Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Protocol for a health technology assessment of COVID-19 vaccination in Ireland

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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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1 Background

COVID-19 is a highly contagious respiratory disease which, as of February 2026, has caused over 7.1 million deaths globally.[1] COVID-19 is caused by the virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) — one of five *Betacoronaviruses,* belonging to the *Orthocoronavirinae* sub-family, which have been found to infect humans. Other *Betacoronaviruses* which have been found to infect humans include the Middle East respiratory syndrome-related coronavirus (MERS-CoV) and SARS-CoV. The *Orthocoronavirinae* sub-family belongs to the *Coronaviridae* family, which are enveloped, positive-strand ribonucleic acid (RNA) viruses.[2]

When viruses replicate in the host cell, mutations in the genetic coding can occur. While some of these mutations have no impact on the characteristics of the virus, others can result in significant changes, such as; enhanced transmissibility, severity of resultant infection and ability to evade an immune response (whether that be an innate or adaptive immune response).[3] Since its discovery in 2019, SARS-CoV-2 has spread and evolved globally, leading to the detection of SARS-CoV-2 variants. These variants are monitored by the World Health Organization (WHO) and the Technical Advisory Group on Virus Evolution (TAGVE). The more significant variants are categorised into one of three groups:

- Variants under monitoring (VUMs): variants with genetic changes that may affect the characteristics of the virus, but for which enhanced monitoring is required to determine if these genetic changes have a phenotypic or epidemiological impact.
- Variants of interest (VOIs): variants with genetic changes that are known to affect how the virus behaves or its potential impact on human health. These variants are referred to using established scientific nomenclature systems, such as those used by Nextstrain and Pango.
- Variants of concern (VOCs): variants with genetic changes that are known to affect how the virus behaves or its potential impact on human health and can cause a detrimental change in disease severity, have a substantial impact on healthcare systems or cause a significant decrease in the effectiveness of available vaccines in protecting against severe disease.[4] These variants are referred to using Greek letters. VOCs identified to date include Alpha, Beta, Gamma, Delta, and Omicron.

The first COVID-19 vaccines that were developed used messenger RNA (mRNA) from the ancestral virus, identified in December 2019. Since then, other COVID-19 vaccine technologies have been developed and include viral vector and protein

subunit vaccines. While these vaccines elicit high levels of virus-specific antibodies in the vaccinated individual, overtime, waning immunity increases the likelihood of breakthrough infections. This is further complicated by genomic mutations and the emergence of variants that decrease the effectiveness of these original vaccines.[5] One of the most notable variants has been Omicron, specifically the subvariant Omicron BA.1, which emerged in November 2021. This subvariant, with its 53 mutations, was phylogenetically distinct from prior lineages, showed enhanced transmissibility, was associated with a significant decrease in vaccine effectiveness and had a substantial impact on healthcare systems globally.[6] As such, variant-adapted bivalent vaccines were developed. The first of these adapted vaccines, which contained mRNA from the ancestral SARS-CoV-2 strain and Omicron BA.1 variant, was approved by the European Medicines Agency (EMA) in September 2022.[7]

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) monitors the genetic and antigenic evolution of SARS-CoV-2 variants and the effectiveness of COVID-19 vaccines against circulating variants. Based on these data, the WHO advises vaccine manufacturers and regulatory authorities on required updates to COVID-19 vaccine antigen composition.[8] In May 2025, the EMA advised that vaccines adapted to target the LP.8.1 variant of the JN.1 family of Omicron subvariants were preferentially recommended, but that vaccines targeting JN.1 or KP.2 strains could still be considered for 2025 vaccination campaigns until updated LP.8.1 adapted vaccines become available.[9] In October 2025, the National Immunisation Office (NIO) in Ireland issued a statement advising that the antigenically-adapted COVID-19 vaccine, Comirnaty LP8.1, was available for all ages and that all older variant-adapted COVID-19 vaccines used for previous campaigns should be removed.[10]

In May 2025, the National Immunisation Advisory Committee (NIAC) in Ireland published updated recommendations on vaccination against COVID-19.[11] The updated recommendations, with respect to the groups eligible for a COVID-19 vaccination, are outlined in Table 1.

