

**STRATEGIC FRAMEWORK
AND ACTION PLAN
FOR THE PREVENTION
AND CONTROL OF
HEPATITIS C
IN NORTHERN IRELAND**

2004-2007

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STRATEGIC FRAMEWORK AND ACTION PLAN FOR THE PREVENTION AND CONTROL OF HEPATITIS C IN NORTHERN IRELAND

SUMMARY OF ACTION POINTS

ACTION 1: A public information campaign for hepatitis C infection is required for Northern Ireland. During 2004/5 DHSSPS should take this forward in conjunction with the relevant statutory and voluntary organisations.

ACTION 2: Further work is required under the auspices of the Northern Ireland Drugs and Alcohol Strategy Team for the prevention of transmission of hepatitis C among injecting drug users. The priority areas for action include: the publication and dissemination of a leaflet for drug users on blood borne viruses including hepatitis C; training courses aimed at professionals working with drug users to raise awareness of diseases carried by blood and other measures to control infection; the development of guidelines and a specific leaflet for those working with drug users.

ACTION 3: DHSSPS should issue further guidance during 2004/2005 on prevention of transmission of serious communicable diseases, including hepatitis C, in healthcare settings.

ACTION 4: All Trusts should ensure that staff are familiar with the risk factors for transmission of hepatitis C infection in healthcare settings, and the measures necessary to prevent them. Trusts should also ensure all staff are aware of their obligation to make occupational health departments aware if they have had a risk factor for exposure to hepatitis C or have acquired hepatitis C infection.

ACTION 5: DHSSPS should ensure that during 2004 a comprehensive evaluation of the surveillance arrangements for hepatitis C is undertaken.

ACTION 6: During 2004, DHSSPS should ensure legislation is developed and progressed to make hepatitis C a notifiable disease.

ACTION 7: DHSSPS should ensure that information is made available to all medical practitioners in Northern Ireland to enable them to (i) recognise the risk factors for, and symptoms of, hepatitis C infection, (ii) have an informed discussion with patients about hepatitis C, (iii) offer testing for hepatitis C infection to patients at risk and (iv) appropriately refer patients with hepatitis C for specialist assessment and management.

ACTION 8: DHSSPS should include the establishment of the Hepatitis C Clinical Service Network as one of the work items under the implementation programme for the hepatitis C strategic framework and action plan. An early priority should be the appointment of at least one specialist hepatitis nurse.

ACTION 9: During 2004, DHSSPS should confirm the introduction of pegylated interferon as a therapeutic option for patients with hepatitis C infection. Strict clinical guidelines will need to be developed.

ACTION 10: A hepatitis C strategic framework and action plan implementation group, reporting to the DHSSPS Chief Medical Officer, should be convened to lead on implementation of the action areas.

1 INTRODUCTION

- 1.1 Hepatitis C virus was first identified in 1989 and has since developed as a serious public health problem. Hepatitis C is predominantly a blood borne infection and is frequently asymptomatic. It can cause liver disease, including cirrhosis. In some people, hepatitis C infection will lead to liver failure or liver cancer.
- 1.2 The prevalence of hepatitis C infection has increased dramatically since it was first identified. The World Health Organisation estimates that approximately 170 million people worldwide are infected with hepatitis C and that 3 to 4 million persons are newly infected each year. In England it is estimated that around 250,000 people are chronically infected with hepatitis C, many of whom are unaware of their infection. In Northern Ireland over 700 people had acquired hepatitis C infection by the end of 2002.
- 1.3 In the UK, injecting drug use is the main way by which hepatitis C is spread. There are other, less common, routes of transmission including sexual intercourse, mother to baby, and skin piercing and tattooing when sterile equipment is not used. Prior to 1991, when screening of blood donors was introduced, a number of those who received blood products were inadvertently infected.
- 1.4 In 2000 the Chief Medical Officer, Dr Henrietta Campbell, asked the Regional Advisory Committee on Communicable Disease Control's (RACCDC), chairman Dr Clive Russell OBE, to make recommendations for a strategy for hepatitis C in Northern Ireland in response to the growing public health threat of hepatitis C infection.

RACCDC and the strategy's development

- 1.5 RACCDC convened a hepatitis C strategy subgroup, under the chairmanship of Dr Michael Callender, to undertake this work and to report back to the committee. The remit of the group was to "develop a hepatitis C strategy for Northern Ireland which would address the spectrum of issues from prevention to diagnosis, treatment and appropriate services".
- 1.6 In December 2001, the DHSSPS Health Protection Team held a regional hepatitis C workshop to inform the further development of the strategy.
- 1.7 In November 2002 the strategy subgroup submitted a report to DHSSPS. That detailed report has been used by DHSSPS to develop this hepatitis C strategic framework and action plan.

Human rights and equality

- 1.8 The 1998 Human Rights Act came fully into force in October 2000. It provides additional focus and emphasis to the rights and freedoms of

individuals guaranteed under the European Convention on Human Rights which includes an article on the right to respect for private and family life, home and correspondence. The Act requires legislation, wherever enacted, to be interpreted as far as possible in a way which is compatible with the Convention rights; makes it unlawful for a public authority to act incompatibly with the Convention rights; and, if it does, allows a case to be brought in a court or tribunal against the authority. DHSSPS is satisfied that this strategic framework and action plan including the proposed addition of hepatitis C to the list of notifiable diseases is compatible with the Human Rights Act (see appendix).

- 1.9 Having carefully considered the matter of the promotion of equality of opportunity in the terms of the 1998 Northern Ireland Act, the Department is satisfied that these proposals will not impact more adversely on any one Section 75 grouping than another, nor will they have any impact upon community relations. There is no statistical evidence available to indicate that one or other of the Section 75 groupings will benefit disproportionately or suffer disproportionately from the proposals. A full equality impact assessment is therefore not deemed necessary (see appendix).

