Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Statement of Outcomes on the Results of the Public Consultation on the Updated National Guidelines for Conducting Economic Evaluation and Budget Impact Analysis in Health Technology Assessments

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body 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.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, 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 of Social Services 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 permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social 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 and social care services, with the Department of Health and the HSE.

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Introduction

The Health Information and Quality Authority (HIQA) has a statutory remit to evaluate the clinical and cost effectiveness of health technologies, and provide advice to the Minister for Health and to the Health Service Executive (HSE). It is recognised that the findings of a HTA may have implications for other key stakeholders in the Irish healthcare system, such as patient groups, the general public, clinicians, other healthcare providers, academic groups, and the manufacturing industry.

HTA guideline documents provide an overview of the principles and methods used in assessing health technologies. They are intended to inform assessments conducted by, or on behalf of HIQA, the National Centre for Pharmacoeconomics (NCPE), the Department of Health and the HSE, as well as health technology developers preparing applications for reimbursement. The purpose of the guidelines is to promote the production of assessments that are timely, reliable, consistent and relevant to the needs of decision-makers and key stakeholders in Ireland.

In 2024, HIQA updated two national HTA guidelines:

- National Guidelines for the Economic Evaluation of Health Technologies in Ireland
- National Guidelines for the Budget Impact Analysis of Health Technologies in Ireland.

The draft updated guidelines were published for public consultation in October 2024. 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 guidelines as a result.

Methods

The aim of the public consultation was to seek feedback to identify any issues with the draft updated guidelines, to consider that feedback, and to amend the guidelines, as necessary.

The consultation process

The draft updated guidelines were published on the HIQA website on 21 October 2024 and were available for public consultation until 2 December 2024. The consultation webpage contained a link to the draft updated guidelines, an infographic, links to the online surveys (using the Qualtrics platform) for online

submission of feedback, and consultation feedback forms that could be downloaded and returned via email or post. To ensure wide dissemination, a press release was issued at the beginning of the consultation period. A request for feedback was also circulated to the Health Economics Association of Ireland membership. Additionally, notifications of the public consultation were posted via social media sites (Twitter/X, Facebook, Instagram and LinkedIn).

Feedback form

The template for submission comprised a general request for feedback to enable respondents to flexibly provide their submission for any aspects of the guidelines. A copy of the submission template is provided in Appendix A. Submission forms for both guidelines were identical, except for the title of the guidelines. Therefore only one submission form is provided as an example.

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 specific to that question.

Feedback relating to specific content in the draft updated guidelines is presented in tabular format alongside direct responses to the feedback (Table 1).

Results

Overall, seven unique and complete submissions were received during the public consultation period. In addition, one incomplete and three blank survey responses were received. As these four responses contained no feedback, they have been excluded from the summary below. Three of the seven complete submissions related specifically to the economic evaluation guidelines, three related to the BIA guidelines and one provided feedback on both guidelines. Of the seven complete submissions, three were submitted via the online survey and four were received by email. All of the submissions were made on behalf of stakeholder organisations or institutions. No submissions were made by individuals acting in a personal capacity.

Summary of feedback

Stakeholder organisations or institutions

Across both guidelines, submissions were received on behalf of the following four stakeholder organisations or institutions:

- The Irish Pharmaceutical Healthcare Association (IPHA)
- HealthTech Ireland
- Patient Advocacy Service
- Dexcom.

Details of the feedback from these organisations and institutions, in addition to actions taken to address this feedback, where appropriate, are provided in Table 1.

Overall, the feedback received can be categorised into the following three broad areas:

1. Reporting (for example, language and accessibility)
2. Process and procedure (for example, the guideline update process)
3. Methodology (for example, discount rates, disease severity modifiers).

A brief summary of the feedback provided by these four organisations and institutions is outlined below.

- The Irish Pharmaceutical Healthcare Association (IPHA) acknowledged and thanked HIQA for the ability to have representation on the HTA Scientific Advisory Group (SAG). In summary, IPHA provided feedback on process and procedure as well as methodology.
    - In relation to process and procedure, IPHA noted concerns in relation to the process for updating the guidelines, the unclear value of patient and public involvement in the guidelines, and other issues pertaining to broader reimbursement decision-making in the health system.
    - From a methodological point of view, IPHA provided feedback in relation to discount rates, the use of clinical opinion, EQ-5D-5L, disease severity modifiers, willingness-to-pay thresholds, distinguishing efficacy from effectiveness, use of cost-effectiveness analyses for historical comparisons, the use of full population versus subpopulations, spillover effects, and choice of comparators.
- HealthTech Ireland welcomed this consultation period. In its submission which focused on process and procedure, HealthTech Ireland noted the importance of providing clear information on the applicability of the guidelines for both industry and the provider.

