



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cálíocht Sláinte

Report on the results of the public consultation on the draft Health Technology Assessment of Birth Cohort Testing for Hepatitis C

June 2021

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Introduction

An Irish National Clinical Guideline for Hepatitis C Screening was endorsed by the Minister for Health in 2017.⁽¹⁾ It included a conditional recommendation to offer once-off testing to all people in Ireland born between 1965 and 1985 (that is, birth cohort testing), subject to the outcome of a full HTA. Following publication of the recommendation, the Health Information and Quality Authority (HIQA) undertook a health technology assessment (HTA) of birth cohort testing for hepatitis C in Ireland. The aim of the HTA was to establish the clinical, cost-effectiveness and budget impact of offering once-off testing to all people in Ireland born between 1965 and 1985.

The draft HTA report was published for public consultation in March 2021.⁽²⁾ This Summary of Outcomes report summarises the feedback received during the public consultation period and outlines HIQA's responses to the issues raised, including any changes that were made to the report as a result.

Methods

The aim of the public consultation was to obtain feedback on any issues that may not have been adequately addressed in the draft HTA report and, based on the feedback, to expand coverage of material requiring further clarification.

The consultation process

The draft HTA was published on the HIQA website on 16 March 2021 and was available for public consultation until 27 April 2021. The consultation webpage contained a link to the draft report, a link to the online survey (using the Crowdsignal platform) for online submission of feedback, and a consultation feedback form that could be downloaded. To ensure wide accessibility, feedback could be submitted via email or an online survey and notifications of the public consultation were posted via social media sites (Twitter, Facebook, Instagram and LinkedIn) on a weekly basis.

A press release was issued at the beginning of the consultation period, and the findings of the draft HTA were reported in the media. The press release and tailored email requests for feedback were sent to a targeted list of stakeholder organisations (individuals and organisations with relevant expertise and those who are likely to be affected by the proposed introduction of a birth cohort testing programme). This included relevant stakeholders within the Health Service Executive (HSE), organisations that represent individuals, families or healthcare professionals that may be affected by the proposed introduction of a birth cohort testing programme.

Feedback form

The template for submission comprised a general request for feedback to enable respondents to flexibly provide their feedback across any aspects of the report that needed to be addressed. A copy of the submission template is provided in Appendix A.

Synthesis

Each submission was recorded (excluding personal information), read in its entirety and, where appropriate, broken down into individual components. In cases where a question was skipped by the respondent, it was assumed that there were no issues of concern.

The submissions were stratified according to whether they were from members of the general public or stakeholder organisations. Feedback considered broad in nature was described narratively. Feedback relating to specific content in the draft report was presented in tabular format alongside direct responses to the feedback. To enhance readability and interpretation, specific comments pertaining to the content of the report were categorised under the following headings:

- target population and project scope
- implementation
- capacity implications and ethical considerations
- clinical governance
- data protection.

Necessary changes to the report were made and highlighted when required.

Results

Overall, 28 unique and complete submissions were received during the public consultation period. Two incomplete survey responses and one duplicate response were also received. As the incomplete responses contained no feedback they have been excluded from the summary below. Twenty-five of the 28 submissions were submitted via the online survey and four were received by email. Of the 28 submissions, 21 were from individual members of the general public and seven were submitted on behalf of stakeholder organisations or institutions.

Summary of feedback

Members of the general public

Twenty-one responses were received from members of the general public. Twenty of these were from people in Ireland and one was from the UK.

Four respondents expressed their view that testing represented an opportunity for prevention of HCV-related sequelae. Two respondents stated their belief that buy-in from the 1965 to 1985 birth cohort would be high, if implementation is supported by an appropriate public education and awareness campaign given the availability of highly effective treatment. One respondent disclosed that they were in favour of the introduction of testing having worked as a nurse for 15 years, during which, they sustained needle stick injuries, but had not been tested.

Two respondents described anecdotal experience of the personal impact that chronic HCV infection can have on one's life, with specific reference to the receipt of contaminated anti-D immunoglobulin, and the serious liver-related complications that may develop, in otherwise healthy people, in the absence of testing and treatment. The verbatim of these responses is presented in Table 1.