Consultation

- 1.10 There will be a three-month consultation period from the date of issue of this document. Please send any comments you wish to make on the proposals to the Health Protection Team, Room C4.22, Castle Buildings, Stormont, Belfast, BT4 3SQ; tel 90520083; email: health.protection@dhsspsni.gov.uk

2 STRATEGIC CONTEXT

2.1 The strategic framework and action plan has been developed in the context of:

- A rising prevalence of hepatitis C infection in Northern Ireland.
- An increase in the levels of injecting drug use in Northern Ireland.
- A lack of public and professional information about hepatitis C infection.
- An acknowledged need for preventive action.
- The absence of clear clinical pathways for the management of patients with hepatitis C infection.

2.2 The pillars of hepatitis C infection control are (1):

- Blood safety.
- Reducing the harm caused by injecting drug use and prevention of sharing of injecting equipment among injecting drug users.
- Strict implementation of preventative measures in healthcare settings.
- Screening of at risk groups.
- Treatment of chronic hepatitis C infection with appropriate therapy.

2.3 The core principles underpinning the strategic framework and action plan are as follows:

- Prevention of hepatitis C infection is a public health priority.
- Action to address hepatitis C will require partnership working at all levels.
- All patients with hepatitis C have a right to quality services for diagnosis and management, irrespective of how they acquired their infection and of race, religion, gender or sexual orientation.

2.4 The subgroup identified the twin aims of a hepatitis C strategy as:

- 1 To achieve a reduction in the prevalence of hepatitis C in Northern Ireland.
- 2 Ensure that individuals with hepatitis C infection are identified and receive high quality, evidence-based management.

The priority action areas identified by the subgroup were:

- 1. Prevention**
- 2. Surveillance**
- 3. Services**

The objectives in each of these action areas are as follows:

Prevention

- 1 To promote greater awareness of hepatitis C in the Northern Ireland population and of the risk factors associated with transmission of the virus.
- 2 To provide information and advice for high risk groups in measures to reduce transmission of infection.
- 3 To increase awareness of hepatitis C amongst healthcare workers.
- 4 To ensure that infected healthcare workers are appropriately identified and treated.

Surveillance

- 1 To establish surveillance arrangements for hepatitis C which can be used to inform public health prevention programmes. Suitable surveillance arrangements would ensure the collection, collation, analysis and interpretation of demographic, risk factor, clinical, virological and pathological information.

Services

1. To ensure testing for hepatitis C infection is offered to all individuals who have been at risk of acquiring infection, in order to aid early diagnosis and investigation. Pre-test discussion should be available to all individuals offered testing to enable them to make an informed decision about consent to the test. Post-test counselling should be available for those individuals with a positive test result.
2. To ensure all individuals with hepatitis C have access to up to date, accurate and evidence based information and advice about their condition.
3. To optimise the assessment and treatment of individuals with hepatitis C virus infection by agreeing evidence based guidelines for management with arrangements for their regular review and updating.
4. To provide comprehensive services, including support services, for patients with hepatitis C.
5. To ensure service providers have appropriate procedures and policies relating to hepatitis C issues in healthcare workers.

3 BACKGROUND INFORMATION ABOUT HEPATITIS C

3.1 The hepatitis C virus

Hepatitis C virus (HCV) was first described in 1989(2) and reliable tests have been commercially available since 1991. This virus accounts for most of the post-transfusion cases and some of the other cases of “non-A non-B hepatitis”. HCV is an RNA virus. There are numerous Types and Sub Types (3). In Northern Ireland, virtually all patients have genotype 1, 2 or 3. The commonest are 1b, 3a and 1a.

3.2 Transmission of hepatitis C infection

3.2.1 Injecting drug use (IDU) and the sharing of injecting equipment (needles, syringes, spoons, water and filters) is the greatest risk factor for transmission of HCV. There is also evidence of transmission by the other routes as shown in Table 1.

Table 1: Main routes of transmission of HCV

Transmission route	Evidence
Injecting Drug Use (IDU)	The prevalence of HCV amongst injecting drug users has been reported as 59% in rural England (4) and 67% in Northwest England(5). IDU accounts for approximately 90% of all HCV transmission.
Transfusion of blood and blood products	Transfusion of HCV positive blood products carries a risk of transmission of 83%(6). However all blood is now screened and this is no longer a major risk factor.
Vertical i.e. mother to infant	If a pregnant woman mother is PCR positive the transmission rate is 6.2%. if the mother is PCR negative there seems to be little risk(6).
Breastfeeding	No definite evidence that HCV is transmitted by breast feeding(7,8). However some risk if mother has high viral load(9).
Sexual	Initially thought to be rare but now increasing evidence for some sexual transmission. Unprotected heterosexual and homosexual intercourse with a HCV infected partner probably carry similar risks(10).
Needlestick injury	There are reports of transmission rates from 0% in Spain(11) to 10% in Japan(12) Overall, the risk of transmission following needlestick injury is probably around 3.3%.

3.2.2 Less common risk factors for the transmission of HCV are tattooing, ear piercing, body piercing or acupuncture with unsterile equipment. The sharing of toothbrushes and razors is also a risk factor.

3.2.3 HIV coinfection increases likelihood of transmission of HCV from mother to infant and by needlestick injury(13,14).

3.2.4 **Transmission in healthcare settings**

Transmission from patients to healthcare workers and from healthcare workers to patients has been documented. Healthcare workers' cases are reported where transmission has occurred following eye-splash(15,16). The prevalence of HCV infection in healthcare workers has been reported from two UK centres - 0.23% in Nottingham(17), and 0.28% at the Royal Free Hospital, London(18), which is higher than the 0.05% reported in UK first time blood donors(19,20). To date there are five reports of transmission of HCV infection from a UK healthcare worker to a patient, not all of which are written up in the literature. There are three well-documented cases of accidental transmission of HCV infection from healthcare worker to patient, two of which occurred in the UK.