- The Patient Advocacy Service noted the useful and clear overview of the role of HTA in guiding public health policy, outlined in the guidelines. The Patient Advocacy Service provided feedback in relation to reporting, process and procedure, and methodology.
    - In relation to reporting, the Patient Advocacy Service suggested improvements to the clarity and presentation of the guidelines to increase its transparency and accessibility, particularly for patient advocates.
    - In relation to process and procedure, the Patient Advocacy Service noted that, from a patient advocacy perspective, more emphasis could be placed on the explicit inclusion of patient voices throughout the HTA and BIA process.
    - In terms of methodology, the Patient Advocacy Service provided feedback on equity considerations, defining subgroups according to the social determinants of health, use of observational data, the inclusion of patient-reported outcomes and real-world patient experiences.
- Dexcom provided feedback in relation to process and procedure, as well as methodology.
    - In relation to process and procedure, Dexcom queried the applicability of sections of the guidelines for medical devices and noted the importance of clarifying HTA processes for medical devices.
    - From a methodology point of view, Dexcom provided feedback on equity considerations, willingness-to-pay thresholds, and probabilistic sensitivity analyses for BIA.

Specific comments on report content

Table 1 Comments received on report content and responses*

Comment	Response (and or amendment, if undertaken)
Irish Pharmaceutical Healthcare Association (IPHA)	
1. IPHA is concerned that in terms of content, these guidelines have not seen any major changes since 2010. The health and technology landscapes have evolved substantially over that time. While the report refers to a stepwise approach, no evidence is provided in terms of what topics were considered for inclusion and the reasoning or methods behind their non-inclusion.	**Response** It is important to note that these guidelines are not intended to be overly prescriptive but rather they establish an overarching framework for the conduct of budget impact analysis (BIA) and economic evaluation of health technologies in Ireland. The overall approach to updating the guidelines used by the HIQA evaluation team involved a documented six-step process (page 12 of the economic evaluation guidelines and page 11 of the BIA guidelines) to ensure the guidelines are updated in a robust and transparent manner. This process included input from the Scientific Advisory Group (SAG) which comprises national and international experts, and was supplemented by a targeted and public consultation to ensure a wide range of views were considered. A systematic and inclusive approach to identifying topics for consideration in the update process was undertaken by the evaluation team. No topics relevant to economic evaluation or BIA were excluded. The referenced

Comment	Response (and or amendment, if undertaken)
	systematic reviews which informed these updates can be reviewed to understand the breadth of topics that were discussed.[1,2] **Amendment** Wording has been added to Page 12 of the economic evaluation guidelines and page 11 of the BIA guidelines to reflect the inclusive approach to topic identification.
2. The systematic literature review cited as informing the BIA updates (page 11, ref #3) was conducted within the context of informing the development of HTA frameworks in countries without such frameworks. The search was up to June 2020, with much of the HTA agency reports published well before this. Is this the most appropriate basis for informing BIA updates?	**Response** To inform the updates to the BIA guidelines, the following systematic review was used: Chugh Y, De Francesco M, Prinja S. Systematic Literature Review of Guidelines on Budget Impact Analysis for Health Technology Assessment. Applied health economics and health policy. 2021;19(6):825-38. It is not the case that the review was specifically conducted to inform the development of HTA frameworks in countries without such frameworks. The objective of the systematic review was "*to review the recommendations for the conduct of a budget impact analysis in national or organisational guidelines globally*." The search strategy of the included review was comprehensive and the review's applicability to the Irish context was deemed relevant.

[1] Manipis K, Viney R, De Abreu Lourenço R, Ng C, Yu A, Meshcheriakova E, et al. Health Technology Assessment methods: Economic Evaluation Canberra: Australian Government, Department of Health and Aged Care; 2023 [cited 2024 June 25]. Available from: https://www.health.gov.au/sites/default/files/2024-01/hta-policy-and-methods-review-draft-paper-hta-methods-economic-evaluation.pdf.
[2] Chugh Y, De Francesco M, Prinja S. Systematic Literature Review of Guidelines on Budget Impact Analysis for Health Technology Assessment. Applied health economics and health policy. 2021;19(6):825-38.