Table 1. Updated National Immunisation Advisory Committee recommendations on vaccination against COVID-19 (May 2025)

1. A COVID-19 vaccine is recommended twice each year for:	▪ those aged 80 years and above ▪ those aged 18-79 years living in long-term care facilities for older adults ▪ those aged 6 months and older with immunocompromise< associated with a suboptimal response to vaccination.
2. A COVID-19 vaccine is recommended once each year for:	▪ those aged 60-79 years ▪ those aged 6 months-59 years with medical conditions~ associated with a higher risk of COVID-19 hospitalisation, severe disease or death.
3. Access to a COVID-19 vaccine once each year should be available for:	▪ health and care workers* who choose to receive a vaccine ▪ pregnant adolescents and adults* who, following discussion with a healthcare provider, choose to receive a vaccine ▪ adults aged 18-59 not included in the groups listed in points 1 or 2 who, following discussion with a healthcare provider, choose to receive a vaccine.

<As defined by the Health Service Executive.[12, 13]
~Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death include: cancer, chronic heart disease, chronic kidney disease, chronic liver disease, chronic neurological disease, chronic respiratory disease, diabetes and other metabolic disorders including inherited metabolic disorders, haemoglobinopathies, immunocompromise due to disease or treatment, body mass index ≥40kg/m^2, serious mental health conditions, children and adults with Down syndrome, children with moderate to severe neurodevelopmental disorders. This list is not exhaustive, and the medical practitioner should apply clinical judgment to consider the risk of COVID-19 infection exacerbating any medical condition that a patient may have as well as the risk of serious illness from COVID-19 infection.
*Pregnant adolescents and adults or health and care workers who also fall into the risk groups outlined in points 1 and 2 should follow the corresponding recommendations.

The Department of Health requested that HIQA complete a health technology assessment (HTA) of various COVID-19 vaccination strategies to inform a decision on COVID-19 vaccination policy in Ireland. Due to the short timeline within which the information needs to be provided, the HTA will be limited to a restricted number of domains.

This protocol presents the methods for estimating the burden of disease associated with COVID-19 in Ireland, and assessing the economic implications associated with various COVID-19 vaccination strategies in Ireland.

1.1 Aims and objectives

The overarching aim of this HTA is to support the work of the Department of Health and provide advice to the Minister for Health and Health Service Executive (HSE) to inform COVID-19 vaccination policy in Ireland. Specifically, and in the context of the updated COVID-19 vaccination recommendations published by NIAC, the aim of this

HTA is to provide advice in relation to potential changes to the groups for whom COVID-19 vaccination is funded by the HSE for the 2027-2028 vaccination campaign onwards. The objectives (that is, terms of reference) for this assessment are to:

- describe the COVID-19 vaccines authorised for use in Ireland
- describe the epidemiology and burden of COVID-19
- summarise the clinical effectiveness and safety of COVID-19 vaccines
- assess the cost effectiveness of COVID-19 vaccination with respect to the subgroups outlined in the NIAC recommendations, where the data allow
- assess the budget impact of COVID-19 vaccination with respect to the subgroups outlined in the NIAC recommendations
- consider any additional implications relating to a potential change in COVID-19 vaccination policy
- based on the evidence in this assessment, provide advice to support a decision regarding potential changes to the COVID-19 vaccination programme in Ireland.

1.2 Stakeholder engagement

1.2.1 Establishment of the Expert Advisory Group

An appropriately represented Expert Advisory Group (EAG) will be convened as a source of expertise to inform the interpretation of the evidence and development of the advice to the HSE. This group will comprise nominees from a range of stakeholder organisations, including patient representation, healthcare providers, and clinical and public health experts.

The terms of reference of the EAG are to:

- Contribute to the provision of high-quality research and considered advice by HIQA to the Department of Health.
- Contribute to the work of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues, outside of group meetings as requested.
- Provide advice to HIQA regarding the scope of the report.
- Review the project plan outline and advise on priorities, as required.

- Support the Evaluation Team during the process by providing expert opinion and access to pertinent data, as appropriate.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to HIQA's development of its approach to evidence synthesis by participating in an evaluation of the process on the conclusion of the project.
- Notify the project lead if a nominee can no longer participate or contribute to the process as non-participation may require alternative EAG membership to be sought.