(i) transmission from an infected cardiac surgeon in Spain, probably as a result of injury to the surgeon's fingers caused by the wire used to sew up the sternum(21).

(ii) a single UK patient undergoing cardiothoracic surgery acquired infection from a healthcare worker(22).

(iii) a single UK patient undergoing gynaecological surgery acquired infection from a gynaecologist(23).

3.3 **Diagnosis**

A 'hepatitis C test' currently involves detection in the patient's blood of antibodies to a hepatitis C antigen (anti-HCV). Patients with anti-HCV antibodies should have a test for HCV RNA, which can be detected in blood by polymerase chain reaction (PCR). HCV positive patients may therefore be PCR-positive or PCR-negative. A positive PCR test indicates that there is active virus replication and that the individual is therefore infectious. Viral load can be assessed by quantitative PCR tests.

3.4 **Prevalence of hepatitis C in the UK**

3.4.1 While the global prevalence may be as high as 3%(24), the prevalence in first time blood donors in the UK is 1:2000 (0.05%) (19, 20) and (0.03%) in Northern Ireland(25). Studies suggest that around 0.4% of people in England are chronically infected with HCV. For a general practitioner with a list of 1,800 patients this equates to seven patients.

- 3.4.2 Globally, there is a rising incidence of HCV infection associated with injecting drug usage. The prevalence of antibodies to hepatitis C among injecting drug users in England and Wales has been shown to be as high as 30%(26). The Scottish report below indicates that as many as 60% of those diagnosed are IDUs – although they also estimate that 50% of all IDUs are infected. www.scotland.gov.uk/library5/health/hceip-00.asp.
- 3.4.3 Prisoners are known to be a high risk group for the transmission of blood borne viruses. In a study of prevalence of blood borne viruses in prisoners in England, 29% of women, 24% of men and 4% of young offenders were shown to have injected drugs at some stage in their life. The prevalence of antibody to hepatitis C infection was 10% in both men and women and 0.6% in young offenders(27). A prevalence survey of blood borne viruses among prisoners in the Republic of Ireland concluded that infection with hepatitis C, secondary to use of injected drugs, is endemic in Irish prisons; the prevalence rate for hepatitis C was 37%(28). A similar survey carried out with committal (entrant) prisoners in the Republic of Ireland found evidence for an association between imprisonment and acquisition of blood borne virus infection(29). These studies highlighted the need to consider the issue of prevalence of blood borne viruses and risk factors among prisoners in Northern Ireland.

3.5 Prevalence in Northern Ireland

- 3.5.1 Due to the absence of robust surveillance arrangements the prevalence of hepatitis C in Northern Ireland is not accurately described. The prevalence in first time blood donors is 0.03%. If this reflected the prevalence in the entire population in Northern Ireland, there would be a total of 480 cases of hepatitis C infection. However, there is pressure for those who have risk factors for blood borne viruses not to present as blood donors. The true prevalence in a population is thus likely to be higher and not lower than the prevalence in first time blood donors.
- 3.5.2 If the prevalence in the Northern Ireland population was as high as the 3% prevalence reported in some other countries(24), the total number infected would be 48,000. NICE(30) has assumed that the prevalence of hepatitis C in England and Wales is 0.4%. The prevalence in first time blood donors is lower in Northern Ireland (0.03%) than in England and Wales (0.05%). Assuming that the prevalence in the Northern Ireland population is lower than in England and Wales by the same ratio of 3/5, the total number of infected individuals in Northern Ireland would be $\frac{3}{5} \times 0.4\%$ i.e. $0.24\% \times 1.66\text{m} = 3,992$. It is likely therefore that the total number of cases in Northern Ireland is closer to the lower figure of 480 than the higher figure of 48,000 and is perhaps around 3,992.
- 3.5.3 Confirmed cases: Almost 700 cases have been confirmed by the Regional Virus Laboratory from 1991 to January 2002(31). In the years 1998-2002 the annual incidence of new cases in Northern Ireland was 3.6 per 100,000 population (58 new cases a year) and this is now rising(32). To date 40% of those genotyped have type 1 and 60% type 2 or 3 infection. In 2002 there were 75 new diagnoses, the highest yearly total reported so far. 89% of infections in

individuals with a known risk factor were associated with injecting drug use (8 of 9).

- 3.5.4 In 2002, the Unlinked Anonymous Prevalence Monitoring Programme survey of injectors was extended to Northern Ireland, 16% (12 of 77) of IDUs who took part had antibodies to hepatitis C. Of the participants, 84% (63 of 75) reported having a voluntary confidential test for hepatitis C. Just over half (5 of 9) of the injectors with hepatitis C from Northern Ireland in the survey were aware of their infection

3.6 Natural history of HCV infection

- 3.6.1 Acquisition of infection is not usually associated with symptoms. Occasionally there is a mild acute hepatitis with nausea and loss of appetite, but rarely jaundice(33).
- 3.6.2 Approximately 80% of people who acquire HCV infection become chronically infected. In chronic carriers, spontaneous clearance of the virus is rare. Of chronic carriers, 10-20% develop cirrhosis within 10 years(33). Factors associated with more rapid progression to severe liver disease are - aged over 40 years at time of infection, alcohol consumption and male gender. Of those with cirrhosis, some develop the complications of cirrhosis such as bleeding oesophageal varices, ascites, encephalopathy, liver cancer and liver failure, which are potentially fatal.
- 3.6.3 Liver cancer:** In patients with cirrhosis there is a risk of the development of liver cancer - hepatocellular carcinoma - of 1.6% per annum(34). This is higher than in cirrhosis from any other cause, including hepatitis B. Because of the high risk, and the possibility of treatment if the cancer is detected early, it is logical that all HCV patients with cirrhosis should be assessed. However there is as yet no evidence for the efficacy of screening programmes in preventing deaths from liver cancer.
- 3.6.4 Since most of the patients with chronic hepatitis C are young and have been infected within the previous 10 years or less, it is predicted that the prevalence of complications of cirrhosis and the incidence of hepatocellular carcinoma from HCV will gradually increase. This would happen even if there were no further new cases(35).
- 3.6.5 There are still many unanswered questions about hepatitis C infection and further work is required in this area.

