

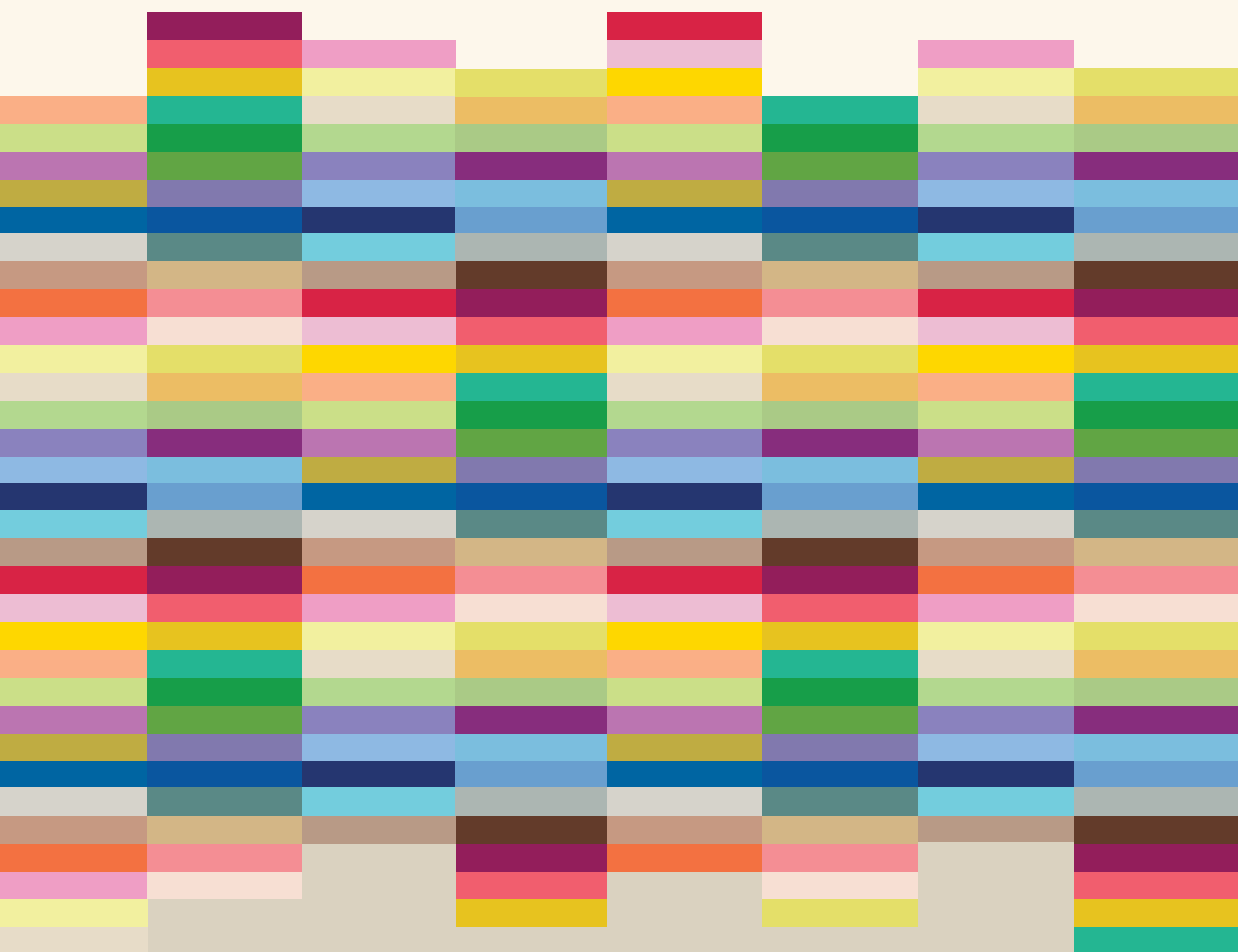
## National Hepatitis C strategy 2011-2014

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Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

# *National Hepatitis C Strategy 2011-2014*



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# 1. Introduction

Hepatitis C is a disease of the liver caused by a virus identified in 1989 as the hepatitis C virus. Hepatitis C is a communicable disease that is spread from person to person by contact with infected blood or body fluids. Intravenous drug use and receipt of unscreened blood or blood products are well established as the major risk factors for the acquisition of hepatitis C infection. In comparison with HIV (Human Immunodeficiency Virus) and hepatitis B, the virus is much less likely to be spread through sexual contact, household contact or by mother-to-child transmission. The distribution of hepatitis C globally differs by time, place and person. In Ireland those at risk of infection are most often socially excluded groups such as drug users, the homeless and immigrants from endemic countries.

Hepatitis C is most commonly an asymptomatic infection both in the acute and early chronic stages. The acute stage of infection tends to go unnoticed therefore it is often difficult to establish when someone became infected. Chronic infection occurs in 70-80% of adults acutely infected. This compares to hepatitis B where chronic infection occurs in only 10% of acutely infected adults. Some non-specific symptoms of chronic disease may occur e.g. ongoing flu-like symptoms, joint pains, abdominal pain, loss of appetite, altered bowel habit, mood swings and insomnia. Complications of chronic hepatitis C include cirrhosis, liver failure and liver cancer. Certain factors have been identified that affect disease progression, e.g. alcohol intake, co-infection with HIV or hepatitis B, super-infection with hepatitis A and older age at infection.

Hepatitis C can now be treated with anti-viral agents, most commonly as a combination of two different agents. Treatment is not without significant side-effects. This can affect the uptake of treatment and also adherence and compliance.

In Ireland by 1994 it became apparent that individuals had become infected with hepatitis C and HIV through transfusion of infected blood or through administration of infected blood products in the State. In 2003, a working group was established by the then Eastern Regional Health Authority (ERHA) to set out key recommendations to enhance prevention, treatment and surveillance of hepatitis C among all infected people in the Eastern Region. In 2004, following on from a year long consultative process, a regional hepatitis C strategy document was produced. It was developed in partnership with the statutory, voluntary and community sectors. Some of the recommendations of that report have been implemented, but many have not. The report was never published.

Following the establishment of the HSE (Health Service Executive) a working group was convened under the auspices of Social Inclusion in 2007 with the objective of developing a national strategy for hepatitis C in Ireland. This document reflects the outcome of the group's efforts.

Implementation of this strategy will require considered, coordinated effort, utilising existing governance and operational structures. Ongoing monitoring and reporting of progress will be integral to this process. Recommended actions will be progressed on a phased, prioritised basis, with those that are deemed budget neutral or cost effective taking precedence in implementation.

## 1.1 Terms of Reference

The terms of reference for the working group are listed below.

- 1 To examine the 2004 ERHA report recommendations and update them as appropriate in the context of the establishment of the HSE.
- 2 To determine the current position regarding the 2004 recommendations.
- 3 To prioritise recommendations for 2011 and the coming three years.
- 4 To agree an action plan.

## 1.2 Membership

A multidisciplinary working group was established with broad representation from healthcare professions, voluntary and statutory organisations, providers and users of services. Three additional subgroups were created to focus on the areas of:

- Surveillance
- Education, Prevention and Communication
- Treatment

The area of screening for and laboratory diagnosis of hepatitis C was addressed by both the surveillance and the treatment subgroups.

Full membership of the Working Group and subgroups can be found in Appendices 1 to 4.

## 1.3 Acknowledgements

The group would like to acknowledge the assistance of the National Cancer Registry of Ireland (NCRI), the Central Statistics Office (CSO), the Liver Transplant Unit in St Vincent's University Hospital, the Irish Blood Transfusion Service (IBTS).

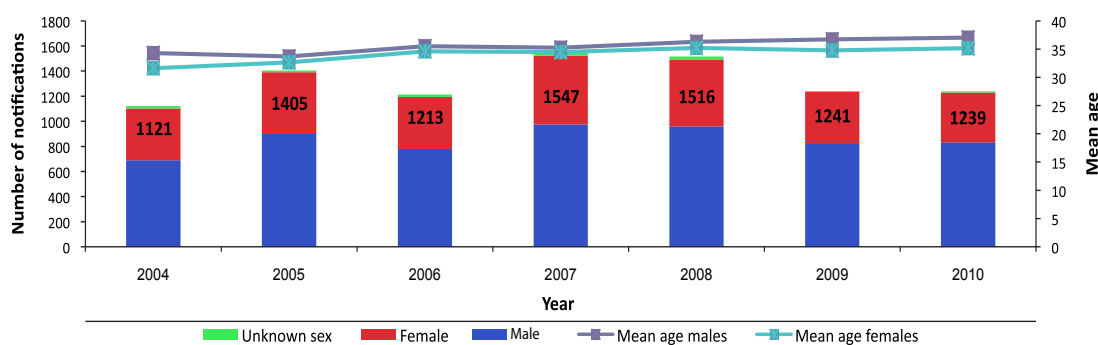
## 2. EPIDEMIOLOGY OF HEPATITIS C INFECTION

### 2.1 Epidemiology of Hepatitis C Infection in Ireland

Comprehensive information about the distribution of hepatitis C infection in Ireland is limited. What information we have comes from routine surveillance and from special studies in high prevalence groups (such as injecting drug users (IDUs) and prisoners) and on people infected through the administration of contaminated blood and blood products. Additional prevalence data are available on blood donors. Sources of information about the burden of hepatitis C disease include the HSE Departments of Public Health and the Health Protection Surveillance Centre (HPSC), the National Virus Reference Laboratory (NVRL) the Hospital Inpatient Enquiry System (HIPE), the National Cancer Registry of Ireland (NCRI), mortality data from the Central Statistics Office (CSO), and liver transplantation data.

#### 2.1.1 Information from Routine Surveillance - Notifications 2004-2010

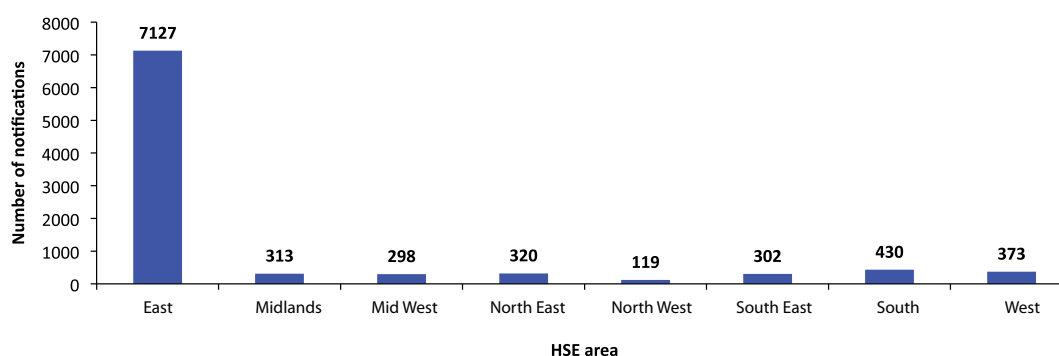
There were 9,282 cases of hepatitis C notified in Ireland between 2004 and 2010. The number of cases and mean age at notification, by sex, are shown in figure 1.



**Figure 1. Number of notifications of hepatitis C and mean age at notification, by sex, 2004-2010**

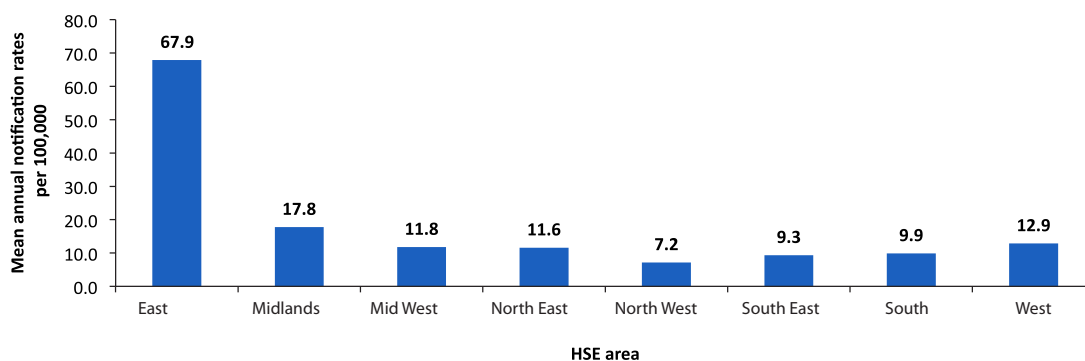
Source: HPSC

The HSE-E reported 77% (n=7127) of cases notified between 2004 and 2010. The total number of notifications and mean annual rate per 100,000 population, for each HSE area are shown in figures 2 and 3, respectively.



**Figure 2. Number of hepatitis C notifications by HSE-area, 2004-2010**

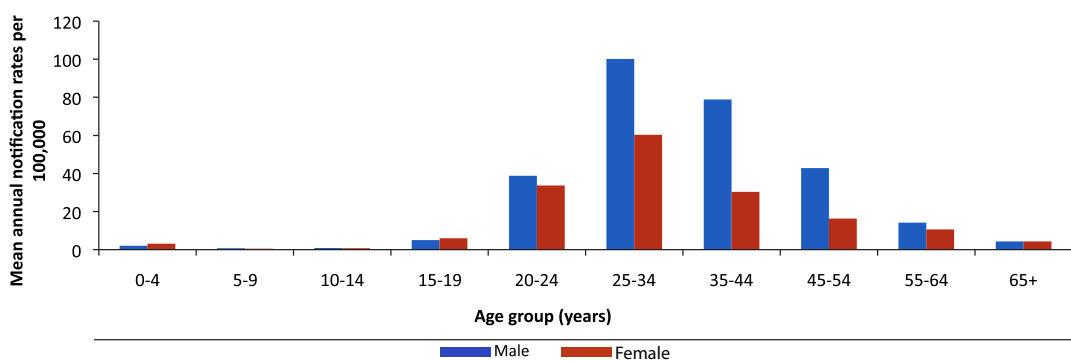
Source HPSC



**Figure 3. Mean annual hepatitis C notification rates (per 100,000 population) by HSE-area, 2004-2010**

Source: HPSC

Between 2004 and 2010, 64% of hepatitis C notifications were male (n=5962), 35% were female (n=3199) and sex was not known for the remaining cases (1%, n=121). The highest notification rates were among young to middle-aged adults. Seventy one percent (n=6560) of cases notified between 2004 and 2010 were aged between 25 and 44 years, and 92% (n=8529) were aged between 20 and 54 years. The mean age for male cases (35.6 years) was higher than that for females (34.1 years). The mean annual age and sex specific notification rates are shown in figure 4.



**Figure 4. Mean annual age and sex specific notification rates (per 100,000 population) for hepatitis C, 2004-2010**

Source: HPSC

Data on most likely risk factors were available for 59% of cases (n=728) notified in 2010. The most common risk factors reported were injecting drug use (76%, n=550), being an asylum seeker/born in an endemic country (9%, n=63), sexual exposure (5%, n=38) and receipt of blood or blood products (3%, n=19).

Of the nineteen cases acquired through blood or blood products, seven were infected in Ireland, five were infected outside Ireland and country of infection was not known for seven. All cases acquired in Ireland were infected many years in the past, but were notified for the first time in 2010. Although information on risk factor was not available for 41% of notifications in 2010, the age and sex profile of these cases did not differ significantly from those for whom information was available.

### 2.1.2 Other sources of information about hepatitis C in Ireland

Little is known about the prevalence of hepatitis C infection in the general population in Ireland. However, hepatitis C is known to be more prevalent in certain sub-groups of the population such as IDUs and prisoners. Hepatitis C may also be a concern for immigrants from high endemicity countries. Several cross-sectional studies have been carried out to estimate the prevalence of hepatitis C in high-risk groups. The results of these are summarised below. Further information is available on those who were infected in the past through the administration of contaminated blood and blood products. Data are also available on blood donors through the screening of this low risk population group.



### 2.1.2.1 Injecting drug users

Based on Irish studies cited below, the hepatitis C prevalence in the population of injecting drug users ranges from 62 to 81%.

One study looking at the clinical records of a random sample of opiate users attending the-then Eastern Health Board methadone clinics in 1997 estimated the prevalence of antibody to hepatitis C virus (anti-HCV) among those tested to be 79%. [1] A cross-sectional survey of the records of IDUs attending 21 specialist addiction treatment centres in the South-Western Area Health Board was carried out between December 2001 and January 2002. This study found that 66% of those sampled, and whose records showed testing for hepatitis C, were anti-HCV positive. [2] A study using the records of IDUs in treatment in Dublin, who had been tested for hepatitis C between September 1992 and September 1997, estimated the anti-HCV prevalence in this population to be 62%. [3] A retrospective cohort study among IDUs in Dublin, tested in the 1990s, estimated an overall incidence of hepatitis C of 66 per 100 person years. [4]

Studies assessing hepatitis C prevalence in IDUs attending general practitioners (GPs) have also been carried out in the Dublin area. A 1999 cross-sectional survey of 571 patients attending 42 General Practitioners (GP) in the eastern region for methadone maintenance treatment reported that 73% of those whose hepatitis C status was known were positive. [5] A further study of GP records for 196 consenting IDUs attending for methadone maintenance, found that 77% had been screened for hepatitis C and that 69% of those tested were anti-HCV positive. [6]

### 2.1.2.2 Prisoners

There are high rates of hepatitis C amongst prisoners on entry to prison due to the high rate of imprisonment for drug related crime. A cross-sectional survey, which included a self-completed risk factor questionnaire and testing of oral fluid specimens, was carried out in nine prisons in Ireland in 1998. The response rate was 88% (n=1205), constituting 45% of the Irish prison population at the time. Over 40% of prisoners reported ever injecting drugs. Thirty-seven percent of prisoners tested were positive for antibodies to hepatitis C. Where only prisoners reporting injecting drug use were considered, 81.3% of those tested were positive for antibodies to hepatitis C.[7] A follow on study, carried out on prison entrants between April and May 1999, found 21.8% of all prisoners sampled and 71.7% of those who reported injecting drug use, to be positive for antibodies to hepatitis C.[8]

Risk behaviours for hepatitis C transmission, such as unsafe injecting practices and tattooing, occur in the prison environment. Confinement to prison is recognised as a specific risk factor for the sharing of drug using equipment. [9] Tattooing in prison has been found to be an independent risk factor for hepatitis C infection in prisoners who have never injected drugs.[8]

### 2.1.2.3 Asylum seekers

Although screening for hepatitis C is not part of the recommended national communicable disease screening programme for asylum seekers living in direct provision, it is offered in some parts of the country. A review of the communicable disease screening service for asylum seekers was carried out in the ERHA (now the HSE Eastern Region) in 2004.[10] This service was estimated to have carried out voluntary communicable disease screening on 35-40% of all new applicants for asylum during the years 1998-2003. Of those screened for hepatitis C between 1999-2003, 1.5% were positive.

### 2.1.2.4 Hepatitis C infection through blood and blood products

Almost 1,700 people have been infected with hepatitis C through the administration of blood and blood products in Ireland. [11][12] These include women infected through anti-D immune globulin, people with haemophilia, recipients of blood transfusion and people who received treatment for renal disease. Transmission of hepatitis C infection through Irish blood and blood products no longer occurs as blood and blood products are now screened for hepatitis C.

At the request of the Consultative Council on Hepatitis C, a national research database of those infected through blood and blood products was established by the HPSC in conjunction with the eight designated hepatology units. The database records information on demographics, hepatitis C exposure, current clinical status, test results, hepatitis C treatment and current management. Most database participants had been infected for over 25 years by the end of 2008. Of those who were chronically infected, 19% had signs of serious liver disease, 14% had developed cirrhosis, 3% had developed hepatocellular carcinoma and 5% had died from liver related causes [13].

### 2.1.2.5 Blood donor screening

The IBTS blood donor screening programme detected an anti-HCV prevalence of 0.018% (46/257358) in new blood donors between 1997 and 2010 (personal communication, IBTS November 2011). This very low prevalence is to be expected as blood donors are unpaid volunteers and individuals who are identified as having relevant risk factors are excluded prior to donation.