1.2.2 Public and targeted consultation

A public and targeted consultation will be conducted to provide a broad range of stakeholders with an opportunity to give feedback on a draft version of the report. The feedback received during the consultation and HIQA's responses to the issues raised, including any changes made to the report as a result, will be published on the HIQA website in a Statement of Outcomes report alongside the final HTA.

2 Description of technology

A description will be provided of the COVID-19 vaccines authorised for use in Ireland. This will include a high-level comparison of the characteristics of the different COVID-19 vaccines (for example, indications, storage, administration and co-administration) and details on the current COVID-19 vaccination programme in Ireland (to include details on the subgroups for whom vaccination is funded).

3 Epidemiology and burden of disease

A description of the epidemiology of COVID-19 and burden of disease associated with COVID-19 in the groups eligible for vaccination as per the NIAC recommendations will be provided. This section will be informed by a review of national and international literature and databases.

COVID-19 is a notifiable disease in Ireland under the Infectious Disease Regulations,[14] and cases should be notified to the Medical Officer of Health. Notifications are reported using the Irish Computerised Infectious Disease Reporting system (CIDR).[15] COVID-19 activity in Ireland is monitored by the Health Protection Surveillance Centre (HPSC).[16] COVID-19 incidence (to include notified cases, emergency department visits, hospital admissions, intensive care unit (ICU)

admissions and mortality) will be estimated from data obtained from the HPSC. Data from the Hospitalised In-Patient Enquiry (HIPE) system will be sought to understand the nature of COVID-19-related hospitalisations (for example, complications of the disease, hospital length of stay and the average cost of admissions).[17] For this HTA, COVID-19 surveillance data will be gathered for the years 2023 to 2025 (inclusive). Data will be restricted to this time period to facilitate the inclusion of data most relevant to the current epidemiological situation, that is, data specific to currently circulating variants in a population exhibiting high levels of immunity (through exposure to previous infection and or vaccination).[18] Limiting the data to 2023 onwards also recognises differences in testing practices during the early years of the COVID-19 pandemic compared with current policies. Specifically this included removal of the recommendation to test all asymptomatic patients and asymptomatic contacts in 2022.[19]

Data will be reported by calendar year as COVID-19 continues to lack seasonality. That is, peaks in the reported number of COVID-19 infections are observed during both the winter and spring/summer, and it tends to be when new variants are identified or following periods of increased largely-attended events.[20] Cross sectional analyses of nationally representative datasets and individual studies will be used, if deemed appropriate. Where there is an absence of Irish data, the best available estimates will be derived from international literature.

The HPSC report COVID-19 vaccination uptake data in Ireland.[21] Trends in HPSC-reported vaccine uptake will be summarised.

While long-COVID is not the focus of this HTA, it is acknowledged that long-COVID (or post-COVID condition) is an important outcome of SARS-CoV-2 infection. As such, a description of the epidemiology and burden of long-COVID in Ireland will be provided to inform the economic evaluations conducted as part of this HTA.

4 Clinical effectiveness and safety

Due to the short timeframe within which advice needs to be provided to the Department of Health and HSE to inform decision-making, a systematic review of the clinical effectiveness and safety of COVID-19 vaccines will not be undertaken. Instead, in the interest of efficiency, evidence from a high-quality, recently published systematic review of the clinical effectiveness and safety of antigenically updated COVID-19 vaccines authorised by the EMA will be used, where available. This reflects a pragmatic approach to evidence synthesis, consistent with the hierarchy of evidence, wherein duplication of effort is minimised.

Table 2 outlines the PICOS (population, intervention, comparator, outcomes and study design) criteria used for selection of the systematic review.

