



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Advice to the National Public Health Emergency Team:

Derogation of healthcare workers, who are deemed close contacts, from restricted movements following COVID- 19 vaccination

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About the Health Information and Quality Authority

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

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

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

Foreword

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious virus which has caused tens of millions of cases of COVID-19 since its emergence in 2019, with a considerable level of associated mortality. In the context of the ongoing COVID-19 pandemic, SARS-CoV-2 constitutes a significant public health concern due to its high basic reproduction rate, the absence of immunity in the human population, the limited evidence of effective treatment approaches, and the constrained supply of vaccines in the early stages of population-level immunisation programmes.

The National Public Health Emergency Team (NPHE) oversees and provides national direction, guidance, support and expert advice on the development and implementation of strategies to contain COVID-19 in Ireland. Since March 2020, HIQA's COVID-19 Evidence Synthesis Team has provided research evidence to support the work of NPHE and associated groups and inform the development of national public health guidance. The COVID-19 Evidence Synthesis Team, which is drawn from the Health Technology Assessment Directorate in HIQA, conducts evidence synthesis incorporating the scientific literature, international public health recommendations and existing data sources, as appropriate.

From September 2020, as part of the move towards a sustainable response to the public health emergency, HIQA provides evidence-based advice in response to requests from NPHE. The advice provided to NPHE is informed by research evidence developed by HIQA's COVID-19 Evidence Synthesis Team and with expert input from HIQA's COVID-19 Expert Advisory Group (EAG). Topics for consideration are outlined and prioritised by NPHE. This process helps to ensure rapid access to the best available evidence relevant to the SARS-CoV-2 outbreak to inform decision-making at each stage of the pandemic.

The purpose of this report is to outline the advice provided to NPHE by HIQA regarding the derogation of healthcare workers who have completed two doses of COVID-19 vaccination and are identified as close contacts of a COVID-19 case. In the context of very limited research evidence, the advice reflects the findings of a facilitated discussion with the HIQA COVID-19 EAG considering key issues regarding this policy question.

HIQA would like to thank its COVID-19 Evidence Synthesis Team, the members of the COVID-19 EAG and all who contributed to the preparation of this report.

A handwritten signature in black ink, appearing to read 'Máirín Ryan'. The signature is fluid and cursive, with the first name 'Máirín' and the last name 'Ryan' clearly distinguishable.

Dr Máirín Ryan

Deputy CEO & Director of Health Technology Assessment

Health Information and Quality Authority

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Particular thanks are due to the COVID-19 Expert Advisory Group (EAG) and the individuals within the organisations listed below who provided advice and information.

The membership of the EAG was as follows:

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The advice is developed by HIQA's COVID-19 Evidence Synthesis Team with support from HIQA's COVID-19 Expert Advisory Group. Not all members of the Expert Advisory Group and Evidence Synthesis Team are involved in the response to each research question. The findings set out in the advice represent the interpretation by HIQA of the available evidence and do not necessarily reflect the opinion of all members of the Expert Advisory Group.

Conflicts of Interest

None declared.

Advice to the National Public Health Advisory Team

The purpose of this report is to provide advice to the National Public Health Emergency Team (NPHET) on the following policy question:

"Should healthcare workers who have completed two doses of COVID-19 vaccine be considered for derogation from restricted movements where they are identified as close contacts of confirmed cases of COVID-19?"

In the context of very limited research evidence regarding a number of key factors to inform this policy question, the advice from HIQA is informed by the expert opinion of the HIQA COVID-19 Expert Advisory Group (EAG) following a facilitated discussion on the key considerations identified.