Table 1. Verbatim of personal experiences with HCV*

Number	Comment
1	"Having read through the evidence from other age cohort studies and taking economic factors into consideration I am in favour of birth cohort screening for Hepatitis C. As a daughter of a woman infected with hepatitis C via contaminated anti-D I have seen the damage this virus can cause to otherwise healthy people. Screening makes sense as otherwise the problem may be compounded through lack of treatment since it is often a long time before symptoms arise and these symptoms may be vague."
2	"I heard this on the radio. In 1984 when I was 14, I developed hepatitis C and so did my sister. In 2014, 30 years later, my dad who never drank or smoked developed liver cancer and passed away. I really feel there is a link that my dad also developed undiagnosed hepatitis c at the time and that this resulted in him developing liver cancer 30 years later."

* Responses have been slightly amended to correct for minor grammatical errors and or typos.

Stakeholder organisations or institutions

Seven responses were received on behalf of stakeholder organisations or institutions.

The responses were from:

- Gilead Sciences
- Irish Prisons Service
- Roche Diagnostics Limited
- the Hepatitis C Partnership
- the Irish College of General Practitioners (ICGP)
- the National Cancer Control Programme (NCCP)
- UISCE – Advocacy for People who use Drugs.

The Irish Prison Service expressed support of the HTA's findings, recognising the importance of the diagnosis and treatment of HCV in the prison setting. The Irish Prison Service also stated the view that birth cohort testing would capture a significant proportion of the current intravenous drug user population and complement its existing direct observation policy supervised by registered nurses. This policy entails the direct administration of prescribed medications to patients in correctional facilities.

Similarly, the NCCP expressed support in favour of the introduction of birth cohort testing for HCV to allow for the identification and delivery of available, effective treatments which ultimately will prevent the development of cancer. As noted by the NCCP, HCV infection is a risk factor associated with hepatocellular carcinoma (HCC) and Non-Hodgkin's Lymphoma (NHL).^(3, 4) In 2020, a report by the National Cancer Registry Ireland (NCRI) found that the risk of developing liver cancer and NHL is up to 24 times and two times higher, respectively, in those that develop chronic HCV infection compared with those that do not have infection.⁽⁴⁾ Given the association between HCV and the development of HCC and NHL, the NCCP commented that the approach aligned with the National Cancer Strategy's focus on prevention of cancer.

Roche Diagnostics passed on information regarding the upcoming launch (planned for the end of 2021) of their Elecsys® HCV Duo, an immunoassay for the in vitro qualitative determination of HCV core antigen and antibodies to HCV in serum and plasma. Based on the feedback provided by Roche, the assay enables the simultaneous detection of anti-HCV and HCV core antigen from a single sample in two separate, parallel reactions. Roche Diagnostics® noted that this could facilitate the implementation of a simplified single-specimen testing algorithm. However, relevant clinical data have not yet been published and independent clinical validation will be required prior to adoption of standalone diagnostic tests within the testing algorithm. Therefore, Roche Diagnostics' Elecsys® HCV Duo is not considered further in the current HTA.

Gilead expressed support in favour of the introduction of birth cohort testing, noting that it could have a substantial impact in identifying more people who are currently living with HCV. However, Gilead also raised concerns regarding a lack of comprehensive data on HCV disease in Ireland and regarding Ireland's progress towards achieving the HSE's target of making HCV a rare disease by 2026.⁽⁵⁾ To combat these challenges, Gilead stated their belief that the State's health authorities need to implement all of the recommendations in the National Clinical Guideline published in 2017, including the prioritisation of screening for other at-risk groups.⁽¹⁾ Noting the HTA's finding that a birth cohort testing programme could initially adopt a pilot, which could be phased into wider practice over time, Gilead suggested that similar pilot programmes could be introduced to target other at-risk groups and gradually expanded thereafter.

The Hepatitis C Partnership, UISCE and the ICGP recognised the need for provision of a training module to ensure that GPs have the knowledge to deliver the patient-centred care required for HCV and that this care is provided in a compassionate and inclusive manner to encourage honest disclosure on the part of patients. The Hepatitis C Partnership and UISCE advocated the involvement of patients or peer workers in the development of the proposed training module. All three organisations also highlighted the strategic importance of an involved role during the planning of any proposed birth cohort testing programme to ensure its successful implementation.

Specific feedback relating to the content of the report received during the public consultation is presented in Table 2.

