



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Protocol for an evidence summary of public health measures to limit the transmission of SARS-CoV-2 at mass gatherings

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Purpose and aim

The purpose of this protocol is to outline the process by which the Health Information and Quality Authority (HIQA) will synthesise evidence to inform advice from HIQA to the National Public Health Emergency Team (NPHE). The advice will take account of expert interpretation of the evidence by HIQA's COVID-19 Expert Advisory Group. This evidence synthesis was requested by NPHE to address 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 two research questions (RQs) were designed to inform the 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?

For the purpose of these review questions, the following is the definition of a mass gathering, which is adapted from the definition used by the World Health Organization (WHO).

Mass gatherings are events where there is a concentration of people at a specific location for a specific purpose over a set period of time. They can include a single event or a combination of several events at different venues and constitute a diverse range of gatherings such as sports, music / entertainment, religious events, family events (such as weddings, funerals etc.), large conferences and exhibitions, as well as community, charity events and other types of events. Attendance at the place of work, education and childcare for the purposes of work, education or childcare respectively would not ordinarily constitute a mass gathering.⁽¹⁾

1. Process outline

A standardised approach to the process has been developed and documented to allow for transparency and to aid in project management. Five distinct steps have been identified in the process for completion. These are listed below and described in more detail in Sections 2.1-2.5.

1. Identify document types of interest.
2. Search relevant databases and websites of relevant national and international agencies.
3. Screen identified documents.
4. Data extraction and quality appraisal of included documents.
5. Summarise findings.

2. Review process

2.1 Identify document types of interest

A scoping review of the literature was carried out in preparation for this evidence summary and based on the volume of literature available and project timelines, an overview of public health guidance and primary research studies was considered to be the most efficient method to address the above research questions.

The evidence underpinning the above review questions will be identified from the following document categories:

- a) Public health guidance, frameworks and tools
- b) Primary research studies.

2.2 Search relevant databases

- a) Public health guidance, frameworks and tools

For RQ1, the websites listed below will be reviewed to identify public health guidance, frameworks and tools relating to measures advised to prevent transmission of SARS-CoV-2 at mass gatherings, including the conduct of pilot events. These websites were chosen based on widespread use of the organisation's advice and the countries being in a similar phase of pandemic response as Ireland. The list of websites for inclusion was also informed by the experience of HIQA's COVID-19 evidence synthesis team in conducting rapid reviews of public health measures.

- b) Primary research studies

For RQ2, a systematic literature search will be conducted in Cochrane, Embase (OVID), Medline (OVID), Google, Web of Science and Europe PMC, to identify evidence regarding the effectiveness of public health measures to prevent the transmission of SARS-CoV-2 at mass gatherings. The search strategy is presented in Appendix 1.

International public health agencies:

- World Health Organization (WHO)

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?healthtopics=b6bd35a3-cf4f-4851-8e80-85cb0068335b&publishingoffices=aebab07-3d0c-4a24-b6ef-7c11b7139e43&healthtopics-hidden=true&publishingoffices-hidden=true>

- European Centre for Disease Prevention and Control (ECDC)
https://www.ecdc.europa.eu/en/search?s=&sort_by=field_ct_publication_date&sort_order=DESC&f%5B0%5D=diseases%3A2942

National governments and public health agencies:

EU/EEA countries

- Austria
 - <https://www.sozialministerium.at/en.html>
 - <https://corona-ampel.gv.at/aktuelle-massnahmen/bundesweite-massnahmen/>
 - <https://metropole.at/coronavirus-updates-in-english/>
- Belgium
 - <https://www.info-coronavirus.be/en/faq/>
 - <https://www.info-coronavirus.be/en/covid/>
 - <https://www.info-coronavirus.be/en/>
 - <https://www.sciensano.be/en/health-topics/coronavirus>
- Czech Republic
 - <https://www.vlada.cz/en/media-centrum/aktualne/measures-adopted-by-the-czech-government-against-coronavirus-180545/>
 - <https://covid.gov.cz/opatreni>
 - <https://koronavirus.mzcr.cz/en/>
- Denmark
 - <https://coronasmitte.dk/en>
 - <https://www.sst.dk/da>
 - https://virksomhedsguiden.dk/erhvervsfremme/content/temaer/coronavirus_og_din_virksomhed/
- Finland
 - <https://stm.fi/en/frontpage>
 - <https://thl.fi/en/web/thlfi-en>
 - <https://valtioneuvosto.fi/en/information-on-coronavirus/current-restrictions>
- France
 - <https://www.gouvernement.fr/info-coronavirus>
 - <https://solidarites-sante.gouv.fr/>
 - <https://www.hcsp.fr/Explore.cgi/AvisRapports>