Comment	Response (and or amendment, if undertaken)
	For each included guideline, it was checked to see whether an update existed since the systematic review was conducted. Any new guideline was considered as part of this update.
3. Discount Rates DEPR guidance advises the use of a hyperbolic discount rate for longer-term time horizons — the guidelines currently ignore this stipulation which could be impactful under particular circumstances (e.g., when assessing childhood vaccination programmes). It should be noted that the DEPR discount rate is informed by environmental economics research and is not directly applicable to a healthcare context. A review of the use of this approach should be considered by HIQA. Ireland has a high discount rate when compared internationally. According to the OHE report referred to above which included 14 HTA agencies; in guidelines published up to 2022, *"the majority of HTA agencies have discount rates falling within the range of 2.5% and 3.5%."*	**Response** The Public Spending Code states that hyperbolic discounting (which is when the discount rate begins to decline after a certain period into the future) is considered permissible for economic evaluations with a time horizon extending beyond 30 years.[3] The Department of Public Expenditure NDP Delivery and Reform sets the discount rate for the public sector in Ireland and it is established using a published formula.[4] HIQA is not authorised to make any changes to the discount rate. It is important to note that discount rates are set at the individual national level and therefore vary between countries. A systematic review of official discount rates in guidelines of health economic evaluations reported that discount rates of 3% and 5% were most frequently used internationally.[5]

[3] Department of Public Expenditure NDP Delivery and Reform. Public Spending Code: Central Technical References and Economic Appraisal Parameters Department of Public Expenditure and Reform: Dublin; 2019. Available from: https://assets.gov.ie/43554/70a378231f1540b0a09a0560dc9dd26f.pdf.
[4] Department of Public Expenditure NDP Delivery and Reform. Public Spending Code: Central Technical References and Economic Appraisal Parameters Department of Public Expenditure and Reform: Dublin; 2019. Available from: https://assets.gov.ie/43554/70a378231f1540b0a09a0560dc9dd26f.pdf.
[5] Khorasani E, Davari M, Kebriaeezadeh A, Fatemi F, Akbari Sari A, Varahrami V. A comprehensive review of official discount rates in guidelines of health economic evaluations over time: the trends and roots. The European Journal of Health Economics. 2022 Dec;23(9):1577-90.

Comment	Response (and or amendment, if undertaken)
The employment of differential discounting should be considered in exceptional circumstances as there is evidence of alternative time dependencies with respect to population health preferences. The Guidelines should recognise this in particular as it affects paediatric care.	The Department of Public Expenditure NDP Delivery and Reform states that "there does not appear to currently be a clear rationale for the application of differentiated discount rates across sectors."[6] Further, a systematic review of discounting approaches in national health economic evaluation guidelines reported that the majority of guidelines recommend equal discounting (81%) rather than differential discounting (10%).[7] Therefore, the discounting approach and rate in Ireland is broadly in keeping with the international picture. **Amendment** In accordance with the Public Spending Code, the guidelines have been changed to state that hyperbolic discounting is considered permissible, as a secondary analysis, for economic evaluations with a time horizon extending beyond 30 years. To explain how hyperbolic discounting should be applied, text has been added to page 52 of the economic evaluation guidelines.
4. Survival Analysis & Clinical Opinion HIQA should be clearer on what constitutes a systematic approach, particularly with consideration of how clinical opinion should be incorporated within assessments that require extrapolation of long-term effects.	**Amendment** It has been clarified that while empirical evidence should be sought to inform parameters in the model in the first instance, there may be occasions when these can only be derived through expert opinion. The

[6] Department of Public Expenditure NDP Delivery and Reform. Central Technical Appraisal Parameters: Discount Rate, Time Horizon, Shadow Price of Public Funds and Shadow Price of Labour: 2018 [updated Oct 2018; cited 2025 22 Jan]. Available from: https://www.gov.ie/en/igees-publication/a085b-central-technical-appraisal-parameters-discount-rate-time-horizon-shadow-price-of-public-funds-and-shadow-price-of-labour/.
[7] Williams AO, Rojanasarot S, McGovern AM, Kumar A. A systematic review of discounting in national health economic evaluation guidelines: healthcare value implications. Journal of Comparative Effectiveness Research. 2023 Feb;12(2):e220167.

