Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Technology Assessment of Birth Cohort Testing for Hepatitis C: A short report update

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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Updated Advice to the Minister for Health

HIQA's advice to the Minister for Health is as follows:

- In July 2021, HIQA published a health technology assessment (HTA) of birth cohort testing for hepatitis C virus (HCV). HIQA found that birth cohort testing would be a cost-effective use of resources. However, the prevalence of undiagnosed chronic HCV infection in the 1965-1985 birth cohort (of approximately 1%) was subject to substantial uncertainty. Given uncertainty surrounding the prevalence of undiagnosed chronic HCV infection in the target cohort and concerns regarding the feasibility of reflex testing, HIQA advised that consideration should be given to an initial pilot programme.
- Three studies that were conducted since the publication of the HTA demonstrate an overall reduction in the prevalence of chronic HCV infection in Ireland:
  - A study found that the prevalence in pregnant women attending two maternity hospitals in Dublin had reduced by 65% over a period of 15 to 20 years.
  - A national study by the National Hepatitis C Treatment Programme (NHCTP) showed a decrease in prevalence in the 1965-1985 birth cohort to less than 0.05%.
  - Results from a Health Protection Surveillance Centre (HPSC) national sentinel screening study show a declining prevalence in the general adult population, but that the majority of cases identified were from people in Dublin born between 1965 and 1985.
- The magnitude of this decline in prevalence is larger than expected, but may, at least in part, be explained by the penetration of HCV treatment and that previous studies potentially overestimated HCV prevalence. However, the applicability of this new evidence is impacted by issues relating to study design and sample representativeness.
- At prevalence figures observed in recent studies, birth cohort testing for HCV would not be cost effective. Given potential for regional variation, it is possible that birth cohort testing would be cost effective in areas where prevalence is higher. It may be possible to identify a narrower cohort, on the basis of the age and geographical distribution of prevalent cases, in whom birth cohort testing would be cost effective.

- Although not the subject of the HTA, antenatal HCV testing is likely to be cost effective if the results of the antenatal HCV prevalence study are broadly applicable at a national level.
- In summary, given the findings from these prevalence studies and the high costs associated with birth cohort testing, a national birth cohort testing programme is unlikely to be cost effective. Consideration could however be given to universal antenatal HCV testing, subject to regular review of the costs and consequences relative to risk-based testing.

1 Overview

In July 2021, HIQA published a health technology assessment (HTA) of birth cohort testing for hepatitis C.[1] The HTA was undertaken following the publication of an Irish National Clinical Guideline for Hepatitis C Screening that conditionally recommended offering one-off testing to people in Ireland born between 1965 and 1985 (that is, birth cohort testing), subject to the outcome of a full HTA.[2] The 1965-1985 cohort was selected based on national epidemiological data which showed that the prevalence of hepatitis C in Ireland was highest in this group.[2-4]

Since the publication of HIQA's HTA, three studies[5, 6] have been conducted which provide additional information on the prevalence of undiagnosed hepatitis C virus (HCV) infection in Ireland. This short report summarises these studies and outlines their impact on the HTA's findings and advice. The published HTA is summarised in section 2, the new prevalence data are described in section 3 and the impact of this evidence on the HTA's findings is outlined in section 4. Given the resource implications associated with the potential introduction of birth cohort testing, the short report focuses on the estimates of cost effectiveness.

2 Summary of published HTA

2.1 Birth cohort testing for HCV

Hepatitis C is a blood-borne virus that predominantly affects the liver and commonly causes progressive liver disease.[7] The progression of chronic HCV infection is often asymptomatic and slow, with people that are chronically infected potentially not presenting with symptoms for up to several decades following initial virus acquisition.[8] In the absence of treatment, this can lead to the accumulation of liver scarring and contribute to the development of severe complications, such as liver cirrhosis and hepatocellular carcinoma (HCC), which can result in liver failure-related mortality.[9] Within the last 10 years, safe and effective therapies have become available for those that are diagnosed with chronic HCV infection.[8, 10, 11]

In Ireland, testing for HCV is routinely offered to people according to established risk criteria (such as those who have ever injected unprescribed or illicit drugs, and people on renal dialysis) and people that have symptoms of chronic HCV infection. Birth cohort testing involves offering one-off testing for HCV infection to people born during a particular period of time where no prior ascertainment of risk is undertaken. Rather, for this cohort, there is evidence (such as epidemiological trends) of an elevated risk of exposure relative to the rest of the general population.