Table 2. Comments received on report content and responses

Comment	Response
Target population and project scope	
Inclusion of routes of transmission outside the PWID population. For example, those who acquired infection through sexual activities.	It is proposed that birth cohort testing would be provided to all people in Ireland born between 1965 and 1985, independent of risk factors, who accept an invitation to receive testing for HCV.
Clarification is needed on the inclusion criteria for those recently tested for HCV or those who may have undergone past treatment	It is expected that all people in the 1965 to 1985 birth cohort will be offered testing for HCV. As described in chapter 7.4.2: "Within the 1965-1985 birth cohort, there will be subgroups who, at the time of invitation to attend for testing, will have received HCV testing in the previous 12 months. These subgroups include (but are not limited to): patients known to have chronic HCV and those with test results consistent with having been previously exposed, but having cleared the virus; people that are currently active blood donors and have not experienced any type of HCV risk exposure since their most recent blood donation (since HCV testing is undertaken as part of the blood donation process); patients that have initiated immunosuppressant therapy (where HCV testing is often recommended at therapy initiation); and those that have received occupational-related testing (for example, healthcare workers). While these people will be invited to attend for testing, they may reasonably decline testing on the grounds that they are at low risk of infection and have been recently tested."
Does refusal to provide background information in terms of risk behaviour exclude patients from testing	Refusal to disclose risk behaviour will not exclude patients from birth cohort testing. It is proposed that birth cohort testing would be provided to all people in Ireland born between 1965 and 1985, independent of risk factors (see chapter 2.6), who accept an invitation to receive testing for HCV. Furthermore, the operation of a testing programme should be sensitive to the potential stigma associated with a diagnosis of HCV (see chapter 8.3).
Extend birth years of target cohort up to 1990, given people were still in receipt of contaminated blood products	The 1965-1985 birth cohort was identified in the 2017 National Clinical Guideline on the basis of national epidemiological information. ⁽¹⁾ As such, the clinical and cost-effectiveness of testing those born outside of the 1965-1985 age demographic has not been assessed in the current HTA. The HTA's Advice proposes that the performance of a potential testing programme is evaluated on an annual basis. Should a testing programme prove to be clinically significant and value-for-money, expansion of the target cohort could be considered in the presence of reliable prevalence estimates in other cohorts.
Can panel testing for other hepatitis strains be included given the prevalence of HBV in certain migrant populations	The scope of the current HTA was to assess the clinical and cost-effectiveness of offering HCV testing to people in Ireland born between 1965 and 1985. Therefore, offering HBV testing in addition to HCV testing has not been evaluated. Separately, several Irish studies have investigated the potential for offering testing for bloodborne viruses in particular settings. ⁽⁶⁻⁹⁾
Implementation	
Organisations for under-represented and vulnerable populations should be involved in the development of testing	The Advice arising from the HTA supports the view that, to maximise testing uptake and engagement, organisations which represent vulnerable and hard-to-engage population groups should be involved during the development of the implementation plan pursued by any proposed testing programme.

programme's clinical pathway to identify and engage these groups	
What motivations are going to be highlighted to encourage opt in organised testing follow up	A testing programme with in-built mechanisms for monitoring of follow-up and linkage to care is described in chapter 7.2. Mechanisms promoting information and awareness are outlined in chapter 7.5. Information provided as part of an invitation to participate in testing and treatment should be presented in a manner acceptable to varying levels of health literacy in the target cohort (see chapter 8.5)
What is the advised timescale in terms of access to treatment following a positive test and will patients be assured of local access	On foot of a decision to introduce a testing programme, the development of an implementation plan would be the responsibility of the HSE. As part of an implementation of a testing programme, quality standards should be established in relation to key performance metrics such as time to treatment (see chapter 7.2).
As per stipulations in the current community treatment guidelines all non-OST positive cases must be presented to the CAG for treatment. How will this impact access to treatment for those identified	On foot of a decision to introduce a testing programme, the development of an implementation plan would be the responsibility of the HSE. The implementation plan should consider the most appropriate way to provide access to treatment for patients with HCV identified by the testing programme.
The proposal to initiate a large pilot programme in Ireland East has merit. Early involvement with the fourteen existing 'research engaged' GP practices in Ireland East should be considered.	Clarification added to Chapter 7.7 to reflect that if a pilot programme is pursued, consideration should be given to early engagement with primary care stakeholders to inform its planning.
The COVID-19 pandemic has demonstrated that a substantial number of people don't have a GP. There is a need to identify a pathway to engage these people in the screening programme.	Not all members of the birth cohort will be registered with a GP and, as acknowledged in chapter 8.5, this may have equity implications for the implementation of birth cohort testing. However, it is unlikely that any other setting could provide better accessibility for those availing of birth cohort testing while also being acceptable for taking blood samples. To mitigate against potential inequities, alternative approaches to improve access for some hard to reach groups, such as the use of mobile phlebotomy clinics, could be considered. The development of alternative approaches for reaching population subgroups should be developed in collaboration with representative bodies of relevant stakeholder groups.
The timing of phlebotomy to ensure timely delivery of samples to the testing laboratory may be problematic in some areas.	Potential difficulties associated with the timely delivery of venous blood samples is acknowledged throughout the report. The use of dried blood spot samples may offer a potential solution to this challenge (see Appendix A).