## 2.2 Current burden of hepatitis C disease

In 2001, Kavanagh et al [14] examined the prevalence of hepatitis C and its prognostic co-factors in a group of IDUs attending a community based drug treatment clinic in the Eastern Region. Using their results and published data regarding the prevalence of opiate dependency in Ireland, the authors estimated the long term burden of hepatitis C related disease among IDUs in Ireland based on current figures. After 20 years of persistent viraemia, they estimated that there would be 1,214 cases of hepatitis C related cirrhosis nationally. This is based on published estimations that 22% of those with chronic viraemia for 20 years progress to cirrhosis. Further progression of these cases, again using published estimates, would result in approximately 35 cases of hepatocellular carcinoma, 60 cases of hepatic decompensation and 50 liver related deaths per annum.

The Kavanagh paper was based on an estimated 5,519 IDUs in Ireland with chronic hepatitis C infection. However, it is likely that the true figure is considerably higher than this. A recently published study on the burden of hepatitis C infection in Ireland estimated that by the end of 2009 there were about 10,000 people in Ireland who had been diagnosed with hepatitis C and had chronic infection, with drug use being the most likely risk factor in 80% of these. Taking account of the high proportion of hepatitis C infections that remain undiagnosed, the authors estimated that 20,000 to 50,000 people in Ireland are chronically infected with hepatitis C virus, a population prevalence of 0.5-1.2%. [15]

### 2.2.1 Hospital In-Patient Enquiry Data

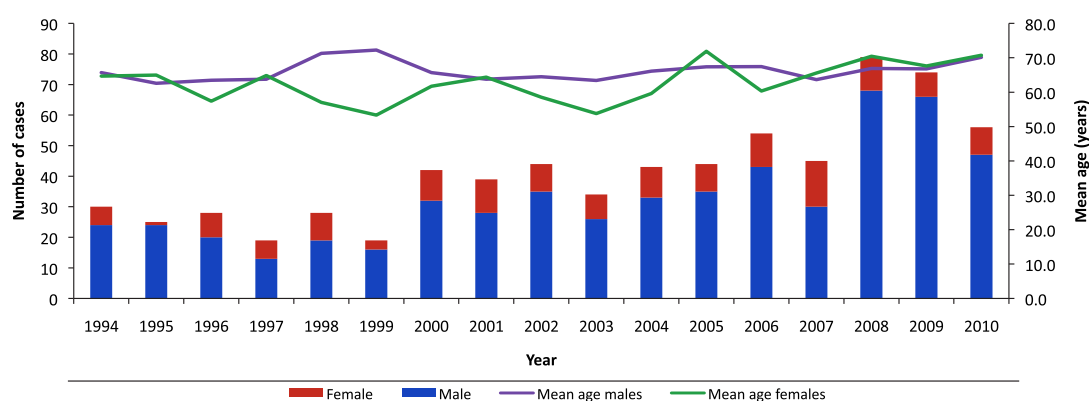
The HIPE scheme is a computer-based health information system designed to collect medical and administrative data regarding discharges and deaths from acute hospitals (excluding private hospitals). Each discharge record represents one episode of care and patients may have been admitted more than once, or to more than one hospital, with the same diagnosis.

The HIPE acute hospital coverage, between 2005 and 2010, varied from 96% to almost 100%. During this period, there were 2,800 discharges with a principal diagnosis of chronic viral hepatitis C. Sixty four percent were males and the mean annual age at admission ranged from 40 to 45 years. During the same period, there were 1,193 discharges with a principal diagnosis of primary liver cancer. Seventy eight percent were males. The mean annual age at admission ranged from 60 to 65 years. (Personal communication: Economic and Social Research Institute, Nov 2011).

More detailed information on hepatitis C associated healthcare utilisation is available in Appendix 5.

### 2.2.2 National Cancer Registry of Ireland

Hepatocellular carcinoma (HCC) is the most common form of primary liver cancer. Seven hundred and three cases of HCC were registered with the NCRI between 1994 and 2010. The vast majority of these (79.5%) were male (figure 5). (Personal communication: NCRI, Nov 2011).



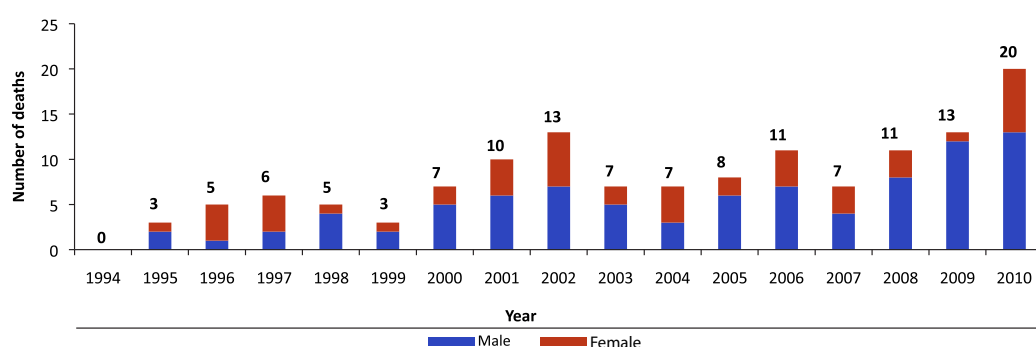
**Figure 5. Number of cases of hepatocellular carcinoma registered with the National Cancer Registry of Ireland by sex and mean age, 1994-2010**

Source: NCRI

Chronic infection with hepatitis B and hepatitis C are the most important causes of HCC. A systematic review of all published data from nine European countries on the prevalence of chronic hepatitis B and hepatitis C infection among HCC cases found a prevalence of anti-HCV positivity of 34.3%, with an additional 6.5% being positive for both anti-HCV and hepatitis B surface antigen (HBsAg). [16] Prevalences from a smaller study in the United Kingdom were 27.5% and 2.5% respectively. Therefore, although NCRI data do not specify underlying cause, it is likely that somewhere in the region of 30% of HCC cases here are anti-HCV positive.

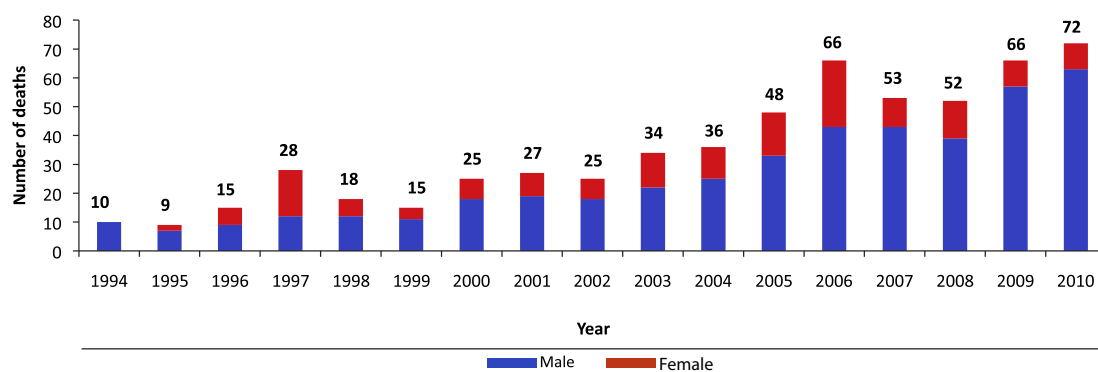
### 2.2.3 Central Statistics Office mortality data

Although no deaths were coded to hepatitis C during the period 1994-2006 ('unspecified viral hepatitis C'), 85 deaths were coded to 'other specified viral hepatitis without mention of hepatic coma'. This category includes deaths due to acute or chronic hepatitis C, hepatitis delta, hepatitis E or other specified viral hepatitis. Therefore, it is likely that most of these deaths were due to hepatitis C. There were 51 deaths coded to acute (n=20) and chronic hepatitis C (n=31) between 2007 and 2010 (figure 6). Between 1994 and 2010, there were 599 deaths from primary liver cancer, of which 73% were male (figure 7). (Personal communication: Central Statistics Office, May 2007).



**Figure 6. Number of deaths due to other specified viral hepatitis without mention of hepatic coma (mostly hepatitis C), 1994-2006 and number of deaths due to 'acute hepatitis C' and 'chronic viral hepatitis C', 2007-2010**

Source: CSO



**Figure 7. Number of deaths due to primary liver cancer, 1994-2010**

Source:CSO

#### 2.2.4 Liver transplants

The national liver transplantation unit in St Vincent's University Hospital, Dublin, carried out 311 liver transplants between 2000 and 2006. Twenty-five of these were known to be as a consequence of hepatitis C infection and a further seventeen were due to hepatitis C and another indication, such as alcoholic liver disease or HCC. (Personal communication: Liver Transplant Unit, St Vincent's University Hospital Dublin, April 2007).

### 2.3 Hepatitis C in England and Wales

Based on a variety of data sources, a recent statistical model predicted that, in 2003, there were 231,000 hepatitis C antibody positive individuals aged between 15 and 59 years in England and Wales. The model predicts that 31% of hepatitis C infections are in current IDUs, 57% in ex-IDUs and 12% are in the non-IDU population. The ratio of hepatitis C infected men to women is estimated to be 2.4:1 and amongst those aged 15-59 years, in England and Wales, the prevalence of chronic infection is predicted to be 0.53%. [17]

### 2.4 Hepatitis C in Europe

The annual European communicable disease epidemiological report 2010 states that the highest rate of newly reported hepatitis C cases in 2008 was reported by Ireland (35/100,000), followed by Iceland (29/100,000), Sweden (27/100,000) and Finland (22/100,000), with the overall European rate being 9/100,000. [18] However, they point out that, due to the nature of the disease (mainly chronic, asymptomatic infections), the relatively recent introduction of surveillance of hepatitis C in many countries and the differences between the surveillance systems used, the currently available data do not permit comparisons between countries in Europe.

### 2.5 Hepatitis C Globally

The estimated global prevalence of hepatitis C is 2 – 3%, representing as many as 170 million people infected worldwide. [19] Geographic and temporal variability exists with different patterns of age-specific variability. [20] Low prevalence countries (<1%) include the United Kingdom, Germany, Canada, and Scandinavian countries. Higher prevalences (1-2.5%) are reported from the USA, Japan and Italy. The highest prevalences are reported from countries in Africa and Asia with the highest reported prevalence in Egypt at 22%. [21] However epidemiological data from the developing world is limited.

Age-specific patterns in the USA and Australia indicate that prevalence is highest in 30-49 year olds. In Japan, China and Italy, persons over 50 years of age have the highest prevalence.

Risk factors for acquisition of hepatitis C also differ globally. In the developed world the main risk factor for new hepatitis C infections is injecting drug use whereas in the developing world the main risk factors are unsafe therapeutic injections and transfusion of contaminated blood.

The rising incidence of HCC in many countries is attributed to hepatitis C infection. In Japan, where the peak prevalence of hepatitis C infection is in the 60-70 year age group, 90% of reported HCC is due to this infection. Countries where the peak prevalence of hepatitis C infection is in younger age groups, may see an increase in HCC as their population ages. Australia has projected a tripling in the incidence of hepatitis C related liver failure and HCC by the year 2020 with an associated steep rise in health-care expenditure. [21, 22]

Data compiled by the World Health Organization (WHO) on prevalence rates in different WHO regions are presented in Table 1. However, the data shown are not necessarily accurate due to differences in the population groups studied, methods of data collection, limited data availability for some countries and interpretation between countries. [23] Prevalence rates also date back to 1999 and an update is currently awaited from the WHO.

Globalisation over recent decades has seen a large increase in the movement of people which in turn contributes to the increased spread of infectious diseases. The European Academies Science Advisory Council issued a statement in August 2007 on the impact of migration on infectious diseases highlighting the fact that “most migrants to the EU are healthy but in population terms may bear a disproportionate burden of infectious disease.” In their statement they commented on the lack of comprehensive data and the scant attention paid to the public health implications of migration in EU policy development.[24]

**Table 1: Hepatitis C estimated prevalence and number infected by WHO Region**

WHO Region	Total Population (Millions)	Hepatitis C prevalence Rate %	Infected Population (Millions)	Number-of countries by WHO Region where data are not available
<b>Africa</b>	602	5.3	31.9	12
<b>Americas</b>	785	1.7	13.1	7
<b>Eastern Mediterranean</b>	466	4.6	21.3	5
<b>Europe</b>	858	1.03	8.9	19
<b>South-East Asia</b>	1 500	2.15	32.3	3
<b>Western Pacific</b>	1 600	3.9	62.2	11
<b>Total</b>	<b>5 811</b>	<b>3.1</b>	<b>169.7</b>	<b>57</b>

Source: Weekly Epidemiological Record. N° 49, 10 December 1999, WHO

## 2.6 Current epidemiological knowledge about hepatitis C in Ireland - what is missing and how can we improve?

### 2.6.1 Improving the routine surveillance system

Chapter 4, section 4.3 describes the current deficiencies of the routine surveillance system for hepatitis C. These deficiencies result in a lack of complete epidemiological knowledge regarding hepatitis C in Ireland and therefore need to be addressed. If the recommendations described in Chapter 4, section 4.4 are implemented, the information from routine surveillance should improve in terms of completeness and quality.

### 2.6.2 A population prevalence study

While the prevalence of hepatitis C infection has been extensively investigated in selected high risk population sub-groups, the prevalence in the general population has not been measured previously. A scoping exercise carried out in 2006 proposed four different options for estimating hepatitis C prevalence in the general population in Ireland. [25] A proposal has now been submitted to the HSE for funding of one of these options, a study based on self-collected oral fluid sampling on a sample of the population. The study draws on the approach that was successfully used to measure the prevalence of hepatitis B infection in Ireland. [26] While it has certain limitations, in terms of representativeness of the population and lack of information about risk factors, it is considered the most feasible option and the one most likely to secure a reasonable response rate.

### 2.6.3 Historical trends in hepatitis C diagnoses

Given the number of cases notified since hepatitis C became notifiable in 2004 (figure 1), and the fact that the majority of those ever infected will remain infected for life, it is clear that a very large number of people in this country are currently hepatitis C infected, many of whom were infected prior to 2004. A recent study carried out by the HPSC and the National Virus Reference Laboratory (NVRL) has estimated that 20,000 to 50,000 people in Ireland are chronically infected with hepatitis C.[15] The risk factor for hepatitis C acquisition in the majority of these cases is IDU.

A modelling exercise is required to further describe the trends in infection and identify future disease burden. This exercise will then inform the planning of future service requirements. Such a project is currently being carried out jointly by the Health Research Board (HRB), HSE Eastern Region, HPSC and NVRL. The basis for this work is the use of the National Drug Treatment Reporting System (NDTRS) to create an injecting curve of treated IDUs and then apply hepatitis C incidence rates. Adjustments will be made to take account of hepatitis C acquired by means other than injecting drug use.

#### **2.6.4 Estimating hepatitis C incidence**

There is little published information about the incidence of hepatitis C infection in Ireland. As laboratory markers do not distinguish acute from chronic hepatitis C infection, and most cases of acute infection are asymptomatic and therefore go undetected, estimation of incidence would require the follow up of a group of individuals over time to identify seroconversions. The feasibility of collating data nationally on routine testing of IDUs should be explored with a view to estimating incidence on an ongoing basis.

#### **2.6.5 Register of patients infected with hepatitis C virus**

The ERHA obtained approval in 2004 from the office of the Data Protection Commissioner (DPC) to establish a register of drug users who are antibody positive for the hepatitis C virus. The aim of this register in the first instance is to track a patient journey from notification to referral for specialist assessment. To date only a limited amount of information has been captured on this database. To maximize the opportunity to plan and assess the health services response to this infection, a fulltime database manager with a clinical background is required. The overall aims of the register, articulated in 2004, are still relevant. The register should be expanded to capture all cases of hepatitis C nationally, other than the state-infected, who are already captured on the database described in Section 2.1.2.4.

### **2.7 Summary**

Information on hepatitis C infection in Ireland is improving but there are many gaps in our knowledge. Data are available from a variety of sources including routine surveillance and special studies. The data show a high prevalence of hepatitis C in certain populations, namely those infected in the past through administration of blood and blood products, and the ongoing larger group of IDUs. The prevalence in the general population is unknown. Recommendations will be made for the improvement of the routine surveillance system and for further studies and research to address current gaps in knowledge. These developments are necessary to enable better prevention and control of hepatitis C and to guide service planning for those with hepatitis C disease.

## 3. Progress on 2004 Recommendations

### 3.1 Introduction

As previously stated, a working group came together in 2003 to produce a strategy for the prevention, treatment and surveillance of hepatitis C in the Eastern Region. A wide consultation process was undertaken and the strategy was developed in partnership with the voluntary and statutory sectors. A total of 48 key recommendations were made.

It must be emphasised again that this report was never published. As a consequence, an implementation plan was never devised and therefore recommendations could not be formally introduced.

A much needed and comprehensive strategy – underpinned by legislation – has been devised for the care of patients infected with hepatitis C through the administration of contaminated blood and blood products. This gives these patients a statutory entitlement to a wide range of healthcare services without charge for the duration of their lives.

In contrast there has been no strategic approach to the management of hepatitis C in Ireland for those infected or at risk of infection through other routes. Any progress that has been made has been made at a local level and through the initiatives of different organisations, agencies or individuals.

### 3.2 Surveillance

In 2004 problems identified with the notification system included many incomplete notifications and anecdotal evidence of non-notification, despite this being a legal requirement. Efforts to improve the notification system have proven difficult to surmount for a variety of reasons including perceptions of data confidentiality breaches and threats of legal action. The end result is that one third of hepatitis C notifications do not have patients' names.

Enhanced surveillance was also recommended in the 2004 report, in particular the capturing of data on risk groups. This has been partially successful but in a time-consuming fashion with an inappropriate use of resources and not uniformly across the country.

A database for surveillance and progress monitoring in relation to IDUs in the Eastern Region was set up on foot of the 2004 report and as a result of hepatitis C infection being made a notifiable disease. This database is still in development stage. Recommendations were made in 2004 for its enhancement but have not been implemented due to recruitment difficulties within the HSE.

Chapter 4, section 4.4 contains recommendations to enhance the surveillance of hepatitis C in Ireland.

### 3.3 Treatment access, delivery and adherence

In relation to encouragement of testing, particularly in those at moderate to high risk, the use of peer support networks was recommended in 2004. This has not been carried out. Some progress has been made in making relevant educational programmes available and these could be expanded.

A recommendation was made in 2004 that existing protocols and guidelines for referral to specialist services should be modified to take into account the sub-culture of illicit drug use and social marginalisation. The present report will recommend the establishment of an Expert Group to provide guidance on clinical issues and to develop standard protocols (see Chapter 7, recommendation 29).

A number of recommendations in relation to support staff in primary care were made in 2004. Again these have not come to fruition and the matter is being addressed in the current report.

Greater cooperation between hepatology and infectious disease services and the Irish Prison Service (IPS) was recommended as many prisoners are hepatitis C positive. The establishment of a framework that would enable those involved with the clinical care of prisoners to work collaboratively with staff from the hepatology or infectious

disease services was recommended. Initiatives are being developed locally at two prison sites in Dublin but no national evidence-based framework has been put in place to date.

The importance of the Clinical Nurse Specialist's (CNS) role in increasing the proportion of hepatitis C positive individuals who could avail of treatment and maintaining patients in treatment was acknowledged in 2004 and there has been some progress in the recruitment of additional CNSs.

As there is no central collation of data of persons in receipt of anti-viral treatment it is not possible to say how many people have been treated overall. It is also impossible to estimate how many of those who have been treated are not in the state infected category. Because of this it is difficult to set a target as to how many might be treated over the next number of years, but that is something that will be addressed by a needs assessment in recommendation 34 of this report.

### **3.4 Education and information**

A range of recommendations pertaining to the Addiction Services was made in 2004. These recommendations concerned programmes to slow down the progression from smoking to injecting heroin, expanded needle/syringe exchange and education to drug takers. There has been only patchy and unquantified progress in this regard. Recommendations from this group in relation to peer support and other education and prevention measures will be re-iterated in Chapter Five. The National Advisory Committee on Drugs (NACD) and National Drugs Strategy Team (NDST) prepared an assessment of needle exchange provision in Ireland for the Minister for State with responsibility for the National Drugs Strategy in March 2008. This assessment has not been published.