2.2 HTA purpose and methods

The overarching aim of the HTA was to establish the clinical, cost effectiveness and budget impact of offering testing to all people in Ireland born between 1965 and 1985 to inform decision-making. The HTA included:

- a description and assessment of the diagnostic tests for detecting HCV and the first-line treatments available in Ireland
- a review of the epidemiology of HCV in Ireland (including estimation of prevalence within the 1965-1985 birth cohort)
- systematic reviews of the diagnostic test accuracy of using dried blood spot samples for diagnosis of chronic HCV infection and of the cost effectiveness of population-based approaches to HCV testing
- an economic analysis to estimate the cost effectiveness, resource implications and budget impact of birth cohort testing for HCV in Ireland
- assessments of the organisational and ethical issues associated with the decision of whether or not to introduce birth cohort testing for HCV in Ireland.

As part of the HTA, HIQA convened an Expert Advisory Group (EAG) comprising representation from relevant stakeholders to inform and guide the process, provide expert advice and information, and to provide access to data where appropriate. The complete draft report was reviewed by the EAG prior to being made available for targeted and public consultation to provide interested parties the opportunity to comment on the draft report before it was finalised.[12] A statement of outcomes report, summarising feedback received during the six-week public consultation and changes made to the report in response to this feedback, was also published.[1]

2.3 Economic model and prevalence estimates

An economic model, comprising a closed-cohort decision tree and Markov model hybrid, was developed to estimate the cost effectiveness and budget impact of introducing birth cohort testing in Ireland. The cost-utility and budget impact analyses were conducted from the perspective of the HSE over lifetime and five-year time horizons, respectively. These analyses were conducted in line with national HTA guidelines.[13, 14]

In the economic model, systematic and opportunistic birth cohort testing programmes, each implemented over a four-year timeframe, were compared with the current approach of risk-based testing. Systematic testing comprised inviting all patients in the birth cohort to attend a general practitioner (GP) appointment specifically to receive HCV testing. Opportunistic testing comprised offering testing to people that are already attending a GP consultation for another purpose. In both

cases, it was assumed that a blood draw would be performed by a GP or GP practice nurse to test for HCV. Antibody and reflex antigen tests would then be performed sequentially on the patient's blood sample to confirm viraemic infection. Only patient samples that test positive on the anti-HCV antibody test would undergo the antigen test.

Model inputs were derived from a variety of publicly available national and international sources. The prevalence of chronic HCV infection was derived from a 2017 cross-sectional study and estimated to be 1.0% in the birth cohort.[15] This study was based on a random sample (n=3,795) of residual sera from the adult general population in Ireland collected by the National Virus Reference Laboratory (NVRL) between April 2014 and February 2016. To estimate the prevalence of chronic HCV infection in the 1965-1985 birth cohort, an approximation method was applied to the estimates reported by this study and the prevalent population was modelled forward to 2021, with adjustment for incidence and mortality in the intervening years following the study.[3, 16, 17] This study was subject to some important potential risks of bias:

- Over-representation – 60% of the study samples were from the HSE East area, which was found to be the highest prevalence area; 36% of the total Irish adult population live in this area.
- Risk of viral infections – although effort was made to exclude specimens relating to typical HCV risk factors (including those from drug treatment clinics or sexually transmitted infection (STI) clinics, hepatology or infectious disease services, or from asylum seekers) and those sent specifically for HCV testing or STI screening, 80% of specimens were diagnostic samples which, having been submitted to the NVRL for analysis, are likely to have risk factors for viral infections.
- Imprecision – the prevalence estimates were subject to a large degree of uncertainty due to the small number of observed chronic HCV infections (n=33 of 3,795 samples).