<p>The resource implications around GP education for a national Hepatitis C programme via ICGP should be incorporated into any programme.</p>	<p>On foot of a decision to introduce a testing programme, the development of an implementation plan would be the responsibility of the HSE. As part of the implementation plan, the development of a GP education module should be considered alongside the potential opportunity cost from GPs' participation in the training.</p>
<p>Capacity implications</p>	
<p>More recent published evidence demonstrates that Irish general practice undertakes in excess of 30million consultations per annum. It is essential to include this most recent research data on GP workload in the HIQA report.</p>	<p>Acknowledgement of the findings of the cited study has been added to chapter 7, where appropriate.⁽¹⁰⁾</p>
<p>The suggestion that testing is undertaken "at their next GP appointment" is unlikely to effectively engage some males in the target cohort, many of whom visit their GP infrequently. The report states that such deferred consultations "Would potentially reduce displace care and testing costs." The workload is similar regardless of the context in which testing is undertaken.</p>	<p>The comment refers to a specific situation (described in chapter 8.5) in which a hybrid between systematic and opportunistic testing programmes could be adopted where a patient is invited to participate, but with the option of receiving testing at their next scheduled GP visit. This option is highlighted as a model by which the displacement of care could be reduced (when compared with a systematic programme that involves the initiation of a GP appointment specifically for the purpose of testing), where patients are given the option to receive testing at a future appointment scheduled for another purpose. In each situation, the processes governing patient testing and counselling are the same, but with the potential for one fewer GP appointment than would be necessary under a systematic programme.</p>
<p>The absolute number of additional consultations for the testing programme (1-1.5million, page 255) and inevitable impact on workload, with displaced/deferred activity is an important clinical and ethical consideration.</p>	<p>The potential introduction of birth cohort testing should be considered in light of the significant opportunity cost associated with its implementation and the uncertainties surrounding the prevalence of HCV in the birth cohort, uptake rate and feasibility of testing. As discussed in chapter 8.5, a more efficient approach would involve targeted testing of those within the birth cohort at higher risk of infection, but such an approach may not exist in the absence of a common exposure that can be easily identified.</p>
<p>The workload arising from positive and negative tests and managing</p>	<p>The workload arising from testing outcomes, should communication of test results be the responsibility of the GP, and in addressing patient concerns has now been acknowledged in chapter 7.4.2.</p>

patient concerns represents an additional unquantified workload.	
Overview of clinical pathway (Page 226): It is assumed that the programme will require a primary care consultation where a blood sample is obtained. This description does not adequately describe full extent of the roles and responsibilities of GP/nurse/practice team.	A more detailed description of the roles and responsibilities of the GP, nurse and practice team has been added to chapter 7.4.2 (where capacity implications are discussed). On foot of a decision to implement birth cohort testing, the roles and responsibilities of healthcare professionals involved in the delivery of birth cohort testing across the continuum of care should be clearly outlined in the proposed implementation plan and communicated to relevant stakeholders.
Data protection	
Explanation to patients of HCV in terms of being a notifiable disease	There is a legal obligation that all new cases of chronic HCV infection in Ireland are notified to the Medical Officer of Health/Director of Public Health, which in turn are provided to the HPSC on a weekly basis. The notifications are collated in the CIDR system, a confidential name-based surveillance system for managing infectious disease notifications in Ireland. Anonymised information obtained from notifications of HCV is published by the HPSC. A patient with HCV should be advised of the doctor's statutory obligation to provide certain personal details to the Medical Officer of Health/Director of Public Health. Notification of disease is not in contravention of data protection legislation. Sufficient information (for example, information leaflets online and Freephone services) should be provided to patients to ensure awareness of medical practitioners' legal obligation of notification.
Where will patient data be stored and who will have access to it	Development and management of the population frame and any other registry containing patient data must comply with the relevant legislation on data protection including GDPR (see chapter 7.2). ⁽¹¹⁾ Any patient data collected as part of a testing programme must comply with GDPR and the relevant well-established processes for the management and storage of patient health data.
Clinical governance	
The communication of test results is acknowledged as 'a critical component' of the testing programme. It is anticipated that 140-160,000 blood tests would be undertaken per annum: GPs will have consultations with many additional patients who may decline testing. This very substantial additional workload is not considered in the report.	In the CUA and BIA, it was assumed that, following an invitation to receive testing, all patients who attend their general practice agree to undergo testing. In practice, patients may reasonably decline the offer of testing during a GP visit. The number of patients that will attend their GP appointment and subsequently undergo testing is challenging to quantify given the lack of a directly applicable existing testing programme. A description of this limitation of the analysis has been added to chapter 6.6.2. As there is considerable uncertainty surrounding the uptake rate of testing, its influence has been thoroughly investigated via sensitivity analysis and the estimated resource implications presented (see chapter 6.5).

