Adolygiad Cyflym
Canolfan Dystiolaeth COVID-19 Cymru (WC19EC)

Gorchuddion wyneb i leihau trosglwyddiad SARS-CoV-2

Rhif adroddiad – RR00007 (Gorffennaf 2021)

Manylion yr Adolygiad Cyflym
Adolygiad wedi'i gynnal gan: Technoleg Iechyd Cymru **Tîm Adolygu:** • Claire Davis, Lauren Elston, Gareth Hopkin, David Jarrom, Katie McDermott, Jenni Washington, Tom Winfield **Adolygiad wedi'i gyflwyno i WC19EC ar:** 26ain Gorffennaf 2021 **Adroddiad ar yr Adolygiad Cyflym wedi'i gyhoeddi gan WC19EC ar:** 29ain Gorffennaf 2021 **Tîm WC19EC:** ▪ Adrian Edwards, Alison Cooper, Micaela Gal a gyfrannodd at ddrafftio Crynodeb o'r Prif Bwyntiau, adolygu a golygu **Dylid dyfynnu'r adolygiad hwn fel a ganlyn:** Adolygiad cyflym o orchuddion wyneb i leihau trosglwyddiad SARS-CoV-2. Adroddiad RR00007. Canolfan Dystiolaeth COVID-19 Cymru. Gorffennaf 2021. http://www.primecentre.wales/resources/RR/RR00007_Wales_COVID-19_Evidence_Centre-Rapid_Review_Face_coverings_27th-July_2021-cy.pdf **Ymwadiad:** Barn yr awduron yw'r rhai sydd wedi'u mynegi yn y cyhoeddiad hwn, yn hytrach na barn Ymchwil Iechyd a Gofal Cymru o reidrwydd. Mae WC19EC ac awduron y gwaith hwn yn datgan nad oes ganddynt unrhyw fuddiannau sy'n gwrthdaro.

Gorchuddion wyneb i leihau trosglwyddiad SARS-CoV-2
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CRYNODEB O'R PRIF BWYNTIAU

Cefndir / Nod yr Adolygiad Cyflym

Mae effeithiolrwydd gorchuddion wyneb wrth leihau trosglwyddiad SARS-CoV-2 trwy gadw defnynnau i mewn a'u hatal rhag cyrraedd pobl sy'n agored i haint (rheoli'r ffynhonnell) a/neu drwy atal anadlu defnynnau sydd yn yr awyr i mewn (diogelu'r gwisgwr) yn ansicr.

Beth ydy Adolygiad Cyflym?

Adolygiadau o ymchwil sydd eisoes yn bodoli ydy ein hadolygiadau cyflym, gan ddefnyddio amrywiad ar y dull adolygu systematig, lle caiff cydrannau'r broses adolygu eu talfyrru neu eu hepgor i gynhyrchu'r dystiolaeth er mwyn hysbysu rhanddeiliaid mewn ffrâm amser fer ond eto bob amser rhoi sylw i duedd. Maent yn dilyn, cyn belled â phosibl, yr argymhellion o ran methodoleg a'r safonau gofynnol ar gyfer cynnal adolygiadau cyflym. Maent wedi'u seilio ar brotocol strwythuredig, chwilio systematig, sgrinio, tynnu data, arfarnu beirniadol a chyfuno'r dystiolaeth berthnasol i ateb cwestiwn penodol a nodi bylchau allweddol mewn ymchwil. Rhoddir blaenoriaeth, lle bo'n ddichonol, i astudiaethau sy'n cynrychioli cyfuno tystiolaeth yn gadarn. Maent yn cael eu cwblhau o fewn 1-2 fis, gan ddibynnu ar ehangder a chymhlethdod y pwnc/ cwestiwn/ cwestiynau ymchwil, graddau'r sylfaen dystiolaeth a'r math o ddadansoddi sy'n ofynnol i gyfuno'r dystiolaeth.