3.7 Available interventions for hepatitis C infection

There are a number of drug treatments for hepatitis C. The specific treatment regimens and guidelines for their use are considered in more detail under the services section of this strategic framework and action plan (Chapter 5). The mainstay of treatment has been interferon with the antiviral ribavirin, although recent studies have indicated that pegylated interferon may be more effective.

4 CHALLENGES FOR THE PREVENTION AND CONTROL OF HEPATITIS C IN NORTHERN IRELAND

The hepatitis C strategy subgroup considered the evidence regarding HCV infection in Northern Ireland, including the results of a recent audit carried out under the auspices of the regional multiprofessional audit group. The group identified a number of issues which represent a challenge in the regional approach to the control of HCV infection. These may be summarised as follows.

4.1 Prevention

The rising prevalence of hepatitis C infection in Northern Ireland is in some part due to a failure of preventive efforts. To date the prevention of hepatitis C infection has not received the same attention from the public or health professionals as other serious infections such as meningitis or HIV. This requires urgent action.

The commonest known risk factor for acquisition of Hepatitis C Infection is through the sharing of blood-contaminated needles and injecting equipment among injecting drug users. This group are a priority for targeted action to reduce the transmission of hepatitis C.

4.2 Detection

The Northern Ireland Blood Transfusion Service screens all potential blood donors. However greater efforts are required to improve detection in the population at risk, in particular injecting drug users. All clients utilising the services of Trust community addiction teams and who have a history of injecting drug use are offered a hepatitis C test. However (i) not all patients give a history of injecting drug usage initially, (ii) others are not initially able to consent, (iii) some decline to be tested and (iii) others default before a blood sample is obtained. Unlinked anonymous testing has been in place at drug treatment services since June 2002.

There is a need for increased awareness of HCV among health professionals to ensure patients who have been at risk are offered testing.

4.3 Surveillance and public health action

Effective surveillance arrangements are critical to the application of effective control measures for hepatitis C. The current surveillance arrangements for hepatitis C in Northern Ireland involve several unlinked and incomplete databases which do not facilitate timely public health action. The existing databases are as follows:

1. The RGHT hepatitis clinic database which only has data on patients referred including risk factors, clinical data, virus data, biopsy data, and drug treatment and outcome data.

2. The Northern Ireland Regional Virus Laboratory database of all HCV positive samples detected in Northern Ireland since tests became available. This includes virological data plus data supplied on request forms. Some of the patient identification data on request forms has been partially anonymised.
3. The Communicable Disease Surveillance Centre (CDSC) (Northern Ireland) database of laboratory confirmed cases together with further limited clinical data obtained from the public health physicians of the four Health Boards.

Information about the prevalence of hepatitis C among ‘high risk’ populations in Northern Ireland is currently lacking. A programme of unlinked anonymous testing of IDUs attending drug treatment centres has recently been commenced in Northern Ireland and the feasibility of expanding this to include those attending needle exchange facilities needs to be considered. In addition information is urgently needed about the prevalence of blood borne viruses, including hepatitis C, among the prison population in Northern Ireland.

Currently the Consultants in Communicable Disease Control (CCDCs) at the four Health Boards receive information on laboratory confirmed cases from the Regional Virus Laboratory. The local CCDC is responsible for the follow-up of individual cases to determine what public health action, if any, is required for example in the event of a cluster of cases or an infected healthcare worker. The public health action in relation to prevention of infection and targeted intervention would be facilitated if hepatitis C were a notifiable disease.

4.4 Specialist services

All patients with a positive test for hepatitis C should be offered PCR testing and referral to an appropriate specialist, usually a hepatologist. Liver biopsy performed by a hepatologist informs the need for further treatment. The results of the recent audit of hepatitis C management in Northern Ireland indicated a clear gap between the numbers with a positive test and the numbers receiving further investigation and treatment. Some of this is due to professional factors (failure to refer) and patient factors. There are currently two medical consultants in Northern Ireland providing a specialist service for investigation and management of hepatitis C, based at the Hepatology Clinic at the Royal Group of Hospitals Trust (RGHT) in Belfast with a specialist hepatitis nurse recently appointed. An effective and regionally coordinated hepatitis C service is a prerequisite for infected patients to get appropriate investigations and treatment.

4.5 Regional Virus Laboratory

The Regional Virus Laboratory provides a service for anti-HCV testing including PCR testing and virus genotyping. So far, quantitative PCR testing as a measurement of viral load has been carried out only on a research basis

but may become more important in managing the drug treatment of hepatitis C patients.

4.6 Drug treatment

To date a limited number (< 100) HCV patients have received antiviral drug treatment for their infection(36). Most of these have been managed at the RGHT Liver Clinic or in conjunction with the Liver Clinic. All patients are managed according to a single protocol. Current treatment is usually with a combination of interferon and an anti-viral drug, ribavirin. However there is now strong evidence to support the use of pegylated interferon, given its documented effectiveness(37).

4.7 Patient support

The RGHT Liver Support Group is a branch of the British Liver Trust which offers support and advice to patients with hepatitis C. There are other active patient support groups focusing on patients infected through blood transfusion (Transfusion C Positive), haemophilia treatment or IDU. These groups provide valuable support to infected individuals and do important work in the area of prevention of transmission. The work of these groups needs to be recognised and supported.

