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12th December 2018

Ms Sarah Cremin,
Committee Secretariat,
Public Accounts Committee,
Leinster House,
Dublin 2.

Re: Follow up issues meeting 22nd Nov. (PAC32-I-1201)

Dear Sarah,

I refer to recent correspondence from the Committee to Mr. John Connaghan, Director General, Health Service Executive in respect of follow-up issues from our attendance at the Committee meeting on Thursday 22nd of November 2018 regarding Hepatitis C treatment in Ireland.

Please find below for the attention of the Public Accounts Committee members responses on the matters raised.

If any further information is required please do not hesitate to contact me.

Yours sincerely,

Ray Mitchell
Assistant National Director
Parliamentary Affairs Division

Encl.

Briefing Note for the Public Accounts Committee

1. A note on the development of national screening guidelines for Hepatitis C.

Response:

Chapter 15 of the 2017 report by the Comptroller & Auditor General (C&AG) on the Treatment of Hepatitis C in Ireland examined a number of areas including the available evidence in relation to the prevalence of hepatitis C in Ireland and the various plans and strategies adopted in the management of the virus. The C&AG noted in its report that screening for hepatitis C has been ongoing across a number of healthcare settings but that prior to 2017 a national guideline for hepatitis C screening was not in place. This position is correct in that prior to 2017 and particularly since hepatitis C became a notifiable disease in 2004, those at risk or known to have been at risk of contracting hepatitis C have been offered testing mainly in addiction services treatment centres and in other healthcare settings but no national approach or guideline to screening had been developed. The C&AG noted that when it was disclosed that women in the 1970's and 1990's had been administered known contaminated Anti D Immunoglobulin a national screening programme was initiated to test all women who had received the blood product. There has not been a national screening programme for hepatitis C in Ireland among the general population nor is one considered to be necessary. The World Health Organisation states that the most appropriate approach to screening depends on each country's unique epidemiology in relation to hepatitis C and in Ireland which is considered to be a country of low prevalence, screening is based on risk and the national guidelines which have been developed takes account of this and define where screening should take place and amongst which groups. The Health Protection Surveillance Centre (HPSC) of the HSE has played a pivotal role in publishing information on hepatitis C infection in the years since the virus was identified in 1989 and is responsible for collating data in relation to notifications.

The National Clinical Guideline no 15 on Hepatitis C Screening was developed by the National Hepatitis C Screening Guideline Development Group (GDG). The GDG was established in conjunction with the National Hepatitis C Strategy 2011-2014 which sets out a number of recommendations in relation to screening and the development of the guideline was led by the HPSC of the HSE. The guideline was published in July 2017. The GDG was chaired by a Specialist in Public Health Medicine from the HPSC and membership of the group was inclusive of clinicians, researchers, patient representatives and other key stakeholder healthcare professionals providing care to those with hepatitis C infection or those at risk of hepatitis C infection and those actively carrying out screening and testing within their relevant healthcare settings.

A copy of the guidelines and other relevant publications relating to screening and testing can be accessed at – http://www.health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines/ and http://www.hpsc.ie/a-z/hepatitis/hepatitisc/guidance/

2. A note on the reviews that have been carried out and the lessons learned from these reviews and a specific note on the outcomes of the report on Portiuncula Hospital, Ballinasloe.

Response:

Background to this note

Incident review is an on-going feature of the incident management process. In the majority of cases, incident review is carried out at a service level in conjunction with service users and their families. The following outlines a sample of reviews which were in the public arena and the manner in which lessons learned have been addressed.

1. Portiuncula Hospital

A number of themes emerged from the Walker Report into adverse events in Portiuncula Hospital. These included:

- Maternity network (governance and leadership)
- Cardiotocography (CTG) interpretation
- Quality & Safety
- Use of activity data and learning from incident reviews
- Model of care (autonomous midwifery practice)

Maternity Networks – each hospital group is required to develop a maternity network. Processes are well developed in each hospital group, and the National Women and Infants' Health Programme (NWIHP) is supporting the development of these networks with funding and regular meetings.

CTG Interpretation – CTG interpretation emerges a factor in many adverse event reports. NWIHP has a multi-disciplinary group, including patient representatives, updating the CTG guidelines. When the guidelines are completed a new system for training and accreditation will be introduced.

Quality and Safety – Each maternity network has been allocated a quality and safety lead for maternity services. In addition a maternity specific Serious Incident Management Forum has been established in five of the six networks. It is expected the sixth will commence in 2019. This brings a more focused approach to the management of maternity related events, and significantly enhances the learning among all hospitals within the network.

Activity data, and incident reviews – The Irish Maternity Incident System data (suite of 37 maternity and neonatal measures) and the Maternity Patient Safety Statements are used by the maternity networks and NWIHP to monitor progress. NWIHP also requests copies of all incident reviews, so that recommendations and learning can be shared across the six maternity networks.

