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

Health Technology Assessment (HTA) Expert Advisory Group Meeting (NPHET COVID-19 Support)

Meeting no. 7: Monday 18th January 2020 at 11:00

(Zoom/video conference)

(DRAFT) MINUTES

Attendance:		
Chair	Dr Máirín Ryan	Director of Health Technology Assessment & Deputy Chief Executive Officer, HIQA
	Prof Karina Butler	Consultant Paediatrician and Infectious Diseases Specialist, Children's Health Ireland & Chair of the National Immunisation Advisory Committee
	Dr Jeff Connell	Assistant Director, UCD National Virus Reference Laboratory, University College Dublin
	Dr Eibhlín Connolly	Deputy Chief Medical Officer, Department of Health
	Prof Máire Connolly	Specialist Public Health Adviser, Department of Health and Adjunct Professor of Global Health and Development, National University of Ireland, Galway
	Prof Martin Cormican	Consultant Microbiologist & National Clinical Lead, HSE Antimicrobial Resistance and Infection Control Team
	Dr Ellen Crushell	Consultant Paediatrician, Dean, Faculty of Paediatrics, Royal College of Physicians of Ireland & Co-National Clinical Lead, HSE Paediatric/Neonatology Clinical Programme
	Dr John Cuddihy	Specialist in Public Health Medicine & Interim Director, HSE- Health Protection Surveillance Centre (HPSC)
	Cillian F De Gascun	Consultant Virologist & Director of the National Virus Reference Laboratory, University College Dublin
	Dr Lorraine Doherty	National Clinical Director Health Protection, HSE- Health Protection Surveillance Centre (HPSC)
	Ms Josephine Galway	National Director of Nursing Infection Prevention Control and Antimicrobial Resistance AMRIC Division of Health Protection and Surveillance Centre
	Dr David Hanlon	General Practitioner & National Clinical Advisor and Group Lead, Primary Care/Clinical Strategy and Programmes, HSE
	Dr Patricia Harrington	Deputy Director, Health Technology Assessment, HIQA
	Dr Derval Igoe	Specialist in Public Health Medicine, HSE- Health Protection Surveillance Centre (HPSC)
	Dr Siobhán Kennelly	Consultant Geriatrician & National Clinical & Advisory Group Lead, Older Persons, HSE
	Ms Sarah Lennon	Executive Director, SAGE Advocacy
	Mr Andrew Lynch	Business Manager, Office of the National Clinical Advisor and Group Lead - Mental Health, HSE
	Dr Gerry McCarthy	Consultant in Emergency Medicine, Cork University Hospital & National Clinical Lead, HSE Clinical Programme for Emergency Medicine

	Sarah M O'Brien	Specialist in Public Health Medicine, Office of National Clinical Advisor & Group Lead (NCAGL) for Chronic Disease
	Ms Michelle O'Neill	Deputy Director, HTA Directorate, HIQA
	Dr Margaret B. O'Sullivan	Specialist in Public Health Medicine, Department of Public Health, HSE South & Chair, National Zoonoses Committee
	Dr Lynda Sisson	Consultant in Occupational Medicine, Dean of Faculty of Occupational Medicine, RCPI & HSE National Clinical Lead for Workplace Health and Well Being
	Prof Susan Smith	Professor of Primary Care Medicine, Royal College of Surgeons in Ireland
	Dr Patrick Stapleton	Consultant Microbiologist, UL Hospitals Group, Limerick & Irish Society of Clinical Microbiologists
	Dr Conor Teljeur	Chief Scientist, Health Technology Assessment, HIQA
	Ms Anne Tobin	Assessment and Surveillance Manager, Medical Devices, Health Products Regulatory Authority
	Dr Lelia Thornton	Specialist in Public Health, HSE- Health Protection Surveillance Centre (HPSC)
	Prof Mary Keogan	Consultant Immunologist, Beaumont Hospital & Clinical Lead, National Clinical Programme for Pathology, HSE
In attendance	Dr Eamon O'Murchu	Senior HTA Analyst, Health Technology Assessment, HIQA
	Dr Christopher Fawsitt	Senior Health Economist, Health Technology Assessment, HIQA
	Dr Laura Comber	HTA research analyst, Health Technology Assessment, HIQA
Secretariat	Ms Natasha Broderick	HTA analyst, Health Technology Assessment, HIQA
Apologies	Dr Orlaith O'Reilly	Joint Clinical Lead, HSE Integrated Programme for Prevention and Management of Chronic Disease
	Dr Eavan Muldoon	Consultant in Infectious Diseases, Mater Misericordiae University Hospital, National Clinical Lead for CIT and OPAT programmes & HSE Clinical Programme for Infectious Diseases
	Dr Michael Power	Consultant Intensivist, Beaumount Hospital & National Clinical Lead, HSE Clinical Programme for Critical Care
	Ms Sinead Creagh	Laboratory Manager at Cork University Hospital & Academy of Clinical Science and Laboratory Medicine
	Dr Vida Hamilton	Consultant Anaesthetist & National Clinical Advisor and Group Lead, Acute Hospital Operations Division, HSE
	Prof Paddy Mallon	Consultant in Infectious Diseases, St Vincent's University Hospital & HSE Clinical Programme for Infectious Diseases
	Dr Desmond Murphy	Consultant Respiratory Physician & National Clinical Lead, HSE Clinical Programme for Respiratory Medicine