Comment	Response (and or amendment, if undertaken)
	importance of transparency in deriving expert opinion has been included (page 50 of economic evaluation guidelines and page 36 of BIA guidelines).
5. Patient & Public Involvement The Guidelines are unclear on the value of patient engagement and submissions.	**Response** Patient and public involvement (PPI) is central to the HTA process more broadly and is usually captured in greater depth in other domains of HTA (for example, patient, social and ethical aspects) and or through patient submissions. These particular aspects are beyond the scope of these economic guidelines. The role of PPI will be detailed further in the planned comprehensive update to the existing national stakeholder engagement in HTA guidelines.[8] Of note, PPI representatives on the SAG are actively providing important contributions to the process of updating the suite of national HTA guidelines.
6. EQ-5D-5L It appears that HIQA have downgraded the importance placed on the use of the EQ-5D-5L Irish value set. This value set reflects the preferences of the people of Ireland. No justification is currently provided for why it is appropriate for the NCPE to use a 3L value set representing UK preferences published in 1999 at the expense of a more up-to-date Irish-specific value set that is publicly available.	**Amendment** The importance of having an EQ-5D-5L value set for Ireland is now acknowledged in the economic evaluation guidelines (page 46). Text has been added to make it clearer that the guidelines do not state a preference for the EQ-5D-3L over the EQ-5D-5L, or vice versa, though the choice of instrument should be justified with consideration to the validity and reliability of the measure (see page 46 of the economic evaluation guidelines).
7. Disease Severity Modifiers	**Response**

[8] https://www.hiqa.ie/reports-and-publications/health-technology-assessments/guidelines-stakeholder-engagement

Comment	Response (and or amendment, if undertaken)
There is evidence of greater societal preference regarding the cost associated with preventing/treating severe diseases. This has led to the use of severity modifiers which can be readily incorporated within economic evaluations to understand if relevant interventions may be more appropriately assessed using a higher WTP threshold on the basis of meeting particular criteria (e.g., QALY loss associated with disease). Such modifiers are currently employed by NICE and Sweden's TLV. The guideline currently states that 'no modifiers are currently accepted for use in economic evaluations in Ireland.'	No quantitative modifiers are currently accepted for use in economic evaluations in Ireland, although factors such as disease severity and rarity can be accounted for narratively in the assessment. **Amendment** Further clarity has been added to page 63 of the economic evaluation guidelines.
8. WTP Thresholds In relation to drugs, thresholds of €20,000 and €45,000 per QALY have been used previously in conjunction with budget impact thresholds to determine the level of authority. Although not formally referenced in published agreements, it is known that thresholds above these values have also been used by decision-makers in Ireland. IPHA believes the previous wording provided greater clarity and should be maintained.	**Response** The new wording better reflects that the willingness-to-pay thresholds of €20,000 and €45,000 per QALY have been used previously, in conjunction with budget impact thresholds, to determine the level of authority required within the HSE to make funding decisions, rather than what the decision itself should be.
9. Efficacy vs effectiveness "Economic assessments should be based on the effectiveness of the competing technologies and uncertainty surrounding these estimates	**Response** It is important to note that "effectiveness" follows from "efficacy", and cost-effectiveness assessments should be based on evidence of comparative effectiveness of the intervention versus the comparator(s).

Comment	Response (and or amendment, if undertaken)
assessed through sensitivity analyses and modelling techniques to enhance the robustness of the HTA findings." (Page 32) Wording appears to suggest that effectiveness should be prioritised over efficacy. This is slightly contradictory to what is presented elsewhere in the guideline.	"Effectiveness" and "efficacy" are not necessarily mutually exclusive concepts. Efficacy indicates an identifiable treatment effect, and is a natural and necessary precursor to comparative effectiveness. Further elaboration on this is best placed in the clinical effectiveness guidelines[9] (in an upcoming update) rather than within the economic evaluation or BIA guidelines.
10. Consistency with previous HTAs/past decisions Page 59 refers to making comparisons with ICERs of technologies previously assessed as *"helpful when an ICER is substantially lower than that of other technologies considered to be cost effective and that were funded, or when an ICER is substantially higher than that of a technology previously rejected as not cost effective."* In general, an economic evaluation is conducted at a point in time and should be based on best available data at that time. The relevant comparison is with the appropriate comparator technologies and expressed in terms of an ICER that can be interpreted relative to a WTP. Comparisons with historical assessments could be misleading given inflation, newer data and methodological evolution (i.e., there is clear heterogeneity in such comparisons).	**Response** It is agreed that the wording may have caused confusion given that it moves away from the focus of the preceding points in this section (on opportunity cost and willingness-to-pay), which explain how to interpret results from a cost-effectiveness analysis. **Amendment** Wording which described the comparison of an ICER with that of a previously assessed technology has been removed from page 63 of the economic evaluation guidelines.
11. EMA Label *"For drugs, the population should be defined by the authorised therapeutic indication for the product, where applicable."* (Page 29)	**Response** When undertaking an economic evaluation it is important that the target population is in accordance with the authorised therapeutic indication (or intended purpose for medical devices/diagnostics).