2.4 Key findings from the HTA

The economic evaluation found that the introduction of birth cohort testing (whether systematic or opportunistic) would lead to increased costs and benefits, with systematic testing yielding the largest benefit of the modelled alternatives. The incremental cost-effectiveness ratios (ICERs) for both systematic and opportunistic birth cohort testing were under €10,000 per quality-adjusted life year (QALY) gained, relative to the next best alternative. This suggested that testing was cost effective given a willingness-to-pay (WTP) threshold of €20,000 per QALY gained typically used in Ireland.

Compared with no birth cohort testing, the incremental budget impact of introducing systematic birth cohort testing and opportunistic birth cohort testing was estimated at €65 million and €44 million, respectively. It was found that the introduction of systematic or opportunistic birth cohort testing would present logistical challenges for the health system, particularly for primary care and hospital laboratories.

The economic model's estimates were most sensitive to changes in the uptake rate of testing (estimated at 41%), prevalence of undiagnosed chronic HCV infection (estimated at approximately 1%), the background rate of detection and disease progression rates. The univariate threshold analysis demonstrated that birth cohort testing would become less cost effective with reductions in the prevalence of chronic HCV infection.

2.5 Advice to Minister for Health

HIQA's advice to the Minister noted that there was potential for a significant cohort of undiagnosed people in the 1965-1985 birth cohort. Accordingly, HIQA's analysis demonstrated that a birth cohort testing programme would be a cost-effective use of resources, but would also require a significant upfront investment.

Given uncertainty surrounding the prevalence of undiagnosed chronic HCV infection in the target cohort and concerns regarding feasibility, HIQA advised consideration be given to an initial pilot programme. HIQA's advice also noted that further research (such as surveying members of the general public) could also be considered to reduce uncertainty around the likely test uptake rate.

3 New prevalence data

3.1 Description and findings of new studies

Three studies have been conducted and published that provide additional evidence on the prevalence of HCV infection in Ireland. These studies are described below in order of their relevance to the HTA:

- Birth cohort study – a national study of HCV prevalence in the 1965-1985 birth cohort by the National Hepatitis C Treatment Programme (NHCTP) and NVRL (based on data collected between March 2021 and May 2022).[6]
- HPSC sentinel screening study – a national study of HCV prevalence in the adult population by the NHCTP, the Health Protection Surveillance Centre (HPSC) and the NVRL (data collection from the second half of 2022 to the first quarter of 2023).[6]

- Antenatal study – a Dublin-based study (published in 2021) of routine screening for hepatitis C in pregnant women by the NHCTP and the NVRL (data collected in 2018).[5]

Birth cohort study

This study was undertaken by the NHCTP to address the uncertainty surrounding the prevalence of chronic HCV infection in the 1965-1985 birth cohort.[6] It comprised an initial pilot study in which residual sera were collected from samples submitted by GPs to the biochemistry laboratory in St. Vincent's University Hospital for blood tests in people born between 1965 and 1985. The samples were irreversibly anonymised and transferred to the NVRL for HCV analysis by batch testing. This pilot study was then expanded to laboratory samples from other major hospitals to provide a nationally representative prevalence estimate.

A total of 6,080 samples were collected comprising between 499 and 1,050 samples from each of eight hospitals (three Dublin-based, one from each of Cork, Kilkenny, Limerick, Sligo and Waterford). Of these, 27 samples (0.44%) were anti-HCV antibody positive and only two (0.03%; 95% CI: 0.01% to 0.13%) were HCV antigen positive.

HPSC sentinel screening study

This study was undertaken to generate additional information regarding the prevalence of chronic HCV infection in the adult population in Ireland, including in the 1965-1985 birth cohort.[6] The study was based on HCV testing of residual sera in GP-sourced specimens from acute biochemistry laboratories that had undergone testing for SARS-CoV-2 antibodies as part of the National Serosurveillance Programme (NSP). Demographic data including age, gender and location were available for each sample collected as part of this study.