Cwestiynau'r Adolygiad Cyflym

1. Pa mor **effeithiol ydy gorchuddion wyneb** wrth leihau lledaenu trosglwyddiad SARS-CoV-2 yn y gymuned (h.y., lleoliadau y tu allan i ofal iechyd)?
2. Pa mor effeithlon ydy **gwahanol fathau o orchuddion wyneb** sydd wedi'u dylunio i'w defnyddio mewn lleoliadau cymunedol?

Darganfyddiadau Allweddol

Graddau'r sylfaen dystiolaeth

- Nododd chwiliadau rhagarweiniol 18 o erthyglau wedi'u seilio ar adolygiadau – 6 adolygiad systematig a 12 adolygiad cyflym, yn bennaf o gyfnod cynnar yn y pandemig (Canolfan Dystiolaeth Covid-19 Cymru, Crynodeb Cyflym o Dystiolaeth, Gorffennaf 2021).

Tystiolaeth o'r ansawdd gorau

- Rydym nawr yn canolbwyntio ar y **2 adolygiad mwyaf cyflawn a chyfoes**, gydag 31 o astudiaethau (Public Health England 2021) a 39 o astudiaethau (Chou et al. o gwmpas 2020) a 2 astudiaeth sylfaenol arall.

Diweddaredd y sylfaen dystiolaeth

- Adroddodd PHE hyd fis Medi 2020; adroddodd Chou hyd fis Mehefin 2021.

Tystiolaeth o effeithiolrwydd

- Mae'r dystiolaeth o ran effeithiolrwydd gorchuddion wyneb wrth leihau lledaenu trosglwyddiad SARS-CoV-2 yn y gymuned ac effeithlonrwydd gwahanol fathau o orchuddion wyneb **dal yn gyfyngedig** ac mae casgliadau'n dibynnu ar ffynonellau tystiolaeth **o ansawdd isel** gyda risg uchel o duedd.
- Mae'r dystiolaeth yn awgrymu bod gorchuddion wyneb o ryw fudd wrth atal trosglwyddiad SARS-CoV-2 ond mae **astudiaethau o ansawdd uwch yn awgrymu bod y budd hwn yn gymharol fach**.
- Nid oedd yna unrhyw dystiolaeth ynglŷn â gorchuddion wyneb i atal trosglwyddiad SARS-CoV-2 mewn lleoliadau cymunedol penodol (e.e., ysgolion, trafnidiaeth gyhoeddus); i blant a'r glasoed; ynglŷn â natur dymhorol; graddau'r diogelu i wisgwyr ac eraill.
- Mae'r dystiolaeth yn awgrymu bod gorchuddion wyneb a ddefnyddir yn gyffredin yn effeithiol i ryw raddau wrth hidlo defnynnau. **Mae masgiau meddygol, i bob golwg, yn fwy effeithlon** na masgiau ffabrig er bod rhai astudiaethau'n awgrymu eu bod yr un mor effeithlon.
- Gallai dulliau sy'n rhoi mwy o sylw i ffactorau drysu wella ansawdd astudiaethau arsylwadol.

Tystiolaeth o niweidiau

- Cofnododd astudiaethau niweidiau yn is-optimaidd ond **nid oedd unrhyw awgrym o niweidiau difrifol** o wisgo gorchuddion wyneb. Mae rhai pobl yn dweud eu bod yn anghyfforddus neu'n dweud eu bod yn ei chael hi'n anodd anadlu (roedd y cyfraddau'n amrywio'n sylweddol – 15% i 75% – ar draws 3 astudiaeth).
- Mae yna bryderon amgylcheddol ynglŷn â graddau cynhyrchion nad ydynt yn rhai bioddiraddiadwy.