- o https://www.has-sante.fr/jcms/fc_2875171/en/resultat-de-recherche?FACET_THEME=c_64654%2Fc_64679%2Fp_3203414
- Germany
 - o <https://www.bundesregierung.de/breg-en>
 - o <https://www.zusammengegencorona.de/en/?articlefilter=all>
 - o https://www.rki.de/DE/Home/homepage_node.html;jsessionid=360826C43D1A5736B0C0F3521211B355.internet102
- Iceland
 - o <https://www.covid.is/english>
- Ireland
 - o <https://www.gov.ie/en/campaigns/c36c85-covid-19-coronavirus/>
 - o <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/>
- Italy
 - o <http://www.salute.gov.it/portale/nuovocoronavirus/homeNuovoCoronavirus.jsp>
 - o <https://www.governo.it/it/articolo/domande-frequenti-sulle-misure-adottate-dal-governo/15638>
- The Netherlands
 - o <https://www.government.nl/topics/coronavirus-covid-19>
 - o <https://lci.rivm.nl/richtlijnen/covid-19>
 - o <https://www.rijksoverheid.nl/>
- Norway
 - o <https://www.fhi.no/sv/smittsomme-sykdommer/corona/>
 - o <https://www.helsedirektoratet.no/>
 - o <https://www.regjeringen.no/en/topics/koronavirus-covid-19/id2692388/>
- Portugal
 - o <https://covid19estamoson.gov.pt/>
 - o <https://www.visitportugal.com/en/node/421175>
 - o <https://covid19.min-saude.pt/>
- Spain
 - o <https://www.lamoncloa.gob.es/lang/en/Paginas/index.aspx>
 - o <http://www.exteriores.gob.es/Portal/es/Paginas/inicio.aspx>
 - o <https://www.msrebs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm>
- Sweden
 - o <https://www.government.se/government-policy/the-governments-work-in-response-to-the-virus-responsible-for-covid-1/>
 - o <https://www.folkhalsomyndigheten.se/smittskydd-beredskap/utbrott/aktuella-utbrott/covid-19/>

- o <https://www.krisinformation.se/>

UK countries

- England
 - o <https://www.gov.uk/coronavirus>
- Northern Ireland
 - o <https://www.nidirect.gov.uk/campaigns/coronavirus-covid-19>
 - o <https://www.publichealth.hscni.net/>
- Scotland
 - o <https://www.gov.scot/coronavirus-covid-19/>
 - o <https://www.hps.scot.nhs.uk/a-to-z-of-topics/covid-19/>
- Wales
 - o <https://gov.wales/coronavirus>
 - o <https://phw.nhs.wales/topics/latest-information-on-novel-coronavirus-covid-19/>

Non-EU/EEA/UK countries

- Israel
 - o https://www.gov.il/en/departments/ministry_of_health
 - o <https://www.gov.il/en/Departments/Guides/ramzor-cites-guidelines?chapterIndex=1>
- Switzerland
 - o <https://www.bag.admin.ch/bag/en/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov.htm>
- US Centers for Disease Control and Prevention (CDC)
<https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

2.3 Screen identified documents

For RQ1, all relevant frameworks, tools and guidance documents identified through searching the above websites and which provide advice on public health measures to limit the transmission of SARS-CoV-2 at mass gatherings (including both indoor and outdoor settings) or the conditionality (for example disease incidence, vaccination rates) necessary to reintroduce mass gatherings, will be included. Documents will also be included should they provide advice on the conduct of pilot mass gathering events. Public health restrictions that are currently in place in each country (for example, numbers permitted at events) will be detailed.

For RQ2, all potentially eligible primary research studies identified in the database search will be exported to Covidence systematic review software (available at www.covidence.org) and single screened against the Population, Exposure, Comparator, Outcome and Study design (PECOS) framework with any uncertainty checked by a second reviewer. Relevant governmental reports identified through RQ1 will also be included. The PECOS framework specifying the inclusion and exclusion criteria for RQ2 is detailed in Table 1 below.

