Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Advice to the National Public Health Emergency Team:

Public health measures to limit the transmission of SARS-CoV-2 at mass gatherings

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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 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 (NPHET) 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 NPHET 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 NPHET. The advice provided to NPHET 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 NPHET. 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 NPHET by HIQA, with consideration of the scientific literature, international public policy and input from the COVID-19 EAG regarding the policy question: "What public health measures are necessary to enable mass gatherings to occur safely in both indoor and outdoor settings?" The advice also reflects the findings of a discussion with the HIQA COVID-19 EAG considering key issues relating to the 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.

Dr Máirín Ryan

Deputy CEO & Director of Health Technology Assessment

Health Information and Quality Authority

Acknowledgements

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Particular thanks are due to Library and Information Services at the Health Service Executive (HSE) and the Expert Advisory Group (EAG).

Membership of the Expert Advisory Group involves review of evidence synthesis documents and contribution to a discussion which informs the advice from HIQA to NPHET. It does not necessarily imply agreement with all aspects of the evidence synthesis or the subsequent advice.

The membership of the EAG was as follows:

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Dr Jeff Connell	Assistant Director, UCD National Virus Reference Laboratory, University College Dublin
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The advice is developed by the HIQA Evidence Synthesis Team with support from the 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 evidence synthesis is to provide advice to the National Public Health Emergency Team (NPHET) on the following policy question:

> "What public health measures are necessary to enable mass gatherings to occur safely in both indoor and outdoor settings?"

The following research questions (RQs) were developed to address this policy question:

- RQ1: What public health measures are advised internationally to limit the transmission of SARS-CoV-2 at mass gatherings (including both indoor and outdoor settings)?
- RQ2: What is the evidence that public health measures aimed at limiting the transmission of SARS-CoV-2 at mass gatherings (including both indoor and outdoor settings) are effective?

The key points of this evidence synthesis, which informed HIQA's advice, are as follows:

- Mass gatherings play an important role in society, but since the onset of the COVID-19 pandemic in early 2020, due to the high risk of superspreading at these events, they have generally been restricted or prohibited in order to mitigate or prevent transmission of SARS-CoV-2.
- Superspreading events (SSEs) are defined as events that transmit infection to a larger number of individuals than is usual, and have been a feature of the COVID-19 pandemic.
- With the ongoing roll out of COVID-19 vaccination campaigns globally, mass gatherings are being permitted once again. However, a large proportion of the population remain unvaccinated and there are concerns regarding the impact of circulating variants of concern (VOCs).
- This evidence summary consisted of two research questions (RQs):
    - RQ1 was a review of websites of public health agencies and governmental departments from 22 countries and two international agencies to identify public health guidance relating to measures advised to reduce the transmission of SARS-CoV-2 at mass gatherings, as well as information relating to pilot events. The information

summarised in RQ1 is correct as of 10 June 2021, but may be subject to change.

- RQ2 was a systematic search for primary research studies published from 1 January 2020 up to 3 June 2021 to identify evidence regarding the effectiveness of public health measures to prevent the transmission of SARS-CoV-2 at mass gatherings.