Goblygiadau i bolisi

- **Fe allai gorchuddion wyneb chwarae rhan** mewn atal trosglwyddiad SARS-CoV-2 dros gyfnodau nesaf y pandemig.
- Mae gorchuddion wyneb fel rheol yn rhan o **becyn o fesurau** (hylendid dwylo, cadw pellter, awyru ac ati) ac mae mwyafrif y dystiolaeth o fewn y cyd-destun hwn. **Mae'n bosibl na fydd jest gwisgo masg, heb unrhyw fesurau atal eraill, yn effeithiol**.
- Mae **astudiaethau o ansawdd uwch yn awgrymu** y gallai gorchuddion wyneb gael **effaith gymedrol** ond y dylid ystyried hyn wrth wneud penderfyniadau.
- Mae'n bosibl y gallai fod o fudd darparu **negeseuon iechyd cyhoeddus** ynglŷn â nodweddion gorchuddion wyneb sydd, i bob golwg, yn fwy effeithiol (h.y., **masgiau meddygol**) ac ynglŷn â ffyrdd effeithiol o ddefnyddio masgiau (yn gorchuddio'r trwyn a'r geg).
- **Nid oes unrhyw dystiolaeth eglur** i awgrymu y **dylid esemptio poblogaethau cleifion penodol fel mater o drefn**, gan gynnwys pobl â chyflyrau meddygol a phlant, rhag gwisgo gorchuddion wyneb.

Cryfder y Dystiolaeth hyd yma

Ar hyn o bryd, ystyrir mai **"hyder isel"** sydd yng nghryfder y dystiolaeth.

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1. BACKROUND

This Rapid Review is being conducted as part of the Wales COVID-19 Evidence Centre Work Programme. The topic was identified by TAG leads as high priority for review and then refined in discussion with stakeholders.

1.1 Purpose of this review

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes COVID-19, can be transmitted by respiratory droplets. These droplets are expelled by an infected person and can cause transmission if they reach the mouth, nose, or eyes of a susceptible person. Larger respiratory droplets that are expelled during sneezing or coughing may not remain in the air for long periods. However, it is thought that smaller droplets that are expelled during breathing and speaking or that result from evaporation of larger droplets may have a longer lasting presence (World Health Organisation 2020b). Face coverings may have a role in **reducing transmission** by containing droplets and preventing them reaching susceptible people **(source control)** and/or by **preventing inhalation** of droplets which are present in the air **(wearer protection)** (Welsh Government 2021).

The World Health Organization (WHO) has recommended that governments encourage people to wear face coverings as **part of a comprehensive strategy** of measures to prevent transmission of SARS-CoV-2. They highlight that masks should be worn when in crowded settings, where **social distancing** is not possible, or in rooms with poor or unknown **ventilation** (World Health Organisation 2020a). Many governments have adopted face coverings in the community as part of their infection control measures. In Wales, regulations state that a face covering is something that covers the nose and mouth. It can be a reusable or single-use medical or cloth mask, and includes scarves, bandanas, and religious garments. At present, face coverings must be worn in all indoor public places in Wales. This includes public transport and taxis, and applies to places serving food and drink, unless customers are seated to eat or drink (Welsh Government 2021).

In the earliest stages of the pandemic, decisions on face coverings were required to rely on evidence that related to transmission of other viral respiratory infections, such as influenza, severe acute respiratory syndrome (SARS-1), and Middle East respiratory syndrome (MERS). Evidence on the effectiveness of face coverings to prevent transmission of other viral respiratory infections was inconclusive, with authors of different sources of secondary evidence drawing differing conclusions (Public Health England 2021). In the absence of scientific consensus, **policy decisions were made with regard to the plausibility** of face coverings having a role in reducing transmission of SARS-CoV-2 and the low likelihood that harms would be present.

During the pandemic, evidence on the effectiveness of face coverings has developed in tandem with the use of face coverings in infection control measures and several previous reviews have been conducted. As new evidence is likely to be continually available (Chou et al. 2020c, Public Health England 2021), it is important to provide timely and up to date reviews to support decision-making.

The purpose of this rapid review is to identify and examine evidence on the effectiveness of face coverings to reduce the spread of transmission of SARS-CoV-2 in the community and on the efficacy of different types of face coverings.