<p>It is unclear how results will be communicated to the patient. This is a very important clinical governance issue and raises ethical considerations. Communication of both positive and negative results is important. The clinical governance of test results must be clearly outlined.</p>	<p>On foot of a decision to introduce a testing programme, responsibility for communicating test results to programme participants should be clearly defined by the HSE. For existing screening programmes in Ireland, responsibility for communication and follow-up differs by programme (see chapter 7.2).</p>
<p>Ethical considerations</p>	
<p>It is not clearly defined if contact tracing of Hepatitis C should/will be undertaken, and in what circumstances. This requires clear clinical guidance.</p>	<p>Contact tracing of notified HCV cases should be undertaken as per current best-practice procedures and protocols. As described in chapter 8.3.2, it is important to ensure that contact tracing is not perceived as a threat to the infected individual, such that they may be reluctant to engage with health services. These factors should be considered during the planning of targeted education interventions and the development of an implementation plan, should birth cohort testing be introduced.</p>
<p>Some patients may choose not to attend their GP if they perceive that Hepatitis C testing will be promoted/undertaken. This is an ethical consideration to avoid patient coercion to participate in testing.</p>	<p>Participation in the proposed programme is entirely voluntary and on the basis of informed consent. All patients should have full autonomy to decline the invitation of testing, including during GP attendance. If a systematic birth cohort testing programme is introduced, it is anticipated that people from the 1965-1985 birth cohort would be invited to attend general practice specifically to undergo HCV testing. Public awareness of the availability of effective and safe diagnostics and treatment for HCV in addition to awareness of the clinical consequences of undiagnosed chronic HCV infection should be in place to ensure that uptake is maximised within the birth cohort.</p>

Key: BIA – budget impact analysis; CAG – Health Service Executive clinical advisory group; CIDR – Computerised Infectious Disease Reporting; CUA – cost utility analysis; GDPR – General Data Protection Regulation; GP – general practitioner; HBV – hepatitis B virus; HCV – hepatitis C virus; HPSC – Health Protection Surveillance Centre; HSE – Health Service Executive; ICGP – Irish College of General Practitioners; OST – opioid substitution therapy; PWID – people who inject drugs.

* Comments have been edited to reflect the key points of relevance to the HTA.

Changes to the report from the consultation process

The following changes were made to the draft report in response to comments and feedback received through the consultation process:

- Additional data in relation to the burden of liver cancer in Ireland, provided by the NCCP, has been included in chapter 3.
- An acknowledgement has been added to chapter 6.6.2 to note that the modelled analysis did not account for patients attending their GP consultation and declining the offer of HCV testing.
- The need for the involvement of representative stakeholder organisations (such as ICGP) and local organisations that represent vulnerable and hard-to-reach population groups during the development of the implementation plan for any proposed birth cohort testing programme in 7.2.
- The workload arising from positive and negative testing outcomes, in terms of communication of test results and addressing patient concerns, has been acknowledged in chapter 7.2.1 and 7.4.2.
- A brief overview of the roles and responsibilities of the GP, nurse and practice team has been added to chapter 7.3.1.
- Findings from a study published in 2021⁽¹⁰⁾ describing current activity levels of GPs in Ireland have been cited in chapter 7.4.2.
- The need to consider early engagement with primary care stakeholders if a decision is taken to include a pilot programme, so to inform its planning (chapter 7.7).
- The need for the development of a training module for GPs to support implementation of birth cohort testing is highlighted in the Executive Summary and Advice to the Minister.

In addition to the changes made above, the Advice to the Minister, an Executive Summary and a plain language summary are presented in the final report. Every attempt has been made in the plain English summary, the Executive Summary and the Advice to the Minister to further emphasise issues of importance that were highlighted during the consultation process.