- The World Health Organization (WHO) and US Centers for Disease Control and Prevention (CDC) strongly advise that a thorough risk assessment should be conducted in advance of any planned mass gathering and that there should be clear action plans for events. The US CDC further advises that the level of risk needs to be carefully considered before organising any event, with promotion of healthy behaviours (for example, mask wearing) and healthy environments (for example, ventilation) throughout. Event organisers need to be prepared in case of someone getting sick during and after the event and there should be good communication with contact tracing services.
- As of 10 June 2021, mass gatherings are generally permitted, to varying degrees, in all 22 included countries, with generally fewer attendees permitted in indoor events than outdoor events.
- Austria, Denmark, Czech Republic, France, the Netherlands and Portugal currently require COVID-19 health certification (that is, proof of vaccination, immunity and or recent negative test, to demonstrate that an individual is at low risk of acquiring or transmitting SARS-CoV-2) in order to access mass gathering events. Six other countries (Belgium, Germany, Italy, Norway, Sweden, and Switzerland) have plans to introduce COVID-19 health certification as a requirement for accessing certain mass gathering events, over the coming months, while England is currently piloting this process.
- Considerable variability was observed in terms of pre-event testing requirements and these appear to be in flux. Twelve of the 22 included countries have stated plans to undertake (or are currently undertaking) pre-event testing:
    - polymerase chain reaction (PCR) or antigen tests are specified by six countries (Austria, Czech Republic, France, Italy, Norway and Switzerland)
    - PCR tests only are specified by three countries (Belgium, Denmark and Portugal), and antigen tests only are specified by three countries (England, Germany, the Netherlands)

  - differences were also noted in the requirements for the timing (ranging from seven days prior to on-site) and sampling (self-sampled/self-tested or provider taken) of the pre-test.

- Israel, which was one of the first countries to introduce a 'Green Pass' system, cancelled the 'Green Pass' requirements as of 1 June 2021 due to the low infection rates and the continuing downward trend of all indicators. There is now unrestricted access to all establishments and sectors in Israel, without any requirements for proof of vaccination, recent negative test or recovery from COVID-19.

- All restrictions on mass gatherings are set to be removed by June 2021 in France and Iceland, by July 2021 in Austria, England and Finland (for outdoor events), and by August 2021 in Finland (for indoor events). Denmark, the Netherlands and Sweden have stated that all mass gathering restrictions will be lifted only when certain targets or indicators have been met.

- There are reports of completed, ongoing or planned pilot events in 15 of the 22 included countries (Austria, Belgium, England, France, Germany, Ireland, Italy, the Netherlands, Northern Ireland, Norway, Portugal, Scotland, Spain, Switzerland and Wales). The most comprehensive programmes to-date include those currently being conducted in the Netherlands and England.

- Eleven relevant studies were identified that provided evidence regarding the effectiveness of public health measures to prevent the transmission of SARS-CoV-2 at mass gatherings. Five of the 11 studies related to concerts or festivals, two related to sporting events, one to a graduation ceremony, one to the Hajj pilgrimage, one to a protest rally and one study related to a business conference and a theatre performance that occurred in the same venue on different dates.

- There is evidence from 11 studies that implementing a range of public health measures can reduce the risk of SARS-CoV-2 transmission at mass gatherings. However, there were important limitations associated with these studies. While one included study reported that extremely stringent mitigation measures substantially reduced the risk of transmission, it is unlikely that risk can be eliminated entirely.

- All studies adopted a layered mitigation approach involving multiple public health measures, therefore it was not possible to determine the effectiveness of any single measure. The most commonly implemented measures were provision of hand sanitiser, wearing of face masks, ensuring adequate ventilation, health screening, and contact tracing.

- Ten of the 11 included studies focused on events that took place outdoors or in indoor settings with specified minimum levels of ventilation. The other study did not include a specific focus on ventilation or outdoor activities. The potential effect of ventilation in limiting transmission at indoor mass gatherings was reported in two included studies.
- While some of the findings from the eight studies that trialled pre-event testing are promising, it is important to note that positive cases were detected post-event in four of these studies. It is not known if transmission occurred during the event despite various mitigation measures in place, or if these cases were already infected, but either not yet detectable or missed at the time of testing. It is also not known whether these positive cases seeded further cases in the community as onward transmission was not measured in any included study.
- While there is a movement to reopen society and allow mass gatherings to occur once again, it is important that a suite of public health measures are implemented to mitigate the associated increased risk of transmission with these events. These public health measures may include pre- and post-event testing, capacity restrictions, excluding vulnerable populations, health screening, cohorting, requirements for adequate ventilation, face masks, hand hygiene, contact tracing and physical distancing. Although there is general consistency with regards to the implementation of most of these public health measures at mass gatherings, there is considerable variability in terms of COVID-19 health certification and pre-event testing.
- The risk of SARS-CoV-2 transmission at mass gatherings can be reduced by implementing a range of public health measures; however, it is unlikely that this risk can be eliminated entirely. Therefore, caution is strongly advised when proceeding with the relaxation of mass gathering restrictions with due consideration given to the levels of vaccination coverage, rates of community transmission and the risk posed by circulating VOCs.