Recommendations in relation to prevention of sexual transmission and transmission through snorting of cocaine were made in 2004. However, due to the limited evidence in relation to these routes of transmission, recommendations will not be proposed in this current document. Recommendations in relation to tattooing were made in 2004. However, a formal approach to tattooing practices is still lacking. Recommendations in this regard are repeated in this report.

### **3.5 Conclusion**

There was considerable disappointment amongst those who contributed that subsequent to the completion of the 2004 ERHA report it was not published. For that reason, no implementation strategy could be agreed and many of the recommendations from 2004 were not implemented and are repeated in this report. Given the experience of 2004 it was decided to produce an action plan with time lines - these can be found in Chapter 9.

The HSE is committed to the implementation of this plan on a phased, prioritised basis, with due regard to the current employment and resource constraints



## 4. Surveillance

### 4.1 Introduction

Good quality information about hepatitis C in Ireland is needed so that appropriate actions can be taken at population and individual levels. At population level epidemiological information is required about the number and demographics of people infected, the modes of acquisition of infection, and trends in incidence and prevalence of infection and risk factors. It is necessary to know what genotypes are in circulation in Ireland and whether cases are linked, and if so how. This information is essential to guide the development of prevention and control activities and to plan the appropriate treatment services. Such information will also allow the evaluation of the effectiveness of any current or future interventions. Individual cases may need follow-up to establish the source of infection, to ascertain whether any ongoing public health risk exists and to prevent further transmission of infection.

### 4.2 Current situation

Hepatitis C became a notifiable disease in Ireland on 1st January 2004.[27] Prior to this, hepatitis C could be notified under the category “viral hepatitis, type unspecified”. Cases of hepatitis C (hepatitis C antibody, antigen or nucleic acid positive) must be notified by the clinician and by the identifying laboratory to the Medical Officer of Health (MOH), who is the Director of Public Health (DPH). A copy of the current clinical notification form is available in Appendix 6 and the recommended data items to be included in laboratory notifications are listed in Appendix 7. Notifications are confidential within the Department of Public Health. On receipt of a notification by the Medical Officer of Health, it is checked against local infectious diseases notification databases or the Computerised Infectious Disease Reporting (CIDR) system to ascertain whether or not it represents a new notification e.g. to avoid duplicate entries for persons who have regular tests to check viral status.

If the case has been previously notified by another source, a new notification is not recorded. Follow up with the notifying clinician should determine that the case is receiving appropriate management with regard to hepatitis A and B vaccination and advice on transmission risks. In most cases, no further public health action will be required other than to update records as extra information becomes available e.g. genotype.

If the case has not been previously notified, the status of the case is confirmed with the notifier. If the case is newly diagnosed then further action may or may not be necessary, depending on the information provided or obtained from the relevant clinician.

Public health follow-up may involve:

- Obtaining information e.g. demographic, clinical, risk exposure category and likely source of infection as per the enhanced surveillance dataset.
- Determining and agreeing what further investigation is required e.g. to rule out a healthcare acquired infection.
- Providing advice if necessary to the clinician in relation to appropriate vaccination, clinical referral and assessment.
- Ensuring cases are advised on how to minimise the risk of transmitting infection.

Follow up is dependent on the quality and completeness of notification data. If details of the notifier or clinician are not provided on the notification form then they cannot be contacted to enable routine public health follow up as described above. Contact is not ordinarily made with the patient. The MOH sends a return of cases notified, **without personal identifiers**, to the HPSC weekly. The HPSC collates these data nationally and publishes weekly, quarterly and annual reports ([www.hpsc.ie](http://www.hpsc.ie)). The recently agreed process for managing hepatitis C notifications in Departments of Public Health is available in Appendix 8.

### 4.3 Appraisal of the current situation

Hepatitis C requires laboratory confirmation for diagnosis. It is rarely diagnosed on clinical grounds, as presentation with acute hepatitis C is uncommon and many patients present with non-specific symptoms. Although the information on hepatitis C is greatly improved since it became a notifiable disease, there are deficiencies in the current surveillance system:

- Due to the predominantly asymptomatic nature of the condition, it is likely that many infections go undetected.
- Trends in the number of notified cases reflect only the numbers of people being tested, rather than the true incidence or prevalence of infection. The majority of people currently being tested in Ireland are from high-risk groups attending services where screening programmes exist or are individuals under investigation for liver disease.
- Trend data are only available since 2004 when hepatitis C became notifiable for the first time.
- Many notifications are incomplete and there is a lack of enhanced surveillance data
- To date, little information on specific laboratory results, in particular genotype, has been provided with notifications.

Notification data cannot be taken as an accurate reflection of trends in incidence for the following reasons:

- Most acute cases of hepatitis C infection are asymptomatic and it is not possible to distinguish between acute and chronic cases in laboratory tests.
- Cases notified in a particular year may have acquired their infection many years previously.
- Hepatitis C became a notifiable disease for the first time in 2004 so it is likely that some of the cases notified since then are not newly diagnosed, rather they represent a “backlog” of previously diagnosed cases.
- With raised awareness of hepatitis C among professionals and the public in recent years, there has been an increase in the level of testing and consequently in the identification of already infected individuals.

Many notifications received by the DPH do not contain full names and addresses and patients are notified by initials only.[28] The proportion of hepatitis C notifications containing initials rather than full names had increased from 12% in 2004 to 33% in 2007 (personal communication, Department of Public Health, HSE Eastern Region). This means that duplicate notifications cannot be identified and removed. Duplicate notifications are common for hepatitis C, as a case may be tested repeatedly over several years, or the case may be notified by both the clinician and the laboratory, or by notifiers in different regions.

Also, without full identifiers, it is not possible for the DPH to investigate a case and take public health action where appropriate. In 2007 in the Eastern Region there were 1213 hepatitis C notifications. In 400 cases, only initials were given, thereby preventing further public health follow-up.

Notification of cases of hepatitis C is a legal requirement. However, the provision of enhanced surveillance data is not. Risk factor information is rarely provided on laboratory request forms or on notifications from clinicians. Of the 813 notifications with full patient names received by the Eastern Region in 2007, risk factor information or proxies were available in 421 cases (52%). The proxies used included attendance at a drug treatment clinic, asylum seeker or refugee status, intravenous drug use or imprisonment. Use of these demographic factors as proxies for establishing the mode of hepatitis C acquisition has not been formally evaluated. For the remaining 48%, contact must be made with the patient’s clinician to obtain additional information. Unfortunately many notifications have limited information on the patient’s clinician, resulting in very time consuming and often fruitless follow-up, particularly in areas with large volumes of hepatitis C notifications. Pending resolution of these deficiencies, it is a half-time job in the HSE Eastern Region to chase and verify enhanced surveillance data.

The lack of complete surveillance data impacts on service planning. The first year progress report on the Scottish Action Plan 2006-2008 documented that, of the 37,500 chronically infected patients in Scotland, only 20% had accessed specialist care and, of these, only 20% had received anti-viral treatment.[29] As Ireland does not currently maintain a national register of all patients infected with hepatitis C, similar data is not available but it is widely held that there is a large unmet need. A national register would facilitate:

- Ready access to numbers of patients who have been treated, who are on treatment, and who are awaiting treatment

- Enhanced clinical and epidemiological follow-up of patients and provision of optimal care including
  - Collection of data on treatment outcomes
  - Ascertainment of long-term disease outcomes and re-infection rates
  - Improved “loss to follow-up” rates

A national database has been established to record data on infection acquired through blood and blood products. Subsequent to the 2004 ERHA report, a database for surveillance and progress monitoring in relation to IDUs was set up in the Eastern Region. Although recommendations were made for the development of this database, the project remains in its earliest stages with lack of progress due to recruitment difficulties within the HSE. Adequate funding is essential and an ethical imperative for the development and, in particular, the ongoing maintenance of a register.

## 4.4 Recommendations

### ***Strengthening the quality and completeness of the hepatitis C notification system***

Ideally, the most efficient system would be a system based on notification of cases from laboratories. This system would require that all requesting clinicians enter a range of information on a laboratory request form including full patient identifiers (name and address), country of birth, ethnicity, likely country of acquisition of infection, any available relevant risk factor information, information as to whether this case is newly diagnosed or previously diagnosed, and clinician details. In completing the forms, notifying clinicians should make a judgement on how they believe their patient acquired their infection. This information would then be entered by laboratory personnel onto the lab result that is sent via CIDR to the Departments of Public Health. The report should also include detailed laboratory results such as RNA status and genotype.

Unfortunately it is recognised that in a time-pressured environment this ideal system may not be feasible. As a minimum it is recommended that all laboratory requests contain full patient identifiers and full clinician details and that samples are not processed unless this information is provided. Laboratories should check their systems for previous testing on the same individual. This information should then be transmitted with the laboratory result to the Departments of Public Health.

Additional relevant information is obtained from clinical notifications. Therefore, efforts should be made to encourage clinicians to notify newly diagnosed hepatitis C cases and to remind them of their statutory obligation. Systems must be developed that facilitate them to do so.

<b>Recommendation 1</b>	All laboratory requests for hepatitis C serology must contain full patient identifiers and full clinician details. This information should then be transmitted by laboratories to Public Health
<b>Organisation Responsible</b>	Clinicians Laboratories

<b>Recommendation 2</b>	Encourage clinicians to notify newly diagnosed cases of hepatitis C and to provide as much relevant information as possible.
<b>Organisation Responsible</b>	HSE in conjunction with practicing clinicians

### ***Improving surveillance of newly-diagnosed cases of hepatitis C infection***

Enhanced surveillance of hepatitis C should become the norm to enable appropriate public health follow up. If recommendation 1 and 2 above are implemented this will improve the efficiency of the current system which is labour intensive. Appendix 9 contains the recommended enhanced surveillance form which should be completed through information received from laboratories and clinicians and/or contact made by public health staff with the patient's clinician.

<b>Recommendation 3</b>	Undertake enhanced surveillance of all cases of newly diagnosed hepatitis C infection
<b>Organisation Responsible</b>	Departments of Public Health

<b>Recommendation 4</b>	Establish a <b>national</b> register of hepatitis C infected patients (other than those referred to as “state-infected”)
<b>Organisation Responsible</b>	Departments of Public Health – led by the Department of Public Health, HSE Eastern Region

### ***Enabling appropriate public health follow-up of newly diagnosed cases***

Follow-up is imperative to prevent secondary spread and to identify the likely source of infection. Improving the notification system as outlined above will enable appropriate public health follow-up of notified cases as discussed in section 4.2.

<b>Recommendation 5</b>	Instigate appropriate public health follow-up on all cases of newly notified hepatitis C infection
<b>Organisation Responsible</b>	Departments of Public Health

### ***Improving knowledge with regard to hepatitis C infection in Ireland***

Chapter 2 highlighted current gaps in the knowledge regarding hepatitis C infection in Ireland. Gaps exist with regard to incidence, prevalence, trends and future disease burden. Data on the prevalence of hepatitis C in migrant populations should be acquired and reviewed to establish whether or not hepatitis C infection is a concern for ethnic minority groups in Ireland.

The proposals laid out in Chapter 2, section 2.6.2, should be carried out.

<b>Recommendation 6</b>	Undertake a population prevalence study as outlined in Chapter 2, section 2.5
<b>Organisation Responsible</b>	HPSC

<b>Recommendation 7</b>	Complete a modelling exercise to estimate future disease burden and aid service planning as outlined in Chapter 2, section 2.5
<b>Organisation Responsible</b>	HSE - Department of Public Health (HSE East), HPSC HRB & NVRL

<b>Recommendation 8</b>	Conduct follow-up studies amongst IDUs to identify seroconverters and therefore incidence rates. A national register as per recommendation 4 will facilitate this
<b>Organisation Responsible</b>	HSE and service providers

## 5. Education, Prevention and Communication

### 5.1 Introduction

This chapter makes a number of recommendations on initiatives to reduce new cases of infection and to reduce transmission of infection from those who are infected. The recommendations are broad in nature and are aimed at those populations who are most at risk of infection, namely drug users, prisoners and immigrants from endemic countries. This chapter also addresses communication issues around hepatitis C to improve the accuracy and consistency of current materials used for patients, those at risk and health care providers.

The guiding principles that inform this work are:

1. All actions should be based on the best available evidence.
2. Harm reduction, which aims to reduce drug related harm to individuals and communities, will be emphasised through a wide range of policies and programmes. These will include a wide variety of approaches including needle/syringe exchange programmes. This principle is underpinned by the premise that harm reduction methods should be available to all.
3. A partnership approach between all levels of government, voluntary and community organisations, and healthcare providers is recognised as essential in the prevention and control of hepatitis C.
4. The recognition that a range of social factors such as poverty, housing, education and employment status influence an individual's ability to manage their own health.

#### 5.1.1 Collaboration

To ensure maximum effectiveness in the delivery of an education and prevention strategy the engagement of all agencies in both the statutory and voluntary sectors is required. The following, while not exhaustive, indicates the key agencies that should participate in this strategy.

- HSE
- Specialist Treatment Services
- Regional and Local Drug Task Forces
- Voluntary Agencies
- Service User Groups
- Prison Services

#### 5.1.2 Peer education

The involvement of individuals who are directly affected by hepatitis C or at risk of infection is desirable in the development and implementation of all hepatitis C related interventions. The Third Collaborative Injection Drug Users Study / Drug Users Intervention Trial (CIDUS III/DUIT) designed and evaluated a six-session behavioural peer-education intervention.[30] Conceptually, the peer-education intervention drew on aspects of Social Learning Theory, the Information, Motivation, and Behavioural skills model, peer education and leadership. The programme was developed through an iterative process and through strong engagement with potential participants and local communities. The programme also addressed facilitator training and quality assurance of intervention delivery. Participants learn the role of a peer educator and are given appropriate tools to enable them to adopt this role. Sessions focus on injection-related risk and sexual risk behaviour. Participants are actively prepared to encourage further peer education and personal risk reduction. This model is one that could be developed and adapted for use in Ireland.

#### 5.1.3 Target Populations

Injecting drug users are at the highest risk of contracting hepatitis C. Chapter 2, section 2.1.2.1, estimated that the prevalence of hepatitis C in IDUs in Ireland ranges from 62 per cent to 81 per cent. Within a year of injection initiation, between 50 and 66 per cent of injectors will be infected with hepatitis C. The 2004 report outlined the various risk behaviours associated with hepatitis C infection among IDUs including sharing of syringes and other injecting paraphernalia, backloading and unhygienic injecting. As injecting drug use is associated with such a high risk of contracting hepatitis C, any strategy for the management of hepatitis C must also address the issues of drug use which include prevention, treatment and rehabilitation. Hepatitis C can be just one of many health

concerns faced by injecting drug users, whose health is often affected by other social factors. Intravenous drug users are often socially excluded, experience poor health and lack access to appropriate primary and other health care services. Therefore, a more holistic approach to the health and well being of injecting drug users is required to improve their general health status and their health outcomes from hepatitis C infection. This section will also focus on certain subgroups of the drug-using population.

#### **5.1.3.1 Prisoners**

The high rates of hepatitis C in prison inmates pose health risks to both inmates and staff. The European Monitoring Centre for Drugs and Drug Addiction state that “good prison health is good public health”. [31]

A comprehensive approach to harm reduction in the prison setting should be adopted to reduce drug use, blood-borne virus transmission and new cases of hepatitis C, and should include:

- Substance misuse awareness programmes
- Supply and demand reduction programmes
- Drug free areas
- Prison needle exchange programmes
- Sterilisation equipment
- Substitution therapies
- Support programmes
- Formal links should be developed between the prison services and the addiction services to enable continuity of care for prisoners with drug addictions on release from custody.

Since 1992 several countries have introduced prison-based needle exchange programmes (PNEP) as a result of increasing evidence of injecting drug use in prisons, the specific risks of injecting in a prison environment and the recognised role that prisons play in the spread of infectious diseases. Individual PNEP have been evaluated and the evidence for PNEP has been systematically reviewed on several occasions. One of the authors of an international review in 2004 commented “prisoners come from the community and most return to it. What is done – or not done - in prisons with regard to HIV/AIDS, hepatitis and drug use therefore has an impact on all”. [32] This international review has been repeated as recently as 2006 and included site visits to different PNEP and in-depth reviews of PNEP in Switzerland, Germany, Spain, Moldova, Kyrgyzstan and Belarus. [33]

In summarising the findings of individual programme evaluations and systematic reviews the following evidence-based facts can be highlighted. [32-40]

#### **Prison-based Needle Exchange Programmes**

- Are safe
- Decrease needle-sharing practices among prisoners
- Reduce disease transmission including HIV and hepatitis C
- Have other positive outcomes for prisoners’ health
  - o Increased referral to treatment services
  - o Fewer overdose events
  - o Reduced polydrug use
- Do not undermine safety and security
- Do not lead to increased drug use, injecting or initiation among prisoners
- Do not undermine abstinence based programs
- Have been successfully introduced in a range of prison environments
- Have successfully employed different methods of needle distribution to meet the needs of staff and prisoners in a range of prisons.
- Protect the human rights of prisoners

The provision of bleach and methadone has been established as an insufficient response to reducing the transmission of hepatitis C in the prison setting. Prison-based needle exchange programmes have been recommended by medical, legal and community-based experts as well as United Nations agencies and the WHO.

The Beckley Report (no 12) [41] referred to existing barriers to the introduction of harm reduction services in the prison setting including;

- Possibility that the provision of services will undermine measures taken inside the prison to reduce the supply of drugs
- Denial by prison authorities that the problem of drug use and injecting exists
- Limitations in the introduction of infection prevention services due to budget constraints or overcrowding
- Lack of political will
- Policies that prioritise zero-tolerance to drug use over the risk of infection

A variety of international instruments and declarations exist with regard to the human rights of prisoners. Ultimately service provision to prisoners should mirror that in the community.

### **5.1.3.2 Homeless**

A profiling exercise, commissioned by the NACD in 2005, found that 64% (n=226) of people experiencing homelessness had recently used illicit drugs.[42] Methadone use was confined to the Dublin homeless and comprised 18% of the study group, of whom 28% were not prescribed it. Over one-in-two current injectors reported sharing injecting paraphernalia in the previous four weeks (53%). Over half of problematic drug users were hepatitis C positive (51%) compared to 23% of the total study population. Individuals who had ever injected were also significantly more likely to be hepatitis C positive. Low numbers of problematic drug users were currently receiving treatment for hepatitis C (11%).[43]

Previous studies have also found high levels of risk behaviours – sharing of needles, injecting in public places and a younger age of first drug use.[44] [45] A submission on behalf of the Safety Net Service and the Ana Liffey Drug Project outline a rising prevalence of hepatitis C within the homeless population from an estimate of 5% in 2001 to 35% in 2005. They highlight the fact that 54% of those who have hepatitis C and inject drugs do not always use clean needles and the fact that there are no dedicated facilities for homeless people who do not attend a methadone treatment centre to obtain advice regarding hepatitis C. [46]

Some of the issues uncovered by research to date include:

- Services for homeless people that are under-resourced and lacking in appropriately trained staff
- Lack of needle exchanges and safe clean injecting environments
- Structured treatment programmes that are inappropriate for homeless drug users
- Delays between initial assessment and drug treatment
- Difficulties accessing methadone maintenance treatment for a variety of reasons including
  - o lack of a permanent address,
  - o waiting lists,
  - o harsh sanctioning for failing urinalysis
  - o problems in attending daily methadone clinics
- Insufficient detoxification and residential places and a lack of aftercare
- Difficulties meeting the multiple needs of homeless drug users including accommodation, retraining, employment and social support

### **5.1.3.3 Minority Ethnic Groups/ New Communities**

Little is known either nationally or internationally on the use of illicit drugs by immigrants or minority ethnic groups (MEGs). Merchant's Quay Ireland (MQI) undertook qualitative research to increase knowledge of problematic drug use in new communities in Ireland.[47] A review of the literature revealed:



- Extent of drug use among new communities is not equally prevalent among all minority ethnic groups
- Differences may be explained by relative socioeconomic disadvantage, discrimination and by the values and traditions of specific ethnic groups
- Statistics reveal that foreign nationals including people from minority ethnic groups are often under-represented in drug treatment statistics and over-represented in crime statistics
- European research has mostly found that drug use among minority ethnic groups is less than that found among the indigenous populations

Drug use was found to be a problem for some immigrants, with a range of drugs being used and administered in different ways. There were some cultural variations in types of drugs used. The fieldworkers found drug users from new communities in Ireland difficult to reach as they remained hidden, were highly mobile and rarely associated with Irish drug users.