[9] https://www.hiqa.ie/reports-and-publications/health-technology-assessment/guidelines-evaluating-clinical-effectiveness

Comment	Response (and or amendment, if undertaken)
It is appropriate for the target population to be consistent with the EMA label. However, this should not be interpreted as a restriction on whether or not a P&R application can be submitted based on a subpopulation only. An application for a subpopulation only can be the most appropriate approach when there are capacity constraints within the system, where affordability is a challenge, and where cost effectiveness is prioritised due to unmet need. It is also worth bearing in mind the time spent preparing and evaluating a comprehensive dossier for a full indication (and subsequent delay in patients accessing the therapy) when ultimately a subpopulation is what will inevitably be reimbursed.	**Amendment** This point has been re-emphasised, but the relevant section has been reordered to make it clearer that specific subpopulations may also be included as part of the assessment (page 33 of the economic evaluation guidelines).
12. Spillover effects The appropriate incorporation of spillover effects within the context of economic evaluation is a growing area of methodological interest. Health benefits derived from the available technology should be accounted for all individuals, not solely patients. As described by the HIQA guidelines: *"All health benefits accruing to individuals should be included in the assessment of outcomes."*	**Amendment** Consideration of the use of family and caregiver health spillovers (or simply, the impacts on family and caregiver health) as part of a secondary analysis is now included on page 29 of the economic evaluation guidelines.
13. Choice of comparator(s) *"Technologies that do not have marketing authorisation (or CE mark for medical devices) for the indication defined may also be considered for the comparator if they are part of established clinical practice for that indication."* (page 28)	**Response** While transparency is key in that *"the comparator(s) should be clearly identified and justified with sufficient detail provided to allow their relevance to be assessed,"* it may not be necessary for clinical opinion to be sought in every instance. In many cases, the standard care in Ireland is

Comment	Response (and or amendment, if undertaken)
Request adding a statement that such comparators are supported by robust and referenced clinical opinion.	very well understood, the choice of comparators is clear, and identification and justification is possible without additional clinical opinion. HTA agencies generally have sufficient in-house expertise to search for and interpret this type of information and additional clinical opinion is often not required.
Patient advocacy service	
14. The introduction of the guidelines provides a useful and clear overview of the role of Health Technology Assessment (HTA) in guiding public health policy. However, from a patient advocacy perspective, more emphasis could be placed on the explicit inclusion of patient voices throughout the HTA and BIA process. It is essential to make more explicit how patient groups and advocates can engage in the process, particularly in ensuring the assessment aligns with patient needs, preferences, and equity considerations. Ensuring that patient perspectives are not just considered but integrated into decision-making is crucial for a more inclusive and human-centred assessment.	**Response** As per the response to comment #5, PPI is central to the HTA process more broadly and is usually captured in greater depth in other domains of HTA (for example, patient, social and ethical aspects) and or through patient submissions. These particular aspects are beyond the scope of these economic guidelines. The role of PPI will be detailed further in the planned comprehensive update to the national stakeholder engagement in HTA guidelines.[10]
15. While the guidelines mention stratified analysis for subgroups, they primarily focus on clinical characteristics (age, sex, etc.), and patient preferences or disparities in healthcare access are not given much attention. For example, vulnerable populations, such as those from marginalised groups or with multiple comorbidities, may experience unique barriers to access and could benefit from tailored healthcare solutions.	**Response** It is recognised that vulnerable populations, such as those from marginalised groups or with multiple comorbidities, may experience unique barriers to access. **Amendment**

[10] https://www.hiqa.ie/reports-and-publications/health-technology-assessments/guidelines-stakeholder-engagement

Comment	Response (and or amendment, if undertaken)
	To reflect this point, wording has been added that subgroups may also be defined according to social determinants of health (see page 53 of the economic evaluation guidelines).
16. While the guidelines rightly place emphasis on evidence-based data (e.g., RCTs, meta-analyses), it does not sufficiently address the inclusivity of the data used. While the guidelines mention the use of RCTs, these studies often exclude vulnerable populations, such as the elderly, individuals with disabilities, and those with comorbidities, which means the results may not fully reflect the needs of these populations. To ensure that the technology evaluation process is inclusive, the guidelines should advocate for the inclusion of diverse patient populations in clinical trials and the use of real-world evidence to better understand the efficacy and safety of technologies in the populations they are intended to serve.	**Response** RCT and observational data have complementary roles in the evidence ecosystem, and answer different research questions. While evidence from RCTs should be used to quantify efficacy in the reference case analysis, it is already acknowledged within the guidelines that data from observational studies (that is, real-world evidence) *"may be submitted to supplement the available RCTs and to enhance the generalisability and transferability of the results."* (see page 36 of economic evaluation guidelines and pages 34-35 of BIA guidelines). It is important to note that these guidelines outline the methods for conducting economic evaluations and BIAs. Developing recommendations for the appropriate conduct of clinical trials is beyond the scope of these guidelines.
17. The guidelines emphasise the need for a well-structured report with clear documentation of all assumptions and the ability to validate results through third-party review. While transparency is crucial, the guidelines do not emphasise the importance of accessible reporting for patient groups. Complex models may be difficult for non-experts to understand, and patient groups could be excluded from ongoing meaningful participation in the	**Amendment** The importance of the economic evaluation/BIA report being accessible for the target audience has been emphasised in this update. The guidelines have been updated to state that consideration should be given to the inclusion of plain language summaries, infographics and other patient-

