used. It was felt that the tests used and the practices of all laboratories should be subject to evaluation, to ensure some degree of quality assurance.

At the present time, laboratory assays cannot differentiate between acute and chronic HCV infection (except seroconversion).

The kinetics of disappearance of passive antibody in infants born to HCV seropositive mothers is uncertain. The recommendation on testing for vertical transmission of HCV reflects this uncertainty.

There is evidence that the response to different treatment regimens varies according to the genotype of the hepatitis C virus, and that pretreatment quantitative HCV RNA (nucleic acid detection) testing can provide an important baseline against which to measure the risks and benefits of treatment. The importance of these new data underlie the recommendations on genotyping and quantitative HCV RNA.

Quality assurance

3.1 The Bureau of Medical Devices (Health Protection Branch, Health Canada) should establish a licensing program for HCV

diagnostic kits similar to that established for HIV testing.

3.2 All laboratories performing HCV testing should participate in external proficiency testing programs. Each province should put in place a system that ensures compliance with and reviews the results of proficiency testing.

Window period

3.3 Protocols for post-exposure surveillance of patients for seroconversion should take into account the estimated mean seroconversion window. For anti-HCV in immunocompetent patients (using third generation EIAs) it is 10 weeks; this figure is based on population studies among transfusion recipients (data obtained from limited studies of post-transfusion HCV infection).

Supplemental testing

3.4 Despite the high specificity of current EIAs in the detection of anti-HCV, false positive reactions occur in populations with a low prevalence of infection. Therefore, all screening algorithms must include supplemental testing. A positive anti-HCV result is defined as a repeatedly reactive EIA and a positive supplemental test result. Only this result should be reported to the treating physician and public health authorities. Acceptable supplemental testing includes

- recombinant immunoblot assay (RIBA)
- a second manufacturer s EIA (all dual EIA algorithms with expanded grey zones must have been validated for the specific kits used)
- nucleic acid detection

3.5 If reporting of all HCV infected patients to public health authorities is deemed necessary, centralized supplemental testing (in the public health laboratory) should be considered, or there should be validation that all laboratories performing supplemental HCV testing are reporting confirmed HCV cases.

Nucleic acid detection

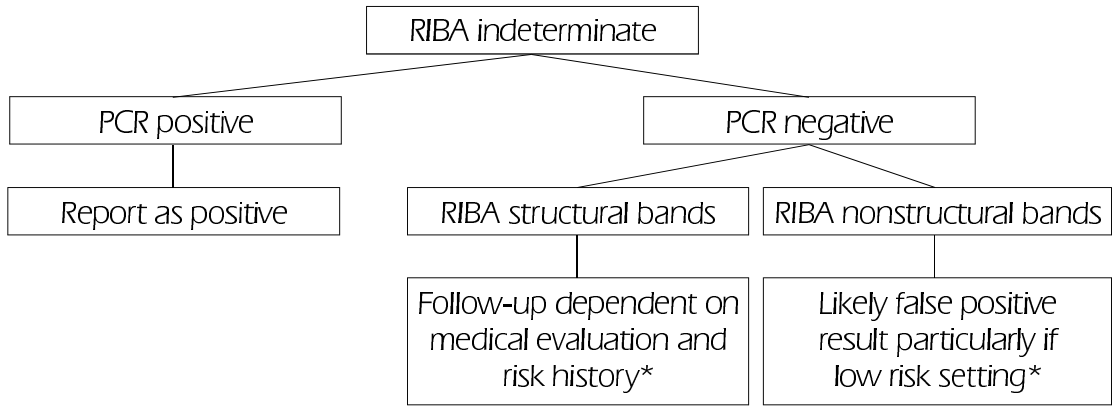
3.6 Although EIA for the detection of anti-HCV should remain the test of choice for initial assessment of specimens in both immunocompetent and immunosuppressed hosts (e.g. patients with hematologic malignant disease, HIV-infected patients, patients with congenital or acquired immunodeficiency, organ and bone marrow transplant recipients), HCV nucleic acid detection (HCV RNA) should be performed in immunosuppressed patients who have a negative anti-HCV result but in whom HCV infection is suspected.

