

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

Meeting no. 4: Tuesday 3rd November 2020 at 12:00

(Zoom/video conference)

(DRAFT) MINUTES

Attendance:

Chair		
Dr Máirín Ryan	Director of Health Technology Assessment & Deputy Chief Executive Officer, HIQA	
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	
Ms Sinead Creagh	Laboratory Manager at Cork University Hospital & Academy of Clinical Science and Laboratory Medicine	
Dr John Cuddihy	Specialist in Public Health Medicine & Interim Director, HSE- Health Protection Surveillance Centre (HPSC)	
Dr Lorraine Doherty	National Clinical Director Health Protection, HSE- Health Protection Surveillance Centre (HPSC)	
Dr Vida Hamilton	Consultant Anaesthetist & National Clinical Advisor and Group Lead, Acute Hospital Operations Division, HSE	
Dr David Hanlon	General Practitioner & National Clinical Advisor and Group Lead, Primary Care/Clinical Strategy and Programmes, HSE	
Dr Patricia Harrington	Head of Assessment, Health Technology Assessment, HIQA	
Dr Derval Igoe	Specialist in Public Health Medicine, HSE- Health Protection Surveillance Centre (HPSC)	
Prof Mary Keogan	Consultant Immunologist, Beaumont Hospital & Clinical Lead, National Clinical Programme for Pathology, HSE	
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	
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	

	Dr John Murphy	Consultant Paediatrician & Co-National Clinical Lead, HSE Paediatric/Neonatology Clinical Programme
	Ms Michelle O'Neill	HRB-CICER Programme Manager, 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
In attendance	Mr Barrie Tyner	Information Scientist, Health Technology Assessment, HIQA
	Dr Karen Cardwell	Postdoctoral Researcher HRB-CICER, Health Technology Assessment, HIQA
	Dr Kieran Walsh	HTA research analyst, Health Technology Assessment, HIQA
	Ms Susan Ahern	Health Services Researcher, Health Technology Assessment, HIQA
	Dr Susan Spillane	Senior HTA Analyst, Health Technology Assessment, HIQA
Secretariat	Dr Kirsty O'Brien	Health Services Researcher, Health Technology Assessment, HIQA
	Ms Natasha Broderick	HTA analyst, Health Technology Assessment, HIQA
	Dr Sarah M. O'Brien	Specialist in Public Health Medicine, Office of National Clinical Advisor & Group Lead (NCAGL) for Chronic Disease
	Ms Josephine Galway	National Director of Nursing Infection Prevention Control and Antimicrobial Resistance AMRIC Division of Health Protection and Surveillance Centre
	Dr Niamh Bambury	Specialist Registrar in Public Health Medicine, HSE- Health Protection Surveillance Centre (HPSC)
	Prof Karina Butler	Consultant Paediatrician and Infectious Diseases Specialist, Children's Health Ireland & Chair of the National Immunisation Advisory Committee
	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 Cillian de Gascun	Consultant Virologist & Director of the National Virus Reference Laboratory, University College Dublin
	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, Beaumont Hospital & National Clinical Lead, HSE Clinical Programme for Critical Care
	Dr Gerard O'Connor	Consultant in Emergency Medicine, Mater Misericordiae University Hospital HSE Clinical Programme for Emergency Medicine

Proposed Matters for Discussion:

1. Welcome

The Chair welcomed all members. It was noted that while minutes from the EAG meeting of 20.10.2020 have been circulated, due to the short review time, they will not be formally considered until the next meeting of the EAG.

2. Apologies & Introductions

Apologies as noted above.

