15 Hepatitis C treatment in Ireland

15.1 Hepatitis C is a disease caused by a virus that infects the liver. In time, it can lead to cirrhosis, liver cancer and liver failure. Six major subtypes (genotypes) of the hepatitis C virus cause infection. Genotype 1 and 3 are the most common strains in Ireland.

15.2 Some people who get hepatitis C have it for a short time and then get better without treatment. This is called acute hepatitis C. However, it is estimated that about 75% of those infected fail to clear the virus and develop long-term, or chronic hepatitis C.[1]

15.3 The Health Service Executive (HSE) estimates that 20,000 to 30,000 people in Ireland have hepatitis C. A small proportion of these are individuals infected through the administration of blood and blood products mostly between the 1970s and 1990s. With the introduction of screening of blood donors for hepatitis C antibodies in 1991 in Ireland, new transfusion-related hepatitis C cases have almost disappeared. At present, injecting drug use is the most common risk factor.

15.4 The HSE has set a target to make hepatitis C a rare disease in Ireland by 2026.

15.5 The cost of hepatitis C treatment is significant and varies depending on type of drugs used, the list price of the drug and length of treatment. A course of treatment can cost between €23,000 and €92,000. Advances in the drugs used to treat hepatitis C have resulted in significantly improved treatment outcomes in recent years and a reduction in side effects. Research cited in the *Public Health Plan for the Pharmaceutical Treatment of Hepatitis C*, *2014* noted that treatment of hepatitis C was cost effective irrespective of the level of liver damage present.

15.6 This examination

- reviews the costs of compensation and treatment and patient profile for individuals infected through the administration of contaminated blood and blood products mostly between the 1970s and 1990s
- considers available evidence in relation to the prevalence of hepatitis C in Ireland
- assesses the strategies and plans adopted in relation to the treatment of hepatitis C
- reviews progress in implementing the national treatment programme established in 2015.

Infection through the administration of contaminated blood and blood products

15.7 In early 1994, it was discovered that a blood product — anti-D immunoglobulin — contaminated with hepatitis C had been administered to women in the State between 1977 and 1979 and between 1991 and 1994. Additionally, a number of people were also infected through other contaminated blood products, blood transfusions and treatments. In February 1994, the Irish Blood Transfusion Service instituted a national hepatitis C screening programme for all women who had received anti-D between 1970 and 1994.

1 *Public Health Plan for the Pharmaceutical Treatment of Hepatitis C*, December 2014.

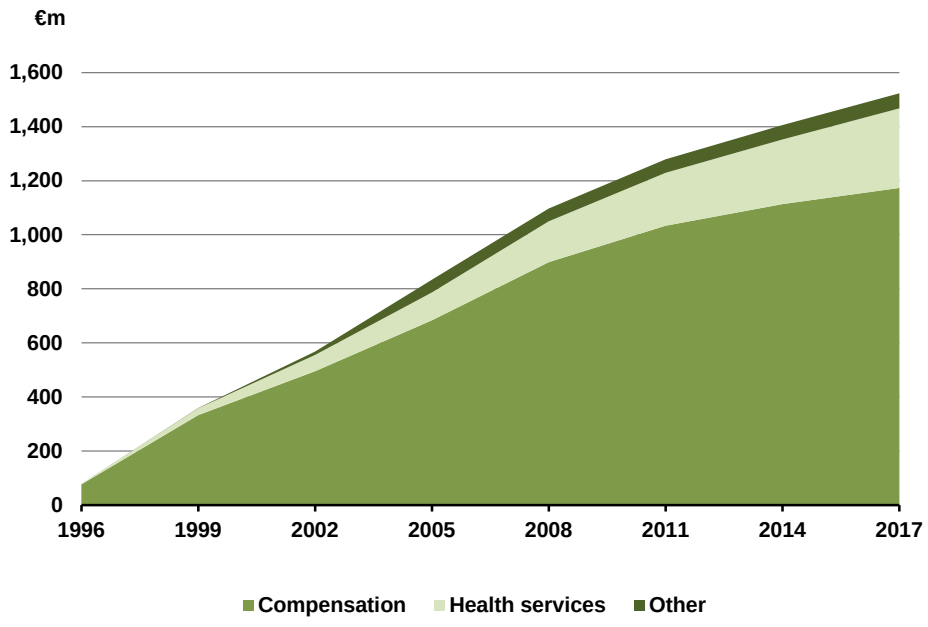
15.8 It is estimated that around 1,700 people were infected with the hepatitis C virus through the administration of contaminated blood and blood products in Ireland. A number of schemes, the majority of which had a legislative basis, were implemented to provide supports for persons infected through contaminated blood and blood products.[1]

15.9 Schemes put in place to compensate and support State-agency infected hepatitis C sufferers were extended in 2002 to support HIV positive persons similarly infected.

15.10 Expenditure incurred in relation to compensation and other health services provided to individuals infected through the administration of contaminated blood and blood products is recorded in a number of different accounts including the Department of Health Appropriation Account, the HSE financial statements and special accounts set up to administer compensation and insurance schemes. As a result, the total costs incurred in this regard are difficult to identify.

15.11 Figure 15.1 shows that up to end 2017, expenditure of around €1.5 billion has been incurred, which mostly relates to compensation and health services. A breakdown of these costs is included at Annex 15A.

Figure 15.1 Cumulative costs incurred in relation to infection through administration of contaminated blood and blood products, 1996 to 2017



Source: HSE Financial Statements; HSE Appropriation Accounts 2005 to 2014; Health Appropriation Accounts 1995 to 2017; (Annex 15A).

Compensation

15.12 A large proportion of the costs incurred relate to compensation and associated costs. Legislation was enacted in 1997 and 2002 to provide for compensation of persons infected through contaminated blood and blood products. Total expenditure of €1.17 billion including compensation and associated legal costs was incurred since the establishment of the schemes.

1 Appropriation Act 1995, Hepatitis C Compensation Tribunal Act 1997, Health (Amendment) Act 1996, Hepatitis C Compensation Tribunal (Amendment) Act 2002 and Hepatitis C Compensation Tribunal (Amendment) Act 2006.

15.13 The highest level of annual expenditure was incurred in 1998 when the costs of compensation and associated legal costs totalled €132 million. Between 1999 and 2009, annual expenditure was between €50 million and €70 million. Annual expenditure has been decreasing since then and was between €18 million and €21 million between 2015 and 2017.

Health services

15.14 The majority of the remaining expenditure related to hospital and primary care services provided without charge. Expenditure of around €295 million was incurred by the HSE (and its predecessor health boards) during the period between 1996 and the end of 2017 in this regard. Since 2000, the average spend has been between €10 million and €20 million per annum.

Other costs

15.15 An insurance scheme was set up under the Hepatitis C Compensation Tribunal (Amendment) Act 2006. The scheme enables people with State acquired hepatitis C and/or HIV to take out life assurance, mortgage protection cover and travel insurance at standard rates. Since the inception of the scheme, expenditure of approximately €9 million has been incurred. The HSE initially expected to incur expenditure of about €90 million over the life of the scheme. However, the HSE noted that it does not have a current estimate of future expenditure to be incurred on the scheme.

15.16 Expenditure of €47 million was also incurred in relation to formal enquiries into infection through contaminated blood and blood products.

Hepatitis C patient profile

15.17 A national hepatitis C database was established in 2004 to collect data in relation to people infected with hepatitis C through contaminated blood and blood products. The database was established and is maintained by the Health Protection Surveillance Centre (HPSC) which is part of the HSE. It examines the progression of infection, evaluates the outcomes of treatment and also provides information for planning of services.

15.18 With regard to the cohort who were infected through the receipt of contaminated blood and blood products, patients must give consent to have their information recorded on the database.[1] Information is collected from the participants' health records in the eight participating hepatology units. Of the 1,700 people estimated as infected with the hepatitis C virus, the database at end 2013, included information in relation to 1,320 people representing a participation rate of 78%.

15.19 Data collected during the period 2010-2013 shows that, of the database participants in the period, 813 (62%) became chronically infected.[2] Figure 15.2 profiles the status (at end 2013) of those patients chronically infected.

1 Infected patients who are deceased can be entered into the database without consent provided these patients did not refuse consent when alive.

2 *National Hepatitis C Database for infection through blood and blood products, Annual Report 2015.* The report includes data on database participants up to the end of 2013.