4.8 Predicted morbidity from hepatitis C in Northern Ireland

If the figure of 3,992 (see above) is used as an estimate of prevalence of hepatitis C in Northern Ireland and using the assumptions of the rates of clinical progression made by the Scottish Health Purchasing Information Centre(38), it is predicted that the following morbidity could arise amongst hepatitis C patients in the next 20 years, if they remain untreated:

	Morbidity	No. of patients affected
1.	Moderate or severe disease	1,816
2.	Cirrhosis	286
3.	Complications of cirrhosis:	
	ascites	42
	bleeding varices	42
	hepatic encephalopathy	42
4.	Hepatocellular carcinoma	148
5.	Liver transplantation	16

The cost to the HPSS of untreated hepatitis C over the next 20 years could be as much as £10.7m.

5 ACTION PLAN FOR THE PREVENTION, MANAGEMENT AND CONTROL OF HEPATITIS C INFECTION IN NORTHERN IRELAND

The principal actions are required in the areas of

Prevention
Surveillance
Services

5.1 Prevention

General public

A substantial proportion of people with chronic hepatitis C remain unaware of their infection. Concerted effort is therefore required to raise awareness of hepatitis C infection and the risk factors for transmission among the general public. Those groups with risk factors who may need to come forward for testing should be specifically targeted, e.g. injecting drug users.

ACTION 1: A public information campaign for hepatitis C infection is required for Northern Ireland. During 2004/5 DHSSPS should take this forward in conjunction with the relevant statutory and voluntary organisations.

Injecting drug users

There is a wealth of prevention measures that can potentially impact on the level of HCV in the injecting population. Most of these target the number of injecting drug users and the levels of equipment sharing. Some interventions will have the primary aim of preventing or reducing HCV transmission. Other interventions, such as substitute prescribing, will have prevention or reduction of HCV transmission as one of a range of desired outcomes.

Type of prevention approaches

Prevention approaches can be designed to reduce the number of injectors in a population e.g.

- ensuring access to effective drug treatment;
- preventing initiation into injecting.

Prevention approaches can also be designed to reduce the sharing of Injecting equipment by:

- ensuring access to needle and syringe exchange facilities;
- ensuring access to sufficient numbers of needles and syringes; and
- providing wider injecting paraphernalia (e.g. citric acid, water, filters and spoons).

Prevention approaches can also aim to improve knowledge of HCV and the risk factors by:

Providing education and training to injectors, (especially new and young injectors who may not yet be infected) and young people at risk of injecting drugs (especially marginalised young people), to encourage them to change their injecting behaviour, developing new ways of getting the message through to drug users such as peer education, outreach services, information campaigns, outreach schemes, and training of healthcare workers.

Overall, a strategy to prevent the spread of HCV should clearly not rely upon one of the above approaches, but should tackle the problem in a range of ways, with a combination of interventions.

A number of initiatives have already been initiated by the DHSSPS which will have an impact on the prevention of blood borne virus transmission among injecting drug users. These include:

- 1 Introduction of a free needle and syringe exchange scheme in community pharmacies in Northern Ireland from 2002.
- 2 The extension of this service following amendments to the Misuse of Drugs Act to include the provision of paraphernalia.
- 3 In January 2003 the DHSSPS recommended the wider introduction of substitute prescribing services in response to reports on the prevalence of local problem heroin use and research evidence on effectiveness. Since then regional guidelines, using a shared care approach, have been developed for consultant psychiatrists, community pharmacists, general practitioners and the other key professionals; a multidisciplinary training programme accredited through the University of Ulster has been established; systems for the evaluation and monitoring of the service have been designed. Interim arrangements were introduced in September 2003 with recurring resources being made available from 1 April 2004. A leaflet aimed at users and designed in consultation with user groups has been produced and is widely available.
- 4 The Northern Ireland Drug and Alcohol Strategy Team has provided funding to a range of schemes which are aimed at providing support to drug users and their families, including outreach schemes; the development of a drug user network and the publication and dissemination of safer injecting leaflet distributed through the needle and syringe exchange scheme.

ACTION 2: Further work is required under the auspices of the Northern Ireland Drugs and Alcohol Strategy Team to prevent transmission of hepatitis C infection among injecting drug users. The priority areas for action include: the publication and dissemination of a leaflet for drug users on blood borne viruses including hepatitis C; training courses aimed at professionals working with drug users to raise awareness of diseases

carried by blood and other measures to control infection; the development of guidelines and a specific leaflet for those working with drug users.

Body piercing

Local authorities here have the duty to register and control acupuncture, tattooing, ear piercing and electrolysis premises under Articles 12-16 of the 1985 Local Government (Miscellaneous Provisions) (Northern Ireland) Order.

In England and Wales, in 2003, the legislation was amended to include from 1 April 2004 cosmetic piercing (piercing of the body including ear piercing) and semi-permanent skin-colouring (including micropigmentation, semi permanent make-up and temporary tattooing) and enabling local authorities to make byelaws relating to the cleanliness and hygiene of such premises, practitioners and equipment.

It is the DHSSPS Health Protection Team's intention to have the 1985 Order amended and cover these other activities in a further Local Government (Miscellaneous Provisions) Order that DOE is in the process of legislating.

Hepatitis C in prisoners

DHSSPS, in conjunction with the Northern Ireland Prison Service, are currently undertaking a survey to determine the prevalence of blood borne viruses and risk factors for their transmission among Northern Ireland prisoners. This information will be used to inform future prison policy on the prevention and control of blood borne viruses and the provision of services for prisoners already infected.

Prevention in healthcare settings

Comprehensive measures are already in place to ensure that the chances of acquiring hepatitis C infection from blood, blood products, or organs and tissues for transplantation are extremely low.