A number of presentations were delivered to the COVID-19 EAG on the key issues relating to this policy question including: COVID-related healthcare worker absenteeism, vaccine mechanism and efficacy, contextual factors, international guidance, ethical considerations, acceptability to stakeholders, wider societal implications and the potential harms and benefits. The key points from these presentations which informed HIQA's advice, are as follows:

- Healthcare workers identified as close contacts must restrict their movements. If asymptomatic, they are tested on days five and 10 following exposure with an end of restricted movements on receipt of a SARS-CoV-2 'not detected' test result from the day 10 test.
- If a healthcare worker has had COVID-19 and is identified as a close contact again within three months of infection, they can continue to work as long as they are asymptomatic, with no requirement for them to restrict movements. These close contacts, unlike other close contacts with no history of infection, do not require testing following last contact unless they are symptomatic.
- Currently in Ireland, derogation of healthcare workers who are identified as close contacts of COVID-19 cases is permitted, but must be in accordance with the processes outlined in the HSE guidance for derogation (guidance document available [here](#)).
 - Such derogation may only be considered for healthcare workers who have been identified as essential to maintaining critical services, and following a risk-based assessment by senior management. The derogation is accompanied by strict conditions of testing, active monitoring and supervision by local management and occupational health.

- Data from the National Incident Management System (NIMS) on healthcare worker absenteeism highlights a continued strain on acute and community services secondary to COVID-19. This includes staff absence due to primary infection, close contact exposure and cocooning by staff who have been identified as being at very high risk of severe outcomes from COVID-19 ('extremely medically vulnerable') due to underlying health conditions (guidance document available [here](#)).
 - All occupational groups were noted to have been affected, with the highest absolute numbers in groups with patient-facing roles.
 - NIMS data are limited to staff employed in the public sector (both acute and community settings). The data were noted to be incomplete with a lag in reporting.
 - Up to January 2021, 14.5% of healthcare workers identified as close contacts subsequently tested positive for SARS-CoV-2. Derogated healthcare workers have been identified as having been a potential source of transmission in a limited number of cases.
- Preliminary results from COVID-19 vaccine trials to date (Pfizer BioNTech 162b, Moderna mRNA-1273, and Astra Zeneca ChAdOx1) have demonstrated high levels of efficacy for protection against symptomatic COVID-19. Currently, there is very limited evidence regarding the effect of these vaccines on onward transmission (that is, if a vaccinated individual can still transmit the SARS-CoV-2 virus); this element was not considered as a primary outcome in any of the trials to date.
 - A number of the trials include proxy measures of transmission capability as secondary or exploratory endpoints with some encouraging preliminary results shown; however, these results stem from limited preliminary analyses undertaken following two months of follow-up data. Final trial results are not expected until between mid-2021 and late 2022.
 - Vaccine post-authorisation surveillance and observational studies will provide further evidence regarding transmission capability; however, these data are not expected in the short to medium term until the wider population is offered vaccination.
- Natural immunity studies of healthcare workers with a history of COVID-19 in the UK have demonstrated promising protective effect against reinfection. The study authors, however, have cautioned that previously infected individuals may still

carry the virus and could possibly still transmit to others, noting that future stages of these studies will better inform this outcome.

- A number of countries include guidance on derogation of healthcare workers. A scoping search was undertaken of international guidance from six health agencies and 18 countries for recommendations regarding the derogation of healthcare workers following COVID-19 vaccination. It was noted that:
 - Norway was the only country included that explicitly considered vaccination under healthcare worker derogation. Guidance from 11 January 2021 specifies that vaccination against COVID-19 does not exempt healthcare workers from quarantine (that is, restriction of movements). The guidance highlights that in times of severe need, these employees (amongst others, such as those at end of the restriction of movement period, travel-related, or who have had lower risk exposure) may be considered for derogation.
 - In terms of COVID-19 vaccinated individuals generally (not specific to healthcare workers), most countries with information available highlighted ongoing observation of public health measures following vaccination given the uncertainty around transmission risk. Poland was the only notable exception with exemption of close contacts from quarantine (that is, restriction of movements) following vaccination.
 - A number of countries noted exemption from restriction of movements for healthcare workers previously infected with COVID-19, including Belgium (previous eight weeks), Norway (previous six months) and France (no documented timeline).
- Department of Health documents, which have been previously endorsed by NPHE, outline ethical principles ([link](#)) and procedural values ([link](#)) for decision-making in a pandemic. The balanced consideration of the following seven ethical principles is outlined as crucial within these documents, particularly in the absence of clear research evidence: minimising harm, proportionality, solidarity, fairness, duty of care, reciprocity, and privacy. These ethical principles must be considered in conjunction with a number of procedural values to inform decision-making within this context; that is, reasonableness, openness and transparency, inclusiveness, responsiveness, and accountability.
- The application of such derogation must be considered in light of the acceptability to all relevant parties, including the healthcare worker themselves, the patient, family members and carers, and other staff working in the facility.