COVID-19 Expert Advisory Group

A meeting of the COVID-19 Expert Advisory Group (EAG) was convened for clinical and technical interpretation of the research evidence and international public policy on 24 May 2021. The following points were raised in respect of the review findings:

- There was a general welcome among the EAG for the cautious reopening of society as this was felt to be important for the mental health of the nation as well as the economic recovery. It was discussed how some European countries were proposing a gradual approach to easing mass gathering

restrictions. There was general consensus among the EAG that a gradual and cautious approach to reopening should be followed in Ireland.

- It was noted that the World Health Organization (WHO) recently updated their guidance to acknowledge that SARS-CoV-2 can be transmitted via long range (greater than 1 metre), and that this transmission risk is particularly elevated in poorly ventilated and or crowded indoor settings, where people tend to spend longer periods of time. The avoidance of mass gatherings in indoor, crowded and poorly ventilated settings was felt to be crucial to prevent superspreading events, considering the updated WHO advice and the findings provided in the evidence summary. Particular concerns were raised about holding mass gathering events in such settings without face masks and physical distancing.

- A clear preference was stated, in the first instance, for outdoor, seated events, involving relatively small numbers, and for a short period of time, with no eating or drinking permitted. Thereafter, an incremental, step-wise approach to easing restrictions was suggested as a means to enable mass gatherings to recommence safely in all settings, while population vaccination coverage increases.

- While the stringent public health measures that were implemented for the Hajj pilgrimage were noted to be very successful in reducing the risk of SARS-CoV-2 transmission to an extremely low level, there was a general consensus that such onerous measures would not be acceptable or feasible in an Irish context.

- Concerns were raised about the impartiality of some of the major pilot event studies conducted to date, given that they were mostly funded and or supported by the events industry. The limited follow-up data in these studies were also noted as a particular limitation. It was suggested that there may be a bias due to under-reporting and low compliance to follow-up testing in some studies as individuals may not want to officially attribute their symptoms to the event, should they view the reopening of such events as important.

- Serious ethical concerns were raised in relation to pilot mass gathering events, particularly where these target or are likely to predominantly include a younger population who are unlikely to be eligible for vaccination until later this year. It was noted that mass gatherings involving a largely unvaccinated younger population is not without risk. The high incidence of SARS-COV-2 infection in this cohort was noted. Although this population may be at low risk

of severe disease from COVID-19, the potential for developing long-COVID was highlighted.

- The purpose of many of the pilot events conducted to date was viewed to be unclear, as the epidemiological impact of the mass gathering was not measured or considered in most of them. While superspreading events may be rare, they can have significant consequences, and this was felt to be a critical issue that needs to be considered in future pilots. It was highlighted that pilot events should be carefully planned and there must be clear public health involvement to mitigate risks as much as possible. A cautious approach should apply to any pilot event, with smaller more manageable events, in lower risk settings, being piloted first.

- The importance of conducting independent research with clear protocols, robust study design, ethics review and transparent and timely reporting was stressed. It was suggested that public health expertise should direct and inform any pilot events in Ireland, given the potential impact on public health.

- There is a sense of urgency in terms of conducting these pilot studies given the movement to significantly ease restrictions and the need for high-quality data to inform decision-making. Coordinated action was emphasised in order to conduct these pilot studies within the short time frame in which the data would be useful. The challenges of conducting such high-quality research in the short term were discussed in the context of severe capacity restrictions facing the health service, particularly in light of the recent cyber attack on the HSE. It was suggested that universities' expertise could be used in such projects, with the aim of obtaining good-quality, timely and informative data.