Data collection and analysis were completed in the first half of 2023. Data were collected for 8,240 samples tested. Of these, ten (0.12%) tested HCV antigen positive. When limited to the birth cohort (n=3,267), six of the samples were positive, giving a prevalence of 0.18% (95% CI: 0.08% to 0.41%) in those born between 1965 and 1985.

Antenatal study

This published study was undertaken to estimate how many pregnant women with HCV infection may be undiagnosed by the current risk factor-guided screening approach used in antenatal settings in Ireland.[5] The study involved testing stored blood samples collected in 2018 from pregnant women who had been screened for the hepatitis B and or human immunodeficiency viruses, but not HCV, in the National

Maternity and the Rotunda Hospitals in Dublin. Of the 4,655 samples tested, 20 (0.43%) samples were anti-HCV antibody positive and five (0.11%; 95% CI: 0.04% to 0.26%) were HCV antigen positive. The two main findings from this study were that there were almost as many undiagnosed chronic HCV infections as were identified by risk factor-guided screening; and that the prevalence of HCV infection was estimated to have reduced by 65% since the publication of a study undertaken in the same hospitals between 2001 and 2004.[18]

3.2 Findings of new studies in the context of existing evidence

Using the prevalence reported by the 2017 cross-sectional study as the basis for its estimates,[15] HIQA's HTA estimated that the prevalence of undiagnosed chronic HCV infection within the 1965-1985 birth cohort was approximately 1%. However, the results of the more recent birth cohort and sentinel screening studies suggest that there has been a marked decrease in the prevalence of undiagnosed chronic HCV infection (to less than 0.2%) since the publication of the 2017 study. Notably, when comparing prevalence of exposure to HCV relative to chronic HCV infection, there were 13.5 times more antibody-positive samples than antigen-positive samples in the birth cohort study compared with only 1.6 times more in the 2017 study. When considering specific demographics, there were 1.7 times more antibody-positive samples in males than females in the birth cohort study compared with 2.8 times more in the 2017 study.

The antenatal study produced a prevalence estimate of 0.11% in a cohort of women. Given that the other two studies found a prevalence approximately 1.7 times higher in men than women, had the antenatal study included men, it may have found a prevalence closer to 0.14%; this would still be lower than the prevalence estimate for the birth cohort in the sentinel screening study. A pooled estimate of prevalence based on a random-effects meta-analysis of the three studies suggests a prevalence of 0.10% (95% PI: 0.03 to 0.34%). The upper bound for the estimate is well below the point estimate of the 2017 study.

There are multiple potential reasons for these dramatic changes. Firstly, given the potential sources of bias outlined in section 2.3, the prevalence of HCV infection in the general population may have been overestimated in the 2017 study. Secondly, the findings of the more recent birth cohort study may indicate the level of treatment penetration and or spontaneous resolution of viral infection in the prevalent population. This rationale is supported by the low prevalence observed in the HPSC sentinel screening and antenatal studies,[5] which provide evidence of a consistent pattern of declining prevalence. It is also supported by the reduction in the proportion of individuals exposed to HCV that had ongoing chronic infection in the recent birth cohort study relative to the 2017 study. However, the recent study's findings may also be subject to applicability issues relating to the representativeness

of the sample. For example, data on risk factors and treatment experience were not available for the samples collected, which creates challenges in drawing clear inferences from the results. Additionally, as the data are based on GP-collected samples submitted for blood tests, they may not reflect the potential yield from an opportunistic birth cohort testing programme. This is because the samples were collected from people who were already undergoing blood tests as opposed to people attending their GP for another reason and opting in to HCV testing. Accordingly, the study also does not provide direct information on the potential yield from a systematic testing programme. Finally, as with other studies based on residual sera, the results are based on samples which had sufficient volume for additional testing (other than for the purpose originally collected) and the impact of this on study findings (that is, how they would compare to samples which were excluded due to insufficient volume) is not known.