The social situation of MEGs was found to constitute a risk for engagement in problematic drug use. Some of the main reasons given for engaging in drug use included:

- A means of escaping from current worries linked to the asylum process and insecure legal status
- A means of escaping from exclusion and isolation
- Experiences of post-traumatic stress disorder, war, torture and trauma
- Living in hostel accommodation with a lack of a family network or social support
- Unemployment or denial of the right to work
- To gain acceptance from, or to “fit in” with their Irish peers

Some of the barriers to accessing drug services identified by this research included:

- A lack of knowledge of existing drug services and what these services have to offer, compounded by an inability to access information about services in their own language
- A feeling of alienation from group work where the majority of participants are Irish
- A fear of breach of confidentiality and concern that drug services might have connections with the Department of Justice or the Gardaí
- Concern that they would encounter racism, either from the clients and/or workers

A worrying increase in the numbers of homeless people from minority ethnic groups has been noted recently and a significant proportion are IDUs (personal communication, Merchants Quay Ireland, May 2008).

## 5.2 Current situation

A number of agencies are involved in current education, prevention and communication initiatives. Services are provided by the HSE, local and regional drugs task forces and by voluntary providers.

The HSE provides education on hepatitis C prevention through a number of routes including health promotion services and education officers and outreach workers of the addiction services nationally. Services are targeted at drug users, drugs services and community groups and are generally provided on an ad-hoc basis, based on requests from drugs services or communities. They are commonly delivered through workshops facilitated by HSE staff. Staff employed by the HSE in addiction and other services also provide brief educational interventions to those at risk of hepatitis C infection.

Both the regional and local drug task forces provide some education and prevention services in relation to hepatitis C. These services are generally delivered through education workers employed by the task forces or through voluntary organisations funded by the task forces. The workshop type format utilised by the HSE is again the most common method of delivery. Additionally a number of task forces, notably the Ballyfermot Drugs Task Force, have developed a range of resources in relation to hepatitis C including a booklet and a DVD.



A number of voluntary agencies in the addiction field provide some educational input in relation to hepatitis C. This work is usually part of a wider range of services delivered to drug users. In addition, some not-for-profit agencies have employed hepatitis C education workers and have produced related resources. Community Response, based in Dublin south city, is an example of one such organisation.

### 5.3 Appraisal of the current situation

The majority of people at risk from or infected with hepatitis C belong to marginalised and socially excluded groups. Marginalised groups can experience difficulties accessing services, they can be difficult for service providers to reach and have greater health and social care needs. Often a targeted approach is required as opposed to a mainstream or universal approach.

The work done to date with regard to education, prevention and communication is of value. However, the levels of provision in relation to education and prevention can be described as reactive and patchy rather than strategic and comprehensive. This approach to education and prevention services can lead to a situation where the information provided to those at risk is inconsistent and not necessarily based on the latest available evidence. Competency-based standards for training in health promotion do not currently exist in Ireland either for general health promotion or specifically in relation to training in issues relevant to injecting drug use.

The most effective way of preventing hepatitis C infection and transmission is by treating drug addiction. The provision of treatment for drug addiction, including methadone substitution, is limited outside of the Eastern Region. Recent figures shown in Table 2 demonstrate this. Long waiting lists and times exist in many places where services are provided. The longer a patient continues to use drugs the less likely they are to respond to treatment for their addiction. Thus, it is imperative that drug addicts who wish to undergo treatment can access appropriate services without delay. It is important to specifically target treatment at young and / or early injectors (within the first 12 months of initiation of injection drug use) as this will have the greatest impact on the prevention of hepatitis C. Action 39 of the National Drugs Strategy (Interim) 2009-2016 states that treatment services dealing with blood borne viruses, with particular emphasis on hepatitis C treatment services, be maintained and developed.[48]

**Table 2: Summary Statistics (December 2011)  
on the numbers of patients on the methadone central treatment list  
at drug clinics or GP practices per HSE area during 2011**

DRUG CLINICS	
	Total Patients during period
HSE Dublin Mid Leinster	3126
HSE Dublin North East	2347
HSE West	239
HSE South	436
Prisons	1673
Drug Treatment Centre Board	718
GENERAL PRACTITIONERS	
	Total Patients during period
HSE Dublin Mid Leinster	2251
HSE Dublin North East	1372
HSE West	222
HSE South	92

Treating and preventing drug addiction can be challenging and some people will continue to inject drugs. Therefore, harm-reduction materials must be provided for those who continue to use drugs, including clean needles and syringes. Other paraphernalia such as smoking foils should also be provided as those who remain addicted

could potentially transition from injecting back to smoking heroin, thus reducing the risk of hepatitis C infection and transmission.

Inadequate provision of harm-reduction materials contributes to the spread of blood borne disease. Provision of safe injecting equipment through needle/syringe exchange programmes has been shown to reduce the frequency of unsafe injecting.[49] Programmes providing harm-reduction materials can also provide a cleaner more hygienic injecting environment for some IDUs e.g. homeless drug users. They also provide a point of contact with the health services and therefore opportunities exist for referral to addiction services, referral to social welfare services and provision of advice and education re safe injecting practices.

Recommendations 62 and 63 of the National Drug Strategy (2001) called for a review of existing needle-exchange facilities with a view to ensuring access for all injecting drug users to sterile injecting equipment and the setting up of a community pharmacy needle and syringe exchange programme was identified as a priority. [50]

Key points made in a review of harm reduction approaches included:

- Needle-exchange programmes (NEPs), which provide clean paraphernalia, advice and education to drug users, are recognised internationally as a key component of harm reduction strategies
- Pharmacy-based NEPs are cost effective and provide an extensive network of contacts for drug users, not all of whom take part in formal programmes
- NEPs have been positively associated with a decrease in the transmission of HIV

This review echoed the recommendations of the National Drug Strategy (2001).

Difficulties can arise when trying to minimise harm amongst drug users under the age of 16. It is not permissible by law to provide those under 16 with clean injecting equipment without parental consent. This poses a barrier to adequate hepatitis C preventative efforts in those under 16.

Knowledge with regard to hepatitis C infection, and in particular treatment, has increased greatly in the last decade. Benefits of treatment now outweigh side effects and the threshold for treatment has changed in some services. Individuals who were tested in the past but not offered treatment for varying reasons e.g. treatment was not available, treatment criteria were not met, chaotic lifestyles and severe drug addiction, may now be able to avail of treatment in some services. They should be informed of the possibility that their infection could now be treated. A national awareness campaign should be undertaken to advise such patients to visit their GP or the drug treatment services, if previously known to them, for assessment. Services must be adequately resourced to enable an appropriate response to such a campaign and the improved surveillance as recommended in Chapter 4 and the needs assessment as recommended in Chapter 7 will help to inform service requirements.

### **Communication and information**

Numerous materials exist that are used to educate service providers, drug users and patients infected with hepatitis C regarding risk factors, risk prevention, symptoms and signs, and management of hepatitis C. Inconsistencies in the information provided are likely as no nationally standardised approach has been adopted to date. Up-to-date, accurate and consistent information needs to be provided to all affected by hepatitis C including patients, drug users and service providers. Domains of information required for the different groups are listed in Tables 3, 4 and 5.

**Table 3: Hepatitis C information needs of service providers**

SERVICE PROVIDERS
Prevalence and incidence
Transmission risks
Screening / diagnostic tests
Treatment options
Treatment benefits and risks
Referral guidelines

**Table 4: Hepatitis C information needs of drug users**

DRUG USERS
Risk factors
Eliminating / Minimising risk
Accessing preventative services
Disease characteristics
Testing for hepatitis C
Treatment benefits and risks

**Table 5: Hepatitis C information needs of patients diagnosed with hepatitis C**

PATIENTS DIAGNOSED
Disease characteristics
Prognosis
Treatment options
Treatment benefits and risks
Complementary therapies
Accessing services

Improved surveillance of hepatitis C as outlined in chapter 4 will aid in the provision of accurate and updated advice. Culturally and linguistically appropriate and literacy-proofed material should be used. Individuals for whom English is not their first language will require access to appropriately qualified interpreters. Alternative methods of disseminating and providing information and education to different target groups should be evaluated and the most effective approach used. The accuracy of scientific information should be agreed and presented in an appropriate format.

Provision of information will increase awareness of hepatitis C and will have a subsequent impact on service demand. This must be anticipated and capacity issues addressed. This will be of particular relevance when contacting individuals who tested positive in the past and did not or could not avail of treatment.

National standards in health promotion qualifications and training are currently being devised. The health promotion aspects of preventing drug use and working with drug users should be incorporated within these standards and should be evidence-based. National standards in health promotion qualifications / training with regard to working with drug users will enable the development of improved informational and educational materials.

#### **UISCE – UNION FOR IMPROVED SERVICES, COMMUNICATION AND EDUCATION**

UISCE is aware of a disparity between the numbers infected with hepatitis C, and those receiving treatment, having encountered many IDUs who have tested positive for hepatitis C, but are unaware of treatment options. Studies indicate that there can be an excellent response to treatment among IDUs in the long term.

There is a need for information to be directed towards current, former and potential IDUs, delivered in imaginative ways, utilising peer workers. Such information should address both treatment and prevention. There are still some misconceptions about treatment, and IDUs need to be updated on all treatment options and criteria for treatment before they are tested. In terms of prevention, switching from intravenous use to smoking heroin and cocaine should be considered. Needle exchange services need to be expanded to cover prisons, out-of-hours and weekends.

Treatment should be available to all those infected with hepatitis C regardless of how the disease is acquired. It is also important that hepatitis C services engage with all those who are infected, whether they are suitable for treatment or not.

Where there are issues of stability preventing treatment, it is important that a care plan is developed through a co-operative approach between the appropriate agencies. Where this involves voluntary agencies, models of best practice regarding inter-agency work should be followed. Prospective patients should be very clear about what is required of them in order to avail of treatment. A significant amount of work is involved in the “pre-treatment” stage to prepare patients for treatment and to improve/maintain their general health, such as advice on diet, alternative therapies and provision of information on other specialised agencies.

Those in prison require the full range of relevant health promotion and treatment services. Not only should these include diagnostic and treatment services, but also access to sterile injecting equipment. A prison sentence can be used opportunistically to initiate treatment, and every effort should be made to identify and encourage suitable prisoners to avail of treatment. UISCE appreciates being invited to contribute to this new strategy and hopes that sufficient resources are made available to ensure its successful implementation.

#### **Vignette 1: UISCE – Union for improved services, communication and education**

## 5.4 Recommendations

### ***Prevention of infection through initiatives targeting injecting drug use***

There are five key strategies to adopt in targeting ongoing illicit and injecting drug use.

1. Treat existing drug addiction
2. Prevent transition from smoking heroin to injecting
3. Discourage established injectors from initiating others into injecting
4. Increase the provision of harm-reduction materials
5. Improve the deficit in knowledge among staff and those who are injecting in terms of understanding the risks

It is recommended that a co-operative approach to these issues should be taken by the HSE as there are significant opportunities for synergies between the work of the voluntary and statutory sectors.

#### *Treat existing drug addiction*

<b>Recommendation 9</b>	<ul style="list-style-type: none"> <li>• Increase the number of drug treatment facilities including detoxification units, methadone clinics, treatment for addictions other than intravenous heroin use etc, particularly outside of the Eastern Region</li> <li>• Reduce existing waiting lists for treatment</li> <li>• Reduce delays between assessment and treatment</li> <li>• Target young and newly initiated drug users</li> <li>• Provide flexible holistic services that can meet the needs of all drug users including homeless drug users and drug users from new communities</li> <li>• Develop prison-based drug addiction treatment programmes that are linked with community-based programmes for when prisoners are released</li> <li>• Provide after-care and rehabilitation services to prevent relapse</li> </ul>
<b>Organisation Responsible</b>	HSE Existing organisations

#### *Prevent transition from smoking heroin to injecting*

<b>Recommendation 10</b>	<ul style="list-style-type: none"> <li>• Develop interventions to delay / prevent transition from smoking to injecting, including training for staff in motivational interview techniques and brief interventions.</li> <li>• Treat drug addiction in those who have become dependent but are not yet injecting, in line with national performance indicators as outlined in the National Drugs Strategy.</li> </ul>
<b>Organisation Responsible</b>	HSE

#### *Discourage established injectors from initiating others into injecting*

<b>Recommendation 11</b>	Work with established injectors to discourage them from initiating others into injecting through peer education
<b>Organisation Responsible</b>	HSE Voluntary service providers

*Improve provision of harm-reduction materials*

<b>Recommendation 12</b>	<ul style="list-style-type: none"> <li>• Ensure all drug users have access to harm-reduction materials regardless of location</li> <li>• Expand the current provision of harm-reduction materials, particularly outside of the Eastern Region, both in terms of geographical coverage and time</li> <li>• Eliminate the policy of “one for one” needle/syringe exchange</li> <li>• Encourage collaborative links with local Gardai around centres for provision of harm-reduction materials</li> </ul>
<b>Organisation Responsible</b>	HSE Voluntary service providers

<b>Recommendation 13</b>	Promote provision of harm-reduction materials within the pharmacy setting
<b>Organisation Responsible</b>	Department of Health (DoH) HSE

**Targeted strategies for socially excluded groups**

A proposal has been put forward by the Ana Liffey Drug Project and Safetynet to provide an innovative and necessary response to hepatitis C issues among the problem drug using homeless population in Dublin - Dublin Area Homeless Hepatitis C Project. The services offered would include hepatitis screening, harm reduction education and ongoing support for the management of blood borne infectious diseases including hepatitis C. Active targeting and outreach work would be employed to facilitate inclusion. The project should also include evaluation, review and research.

<b>Recommendation 14</b>	Pilot and evaluate the Dublin Area Homeless Hepatitis C Project
<b>Organisation Responsible</b>	Safetynet Ana Liffey Drug Project Mountjoy Street Family Practice HSE

<b>Recommendation 15</b>	<p>Implement recommendations from the MQI report entitled “Drug Use Among New Communities: an exploratory study” on a national basis including:-</p> <ul style="list-style-type: none"> <li>• Engage hard-to-reach drug users, including those from EMGs, through drugs outreach teams</li> <li>• Promote community engagement in the design and delivery of services</li> <li>• Recruit staff from EMGs into the drug services</li> <li>• Provide anti-racist and cultural competency training to staff in the drug services as part of a wider initiative for all health and social care providers</li> <li>• Provide culturally-specific drug awareness training to different cultural groups as indicated</li> </ul>
<b>Organisation Responsible</b>	HSE - Drug treatment services

**Guidelines governing tattooing, permanent make up or body piercing**

There are currently no guidelines or regulations governing tattooing, permanent make up (PMU) or body piercing in Ireland. Draft guidelines have been sent to the DoH that address

- Infection risks associated with body piercing, tattooing and permanent make-up
- Best practice standards with regard to
  - o premises, procedures and treatments
  - o client information and consent
  - o equipment, cleaning and decontamination
  - o waste management

The issue of tattooing in prisons should also be addressed. A study in Ireland in 1999, of 607 prison entrants, identified tattooing in prison as the only independent risk factor for a positive antibody test in prisoners who had never injected drugs.[8]

<b>Recommendation 16</b>	<ul style="list-style-type: none"> <li>• The DoH to approve both the draft “Best Practice Guidelines for Body Piercing” and draft “Best Practice Guidelines for Tattooing and Permanent Make Up” and issue to practitioners nationwide.</li> <li>• The DoH to appoint an agency or representative to monitor the implementation of these guidelines following roll-out to practitioners nationwide.</li> <li>• Regular inspections, in the interests of public health and health and safety in the workplace, to ensure adherence to standard precautions.</li> <li>• Develop an information leaflet to inform the public of the health risks involved in body piercing, tattooing and PMU and to highlight the dangers inherent in unprofessional and/or self-administered tattoos and/or piercing.</li> </ul>
<b>Organisation Responsible</b>	DoH

**Communication and information**

Up-to-date, accurate and consistent information needs to be provided to all affected by hepatitis C.

<b>Recommendation 17</b>	Review existing informational and educational material that is in current use with a view to proofing (culturally, linguistically and literacy), standardising and improving the quality of information
<b>Organisation Responsible</b>	HSE

<b>Recommendation 18</b>	Facilitate access to a standardised accredited interpreting service for individuals who do not have English as their first language
<b>Organisation Responsible</b>	HSE – Social Inclusion Directorate

<b>Recommendation 19</b>	Provide clear, consistent and updated advice on the transmission risks of hepatitis C to those involved in the diagnosis and management of hepatitis C patients in the community.
<b>Organisation Responsible</b>	HSE - Departments of Public Health, HPSC

<b>Recommendation 20</b>	Include competency based training modules on harm reduction for all those working with drug users in a community setting that are guided by national standards in health promotion
<b>Organisation Responsible</b>	HSE via Social Inclusion Governance Group

<b>Recommendation 21</b>	<ul style="list-style-type: none"> <li>• Employ staff trained to an appropriate standard in all services engaged in health promotion to prevent hepatitis C infection.</li> <li>• Develop minimum standards of education for outreach and other staff who are in direct contact with IDUs</li> <li>• Standardise recruitment and training for peer educators that is evidence-based and continuously evaluated. A model similar to that used by the CIDUS III/DUIT Study (see section 5.1.2) could be developed.</li> <li>• Increase learning from peer education models already in place (e.g. UISCE, Community Response)</li> </ul>
<b>Organisation Responsible</b>	HSE Voluntary service providers

<b>Recommendation 22</b>	Plan and implement a campaign to raise awareness amongst those who may previously have been diagnosed with hepatitis C or who may have been at risk of infection in order to redirect them to medical services if this is what they choose
<b>Organisation Responsible</b>	HSE

## 6. Screening and Laboratory Testing for Hepatitis C Virus Infection

### 6.1 Introduction

Screening can be defined as “a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of disease or its complications.”[51]

The objective of screening for the early detection of disease is to benefit the individual and the greater population by reducing morbidity and mortality from the disease. Screening can be opportunistic or as part of a screening programme, which can be universal or targeted. Programmes are formally organised with a defined population to be screened and all activities along the screening pathway must be planned, co-coordinated, monitored and evaluated with the application of rigorous quality assurance. Programmes must ensure that the benefit of screening outweighs any possible harm and must demonstrate a reduction in mortality or morbidity.

There have been many studies on the cost effectiveness of hepatitis C screening programmes most of which fail to demonstrate a benefit when measured in cost per Quality-Adjusted Life Year (QALY). Selective screening of high-risk populations (with high levels of acceptance of screening and adherence to treatment) is more likely to be cost effective than universal screening. The cost of laboratory testing is a significant contributor to the high cost of hepatitis C screening programmes.

In the 2004 Regional Hepatitis C Strategy, guidance was given on those who should be proactively tested for hepatitis C and those who should be considered for testing (see Table 6). Haemodialysis patients and blood, blood product, tissue and organ donors were considered high priority for testing to protect both staff and patients during healthcare related interventions.

Many patients are tested for hepatitis C infection in the community setting. Viral ribonucleic acid (RNA) measurement can be logistically difficult in the community as fresh blood samples need to reach the appropriate laboratory within 6 hours of phlebotomy. This is mostly a problem in ‘out of hours’ services and in many GP practices. Due to these constraints hepatitis C RNA testing cannot currently be recommended in community settings. Unless addressed this will result in increased pressure on overloaded secondary services who are currently best placed, but inappropriately so, to perform hepatitis C RNA testing. Introduction of the hepatitis C antigen test may go some way to alleviate this bottleneck in RNA testing as the same constraints in sample preparation do not apply thereby simplifying logistical problems.