Model of Care – NWIHP has invested in additional midwives in 2018 to commence the roll-out of the support care pathway. NWIHP has established a number of multi-disciplinary working groups who are working to develop a standardised approach for the support care pathway.

2. Portlaoise Maternity

Subsequent to the publication of the review in relation to Portlaoise the National Women and Infants Health Programme (NWIHP) was established. The clinical lead for this programme is Dr. Peter McKenna, Consultant Obstetrician and Gynaecologist. NWIHP was established to lead the management, organisation and delivery of maternity, gynaecological and neonatal services within the HSE.

The role for NWIHP derives from the Maternity Strategy which is Government policy.

3. Miscarriage Misdiagnosis

This report resulted in the following changes being put in place:

- Guidelines for the management of early pregnancy complications developed by the HSE's Clinical Programme for Obstetrics & Gynaecology.
- The establishment of a dedicated Early Pregnancy Unit in all Maternity units nationally.
- Introduction of a protocol to require a 2nd ultrasound to confirm a diagnosis of miscarriage.
- Multidisciplinary Team training for all staff involved in early pregnancy care developed and available.

- Each unit required to develop a policy and a service for supporting women who have suffered a miscarriage.

4. Maternal death investigation 'Savita Halappanavar'

All of the previously made points apply to the learning from investigation into the maternal death of Ms. Savita Halappanavar.

Many of the developments within the briefing note also apply to maternal deaths.

- Development and implementation of the Maternity Early Warning Score system to assist in recognising and responding to clinical deterioration.
- Development of Clinical Communication Guidelines for Maternity Services.
- NWIHP have contacted the coroners to seek to have all maternal deaths reported to the coroners.
- All maternal deaths are reported to NWIHP. If a maternal death is deemed direct, then it is subject to an external review which should be coordinated through NWIHP.

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3. A note providing an update on the changes being made in relation to clinical assessment.

Response:

Clinical governance in relation to doctors is the responsibility of the relevant line manager and falls within the remit of the Operational Divisions subject to HSE HR policy and guidance.

In addition to individual regulatory requirements of the Irish Medical Council, Doctors are subject to the same policies and procedures as other HSE staff. This includes but is not limited to the following:

- The HSE Code of Standards and Behaviour (June 2009)
- HSE Disciplinary Procedure (2007)
- Performance Management in the HSE (2012) – (Chapter 7 – Managing Underperformance in the HSE: The Performance Improvement Plan).

Doctors may require retraining as part of the outcome of a disciplinary hearing, investigation of an incident or following a legal settlement with or without admission of liability. As stated in the response to the PAC dated 16th August 2018, there is no mandatory requirement for retraining or supervision following legal settlements without admission of liability.

Under the Statement of Partnership with the HSE and the State Claims Agency (SCA) there is an executive management forum for the Clinical Indemnity Scheme. This is the forum for collaboration and sharing between the two agencies for learning and sharing of adverse clinical incidents. In the course of claims management or analysis by the SCA, trends may emerge which suggest concerns regarding the clinical practice of an individual clinician. In such a circumstance the SCA will bring these concerns to the attention of the CEO / General Manager of the healthcare enterprise and recommend that an investigation of the clinician's practice takes place. The SCA will seek assurance that this investigation is undertaken in a timely manner and its recommendations which may include retraining or supervision are implemented.

Under the Medical Practitioners Act 2007, individual medical practitioners have a responsibility to develop an annual personal development plan for professional competency. These portfolios are subject to audit (both random and risk based) by the Medical Council and relevant Post Graduate Training Bodies.

The Medical Council has the authority to assess an individual medical practitioner for an assessment of performance and can mandate retraining and supervision.

Unlike the NHS, the HSE does not have a National Clinical Assessment Service (NCAS) through which concerns about practicing clinicians can be managed. This includes impartial advice assessment and intervention and training courses.

HSE Leadership, recently approved a proposal from HSE National HR for a Service Level Agreement with NCAS (note the name of this service is changing to Practitioner Advice Service). This will support the Operational Divisions to manage cases of under-performance appropriately. The development of this proposal is currently being worked through.

The need for specific assessment services for doctors is well recognised internationally. Highly trained doctors are a valuable resource for any organisation. National Clinical Assessment Service is a unique service, and dedicated arm of the NHS, designed and developed to deal with doctors, dentists and pharmacist in recognition of this.

NCAS use a triage system on an advice and support line, and with experience, have reduced the need for full assessment for doctors to 6% of referred cases. The assessment process includes a medical assessment, psychological assessment and performance assessment, providing clear recommendations for the employer using a scaled down approach, it is estimated that a bespoke Irish advisory line will receive approximately 100 cases per year, 6% of which would require a full assessment. A full assessment, depending on the complexity could cost up to €30,000 per year.