3. Conflicts of Interest

All members had completed a conflict of interest (COI) and confidentiality statement. No new conflicts raised in advance of this 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
1.	RQ 20 – Conditions that are at very high risk (extremely medically vulnerable) from COVID-19	Drafted
2.	RQ 21 – Activities or settings associated with a higher risk of SARS-CoV-2 transmission	Drafted
3.	Review of international public policy response for weekly update	Scoping beginning 2/11
4.	Database of public health guidance reviewing international public health guidance	Ongoing – updated 3 times a week
5.	Public health guidance: - Vulnerable groups - Long Term Care Facilities	Ongoing

5. Presentation of evidence summary on activities or settings associated with a higher risk of SARS-CoV-2 transmission.

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

Emerging evidence in relation to what constitutes higher risk areas, activities or workplaces in regard to transmission of COVID-19

This advice was requested in a letter from the Acting CMO to HIQA, dated 2 Oct 2020. In response, HIQA developed a protocol for an evidence summary which was disseminated to the EAG and presented for information at the meeting of 20 Oct 2020. As per the agreed deliverables document, the following research question (RQ) was formulated:

What activities or settings are associated with a higher risk of SARS-CoV-2 transmission?

The Chair thanked the members for reviewing the draft evidence summary circulated last week and the initial feedback received. A presentation was provided on the key points of the evidence summary.

The following points were raised as matters for clarification or discussion by the EAG:

- The low secondary attack rate in health care was queried. The evaluation team highlighted, that despite a large number of clusters, the observed low level of onwards transmission was likely due to consistent use of IPC measures.
- The timing on when the studies were undertaken and the impact of events this may have had was queried, particularly in relation to studies from early in the pandemic before restrictive measures were in place. The evaluation team highlighted that a lot of the reports were from June – August. The studies were therefore assumed to be time sensitive, with a high risk of publication bias. It was noted that the activities or settings considered to be high risk is likely to change over time as new evidence emerges. Furthermore it was highlighted that reported transmission will have been dependent on the pandemic stage in that country and the extent to which mitigation measures (testing and IPC) had been adopted in the particular setting.
- It was noted that the HSPC data illustrated similar findings in relation to household clusters. However, it was emphasised that the initial infection will have been acquired elsewhere in the community. A question was raised about whether the studies identify the source of the index infection. The evaluation team noted that while studies reported that social settings are driving infections, many were not be able to pinpoint definitively where the infections occurred.
- Issue of possible publication bias was raised, with more novel or interesting settings being more likely to be published.
- The EAG noted that settings in other countries may not be comparable with settings here e.g. bars/restaurants in France or Spain may not be the same as bars/restaurant in Ireland.
- Clarification was sought on the definition of shopping centres/malls used in the report and a question raised about the inclusion of Irish data. The evaluation team highlighted that definitions varied across papers with some papers not providing a clear definition. However, in general it appeared to be shopping malls rather than shops where these clusters occurred. No Irish data were identified for inclusion; however it was highlighted that as per the protocol, individual reports of outbreaks were excluded.
- Concern was expressed in relation to the quality of the data and its applicability to Ireland. The importance of estimating risk relative vs. absolute risk was also highlighted. The evaluation team acknowledged that estimates are subject to limitations e.g. recall and publication bias, with only one case control study identified for inclusion. It was agreed that risk estimations in each setting should be considered in the context of the community prevalence. Substantial modelling would be required to estimate risk; however estimates would be associated with considerable uncertainty given the quality of the underpinning data.

- It was noted that given the timing of the various studies included in the report, most would have related to periods when schools were closed. The EAG queried if Irish data comparing risk in schools compared with other settings were available, or data by school type (primary vs. secondary school). It was noted from the HPSC data on clusters in schools, that the test positivity rate has been low in this setting, and that where outbreaks have occurred, it is likely that transmission occurred outside the school. It was noted that members of the HPSC are in the process of drafting a paper regarding the evidence of transmission in Irish schools, again highlighting that transmission rates were low.
- It was queried how household transmission results were interpreted in the different studies. It was noted that there is a difference between transmission within families and house parties or house-to-house transmission, with family transmission arguably being less modifiable. There was concern that an estimated SAR of 18% may not be viewed as that high, where people may think they have an 80% chance of not getting the virus in the household settings. The evaluation team noted that household transmission although not clearly defined in papers, is largely presumed to reflected family household/people living together. The household SAR was noted to be high relative to estimates for other respiratory viruses and settings. There was a suggestion that this may be useful to be used as a baseline risk against which to report the risk in other settings.
- It was acknowledged that much of the guidance in the public domain is supported by the findings of this report. Although various guidance documents discuss the importance of ventilation in minimising transmission risk, it was discussed that this mitigating measure may not be as well known by the public compared with hand washing and social distancing advice.