Table 2. PICOS (population, intervention, comparator, outcomes and study design) criteria used for review selection

Population	▪ those aged ≥80 years ▪ those aged 60-79 years ▪ those aged 18-79 years living in long-term care facilities ▪ those aged ≥6 months living with immunocompromise associated with a suboptimal response to vaccination[¥] ▪ those aged 6 months to 59 years living with underlying medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death[~] ▪ healthcare workers ▪ pregnant adolescents or adults ▪ those aged 18 to 59 years without immunocompromise[¥] or underlying medical conditions[~]
Intervention	All antigenically updated COVID-19 vaccines authorised by the European Medicines Agency.
Comparator	No vaccination as defined by study investigators, recognising that some level of background immunity likely exists in the comparator groups either from previous infection or previous vaccination, but where the individual's vaccination status is considered to not be up-to-date.
Outcomes	Effectiveness – main outcomes (laboratory-confirmed) ▪ COVID-19 acute infection ▪ COVID-19-related emergency department visits ▪ COVID-19-related hospitalisation ▪ COVID-19-related intensive care unit admissions ▪ COVID-19-related deaths ▪ Long COVID/post-COVID-19 condition as defined by the World Health Organization[*] Safety – main outcomes ▪ serious adverse events[+] related to vaccination Safety – additional outcomes ▪ all adverse events including: ○ solicited adverse events – local and systemic reactions ○ unsolicited adverse events – spontaneously reported/other adverse event.
Study design	Systematic review(s) of randomised controlled trials and non-randomised studies with a control group.

[¥]Living with immunocompromise associated with a suboptimal response to vaccination, as defined by study authors.
[~]Underlying medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death, as defined by study authors.
[*]The continuation or development of new symptoms three months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least two months with no other explanation.[(22)]
[+]An adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect.[(23)]

For the purpose of this HTA, systematic review(s) will only be considered eligible if they comprise the following characteristics:

- published within the last 12 months (from 21 December 2024 to 22 December 2025)
- include data from EU/EEA countries, the UK or the US
- include disaggregated data for 2023 onwards (to facilitate the inclusion of data relevant to the current situation, that is, data specific to currently circulating variants)
- a clearly stated set of objectives with an explicit, reproducible methodology
- a systematic search of at least two databases, which attempts to identify all studies that would meet the eligibility criteria
- a systematic presentation and synthesis of the characteristics and findings of the included studies
- a critical appraisal of the available evidence.

Two reviewers on the project team will independently appraise the quality of any eligible systematic reviews using the AMSTAR 2 tool (A Measurement Tool to Assess Systematic Reviews, version 2).[24]

Where data for subgroups of interest are lacking, the following platforms will be searched to identify relevant information on the clinical effectiveness and safety of COVID-19 vaccines:

- Vaccine Effectiveness, Burden and Impact Studies (VEBIS) in Europe[25]
- monitoring reports from the COVID-19 vaccine surveillance strategy in the UK.[26]

Where data for subgroups of interest are still lacking, the following US platforms will be searched to identify relevant information on the clinical effectiveness and safety of COVID-19 vaccines:

- Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network (VISION)[27]
- Investigating Respiratory Viruses in the Acutely Ill (IVY) network.[28]

Data from the four sources outlined above will only be eligible for inclusion if they were collected in 2023, 2024 or 2025.

5 Economic evaluation

An economic evaluation comprising a cost-effectiveness analysis (CEA) and a budget impact analysis (BIA) will be conducted. In line with national guidelines,[29] the CEA will be conducted from the perspective of the publicly-funded health and social care system (HSE). In circumstances where it may be appropriate to adopt a wider perspective, the guidance also provides for this possibility, but it must be clearly justified and supported by sufficient evidence.[29] It is argued that economic evaluations of vaccines should adopt a broader perspective than that of the healthcare payer and should be conducted from the societal view to incorporate their full value.[30] The elements of vaccines that may be undervalued when a payer perspective is adopted include the prevention of complications, health gains for caregivers, herd effects, community benefits, enhanced productivity and the promotion of equity.[30] Furthermore, in the case of highly contagious diseases affecting a large cohort annually, productivity losses (associated with both paid and unpaid work) can be significant. Consideration will be given to also conducting the CEA from the societal perspective following review of the evidence for indirect or societal effects.

A summary of the model characteristics for each of the CEA and BIA is presented in Table 3.

Table 3. Model characteristics for CEA and BIA

Model characteristics	CEA	BIA
Perspective	Publicly-funded health and social care system (HSE)	Publicly-funded health and social care system (HSE)
Time horizon	One year	Five years
Discount rate	N/A	N/A
Outcome	ICER or incremental net monetary benefit (INMB)	Incremental cost per annum
Sensitivity analysis	Probabilistic and deterministic	Probabilistic and deterministic

Key: BIA – budget impact analysis; CEA – cost-effectiveness analysis; HSE – Health Service Executive; ICER – incremental cost-effectiveness ratio; N/A – not applicable; QALY – quality-adjusted life year.