Findings from the HPSC sentinel screening study indicate that the majority of cases of undiagnosed chronic HCV infection are in the 1965-1985 birth cohort and that prevalence within the birth cohort may be somewhat higher than that estimated in the NHCTP and NVRL's birth cohort study. The HPSC sentinel screening study may provide an opportunity to identify a narrower birth cohort, on the basis of the age and geographical distribution of prevalent cases. With regards to the wider general population, the current evidence points to a declining prevalence of chronic active HCV infections and demonstrates clear progress towards Ireland's HCV elimination targets.

3.3 Updated economic evaluation

The economic model from the HTA was used to explore the impact of the new prevalence information on the cost-effectiveness of the introduction of birth cohort testing. The parameters and assumptions from the previously published economic evaluation were left unchanged. Based on the 2017 birth cohort study, the prevalence in the birth cohort was estimated at 1.0%. The more recent studies have generated estimates of between 0.03% and 0.18%. The economic model was run for a wide range of prevalence values from 0.0% to 1.0% to determine at what prevalence a birth cohort testing programme would be considered cost effective according to willingness-to-pay thresholds of €20,000/QALY and €45,000/QALY.

For opportunistic birth cohort testing, a minimum prevalence of 0.38% would be required for the programme to be considered cost effective at a willingness-to-pay threshold of €20,000/QALY (Table 3.1). The required minimum prevalence for cost effectiveness reduces to 0.19% if the willingness-to-pay threshold is €45,000/QALY. The necessary minimum prevalences for systematic testing to be considered cost

effective relative to opportunistic testing are 0.42% at €20,000/QALY and 0.21% at €45,000/QALY.

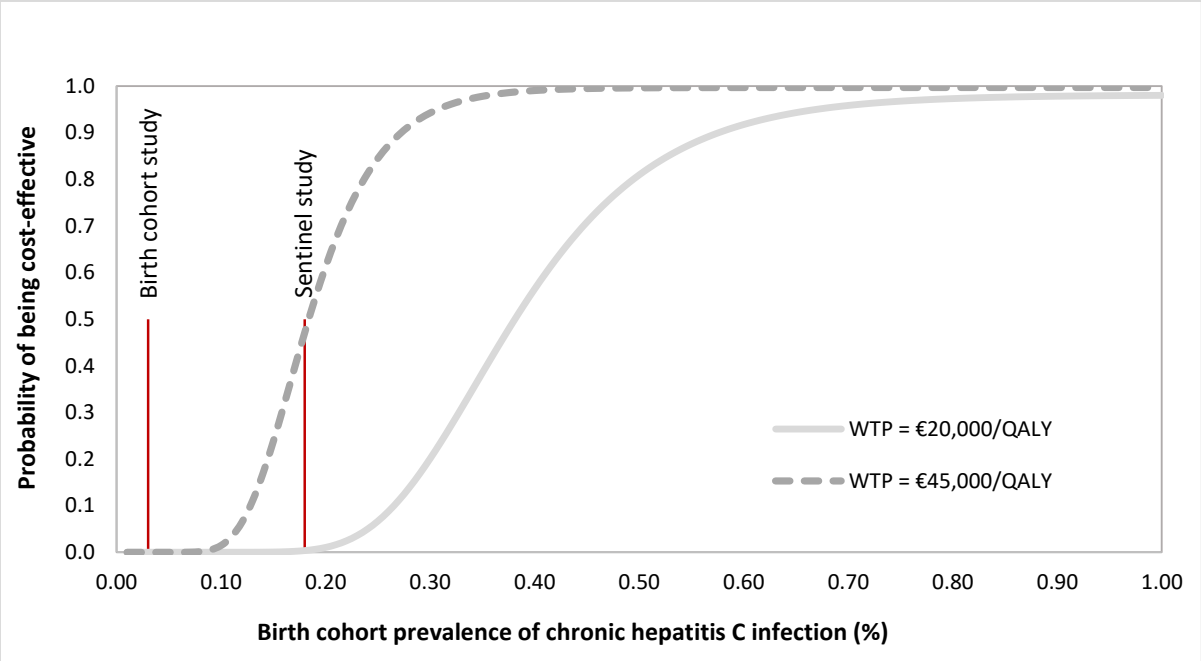
Table 3.1 Prevalence at which testing has a probability of greater than 0.5 of being cost effective