Table 1: PECOS for RQ2

Population	Individuals of any age
Exposure	Any mass gathering [†] in the context of the COVID-19 pandemic where public health mitigation measures were in place.
Comparator(s) (if relevant)	<ul style="list-style-type: none"> ▪ control group who did not attend any mass gathering (accounting for confounders) ▪ alternative intervention arms trialling different types/intensity of public health measures.
Outcome	<p>Primary outcomes</p> <ul style="list-style-type: none"> ▪ biological/epidemiological outcomes (for example, RT-PCR or antigen test results, changes to incidence at a population level, whole genomic sequencing, secondary attack rates, household transmission, cluster/spatial analysis). <p>Secondary outcomes</p> <ul style="list-style-type: none"> ▪ environmental outcomes (for example, air, surface and wastewater sampling for SARS-CoV-2 RNA, environmental and ventilation analysis) ▪ behavioural outcomes (for example, adherence to public health measures, observed behaviours at events, knowledge, attitudes and beliefs). ▪ healthcare utilisation (for example, hospital and ICU admissions, testing referrals or testing rates in subsequent weeks).
Study design	<p>Include:</p> <ul style="list-style-type: none"> ▪ Primary research studies including interventional studies, observational studies, environmental studies, mechanistic studies and epidemiological investigations, of SARS-CoV-2 transmission at mass gatherings, where public health measures were trialled and or where the aim was to understand the dynamics of transmission in such settings. <p>Exclude:</p> <ul style="list-style-type: none"> ▪ animal studies ▪ mathematical and statistical modelling studies ▪ studies involving attendance at the place of work, education and childcare for the purposes of work, education or childcare respectively ▪ studies involving small gatherings[‡]

	<ul style="list-style-type: none">▪ epidemiological investigations at mass gatherings where no mitigation measures were in place (for example, during the early stages of the pandemic, or where elimination has been achieved)▪ studies relating to non-SARS-CoV-2 infectious diseases.▪ reviews (but included studies will be screened for relevance).▪ media reports and press releases (but attempts will be made to identify any linked research article).▪ editorials and opinion pieces (unless these are relevant for RQ1).
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†Mass gatherings are events where there is a concentration of people at a specific location for a specific purpose over a set period of time. They can include a single event or a combination of several events at different venues and constitute a diverse range of gatherings such as sports, music / entertainment, religious events, family events (such as weddings, funerals etc.), large conferences and exhibitions, as well as community, charity events and other types of events. Attendance at the place of work, education and childcare for the purposes of work, education or childcare respectively would not ordinarily constitute a mass gathering.⁽¹⁾

‡Small gatherings are informal in nature and may occur with family and friends that one regularly socialises with, often at someone's residence. They typically do not involve long distance travel.⁽²⁾

2.4 Data extraction and quality appraisal of included documents

Data extraction and quality appraisal will be performed by one reviewer, and double checked by a second reviewer. Data extraction templates are detailed in Appendix 2.

Data collected for each document category are as follows:

1. Public health guidance, frameworks and tools: Country or organisation, guidance/document title, URL, date, current recommendations, plans and conditionality for reopening, sector specific guidance, pilot events.
2. Primary research studies: study descriptors, sample size, population demographics, setting, public health measures in place, pre/post-event activities, epidemiological and vaccination situation, outcomes relating to transmission of SARS-CoV-2 at mass gatherings, author conclusions. The primary outcomes of interest will be biological or epidemiological (for example, the rates of infection post-event). The secondary outcomes will be environmental (for example, surface and air sampling), behavioural (for example, adherence to public health measures), and healthcare utilisation (for example, hospital and ICU admissions, testing referrals or testing rates in subsequent weeks).

The relevant National Heart, Lung and Blood Institute (NIH) Quality Assessment Tool will be used for the quality appraisal of included studies.⁽³⁾ A formal quality appraisal tool does not exist for mechanistic or environmental studies, however these studies will be informally appraised to identify any potential methodological limitations.

2.5 Summarise findings

A descriptive overview of the identified evidence to date for both review questions will be compiled.