3.7 Qualitative HCV RNA assays are not required on all anti-HCV positive patients. However, such testing may be useful in the following situations:

- resolution of indeterminate HCV serology (see Figure 1)
- detection of infection in anti-HCV negative immunocompromised patients
- detection of HCV infection in the infant born to an anti-HCV positive mother (the optimal timing and frequency of monitoring requires data from prospective cohort studies)
- documentation of viremia in anti-HCV positive patients with repeatedly normal liver function tests (for anxiety relief rather than to guide clinical management)
- determination of the response to antiviral treatment and the durability of that response

3.8 At present there are insufficient data on the efficacy of early antiviral therapy or on the transmission risk to patients from seroconverting health care workers to justify the use of HCV RNA assays in monitoring health care workers after a parenteral exposure to HCV.

Figure 1. Handling of RIBA indeterminate samples



* comments on the laboratory reports reflecting the relative probability of these two interpretations may be useful

Vertical transmission of HCV

3.9 The optimal laboratory protocol for monitoring vertical transmission of HCV infection is uncertain. However, the diagnosis of infection can be assessed by antibody testing later than 12 months after birth. The durability of antibody should be determined (i.e. residual maternal antibody ruled out) by follow-up testing. In infants documented to be HCV RNA positive, follow-up testing is recommended to determine persistence versus clearance of viremia. HCV RNA testing at three months of age may be useful for detection of infection in infants born to anti-HCV positive mothers, but requires further validation.

Seroprevalence studies

3.10 Pooled serum testing can be a cost-effective method for performance of seroprevalence studies for epidemiologic purposes. This approach must be validated for each specific manufacturer s product used.

3.11 Saliva may be useful for epidemiologic seroprevalence studies. The sensitivity and specificity of specific combinations of collection kits and assay systems must be determined before their application in these studies.

Genotyping and quantitative HCV RNA

3.12 In patient management, pretreatment genotyping provides important information with respect to the risks and benefits and the duration of treatment. Opportunities should be made available for accessing genotyping services in Canada.

3.13 Pretreatment quantitative HCV RNA assays provide important information with respect to the risks/benefits of treatment and duration of therapy, and should be made available.

3.14 Laboratories performing qualitative and quantitative HCV RNA testing and genotyping should participate in external quality assessment programs for these assays, established and coordinated centrally.

Research

3.15 Research is needed in the following areas:

- ongoing evaluation of new commercial or in-house assays for HCV testing (screening, supplemental HCV RNA and genotyping)
- new assays developed for the detection of acute HCV infection

- further evaluation of assays for use in pool testing of serum and saliva/urine-based assays
- investigation of protocols/technologies for stabilizing HCV RNA for transport
- the potential role of genotyping for public health surveillance, specifically, regional variability in genotypes, the prevalence of mixed infection, association of genotyping with risk history, and documentation of reinfection events (additional molecular techniques [sequencing] may be useful for defining transmission patterns and outbreaks)
- the contribution of genotype to immunoblot-indeterminate PCR negative samples
- the influence of reinfection events on predominant genotype, pathogenesis and natural history of HCV infection (injection drug user cohort)
- the natural history of anti-HCV positive, PCR negative patients and HCV infection associated with neonatal transmission

4. Injection Drug User Issues Working Group

Despite some efforts targeted at injection drug users (IDUs), the involvement of public health in Canada has not yet had a measurable impact on the hepatitis C epidemic in this group. There has been piggy-backing onto existing HIV/STD programs, which themselves are still not adequate, but these cannot be expected to take into account the special characteristics of the HCV epidemic.

HCV is more easily transmitted through the percutaneous/parenteral route than is HIV, and infection is acquired earlier after initiation of injection drug use. Prevention efforts should therefore target above all (but not exclusively) new IDUs and those who are contemplating injection. Minute amounts of blood may be sufficient to transmit hepatitis C, so the risk associated with sharing of drug equipment such as spoons, pipes and straws, or with tattooing and body piercing may be higher than that for HIV. On the other hand, many HIV prevention strategies (e.g. needle exchange programs) will also help to prevent hepatitis C.

At the social and legal level, improving the attitudes of the public towards IDUs and treating drug use as a health issue rather than a criminal issue may contribute to the prevention of both HCV and HIV infection. Some of the current legislation on drug use may have the effect of preventing access to services.