Subgroup	Willingness-to-pay threshold	
	€20,000/QALY	€45,000/QALY
Opportunistic vs no birth cohort testing		
1981-1985	0.37%	0.18%
1976-1980	0.36%	0.18%
1971-1975	0.38%	0.18%
1965-1970	0.38%	0.19%
Overall	0.38%	0.19%
Systematic vs opportunistic birth cohort testing		
1981-1985	0.40%	0.20%
1976-1980	0.39%	0.19%
1971-1975	0.44%	0.22%
1965-1970	0.42%	0.21%
Overall	0.42%	0.21%

Key: QALY – quality-adjusted life year.

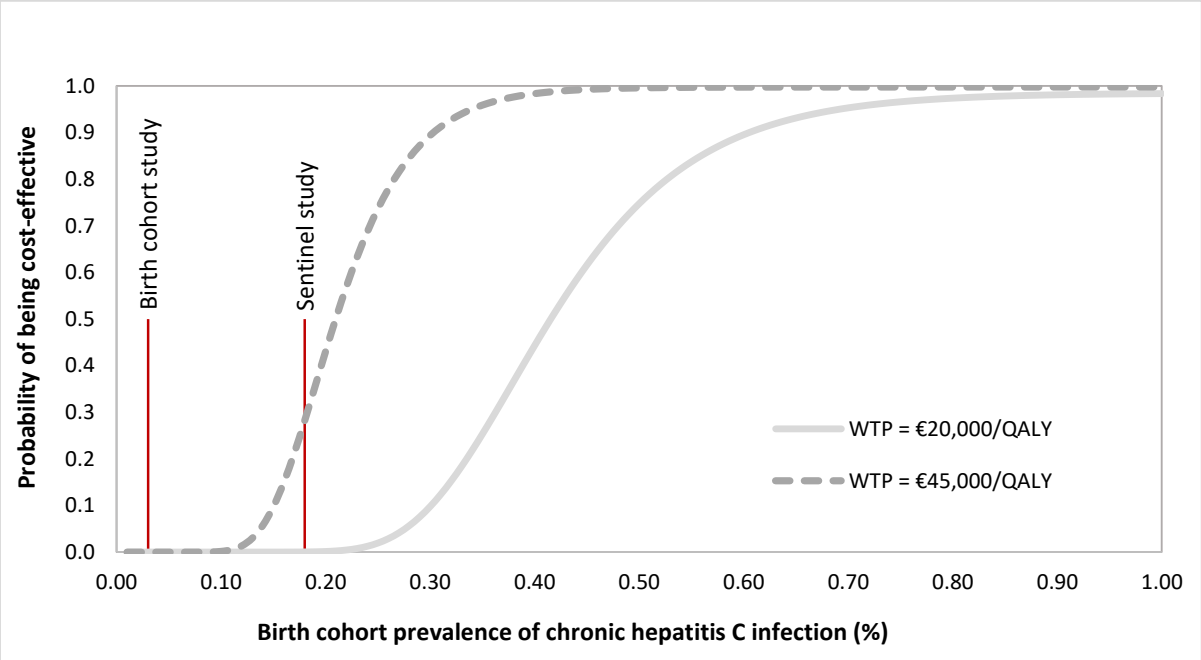
To put these figures into context, the results of the sentinel screening study produced the highest estimate of prevalence in the birth cohort at 0.18%. At that prevalence, opportunistic birth cohort testing could be considered cost effective at a willingness-to-pay threshold of €45,000/QALY (Figure 3.1), but not at €20,000/QALY (Figure 3.2). With a prevalence of 0.18%, systematic birth cohort testing would not be considered cost effective compared with opportunistic testing.