Figure 15.2 Profile of patients on hepatitis C database as at end 2013

		Status	
	Chronically infected	**Alive**	**Deceased**
Spontaneous resolution	27	23	4
Treated with successful outcome	224	215	9
Treated and outcome not successful	166	111	55
Not treated	396	279	117
Total	**813**	**628**	**185**

Source: *National hepatitis C database for infection acquired through blood and blood products in Ireland,* 2015 Report

15.20 The data collected between 2010 and 2013 shows that at end 2013

- just over half of those with chronic infection received treatment or had a spontaneous resolution and of those that received treatment, the outcome was successful in 57% of cases[1]
- 390 surviving participants were chronically infected and had not been successfully treated; of these 91 had clinical signs of severe liver disease
- 185 participants who had been chronically infected were deceased, with death from liver disease recorded in 73 cases
- among participants that had developed chronic infection, 23% had died compared to 8% among those that had not become chronically infected.

15.21 The HSE has pointed out that the report is not up to date, and does not take account of the substantial progress made in the treatment of hepatitis C since 2013. It noted that a further round of data collection has been conducted which includes data up to end 2017. A report is due to be published before the end of 2018.

15.22 In December 2016, the Department of Health set a target that all patients infected through receipt of contaminated blood and blood products identified as being suitable for treatment would have been offered and/or commenced on treatment by end 2017. The HSE stated it achieved this target and reported a 98% cure rate for those patients who opted to accept treatment.

Hepatitis C prevalence

15.23 The HSE's departments of public health play a key role in the process of surveillance of hepatitis C through notifications of hepatitis C to the Medical Officer of Health. There are eight departments of public health covering the Republic of Ireland.

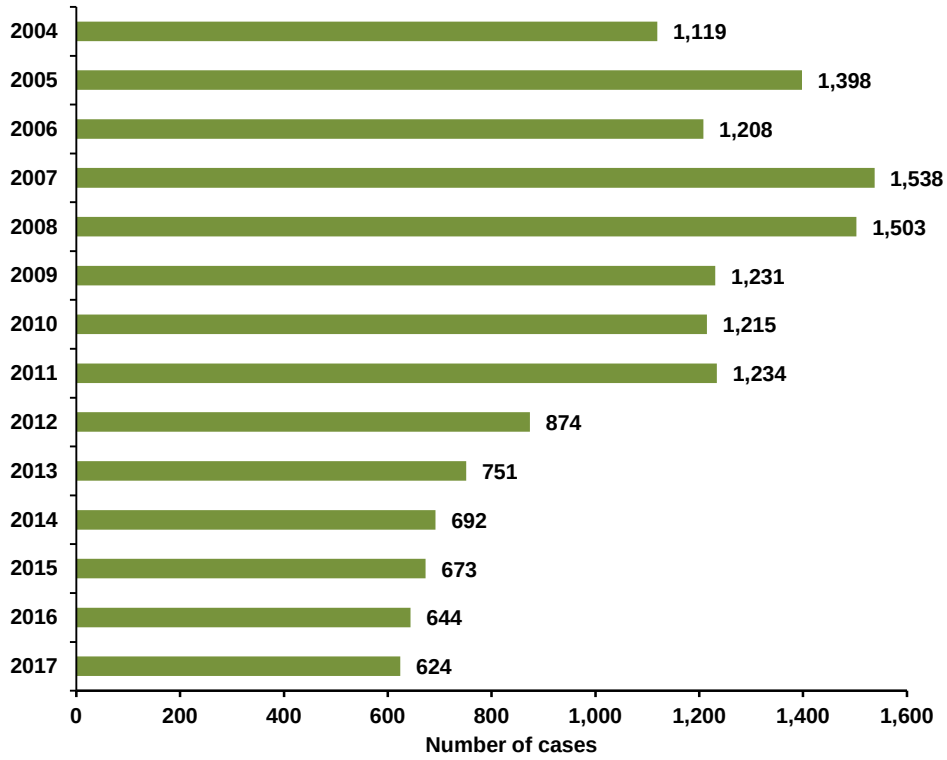
15.24 A database was set up to record details of all notifications of hepatitis C when it became a notifiable disease in 2004. All new notifications of hepatitis C (regardless of route of infection and whether clinical or laboratory diagnosed) are notifiable under the Infectious Diseases Regulations since 2004. All medical practitioners, including clinical directors of diagnostic laboratories, are required to notify the local Director of Public Health of notifiable infectious diseases. A basic dataset of information is requested on all notifiable diseases.[2] In relation to hepatitis C, additional information relating to risk factors for acquisition of hepatitis C, and details of laboratory test results is requested on notified cases.

1 Spontaneous resolution refers to a situations where a patient tested positive for the hepatitis C virus but tested negative at a later stage without having undergone treatment.

2 This includes name, address, date of birth, age, sex, country of birth, country of infection, phone number, occupation, details of the disease being notified and notifier details.

15.25 Between 2004 and 2017, the total number of hepatitis C cases notified was 14,704 (see Figure 15.3). The number of cases notified peaked in 2007 when 1,538 cases were notified but have continued to drop since then and in 2017, 624 cases were notified.

Figure 15.3 Hepatitis C cases notified, 2004 to 2017



Source: Health Service Executive — Health Protection Surveillance Centre

15.26 The HSE estimates that between 20,000 and 30,000 people are infected with hepatitis C. This estimate is based on a number of reports as follows

- A 2012 report[1] noted that about 10,000 individuals had been diagnosed with the virus and were living with chronic infection at the end of 2009. Another report[2] in 2017 noted that the extent of under diagnosis in Ireland was unknown but that assuming levels of between 50% and 67% would suggest that between 20,000 and 30,000 individuals were infected.
- A modelling study[3] in hepatitis C prevalence in 2015 carried out for 28 EU countries estimated the number infected with the hepatitis C virus in Ireland at 29,500.

15.27 The HSE's estimate of hepatitis C prevalence suggests a significant number of undiagnosed cases. This is in line with estimates of the level of undiagnosed cases in the UK which puts the level of undiagnosed cases at 50%.[4] However, the absence of a general screening programme means that the true prevalence rate is unknown. Most studies undertaken to date have sought only to calculate the prevalence within specific risk groups.

15.28 The HSE noted that it uses clinically peer reviewed international publications and studies in monitoring hepatitis C prevalence, in addition to data from the HPSC database relating to hepatitis C notifications. It noted also that it continues to monitor developments in relation to research in this area in order to obtain more precise information in relation to overall hepatitis C prevalence in Ireland.

1 Thornton et al. *Determination of the burden of hepatitis C virus infection in Ireland*. Epidemiology and Infection, (2012).

2 Carew et al *Incidence of hepatitis C among people who inject drugs in Ireland.* Hepatology, Medicine and Policy (2017).

3 Razavi et al. *Hepatitis C virus prevalence and level of intervention required to achieve the WHO targets for elimination in the European Union by 2030: a modelling study*. Lancet Gastroenterol Hepatol 2017 published Online March 14, 2017.

4 Public Health in England, *Hepatitis C in the UK*, 2017 report.

15.29 With regard to reducing under-diagnosis, the HSE in collaboration with the Department of Health published the *National Screening Guideline for Hepatitis C* in 2017. The guidelines acknowledged that while screening for hepatitis C had been ongoing in many settings, national guidance for healthcare providers had not been developed. The screening guideline makes recommendations on who should be offered screening for hepatitis C virus (HCV) infection and how screening should be undertaken. The HSE noted that the implementation of these guidelines will be critical in identifying cases of hepatitis C not previously screened. It also stated that considerable uncertainty remains regarding the degree of under-diagnosis of hepatitis C in Ireland.

Treatment strategies and plans

15.30 Since 2004, there have been a number of initiatives to develop and implement strategies to treat hepatitis C as set out in Figure 15.4.

Figure 15.4 Hepatitis C strategy and plan development timeline, 2004 to 2017

Source: Office of the Comptroller and Auditor General

15.31 A strategy document produced by the then Eastern Regional Health Authority in 2004 set out recommendations to enhance prevention, treatment and surveillance of hepatitis C among infected people in the eastern region.[1] The report was never published and an implementation plan was not developed.

National hepatitis C strategy 2011 — 2014

15.32 In September 2012, the HSE published a national hepatitis C strategy covering the period 2011–2014. The strategy noted that as part of their range of statutory entitlements under the terms of the Health (Amendment) Act 1996, comprehensive strategies had been put in place for patients who acquired hepatitis C through contaminated blood and blood products. The needs of those who acquired hepatitis C through other means had not been addressed.