Comment	Response (and or amendment, if undertaken)
process due to a lack of clear, patient-friendly summaries in all reporting that should be made available.	friendly communication tools, where appropriate (see page 60 of the economic evaluation guidelines and page 40 of the BIA guidelines).
18. Transparency and Accessibility Economic evaluations often involve complex methodologies and technical reporting, which can hinder engagement from non-specialist stakeholders, including patient groups. Clear and accessible communication is essential for building trust and understanding among all healthcare stakeholders. To improve the clarity and presentation of the guidelines, the document would benefit from simplifying technical jargon, improving the structure and flow, and offering patient-centred insights that are clearer to patient advocates. The inclusion of more visual aids, concise summaries, and explicit patient perspectives would significantly enhance accessibility, ensuring that the guidelines are not only useful to policy-makers but also to those advocating for patient rights and equitable healthcare. The plain language summary is an important feature of the document but could be further expanded to make it more accessible. The current summary provides a brief overview of the guidelines but does not dive into the practical patient-centric implications of the BIA process.	**Response** Every effort has been made by the project team to write the guidelines as clearly as possible, in light of the very technical nature of the topic. While it is agreed that writing as plainly as possible is to be encouraged, it is important that the various technical nuances contained within the guidelines be retained to avoid any ambiguity. Striking the right balance is important. In relation to expanding the plain language summaries, the SAG agreed that the level of detail currently contained within them is appropriate. A plain language summary (page 16 of the economic evaluation guidelines and page 15 of the BIA guidelines) and an infographic are new additions to these economic guidelines, which aim to support their understanding. There is also a detailed glossary at the end of both guidelines, which has been updated with new terms (pages 77-95 of the economic evaluation guidelines and pages 48-58 of the BIA guidelines).
19. Patient-Centred Focus The guidelines present a solid framework for cost-effectiveness evaluations but do not explicitly require the inclusion of patient-reported outcomes or real-world patient experiences. These elements are crucial for understanding the broader impact of health technologies on patients' quality of life and	**Response** A discussion on the use of various clinical endpoints is beyond the scope of these economic guidelines. Further guidance on the use of clinical endpoints, including patient-reported outcomes (PROs), is available in the

Comment	Response (and or amendment, if undertaken)
daily experiences.	Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland.[11]
20. Equity Considerations While the guidelines appropriately weight all Quality-Adjusted Life Years (QALYs) equally, they fall short of addressing disparities in healthcare access and outcomes. Health technologies can have varied effects on vulnerable groups, including those in rural areas, socioeconomically disadvantaged populations, and individuals with disabilities.	**Response** There are significant methodological issues concerning the derivation of equity weights and the circumstances and mechanisms by which these would apply to QALY calculations. Typically there are very limited data available to underpin studies that take into account equity concerns. However, equity can be considered as part of other HTA domains (for example, patient, ethical and social aspects) and or through patient submissions. Therefore, while equity considerations may not be addressed using formal weights, they can still be taken into account to inform decision-making.
21. Timeliness Lengthy evaluation processes can delay access to potentially life-saving or life-enhancing health technologies. Patients with urgent needs may be disproportionately affected by these delays, which can exacerbate health inequalities.	**Response** Procedural issues, such as timelines for conducting evaluations, are beyond the scope of these economic guidelines.
HealthTech Ireland	
22. HealthTech Ireland welcomes this consultation period. HTA will potentially be used by the healthcare provider as a means to evaluate and enable digital transformation, and by industry as a guideline to what is required. Ensuring these guidelines factor this in and provide clarity on their	**Response** The guidelines are intended to apply to economic evaluations or BIAs undertaken as part of health technology assessments carried out to

[11] https://www.hiqa.ie/reports-and-publications/health-technology-assessment/guidelines-evaluating-clinical-effectiveness