**Table 6: Who should be tested for hepatitis C virus infection**

Patients who should proactively be offered testing for hepatitis C
<ul style="list-style-type: none"> <li>• Haemodialysis patients</li> <li>• Blood, blood product, tissue and organ donors</li> <li>• Persons who have had an anti-D or a blood product transfusion prior to 1991</li> <li>• All drug users, especially those who have injected drugs or shared 'works', including prisoners</li> <li>• Babies born to hepatitis C infected mothers</li> <li>• Immigrants from countries of high endemicity for hepatitis C infection</li> <li>• Persons, including healthcare workers, who have had potential percutaneous or mucous membrane exposure to hepatitis C</li> <li>• HIV or hepatitis B infected patients</li> <li>• Those with unexplained persistently raised serum transaminases</li> </ul>
Patients for whom hepatitis C testing should be considered
<ul style="list-style-type: none"> <li>• Sexual partners of people who have hepatitis C (low risk)</li> <li>• Men who have sex with men who present for sexually transmitted disease screening (low risk)</li> <li>• Those with tattoos or body piercing</li> <li>• As part of antenatal screening</li> </ul>

Source – 2004 ERHA Regional Hepatitis C Strategy

## 6.2 Laboratory Testing

### 6.2.1 Laboratory Methods for Hepatitis C Testing

Screening for hepatitis C involves testing blood for the presence of antibodies to the hepatitis C virus or more recently the detection of hepatitis C antigen in serum. The initial screening test used is an enzyme immunoassay (EIA) test. Infection is confirmed by a second alternative antibody test, commonly a line immunoassay. Antibody and antigen testing can identify acute, chronic or resolved infection. Chronic infection must be confirmed by further testing for the presence of viral antigen or nucleic acid on a second sample taken 6 months after the first.

Molecular investigation consists of the detection of hepatitis C RNA, hepatitis C genotype testing and estimation of viral load. At least six different genotypes of the hepatitis C virus exist and therefore genotyping is carried out in cases of confirmed chronic infection. Genotyping is relevant as different genotypes respond differently to anti-viral treatment. Genotyping can also be used when trying to establish the source of infection.

Success of hepatitis C treatment is defined as testing negative for hepatitis C RNA six months after cessation of therapy, termed a sustained virological response (SVR). The rate of response to therapy is also an important predictor of sustained response with a rapid decline in viral load being a strong predictor of treatment success.

A more technical description of laboratory methods can be found in Appendix 10.

### 6.2.2 Availability of Serological Investigation of Hepatitis C in Ireland

The current situation regarding serological investigation for hepatitis C infection in Ireland was established in 2007 through a telephone survey, carried out by the HPSC, of 66 diagnostic laboratories (Table 7).

Of the 66 laboratories, 18 perform serological diagnostic tests for hepatitis C. The rest do not undertake any hepatitis C diagnostic testing.

Of the 18 laboratories who do test, the NVRL performs the most assays including serological tests (EIA, line immunoassay, antigen and antigen-antibody combination assay) and molecular investigations (hepatitis C RNA viral load and genotyping).

**Table 7: Results of a telephone survey to determine what serological tests for hepatitis C are carried out in 66 diagnostic laboratories in Ireland (HPSC 2007)\***

Serological tests done	No. of labs
None	48
EIA testing only	15
EIA + line immunoassay testing	2
EIA, line immunoassay, Ag/Ab combination assay and molecular investigations	1

\* molecular investigations are also done in a research laboratory in UCC

Of the remaining 17:

- Two laboratories perform initial antibody screening tests (i.e. EIA) and confirm positive EIA by line immunoassay. They then refer anti-HCV positive samples to the NVRL for molecular investigation.
- One laboratory performs initial antibody screening tests (i.e. EIA) and refers reactive samples to the NVRL for confirmation of results (i.e. line immunoassay) and to the virology research laboratory at University College Cork (UCC) for molecular investigation.
- Fourteen laboratories perform initial antibody screening tests (i.e. EIA) but refer reactive samples to the NVRL for confirmation and further molecular analysis if required.

## 6.3 Appraisal of the Current Situation

### 6.3.1 Persons who have had an anti-D or a blood product transfusion prior to 1991

It is estimated that nearly 1,700 people have been infected with hepatitis C through the administration of contaminated blood and blood products. The routine screening of blood for hepatitis C antibody began in 1991. A targeted lookback programme began in January 1995 to identify recipients of potentially infected blood prior to 1991. A more generalised optional screening programme was instigated in September 1995 to reach those individuals who were not identified through the lookback exercise. With regard to women infected through the administration of contaminated anti-D, a national hepatitis C screening programme was initiated by the IBTS in 1994.

### 6.3.2 All drug users, especially those who have injected drugs or shared 'works'

Drug users who attend drug addiction services are screened on first presentation for blood borne viral infection, including hepatitis C. Different protocols are employed with regard to the frequency of hepatitis C screening thereafter in those who are either negative or antibody positive but hepatitis C RNA negative. Individuals who are repeatedly exposed to risk factors will require ongoing screening.

Not all IDUs will present for addiction treatment and a significant proportion will continue to inject. Of these a certain number will attend services providing harm-reduction materials, providing a point of contact with the health services and an opportunity to screen for blood borne viruses including hepatitis C.

#### 6.3.2.1 Prison population

The Irish Prison Service healthcare standards (2006) state in their clinical policy on screening for infectious or communicable diseases that "in view of the long-standing association between I/V drug use, infection with communicable diseases (in particular hepatitis B, C, and HIV), and criminality with the risk of incarceration it has been long-standing healthcare policy and practice to regard the prison population as being at high risk for such conditions. In this context it is recommended that all persons entering prison who volunteer a background history with risk factors for any infectious disease should be offered any available screening for that condition." [51] Many prisoners have been tested in the past and details and results of previous tests should be sought to avoid duplication and unnecessary testing.

The health care standards also outline the expected standard of care in relation to hepatitis C.[52] Prisoners should be provided with

1. General health information in relation to hepatitis C.
2. Advice and testing for hepatitis C where clinically indicated.
3. Referral to appropriate specialist services.
4. Treatment and support for those infected with hepatitis C.

These standards with regard to hepatitis C screening and care in the prison population need to be fully implemented. Some progress in this area has been made with the recent appointment of addiction nurses and the establishment of inreach services in two prisons.

### 6.3.2.2 Women Working in Prostitution

The Women's Health Project for Women Working in Prostitution is a service provided by the HSE and offers free screening for blood borne viruses and other sexually transmitted infections. The service is based in Dublin and covers the former East Coast, Northern and South Western Areas. A review of 150 new attendances at the clinic between 1991 and mid 1997 found that eight per cent reported current intravenous drug use. Sixty-six per cent overall were tested for antibody to hepatitis C and 8.1% were positive. Injecting drug users were significantly more likely to test positive (83.3% Vs 3.2%).[53]

### 6.3.2.3 Immigrants from countries of high endemicity for hepatitis C infection

Some asylum seekers have contracted infection through injecting drug use but many come from endemic countries in the developing world and acquired infection through re-use of needles and syringes in impoverished healthcare settings. Hepatitis C screening is not officially recommended as part of the screening programme but is carried out routinely in all Dublin reception centres and in some other accommodation centres around the country. The degree of testing carried out depends on the ability to transport specimens to the laboratory in a timely fashion. Some difficulties exist, particularly in more rural areas, with transport of PCR specimens within the required timeframe and therefore patients are referred to specialist services on the basis of positive antibody results.

Currently only immigrants who apply for asylum and who reside in direct provision accommodation are offered hepatitis C screening in some areas around the country. The number of asylum applications has decreased in recent years and asylum was only granted in 7% of finalised asylum cases between 2001 and 2010. Far greater numbers enter the country on work permits, work visas and student visas. Many of these immigrants are from endemic countries. With the enlargement of the EU many more people have immigrated to Ireland from the new member states where hepatitis C infection is more prevalent.

Information on asylum applications and work permits are presented in Table 8 and Table 9. Data on asylum applications were provided by the Office of the Refugee Applications Commissioner and data on work permits were provided by the Department of Jobs, Enterprise and Innovation. The information is categorised according to the hepatitis C prevalence in the country of origin. The majority of immigrants come from countries where the prevalence is greater than 2%.

**Table 8: Number of asylum applications between 2001 and 2010 by hepatitis C prevalence in country of applicant**

Hepatitis C prevalence (%) <sup>[19]</sup>	Number of asylum applications	%
<1%	1031	1.8
1-1.9%	2858	5.1
2-2.9%	21439	38.5
>2.9%	29135	52.3
Unknown	1278	2.3
<b>Total</b>	<b>55741</b>	<b>100</b>

**Table 9: Number of new work permits issued in Ireland between 2000 and 2010 by hepatitis C prevalence in country of applicant**

Hepatitis C prevalence (%) <sup>[19]</sup>	Number of new work permits issued	%
<1%	443	0.4
1-1.9%	29222	23.2
2-2.9%	90928	72.2
>2.9%	5049	4
Unknown	240	0.2
<b>Total</b>	<b>125882</b>	<b>100</b>

An expert group is currently being established under the auspices of the HPSC to review guidelines for the infectious disease screening of asylum seekers and to extend the guidelines to include all new entrants to the Irish healthcare system.

### 6.3.3 Persons including healthcare workers who have had percutaneous or mucous membrane exposures to potentially hepatitis C infected blood

A document on the prevention of transmission of blood-borne diseases in the health-care setting was published by the DoHC in 2005.[54] This document does not specifically address the issue of post-exposure investigation but gives clear guidance on reducing the risks of transmission in health-care settings from infected patients, staff, and devices or instrumentation. All health-care employers should have formal written procedures in place in the event of occupational blood exposures (e.g. needle-stick injuries) to potentially blood borne virus infected material. Expert advice should be easily and promptly available e.g. through emergency departments, via a 'hotline' or through direct access to occupational health or infectious disease services. Lookback policies must exist in the event of patient exposure to potential hepatitis C infection.

The infectivity of health-care workers who are hepatitis C RNA positive is uncertain. With regard to screening of healthcare workers, these guidelines recommend that staff who perform exposure-prone procedures (EPP) must be tested for antibodies to hepatitis C virus and, if positive, subsequently tested for hepatitis C virus RNA. The guidelines also contain recommendations for screening of patients pre-dialysis.

### 6.3.4 Antenatal screening

The prevalence of hepatitis C in antenatal populations is in the region of one per cent or less.

One of the primary aims of universal antenatal testing for infections is to intervene if possible and prevent mother-to-child transmission of infection and adverse outcomes for the child. Antenatal screening for maternal HIV infection is a clear example of the application of this principle. In the case of antenatal screening for hepatitis C, there are no current evidence-based interventions that reduce transmission from mother-to-child. To date insufficient evidence exists to recommend specific obstetric intervention or to recommend against breastfeeding. No critical hepatitis C RNA titre in the mother has been established which is associated with increased risk of vertical transmission. In addition, treatment of hepatitis C in pregnancy is contra-indicated.

Early treatment in children is problematic due to difficulties with establishing definitive HCV status and a lack of suitable treatment for children under three. The natural history of the disease in children, particularly those infected through vertical transmission, is unclear. Concerns exist with regard to the long term effects of treatment in children. The benefits of treating asymptomatic children have not been clearly demonstrated to date.

For these reasons universal antenatal testing for hepatitis C is not currently recommended. Targeted screening should be carried out for women at high risk, with declared risk factors. However, some maternity units carry out universal testing.

### 6.3.5 Babies born to hepatitis C infected mothers

Babies born to hepatitis C infected mothers should be screened for hepatitis C infection. Vertical transmission rates are in the order of 5%, with higher rates reported where mothers are co-infected with HIV. Diagnosis of hepatitis C infection soon after birth can be difficult and prolonged follow-up is necessary to make a definitive diagnosis.

Some parents of infants who are referred for further assessment and treatment for hepatitis C require additional support to ensure they bring their child to clinic appointments. Currently, clinical nurse specialists in paediatric clinics endeavour to ensure that appointments are kept.

## 6.4 Recommendations

<b>Recommendation 23</b>	<ul style="list-style-type: none"> <li>• Provide ready access for GPs and other community healthcare providers to diagnostic facilities.</li> <li>• Optimise transport of samples to the laboratories by the provision of a responsive courier service.</li> </ul>
<b>Organisation Responsible</b>	HSE – Access to Diagnostics (GP/Community) Initiative Governing Group

<b>Recommendation 24</b>	<ul style="list-style-type: none"> <li>• The IPS to implement the recommendations in parts one and two of the report “Hepatitis B, Hepatitis C and HIV in Irish Prisoners: Prevalence and Risk” with regard to infectious disease control.</li> <li>• Provide every prisoner on committal with a hepatitis C risk assessment, including details of previous virological tests, and offer screening for blood-borne viruses, including hepatitis C, if required.</li> <li>• Monitor uptake of testing</li> <li>• Ensure appropriate follow-up is provided</li> </ul>
<b>Organisation Responsible</b>	Irish Prison Service

<b>Recommendation 25</b>	The NVRL, on request, to release results of previous tests to medical practitioners with the patient’s consent
<b>Organisation Responsible</b>	NVRL

<b>Recommendation 26</b>	Establish guidelines with regard to hepatitis C screening of individuals from endemic countries / new entrants to the Irish healthcare system.
<b>Organisation Responsible</b>	HPSC Scientific Advisory Committee

<b>Recommendation 27</b>	<ul style="list-style-type: none"> <li>• Continue targeted antenatal screening for those with risk factors for hepatitis C infection</li> <li>• Regular review of the evidence with regard to universal antenatal screening</li> </ul>
<b>Organisation Responsible</b>	Maternity Hospitals General Practitioners

<b>Recommendation 28</b>	Offer and promote screening for hepatitis C and other blood-borne diseases to those who attend services such as Needle-Exchange Programmes and other harm-reduction services
<b>Organisation Responsible</b>	HSE Drug services

## 7. Treatment

### 7.1 Introduction

The 2004 strategy document identified challenges with regard to treatment access, delivery and adherence and made recommendations on improving assessment and treatment. Short, medium and long term goals with regard to treating those with hepatitis C were outlined.

This current chapter on treatment and support has been prepared to update the recommendations in the previous 2004 report. The aims are:

- To discuss recent advances in treatment
- To identify current treatment initiatives
- To make recommendations, applicable to the Irish context, on the future development of treatment and support services

Throughout this chapter, vignettes are provided to illustrate some of the different models of care that are in operation.

### 7.2 Drug Treatments

#### 7.2.1 New Drug Developments

For the past 10 years, standard therapy has been some form of pegylated interferon and ribavirin for 24–48 weeks, based on genotype. The limitations of these medications are well known. For genotype 1, the most common genotype in the United States and Europe, this has produced an SVR (sustained viral response/equated with cure) rate of only about 40%. Pregnant patients or those with advanced renal disease are unable to use ribavirin. Likewise, interferon therapy excludes patients with autoimmune diseases, severe depression and mental illness, decompensated liver disease (Child-Turcotte-Pugh score more than 6), or decompensated cardiac or pulmonary disease. In addition to contraindications, side effects and low response rates have led to investigations for treatment alternatives.

New drug therapies such as protease and polymerase inhibitors called new direct-acting antivirals (DAAs) have been developed over the last decade. In genotype 1 patients, very promising results have been reported when the protease inhibitors telaprevir or boceprevir (and other drugs in earlier phase studies) is added to the standard of care (SOC). The final results of phase III studies have shown that SVR rates are increased from less than 50% (PEG-IFN plus RBV) to 70% (in PEG-IFN plus RBV plus the protease inhibitor). Overall, protease inhibitors hold promise in treating patients with chronic HCV, with improvements in responses to up to 80% in those undergoing first treatment, in those who have previously failed treatment and in those co-infected with HIV. Beginning in mid-2011 in the USA, both telaprevir and boceprevir were approved for use in conjunction with pegylated interferon and ribavirin for the treatment of hepatitis C. These drugs have now been approved for use in most European countries including Ireland.

While DAAs provide a tremendous improvement in SVR for many patients there are still treatment failures, side effects, and many patients excluded. Ongoing research supports their successful use as a first line treatment as well as in previous non-responders. The newer drugs provide an opportunity to treat these patients, most with mid to later-stage disease who cannot wait for additional options. Anaemia may be a problem with the addition of these medications as well as new gastrointestinal side effects and rashes, which may be an important consideration in patient tolerance and selection of DAA. There is cross-resistance among the NS3/4A drugs, and therefore treatment failure/resistance to one drug in this category will likely be seen in all of them.

New promise is anticipated with the polymerase inhibitors and other agents targeting cyclophilin or other intracellular proteins. Current DAA medications do show some efficacy against alternate genotypes and this expanded efficacy will likely be true for the newer generations which are currently in the pipeline.

The longer-term picture for the treatment of hepatitis C will likely include a cocktail of several different DAA medications targeting different sites.

An important point in the treatment of HCV is that, as opposed to HIV or HBV, a cure is possible. Directly acting antivirals provide the opportunity to reduce treatment times in many patients and may increase cure rates to up to 70% or more. We are seeing new side effects and new resistance patterns as we employ DAA, but literature is currently reporting improved tolerability of later generation drugs, new targets of action, innovative ways to approach resistance, efficacy with alternate genotypes, and the success of interferon free regimens. We anticipate

well tolerated cocktails of oral medications in the not too distant future, which will simplify the management of this infection.

Advances have also occurred in the diagnosis of complications of hepatitis C infection. Hepatic ultrasonic transient elastography is a new, non-invasive, rapid method to evaluate liver fibrosis. The patient does not require admission, and the procedure does not have to be performed in a hospital setting, unlike liver biopsy. Fibrosis is estimated by the measurement of liver stiffness. A reduction in elasticity can relate to fibrosis or cirrhosis. In Ireland some centres have applied this technology and it has proven popular with patients. Some patients have used the information from the results of the scan to alter their alcohol and drug intake. It has also highlighted the desirability for treatment in individual cases where this was previously unquantifiable.

Previously, therapy was indicated for chronic hepatitis C infection if there was established moderate to severe activity or significant fibrosis documented on liver biopsy. This approach has been influenced by three issues. Initially, treatment outcomes for interferon monotherapy were poor with overall response rates in the region of 24%. Since the introduction of combination therapy, response rates have increased to over 50% in genotype 1 patients and over 80% in genotype 2 & 3 patients. Therefore with improved outcomes, the risk benefit ratios of treatment have altered, significantly favouring the treatment of chronic hepatitis C infection. Secondly, cost modelling based on combination therapies has demonstrated that treatment is beneficial even in patients with minimal histological damage. Thirdly, the evolution of technologies to evaluate the stage of histological injury (as discussed above), avoiding the need for liver biopsy, should enable more timely access to treatment. Ultimately, more patients with chronic hepatitis C infection can now be offered individualised treatment.

This is a technical overview of new and emerging therapies. How these therapies will be made available to patients and the more detailed clinical assessments and associated factors in relation to translating new drug discovery into clinical action are the subject of guidelines being developed by clinical experts.

### 7.2.2 Treatment in general practice

Considerable work has been done by the Dublin Area Hepatitis C Initiative Group (DAHICIG) in recent years.[6] The initiative included the development of clinical guidelines derived from scientific evidence and expert consensus obtained using the Delphi technique.<sup>1</sup> The guidelines cover general care, immunisation, screening, diagnosis, work-up and onward referral to specialist services. A complex pilot intervention study using these guidelines was designed and evaluated. The evaluation to date has concluded that general practice has an important role to play in the care of people at risk of hepatitis C. With appropriate support, GPs can effectively implement current best practice among groups who are infected. The need for additional supports is emphasised by the DAHCIG, particularly the development of a primary care nurse liaison service. A more detailed description of these guidelines can be found in Appendix 11.

## 7.3 Current situation

Different patient groups with hepatitis C, who could potentially benefit from treatment, have been identified.