15.33 The strategy made 36 recommendations covering areas of surveillance, education prevention and communication, screening, treatment and laboratory testing. The majority of the recommendations were to be implemented over the life of the strategy. The strategy did not set target outputs in terms of overall treatment numbers or expected outcomes stated in terms of reduction in prevalence of hepatitis C. The status of these recommendations at December 2017 is outlined in Figure 15.5.

1 The Eastern Regional Health Authority was subsumed into the Health Service Executive upon establishment in 2005.

Figure 15.5 Status of recommendations included in 2011–2014 national hepatitis C strategy

Classification of recommendations	No.	Progress in implementing recommendations
Surveillance	8	
Education, prevention and communication	14	
Screening and laboratory testing	6	
Treatment	8	

Source: Health Service Executive

Key: Implemented; Partially implemented; Not implemented

15.34 Of the 36 recommendations outlined in the strategy, the HSE confirmed that ten have been fully implemented, 25 partially implemented and one has not been implemented. The recommendation where no implementation action had been taken relates to the establishment of a postgraduate diploma in hepatitis C management for physicians and nursing staff. The HSE stated that this is no longer deemed necessary. Detail in relation to the status of the individual recommendations is included at Annex 15B.

15.35 Surveillance relates to information about the number and demographics of persons infected, the modes of acquisition of infection and trends in the incidence and prevalence of infection and risk factors. While the strategy recommended the development of a national register of patients with hepatitis C, this has not been progressed.

15.36 A number of databases exist that include information in relation to patients infected with hepatitis C

- As outlined in paragraph 15.17, the national hepatitis C database was established in 2004 to collect data in relation to people infected with hepatitis C through contaminated blood and blood products.
- As outlined in paragraph 15.25, a database managed by the HPSC records details of all notified cases of hepatitis C since 2004. This database does not account for the treatment status of patients. 14,704 cases had been notified by end 2017.

15.37 The HSE noted that it has also developed a treatment registry as part of the national hepatitis C treatment programme. This registry managed by the National Centre for Pharmacoeconomics (NCPE) on behalf of the HSE records data in relation to treated patients, patients that are undergoing treatment and patients awaiting treatment.

15.38 Information is collated from the treatment sites and recorded on a treatment registry. The registry records anonymised patient details using patient initials and date of birth. The treatment sites provide information in relation to a patient's progression through treatment including the type of regimen used, duration of treatment and the outcome. At 31 December 2017, just over 3,600 patients were recorded on the treatment registry.

15.39 The patient data contained on the treatment registry is not shared or matched against patient data maintained by the national hepatitis C database of patients infected through blood and blood products or the national register of hepatitis C cases notified under infectious diseases legislation, both of which are managed and operated by the HPSC. As a result, it is not possible to use the information available from the registry to estimate how many of the patients included in the national hepatitis C notifiable disease database have undergone treatment.

15.40 The HSE also stated that it has sought to link the records of the treatment registry with those of the notifications database also operated by the HPSC in order to establish an overall national register of patients with hepatitis C. However, obstacles such as gaining retrospective patient consent and restrictions surrounding data protection make this challenging.

15.41 The HSE outlined that the national hepatitis C treatment programme has been working through the Office of the Chief Information Officer and the HSE ICT Division in developing a sustainable electronic platform to further enhance the capabilities and efficiency of the existing registry.

15.42 In relation to treatment, the strategy did not set targets in terms of numbers to be treated or reductions in hepatitis C prevalence over the life of the strategy. The strategy recommended the development of an expert group to provide guidance on clinical issues and the development of protocols for testing, diagnosis, evaluation, referral for treatment, monitoring of treatment and monitoring of patients not on treatment. Many of these recommendations were implemented as part of the national treatment programme established in 2015.

15.43 The HSE noted that the *National Hepatitis C Strategy 2011–2014* was developed during a period where numbers of patients accessing treatment was low and it was estimated that between 20,000 — 50,000 people were infected. Targets were not set as a national approach to treatment, guidelines and a treatment programme had not been developed.

15.44 Recommendations in relation to the provision of treatment in community and prison settings are being progressed over the period 2017 to 2019. The HSE have responsibility or partial responsibility with other entities for implementing 24 of the 36 recommendations. The remaining recommendations are the responsibility of various bodies including the Department of Health, the Irish Prison Service and the Health Information and Quality Authority.

15.45 A steering group from the social inclusion division of the HSE oversees and monitors the implementation of the recommendations. The group meets bi-annually to review strategy progress. The HSE stated that recommendations included in the 2011–2014 strategy have not been implemented in some cases due to a lack of resources and a clear implementation plan. Also in some cases, recommendations have now been superseded by more current strategies. It was also noted that the implementation of the recommendations is an ongoing process.

Public health plan for pharmaceutical treatment of hepatitis C

15.46 In 2014, the Department of Health published a report titled *Public Health Plan for the Pharmaceutical Treatment of Hepatitis C*. This report tasked the HSE with establishing a national hepatitis C treatment programme, which commenced in 2015.

15.47 Taking account of the cost of treatment and the (estimated) size of the population to be treated, the plan recommended a multi-annual treatment programme so that the cost could be spread over a number of years. It also recommended clinical prioritisation to ensure patients at greatest clinical risk, in particular those patients with a risk of death or irreversible damage within the next 12 months, would be treated within a managed budget. It recognised that such a treatment approach would require strong governance and management structures and robust clinical leadership and participation.

Programme Advisory Group — ten year high level plan 2016

15.48 In 2016, the National Hepatitis C Treatment Programme Advisory Group established a high level ten-year plan for the future of the Programme. In addition to the provision of treatment based on clinical need and expansion of clinical treatment criteria, the plan set the following targets

- 2016-2017 — establish required governance structures, develop a strategic plan, work collaboratively with all hepatitis C initiatives nationally to improve surveillance, education, and pathways to care and monitor developments in therapeutic treatments for hepatitis C.
- 2017-2019 — devise strategies for the continued identification of patients and explore the feasibility of developing shared models of care across community and acute hospital settings.
- 2019-2025 — provision of treatment to patients with hepatitis C across community and acute hospital settings.
- 2026 onwards — the aim was to progress towards making hepatitis C a rare disease in Ireland.

15.49 The governance structures specified in the plan were put in place in March 2016. These included the appointment of a programme manager and a clinical lead. In 2017, a pilot programme in HSE addiction services commenced with the aim of extending treatment to community and acute settings. Following evaluation of this pilot, it is planned to expand treatments to other drug treatment centres and examine the feasibility of providing treatment in other settings including prisons and community pharmacy settings.

Progress in delivering treatment and related cost

15.50 A database recording information on the numbers of patients treated was first established by a group of clinicians in 2012. Following the establishment of the hepatitis C treatment programme in 2015, the existing registry was developed to record patient information and outcomes with a view to monitoring the effectiveness of drug regimens and the treatment programme.

15.51 The HSE stated that complete and accurate data in relation to the numbers of patients treated, the drug regimens used, the costs of treatment and outcome for the years 2004 to 2014 was not readily available due to the absence of a comprehensive treatment registry for those years. The HSE noted that collation of this information would require a trawl of all patient files in individual hospitals. For the purpose of this examination, the HSE sought information from hospitals providing treatment for hepatitis C for those years.

15.52 While the HSE noted that the data is incomplete, based on its best estimates, about 147 patients were treated each year. 86% completed treatment and a successful outcome was achieved in 69% of cases. The HSE does not have complete information in relation to the costs of treatment over the period.

National hepatitis C treatment programme

15.53 The ultimate aim of the national hepatitis C treatment programme which commenced in 2015 is to provide treatment across a range of healthcare settings to all persons living with hepatitis C in Ireland. In 2015, the Department of Health allocated €30 million for the treatment of hepatitis C to enable the treatment of approximately 300 people. The Department of Health has continued to allocate this amount each year since 2015 for the programme on the basis that improved commercial terms would be negotiated with drug suppliers so as to expand the numbers treated within the allocation.

15.54 The Department of Health engages regularly with the programme manager of the national hepatitis C treatment programme, with regular performance reports being provided detailing the expenditure and progress to date.