It is widely accepted that the key control measure in relation to the transmission of all blood borne viruses, including hepatitis C, in clinical settings is strict adherence to infection control measures. All HSS Trusts in Northern Ireland have standard infection control measures covering prevention of blood borne viruses and in particular advice about safe handling and disposal of sharps, decontamination, sterilisation of instruments and guidelines for the prevention and control of blood borne virus infections in renal dialysis units.

Healthcare workers infected with hepatitis C

The Department of Health in England has issued guidelines on the management of hepatitis C infected healthcare workers. Further guidance is being developed on serious communicable diseases (TB, HIV, hepatitis B,

hepatitis C) in healthcare workers. A consultation document on this issue was issued in Northern Ireland on 13 March 2003 entitled *Health Clearance for Healthcare Workers for Serious Communicable Diseases*. It is available at <http://www.dhsspsni.gov.uk/publications/2003/healthclear.pdf>

ACTION 3: DHSSPS should issue further guidance during 2004/2005 on prevention of transmission of serious communicable diseases, including hepatitis C, in healthcare settings.

Occupational exposure

Due to the nature of their work certain staff working in the HPSS remain at risk of exposure to the blood of patients infected with hepatitis C. Existing evidence would suggest that the risk of transmission from a single exposure from hepatitis C antibody positive source is probably between 1.2% and 3%. All healthcare workers must report occupational exposures to blood to their occupational health departments or a GP in order that these may be followed up appropriately. Any exposed healthcare worker who acquires hepatitis C infection during this follow-up should be referred for specialist advice.

A key measure in minimising the risk of occupational exposure to hepatitis C infection is to ensure that all staff are fully trained in the safe handling and disposal of sharps.

ACTION 4: All Trusts should ensure that staff are familiar with the risk factors for transmission of hepatitis C infection in healthcare settings, and the measure necessary to prevent them. Trusts should also ensure all staff are aware of their obligation to make occupational health departments aware if they have had a risk factor for exposure to hepatitis C or have acquired hepatitis C infection

5.2 Surveillance

5.2.1 High quality surveillance arrangements are required to profile the epidemiology of hepatitis C infection, inform public health action and monitor the outcome of preventive efforts. In order to provide robust data for public health action, the following objectives of a surveillance system for hepatitis C should be fulfilled. It should enable:

1. Detection of changes in disease patterns including outbreaks to enable early public health action to be taken when appropriate.
2. Evaluation of control measures.
3. Provision of data for health service planning.

Specifically surveillance arrangements for hepatitis C should have the following objectives:

1. To estimate the magnitude of morbidity and mortality due to hepatitis C.
2. To monitor the long term epidemiological trends in order to allow for health service planning.
3. To determine the risk factors for transmission of hepatitis C in order that appropriate public health preventative action may be taken.
4. To ensure the appropriate investigation management of cases with hepatitis C.
5. To show the distribution of genotypes of hepatitis C virus that affect treatment allocation.
6. To determine the circumstances and reasons for hepatitis C testing.
7. To provide data and generate hypotheses for further studies.

ACTION 5: DHSSPS should ensure that during 2004 a comprehensive evaluation of the surveillance arrangements for hepatitis C is undertaken. This evaluation should:

1. Document the current surveillance systems.
2. Measure the performance of the current surveillance systems against international criteria.
3. Determine the need for any changes to the surveillance system.
4. Make recommendations for the future surveillance arrangements for hepatitis C in Northern Ireland.

5.2.2 A key factor in ensuring that all new cases of hepatitis C are appropriately followed up is making hepatitis C a notifiable disease. 'Hepatitis A', 'hepatitis B' and 'hepatitis unspecified: viral' are all currently notifiable diseases in Northern Ireland but on solicitor's advice it is accepted that hepatitis C, once identified and named, no longer falls within the 'hepatitis unspecified' category. England and Scotland have only one category named 'viral hepatitis'. The Republic of Ireland is still considering making hepatitis A, B and C individually notifiable but by microbiology laboratory directors. Such an addition in Northern Ireland would make individual medical practitioners responsible for notifying cases of hepatitis C to their Board's Director of Public Health in order for appropriate public health action to be taken. In 2002 the RACCDC recommended that hepatitis C should be made a notifiable disease.

ACTION 6: During 2004 the DHSSPS should ensure legislation is developed and progressed to make hepatitis C a notifiable disease.

5.2.3 Patients with hepatitis C infection may develop the specific life threatening complications of oesophageal varices and hepatocellular carcinoma. These

complications are more common in patients with cirrhosis and, as such, it will be necessary to have appropriate surveillance arrangements in place to detect these conditions in patients with cirrhosis secondary to chronic hepatitis C infection.

5.3 Improving services

5.3.1 It is essential that high quality and accessible services are available for the diagnosis and management of patients with hepatitis C infection. Current information would suggest that there is a gap in the provision of services for the detection, diagnosis, specialist assessment, and treatment of patients with hepatitis C infection.

Detection of hepatitis C infection

5.3.2 The available data would suggest that there are a significant number of people in Northern Ireland in whom hepatitis C infection remains undetected. This may be due to a number of factors including a lack of awareness among both the public and health professionals of hepatitis C infection, or reluctance among those at risk to come forward for testing. It is essential that all those who have been at risk of hepatitis C infection are identified and offered testing, as those who are positive may benefit from specialist medical interventions.

5.3.3 The first point of contact for patients with hepatitis C infection may well be their general practitioner. It is therefore important that all general practitioners are aware of the risk factors for acquisition, and the symptoms and signs of hepatitis C infection. They also need to know who to test for hepatitis C infection and what the referral pathways are for specialist referral of patients with confirmed infection. Similarly, patients may present in other settings such as drug treatment centres, genitourinary medicine clinics, hepatology/gastroenterology clinics, infectious diseases, renal units and prison medical services. It is thus important that all medical practitioners are aware of hepatitis C and how to diagnose it.