The Chair noted that some clarifications will be made to the draft report based on the above points. The draft was otherwise accepted by the EAG as a fair reflection of the evidence synthesis that was undertaken.

6. Advice: High risk activities and settings for the transmission of SARS-CoV-2 (*for discussion*)

A short presentation was given noting the specific policy question under review and the key findings of the report. In the context of this evidence, the EAG was asked for their input in order to formulate the advice. Suggested issues to be considered included how advice might be communicated to the public, barriers to self-isolation in different settings, factors impacting potential occupational high risk settings, and the role of retrospective contact tracing / source finding.

Feedback on advice from EAG:

- Irish data would be useful to inform policy and as part of the communication campaign with the public. A retrospective contact tracing study had commenced in Ireland, but it has been temporarily paused due to the introduction of Level 5 restrictions. It is due to recommence when measures are eased. It was noted that a case control study design could also be informative.

- While there will always be a risk, it is important that the public are aware that certain settings are associated with a lower level of risk and are typically safer, for example, being outdoors versus indoors. Equipping the public with knowledge on different levels of risk may help people to live better with COVID-19.
- There is a distinction between controlled and uncontrolled environments, supervised and unsupervised environments. The age groups involved are also an important factor, risk of transmission appears to be lower in younger children. These have important implications for the risk of transmission given the substantial difference in awareness of, adoption and adherence to effective public health measures in different settings. For example, schools are supervised, controlled environments whereas house parties are unsupervised, uncontrolled environments with the level of risk assumed to be significantly higher in the latter. When implementing factors to mitigate risk, the relative importance of the settings and activities to the individual and to society as a whole should be considered.
- Although schools, may potentially be viewed as high risk settings (due to high density, close proximity for prolonged durations, indoor setting etc.), it was noted that this is not reflected in the Irish data with relatively few clusters (<2% of all reported clusters), consistently low test positivity rates and limited evidence of transmission occurring in the school setting. This highlights that transmission risks within school populations can be effectively mitigated with the implementation of protective measures.
- Since the start of the pandemic, there has been widespread adoption of new measures by health and social care services and other supports to minimise the risk of transmission. There is concern that some very vulnerable populations have cut themselves off from services that are essential to their health and wellbeing, as they are not confident that they can safely use these services, and are fearful that they may become infected if they do. It is important to provide reassurance to these individuals that where appropriate measures are in place, services are safe to use.
- The repercussions of onward transmission need to be highlighted, particularly when there are household members who are extremely medically vulnerable, as such individuals need to be supported when self-isolating.
- Evidence of reduced transmission in outdoor and better ventilated settings highlights the importance of adequate ventilation as a means to mitigate risk in settings where higher densities and longer duration of contact cannot reasonably be avoided. Greater emphasis on the importance of ventilation, as part of a comprehensive range of measures may help to reduce the level of risk in different settings.
- Effectively self-isolating (and restricting movements for household members) may be more challenging now compared to earlier in the pandemic, as support from volunteer organisations that was widely available during the initial lockdown (for shopping and medications) may not be as accessible now. The supports that are available to help individuals and households need to be clearly communicated.
- Of particular concern are household members who are in the extremely medically vulnerable group. These individuals are at a significantly higher risk of poorer outcomes should they become infected with SARS-CoV-2. These individuals need to be protected and any supports, such as alternative accommodation for the positive case, should be considered.

Mandatory hospitalisation or segregation of COVID-19 cases was noted to have been used in some Asian countries to control spread.

- The relatively low certainty of the included data and the potentially limited relevance to the Irish setting were noted as limitations. The context is important for the interpretation of these data, in that the activities that occur in a specific setting in one country may be different to activities that occur in the same setting in Ireland.
- Information on superspreading events in the Irish context is currently lacking. Understanding where index cases in household settings acquired the infection is also limited. Better Irish data on the source of infection and risk of transmission associated with different settings and activities would support public health education and awareness campaigns and further aid policy decisions.
- Behavioural studies note that there may be fatigue with advice. A query around whether the advice could be weighted, so that it is clear what the best and worst types of behavior are was raised.