It is proposed that SLA for an initial block contract for a National Advisory and Support Line be established, followed by a cost per case model for 2019. This can be reviewed and monitored for the estimates for 2020.

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4. A copy of the Health Protection Surveillance Centre epidemiology report in numerical format.

Response:

Please find enclosed a full copy of the report *(Appendix Issue 4 - Hepatitis C Annual Report 2017.pdf)* on the Epidemiology of Hepatitis C in Ireland 2017 as referenced and which can also be accessed at – http://www.hpsc.ie/a-z/hepatitis/hepatitisc/hepatitiscreports/hepatitisannualreports/Hepatitis%20C%20Annual%20Report%2020017.pdf

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5. A note on the project team established to examine local reviews.

Response:

Learning is one of the principles upon which the *HSE's Incident Management Framework* is based. It identifies a range of tools and methods to be used to share learning from incidents at local, individual service and organisational levels. *[Incident Management Framework 2018 P11]*.

1. **Current Practice**

At a local level, once a review has been completed, learning is expected to be shared across the service in which the incident occurred. Where appropriate, learning is also be shared with the wider organisation through the relevant Quality and Safety Committee.

At a national level, learning from significant incidents is shared with the relevant service functions and/ or clinical programmes so that it can inform their work.

A national annual process is also in place to conduct an analysis of a sample of review reports completed in the previous year. This analysis is used to identify common learning in relation to issues identified as contributing to incidents, for example, clinical communication/handover, team working, task design, knowledge and skills, workload, staffing levels and skill mix. The outcome of this analysis is shared with the relevant national HSE functions to inform their work-plans and to identify areas where the development of organisational policy or guidance is required.

2. Plan to enhance learning from incidents

Though the current practice outlined above remains valid, the HSE has identified that there are also a number of other ways in which learning can be captured and shared.

The further development of systems for sharing learning was initiated in 2018 and work will be completed in 2019. This will enable a more structured and consistent approach to learning from incidents.

The approach being taken involves the delivery of two discrete but linked work streams.

Developing recommendations
The first work stream will review the evidence in relation to making recommendations in a manner that are evidence based, promote learning, are practical, relevant and in line with best practice.

The need for this project arises from findings in the annual analysis undertaken that many recommendations are not sufficiently linked to findings in the review reports examined. They can also be vague and lacking specificity. This leads to difficulty in both implementation and any evaluation of the extent to which recommendations result in improving safety.

This project will also challenge the notion that whilst a recommendation may be applicable to the specific service in which the incident occurred, it may not be applicable to 'all similar services'. In these instances it may be more appropriate to present this information as 'lessons learned' rather than recommendations. This will enable services to consider the applicability of the 'lessons learned' to their context, risk assess their current practice and make any changes or improvements identified as required as a consequence of this assessment.

Development
The second project is focused on putting in place a system whereby 'lessons learned' from incident reviews can be provided to a single point within the organisation. This information can then be considered by relevant clinical and patient safety experts in conjunction with information from a number of other sources [e.g. the coronial process, closed claims and complaints]. The aim of this process will be to consider the most appropriate methods for disseminating this learning, for example learning events, learning notices or policy/programme changes.

Work has commenced with an examination of international practice in this area so that his can be used to inform the system to be developed in 2019.

Health Service Executive
December 2018

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

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Annual Epidemiological Report

November 2018

Hepatitis C in Ireland, 2017

Key Facts

Number of cases, 2017: 620

Crude notification rate, 2017: 13/100,000 population

The number of notifications of hepatitis C decreased by 4% in 2017 compared to 2016 (n=644). While notifications have declined each year since 2012, the rate of decline is slowing and notification rates are stabilising. The highest notification rates are in the greater Dublin area; 70% of cases in 2017 were notified by HSE East. Seventy two percent of 2017 cases were male and the median age at notification was 42 years for males and 41 years for females.

Most hepatitis C infections in Ireland are acquired through sharing equipment when injecting drugs.

There was an increase in hepatitis C notifications in men who have sex with men (MSM) in 2016. The number of cases identified as MSM decreased in 2017, but remained elevated compared with the years prior to 2016.

Suggested citation: HSE Health Protection Surveillance Centre. Hepatitis C Annual Report 2017. Dublin: HSE HPSC; 2018

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Background

The hepatitis C virus (HCV) was first identified in 1989. It primarily affects the liver and is a major cause of liver disease worldwide. Hepatitis C is most commonly transmitted through sharing contaminated equipment when injecting drugs or through receipt of unscreened blood or blood products (this is no longer a risk in Ireland).[1,2,3] Sexual, occupational and vertical (mother to infant) transmission can also occur but are less common. The risk of sexual transmission is increased in men who have sex with men (MSM), particularly those who are HIV positive or have other sexually transmitted infections.[4] The overall prevalence of chronic hepatitis C in adults in Ireland is estimated to be between 0.4 and 0.8%[5] and is similar to other northern European countries.[6]