The harm reduction model should be used as the basis for hepatitis C prevention programs. The guiding principle of this model is to minimize harm. The model may include strategies to prevent initiation of injection drug use and to enhance safe injection among those who are injecting, and may emphasize detoxification and rehabilitation services. Abstinence could be one goal, but it is not necessary and should never be a condition of access to services. The harm reduction model is a humanistic and pragmatic approach that precludes repressive interventions.

A healthy public policy is necessary to support a strong national hepatitis C prevention strategy. Coordination between the main stakeholders public health, police, mental health, drug user services is necessary at the federal and provincial/territorial level and locally in order to ensure a coherent strategy. Issues related to drug use are better handled by the health care and social services system than by the criminal justice system, and, in line with this, reallocation of funding would provide the means for comprehensive programming.

The HIV, AIDS and Injection Drug Use National Action Plan[6] is endorsed but, given the specific characteristics of hepatitis C, additional interventions are needed. Implementation of a comprehensive program, including multiple strategies for these measures, is not possible without adequate funding.

Recommendations

4.1 Hepatitis C prevention programs should adhere to the harm reduction model as a health promotion strategy.

4.2 A federal-provincial advisory committee should be created to ensure the implementation of a hepatitis C national action plan on IDU issues.

4.3 Where there is significant overlap of issues, other bloodborne infectious diseases often found among drug users should also be addressed by the committee.

4.4 Drug users themselves must be included at all levels of discussion and intervention. This involves the creation, provision of resources for and continuing support of drug user groups at federal/provincial/territorial and local levels.

Preventing transmission individual level

4.5 Awareness about hepatitis C should be increased through dissemination of information, education, and communication targeting drugs users and those at high risk of initiating injection.

4.6 Outreach services directed to recently initiated injectors (through peer educator groups or outreach workers) should be increased.

4.7 Drug users and those at risk of initiating injection should be educated about alternatives to injection and about safe injection practices.

4.8 There should be increased access to drug abuse treatment, including a wide range of substitution treatments and low threshold interventions[h]. Substitution can also be considered a means of preventing initiation of injection, but more research is needed.

4.9 Physicians, nurses, social workers, school educators, and other appropriate workers, including outreach workers, should be trained to identify and offer early intervention to youth contemplating injection drug use.

Preventing transmission community level

4.10 Drug education programs should be updated to include accurate and complete information so that youth can make informed decisions.

4.11 Drug education and funding should primarily have a health focus. Cooperation between community policing, drug user groups, and the social agencies is vital to the success of the hepatitis C prevention and control program.

4.12 Community prevention programs need to be based on a comprehensive harm reduction model and should include needle exchange; safe injection sites; access to sterile drug use paraphernalia; greater access to detoxification and rehabilitation services, particularly for minors and young adults; well-coordinated and integrated health care and social services; user advocacy groups; lifeskills programs; and low threshold substitution therapy.

4.13 Measures, including regulatory measures, should be taken to ensure that personal services (e.g. tattooing, body piercing, acupuncture) are delivered safely.

4.14 Preventive measures available in the community should be available in the prison setting.

Preventing transmission family/networks

4.15 Medical and social services should be available to support families in difficulty and parents of young drug users.

[h] Interventions that are user friendly and accessible without any specific conditions attached, such as abstinence or the promise to be abstinent.

4.16 Interventions targeting drug user social networks should be implemented to promote modes of use other than injection.

Preventing transmission social/legal

4.17 Since social isolation and exclusion can increase the risk of hepatitis C, interventions to increase the general public understanding about drug use and drug users should be developed and implemented.

4.18 In recognition that some current legislation may contribute to the spread of hepatitis C and other bloodborne pathogens and present barriers to health action, and in support of the HIV/AIDS National Action Plan recommendations, it is proposed that the Minister of Health establish a national committee to review current drug laws and develop a plan to implement necessary changes.

Keeping infected IDUs healthy

4.19 Screening IDUs for hepatitis C provides an opportunity for counselling, treatment and other medical interventions and should be part of a comprehensive program based in settings providing services adapted to drug users.

4.20 All HCV-infected people, including IDUs, should be considered eligible for assessment and treatment. Compliance issues should be addressed on an individual level as with other diseases or populations.