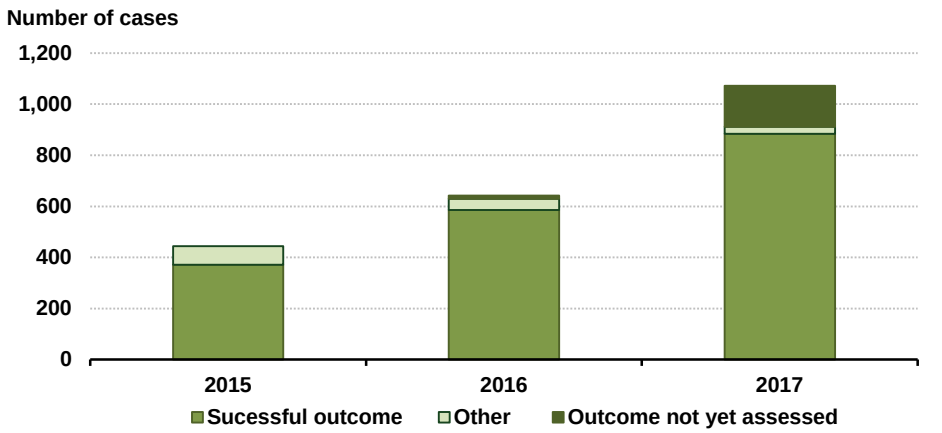
15.55 Available information is analysed in relation to the numbers of patients requiring treatment, the treatments available and the treatment outcomes. Based on that analysis the HSE enters into negotiations with drug companies and agrees contracts for the purchase of drugs. The Primary Care Reimbursement Service (PCRS) reimburses the treatment centre for the full cost of the drug purchased and claims any rebate that is available from the drug company. Prior to 2018, many of the agreements reached with the drug companies involved rebates where certain volumes are purchased.

15.56 There are eight main treatment centres across Ireland. Patients are tested at these centres and if infected with hepatitis C, the diagnosis is notified to the Medical Officer of Health in Departments of Public Health and the national database under the Infectious Diseases Regulations. The treatment centre selects suitable patients for treatment, purchases the drug directly from the drug company under the contract, delivers the treatment programme and seeks reimbursement of drug costs from PCRS.

Treatment outcomes

15.57 The total number of patients treated in the period 2015 to 2017 and the treatment outcome is set out below in Figure 15.6.

Figure 15.6 Outcomes of treatments provided, 2015 to 2017



Source: Health Service Executive, National Hepatitis C Treatment Registry

15.58 The outcome of treatment is measured twelve weeks after the end of treatment. Over the period 2015 to 2017, a total of 2,133 patients have completed treatment (1,061 patients in 2017) and information in relation to treatment outcome is available for around 90% of these patients. This shows that the treatment was successful in clearing the virus in around 94% of cases. The HSE has stated that since 2017, this rate is now between 95% and 100%.

Spend in 2017

15.59 The Department of Health allocated the hepatitis C treatment programme a net budget of €30 million for 2017 and specified that

- the sickest patients should be treated first
- all State-infected patients should be offered and/or commenced treatment by end 2017.

15.60 The budget allocation did not set out the expected numbers to be treated. Around 97% of the budget covers expenditure on drugs and medicines with 3% being used to meet costs associated with the maintenance of the national hepatitis C register and staff costs associated with administering the service at the various treatment centres.

15.61 In September 2016, the HSE set about estimating the number of patients that could commence treatment in 2017 within the budget available. To that end, information was sought from each treatment centre on the number of patients identified as ready and likely to complete treatment.

15.62 On this basis, the HSE estimated that around 1,600 patients could commence treatment over the 14 month period 1 November 2016 to end December 2017. Information obtained from the treatment centres also showed that the ratio of patients identified as ready for treatment was in the order of 3:1 in respect of genotype 1: genotype 3.[1]

15.63 In October 2016, the HSE entered into negotiations to secure more favourable terms with drug suppliers. Price reductions on the list price of the drugs were negotiated based on the purchase of specified volumes of particular drug types and the length of treatment.[2] The national hepatitis C treatment programme selected a preferred drug type for the treatment of each genotype based on what offered best value.

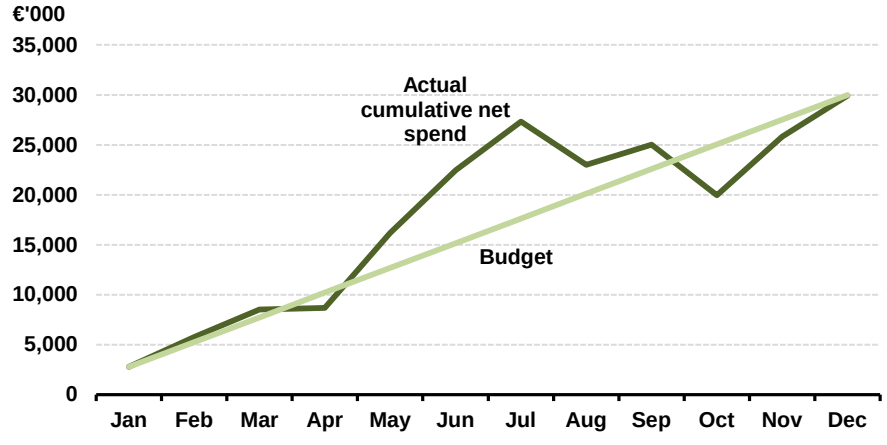
15.64 The price reductions were provided in the form of rebates following the purchase of the drugs at list price. The agreements, signed in November 2016, covering the period November 2016 to December 2017, provided for the purchase of 1,200 genotype 1 treatments and 400 genotype 3 treatments (i.e. a ratio of 3:1). The implied average treatment cost was €22,405.

15.65 The HSE also developed treatment guidelines which specified that the sickest patients who were ready for treatment would be provided with treatment in the first instance. In early 2017, treatment parameters were expanded by the treatment programme advisory group, and the treatment centres were advised to select patients based on readiness for treatment, in addition to considering patients on the basis of clinical need as per the HSE's national treatment guidelines.

15.66 The programme spend was managed by reference to the cumulative net spend — expenditure incurred in purchasing drugs and rebates received from drug suppliers. The cumulative net spend for a given month may not fully reflect the value of rebates due from suppliers (not yet received) in relation to drugs purchased.

15.67 Total net spend in 2017 was just over €29.9 million. Around 1,072 patients commenced treatment in 2017, at an average net cost of €27,911.[3] Figure 15.7 shows the cumulative net spend of the programme compared to the cumulative net budget allocation during 2017. At July 2017, the cumulative net spend of the programme stood at €27.3 million. This led to the temporary suspension of the programme by the HSE.

Figure 15.7 Cumulative net spend and net budget allocation for 2017



Source: Health Service Executive performance reports

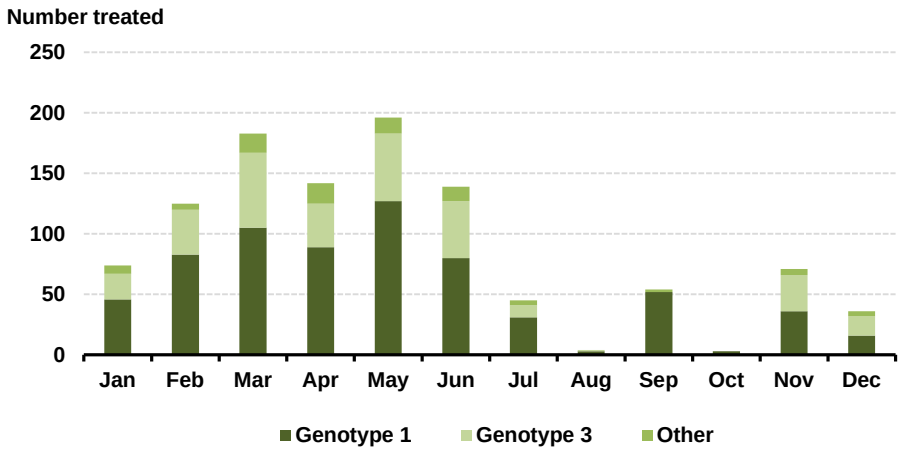
1 The most common genotypes of the hepatitis C virus in Ireland are genotype 1 and genotype 3.

2 Each treatment can range from eight weeks to 24 weeks.

3 Total cost incurred on the programme in a given year may reflect costs for patients where the drugs were purchased in the year preceding the year treatment commences.

15.68 Recovery of rebates between July and October provided scope for treatment to resume after the summer, as indicated in Figure 15.8.