ACTION 7: DHSSPS should ensure that information is made available to all medical practitioners in Northern Ireland to enable them to (i) recognise the risk factors for and symptoms of hepatitis C infection, (ii) have an informed discussion with patients about hepatitis C, (iii) offer testing for hepatitis C infection to patients at risk and (iv) appropriately refer patients with hepatitis C for specialist assessment and management.

Information about hepatitis C

5.3.4 Information should be available to those who feel they may be at risk and who present themselves for testing. Practitioners carrying out testing of individuals should ensure that an appropriate discussion takes place to allow informed consent. All individuals being tested should be assured of confidentiality.

Once a positive test result has been received it is essential that confirmatory testing is undertaken and the patient is referred for specialist assessment. At this time patients should receive further detailed information about hepatitis C.

Specialist assessment of patients with hepatitis C infection

- 5.3.5 Patients with hepatitis C infection should be referred to a specialist service, usually led by a hepatologist or gastroenterologist with expertise in the area of hepatitis C diagnosis and management. This service should be operating within a specialist Northern Ireland Hepatitis C Clinical Service Network (see below). This network would function as a managed clinical network and would be responsible for co-ordinating the overall management of all patients in Northern Ireland with hepatitis C infection. It may also be necessary for the patient's general practitioner to be actively involved in the management of their patient, and this may be particularly relevant in the management of injecting drug users.
- 5.3.6 Evidence is emerging from a number of specialist centres in Scotland of the effectiveness of specialist nurse led clinics and community based services in the prevention, management and follow up of patients with hepatitis C. These models of care should be considered for Northern Ireland and incorporated in the arrangements for the clinical service network.
- 5.3.7 There is evidence from Northern Ireland and other UK centres that (a) there are significant waiting times for treatment for hepatitis C and (b) there is a high non-attendance rate among patients offered appointments at services. The consensus view of the Royal Colleges of Physicians in Edinburgh is that the requirement for liver biopsy to determine selection of patients for therapy is no longer essential, this should help speed up access to specialist treatment for patients. Specialist services will need to ensure that they consider the wider issues of support for patients, including dealing with mental health problems, to ensure patients attend services when required.

Hepatitis C Clinical Service Network

- 5.3.8 Appropriate members of a Hepatitis C Clinical Service Network would be as follows:
- Chair appointed by the Chief Medical Officer
 - A lead clinician with experience in the diagnosis and management of viral hepatitis.
 - A network of clinicians with the necessary expertise to diagnosis and manage hepatitis C. These may be hepatologists or gastroenterologists with an interest in liver disease.
 - A specialist hepatitis nurse; these nurses would provide a service to patients who are being referred, managed and treated for chronic

hepatitis C. The roles so undertaken would include post-test counselling after a positive test result.

- A virologist from the Regional Virus Laboratory.
- A pathologist with expertise in the assessment of liver biopsies, grading and staging of liver histology according to internationally established criteria.
- A radiologist with expertise in hepatic radiology and hepatocellular carcinoma surveillance.
- A general practitioner
- A genitourinary medicine physician
- A representative from hepatitis C support services

Although the majority of hepatitis C patients who have been investigated and managed in the context of a specialist hepatology service i.e. that provided at the RGHT, it is envisaged that the large numbers of cases will mean patients will have to be managed within wider hospital services in the province, preferably by a gastroenterologist with a specialist interest in hepatitis C who is linking in with the Northern Ireland clinical service network for hepatitis C. Specialist nurse services are seen as an integral part of the specialist hepatitis C service. Initially these specialist nurses should be appointed as part of this clinical service network, based at the Regional Hepatology Service at the RGHT, and provide outreach services to other Trusts within the context of the clinical service network. It is also likely that there will be shared care with other secondary and primary care services.

Roles and responsibilities of the Hepatitis C Clinical Service Network:

1. To develop clear protocols for the management of patients with hepatitis C infection in primary and secondary care.
2. To develop care pathways including referral and ongoing management arrangements for all patients and specific care pathways for designated groups of patients such as injecting drug users, children with hepatitis C, prisoners, and patients with HIV co-infection.
3. To facilitate further research.
4. To advise on surveillance arrangements for hepatocellular carcinoma and oesophageal varices.
5. To undertake audit and monitoring of the standards of care provided by hepatitis C services in Northern Ireland.

ACTION 8: DHSSPS should include the establishment of the Hepatitis C Clinical Service Network as one of the work items under the implementation programme for the hepatitis C strategic framework and action plan (see below). An early priority should be the appointment of at least one specialist hepatitis nurse.

Treatment of hepatitis infection

5.3.9 Clinical guidelines will need to be developed for the appropriate investigation and treatment of patients with hepatitis C infection. DHSSPS endorses the current NICE guidelines in relation to the use of Interferon Alpha and Ribavarin for the treatment of chronic hepatitis C, including pegylated interferon. Use of pegylated interferon will ensure better clinical outcomes for a substantial proportion of patients. However the introduction of pegylated interferon will require the development of appropriate guidelines for its use. Additional resources are required and funding has been made available through the Regional Medical Services Consortium.

ACTION 9: During 2004 the DHSSPS should confirm the introduction of pegylated interferon as a therapeutic option for patients with hepatitis C infection. Strict clinical guidelines will need to be developed.

6 TAKING THE WORK PROGRAMME FORWARD

- 6.1 A programme of work will need to be developed to take forward the implementation of the actions recommended under this strategic framework and action plan. DHSSPS Health Protection Team should be responsible for defining the scope of this work and for convening a hepatitis C strategic framework and action plan implementation group to take the work programme forward. Appropriate membership of this group would include:

A director of public health

A consultant in communicable disease control

A consultant hepatologist from RGHT

A consultant gastroenterologist from a Trust outside Belfast.