7. Presentation of conditions that are at very high risk (extremely medically vulnerable) from COVID-19

It was noted that NPHE had requested the HIQA evaluation team undertake a review to address the following policy topic:

Based on the available international evidence, is the current definition of what constitutes “extremely medically vulnerable” (i.e., among those who were previously asked to cocoon) in relation to COVID-19 appropriate?

This advice was requested in a letter from the Acting CMO to HIQA, dated 2 Oct 2020. As per agreed processes, HIQA developed a protocol for an evidence summary which was disseminated to the EAG and presented for information at the meeting of 20 Oct 2020. As per the agreed deliverables document, it included the following research question (RQ):

What is the evidence underpinning the categorisation of ‘extremely medically vulnerable’ groups who may be at risk of severe illness from COVID-19?

The Chair thanked the members for reviewing the draft evidence summary circulated last week and the initial feedback received. A presentation was provided on the key points of the evidence summary.

The COVID-19 Expert Advisory Group identified additional factors for consideration to inform both this policy question and potential further research and policy questions. These included:

- It was noted that HIV patients are currently not in the extremely medically vulnerable group in Ireland and therefore not specifically included in the report. It was noted that the ISARIC WHO CCP publication from the UK may be of interest. <https://pubmed.ncbi.nlm.nih.gov/33095853/>. It was noted that where there is information on HIV for example, it should be analysed and fed back. It was also noted that it is important to react quickly to any new data as this affects many people and their ability to work etc.

- It was noted that the US CDC guidance on risk for pregnant women had been updated since completion of the draft review, with a change in the recommendation from 'may be at risk' to 'at risk' of severe disease. The team noted that these updates would be included in the final review. It was noted that any changes such as this are of great concern to frontline workers in different settings and that there is a need to rapidly respond to new information with clear advice that takes appropriate consideration of relative vs. absolute risk.
- A question was raised as to whether the review had found evidence relating to the risk associated with different types of immunosuppressant therapies. It was mentioned that HSE had looked at a large number of immunosuppressant medicines and made a judgment in terms of treatments associated with very significant levels of risk vs. those that were lower risk. It was also noted that the Interim Clinical Guidance for Immunosuppressant Therapy on the HSE website had been updated recently. The evaluation team highlighted that while a number of studies with patients were on immunosuppressants were identified, the data were poorly described and that it was not clear if the patients were significantly immunosuppressed to cause an increased risk of severe disease.
- It was noted that there is a need for clear communication around immunosuppressant therapy and the risk of unintended consequences, for example the potential greater risk of serious adverse outcomes if a patient elects to discontinue treatment in an attempt to mitigate risk from COVID-19 than if the original treatment was continued.
- It was acknowledged that that topics of immune deficiency and suppression are bodies of work in themselves and may warrant additional review as there is substantial heterogeneity within this population. There are emerging data suggesting that certain immunosuppressants may be preferable to others.
- It was asked if any of the studies had reported the relative risk at which individuals would fall into different risk categories (high risk, very high risk etc). The evaluation team noted that this had been poorly reported in the studies while the international guidance reviewed had not specified thresholds at which an individual would automatically be considered to be at a high or very high level of risk.
- An individual may be classified as at very high risk (extremely medically vulnerable) from COVID-19 if they have a rare disease despite some rare diseases not being associated with any increased risk. This may have implications for an individual's ability to work. In a similar way, this information is important for children attending schools who have a rare disease and think they are at higher risk, but may not be. This information is important so we can better understand what groups may need to cocoon.
- For the risk associated with age, it was suggested that the report should be careful to caveat this association. It is unclear in many of the studies if the older population is resident in nursing homes and/or have comorbidities vs. those who are healthy, over 70 and living at home.