Figure 15.8 Numbers that commenced treatment by genotype in 2017

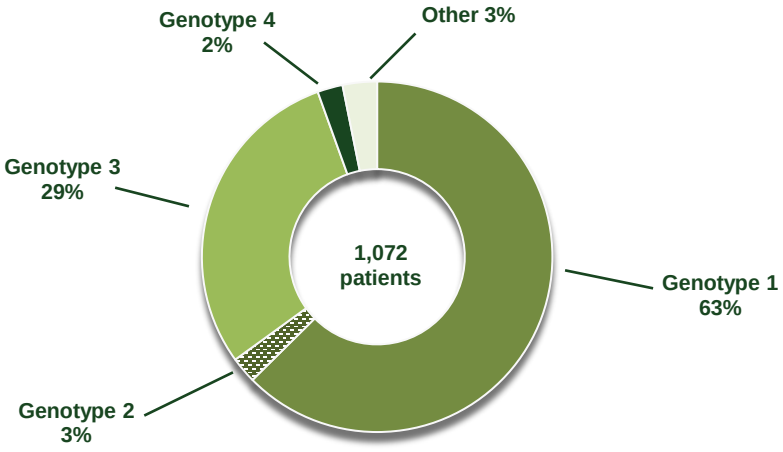


Source: Health Service Executive National Hepatitis C Treatment Registry

Notes: a Other includes genotype 2, genotype 4, genotype 6, mixed genotype and unknown genotype.

15.69 Over the course of 2017, the programme treated almost 300 less than they had targeted, at an average cost of around 25% more per patient. As shown in Figure 15.9, of the patients that commenced treatment in 2017, 671 patients or 63% were genotype 1 and 316 patients or 29% were genotype 3 (a ratio of 2.1:1). 8% of those treated were other genotypes.

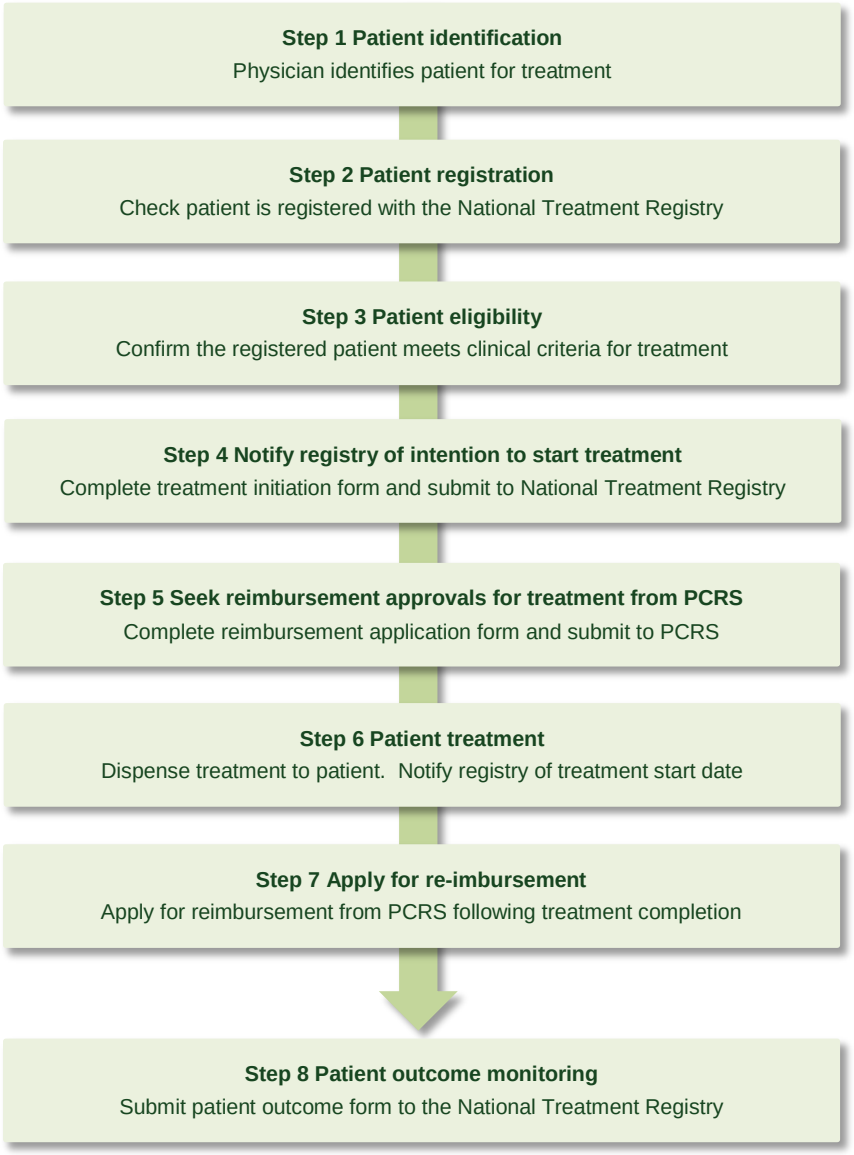
Figure 15.9 Number of patients that commenced treatment in 2017 by genotype



Source: Health Service Executive National Hepatitis C Treatment Registry

Notes: a Other includes genotype 6 (two patients), mixed genotypes (nine patients) and unknown genotypes (23 patients).

Figure 15.10 National treatment registry process



Source: Health Service Executive, National Hepatitis C Treatment Programme

15.70 All patients selected for treatment must be registered on the National Treatment Registry (Figure 15.10). Prior to a patient commencing treatment, each site is required to complete a treatment initiation form and submit this to the National Treatment Registry. Approval for reimbursement is also required from PCRS prior to treatment commencing.

15.71 This information is required on a regular basis as it assists the programme in monitoring the budget spend and ensuring that the budget at all times supports the number of patients selected for treatment. However, in relation to the early part of 2017, the HSE noted that these controls did not operate as intended because a number of treatment centres did not notify the national treatment registry that a patient had commenced treatment and/or had commenced patients' treatment prior to receiving reimbursement approval from PCRS.

15.72 As a result, the programme only became aware of the actual numbers being treated and the total costs once claims were submitted by the treatment centres to PCRS for reimbursement. This first became evident around April 2017 when the claims submitted by the treatment centres showed that, if the treatment commencement rate between January and April 2017 continued, the available budget would be fully utilised by October 2017.

15.73 By June 2017, the claims being submitted by the treatment sites showed a significant increase in numbers commencing treatment. In addition, the claims were also showing that the expected drug regimen had not been prescribed in all cases for clinical reasons. In particular, a number of genotype 1 patients had been prescribed alternative drug regimens at approximately twice the average price of the preferred drug regimen.

15.74 By end July 2017, when the HSE had planned to have utilised around 60% of the net budget available, the majority of the net budget available had been used. The programme was suspended to allow the HSE to determine how many patients the remaining budget could support to commence treatment to end 2017.

15.75 In September 2017, treatment centres were advised that they could recommence treatment but could only select patients for treatment in instances where the preferred regimen was being used to treat genotype 1.

15.76 The HSE stated that this decision was taken in order to support clinicians in having access to some treatment until such time as an updated financial position was available. In October 2017, treatment centres were advised that they could select patients for treatment based on those in most critical need such as those with chronic liver disease.[1] These measures continued through to the end of 2017 to ensure that the programme operated within budget for the year.

Future treatment of hepatitis C

15.77 The HSE has stated that the cost of drugs may no longer be the limiting factor in the treatment of hepatitis C. The cost of drugs to treat hepatitis C has reduced significantly since the national treatment programme commenced in 2015 and recent procurement exercises have enabled the HSE to significantly increase the number of patients to whom it can provide treatment.

15.78 However, factors such as a defined number of treatment sites currently providing treatment to patients mostly within the hospital setting may be the main limitation until such time as further treatment sites are identified and established.

15.79 The HSE established two new treatment sites on a pilot basis within the addiction service in 2017 and a third site in 2018. The HSE stated that further sites are planned in 2018 and this will enable an enhancement of treatment capacity beyond the volume that can be commenced within the confines of the hospital setting. This extension of treatment to the community also supports the programme's aim of integrating hepatitis C treatment across all healthcare settings.

15.80 Targets have as yet not been developed regarding annual treatment numbers up to 2026. Instead, the national hepatitis C treatment programme has been encouraging treatment sites to provide treatment to as many patients as possible.

1 Chronic liver disease was based on Childs Pugh Score of A, B or C.

15.81 The annual budget is set to remain at €30 million. The cost of drug treatments has continued to fall with the average treatment cost per patient in 2018 expected to be less than €15,000.

Conclusions and recommendations

15.82 A number of schemes and supports were put in place for the 1,700 people infected with the hepatitis C virus through the administration of blood and other products in Ireland mostly between the 1970s and 1990s. To date, expenditure of just over €1.5 billion has been incurred in this regard. Over three quarters of the costs incurred relate to compensation and associated costs including legal and administration costs. The majority of the remaining expenditure was incurred in relation to hospital and primary care services provided to these patients without charge.