The acute stage of hepatitis C infection is usually asymptomatic, but approximately 75% of those infected develop chronic infection, which can cause cirrhosis of the liver, hepatocellular carcinoma (liver cancer) and liver failure. Between 10 and 20% of those who are chronically infected develop cirrhosis after 20-30 years of infection.[7] Of those with cirrhosis, 1.5 to 2.5% will go on to develop hepatocellular carcinoma (liver cancer) each year.[1] Liver disease progression is faster in those with high alcohol consumption and in those who are co-infected with HIV and/or hepatitis B.[7]

There have been significant improvements in the treatment of hepatitis C in recent years. The latest generation of direct-acting antiviral drugs (DAAs) can cure more than 95% of patients using all oral drug regimens, which have fewer side effects than previous treatments.[8]

Methods

The figures presented in this summary are based on data extracted from the Computerised Infectious Disease Reporting (CIDR) System on 23rd October 2018. These figures may differ from those published previously due to ongoing updating of notification data on CIDR. Notification rates are expressed per 100,000 population and are calculated using the 2016 census.

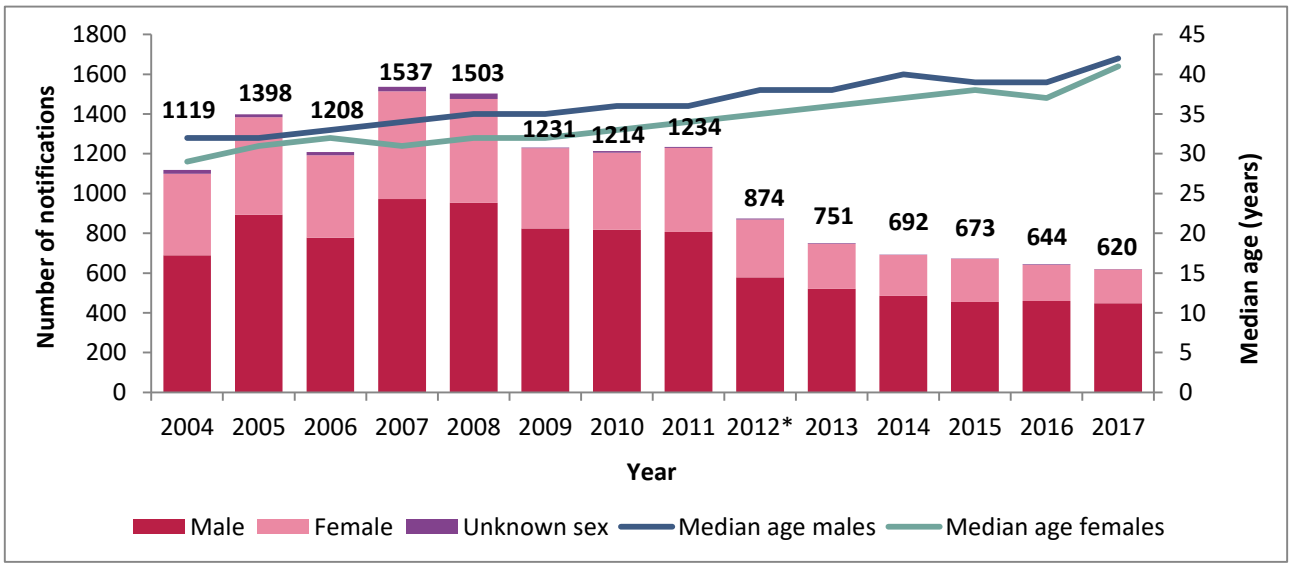
Epidemiology

Number of notifications and notification rates

There were 620 notifications of hepatitis C in 2017 (13/100,000 population). This is a small decrease compared to 2016 (n=644, 13.5/100,000 population) (figure 1). Although hepatitis C notifications have declined by 60% since peak levels in 2007 (n=1537), recent trends indicate that the notification rate is stabilising. Notification rates for each HSE area for the past four years are shown in figure 2. The notification rate was significantly higher in HSE E compared to the rest of Ireland; 70% of cases (n=433, 25/100,000 population) in 2017 were reported by HSE E.

Almost three quarters (72%, n=448) of hepatitis C notifications in 2017 were male, 28% (n=171) were female and sex was not reported for one case. The highest notification rates were in adults aged between 35 and 54 years (figure 3). In this age group the notification rate was 27.5/100,000 population (n=377, 61% of cases). The median age at notification has gradually increased from 31 years in 2004 to a high of 41 years in 2017.