A consultant virologist

A hepatitis specialist nurse

A regional epidemiologist

A health promotion specialist

A DHSSPS Senior Medical Officer

The Regional Drug and Alcohol Strategy Team co-ordinator or a Community Drug and Alcohol co-ordinator

Health Promotion Agency Northern Ireland

Acute services representatives from Boards/Trusts/DHSSPS

Patient representatives, including representatives of injecting drug users.

- 6.2 The strategic framework and action plan implementation group should be convened within three months of the end of the consultation period.

ACTION 10: A hepatitis C strategic framework and action plan implementation group, reporting to the DHSSPS Chief Medical Officer, should be convened to lead on the implementation of the action areas.

STRATEGIC FRAMEWORK AND ACTION PLAN FOR THE PREVENTION AND CONTROL OF HEPATITIS C IN NORTHERN IRELAND

HUMAN RIGHTS CONSIDERATION

Justification for the proposal to make hepatitis C a notifiable disease is made on public health grounds. ‘Hepatitis A’, ‘hepatitis B’ and ‘hepatitis unspecified: viral’ are currently all notifiable diseases in Northern Ireland but on legal advice it has been accepted that hepatitis C, once identified and so named as it has been since 1989, no longer falls within the ‘hepatitis unspecified’ category. To properly monitor the incidence of this disease, and maintain unambiguous records, it is therefore necessary to list it under its specific name. This will involve adding hepatitis C to the diseases currently listed in the Public Health Notifiable Diseases Order (Northern Ireland) 1990 which was made under the Public Health Act 1967.

Article 8 of the European Convention on Human Rights reads, in part, “Everyone has the right to respect for his private and family life, his home and his correspondence. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”

The present obligatory notifiability in regard to other listed diseases is undertaken specifically for the protection of health. It requires the Department and the Health Service only to record the incidence of the disease in question, along with the individual’s name and address, but not to follow through with any particular action in relation to anyone so named. There is nothing in the proposed change to add hepatitis C (or novel about it) that contravenes that article on respect for private life, since the existing laws on notifiability of infectious diseases are presently accepted, as necessary public health protection measures.

It is also intended to enhance surveillance of hepatitis C infections by monitoring patterns of infection and to try to increase detection of undiagnosed infections. This will be done in order to minimise transmission, and reduce consequent illness and disability. This and the legislative change on notifiability is intended to bring about greater public health and safety, and benefit the general population and those individuals unfortunately infected with the virus. Nobody will be penalised for having the virus or be disadvantaged by virtue of notification.

SECTION 75 EQUALITY SCREENING

The strategic framework and action plan makes a number of proposals including a public information campaign, evaluation of surveillance arrangements, the establishment of a Hepatitis C Clinical Service Network and adding hepatitis C to the list of notifiable diseases. The plan is essentially about enhancing and improving existing services and does not involve any radical policy reassessment or major resource reassignment.

Section 75 of the Northern Ireland Act 1998, from 1 January 2000, placed statutory equality related duties on all government departments and other public authorities. From that date public authorities have to have “due regard to the need to promote equality of opportunity” between people in terms of the following dimensions:

- religious belief;
- political opinion;
- racial group;
- age;
- marital status;
- sexual orientation;
- sex/gender;
- disability;
- whether or not someone has dependants.

Without prejudice to the equality duty, public authorities must also have regard to the desirability of promoting good relations between:

- persons of different religious belief;
- persons of different political opinion; or
- persons of different racial group.

When a new policy is being considered, the responsible public authority must screen its proposals in order to determine whether they should be subject to a full equality impact assessment, which would be carried out in accordance with guidance issued by the Equality Commission for Northern Ireland.

The Equality Commission specifies the following screening questions.

- a. Is there any evidence of higher or lower participation or uptake by different groups?
- b. Is there any evidence that different groups have different needs, experiences, issues and priorities in relation to the particular policy?
- c. Is there an opportunity to better promote equality of opportunity or good relations by altering policy or working with others in government or the community at large?
- d. Have consultations in the past with relevant representatives, organisations or individuals within groups indicated that particular policies create problems that are specific to them?

Hepatitis C is a virus first identified in 1989. Injecting drug users (IDUs) have the greatest risk factor for its transmission. Most new confirmations of hepatitis C infection are sourced from them. Prisoners are another noted at-risk group. Infection can occur in healthcare settings and hepatitis C has been transmitted by blood products and blood transfusion although it is now screened out. Infection via sexual intercourse was initially thought to be rare but there is now increasing evidence of some sexual transmission.

IDUs will be a priority target group for the reduction of transmission. They do not constitute a group subject to section 75 consideration. However it is accepted that all patients with hepatitis C have a right to quality services for diagnosis and management, irrespective of how they acquired their infection or where they are located.

Having carefully considered the matter of the promotion of equality of opportunity in the terms of the 1998 Act, the Department is satisfied that the proposals will not impact more adversely on any one Section 75 grouping than another, nor will they have any impact upon community relations. There is no statistical evidence available to indicate that one or other Section 75 grouping will benefit disproportionately or suffer disproportionately from the proposals. Therefore as each of the Section 75 dimensions, in this instance, comes up with a negative answer, a full equality impact assessment is not deemed necessary.

The fact that groups representing some of those who have or have had hepatitis C infection may not necessarily welcome notifiability because of fears of a diminution in confidentiality as regards the recording of personal details in the Health Service, and their transmission onwards to DHSSPS, does not bring the issue within the ambit of equality law or the equality duty. All people diagnosed as being infected with hepatitis C once it becomes a specific notifiable disease will be subject to the same process of notification to the Department, and to the publication of anonymised numeric details by CDSC as are those currently diagnosed with and recorded as having any other notifiable disease.

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