Proposed Matters for Discussion:

1. **Welcome**

   The Chair welcomed Dr Lelia Thornton to the EAG group, who is replacing Dr Mary O'Riordan as the HPSC representative

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2. Apologies & Introductions

Apologies as noted above.

3. Conflicts of Interest & Meeting Minutes

Conflict of interest and confidentiality statements are required for all members with new potential conflicts to be discussed with the Chair in advance of meetings. Completed statements have been received from all members, with no new conflicts raised in advance of this meeting.

The minutes of the meeting on 9 December 2020 were accepted as a fair and accurate representation of the discussion. The Chair noted that the minutes from the meeting on 25 November 2020 were inadvertently not circulated for review. It was noted that thesewould be circulated before the next EAG meeting and discussed at the beginning of that meeting.

4. Work Programme

The group was provided with an overview of the current status of the work programme including:

No.	Review Questions	Status of work	NPHET date
1.	Rapid review of current public health guidance for community settings and infection prevention and control measures in health care settings.	complete	14 Jan 2021
2.	Potential impact of different testing scenarios to reduce the duration of restriction of movements and or number of tests for close contacts of a COVID-19 case	complete	14 Jan 2021
3.	Derogation from restricted movements required for healthcare workers after vaccination	ongoing	21 Jan 2021
4.	Interventions in an ambulatory setting to prevent progression to severe disease in COVID-19 patients	ongoing	28 Jan 2021
5.	Analysis of factors associated with outbreaks of SARS-CoV-2 in nursing homes in Ireland	ongoing	4 Feb 2021
6.	Review of international public policy response for weekly update	ongoing	Partial update 28 Jan 2021 Full update early Feb
7.	Measures to support self-solation and RoM	scoping 18 Jan 2021	11 Feb 2021
	Database	ongoing	
	Public Health Guidance:	ongoing	

	• Vulnerable groups • LTCFs		

5. Presentation on Derogation of Healthcare workers after COVID-19 Vaccination- Key issues for consideration

The EAG were reminded that NPHET had requested the HIQA evaluation team undertake a facilitated discussion to address the following policy topic:

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?"

A number of presentations were delivered by EAG members 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 following points were raised as matters for clarification or discussion by the EAG:

- 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.
- The current HSE guidance facilitates a standard approach to risk assessment for derogation.
- There is risk attached to each derogation, and that there has been a small number COVID-19 cases associated with the derogation of healthcare workers. However, the risk per derogation is unknown, particularly in light of high community prevalence.
- The data from NIMS on derogations is incomplete and subject to time lags. Derogations were not been formally monitored up until December 2020. It was clarified that the data from the NIMS system relates to HSE settings, not for example private residential care facilities.
- A question arose as to whether there has been any experience of derogating vaccinated HCWs in the past for any other infectious agent. It was noted that for varicella infection, past evidence of immunity or a history of full vaccination is looked for in HCWs and, that where this exists or there is evidence of immunity, HCWs can continue to work. However, given the very limited evidence for COVID-19 and the potential for transmission despite vaccination or past evidence of immunity it would be premature to adopt this approach.
- The following aspects in relation to current policy for healthcare workers were confirmed:

    - 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.
    - Healthcare workers who have had a COVID-19 infection in the preceding three months are not considered close contacts.

6. **Advice: Derogation of HCW***(for discussion)*

In the context of the background material presented, the EAG was asked for their input in order to formulate the advice.

The question posed to the EAG members was:

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?