- It was questioned where ethics approval of such studies would sit given that these types of studies would be outside the remit of institution-level research ethics committees.

- It was stated that Ireland is currently at a critical juncture in terms of reopening and there will be pressure to allow mass gatherings to occur. In the absence of well-designed pilot studies, an alternative is to continue with the current measures that are in place and wait until there is sufficient vaccination coverage in the population before permitting mass gatherings. However, it was acknowledged that this may not be acceptable.

- The relative advantages and disadvantages of PCR-based and antigen-based pre-event testing were discussed. While PCR tests were acknowledged as having higher sensitivity than antigen tests, it was suggested that antigen

tests may be more appropriate for short-term events as these correlate well with infectivity, may be more feasible to deploy at events given their rapid turn around time, and are cheaper. However, a point was raised that while the reagents for antigen tests may be cheaper, the logistics of organising teams of trained professionals to obtain or supervise samples and administer antigen tests at events (as occurred in some of the included studied) would be challenging and costly. It was suggested that PCR-based pooled sample testing of households or friend groups/bubbles may be a potentially useful option for pre-event testing. Importantly, it was acknowledged that any pre-event testing will not detect 100% of cases and as such it would need to be combined with other measures. Particular importance was placed on adequate ventilation, face mask use, physical distancing and transport to and from mass gathering events.

- The use of trained professionals to collect and process samples, will increase the reliability of any pre-event testing. Self-testing[1] (or unsupervised self-sampling[2]) for pre-event testing may not be the preferred approach given the potential for the sub-optimal quality of specimen collection, which may undermine the reliability of the entire testing process.

- In relation to the stated policy question, instead of "what are the minimum public health *measures* necessary", it was suggested that it could be framed as "what are the public health *conditions* necessary" for mass gatherings to safely occur. It was stated that decisions on the easing of mass gathering restrictions should not be separated from the level of infection in the community and the level of vaccination coverage in the population.

- While the lifting of mass gathering restrictions in Israel was viewed as a clear outlier, it was noted that England, France and Finland are also proposing relatively rapid lifting of mass gathering restrictions over the coming weeks. Caution was urged with regards to following our neighbours' lead given that in Ireland, the younger population, who have a higher COVID-19 incidence, may not be vaccinated until September. Additionally differences in the epidemiological situation between Ireland and these other countries may explain different strategies. It was suggested that there may also be legal

[1] Self-test requires an individual to collect a specimen from their nose or throat (can be a nose swab, throat swab, saliva or a combination of all), conduct the test and interpret the results according to the instructions provided. This is done using a single-use self-test kit that can be used at home (or in another setting) and without any specialised laboratory equipment or training.
[2] Self-sampling) refers to an individual collecting their own swab, or specimen, for a SARSCoV-2 test. This test could be performed using a self-test or could be performed in a laboratory (or other healthcare setting) by a trained person

consequences from easing mass gatherings too quickly should this prompt another wave of infections.

- It was noted that COVID-19 cases are commonly associated with activities that occur before and after the mass gathering event (for example, due to shared transport or social events), and that this was observed by public health teams in previous outbreaks, particularly in relation to sporting events.

- It was reiterated that not all mass gatherings carry the same level of risk. While transmission can occur at any gathering, the risk of transmission differs (for example, indoor vs outdoor, seated vs unseated, short vs long duration etc.). It was felt that there should not be a blanket ban on all mass gatherings and that this should be clearly communicated.

- The recent cyberattack on the HSE was discussed in relation to its impact on the operation of the entire health service. The laboratory and radiology services were identified as being particularly affected, and another wave of COVID-19 cases, for whatever reason, may completely overwhelm the system. This further emphasises the need to proceed with caution.