1. Injecting drug users (current and former) of whom approximately 10,000 are infected with hepatitis C. This number is an estimate based on the number of drug users in treatment .
2. Patients infected through contaminated blood and blood products (often referred to collectively as 'State infected'). These patients, of whom there are approximately 1,700, link well with services and can avail of specialist services in eight designated hospitals.
3. Patients who are referred to as sporadic cases of infection as no obvious source of infection can be determined. These patients are usually diagnosed through their attendance at specialist services. Improved national surveillance should prospectively provide data on the numbers of patients affected.
4. Immigrant populations including asylum seekers. Asylum seekers are currently the only migrant population who are offered screening. Incomplete enhanced surveillance data precludes an estimation of the numbers affected.
5. Patients co-infected with hepatitis C and HIV. These patients are usually cared for by the infectious disease services at three sites nationally
6. Patients infected with hepatitis C who also drink alcohol are at particular risk, particularly if drinking levels are at or above the Irish norms. It is important that any treatment programme for any people who are infected with hepatitis C would address the alcohol issue and make arrangements for alcohol reduction strategies to be made available to the individual patients.

1 The Delphi technique involves an iterative approach, designed to measure consensus among individual responses. Face-to-face participation is not required. A series of questionnaires interspersed with information summaries and feedback from preceding responses are usually employed.



Hepatitis C treatment in Ireland is in line with international guidelines. Treatment is most commonly delivered in a hospital setting, in centres with a special interest in hepatitis C.

#### **MATER HOSPITAL/THOMPSON COMMUNITY DRUG TREATMENT CENTRE COLLABORATION**

The Mater Hospital / Thompson Community Drug Treatment Centre collaboration for the treatment of patients with hepatitis C was established in 2006. The collaboration was initiated because many patients in the community with hepatitis C who were referred to the hospital for evaluation were not completing the evaluation process. Several reasons for patients not being fully evaluated related to difficulties communicating with them in the community e.g. appointments were not being made appropriately, patients were moving homes frequently and appointments were going to the wrong address.

Currently the staff of the infectious disease (ID) clinic in the Mater hospital (nurse specialist, secretary, ID consultant) meets monthly with the staff of the Thompson centre (nurse, administrator, GP coordinator) to review patients who are eligible for treatment, stable, and motivated to complete treatment. An initial evaluation takes place at the Mater hospital ID clinic to familiarise patients with the hospital and to link them with the infectious diseases clinic and Mater hospital consultations, if it is deemed necessary in the future. The evaluation includes baseline bloods, diagnostic tests, consents and scheduling of further investigations. The Mater hepatitis C nurse specialist plays a key role in co-ordinating services. Subsequently all visits, before and after the initiation of hepatitis C specific therapy, take place at the Thompson Centre where the Mater nurse specialist attends once a week. Problems are discussed weekly with the Mater nurse specialist, GP coordinator and ID consultant as needed. Monthly meetings of the joint Mater/Thompson Centre team are used as a forum for case management of those already on treatment as well as evaluation of those who are eligible for treatment.

Through the application of this model of community/hospital partnership, more patients with hepatitis C and 'stable' substance misuse are receiving HCV treatment with good adherence and follow-up.

#### **Vignette 2: An on-site programme at the Thompson Centre in association with the Infectious Disease services at the Mater Hospital, Dublin**

Several models of care can currently be described in Ireland. Different sectors of the healthcare services are involved with different links between the services. The services principally involved in the treatment and management of patients with hepatitis C are:

- Hospital based consultant-led services  
These services are provided by the specialities of hepatology, gastro-intestinal medicine and infectious diseases. Patients are managed on a day to day basis by nurse specialists with consultant supervision.
- Drug treatment services  
Four sites in the Dublin area deliver anti-viral treatment to patients at the clinics where they receive methadone treatment.
- Prison services  
An infectious disease consultant has been appointed to Wheatfield and Cloverhill prisons, resulting in improved screening and referral rates for hepatitis C. Expansion of these services is recommended.
- Services provided by GPs specialising in substance abuse
- Community general practice services  
The methadone protocol has been in existence since 1998. Approximately 3000 patients attend GPs in community for methadone treatment. Many of these patients are hepatitis C positive.

### HEPATITIS C TREATMENT PROGRAMME AT THE DRUG TREATMENT CENTRE BOARD

In 2003, a pilot on-site hepatitis C programme was established at the Drug Treatment Centre Board (DTCB) incorporating directly observed hepatitis C treatment. Directly observed therapy (DOT) has been shown to work well for the treatment of HIV and TB in drug users on methadone maintenance. The rationale for the pilot programme was to treat both a patient's hepatitis C infection and drug addiction at the same site with a view to improving the adherence of patients to a hepatitis C treatment schedule. The aim was to demonstrate a 'proof of concept'; that patient retention in treatment can be improved if therapy is directly observed and delivered in a specialist drug treatment setting with appropriate on-site medical and psychiatric support. The medical care was delivered under the guidance of a Consultant in Infectious Diseases based at St. James's Hospital (SJH). Patients received regular psychiatric review and were monitored for psychiatric complications of therapy and potential relapse into active addiction. Day to day monitoring was coordinated by an appointed nurse at the DTCB.

#### **Vignette 3: An on-site programme at the Drug Treatment Centre Board in association with the Infectious Diseases services at St. James' Hospital, Dublin**

Care of infected drug users can be limited by

- chaotic lifestyles
- social deprivation and exclusion
- imprisonment
- poor attendance at clinic appointments
- failure to adhere to treatment
- unsuitability for treatment as a consequence of ongoing drug or alcohol use.

Care may also be hindered by suboptimal social, childcare and addiction support.

Most services are supported by hepatitis C liaison clinical nurse specialists (HCLNS) who can be based in hospitals or in the community. Liaison nurse specialists play a role in enabling a patient to enter treatment and in maintaining patients in treatment programmes. A HCLNS in the former Northern Area Health Board was appointed in 2002 and facilitates the delivery of hepatitis C treatment to drug users in various drug treatment clinics in the north side of Dublin and to drug users attending GPs in this area. Clinical nurse specialists based in the community (e.g. in the addiction services) liaise with specialist services to enable patient-centred care. Clinical nurse specialists in hospital-based positions work collaboratively with relevant primary healthcare providers as appropriate. Medico-legal concerns exist with regard to clinical responsibility. These concerns may be addressed by ensuring that all nurses work under the clinical guidance of the gastroenterologist or infectious disease consultant in matters relating to hepatitis C management and in collaboration with primary healthcare workers for primary care related matters.

### HEPATITIS C TREATMENT AT ST JAMES' HOSPITAL IN CONJUNCTION WITH THE DUBLIN SOUTH-WEST ADDICTION SERVICES

The Hepatology team at St James' Hospital offers a comprehensive range of services and sees approximately 4,000 hepatitis C patients per year. Clinics have been developed to meet the needs of the various client groups who access these services, including injecting drug users (IDUs) infected with hepatitis C.

Since late 2005, a clinical nurse specialist provides a nurse-led hepatitis C education and treatment clinic for IDUs who attend a Consultant Hepatologist. This nurse-led clinic is provided in collaboration with the GP co-ordinator for the local drugs service at community based methadone services and at SJH outpatient departments.

An audit performed at eighteen months demonstrated that patients can be successfully treated at the addiction centres with sustained virological responses comparable to hospital based services once treatment has commenced. However, following initial assessment, there was a significantly longer lead-in time before treatment was commenced. Patients were also significantly more likely to refuse, default or become unsuitable for treatment compared with hospital-based patients. While on treatment, these patients required more interventions than hospital-based patients. However, rates of recidivism for drug use were not increased. Therefore while this service is invaluable in treating a difficult population, consideration must be given to the efficacy and efficiency of treating this population in directing further service provision.

#### **Vignette 4: An on-site programme at the Castle Street HSE Addiction Clinic, Dublin 8 in association with the hepatology services at St. James's Hospital, Dublin**

## 7.4 Appraisal of the current situation

Comprehensive services have been put in place for patients who acquired hepatitis C through contaminated blood and blood products. However, the needs of those who have acquired hepatitis C through other means have not been adequately addressed to date. The establishment of a national register will provide accurate data on the number of people who are infected, the number who are in treatment and the number awaiting treatment, as per recommendation 4, chapter 4. The population prevalence study (recommendation 6) and modelling exercise (recommendation 7) recommended in Chapter 4 will also provide invaluable data to enable effective service planning.

Limitations to the care of IDUs who are infected have been described above. Models of care that have been designed to try and address some of these issues have also been described. However it is estimated that the number who are in treatment or who have been treated is outweighed by the number of people who could benefit from but have been unable to access treatment for a variety of reasons.

Other subgroups of the population also face difficulties in accessing services. Due to the nature of accommodation provided to asylum seekers through the dispersal system many asylum seekers are at risk of loss to medical follow up in the community. Concern has been raised that the government's current integration strategy excludes asylum seekers. [55] [56] Other immigrants may also have difficulty accessing services, both for hepatitis C infection and addiction, due to a lack of familiarity with the Irish health care system and language barriers.

The reliance on the availability of escorts for prisoners to attend out-patient appointments can reduce compliance. Lack of needle exchange in prison reduces illicit drug stability and therefore suitability for treatment.

Many centres that are currently providing hepatitis C treatment are doing so with externally sourced (i.e. non-Exchequer) funding. This funding is not recurrent leading to fluctuating numbers of patients in treatment and termination of treatment for some prior to completion of the recommended course.

With regard to community hepatitis CNS posts, two additional community posts were approved in Dublin for the South West Addiction Service and the East Coast Addiction Service. The post in the south west has been filled. No equivalent position exists outside Dublin.

Many patients choose to defer or refuse treatment for various reasons which may be personal, financial or social. Until such time as a patient chooses to engage in therapy for hepatitis C, that patient should continue to be assessed in the specialist centre.

### 7.4.1 Issues identified by the hepatitis C community liaison nurse specialist service

- The widespread prevalence of hepatitis C amongst drug users means that the liaison service is completely over-stretched resulting in inadequate service delivery.
- Many service-users require long-term follow-up due to the chronic nature of hepatitis C and a predominance of genotype 1 infection. This significantly impacts on the capacity of secondary services. Waiting times for appointments, liver biopsies, psychiatric screening and engagement in treatment at hospital level have lengthened.
- The impact of chronic hepatitis C on the drug users can present a range of complex health needs. Many of these needs cannot be met at secondary level and require collaboration with primary services to facilitate effective interventions.
- Effective monitoring and follow-up of patients on treatment relies on staff resources, with an emphasis on nurse specialists as co-ordinators of care.

### COMMUNITY HEPATITIS C LIAISON NURSE SPECIALIST

In December 2002, the Addiction Services of the former Northern Area Health Board employed a Hepatitis C Liaison Nurse Specialist (HCLNS) to assist in the clinical management of hepatitis C in 'Dublin North', 'Dublin North East' and 'Dublin North Central'. The role encompasses five core functions:

- clinical caseload,
- patient advocacy,
- education & training,
- audit & research,
- resource person.

The position was approved at clinical nurse specialist level in 2005 by the National Council for the Professional Development of Nurses & Midwives.

Key to the HCLNS role is the shared-care programme between hospital-based specialist services for hepatitis C and community-based addiction services. A collaborative link between the two services optimises the care patients receive. This link is achieved by the work of the HCLNS in co-ordinating clinical support at community level and includes:

- assistance with a holistic assessment of clinical status, client's understanding of diagnosis & stability and referral of patients to hospital follow-up and to support services
- psychosocial support
- preparation of patients for diagnostic procedures
- facilitation of hepatitis C treatment processes in the community.

Treatment in the community occurs under the clinical direction of hospital-based hepatology or infectious disease consultants.

This model of care is consistent with the strategic direction of the HSE: providing services in a primary care setting, whilst easing the burden on secondary services and delivering timely and patient-focused care (DOHC, 2001).

## Vignette 5: The role of the community hepatitis C liaison nurse specialist

### 7.4.2 Issues identified for community-based GPs

- An increasing amount of addiction related care is being delivered in general practice. The observed prevalence of known hepatitis C infection of 73% in a study carried out in the former ERHA [5] indicates the relevance of this issue for GPs.
- Inconsistencies in the management of patients in general practice have been reported. [6]
- Access to community diagnostic services is poor particularly for clinics that operate out-of-hours. Many methadone clinics operate out-of-hours providing replacement therapy to stable patients before or after work.
- Qualitative research, carried out on a small purposive sample of GPs providing methadone maintenance in the former ERHA, reported the principal barriers to guidelines being implemented in their practice as
  - o Lack of resources at practice level
  - o Attitudes of GPs and patients towards hepatitis C
  - o Lack of time on the part of GPs

### **A GENERAL PRACTICE INITIATIVE (HSE EASTERN REGION) TO IMPROVE HEPATITIS C CARE OF CURRENT OR FORMER INJECTING DRUG USERS**

In Ireland and the EU, addiction related care is increasingly delivered in primary care. Research conducted in 1999 in Ireland demonstrated that hepatitis C infection was common among patients attending general practice for methadone treatment, and highlighted a need for additional interventions to enhance screening.

Clinical guidelines were developed for the management of hepatitis C among drug users in general practice and an intervention to implement these guidelines was designed and evaluated.

The clinical guidelines included advice on the primary and secondary prevention of harm associated with hepatitis C infection. Clinical and organisational supports were incorporated into the intervention model and consisted of CME-accredited practice based education and a nurse to liaise with external agencies, assist clinical patient care, initiate / coordinate liver specialist referrals and support patients being assessed for treatment.

This initiative was evaluated by a randomised trial in 25 GP practices. At baseline, 77% had been screened for hepatitis C; of those who were HCV positive, 30% had been referred for assessment by a liver specialist.

After six months, patients attending practices where the intervention was in place were found to be significantly more likely to have been screened for hepatitis C, less likely to have provided a urine sample that contained an illicit drug metabolite and more likely to have been given advice on reducing alcohol consumption. Hepatitis C positive patients were also more likely to have been referred to a liver specialist.

The findings of this evaluation highlight the importance of evidence-based approaches in addressing hepatitis C-associated harm and the central role of general practice, with appropriate resources and professional frameworks, in any strategic response.

#### **Vignette 6: A general practice initiative (HSE Eastern Region) to improve hepatitis C care of current or former injecting drug users**

##### **7.4.3 Issues identified by GP specialists in substance abuse (GPSSA)**

- Hepatitis C is an addiction issue as many are infected through injecting drug use. This is also relevant to the long term management of the infection by the patient, particularly with regard to re-infection and alcohol use.
- Multiple issues (personal, social, family, medical, legal, drug-related, alcohol related, psychological and psychiatric) which affect a person's drug-use also affect their ability and suitability to undergo pharmacological treatment. Therefore not all patients who are hepatitis C RNA positive will be suitable for anti-viral treatment.
- Communication between treating doctors and between doctor and patient are essential, particularly during pharmacological treatment.
- GPSSAs who are involved in the management of patients' addiction and infection should be given the resources to develop their interest and skills in delivering care to their patients in collaboration with other groups within and outside the addiction services.
- Clinics in the addiction services need to be adequately resourced to help chaotic patients, including those who are not immediate candidates for pharmacological treatment.

### THE EAST COAST AREA INTEGRATED SHARED-CARE PROGRAMME FOR THE MEDICAL MANAGEMENT OF HEPATITIS C IN THE ADDICTION SERVICE

This programme offers appropriate medical management of hepatitis C by integrating a patient's addiction treatment with their long term management of hepatitis C. The programme is multidisciplinary (GPSSA, psychiatrist, nurses, pharmacist, counsellors and other staff), consensual and patient driven.

Patients who are PCR positive are referred (not triaged) to the hepatology services in St Vincent's Hospital and a follow-up system exists for those who miss appointments. The hepatology services – including the Consultant Hepatologist and the hospital-based nurses - work in close co-operation with the clinical staff in the addiction centre to deliver integrated hepatitis C and addiction treatment for the individual patient. An unparalleled familiarity with the patient's personal, social, family, medical and drug history and regular daily contact with the patient provides for

- an appropriate level of care to all patients, chaotic and stable
- a comprehensive level of support before, during and after treatment
- a heightened ability to detect adverse treatment effects including treatment-induced depression and suicidal ideation
- a reduced likelihood of return to drug and alcohol abuse while on treatment

Patients, who do not attend for treatment, those who do not have a sustained virological response (SVR) after treatment or those who become re-infected, are the largest patient group for the addiction services and receive ongoing follow up. Annual PCRs are carried out on patients who continue to potentially expose themselves to infection.

The integrated addiction/infection management approach lends itself to post treatment surveillance, including regular evaluation of post treatment drug use (including alcohol) and its effect on long term treatment outcome, and forms the basis of an ongoing plan for patients when they move on to community based GPs.

This near-patient, integrated model of care uses the resource of a team who knows their patient, their circumstances and their drug use, to effectively deliver both addiction and hepatitis C related treatment and support.

Screening has been successfully piloted in the Addiction Service in the East Coast Area. This has reached patients who did not previously attend Hepatology when referred and indicates that advanced liver disease is common in patients attending the Addiction Service.

#### **Vignette 7: An on-site programme at the Patrick Street HSE Addiction clinic in Dun Laoghaire, Co. Dublin, in association with the Hepatology services at St. Vincent's Hospital, Dublin**

## **7.5 Recommendations**

The principle that treatment should be available in an equitable manner for all those infected with hepatitis C, irrespective of mode of acquisition, has been firmly agreed by the treatment subgroup and endorsed by the main working group.

A set of recommendations has been drawn up by the treatment subgroup which outlines what the HSE and other agencies should provide and facilitate in order that accessible, equitable, quality care can be delivered to all patients infected with hepatitis C in Ireland as a matter of priority.

Improving access to treatment and supporting patients through treatment will reduce the progression from viral infection to liver damage for many patients. It should also contribute to a reduction in the prevalence of hepatitis C infection, thus reducing the associated clinical and social burden of the disease.

#### **Expert Guidance on Clinical Issues**

Challenges can arise in the diagnosis of hepatitis C and the subsequent management of patients e.g. the ongoing long-term monitoring and management of

- patients who are antibody positive but in whom hepatitis C RNA is not detected
- patients who choose not to avail themselves of, or are not ready or suitable for treatment.

For these patients, clinical pathways should be developed to assist them in working towards treatment suitability. Standardised guidelines reflecting best practice should be readily available to all health care providers, particularly community GPs.

<b>Recommendation 29</b>	<ul style="list-style-type: none"> <li>• Establish an expert group to provide guidance on clinical issues.</li> <li>• Develop standard protocols for testing, diagnosis, evaluation, referral for treatment, monitoring of treatment and monitoring of patients not on treatment.</li> <li>• Monitor and evaluate the implementation of these guidelines.</li> </ul>
<b>Organisation Responsible</b>	Expert Group HIQA (Health Information and Quality Authority)

<b>Recommendation 30</b>	Establish a postgraduate diploma in hepatitis C management for physicians and nursing staff
<b>Organisation Responsible</b>	Accredited third level academic institution Tendering process should be overseen by the expert group

### ***Barriers to treatment uptake and adherence***

Barriers to treatment uptake and adherence to treatment, once initiated, should be addressed, be they social, psychological or related to drug or alcohol use. Peer support is recognised as an effective means of promoting treatment and compliance and peer educators should be appropriately trained as in recommendation 11, chapter 5.

<b>Recommendation 31</b>	Provide patients, particularly those with chaotic lifestyles and other social problems, with practical supports to enable them to attend for and adhere to treatment e.g. child-care
<b>Organisation Responsible</b>	Primary Care Teams

<b>Recommendation 32</b>	Address alcohol issues and provide alcohol reduction strategies for those patients infected with hepatitis C who require them
<b>Organisation Responsible</b>	HSE – Drugs and Alcohol services

### ***Hepatitis C care in custody***

As previously stated the prevalence of hepatitis C amongst prisoners with a history of injecting drug use is particularly high. Those serving custodial sentences should be offered hepatitis C care in line with best practice models

<b>Recommendation 33</b>	Develop, implement and evaluate a treatment model appropriate to the prison setting on a national basis
<b>Organisation Responsible</b>	Expert Group in conjunction with the IPS

### ***Meeting the needs of all patients infected with hepatitis C***

As outlined in section 7.4, the needs of patients infected with hepatitis C through means other than contaminated blood products have not been formally assessed. As part of a needs assessment, international literature should be critically reviewed to evaluate different models of care that exist in terms of efficiency and effectiveness. An economic appraisal of effective models should also be carried out. The merits of increasing the availability of portable ultrasonic diagnostic equipment should be explored in terms of diagnostic accuracy and potential cost-savings.