Research

4.21 Research should be carried out in the following areas:

- the determinants of initiation into injection drug use
- the determinants of drug use reduction and cessation
- the possibility of a link between nonmedical injected steroid use and hepatitis C
- the role of substitution therapy (e.g. methadone) in preventing initiation of injection
- the optimal methods of delivering health care services to IDUs with hepatitis C
- the value of counselling, testing and the consequences of positive or negative test results on IDU behaviours
- the determinants and practices associated with HCV infection
- monitoring of the evolution of the HCV epidemic with respect to prevention programs
- the role of intranasal or inhalation drug use in the spread of hepatitis C infection
- feasibility studies, and process and implementation evaluation studies on specific strategies such as needle exchange programs in correctional settings and community safe injection sites

5. Education Working Group

Experience gained from the HIV epidemic was discussed, and comparisons were made between the educational needs of various groups with regard to HIV and hepatitis C. It was noted that in the mind of the public, HCV is associated primarily with blood transfusion and not with injection drug use. Educational interventions must be developed that keep in perspective the scope of the problem of hepatitis C while diminishing the possibility of over-reaction by the public. Interventions must be targeted not only to groups at high risk but also to the public and to health care providers who may not be comfortable dealing with clients who inject drugs.

To be effective, educational programs must be

- intensive,
- sustained, and
- culturally appropriate.

An intensive program is one that requires active involvement by all parties. Whether the program is based on a one-on-one model or a group

model, it must focus on participation; for example, a role playing exercise would be more intensive than listening to a talk. Educational programs need to be sustained over time, so that messages can be reinforced. Information and knowledge can often be conveyed relatively easily, whereas learning skills, improving motivation and changing attitudes often take longer. In addition, a program that does not take into account cultural values and practices may be inherently flawed.

Basic educational and social marketing strategies were discussed, and recommendations were made on the basis of general principles.

Recommendations

5.1 A federally led national awareness campaign should be developed as a priority.

Unique needs of health care providers

5.2 Through discussion with universities, schools and professional organizations, case-based curricula should be developed for health care providers that take into account their knowledge and comfort when dealing with injection drug users and related issues (including but not limited to hepatitis C).

5.3 A national clearinghouse should be instituted for hepatitis C information, i.e. a central repository where information is readily available for health care providers, patients and the general public, including a 1-800 telephone number (displayed on all information) and Internet access.

5.4 A multifaceted approach to information campaigns/publicity should be developed that would be recurrent and updated, using existing communication vehicles (e.g. newsletters and inserts in professional journals). This approach would also include a series of information products on hepatitis C and risk reduction (e.g. fact sheets and brochures) for the use of health care workers in counselling.

5.5 Laboratories should be encouraged to use the test result report of a new case as a mechanism for distributing relevant information to physicians or to indicate where additional information is available.

5.6 Current continuing education mechanisms, such as a speaker s bureau, should be used to ensure that all health care providers maintain an accurate knowledge base, especially with regard to HCV infection (the disease and its causes [especially injection drug use]), attitudes and knowledge.

Unique needs of the general public

5.7 Segments of the population should be identified and specific messages developed in accordance with the needs of those segments.

5.8 There should be support and help for client groups to become involved in the development and implementation of educational materials for the public.

Unique needs of youth

5.9 A comprehensive health approach/program should be developed to reach youth in schools and other settings. This program would deal with primary prevention and harm reduction, giving particular attention to injection drug use and other risk behaviours.

Unique needs relevant to high-risk groups

5.10 Educational materials should be developed with client groups and disseminated through existing networks, such as methadone clinics and needle exchange programs.

5.11 Educational materials should be developed and support provided for front-line workers dealing with high-risk groups.

6. Blood Supply Issues Working Group

In spite of the possible disadvantages, for people infected with hepatitis C through transfusion there are many potential benefits to knowing that they are infected. Thus, in general, it is desirable that HCV-infected transfusion recipients know their infection status. This might be carried out through hospital-based notification programs, case finding, and public notification. Hospital-based programs will likely identify the largest number of affected individuals.

Recommendations

Lookback and traceback investigations

6.1 Targeted lookbacks, both retrospective and prospective, should be continued. When an HCV-infected donor is identified outside the blood service, complete identifying information should be provided to the blood service to permit lookback.

6.2 Traceback investigations on HCV-infected transfusion recipients should be continued so that other HCV-infected recipients may be identified through a subsequent lookback.

Recipient notification

6.3 Recipient notification programs should be considered in jurisdictions where they have not been carried out. The final decision should be made on the basis of feasibility; regional, local and provincial priorities; other methods available; and the likely yield of such activities (number of yet unidentified HCV-infected recipients).