Figure 3.1 Probability of being cost effective as a function of prevalence: opportunistic versus no birth cohort testing



Key: QALY – quality-adjusted life year; WTP – willingness-to-pay threshold.

Figure 3.2 Probability of being cost effective as a function of prevalence: systematic versus opportunistic birth cohort testing



Key: QALY – quality-adjusted life year; WTP – willingness-to-pay threshold.

The birth cohort testing programmes modelled were based on a blood sample being taken as part of a GP visit. An estimated €50 cost of a visit was incorporated into the overall testing cost. In the case of antenatal testing, it could leverage off the blood sample collection carried out for existing tests, which would potentially reduce the cost of testing by €50 per person and also support high uptake. At the prevalence observed in the antenatal study, systematic antenatal HCV testing would be cost effective relative to opportunistic testing.

4 Updated advice to the Minister for Health

At the time the HTA of birth cohort testing for HCV was undertaken by HIQA, the best available evidence on the prevalence of undiagnosed chronic HCV infection in Ireland was a 2017 cross-sectional study using data from the general population collected between 2014 and 2016.[15] In the HTA, these data were extrapolated forward to estimate the prevalence in 2021, which was subject to a substantial degree of uncertainty. As part of its conclusions, HIQA advised that consideration should be given to an initial pilot programme. This could help address uncertainty surrounding the prevalence of undiagnosed chronic HCV infection in the target cohort and concerns regarding the feasibility of reflex testing.

The NHCTP acted to address the uncertainty regarding the prevalence of HCV by conducting a study in the 1965-1985 birth cohort and a sentinel screening study in the general adult population.[6] As outlined in HIQA's HTA, the prevalence of chronic HCV infection is a key driver of the cost effectiveness of birth cohort testing. The results from these studies, along with the findings of a study in the antenatal population in Dublin, provide evidence from a variety of settings which indicates that the prevalence of undiagnosed chronic HCV infection is declining nationally. The magnitude of this decline is larger than expected, but may be partially explained by the penetration of treatment for HCV and differences in the methods underlying the respective studies (for example, method of sampling and sample representativeness).

The updated economic evaluation indicates that, at the prevalence levels found in the more recent studies, a national birth cohort testing programme would not be a cost-effective use of resources. Although the three available studies differ in their prevalence estimates, neither systematic or opportunistic birth cohort testing would be considered cost effective based on their findings at a willingness-to-pay threshold of €20,000/QALY.

Including HCV testing as part of existing antenatal testing may be cost effective depending on the prevalence in that subgroup. The antenatal study found a prevalence of 0.11% based on two Dublin hospitals. The prevalence of HCV infection has generally been found to be higher in Dublin, so it is likely that the study results

over-estimate prevalence nationally. However, antenatal testing may also be cost effective at a lower prevalence.[16] From a logistical perspective, antenatal testing would entail testing approximately 60,000 people a year, which is substantially less than the estimated 1.5 million people in the birth cohort. An accurate estimate of the cost effectiveness of antenatal HCV testing would benefit from nationally representative data on the prevalence in this cohort and adaptations to the economic model to reflect this population. It may be pragmatic to consider universal antenatal HCV testing which includes systematically offering testing to all pregnant women as part of their routine antenatal care. If implemented, such an approach should be subject to regular review to determine if it is warranted nationally, or whether the choice between universal and risk-based testing should be made according to the local context.

The recent birth cohort and sentinel screening studies confirm the findings of the 2017 study that demonstrated substantial regional variation in the prevalence of HCV infection. The results indicate that the majority of cases of chronic HCV infection are in the Dublin area, and that prevalence is higher in males. It is possible that birth cohort testing would be cost effective in geographic areas where prevalence is higher. Therefore, areas that have better prospects of a high case yield from testing could still be targeted with birth cohort testing. In addition, implementation of a regionalised birth cohort approach guided by up-to-date prevalence information may overcome some of the logistical issues (such as the feasibility of reflex testing) previously identified. Antenatal testing is likely to be cost effective if the results of the antenatal prevalence study are broadly applicable nationally.

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