5.1 Cost-effectiveness analysis

Due to the short timeline within which the HTA needs to be completed, a review of economic modelling studies will not be conducted to inform the model structure of the CEA. Rather, the model structure will be informed by models previously developed by HIQA for economic evaluations of vaccination for other respiratory diseases and models adopted in recently published economic evaluations of COVID-

19 vaccination strategies conducted by independent agencies to inform national policy decision-making.

Where the data allow, CEAs for the following vaccination strategies will be conducted:

- six-monthly vaccination of adults aged 80 years and older
- annual vaccination of adults aged 60 to 79 years (disaggregated by five-year age band).

Due to insufficient data, CEAs will not be conducted for the other groups for whom NIAC has recommended vaccination (that is, those living in long-term care facilities, those with immunocompromise associated with a suboptimal response to vaccination, or those with medical conditions associated with a higher risk of severe disease) as described in Table 1. CEA will also not be undertaken for those groups for whom NIAC has recommended that access to a COVID-19 vaccine should be made available (Table 1).

CEAs will be conducted in accordance with national HTA guidelines and reported in accordance with Consolidated Health Economic Evaluation Reporting Standards (CHEERS 2022) reporting guidelines.[31]

The CEAs will be conducted from the perspective of the publicly-funded healthcare system (HSE) in a hypothetical patient cohort over a one-year period, with consideration also given to the presentation of the societal perspective. The primary outcome of the CEA will be an incremental cost-effectiveness ratio (ICER) expressed in terms of the mean cost per quality-adjusted life year (QALY) gained. There is currently no accepted willingness-to-pay (WTP) threshold for health technologies in Ireland. However, WTP thresholds of between €20,000/QALY and €45,000/QALY are generally employed to interpret evidence of cost effectiveness.

Estimates of the relative effectiveness of potential vaccination strategies identified in the literature (Chapter 4) will be used to populate the economic model. Where possible, model inputs will be informed by national literature and data sources. In the absence of robust national data, data from countries considered to be generalisable to the Irish setting may be a potential source of model input values. Where data from the literature are lacking or subject to considerable uncertainty, the expert input of the EAG will be required to inform suitable model input parameters.

The economic modelling will also require extensive sensitivity and scenario analyses to explore the key sources of uncertainty and how they impact on the conclusions of the economic analysis. This includes accounting for parameter, methodological and model structure uncertainty

5.2 Budget impact analysis

The BIA will provide information for policy-makers regarding the potential affordability of all COVID-19 vaccination strategies detailed in Table 1. It will estimate the costs to the HSE associated with implementing the various vaccination programmes over an initial five-year time horizon, reported in terms of incremental annual cost. Estimates of budget impact will be particularly sensitive to uptake rates for the vaccination programme. A range of scenarios reflecting judgements on uptake rates for vaccination will therefore be considered in the BIA. Estimated resource use (with consideration to the size of the eligible populations) will be used to inform the relevant inputs to the BIA. For parameters that are unsupported by published literature, input from the EAG will be required to inform plausible values. In addition to the cost of the vaccines, changes to organisational processes will be identified and considered as part of the BIA. Furthermore, potential cost offsets, such as prevention of disease sequelae and hospitalisation, will also be considered and included, if appropriate.

6 Additional considerations

The impact of a change to the populations for whom COVID-19 vaccination is funded on resources (such as, human resources, equipment and supplies, and facilities) and associated healthcare interventions (for example, ease of implementation, additional patient education and support services) will be considered. Key ethical and social issues as outlined in the EUnetHTA Core Model associated with a change in populations for whom COVID-19 vaccination is funded will also be considered.[32]

7 Conclusion

The aim of this HTA is to provide advice to the Minister for Health and HSE to inform a decision on COVID-19 vaccination policy in Ireland, specifically in relation to potential changes to the groups for whom COVID-19 vaccination is funded by the HSE for the 2027-2028 vaccination campaign onwards.

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