15.83 The HSE noted that significant progress has been made in providing treatment for hepatitis C as a result of the development of a national treatment programme in 2015 and that all those infected by blood and blood products had been offered treatment by end 2017. Since 2017, about 98% of patients who opted to accept treatment had a successful outcome.

15.84 Hepatitis C became a notifiable disease in 2004, and 14,704 cases had been notified by end 2017. Taking account of likely undiagnosed cases, the HSE estimates that between 20,000 and 30,000 people in Ireland are infected with the hepatitis C virus.

15.85 A strategy published in 2012 recommended the development of a national register of persons infected with hepatitis C. This has not been progressed due to consent and data protection issues. A treatment registry recording details of patients undergoing treatment has been developed and it currently records details in relation to just over 3,600 patients.

Recommendation 15.1

The HSE should progress the development of a national database of patients infected with hepatitis C which is linked to the treatment registry. This would provide useful information in relation to planning a national treatment programme.

HSE Director General's response

Agreed.

It is agreed that the principle and concept of sharing this data and linking both information databases would greatly assist in planning a national treatment programme. However, there are a number of considerations relating to patient consent, legislation and data protection that require resolution prior to linking registries.

15.86 There have been a number of plans and strategies dating back to 2004 in relation to tackling hepatitis C in Ireland. A national hepatitis C treatment programme was established in 2015. An overall target was adopted to make hepatitis C a rare disease in Ireland by 2026, but targets for the number of treatments to be delivered per annum were not set.

15.87 Many of the key governance structures including the appointment of a programme manager and a clinical advisory group did not occur until March 2016. Reliable data is not available in relation to the numbers of patients treated between 2004 and 2014. However, between 2015 and 2017, a total of 2,133 patients completed treatment.

15.88 Given the limited budget available and the variable cost of treatment, the HSE needs to review the numbers that would require treatment each year and the associated budget if the target of making hepatitis C a rare disease by 2026 is to be achieved.

Recommendation 15.2

The HSE should develop a treatment plan which sets out the required number of treatments each year in order to achieve the overall target of making hepatitis C a rare disease by 2026. The plan should define the monitoring and reporting arrangements, the information required for monitoring progress and achievement and escalation routes for managing exceptions.

HSE Director General's response:

Agreed.

It is acknowledged that whilst the cost of the drugs will be a factor in developing a treatment plan, identifying undiagnosed cases, providing treatment in other settings and implementing screening guidelines will be critical components of achieving a status of hepatitis C being a rare disease in Ireland by 2026. Because of the parallel strategies required in order to achieve the programmes aims of making hepatitis C a rare disease in Ireland by 2026 — resources need to be deployed into areas such as screening, testing, providing treatment, access and integration of treatment in community settings. Additionally the national hepatitis C programme is currently scoping the feasibility of appropriate modelling methods to guide treatment planning.

15.89 Total net spend on the hepatitis C treatment programme was around €30 million in 2017 with 1,072 patients commencing treatment at an average net cost of around €28,000. The outturn was significantly different from what was planned.

Recommendation 15.3

The HSE should ensure that there are effective systems and procedures in place for managing the programme budget that includes regular reporting between the treatment centres and the hepatitis C programme on the numbers commencing treatment in order to ensure that the budget available at all times can support the number of patients selected for treatment.

HSE Director General's response

Agreed.

With the advent of pan-genotypic drugs in 2017/2018, the cost of treating a patient with hepatitis C infection is broadly consistent regardless of genotype — this had been a limiting factor in previous years where depending on the patients' genotype this may have resulted in a significant cost differential. The national hepatitis C treatment programme routinely monitors the planned volume of patients to be commenced on a monthly basis at each treatment site in addition to reviewing numbers of patients already commenced each month. The programme also monitors the numbers of patients pending treatment at each treatment site and regularly reviews data to establish where patients registered for treatment have not commenced.

Annex 15A Costs incurred in relation to infection through administration of contaminated blood and blood products

	Hepatitis C Compensation Tribunal Act 1997[a]			Health Services	Tribunal of Inquiry[b]	Total
	S.10	S.11	S.4			
Year	€m	€m	€m	€m	€m	€m
1995	76.2[c]	—	—	—	—	**76.2**
1996	—	—	—	2.8	—	**2.8**
1997	34.3	19.0	—	5.9	—	**59.2**
1998	113.0	19.0	—	8.3	—	**140.3**
1999	59.7	11.4	—	8.4	1.0	**80.5**
2000	47.6	7.0	—	10.3	4.6	**69.5**
2001	49.5	7.6	—	11.6	5.7	**74.4**
2002	44.3	6.4	—	13.0	1.2	**64.9**
2003	46.6	8.3	—	13.8	9.9	**78.6**
2004	53.0	8.5	—	14.2	17.8	**93.5**
2005	63.5	8.5	—	14.8	7.0	**93.8**
2006	64.3	11.3	—	16.8	—	**92.4**
2007	54.9	9.0	—	16.0	—[d]	**79.9**
2008	64.3	11.4	0.2	15.3	—	**91.2**
2009	49.0	5.2	0.4	15.0	—	**69.6**
2010	42.0	6.4	0.9	15.2	—	**64.5**
2011	28.6	3.6	1.3	14.5	—	**48.0**
2012	25.3	3.3	0.7	14.2	—	**43.5**
2013	21.2	3.0	0.9	14.9	—	**40.0**
2014	24.0	3.2	1.7	14.2	—	**43.1**
2015	17.8	2.9	—	19.6	—	**40.3**
2016	18.4	3.0	1.7	17.8	—	**40.9**
2017	15.3	2.4	0.8	17.9	—	**36.4**
Total	**1,012.8**	**160.4**	**8.6**	**294.5**	**47.2**	**1,523.5**

Source: Health Service Executive Financial Statements; Health Service Executive Appropriation Accounts 2005 to 2014; Health Appropriation Accounts 1995 to 2017.

Notes:
a Sections 10 and 11 of the Act provide for pay awards made by the Tribunal to infected persons. Section 4 provides for financial support for insurance costs of infected persons.

b Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters

c Payment to the Special Account established under Section 3 of the Appropriation Act 1995 pending the establishment of the schemes on a statutory footing.

d Expenditure of €28,000 in 2007.

Annex 15B Status of recommendations included in 2011-2014 national hepatitis C strategy

	Recommendation	Responsibility	Implementation	Summary status at end December 2017
Surveillance				
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	●	An average of 95% of notifications have full identifiers.
2	Encourage clinicians to notify newly diagnosed cases of hepatitis C and to provide as much relevant information as possible.	HSE in conjunction with practicing clinicians	●	Notifications come directly from laboratories as soon as diagnosis made.
3	Undertake enhanced surveillance of all cases of newly diagnosed hepatitis C infection.	Departments of Public Health	●	An enhanced surveillance system has been in place since 2007 & available for approx 50% of cases notified.
4	Establish a national register of hepatitis C infected patients (other than those referred to as“state-infected”).	Departments of Health – HSE Eastern Region	●	The national hepatitis C treatment programme has developed a hepatitis C treatment registry of all treated patients or those due to commence treatment. A national registry of all infected individuals has logistical, ethical and confidentiality issues to be considered in addition to patient consent.
5	Instigate appropriate public health follow-up on all cases of newly notified hepatitis C infection.	Departments of Public Health	●	Linked to 3 above. Follow up is prioritised by Departments of Public Health as per ***Guidelines for the management of notifications of hepatitis C in Departments of Public Health 2017.***
6	Undertake a population prevalence study.	Health Protection Surveillance Centre	●	A population prevalence study was carried out in 2016. A paper on this study was published in 2017. Garvey P et al. *Hepatitis C virus seroprevalence and prevalence of chronic infection in the adult population in Ireland: a study of residual sera*, April 2014 to February 2016. Euro Surveill. 2017;22(30):pii=30579. https://doi.org/10.2807/1560-7917.ES.2017.22.30.30579

	Recommendation	Responsibility	Implementation	Summary status at end December 2017
7	Complete a modelling exercise to estimate future disease burden and aid service planning.	HSE - Department of Public Health (HSE East), HPSC Health Research Board (HRB) and National Virus Reference Laboratory (NVRL)		A study was published in 2017 by HPSC and HRB on the incidence of HCV in Persons Who Inject Drugs (PWID). The results contribute to estimating the disease burden as they indicate numbers of PWID infected and their duration of infection. Carew et al. Incidence of hepatitis C among people who inject drugs in Ireland. Hepatology, Medicine and Policy (2017) 2:7. DOI 10.1186/s41124-017-0024-1.
8	Conduct follow-up studies amongst Injecting Drug Users to identify seroconverters and therefore incidence rates.	HSE and service providers		See update under no 7 above but may also be difficult to progress because of data protection limitations.