References

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Appendix A – Copy of submission feedback form



Health Technology Assessment of a birth cohort testing programme to diagnose Hepatitis C

For public consultation

Consultation Feedback Form

Your feedback is very important to us. We welcome responses to all questions as well as any additional comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The closing date for consultation is 5pm on Tuesday 27 April 2021

You may email a completed form to us consultation@higa.ie . You may also complete and submit your feedback online at <http://higa.survey.fm/hta-of-birth-cohort-testing-for-hepatitis-c>

About you

Name	
You or your organisation's country	
Today's Date	

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

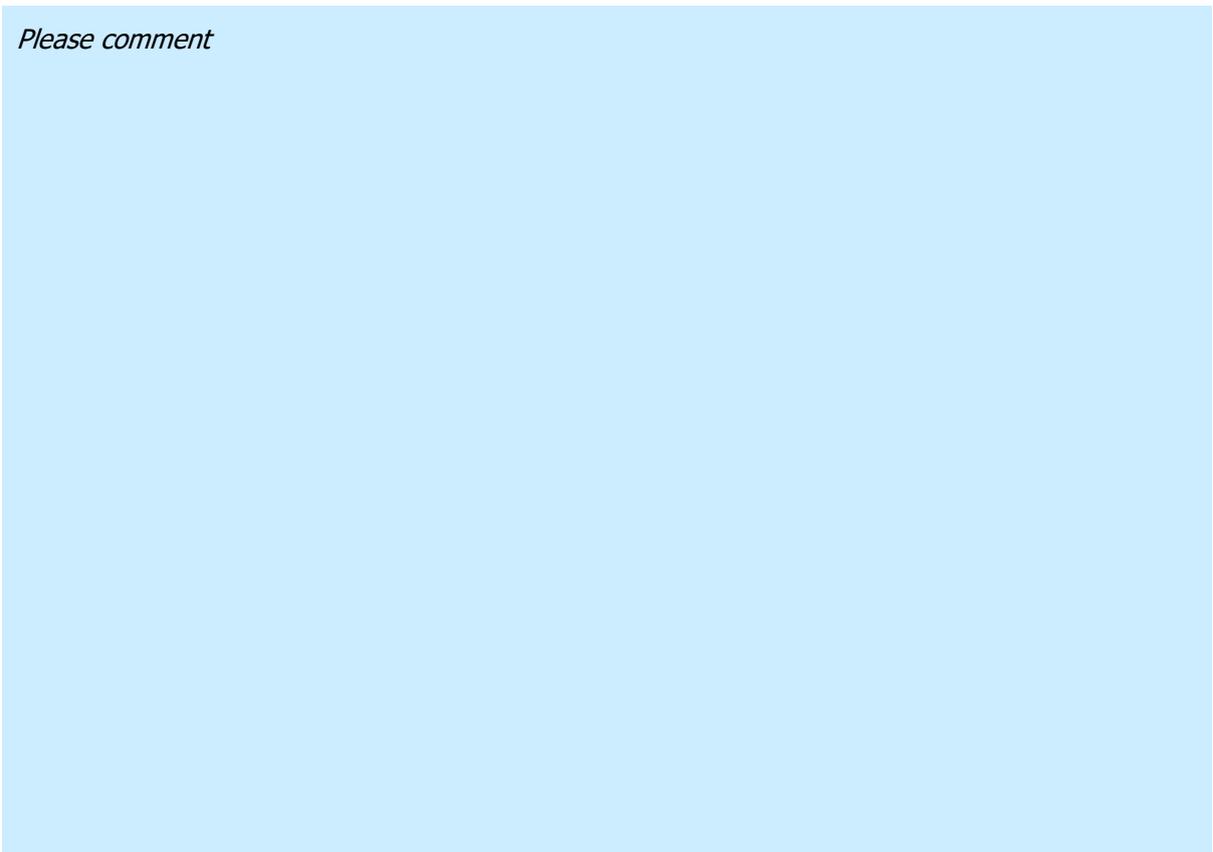
Are you replying in a personal capacity or on behalf of an institution or organisation?

- Personal capacity
- On behalf of an institution
- On behalf of an organisation

Part 2

Please outline any general or specific feedback on the documents. In your response, where applicable, please specify the section to which you are referring.

Please comment



Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on <http://www.hiqa.ie>.

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email:



consultation@hiqa.ie

or complete it online at: <http://hiqa.survey.fm/hta-of-birth-cohort-testing-for-hepatitis-c>

If you have any questions you can contact the consultation team emailing consultation@hiqa.ie.

**Please return your form to us either by email or post before
5pm on Tuesday 27 April 2021**

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

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