Figure 1. Number of notifications of hepatitis C in Ireland, by sex and median age at notification, 2004-2017



*Case definition changed in 2012 - cases known to be resolved excluded from notification

Figure 2. Hepatitis C notification rates/100,000 population in Ireland, by HSE area, 2014-2017

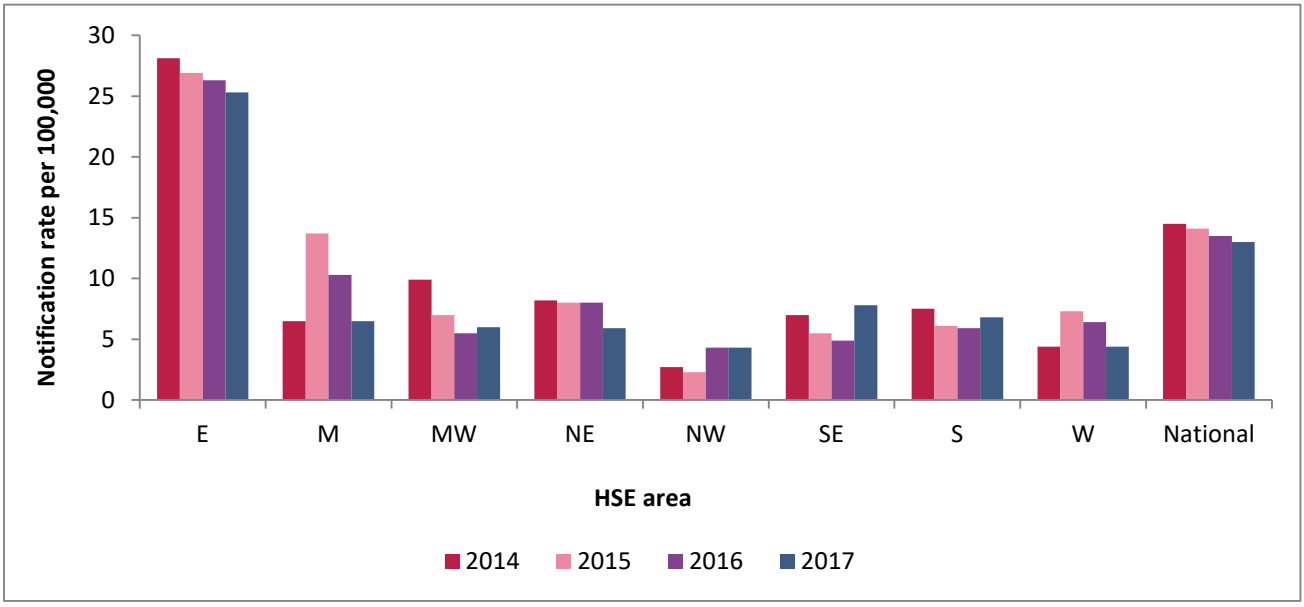
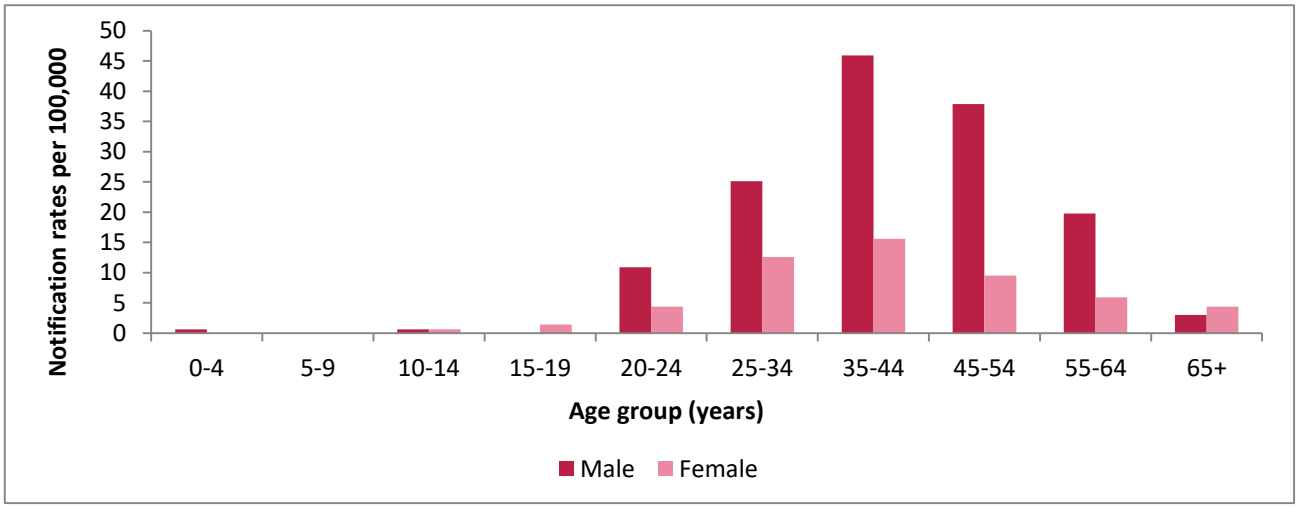