Comment	Response (and or amendment, if undertaken)
applicability for both industry and the provider is critical. As such, we recommend that the new guidelines include clarity in a suitable format, e.g. in the form of perhaps a statement, outlining what types of technologies and programmes are suitable for a full Health Technology Assessment as detailed in the guidelines. Likewise, and equally important, it should also include a statement outlining the types of technologies it is not suitable for. In addition, HealthTech Ireland recognise the growing need for 'Mini-HTA's' of innovative digital technologies/pathways to enable digital transformation.	support decision-making by the Department of Health and HSE. Such assessments, and hence the guidelines, are not limited to specific technologies or interventions. **Amendment** The guidelines are intended to be broad in scope given that they are potentially applicable to all healthcare interventions. However, the wording has been amended to clarify that it is only "within the context" of "economic evaluations conducted by, or on behalf of HIQA, the NCPE, the Department of Health and the HSE, as well as health technology developers preparing applications for reimbursement" that these guidelines apply. The Introduction section has been rearranged to better explain this (see page 19 of the economic evaluation guidelines and page 18 of the BIA guidelines).
Dexcom	
23. Main comment is in relation to the need for a PSA when doing a BIA. For example, ISPOR guidance for BIAs states that: *"Uncertainty of two types is relevant to a BIA: parameter uncertainty in the input values used and structural uncertainty introduced by the assumptions made in framing the BIA. Examples of parameter uncertainty include efficacy estimates for current and new interventions, and of structural uncertainty include changes in expected intervention patterns with the availability of the new intervention and restrictions for use. Because there are limited data for many of the parameters, much of the parameter uncertainty of BIAs cannot be meaningfully quantified and thus standard approaches such as one-way and probabilistic sensitivity analyses cannot be carried out fully. Moreover,*	**Response** For BIAs, it is acknowledged that if there is insufficient information to support parameter values, a PSA may not provide a meaningful estimate of the budget impact. **Amendment** The guidelines have been amended to state that in such instances, a series of deterministic scenario analyses may be more informative for describing

Comment	Response (and or amendment, if undertaken)
much of the uncertainty is structural and not easily parameterised. Thus, scenario analyses should be undertaken by changing selected input parameter values and structural assumptions to produce plausible alternative scenarios." I would encourage HIQA to follow international guidance here and not to overcomplicate things.	uncertainty. Justification for not conducting a PSA in a BIA should be clearly documented. See page 39 of the BIA guidelines.
24. Equity Adding equity as a decision criterion leaves the submitters with an open end and adds an extra dimension to the decision-making; simply by adding the statement QALY it is not a QALY. Moreover, QALYs are used in an unintended way by giving certain patient populations lower or higher value than others.	**Response** As per the response to comment #20, there are significant methodological issues concerning the derivation of equity weights and the circumstances and mechanisms by which these would apply to QALY calculations. However, while equity considerations may not be addressed using formal weights, they can still be taken into account to inform decision-making.
25. Application Overall, it is about drugs, although diagnostics and medical devices are briefly mentioned, but drawn into the same review. Which makes applying it to medical devices questionable. Trials done in medical devices are fundamentally different from pharma trials (more building on previous products) and once a trial is done there is already an improved version of the device.	**Response** The guidelines are not tailored towards the assessment of a particular type of intervention, and the methods apply equally to pharmaceuticals, diagnostics, medical devices, public health programmes, and systemic changes. **Amendment** The Introduction section has been rearranged to better explain the broad scope of the guidelines (see page 19 of the economic evaluation guidelines and page 18 of the BIA guidelines).

Comment	Response (and or amendment, if undertaken)
26. Devices are connected, so digital also becomes a topic. The guidance doesn't speak about digital technology. Clarity is needed on device versus class-based when it is about devices.	**Response** It is noted within the guidelines that they *"are broad in scope and some aspects may be more relevant to particular interventions than others."* (See page 19 of the economic evaluation guidelines and page 18 of the BIA guidelines). Within the context of guidelines that are applicable to a broad range of technologies, it is not possible to list all relevant health technologies. It should be borne in mind that an assessment could look at one or several technologies individually or collectively, depending on the evidence base and needs of the decision-maker. However, procedural issues relating to the selection of HTAs (for example, in terms of device- versus class-based assessments) are beyond the scope of these guidelines.
27. What is the purpose of a CEA if no willingness to pay is mentioned? It is an open end for us to submit dossiers (like with the equity part).	**Response** A range of factors, including cost effectiveness, may be considered as part of decision-making. The lack of a fixed willingness-to-pay (WTP) threshold does not negate the benefit of having an economic evaluation. A cost-utility model provides valuable information in relation to the efficient use of resources, and this can be contrasted with findings used for historical decisions. Further information on the WTP threshold and how it is considered in decision-making is detailed on page 62 of the economic evaluation guidelines.