3. Quality assurance process

The review questions will be led by an experienced systematic reviewer. A minimum of three team members will perform the review. This will permit confirmation that the report accurately reflects the body of literature, and speed up the process, given the short turnaround time. All reports will be further reviewed by two members of the senior management team, to ensure standard operating processes are followed and quality maintained.

4. Review and update

Given the rapidly changing environment, this protocol will be regarded as a live document and amended when required to ensure it reflects any changes made to the outlined processes.

5. Timelines

This rapid evidence synthesis will be conducted in line with the processes and timelines outlined for Phase 2 of HIQA's COVID-19 response. Work will commence on 6 May 2021 and a final draft will be completed by 20 May 2021. Draft outputs from the rapid evidence synthesis will be circulated to HIQA's COVID-19 Expert Advisory Group for review, with a view to providing advice to NPHET on 25 May 2021.

Appendix 1

Search strategy

Search strategy developed in Medline (OVID), which was translated into Cochrane, Embase (OVID), Web of Science and Google.

Population	COVID-19/ OR SARS-CoV-2/ OR exp Coronavirus/ OR (covid-19 or coronavirus or "corona virus" or "2019-ncov" or "2019 ncov").ab,ti. OR (wuhan adj3 virus).ab,ti. OR ("severe acute respiratory syndrome coronavirus 2" or "SARS-COV-2").ab,ti.OR("2019" and (new or novel) and coronavirus).ab,ti.
Intervention	(pilgrim* or (religious adj3 event*) or (sport* adj3 (event* or competition*))).ab,ti. OR ((mass adj2 gathering*) or test event* or test concert*).ab,ti. OR (concert or concerts or gig or rave or festival* or "music event*" or stadium or stadia or "football match*" or "rugby match*").ab,ti.
Date filter	2020 to current

Search strategy for Europe PMC (preprints only)

("2019-nCoV" OR "2019nCoV" OR "COVID-19" OR "SARS-CoV-2" OR "COVID19" OR "COVID" OR "SARS-nCoV" OR ("wuhan" AND "coronavirus") OR "Coronavirus" OR "Corona virus" OR "corona-virus" OR "corona viruses" OR "coronaviruses" OR "SARS-CoV" OR "Orthocoronavirinae" OR "MERS-CoV" OR "Severe Acute Respiratory Syndrome" OR "Middle East Respiratory Syndrome" OR ("SARS" AND "virus") OR "soluble ACE2" OR ("ACE2" AND "virus") OR ("ARDS" AND "virus") or ("angiotensin-converting enzyme 2" AND "virus")) AND (SRC:PPR) AND ("mass gathering")

Appendix 2

Appendix 2.1 Data extraction template for public health guidance, frameworks and tools for RQ1

Country or organisation	Current measures, general guidance and toolkits regarding mass gatherings	Information on pilot events (if relevant)	Plans and conditionality for further reopening (if available)	Links to sector specific guidance
URL (landing page)	<i>Specific information on testing and vaccination requirements (if known)</i>	<i>Dates and locations for pilot events</i>		
Date of last update		<i>Guidance on conduct of pilot events</i>		
		<i>When results are expected</i>		

Appendix 2.2 Data extraction template for primary research studies for RQ2

First author	Sample size (number attending including staff)	Setting (date, timing, event type, location, physical characteristics of venue, duration, intervals, provision/sharing of food, drink, alcohol)	Public health measures in place (face coverings, hand sanitiser, surface cleaning, physical distancing, ventilation)	Pre/post event activities (travel, socialising, engagement with testing)	Epidemiological situation, vaccination rates at time of event	Outcomes (biological/epi, environmental, behavioural/healthcare utilisation)	Author conclusions
Country	Demographics (inclusion/exclusion criteria, age, sex, vaccination/previous infection status)						
Design							
DOI							

References

1. World Health Organization. Key planning recommendations for mass gatherings in the context of COVID-19 2020 [updated 29 May 2020; cited 2021 5 May]. Available from: <https://www.who.int/publications/i/item/10665-332235>.
2. Centers for Disease Control and Prevention (CDC). Guidance for Organizing Large Events and Gatherings 2021 [updated 27 Apr 2021; cited 2021 6 May]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/considerations-for-events-gatherings.html>.
3. National Heart Lung and Blood Institute (NIH). Study Quality Assessment Tools 2021 [cited 6 May 2021]. Available from: <https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools>.

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