Figure 3. Age and sex-specific notification rates/100,000 population for hepatitis C in Ireland, 2017



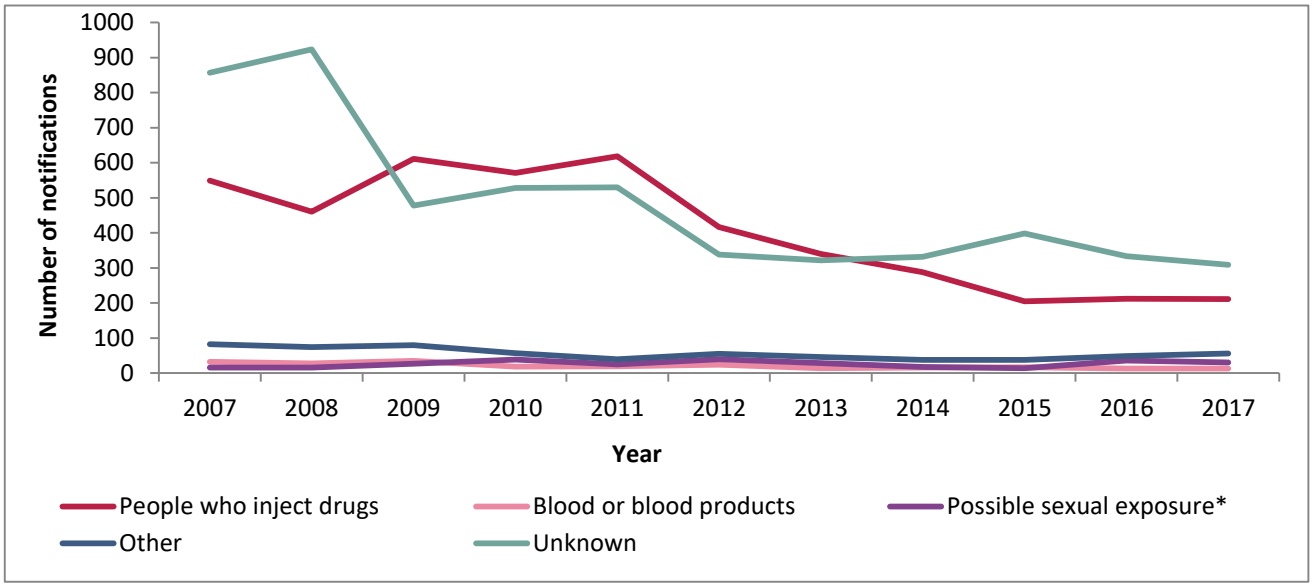
Risk factors

Information on most likely risk factor was reported for half (n=311) of the cases of hepatitis C notified in 2017. Over two thirds (68%, n=211) of these were people who inject drugs (PWID). The proportion of cases attributed to injecting drug use has decreased in recent years (80% in 2014, 75% in 2015, 68% in 2016), but risk factor data were only available for around half of cases notified over the past four years, so this trend should be interpreted with caution (figure 4).

Ten percent (n=31) of cases were likely to have been infected sexually. Fifteen were MSM, twelve were heterosexual and sexual orientation was not reported for four. There were two additional cases identified as MSM; one also injected drugs and this was selected as his most likely risk factor and the risk factor for the remaining case was reported as unknown. There was a significant increase in the number of hepatitis C cases identified as MSM in 2016 (n=31) compared to 2015 (n=8). The number of known MSM cases decreased in 2017 (n=17), but remained higher than seen prior to 2016. The risk of sexual transmission of hepatitis C appears to be particularly high in those who are co-infected with HIV or have other sexually transmitted infections. Almost two thirds (65%, n=11) of the seventeen cases identified as MSM in 2017 were HIV positive at the time of HCV diagnosis. Eighty two percent of the HIV positive MSM cases (n=9) and 33% of the HIV negative MSM cases (n=2) had been recently (in the same year or the previous year) diagnosed with other sexually transmitted infections, particularly gonorrhoea, syphilis and chlamydia (figure 5).