Equally, the acceptability of not applying such derogation in terms of staffing shortages, patient care and service provision must be considered.

- The wider societal impact of such derogation may include an impact on public understanding, particularly of the difference between personal protection and onward transmission risk (in the absence of evidence). This could negatively impact on subsequent adherence to public health measures following roll-out of vaccination to the general population.

COVID-19 Expert Advisory Group

- A meeting of the COVID-19 Expert Advisory Group (EAG) was convened to assess the policy question in light of the above key considerations.
- Based on the facilitated discussion held, the COVID-19 EAG reasoned that:
 - Any consideration of vaccinated healthcare workers should be considered as an amendment to the existing derogation guidance as opposed to an exemption or new policy. The same procedures and processes currently in place for derogation, as outlined by the HSE, should be followed when considering the derogation of a vaccinated healthcare worker (guidance available [here](#)).
 - Healthcare workers should be eligible to be considered for derogation from restricted movements following two doses of COVID-19 vaccine. Derogation can be considered following completion of the vaccine-specific time period to achieve full immunity (as per the licensed indications). As per the HSE guidance, derogation should only apply under exceptional circumstances to maintain essential services, subject to necessary criteria and monitoring.
 - As of January 2021, only two months of follow-up efficacy data are available for the licensed COVID-19 vaccines. Derogation criteria should therefore align with availability of trial data. That is, in the first instance, it should be applied to healthcare workers vaccinated in the previous three months. The policy should be reviewed as further data become available.
- The COVID-19 EAG identified additional factors which should be considered to inform both this policy question and potential further policy questions. These included:
 - A subgroup of the HSE Pandemic Incident Control Team (PICT) has recently considered how COVID-19 vaccination affects the application of

- other public health interventions. The group proposed that as evidence is lacking and the country is in the early stages of the vaccination programme, a precautionary approach should apply — that is, that vaccination history should not at this stage be used to determine whether alterations to current public health guidance are appropriate.
- The current absence of evidence from COVID-19 vaccine trials regarding the effect on onward transmission is the most influential knowledge gap for this policy question. The emergence of evidence in support of reducing transmission may permit less stringent derogation criteria for healthcare workers in the future; however, in the absence of this evidence a precautionary principle should apply. It is noted that complete population immunity is unlikely, therefore transmission risk will likely be reduced rather than being eliminated entirely.
 - While there is a residual transmission risk with derogation, it must be noted that the removal of staff, secondary to close contact exposure, places strain on health services. Such strain may negatively impact on staff ability to follow infection prevention and control (IPC) measures, thus also increasing risk. This is not due to lack of staff diligence or care, but rather the effect of limited time and resources. It is noted that this risk may be exacerbated in the context of outbreaks where multiple staff could be identified as close contacts.
 - Healthcare workers who are close contacts for other infectious agents (such as Varicella) are currently assessed for history of infection, completion of vaccination course or evidence of immunity. If such criteria are fulfilled, the healthcare worker is not deemed a close contact. However, it was noted that it would be premature to adopt this approach for COVID-19 given the risk of mutation with coronaviruses and the uncertainty around key aspects of transmission risk, immunity and asymptomatic infection.
 - Vaccination will not lead to sterilising immunity. Some infections in vaccinated individuals will occur, but will likely be shorter in duration (as there will not be a lag time to mount an immune response) and associated with a lower viral load. Therefore, while risk of transmission will be lower, it will not be zero. Prior infection would typically be expected to provide a more complete protection as it should elicit a neutralising antibody response against the spike protein and other viral antigens (whereas the vaccine will elicit an anti-spike response only). As yet, there is no evidence of vaccine-escape with the new variants of the SARS-CoV-2 virus.