<b>Recommendation 34</b>	Undertake a formal assessment of the needs of individuals infected with hepatitis C, other than through contaminated blood and blood products
<b>Organisation Responsible</b>	HSE

### ***Clinical Nurse Specialist staffing requirements for hepatitis C treatment***

The number of CNSs working in the area of hepatitis C should be expanded to meet the demand for patient treatment. A standardised approach should be adopted to the establishment of nurse specialist posts nationally, both in the addiction services, prison services and hospital-based services. The needs assessment recommended above will establish potential service demands around the country and the number of CNS posts required.

<b>Recommendation 35</b>	Further develop the number of hepatitis C CNS posts based on the findings of the needs assessment in recommendation 34
<b>Organisation Responsible</b>	HSE

### ***Delivery of hepatitis C care to patients through primary care services***

The delivery of services within the primary care setting should be maximised to alleviate the burden of work on hospital services and to provide care to patients in a setting that is most convenient to them. Weekly GP visits by stable patients for methadone substitution could be linked to hepatitis C treatment and monitoring. This work would be supported and facilitated by community HCLNS and by increased access to community diagnostics (see recommendation 23).

<b>Recommendation 36</b>	Develop the role of suitably trained general practitioners in facilitating treatment monitoring in the community
<b>Organisation Responsible</b>	HSE and ICGP (Irish College of General Practitioners)



## 8. Conclusion

The State has put in place, underpinned by legislation, a comprehensive response to hepatitis C for those who became infected through “state infection”.

The recommendations of this report are framed so that all persons infected with hepatitis C will have access to a range of medical treatments and other control measures.

There are many challenges in achieving this, and what is set out here is an action plan over 4 years. We are conscious that all cannot be done at once and we have prioritised some actions. We are also conscious of the need to get the right balance between a standardised approach while allowing flexibility within regions and by clinical services. There are a number of models of treatment described in Chapter 7. Recommendations are made with regard to the need for a formal needs assessment and economic evaluation of existing responses. There are many gaps in data and epidemiology which need to be filled. We have emphasised education, prevention and communication with people who are infected or at risk of infection.

There are a number of further and deeper levels of information and understanding that are required and for that reason we recommend the establishment of an expert working group to take forward some of the specific treatment based recommendations.

We believe that now is an opportune time to develop a cohesive and co-ordinated strategy for the care of all patients infected with hepatitis C in Ireland. With the recent introduction of a unified national structure for our health services the opportunity to develop a nationwide approach to this disease should not be missed. Patient-centred care is one of the core values espoused by the current health services administration. This paradigm of care aligns itself very much with the philosophy behind our document. We believe if our recommendations are implemented in good faith that the response to hepatitis C infection will improve considerably at a population level over the next 3 years.

## 9. Action Plan

This chapter lays out an action plan to improve the care of hepatitis C infected patients in Ireland. The plan is laid out in tabular format and pulls together the recommendations that have been made in the different chapters. Many recommendations are budget neutral and could be implemented without delay. Some simple steps could be taken without any new investment and would lead to a considerable increase in the efficiency of current systems and the care delivered to patients.

No	Recommendation	Organisation Responsible	Timeline
1	All laboratory requests for hepatitis C serology must contain full patient identifiers and full clinician details. This information should then be transmitted by laboratories to Public Health	Clinicians & Laboratories	End 2012
2	Encourage clinicians to notify newly diagnosed cases of hepatitis C and to provide as much relevant information as possible	HSE & Clinicians	End 2012
3	Commence enhanced surveillance of all cases of newly diagnosed hepatitis C infection	HSE - Departments of Public Health	End 2014
4	Establish a <b>national</b> register of hepatitis C infected patients (other than those referred to as "state-infected")	HSE - Departments of Public Health	End 2014
5	Commence appropriate public health follow-up on all cases of newly notified hepatitis C infection	HSE - Departments of Public Health	End 2012
6	Undertake a population prevalence study	HSE - HPSC	End 2014
7	Complete a modelling exercise to estimate future disease burden and to aid service planning	HSE - Department of Public Health East & HPSC NVRL HRB	End 2014
8	Conduct follow-up studies amongst IDUs to identify seroconverters and therefore incidence rates. A national register (as per rec 4 above) will facilitate this	HSE & service providers	1 study / year, starting with Rec 7 above
<b>9</b>	<b>Treat existing drug addiction</b>	HSE & existing organisations	Determined by the Addiction services
9a	Increase the number of drug treatment facilities including detoxification units, methadone clinics, treatment for addictions other than intravenous heroin use etc, particularly outside of the Eastern Region		
9b	Reduce existing waiting lists for treatment and delays between assessment and treatment		
9c	Target young and newly initiated drug users		
9d	Provide flexible holistic services that can meet the needs of all drug users including homeless drug users and drug users from new communities		
9e	Develop prison-based drug addiction treatment programmes that are linked with community-based programmes for when prisoners are released		
9f	Provide after-care and rehabilitation services to prevent relapse		
<b>10</b>	<b>Prevent transition from smoking heroin to injecting heroin</b>		

10a	Develop interventions to delay / prevent transition from smoking to injecting, including training for staff in motivational interview techniques and brief interventions.	HSE	Determined by the addiction services
10b	Treat drug addiction in those who have become dependent but are not yet injecting, in line with national performance indicators.		
11	Work with established injectors to discourage them from initiating others into injecting through peer education	HSE & voluntary service providers	End 2013
12	<b>Improve provision of harm-reduction materials</b>		
12a	Ensure all drug users have access to harm-reduction materials regardless of location	HSE in partnership with voluntary providers	End 2012
12b	Expand current provision of harm-reduction materials, particularly outside of the Eastern Region, both in terms of geographical coverage and time		
12c	Eliminate the policy of "one for one" needle/syringe exchange		
12d	Encourage collaborative links with local Garda around centres for provision of harm-reduction materials	HSE in partnership with voluntary providers and Garda Siachana	
13	Promote provision of harm-reduction materials within the pharmacy setting	DoHC in conjunction with the HSE	End 2012
14	Pilot and evaluate the Dublin Area Homeless Hepatitis C Project	Safetynet, Ana Liffey Drug Project, Mountjoy Street Family Practice, HSE	End 2013 for pilot
15	Implement recommendations from the MQI report "Drug Use Among New Communities: an exploratory study"	HSE - Drug Treatment Services,	End 2013
16	Regulate services that provide body-piercing, tattooing and permanent make-up	DoHC	End 2013
17	Review existing informational and educational material that is in current use with a view to proofing (culturally, linguistically and literacy), standardising and improving the quality of information	HSE	End 2012
18	Facilitate access to a standardised, accredited interpreting service for individuals who do not have English as a first language	HSE - Social Inclusion Directorate	End 2013
19	Provide clear, consistent and updated advice on the transmission risks of hepatitis C to those involved in the diagnosis and / or management of patients in the community	HSE - Departments of Public Health & HPSC	End 2013
20	Include competency based training modules on harm reduction for all those working with drug users in a community setting, that are guided by national standards in health promotion		Mid 2013

21	Staff recruitment and training		
21a	Employ staff trained to an appropriate standard in all services engaged in health promotion to prevent hepatitis C infection	HSE & Voluntary Sector	End 2013
21b	Develop minimum standards of education for outreach and other staff who are in direct contact with IDUs		
21c	Standardise recruitment and training for peer educators that is evidence-based and continuously evaluated		
21d	Increase learning from peer education models already in place		
22	Plan and implement a campaign to raise awareness amongst those who may previously have been diagnosed with hepatitis C or who may have been at risk of infection in order to redirect them to medical services, if this is what they choose		
23	<b>Improve primary and community care facilities for screening and diagnosis</b>	HSE	End 2013
23a	Provide ready access for GPs and other community healthcare providers to diagnostic facilities.		
23b	Optimise transport of samples to the laboratories by the provision of a dedicated, responsive courier service.		
24	<b>Improve prison-based services</b>	HSE – Access to Diagnostics (GP/Community) Initiative Governing Group	End 2013
24a	The IPS to implement the recommendations in parts one and two of the report “Hepatitis B, Hepatitis C and HIV in Irish Prisoners: Prevalence and Risk” with regard to infectious disease control		
24b	Provide every prisoner on committal with a hepatitis C risk assessment, including details of previous virological tests, and offer screening for blood-borne viruses, including hepatitis C, if required.		
24c	Monitor uptake of testing		
24d	Ensure appropriate follow-up is provided		
25	The NVRL, on request, to release results of previous tests to medical practitioners with the patient's consent	Irish Prison Service	End 2013
26	Guidelines to be established with regard to hepatitis C screening of individuals from endemic countries / new entrants to the Irish healthcare system		
27	<b>Antenatal screening</b>	NVRL	Mid 2013
27a	Continue targeted antenatal screening for those with risk factors for hepatitis C infection	HPSC Scientific Advisory Committee	End 2013
27b	Regular review of the evidence with regard to universal antenatal screening		
28	Offer and promote screening for hepatitis C and other blood-borne diseases to those who attend services such as Needle-Exchange programmes and other harm-reduction services.		
		Maternity Hospitals GPs	Ongoing
		Expert Group	Ongoing
		HSE Drug services	Mid 2013

29	<b>Expert guidance on clinical issues</b>		
		Expert Group	Ongoing
29a	Establish an expert group to provide governance on clinical issues.	Expert Group	Mid 2013
29b	Develop standard protocols for testing, diagnosis, evaluation, referral for treatment, monitoring of treatment and monitoring of patients not on treatment	HIQA	Mid 2014
29c	Monitor and evaluate the implementation of these guidelines	Expert Group in conjunction with relevant third level institution	End 2013
30	Establish a postgraduate diploma in hepatitis C management for physicians and nursing staff	Primary Care Teams	Mid 2013
31	Provide patients, particularly those with chaotic lifestyles and other social problems with practical supports to enable them to attend for and adhere to treatment	HSE - Drugs and Alcohol services	Mid 2013
32	Address alcohol issues and provide alcohol reduction strategies for those patients infected with hepatitis C who require them	Expert group in conjunction with the IPS	End 2014
33	Develop, implement and evaluate a treatment model appropriate to the prison setting on a national basis	HSE - Quality and Clinical Care Directorate	End 2013
34	Undertake a formal assessment of the needs of individuals infected with hepatitis C, other than through contaminated blood and blood products	HSE - Integrated Services Directorate	Pending outcome of Rec 34
35	Expand the number of hepatitis C CNS posts based on the findings of the needs assessment in recommendation 34	HSE & ICGP	Mid 2013
36	Develop the role of suitably trained general practitioners in facilitating treatment monitoring in the community		

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## APPENDICES

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## APPENDIX 5: HEPATITIS C ASSOCIATED HEALTHCARE UTILISATION

The Hospital In-Patient Enquiry (HIPE) System and the Primary Care Reimbursement Service (PCRS) provide limited information on the use of HSE healthcare services for individuals with hepatitis C.

### Hepatitis C Associated Hospital Utilisation.

As outlined in Chapter 2, section 2.2.1, the HIPE System contains a record for each discharge following an episode of care from an acute hospital in Ireland. The condition that caused the patient to seek care is recorded as are other co-morbid conditions. Hepatitis C infection is a chronic condition which may be recorded as a co-morbid diagnosis for patients receiving care for other conditions or may be the cause of admission. It is important to re-emphasise that the HIPE system is based on individual discharges and not individual patients. For these reasons, hospital utilisation data associated with Hepatitis C infection require careful interpretation.

Table A presents data for hepatitis C associated hospital utilisation in 2005 and 2006 from the HIPE system. In extracting this data, the International Classification of Diseases (ICD) was used to define groups of conditions related to hepatitis C infection, drug use and complications of liver disease. The total number of discharges, bed days and ICU bed days associated with the conditions are shown. An approximate cost, estimated by matching the Diagnostic Related Group (DRG) associated with each episode of care to a “ready reckoner” cost provided by the Casemix Unit of the HSE, is also displayed.

A number of observations are made concerning these data:

- There is an increase in the number of discharges between 2005 and 2006, approximately 13% to 90% depending on the conditions. This may reflect changing patterns in Hepatitis C associated hospital utilisation. However, it may also reflect increased identification of infection and changing patterns in coding of discharges following episodes of care.
- A large number of episodes of care associated with hepatitis C are recorded with a diagnosis of acute infection (ICD 10 B171), approximately 43% in both years presented. This is surprising as the majority of cases of acute Hepatitis C infection are sub-clinical in nature and may reflect an opportunity to improve the quality of coding of discharges following episodes of care.
- Approximately 18% and 24% of discharges with any diagnostic code for hepatitis C infection, following episodes of care in 2005 and 2006, also had a code indicating a diagnosis of drug use. This is unlikely to reflect the epidemiology of infection in the community. It is more likely to reflect patterns of coding of co-morbid drug use or varying patterns of hospital utilisation between patients with and without co-morbid drug use.
- Approximately 6% of discharges following an episode of care with any diagnosis of hepatitis C **and** drug use, recorded in 2005 or 2006, also had a diagnosis indicating a potential complication of this infection. Approximately 9% and 11% of discharges following an episode of care with any diagnosis of hepatitis C, recorded in 2005 and 2006 respectively, also had a diagnosis indicating a potential complication.
- In 2006, discharges following an episode of care associated with HCV and a complication accounted for 19% of bed days, 32% of ICU bed days and 24% of the costs of discharges following an episode of care associated with hepatitis C. This reflects the more intense utilisation of services by patients with complications.

**Table A: Hepatitis C related hospital utilisation, 2005 and 2006.**

Condition	ICD 10 codes	Discharges 2005	Discharges 2006	Patients 2006	Bed days 2006	ICU days 2006	Total DRG cost 2006 (€)	Cost per episode 2006 (€)
acute HCV	B171*	720	989	656	6247	149	4984717	5040
chronic HCV	B182*	972	1310	893	9675	455	10456372	7982
acute OR chronic (ANY) HCV	B171* OR B182*	1692	2297	1529	15914	604	15428330	6717
ANY HCV AND Drug Use	(B171* OR B182*) AND (F11*-F16* OR F18*-F19* OR T40* OR X62* OR Z503* OR Z715*)	382	702	554	6574	184	5648641	8046
ANY HCV AND Drug Use AND Complications	(B171* OR B182*) AND (F11*-F16* OR F18*-F19* OR T40* OR X62* OR Z503* OR Z715*) AND (C220* OR R18* OR I85* OR K72* OR K74* OR K766* OR K767* OR I982*)	25	45	37	745	46	801762	17817
ANY HCV AND Complications	(B171* OR B182*) AND (C220* OR R18* OR I85* OR K72* OR K74* OR K766* OR K767* OR I982*)	151	252	181	3073	195	3764821	19307
ANY HCV AND Hepatic failure/ fibrosis/cirrhosis	(B171* OR B182*) AND (K72* OR K74*)	86	140	105	1666	125	2442917	17449
ANY HCV and non-bleeding hepatic complications	(B171* OR B182*) AND (K72* OR K74* OR R18* OR K766* OR K767*)	121	215	157	2731	187	3512063	16335
ANY HCV AND ANY Varices	(B171* OR B182*) AND (I85* OR I982*)	42	80	58	865	45	1033046	12913
ANY HCV AND Hepatic failure	(B171* OR B182*) AND (K72*)	25	34	29	617	81	884000	26000
ANY HCV AND HCC	(B171* OR B182*) AND C220*	15	17	13	160	6	508434	29908

\* ICD (International Classification of Diseases) is a hierarchical taxonomy and the term \* is used to indicate any code at a lower level.

Source: HIPE data from the ESRI, accessed via Health Atlas Ireland. Cost data added using the Casemix Unit DRG Ready Reckoner for 2006.

## Hepatitis C associated drug utilisation

The Primary Care Reimbursement Service (PCRS) administers a number of payment schemes for drugs and services including the "Hi-Tech Drugs" (HTD) scheme. The HTD scheme provides arrangements for the supply and dispensing of High Tech medicines through community pharmacies which are generally prescribed or initiated in hospital. Drugs reimbursed under the HTD scheme include a number of drugs used in the treatment of Hepatitis C infection: ribavirin, peginterferon alfa-2a, peginterferon alfa-2b, interferon alfa-2a and interferon alfa-2b. While ribavirin is solely indicated for the treatment of chronic hepatitis C infection, interferon-based drugs have wider indications.

The PCRS Statistical Analysis of Claims and Payments provides the most recent data on the number of prescriptions and ingredient costs for drugs reimbursed under the HTD scheme. However, this information is not provided on a per-patient basis and it is not linked with a diagnosis. This limits the interpretation of the data in table B as not all prescriptions were for the treatment of hepatitis C. In addition, combinations of drugs are not presented.

**Table B: Prescribing frequency and ingredient cost of drugs indicated for the treatment of Hepatitis C infection, reimbursed under the HTD scheme in 2006.**

Drug	Prescribing frequency	% of HTD scheme total	Ingredient cost (€)	% of HTD scheme total
Ribavirin	1125	0.45	773110	0.46
peginterferon alfa-2a	1170	0.47	1221630	0.73
peginterferon alfa-2b	522	0.21	254920	0.15
interferon alfa-2a	463	0.19	158493	0.09
interferon alfa-2b	818	0.33	565878	0.34

Source: Primary Care Reimbursement Service, Statistical Analysis of Claims and Payments 2006.

## APPENDIX 6 – CURRENT CLINICAL INFECTIOUS DISEASE NOTIFICATION FORM

<b>Patient Name:</b> _____ <b>Disease:</b> _____ <b>Date:</b> ____ / ____ / ____	
<b>Notification of Infectious Disease</b>	
ID identifier (official use only) <input style="width: 100%;" type="text"/>	Surname: <input style="width: 100%;" type="text"/>
Patient first name: <input style="width: 100%;" type="text"/>	Address: <input style="width: 100%;" type="text"/>
Contact tel. no: <input style="width: 100%;" type="text"/>	Age: <input style="width: 50px;" type="text"/> Sex: <input style="width: 50px;" type="text"/>
D.O.B.: <input style="width: 100%;" type="text"/>	Occupation/School/Crèche: <input style="width: 100%;" type="text"/>
<div style="border: 1px solid black; padding: 5px;"> <b>Country of birth:</b>            Ireland <input type="checkbox"/> Other <input type="checkbox"/>            if other, specify: _____            Probable country of infection: _____         </div>	
<b>Infectious disease (see list at front):</b> <input style="width: 150px;" type="text"/> <b>Date of onset:</b> <input style="width: 100px;" type="text"/>	
Date of diagnosis: <input style="width: 100px;" type="text"/>	Laboratory results: <input style="width: 150px;" type="text"/>
Type of specimen (stool, blood, csf etc): <input style="width: 150px;" type="text"/>	Case classification: Possible <input type="checkbox"/> Probable <input type="checkbox"/> Confirmed <input type="checkbox"/>
Vaccination status (if vaccine preventable): Complete <input type="checkbox"/> Incomplete <input type="checkbox"/> Unvaccinated <input type="checkbox"/> Unknown <input type="checkbox"/>	Hospitalised: Yes <input type="checkbox"/> No <input type="checkbox"/>
Additional information: <input style="width: 150px;" type="text"/>	
Signed: <input style="width: 150px;" type="text"/>	Title/Position: <input style="width: 150px;" type="text"/>
Date of notification: <input style="width: 100px;" type="text"/>	Name of consultant or GP: <input style="width: 150px;" type="text"/>
<div style="border: 1px solid black; padding: 5px;"> <b>Notifier (stamp may be used) (Please Print)</b>            Name: _____            Address: _____            Tel: _____            Name of consultant or GP: _____         </div>	

## APPENDIX 7 – CURRENT RECOMMENDED DATA ITEMS FOR LABORATORY NOTIFICATIONS OF INFECTIOUS DISEASE

### Infectious Disease Notifications

Suggested Data Items for Labs to report to Public Health

	Data Item	Description
Patient Details	<b>Surname</b>	Surname of patient
	<b>First Name</b>	Firstname of patient
	<b>Address 1</b>	Address where patient resident
	<b>Address 2</b>	
	<b>Address 3</b>	
	<b>County</b>	County where patient resident
	<b>Contact Tel No.</b>	Patient's contact telephone number
	<b>Gender</b>	M, F, NK
	<b>DOB</b>	Date of Birth
	<b>Age</b>	Age of patient
	<b>Patient Type</b>	In-patient, Out-patient, GP patient
	<b>Hospital Number</b>	Patient Hospital number
Specimen Details	<b>SpecimenLabID</b>	Specimen number
	<b>Specimen Type</b>	Type of specimen e.g. blood, csf, stool, urine etc.
	<b>Specimen Date</b>	Date Specimen taken
	<b>DateTest Result</b>	Date Laboratory diagnosis was made
Organism Details	<b>Organism Description</b>	Genus, Species, Type (or equivalent) Also Other Details if available (e.g. phage type, subtypes, markers for HepB etc)
Physician Details	<b>Referring Clinician/GP Details</b>	Name and address of referring clinician or GP
Additional Details	<b>Additional Comments</b>	Insert clinical comments and/or epidemiological information if relevant
	<b>Outbreak Code</b>	Code assigned to outbreak

**Note:** Laboratory Name, Name and Address of Notifier and Date Notification by Laboratory should also be provided by lab when notifying Medical Officer

## APPENDIX 8 - GUIDELINES FOR THE MANAGEMENT OF NOTIFICATION OF HEPATITIS C TO DEPARTMENTS OF PUBLIC HEALTH

### GUIDELINES for the Management of Notification of Hepatitis C to Departments of Public Health.

The notification of hepatitis C cases is an important step in the prevention and control of hepatitis C in Ireland. It is essential that all cases are notified in a timely manner to ensure effective surveillance, prevention, early identification of incidents and prompt control and management of outbreaks.