Feedback on advice from EAG:

- It was noted that the current lack of evidence from COVID-19 vaccine studies regarding the effect on onward transmission is the most influential knowledge gap for this policy question. Such data may become available with the release of results on proxy measures within vaccine trials, and from results of observational type studies following vaccine roll out. It was further highlighted that efficacy data relating to the prevention of symptomatic COVID-19 has to date included two months of follow-up data, with further data expected in the coming weeks.
- It was emphasised that any consideration of derogation for vaccinated healthcare workers should be in the context of an amendment to the existing HSE derogation guidance as opposed to an exemption or a new policy.
- The same procedures and processes currently in place for derogation, as outlined in the HSE guidance, should be followed when considering the derogation of a vaccinated healthcare worker.
- There may be an increased transmission risk with derogation; however, derogation may also reduce transmission risk. Understaffing makes it more difficult for HCWs to adhere to existing IPC measures - this may pose a greater risk than not derogating HCWs. Staff that continue to work in understaffed environments may be less able to adhere to standard IPC measures due to workload pressures and constraints, leading to increased risk of transmission. For example, on average, HCWs may wash their hands in excess of a hundred times in a shift; understaffing can limit their ability to do this properly each time. It was emphasised that this is not due to lack of staff diligence or care, but rather the effect of limited time and resources. This may be a particular issue in wards that experience an outbreak whereby a large number of staff may be deemed close-contacts in quick succession.
- It was noted that the healthcare system is under considerable pressure at the moment due to sustained high levels of community transmission, contributing to

outbreaks in healthcare facilities. This is continuing to pose challenges in terms of maintaining essential services.

- Changes to the derogation criteria needs to be implemented in the safest way that is possible to maintain safe patient care and to maintain patient flow. There also needs to be a focus on protecting the most vulnerable, for example having single bed rooms for those who are at most risk.
- There needs to be clear messaging around the fact that derogation should only occur in extreme circumstances where the health care system is under pressure, to ensure essential care is delivered.
- Amendments to derogation guidance in relation to vaccinated healthcare workers should apply to all health care and social care setting, both public and private.
- It was noted that risk-based assessments are a critical element of derogation, as outlined by the HSE guidance. And that while a single strategy should apply nationally, the availability of support in settings outside of acute care, such as community care, or within the private sector (for example, small independent providers or sole operators) may be limited where occupational health services may not be as accessible. The governance for derogation, and provision of support for these areas needs to be considered.
- In areas where occupational health support is not as accessible, outbreak control teams were highlighted as a potential source of support. However, it was further noted that these teams are also under significant strain given the disease level at present.
- Residential care facilities were noted to be 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.
- Strategies and implementation of derogation relating to vaccinated healthcare workers may be reconsidered as more evidence becomes available. 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 should be carefully communicated that even if you are vaccinated you should continue exercise caution and follow existing IPC measures and public health guidance. Vaccinations do not provide complete protection and although risks will be significantly lower for those who are vaccinated, sterilising immunity is unlikely and some infections will occur. However, infections in vaccinated individuals will likely be shorter in duration and associated with a lower viral load. Therefore, while risk of transmission will be lower, it will not be zero.
- A 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 take precedence over vaccine-induced immunity.

- 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, and this must be clearly communicated. It was noted that although there is no evidence of vaccine-escape with the new variants of the SARS-CoV-2 virus as yet, cases of COVID-19 arising in vaccinated individuals should be considered for whole genome sequencing.
- It was highlighted that if such derogation is applied it must be emphasised that ongoing adherence to all appropriate measures within and outside the healthcare setting is important. That is, similar to ongoing adherence to IPC measures, if a healthcare worker is derogated this does not preclude close contact restrictions in their private life.
- It was highlighted that the time period to achieve immunity was vaccine-specific and should follow the licensed indication (for example the Moderna vaccine is 14 days after the second dose).
- In terms of restrictions on the type of patient seen by derogated healthcare workers on the basis of vaccination, there was a strong consensus that such guidance should not be included and rather that derogation should continue to be seen as an exceptional circumstance considered only for healthcare workers who have been identified as essential to maintaining critical services, and following a risk-based assessment by senior management.
- It was noted that the emergence of new evidence on the duration of natural immunity should be examined which may infer an extension of the timeframe for previously infected healthcare workers to be exempted from close contact status (currently three months).
- Overall the EAG reasoned that 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.

7. What is the evidence on the effectiveness of pharmacological and non-pharmacological interventions in the community setting aimed at reducing progression to severe disease in individuals with suspected or confirmed covid-19 (For information).

The research question was outlined, and the group were informed that the above research question will be discussed at the meeting next week. It was noted that to date a rapid review had been conducted in relation to this research question while a grey literature search on the topic is ongoing.

8. Meeting Close

a) AOB

None noted

b) *Date of next meeting: Monday 25 Jan 2021*