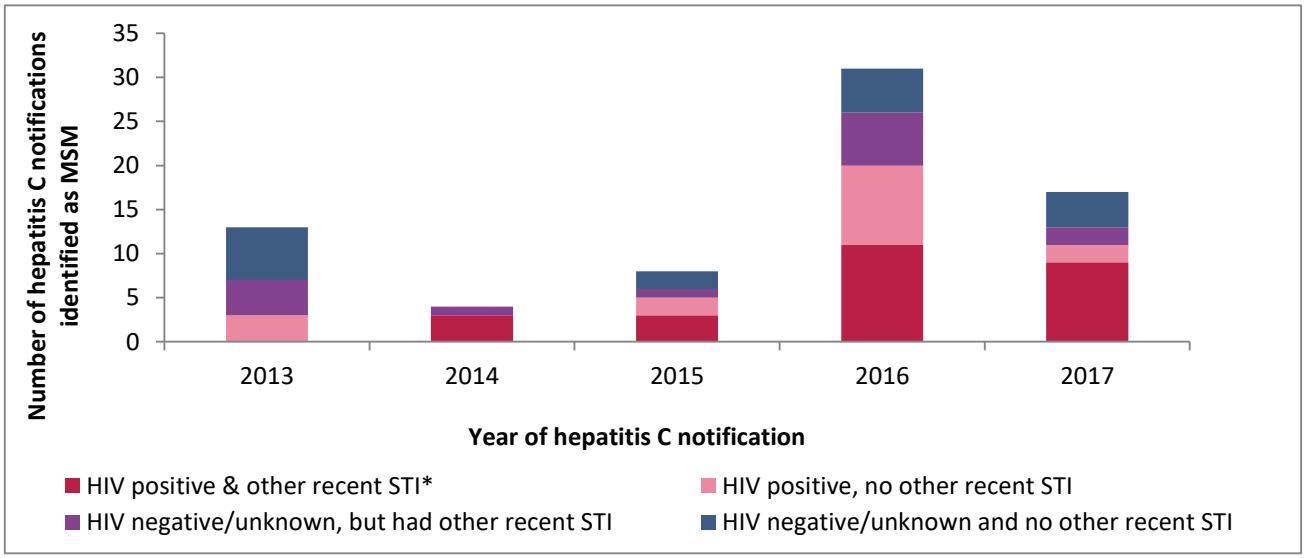
Four percent (n=13) of hepatitis C cases in 2017 were reported as infected through contaminated blood or blood products. Nine were infected outside Ireland and four were infected in Ireland many years ago and notified for the first time in 2017. Other reported risk factors included tattooing or body piercing (3%, n=9), accidental needlestick or blood exposure (3%, n=8) and vertical transmission (mother to infant) (1%, n=4). No risk factor was identified for 27 cases despite follow up by regional public health staff. Figure 4 shows recent risk factor trends for hepatitis C in Ireland.

Figure 4. Number of hepatitis C notifications in Ireland, by most likely risk factor (where risk factor known, 51%, n=5,622), 2007-2017



*Possible sexual exposure includes MSM

Figure 5. Number of hepatitis C cases identified as MSM in Ireland, by HIV status at the time of hepatitis C notification and other recent STI* status, 2013-2017



*Gonorrhoea, syphilis, chlamydia, lymphogranuloma venereum or genital herpes simplex in the same year as hepatitis C notification or in the year prior to hepatitis C notification

Country of birth

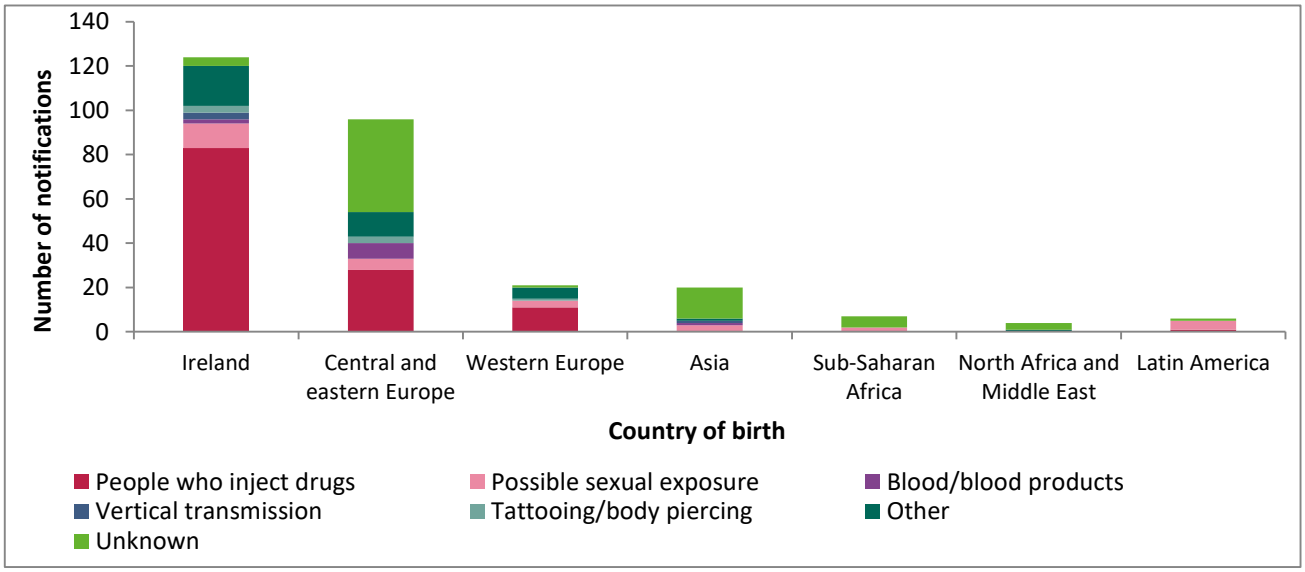
Data on country of birth were available for 45% of hepatitis C cases (n=280) in 2017. Where information was available, 44% (n=124) of cases were born in Ireland, 34% (n=96) were born in central or eastern Europe, 8% (n=21) were born in western European countries other than Ireland, 7% (n=20) were born in Asia, 4% (n=11) were born in Africa, 2% (n=6) were born in Latin America and 1% (n=2) were born in North America. Just over a third of cases with information on country of birth or asylum seeker status were born in a hepatitis C endemic country (≥2% anti-HCV prevalence) or were asylum seekers. As data on country of birth were not very complete, this may not be representative of all cases. Country of birth is more likely to be reported for those not born in Ireland and the actual proportion of hepatitis C cases born in Ireland is likely to be higher than reported here. Figure 6 shows the most likely risk factor for infection by region of birth for the 280 cases where country of birth was known.