Education, prevention and communication				
9	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. Reduce existing waiting lists for treatment Reduce delays between assessment and treatment. Target young and newly initiated drug users. Provide flexible holistic services that can meet the needs of all drug users including homeless drug users and drug users from new communities. Develop prison-based drug addiction treatment programmes that are linked with community-based programmes for when prisoners are released. Provide after-care and rehabilitation services to prevent relapse.	HSE Existing organisations	●	According to the Central Treatment List (CTL) — in 2011 there were 74 Clinics and 311 General Practitioner participating in methadone programmes (excluding prisons) — in 2017 there were 80 Clinics and 376 General Practitioner clinics participating in methadone programmes (excluding prisons). The number of residential beds has increased significantly since 2007, largely due to the increased provision of beds in community based residential facilities. The most recent figures available (including private provision) estimate the current provision nationally at 148 detoxification beds. The figure of 148 detoxification beds is made up of 19 inpatient unit detoxification beds, 125 community based residential detoxification beds and 4 adolescent residential detoxification. As at end December 2017 the % of substance misusers (over 18 years) for whom treatment has commenced within one calendar month following assessment (against a national performance target of 100%) was 98.5%. As at end December 2017 the % of substance misusers (under 18 years) for whom treatment has commenced within one week following assessment (against a national performance target of 100%) was 96.5%. Following an addiction staff scoping exercise (Social Inclusion), under 18 service provision and review of under 18 tier 4 provision additional funding was approved to purchase additional treatment episodes for under-18 residential treatment and for the employment of 4 Clinical Nurse Specialists and 2 Young Persons Counsellors to complement the Community Healthcare (CHO) Organisation 9 multi-disciplinary Tier 3 addiction teams for under-18s in CHO 1, 2, 3, 6. The HSE is currently expanding under 18 services to include employment of 4 Clinical Nurse Specialists and 2 Young Persons Counsellors to complement the CHO multi - Tier 3 addiction teams for under18s across CHO's 1, 2, 3 with one in place in CHO 6. As at end September 2017 925 individuals (9%) registered as homeless on CTL, 9 Opiate Substitution Therapy (OST) clinics operate in homeless hostels in Dublin treating 157 individuals. The Irish Prison Service (IPS) has for many years worked with the community addiction services to ensure planned through-care is in place for all prisoners leaving custody. This works very well via the local addiction teams, and all prisoners initiated on OST in prisons have an identified port release community placement confirmed, prior to commencement of treatment in the prison. This works very well in larger urban areas, however, challenges remain for rural areas where the community infrastructure is limited. Relapse prevention and harm reduction form a significant part of the addiction work in the prison environment. While the IPS does not have any community services, the continuation of this approach is fostered and planned with community services. Admittedly, compliance and engagement with community services is person dependent and some people do choose to disengage from services on release from prison. Nonetheless, all prisoners are informed and linked with community services.

10	Develop interventions to delay / prevent transition from smoking to injecting, including training for staff in motivational interview techniques and brief interventions. 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.	HSE	●	The expected number of staff trained in SAOR Screening and Brief Intervention for problem alcohol and substance use for 2017 was 778. The proportion of **new cases who reported ever injecting** decreased over the period 2009 to 2015, from 19.7% in 2009 to 14.5% in 2015. The proportion of **previously treated cases who reported ever injecting** decreased from 50.2% in 2009 to 46.1%. However the actual number of previously treated cases who reported ever injecting increased by 38.4% over the period from 1,952 cases in 2009 to 2,701 in 2015. The proportion of all cases (including new and previously treated) who reported **current injecting** (past 30 days prior to treatment) remained relatively stable over the period (around 37%). Between 2009 and 2014, the proportion of all cases (including new and previously treated) who reported **ever sharing** remained relatively stable over the period. However in 2015, the proportion of previously treated cases who reported sharing dropped from 52.4% in 2014 to 48.5% in 2015, the lowest rate reported in the seven year period. Health Research Board (2017) Drug Treatment in Ireland National Drug Treatment Reporting System (NDTRS) 2009 to 2015 available at: www.drugsandalcohol.ie/27023 and at www.hrb.ie/publications.
11	Work with established injectors to discourage them from initiating others into injecting through peer education.	HSE Voluntary service providers	●	UISCE (www.myuisce.org) has carried out some research with persons who inject drugs (PWID) in relation to street injecting as part of developing safe injecting facilities (SIFs). No specific peer education programmes to discourage injecting.
12	Ensure all drug users have access to harm-reduction materials regardless of location. Expand the current provision of harm-reduction materials, particularly outside of the Eastern Region, both in terms of geographical coverage and time. Eliminate the policy of “one for one” needle/syringe exchange. Encourage collaborative links with local Gardai around centres for provision of harm reduction materials.	HSE Voluntary service providers	●	Information provided via drugs.ie website http://www.drugs.ie/resources/publications/guides_and_support_booklets Harm reduction approach continues to be rolled out nationally, OST, Naloxone project, Pharmacy Needle Exchange Programmes (PNEX). PNEX pharmacies are based in all Community Healthcare Organisations. 121 pharmacies offer a free needle exchange in major towns and cities outside of Dublin, Wicklow and Kildare. 1600 individual clients use the service nationwide every month. The National Liaison Pharmacist for Addiction Services has been in post since 2011 and the role is to support community pharmacies in the provision of harm reduction services. PNEX continue to educate clients on safe sharps disposal. HSE continues to work collaboratively with Gardai in implementation of National Drugs Strategy.
13	Promote provision of harm-reduction materials within the pharmacy setting.	Department of Health (DoH) HSE	●	PNEX whose remit includes the provision of harm reduction materials are based in all Community Healthcare Organisations and continue to be rolled out nationally

14	Pilot and evaluate the Dublin Area Homeless Hepatitis C Project.	Safetynet Ana Liffey Drug Project Mountjoy Street Family Practice HSE	●	*National Screening Guidelines for Hepatitis C* published in 2017 & includes specific recommendations for homeless population. Treatment for hepatitis C provided to patients under the care of Safetynet during 2017.
15	Implement recommendations from the MQI report entitled “Drug Use Among New Communities: an exploratory study” on a national basis including: Engage hard-to-reach drug users, including those from Ethnic Minority Groups (EMGs), through drugs outreach teams. Promote community engagement in the design and delivery of services. Recruit staff from EMGs into the drug services. 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. Provide culturally-specific drug awareness training to different cultural groups as indicated.	HSE — Drug treatment services	●	Outreach workers funded by the HSE and/or Drugs Task Forces are in place across a number of areas. Their role includes support to hard to reach populations including those from EMGs. Intercultural health training is provided is provided to substance misuse staff across a number of areas as part of the wider health service initiative. Traveller specific SAOR training (brief intervention for problem alcohol use) has been developed and delivered across some areas. Interpreter services used where appropriate to engage service users from EMGs across some areas. In certain areas service user forums are established inclusive of hard to reach drug users. The HSE recruitment policy is inclusive of the recruitment of staff from EMGs. Cultural training is provided across the health services as part of the wider health service implementation of the HSE National Intercultural Health Strategy (NIHS) 2008-2012 (available at https://www.hse.ie/eng/services/publications/socialinclusion/national-intercultural-health-strategy-2007---2012.pdf) The 2nd NIHS 2018-2023 is currently in draft.