- The Infectious Diseases Regulations 1981 amended by ID (Amendment) (No 3) Regulations 2003 (SI No 707 of 2003) requires that medical practitioners, including clinical directors of diagnostic laboratories must notify the Medical Officer of Health in the Department of Public Health of certain infectious diseases.
- Hepatitis C became notifiable under this legislation on January 1<sup>st</sup> 2004.
- Hepatitis C is notified on the standard Notification of Disease form (Appendix 1)
- The template for notification of hepatitis C from laboratory → Medical Officer of Health → HPSC are attached (Appendix 2 & 3). This process usually takes place through CIDR for most parts of the country.
- The Case Definition for Hepatitis C (Hepatitis C Virus) from NDSC Case Definitions Version 1.1 is available at [www.hpsc.ie](http://www.hpsc.ie).

#### **Hepatitis C (Hepatitis C virus) (EU)**

##### **Clinical description**

In symptomatic cases, clinical picture compatible with hepatitis, i.e., discrete onset of symptoms and/or jaundice or elevated serum aminotransferase levels.  
Asymptomatic cases are common.

##### **Laboratory criteria for diagnosis**

One of the following:

- Detection of hepatitis C virus (HCV) specific antibodies
- Detection of HCV nucleic acid from clinical samples.

##### **Case classification**

Possible: N/A  
Probable: N/A  
Confirmed: A case that is laboratory confirmed

##### **Note**

This case definition includes all laboratory confirmed cases; the EU definition is restricted to symptomatic cases only.



The Public Health investigation of hepatitis C cases should be carried out for the following reasons:

- The prevention of secondary spread by advising on risk reduction measures and the protection of contacts.
- To carry out enhanced surveillance of cases to provide epidemiological information to inform public health measures in particular to identify the likely source of infection and inform health service planning.

## **ON RECEIPT OF A NOTIFICATION OF HEPATITIS C FROM A CLINICIAN OR A LABORATORY**

The Medical Officer of Health will:-

- On receipt of notification check with local infectious diseases notification database or CIDR that case has not already been notified e.g. duplicate entries for persons who have regular tests to check viral status. If previously notified by another source the new report is not set up as a new notification.
- If not previously notified confirm the status of the case with the notifier (if known): **newly diagnosed case** or **previously diagnosed case**.
- Enhanced surveillance information should be provided on all new notifications – either using the enhanced surveillance form (attached) or through CIDR system.

### **If newly diagnosed case:**

1. If the case is newly diagnosed the MOH may or may not need to take further action depending on the information provided.

(For example, if the case is identified as an injecting drug user (IDU) attending an addiction service that follows a defined protocol for providing advice minimising the risk of transmission, hepatitis A or B vaccination as appropriate, and investigation and referral as required, then no further public health action will be required).

2. If the source of infection is not stated or is unknown, the MOH should discuss the case with the relevant clinician.
  - To obtain information on the case e.g. demographic, clinical, risk exposure category, likely source of infection as per enhanced surveillance dataset.
  - To determine and agree what further investigation is required e.g. to rule out a healthcare acquired infection.

- To provide advice to the clinician in relation to appropriate clinical referral and assessment.
  - To provide advice to the clinician in relation to the need for hepatitis A, hepatitis B vaccination as appropriate for the case.
  - To ensure cases are advised on how to minimize risk of transmitting infection.
3. Update notification as extra information becomes available e.g. genotype.

**If previously diagnosed case:**

Determine with the clinician

- That case is receiving appropriate management with respect to
  - Advice on hepatitis A and hepatitis B vaccinations
  - Advice on minimising risk of transmitting infection
- In most cases, no further public health action will be required.
- Maintain a record of the notification and actions taken.

***Note – Except in exceptional circumstance contact with the case should only be made following discussion with the notifier and/or clinician (either hospital consultant or general practitioner).***

## APPENDIX 9 – RECOMMENDED ENHANCED SURVEILLANCE FORM FOR HEPATITIS C INFECTION

Enhanced Surveillance Form for Hepatitis C			
Please complete this form for the first notification of a case of hepatitis C			
<b>Patient Details</b>			
Forename initial	<input type="text"/>	Surname initial	<input type="text"/>
Date of birth	<input type="text"/>	CIDR event ID	<input type="text"/>
Sex	Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown <input type="checkbox"/>	Age (years)	<input type="text"/>
HSE Region	<input type="text"/>	Occupation	<input type="text"/>
County	<input type="text"/>	CCA/LHO	<input type="text"/>
Country of birth	<input type="text"/>	If not Ireland, duration of residence in Ireland (years)	<input type="text"/>
<b>Risk group (please answer all)</b>			
Injecting drug user	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	
Sexual contact with known case	<input type="checkbox"/>	<input type="checkbox"/>	
Possible sexual exposure (e.g. multiple, new, or high risk partner(s))	<input type="checkbox"/>	<input type="checkbox"/>	Details <input type="text"/>
Vertical transmission	<input type="checkbox"/>	<input type="checkbox"/>	Risk group of mother <input type="text"/>
Accidental needlestick/occupational exposure	<input type="checkbox"/>	<input type="checkbox"/>	
Tattooing/body piercing (excl. ear lobes)/acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	
Renal dialysis patient	<input type="checkbox"/>	<input type="checkbox"/>	
Recipient of blood/blood products	<input type="checkbox"/>	<input type="checkbox"/>	Product <input type="text"/> Year <input type="text"/>
Recipient of organ or tissue transplant	<input type="checkbox"/>	<input type="checkbox"/>	Details <input type="text"/>
Born in endemic country or asylum seeker	<input type="checkbox"/>	<input type="checkbox"/>	
If other exposure, please specify	<input type="text"/>		
<b>If none of the above</b>	<input type="checkbox"/>	<input type="checkbox"/>	Details <input type="text"/>
Surgical or dental procedures	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Please indicate most likely risk group</b> <input type="text"/>			
<b>Infection likely to have been acquired abroad?</b> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Country <input type="text"/>			
<b>Laboratory Details</b>			
Date of first confirmed HCV positive result	<input type="text"/>	<b>Test*</b>	<b>Result</b>
Laboratory	<input type="text"/>	HCV EIA	Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Weak positive <input type="checkbox"/>
		HCV Immunoblot	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		HCV PCR	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		HCV antibody-antigen	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Please circle HCV genotype (if available)	1 2 3 4 5 6	Further genotyping details <input type="text"/>	
<b>Hepatitis C status at time of notification</b>			
Acute	<input type="checkbox"/>	Chronic	<input type="checkbox"/> Unknown <input type="checkbox"/>
<b>Newly diagnosed case</b> <input type="checkbox"/> Or <b>Case was previously diagnosed, but not notified</b> <input type="checkbox"/>			
Has the case donated blood recently? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>			
If yes, date of blood donation <input type="text"/>			
<b>Notification details</b>			
SPH/M responsible	<input type="text"/>		
Form completed by	<input type="text"/>		
<b>Comments</b>			
<b>Thank you for completing this form</b>			
*The NVRL currently use the following antibody tests: MONOLISA, Centaur, Architect & Ortho EIA tests & INNO-LIA immunoblot test			

## APPENDIX 10 - LABORATORY METHODS FOR HEPATITIS C TESTING

Hepatitis C diagnostics fall into two general categories: serological and molecular investigations. Serological investigations include the detection of hepatitis C antibodies and more recently the detection of hepatitis C core antigen in serum. Serological confirmation of hepatitis C infection can be achieved by using an alternative hepatitis C EIA with different assay format or by the use of hepatitis C line immunoassay.

Molecular investigation includes the quantitative detection of hepatitis C RNA (viral load) and hepatitis C genotype. Nucleic acid testing is an important component of the diagnostic algorithm for confirmation of hepatitis C infection and provides critical prognostic information for guiding treatment and measuring response to antiviral therapy. Success of hepatitis C treatment is defined as testing negative for hepatitis C RNA six months after cessation of therapy, termed a sustained virological response (SVR). The rate of response to therapy is also an important predictor of sustained response with a rapid decline in viral load being a strong predictor of treatment success. Genotype tests are important clinically as they predict most accurately the chance of antiviral response and dictate the duration of therapy, with patients with genotype 2 or 3 more likely to achieve a SVR than genotype 1 or 4. Current guidelines recommend that:

- i. A sensitive nucleic acid test (i.e. low limit of detection of <50 IU hepatitis C RNA/ml) should be used for the determination of hepatitis C RNA.
- ii. A genotype and quantitative hepatitis C RNA (measured in IU/ml) test should be performed on all patients prior to therapy to best assess the probability of response to and to aid selection of an appropriate therapeutic regimen.
- iii. The same type of quantitative test should then be used to monitor response to treatment and the likelihood of a SVR.

Molecular characterisation of hepatitis C virus at the genotypic level is of significant epidemiological benefit in mapping the evolution of hepatitis C infection within defined risk groups. More detailed molecular analysis of the hepatitis C viral genome in the form of hepatitis C phylogenetic studies requires analysis of a hypervariable component of the gene. This type of analysis can be used to establish genetic relationships between cohorts of hepatitis C infected patients.

## APPENDIX 11 - GENERAL PRACTICE GUIDELINES ON THE MANAGEMENT OF HEPATITIS C AMONG DRUG USERS

**NB** – Guidelines are developed as a guide to the management of patients with a particular condition. As each individual patient may differ in many respects, guidelines should only be applied in this context and in accordance with a patient's wishes.

### Screening for hepatitis C

- All people at risk of hepatitis C should be offered testing and any patient with signs or symptoms suggestive of hepatitis, or requesting testing should also be tested.
- Pre-test discussion should take place and include
  - o Information on hepatitis C infection
  - o The benefits and risks of HCV testing,
  - o Reassurance with regard to confidentiality,
  - o Education on how to reduce the risk of transmission,
  - o Discussion on the risk of co-infection with HIV or hepatitis B (patients at risk for hepatitis C should also be offered testing for HIV)
- Post-test discussion should take place and if possible the results should be given in person to the patient by the person who undertook the pre-test discussion
- In the case of a negative result repeat testing should be offered if exposure to the virus occurred within the last six months

### Initial management

- General advice should be given to include
  - o Advice on reducing the risk of further liver damage
    - Patients should be screened for hepatitis B and offered vaccination if non-immune
    - Vaccination against hepatitis A should also be recommended
  - o Information on how hepatitis C is and is not transmitted
  - o Advice on safe drug use
  - o Education on how to reduce transmitting the virus to others
  - o Advice on sexual relationships and mother-to-infant transmission
- Psychosocial supports available to the patient should be identified and referrals made if necessary to relevant agencies / disciplines
- A follow-up appointment should be made

### Subsequent management

The following areas should be explored as a guide to predict which patients may or may not benefit from therapy or to identify issues that may need to be addressed prior to referral for treatment

- Drug use
  - o Non-prescribed opiate
  - o Cocaine use
  - o Non-therapeutic doses of benzodiazepines or tricyclic antidepressants
- Alcohol intake above the recommended weekly limits
- Significant concurrent psychiatric morbidity
- Major concurrent social problems

The following information should be provided when referring a patient to a Hepatology or infectious disease service for further management

- Results of HCV screening test and if available, subsequent PCR / genotype testing (and a copy of the results)
- Clinical evaluation of liver status
- Results of LFT/FBC
- Contact address or telephone number for correspondence with patient
- Current non-prescription drug use

Additional information that could also be provided includes

- Results of tests for other bloodborne viruses (including HIV and HBV)
- Details of vaccinations against hepatitis B and A
- Duration of methadone therapy and dose
- Whether or not the potential risks and benefits of treatment have been discussed

**Case definition for hepatitis C**

*Clinical criteria* Not relevant for surveillance purposes.      *Epidemiological criteria* Not relevant for surveillance purposes.

***Laboratory criteria for diagnosis*****Hepatitis C (acute)**

At least one of the following two:

- Recent HCV seroconversion (prior negative test for hepatitis C in last 12 months)
- Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C virus core antigen (HCV-core) in serum/plasma AND no detection of hepatitis C virus antibody (negative result)

**Hepatitis C (chronic)**

- Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C core antigen (HCV-core) in serum/plasma in two samples taken at least 12 months apart

**Hepatitis C (unknown status)**

Any case which cannot be classified according to the above description of acute or chronic infection and having at least one of the following three:

- Detection of hepatitis C virus nucleic acid (HCV RNA)
- Detection of hepatitis C virus core antigen (HCV-core)
- Hepatitis C virus specific antibody (anti-HCV) response confirmed by a confirmatory (e.g. immunoblot) antibody test in persons older than 18 months without evidence of resolved infection\*

***Case classification***

Possible: N/A

Probable: N/A

Confirmed: Any person meeting the laboratory criteria

**Note:** Resolved infection should not be notified

\*Resolved infection: Detection of hepatitis C virus antibody and no detection of hepatitis C virus nucleic acid (HCV RNA negative result) or hepatitis C virus core antigen (HCV-core negative result) in serum/plasma

## GLOSSARY OF TERMS

### Anti-D

Antibodies against rhesus D antigens. A small amount of the baby's blood can enter the mother's circulation during pregnancy, or larger amounts can enter during delivery. If the mother is negative for rhesus proteins and the baby is rhesus positive, the mother produces antibodies against the rhesus D antigens. These antibodies can pass through the placenta and damage the baby. The risk of disease is higher with subsequent pregnancies with rhesus positive babies. Anti-D immunoglobulin given during or after pregnancy prevents this.

### Cirrhosis

Widespread replacement of liver tissue by fibrotic scar tissue and regenerative nodules, leading to progressive loss of liver function.

### Fibrosis

Liver fibrosis refers to the accumulation of tough fibrous scar tissue in the liver.

### Genotype testing

Hepatitis C genotype tests are used to determine which of the genetically distinct types of hepatitis C virus are present in the patient's blood. Hepatitis C genotype is important in predicting response to anti-viral therapy.

### Hepatitis C EIA (Enzyme Immunoassay) /ELISA (Enzyme-Linked Immunosorbent Assay)

An assay that detects antibodies against specific hepatitis C antigens in a patient's blood. The hepatitis C EIA test is usually used as an initial screening test for hepatitis C antibodies.

### Hepatocellular carcinoma (HCC)

Primary malignancy (cancer) of the liver.

### Liver biopsy

A liver biopsy is a medical procedure involving the removal of a small piece of liver using a special needle. This is then examined under a microscope for signs of liver abnormality.

### Liver function tests (LFTs)

Liver function tests are a group of blood tests which provide information about how the patient's liver is functioning and may act as indicators of liver injury.

**Nucleic acid** is a macromolecule carrying genetic information. Nucleic acids are universal in living things, as they are found in all cells and viruses. The most common nucleic acids are **deoxyribonucleic acid** (DNA) and **ribonucleic acid** (RNA). If a test detects nucleic acid then virus is present.

**Polymerase Chain Reaction** is a technique widely used in molecular biology. It derives its name from one of its key components, a DNA polymerase used to amplify a piece of DNA. PCR can be used to detect viral DNA. The high sensitivity of PCR permits virus detection soon after infection and even before the onset of disease.

### Sensitivity

This measures how often a test turns out positive when it is being used on people who have the disease or condition.

### Specificity

This measures how often a test turns out negative when it is being used on people who do not have the disease or condition.

### Sustained virological response

The absence of detectable hepatitis C RNA in the serum as shown by a qualitative hepatitis C RNA assay with lower limit of detection of 50 IU/ml or less at 24 weeks after the end of treatment.

**Viral Load** The amount of virus ("viral load") in a patient can be quantified by using PCR-based DNA quantitation techniques

## ABBREVIATIONS USED

<b>Anti-HCV</b>	Antibody to hepatitis C virus
<b>CNS</b>	Clinical Nurse Specialist
<b>CSO</b>	Central Statistics Office
<b>DAHCI</b>	Dublin Area Hepatitis C Initiative Group
<b>DoHC</b>	Department of Health and Children
<b>DPC</b>	Data Protection Commissioner
<b>DPH</b>	Director of Public Health
<b>DTCB</b>	Drug Treatment Centre Board
<b>EIA</b>	Enzyme immunoassay, a screening test for hepatitis C
<b>EMGs</b>	Ethnic minority groups
<b>EPP</b>	Exposure-prone procedures
<b>ERHA</b>	Eastern Regional Health Authority
<b>ESRI</b>	Economic and Social Research Institute
<b>GPSSA</b>	GP specialist in substance abuse
<b>HAA</b>	Health (Amendment) Act
<b>HBsAg</b>	Hepatitis B surface antigen
<b>HCC</b>	Hepatocellular Carcinoma
<b>HCLNS</b>	Hepatitis C liaison clinical nurse specialist
<b>HCV</b>	Hepatitis C virus
<b>HIPE</b>	Hospital In-Patient Enquiry System
<b>HIQA</b>	Health Information and Quality Authority
<b>HIV</b>	Human immunodeficiency virus
<b>HPSC</b>	Health Protection Surveillance Centre
<b>HRB</b>	Health Research Board
<b>HSE</b>	Health Service Executive
<b>IBTS</b>	Irish Blood Transfusion Service
<b>ICGP</b>	Irish College of General Practitioners
<b>IDU</b>	Injecting Drug User
<b>IPS</b>	Irish Prison Service
<b>LHO</b>	Local Health Office
<b>MOH</b>	Medical Officer of Health
<b>MQI</b>	Merchant's Quay Ireland
<b>NACD</b>	National Advisory Committee on Drugs
<b>NCRI</b>	National Cancer Registry of Ireland
<b>NDST</b>	National Drugs Strategy Team
<b>NDTRS</b>	National Drug Treatment Reporting System
<b>NEP</b>	Needle-exchange programme
<b>NPV</b>	Negative predictive value
<b>NVRL</b>	National Virus Reference Laboratory
<b>PCR</b>	Polymerase chain reaction
<b>PMU</b>	Permanent make up
<b>PNEP</b>	Prison-based needle exchange programmes
<b>PPV</b>	Positive predictive value
<b>QALY</b>	Quality-Adjusted Life Year
<b>RIBA</b>	Recombinant immunoblot assay, a more specific hepatitis C test
<b>RNA</b>	Ribonucleic acid
<b>SVR</b>	Sustained virological response
<b>WHO</b>	World Health Organization









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