Genotype

Hepatitis C genotype data were collected retrospectively from the National Virus Reference Laboratory and were available for 36% (n=1510) of notifications between 2012 and 2017. Of these, 60% (n=912) were genotype 1, 33% (n=497) were genotype 3, 3% (n=51) were genotype 2, 3% (n=47) were genotype 4 and 3 cases were genotype 6. Subtype was

available for 93% (n=846) of genotype 1 cases. Seventy five percent were genotype 1a and the remaining 25% were genotype 1b.

Figure 6. Number of hepatitis C notifications in Ireland, by most likely risk factor and country/region of birth (where country of birth was known, 45%, n=280), 2017



Co-infections

Co-infection with HIV can increase the risk of acquiring hepatitis C sexually, and both HIV and hepatitis B co-infections can lead to more severe liver disease and an increased risk of liver cancer in those with hepatitis C infection. Four percent (n=23) of hepatitis C cases notified in 2017 were co-infected with HIV. This is a decrease compared to 2016 when 6% (n=39) were HIV positive. Seven cases of hepatitis C (1%) were co-infected with hepatitis B, two of whom were also HIV positive.

Discussion

Hepatitis C notifications have decreased in recent years. The decline was fairly dramatic in 2012 but this may have been partially attributable to the introduction of new case definitions specifically excluding cases known to have resolved infection. While notifications have continued to decline each year since 2012, the rate of decline is slowing and notification rates are stabilising. Trends in hepatitis C notifications are difficult to interpret as cases are frequently asymptomatic or mildly symptomatic for some time, and most cases are diagnosed and notified as a result of screening in key risk groups such as PWID. Therefore, some cases may be diagnosed years after infection and notifications more accurately reflect trends in diagnoses rather than incidence of hepatitis C infection.

Risk factor data were available for half of the cases of hepatitis C notified in 2017. The distribution of risk factors for these cases may differ from cases where data were not available. Where information on risk factor was available, just over two thirds of cases were PWID who were likely to have been infected through unsafe injecting practices. There has been a gradual increase in the median age at notification for all cases of hepatitis C and for cases in PWID. This indicates that the incidence of hepatitis C is likely to be declining in younger people in Ireland. This is supported by data from National Drug Treatment Reporting System (NDTRS), which is maintained by the Health Research Board and is used to monitor treated problem drug use in Ireland. NDTRS data indicated a decline in injecting in newly treated drug users in Ireland between 2010 and 2016. Patients who were new to drug treatment in 2016 were also significantly less likely to have ever injected drugs compared to those who had been previously treated and were re-entering drug treatment in 2016 (13% compared to 46%).[9]

The number of sexually acquired cases of hepatitis C has increased in the last two years, particularly among MSM. Increases in HIV and other sexually transmitted infections have also been identified in MSM and a national multidisciplinary outbreak response group was established in early 2016 to develop an action plan for public health intervention (http://www.hpsc.ie/a-z/specificpopulations/menwhohavesexwithmenmsm/).

Further information available on HPSC website

http://www.hpsc.ie/a-z/hepatitis/hepatitisc/

http://www.hpsc.ie/a-z/hepatitis/hepatitisc/hepatitiscreports/

http://www.hpsc.ie/a-z/hepatitis/hepatitisc/factsheetleaflets/

http://www.hpsc.ie/a-z/hepatitis/hepatitisc/slidesets/

Acknowledgements

Sincere thanks are extended to all those who participated in the collection of data used in this report. This includes the notifying physicians, public health doctors, surveillance scientists, microbiologists, nurses, laboratory staff and administrative staff.

Report prepared by:

Niamh Murphy and Dr Lois O'Connor

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