- A stratified or preferential approach to derogation may be beneficial if there is more than one healthcare worker who can fulfil the essential role, whereby those eligible for derogation are considered relative to the potential overall risk for transmission. That is, derogation of individuals who have completed their vaccination course may take precedence over derogation of non-vaccinated individuals. However, natural immunity may provide greater protection than vaccine-induced immunity overall; this may be particularly relevant to mRNA vaccines.
- It was emphasised that risk assessment should explicitly consider the nature of the close contact exposure as outlined in the current HSE guidance. If derogation of vaccinated healthcare workers is applied, it must adhere to the strict conditions of testing, active monitoring, and supervision by local management and occupational health. Cases of COVID-19 arising in vaccinated individuals should be considered for whole genome sequencing.
- Ongoing vigilance to IPC measures, risk assessment, and observation of public health guidance are of the utmost importance; vaccination should not be seen as a substitute for any of these elements within or outside healthcare settings. This needs to be clearly communicated.
- Though all healthcare services should follow the HSE guidance on derogation, the availability of robust and supportive occupational health and risk assessments are crucial for appropriate derogation practice. It is noted that the availability of such support may not be accessible in settings outside of acute care, such as community care, or within the private sector (for example, small independent providers or sole operators). The governance for derogation, and provision of support for these areas needs to be considered. It was emphasised that a single policy should be applied nationally in relation to derogation.
- Residential care facilities are experiencing a considerable burden of staff absenteeism due to infection rates and close contact exposure. There is an urgent requirement to consider derogation practices for vaccinated staff in these settings.
- Current HSE guidance states that if a healthcare worker has had COVID-19 and is identified as a close contact within three months of infection, they can continue to work as long as they are asymptomatic, with no requirement for them to restrict movement. Recent evidence from immunity-based studies may support an extension of this time frame.

Advice

Arising from the findings above, HIQA's advice to the National Public Health Emergency Team is as follows:

- Healthcare workers who have completed the full COVID-19 vaccination course and the vaccine-specific time period to achieve full immunity (as per the licensed indications) should be eligible to be considered for derogation from restricted movements. In the first instance, this should be limited to those vaccinated within the previous two months given the current maximum follow-up data for the licensed vaccines. This advice is informed by the evidence that the vaccines are efficacious in preventing symptomatic infection and acknowledges absence of clear evidence regarding onward transmission.
- Eligibility for such derogation should be in line with current derogation guidance as outlined by the HSE, that is, such derogation may only be considered for healthcare workers who have been identified as essential to maintaining critical services, and following a risk-based assessment by senior management. The derogation is accompanied by strict conditions of testing, active monitoring, and supervision by local management and occupational health.
- It should be clearly communicated that vaccination does not lessen the requirement for IPC practices or the requirement to observe general public health guidance within and outside of the healthcare setting.
- A stratified or preferential approach to derogation may need to be applied if there is more than one healthcare worker who can fulfil the essential role being considered. This preferential derogation should take into consideration prior history of COVID-19, vaccination and the specific exposure risk that led to identification of the healthcare worker as a close contact.
- A single national derogation policy should apply across all health and social care settings. Consideration should be given to the dissemination of guidance, training in processes including risk assessment, and support for appropriate implementation of derogation practices outside acute care settings where there may be more limited access to occupational health services.
- Current guidance specifies that healthcare workers who have had a confirmed infection within the last three months are exempt from close contact status. Recent evidence from immunity-based studies may support an extension of this time frame.

- This advice should be reviewed and revised as necessary when new data becomes available from ongoing COVID-19 vaccine trials, post-authorisation surveillance and observational studies.

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