16	The DoH to approve both the draft "Best Practice Guidelines for Body Piercing" and draft "Best Practice Guidelines for Tattooing and Permanent Make Up (PMU)" and issue to practitioners nationwide. The DoH to appoint an agency or representative to monitor the implementation of these guidelines following roll-out to practitioners nationwide. Regular inspections, in the interests of public health and health and safety in the workplace, to ensure adherence to standard precautions. 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.	DoH	●	At present the Department of Health are currently finalising an infection prevention and control guidance document for the tattooing and body piercing industry. The purpose of the document is to provide guidance to the industry in relation to minimising the risk of infection to practitioners and clients in the absence of sector specific regulation. It is intended to publish the guidelines later this year. There is no plan to introduce regulation or legislation in this area at this present time. This document sets out best practice in infection control for the tattooing and body piercing industry and is aimed at achieving the highest standards of infection control and prevention in this sector. The draft guidelines were developed by public health practitioners and environmental health experts in conjunction with the Department of Health.
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	●	A hepatitis C leaflet and FAQ, developed by HPSC and Departments of Public Health, are available on HPSC website at http://www.hpsc.ie/A-Z/Hepatitis/HepatitisC/Factsheetleaflets/ Leaflet updated 2017 and available in 7 languages. FAQ updated Jan 2018.
18	Facilitate access to a standardised accredited interpreting service for individuals who do not have English as their first language	HSE – Social Inclusion Directorate	●	Funding has been provided towards interpreting provision for refugees arriving under the Irish Refugee Protection programme. Development and implementation of a comprehensive model of interpreting provision is a key element of the forthcoming HSE National Intercultural Health Strategy 2018 – 2023.
19	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.	HSE - Departments of Public Health, HPSC	●	A hepatitis C leaflet and FAQ, developed by HPSC and Departments of Public Health, are available on HPSC website at http://www.hpsc.ie/A-Z/Hepatitis/HepatitisC/Factsheetleaflets/ Leaflet updated 201. FAQ updated Jan 2018.

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	HSE via Social Inclusion Governance Group	●	Competency based training modules developed for pharmacists working in PNEX Programmes accredited by the Irish Institute of Pharmacy which is responsible for pharmacists' continuous professional development (CPD) including opioid addiction.
21	Employ staff trained to an appropriate standard in all services engaged in health promotion to prevent hepatitis C infection. Develop minimum standards of education for outreach and other staff who are in direct contact with IDUs. Standardise recruitment and training for peer educators that is evidence-based and continuously evaluated. A model similar to that used by the Third Collaborative Injection Drug Users Study/Drug Users Intervention Trial could be developed. Increase learning from peer education models already in place (e.g. UISCE, Community Response).	HSE Voluntary service providers	●	Staff trained as per core training and qualifications for posts held as appropriate. Continuous professional development in place for healthcare workers in engaged in health promotion. Depending on role, staff required to have various qualifications e.g. youth & community studies, SAOR, harm reduction, motivational interviewing, assessment & care planning, CBT. Not achieved/not known Not in all areas but CHO5 co-funds a peer educator as part of South East Recovery College.
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.	HSE	●	National hepatitis C treatment programme established in 2015 — has promoted treatment and encouraged testing through media awareness, publications etc www.hse.ie/hepc . HSE supports World Hepatitis Day annually in July & encourages testing, links to care etc. HSE addiction services and other service providers continually use both opportunistic and on individual patient basis. National hepatitis C screening guidelines published in 2017 make recommendations for testing/screening at a range of healthcare services. Screening, testing treatment and awareness carried out throughout services.

Screening and laboratory testing for hepatitis C				
23	Provide ready access for GPs and other community healthcare providers to diagnostic facilities. Optimise transport of samples to the laboratories by the provision of a responsive courier service.	HSE – Access to Diagnostics (GP/Community) Initiative Governing Group		GPs can send all phlebotomy to NVRL for testing.
24	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. 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. Monitor uptake of testing. Ensure appropriate follow-up is provided.	Irish Prison Service		The IPS is working with our HSE colleagues to manage the risk and provide treatment for all Blood Borne Viruses (BBVs) in the prison population. Expert clinical inputs are bought into the prisons from infectious disease colleagues from the HSE. This is undertaken via in reach services and prisoners also attending routine clinical appointment in the infection disease clinics in local hospitals. To date the IPS and HSE have undertaken mass screening initiatives for HIV and Hep C, followed by a robust treatment and follow up programme. Further similar initiatives are planned for 2018/19, followed by a routine screening programme for all new committals to prison. The prison environment offers an ideal opportunity for the IPS & HSE to target a highly probable population for screening and treatment, thus furthering the national agenda of management of BBV's. This is being built into a revised committal assessment as per above. Audit of the uptake of testing will be facilitated via the Prisoner Healthcare Management System (Multi-disciplinary electronic patient record in the IPS). Follow up treatment and surveillance is based exclusively on best clinical practice, and this is done in conjunction with HSE specialists.
25	The NVRL, on request, to release results of previous tests to medical practitioners with the patient's consent.	NVRL		NVRL releases information when requested. In 2017 81 requests (with patients consent) received.
26	Establish guidelines with regard to hepatitis C screening of individuals from endemic countries / new entrants to the Irish healthcare system.	HPSC Scientific Advisory Committee		Guidelines for screening of migrants for all infectious diseases were published by HPSC in 2015. Available at: http://www.hpsc.ie/A-Z/SpecificPopulations/Migrants/ Specific national hepatitis C screening guidelines (for all population groups) were developed by HPSC-led Guideline Development Group and published in 2017. Available at: http://health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines/prevention/

27	Continue targeted antenatal screening for those with risk factors for hepatitis C infection. Regular review of the evidence with regard to universal antenatal screening	Maternity Hospitals General Practitioners	🟢	National hepatitis C screening guidelines 2017 made specific recommendations for screening of pregnant women. http://health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines/prevention/ 1.1 Standardised targeted risk based HCV screening of antenatal women is recommended. 1.2 Universal HCV screening of antenatal women is not recommended. 1.3 Universal antenatal HCV screening may be reconsidered in the future if HCV treatment during pregnancy becomes possible. Also, if national policy progresses to a policy of birth cohort or total population screening, antenatal screening offers an opportunistic method to reach this particular population cohort.
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	HSE Drug services	🟡	National hepatitis C screening guidelines published in 2017 — disseminated to HSE addiction services including needle exchange programmes. HSE PNEX Programmes regularly refer clients for blood borne virus screening including hepatitis C.
Treatment				
29	Establish an expert group to provide guidance on clinical issues. Develop standard protocols for testing, diagnosis, evaluation, referral for treatment, monitoring of treatment and monitoring of patients not on treatment. Monitor and evaluate the implementation of these guidelines.	Expert Group Health Information and Quality Authority (HIQA)	🟢	The national hepatitis C treatment programme (NHCTP) was established in the HSE in 2015 following recommendations in the Department of Health report "*A public health plan for the pharmaceutical treatment of hepatitis C*" The NHCTP is supported by a Clinical Advisory Group (CAG) whose role is to provide clinical advice /guidance/governance to the programme. The CAG has developed a set of national treatment guidelines for hepatitis C including prioritisation criteria, monitoring and drug regimens. The CAG regularly reviews the treatment guidelines in line with international best practice.
30	Establish a postgraduate diploma in hepatitis C management for physicians and nursing staff.	Accredited third level academic institution Tendering process should be overseen by the expert group.	🔴	Currently no post graduate diploma in hepatitis C management. However, the Irish College of General Practitioners and other medical professional bodies undertake training days as part of CPD.
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 e.g. child-care.	Primary Care Teams.	🟡	The national hepatitis C treatment programme is developing treatment for hepatitis C in community settings so that it can be linked to where the patient is on a methadone programme & reduces need to go to hospital. Some National Government Organisations provide peer support including accompanying patients to hospital appointments.

32	Address alcohol issues and provide alcohol reduction strategies for those patients infected with hepatitis C who require them.	HSE – Drugs and Alcohol services	●	All patients are screened for alcohol use and advice provided where appropriate.
33	Develop, implement and evaluate a treatment model appropriate to the prison setting on a national basis.	Expert Group in conjunction with the IPS	●	The national hepatitis C treatment programme is developing the integration of hepatitis C treatment into the community including the prison setting. The steering group includes representation from the Irish Prison Service. Treatment is provided to patients in prison via hospital outreach & in-reach programmes.
34	Undertake a formal assessment of the needs of individuals infected with hepatitis C, other than through contaminated blood and blood products.	HSE	●	All patients are assessed on an individual basis. The patients infected with hepatitis C through contaminated blood and blood products are assessed as part of the determination of their overall health and social care needs in line with their entitlement to services under the terms of the Health Amendment Act 1996.
35	Further develop the number of hepatitis C Clinical Nurse Specialist (CNS) posts based on the findings of the needs assessment in recommendation 34.	HSE	●	The national hepatitis C treatment programme has provided support to hospital treatment sites to increase number of hepatitis C CNS posts to manage increased number of patients on treatment.
36	Develop the role of suitably trained general practitioners in facilitating treatment monitoring in the community.	HSE and Irish College of General Practitioners (ICGP)	●	The Irish College of General Practitioners and other medical professional bodies undertake training days as part of CPD.

Source: National hepatitis C strategy 2011 — 2014, Health Service Executive