6.4 To facilitate recipient notification programs there should be

- evaluation of programs carried out to date
- technical support (consultation, probabilistic matching, etc.)
- federal support (50% of the cost)
- epidemiologic assessment of success to date (number of HCV-infected transfusion recipients still unidentified)

Public notification

Good data are lacking on the effectiveness of public notification. Nevertheless, such activities may be desirable and in some contexts useful.

6.5 Public notification campaigns should be considered instead of or in combination with recipient notification.

Case finding

6.6 Case finding for HCV infection should be carried out for persons transfused before July 1992. History taking of blood transfusion and blood donation from all patients should constitute part of a complete medical history.

6.7 Improved appropriate teaching during undergraduate and postgraduate medical training and continuing medical education of physicians should be ensured.

Follow-up of HCV-infected transfusion recipients

6.8 Enabling legislation and regulations should be enacted in all jurisdictions to allow full and free sharing of information. Such legislation must safeguard the right to privacy and confidentiality of donors and recipients.

6.9 Public health departments should carry out follow-up on all reports of HCV infection to validate the case and determine the risk factors related to the likely acquisition of the infection.

- if the HCV-infected patient donated blood (or organs, tissue or semen), communicate with the CBS/HQ (or the organs/tissues/semen procurement service)
- if the HCV-infected patient received a blood transfusion (or organs, tissue or semen) communicate with the CBS/HQ (or the organs/tissues/semen procurement service).

6.10 The investigation should include collection of key data for example, type of component, date(s) of transfusion, indication for transfusion, and hospital.

Surveillance

6.11 Trends in transfusion-acquired infection based on data collected by public health should be analyzed, interpreted, and disseminated.

6.12 Surveillance of HCV-infected donors should be routine: data on age, sex, region, risk factors for acquisition, and reason for donation should be routinely collected, recorded systematically, tabulated, and analyzed for surveillance and intervention purposes.

6.13 It should be mandatory to include transfusion history (received or not) on the hospital discharge summary and code it in the provincial database.

6.14 The blood service should develop a recipient database.

6.15 An integrated recipient/donor database (vein-to-vein) should eventually be developed.

6.16 A database of deferred donors should be developed, recorded (reason for deferral), and analyzed.

Compensation programs

6.17 When public health carries out an investigation on reported HCV cases and transfusion is identified as a possible or likely source of infection, detailed and comprehensive data on the transfusion received should be collected and recorded.

6.18 When compensation programs become aware of people possibly or probably infected, the information should be communicated to the blood service and to public health without delay.

Blood safety

6.19 New mechanisms are required to ensure systematic coordination between public health and the CBS/HQ at three levels:

- federal (with perhaps a special role for the Laboratory Centre for Disease Control)
- provincial/territorial (high priority)
- regional

6.20 Policy should be evidence-based, and scientific expertise must be involved in decision making at all stages.

6.21 Systematic evaluation and quality control is required.

Research priority areas

6.22 Important areas for research are as follows:

- the natural history of HCV infection acquired through transfusion
- residual risk (modelling)
- risks and benefits of early notification and treatment
- research-based repository of pre- and post-transfusion serum from recipient and donor
- blood safety of different types of recruitment (directed, allogeneic, etc.)
- blood donor recruitment (donor inclusion and exclusion, health assessment)
- safety of donor pool
  - recruitment
  - geographic mapping of transmissible disease
- epidemiology of transfusion in Canada
- survival following transfusion
- public attitudes and opinions on
  - the right to know
  - perception of risk of infection from transfusion
- blood utilization
- test performance
- viral inactivation/attenuation

Research structural issues

6.23 Data information systems should be developed at the blood service making possible effective surveillance and research into the risk from infectious agents.

6.24 The blood service should develop and maintain analytic capacity to ensure this surveillance and research.

6.25 Collaborations should be established with other researchers (LCDC, public health, academic centres, etc.) to ensure a comprehensive research program.

6.26 The necessary funding should be provided (10% of the blood service operational budget should be available for extramural as well as intramural research).

General Recommendation

To improve communication on various issues connected with HCV, it is recommended that individual Web sites or one central repository be developed where inventories of research in progress, results of evaluations, and requests for participation in research protocols could be posted. E-mail newletters could also be distributed to interested parties.

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Further Reading

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