- The possibility of using vaccination and or immunity status to complement pre-event testing as a requirement for accessing mass gatherings was discussed. It was suggested that this policy may result in legal challenges. Proof of vaccination was viewed as a potential incentive for many young people to get vaccinated, if it was the only means of accessing events. However, given the European Commission recently stated that those who have not been vaccinated should not be at a disadvantage, it was felt there would have to be an option for testing.

- The use of EU digital green certificates that provide proof of either full vaccination, recent negative test result or recovery from COVID-19, to gain access to mass gatherings, was discussed. It was clarified that certain EU countries such as Italy plan to use these green certificates domestically to allow individuals to access mass gathering events.

- While restricting movements before or after mass gatherings to limit potential onward transmission has been implemented in some of the included studies, it was noted that such a measure may not be feasible or enforceable and could only be advisory. However, it was suggested that vulnerable populations may be advised not to attend mass gatherings.

Advice

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

- Not all mass gatherings carry the same level of risk. While transmission can occur at any gathering, the risk differs, and therefore a blanket ban on all mass gatherings is not necessary. Previous advice has highlighted that the transmission pattern of SARS-CoV-2 appears to be highly overdispersed with a small proportion of cases potentially causing the majority of local transmission. Indoor, high occupancy, poorly ventilated environments, where there is shouting and singing, insufficient use of face coverings, and prolonged contact present the highest risk of SARS-CoV-2 transmission.
- The review of public policy from 22 included countries highlighted a movement towards the easing of restrictions on mass gatherings across countries. However, there is a substantial variation in the international approach.
- There is evidence from 11 studies that implementing a range of public health measures can reduce the risk of SARS-CoV-2 transmission at mass gatherings. However, there were important limitations associated with these studies. While one included study reported that extremely stringent mitigation measures substantially reduced the risk of transmission, it is unlikely that risk can be eliminated entirely.
- Irish pilot events may provide useful evidence to guide the safe return of mass gatherings. It is important that such pilot events are conducted independently, with clear protocols, robust study design, ethics review and transparent and timely reporting. Given the significance of mass gatherings for public health, it is important that these pilot events measure the potential health and epidemiological impact of such events, and that their design is informed by public health expertise.
- A cautious and gradual approach to lifting mass gathering restrictions is advised. Measures should be eased incrementally and in line with the public health conditions (that is, the level of infection in the community and the level of vaccination coverage in the population). In the first instance, any organised mass gatherings should be seated outdoor events, that are short in duration with significantly reduced capacity. Small and manageable events should be piloted prior to larger scale events.

- A risk assessment should be conducted in advance of any mass gathering event. It is important that a layered mitigation approach (including, physical distancing, face mask use, adequate ventilation and hand hygiene) is implemented to minimise the risk of transmission. Consideration should be given to congestion control, cohorting of attendees, and prohibiting the consumption of food and drinks.
- In addition to the recommended public health measures, consideration should be given to the use of pre-event testing and 'green certs' (that is, for fully vaccinated people, those with a recent negative test or with a documented history of COVID-19) to gain access to events. The use of trained professionals to collect and process samples will increase the reliability of any pre-event testing.
- Activities that occur before and after mass gathering events may also lead to an increased risk of transmission. Public health measures (including physical distancing, face mask use, adequate ventilation and hand hygiene) should be encouraged in relation to shared transportation, accommodation and socialisation that occur before and after such events. Consideration should be given to advising attendees to restrict their movements for a period of time after the event to minimise the risk of onward transmission, in particular to avoid contact with those at higher risk of severe COVID-19.
- While the risk of SARS-CoV-2 transmission at mass gatherings can be reduced by implementing a range of public health measures, it is unlikely that this risk can be eliminated entirely. This should be clearly communicated to those at higher risk of severe COVID-19. Any relaxation of mass gathering restrictions should give due consideration to the levels of vaccination coverage, rates of community transmission, the risk posed by circulating variants of concern, and the capacity of the healthcare system.

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