The Chair noted that based on this feedback some clarifications will be made to the draft report. The draft was otherwise accepted by the EAG as a fair reflection of the evidence synthesis that was undertaken.

8. Advice: Conditions that are at very high risk (extremely medically vulnerable) from COVID-19 (for discussion).

A short presentation was given noting the specific policy question under review and the key findings of the report. In the context of this evidence, the EAG was asked for their input in order to formulate the advice. Specifically they were reminded that the question was whether there is a rationale upon which to amend the categorisation of 'extremely medically vulnerable' groups who may be at risk of severe illness from COVID-19. Suggested issues to be considered included the level of evidence that might be required to support a recategorisation from very high risk to high risk, the implications of the different risk classifications for individuals in terms of quality of life and employment or education, the implications for healthcare policy including vaccination policy, the consistency of national guidance documents in terms of definitions and or recommendations, and how risk should be communicated.

Feedback on Advice from EAG:

- No sufficiently consistent evidence was identified to support the removal of any group categorised as 'extremely medically vulnerable'.
- It was noted that while not yet published, there are HIPE data which could be shared with the group. HIPE data has limitations as it only reflects comorbidities that were documented in the clinical notes. However, these data has shown that age is the strongest risk factor for hospital death in Ireland, with COPD and kidney disease also mentioned as strong risk factors.
- The issue of age over 70 years as a risk factor was discussed and the point raised that some of the data may not be adjusted for multimorbidity or by socioeconomic status. The concern was that healthy 75 year olds are cocooning, while less healthy, higher risk 50 year olds are out in the community. There is a danger of medicalisation of older people. The Danish advice was mentioned as an alternative model to base age-related advice on, where age and comorbidity status is taken together.
- There is a lack of consensus on what the definition should be for severe respiratory disease, and the definition given in the studies should be added, where available.
- It was noted that there has been an increase in requests from families for home schooling as a result of fears about medical risks. The advice up to now has been, if a younger person has a condition and is well enough to normally attend school then in the context of COVID-19 this person can attend in person classes, likewise if they normally cannot attend then they cannot attend during the pandemic and supports need to be provided so that they can continue education remotely.
- While children with comorbidities identified in the various at risk groups were noted to be at higher risk than children without these conditions, it was emphasised that all national and international data indicate that the absolute risk of severe consequences from COVID-19 is very low in children.
- Obesity is not currently listed in extremely medically vulnerable in Ireland and was outside the scope of this review, however, it was noted by a member of the EAG that Irish hospital data showed it was a risk factor for hospitalisation, but not an independent risk for mortality.

- It was pointed out that the decision about who is included in the extremely medically vulnerable list has really important implications for people, in terms of quality of life etc. Some individuals, where they cannot work from home, may only be entitled to pay from work if they fall into extremely medically vulnerable category.
- The EAG queried what level of risk is needed to move a category from high risk to very high risk or vice versa. It was clarified that there is no established acceptable risk criteria, and it was highlighted that this is a current gap where clarity would be beneficial. However, it was noted that it is difficult to clarify how much evidence is needed and what risk is acceptable for downgrading. There was a query around whether we can make a decision to move a condition from the very high risk group to the high risk group without having a pre-determined metric to make that decision. It was clarified that this is often based on expert medical opinion, and highlighted that other countries have removed groups from their list based on new evidence.
- The term 'risk of infection' was noted to be extremely broad and may not be appropriate (for example, following splenectomy, there is a specific risk of severe infection from encapsulated bacteria, but this does not necessarily mean there is an increased risk of severe infection from other organisms). Consideration should be given to refining the language to specify that it is conditions or treatments that significantly increase the risk of viral infections.
- The risk categories were noted to have extremely important implications for vaccine policy as they will inform vaccine allocation
- It was suggested that there is a need for a clear process for when evidence emerges on risk categories and the requirement for updating categories.
- It was highlighted that studies need to be considered in the context of: early vs late studies, residential settings of those who experienced adverse events, and comorbidity. Also the importance of the language chosen when communicating advice was stressed.

9. Meeting Close

a) *AOB*

None noted

b) *Date of next meeting:* will be communicated in due course