*Comments have been edited for brevity and to correct for minor grammatical errors and or typos.

Changes to the report from the consultation process

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

- Further clarification of the guideline update process is provided on page 12 of the economic evaluation guidelines and page 11 of the BIA guidelines.
- Throughout the guidelines, wording has been revised to improve understanding, where appropriate.
- The importance of the economic evaluation and BIA reports being accessible for the target audience has been emphasised. It is now stated that consideration should be given to plain language summaries, infographics and other patient-friendly communication tools, where appropriate (see page 60 of the economic evaluation guidelines and page 40 of the BIA guidelines).
- The Introduction section has been rearranged to better explain the scope of the guidelines (see page 19 of the economic evaluation guidelines and page 18 of the BIA guidelines).
- In accordance with the Public Spending Code, the guidelines have been changed to state that hyperbolic discounting is considered permissible, as a secondary analysis, for economic evaluations with a time horizon extending beyond 30 years. To explain how hyperbolic discounting should be applied, text has been added to page 52 of the economic evaluation guidelines.
- When undertaking an economic evaluation or BIA, it is important that the target population is in accordance with the authorised therapeutic indication (or intended purpose for medical devices/diagnostics). This point has been re-emphasised, but this section has been reordered to make it clearer that specific subpopulations may also be included as part of the assessment (page 33 of the economic evaluation guidelines and page 28 of the BIA guidelines).
- Clarity has been provided that while empirical evidence should be sought to inform parameters in the model in the first instance, there may be occasions when these can only be derived through expert opinion. The importance of transparency in such instances has been emphasised (page 50 of economic evaluation guidelines and page 36 of BIA guidelines).
- The importance of having an EQ-5D-5L value set for Ireland is now acknowledged in the guidelines. It is clarified that these guidelines do not state a preference for one EQ-5D version over the other, though the choice of

instrument should be justified with consideration to the validity and reliability of the measure (see page 46 of the economic evaluation guidelines).

- Further clarity has been added regarding disease severity modifiers to page 63 of the economic evaluation guidelines.
- Wording which described the comparison of an ICER with that of a previously assessed technology has been removed from page 63 of the economic evaluation guidelines, given that it may have caused confusion.
- Consideration of the impacts on family and caregiver health (also called 'health spillovers'), as part of a secondary analysis, is now included on page 29 of the economic evaluation guidelines.
- It is recognised that vulnerable populations, such as those from marginalised groups or with multiple comorbidities, may experience unique barriers to access. To reflect this point, wording has been added that subgroups may also be defined according to social determinants of health (see page 52 of the economic evaluation guidelines).
- For BIAs, it is acknowledged that if there is insufficient information to support parameter values, a probabilistic sensitivity analysis (PSA) may not provide a meaningful estimate of the budget impact. The guidelines have been amended to state that in such instances, a series of deterministic scenario analyses may be more informative for describing uncertainty; however, justification for not conducting a PSA in a BIA should be clearly documented (see page 39 of the BIA guidelines).

Appendix A – Copy of submission feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guidelines for the Economic Evaluation of Health Technologies in Ireland For public consultation

Consultation Feedback Form

Your feedback is very important to us. We welcome 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 consultation remains open until 5pm on 2 December 2024

You may email a completed form to us at consultation@hiqa.ie . Alternatively, you can post the completed form to: Health Information and Quality Authority, George's Court, George's Lane, Dublin 7, D07 E98Y. You may also complete and submit your feedback online here.

About you

Name	
Your or your organisation's country	
Today's Date	
Would you like your name and or that of your organisation to be kept confidential and excluded from the published summary of responses?	

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 *Please name*

☐ On behalf of an organisation *Please name*

Part 2

Please provide any general or specific feedback you have on the draft assessment. Where applicable, please specify the section of the assessment to which you are referring.

Please comment

Part 3

Please outline any issues with the clarity or presentation of the report. 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 you can post it to Health Information and Quality Authority, George's Court, George's Lane, Dublin 7, D07 E98Y:

or you can complete the form online at:
https://hiqa.qualtrics.com/jfe/form/SV_cU4x7xxSBIPmxQa

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

Please return your form to us either by email or post before 5pm on 2 December 2024

Please note that the Authority is subject to the Freedom of Information (FOI) 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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