2. RESULTS

We identified **two evidence reviews** that examined the effectiveness of face coverings on reducing transmission of SARS-CoV-2. These reviews are the main sources of evidence for this report. One of the reviews, by **Public Health England** (PHE), focused on transmission in the community (Public Health England 2021). The second, more recent review covered both health and community settings (Chou et al. 2020c); for this report we have only included findings from **Chou et al.** (2020c) that relate to the community setting. Details on these reviews are provided in Tables 1 and 2 and outlined below.

We also identified **two primary studies** that were published since the two included reviews completed their searches (Gonçalves et al. 2021, Kwon et al. 2021). Both primary studies used observational methods to examine the effectiveness of face coverings on reducing transmission of SARS-COV-2. Neither examined the efficacy of different types of face coverings. Details on this study are provided in Table 3 and outlined below.

2.1 Effectiveness of face coverings to reduce the spread of SARS-CoV-2 in the community

2.1.1 Evidence from previous reviews on transmission of SARS-CoV-2

Public Health England examined the effectiveness of face coverings in reducing transmission of SARS-CoV-2 in the community (Public Health England 2021). They identified **17 relevant studies**: 12 studies used population-level approaches to assess the association between changes in use of face coverings and the total number of people testing positive; three studies used individual-level approaches to assess the association of individuals use of masks and their risk of infection; two studies were descriptive, one of which detailed investigations of spread in single settings (a hair salon). A range of countries from Asia, Europe, and North America was represented in studies. One study included the United Kingdom and made between-country comparisons; however, the different rules on face coverings across the four nations of the United Kingdom were not appropriately reflected in the methods (Aravindakshan et al. 2020).

The PHE review reports that studies **generally found an association between the use of face coverings and a reduction in transmission** of SARS-CoV-2. Higher quality studies that use more robust analyses suggest that **high levels of face covering use are associated with a modest reduction** in transmission. Several of the included studies examined the impact of policies that required employees in close contact occupations (e.g., hairdressers) to wear face coverings but not the general public. Findings of these studies were inconsistent but suggested that this approach would not provide the same benefits as universal face coverings.

These findings in this review should be seen in the context of important methodological limitations of the included studies, especially **confounding factors**. For the population-level studies, the time frame over which data were collected saw a number of simultaneous changes to pandemic restrictions and people's behaviour, alongside mask use. In addition, authors of studies conducted in the early stages of the pandemic have noted that the introduction of mandatory face coverings could be seen by people as a signifier of the seriousness of the pandemic, and this modified their behaviour beyond mask use. For individual-level studies, self-reported past use of face coverings may not be accurate, and studies cannot account for transmission from contacts with people with COVID-19 who were not taking part in the study. These limitations **make it difficult for studies to determine** the extent to which the observed effect was due to use of face coverings, other co-occurring changes, or a combination of both.

A more recent review by **Chou et al.** (2020c) was conducted as a living rapid review. Findings were first published in June 2020 and six updates have since been produced. The latest update from July 2021 includes studies published up until early June 2021. The review aimed to examine the effectiveness of face coverings in preventing the transmission of SARS-CoV-2 and other viral respiratory infections in both community and health settings. At the time of this report, the living review had identified **one randomised controlled trial (RCT) and three observational studies** relating to SARS-CoV-2. Further details on this review are available in Table 2.

Chou et al. (2020c) reported that there appears to be a **small reduction in risk** of SARS-CoV-2 infection associated with use of face coverings. However, this is based on limited evidence and is considered as **low certainty**. Evidence from one observational study suggests that face coverings only reduced risk when they were **worn throughout the duration of contact** with an asymptomatic case and do not reduce risk if they were worn for only part of contact (Doung-Ngern et al. 2020).

Chou et al. (2020c) also reported on harms associated with mask wearing. They reported that recording of harms was suboptimal across studies but there was **no indication of serious harms from wearing face coverings**. Some participants reported discomfort or the **feeling of breathing difficulty**, although rates varied substantially between studies (from 15% to 75% across three studies).

As with studies in the PHE review (Public Health England 2021), studies included in Chou et al. (2020c) should be seen in the context of **important limitations**. The observational studies were reliant on accurate self-reporting of past use of face coverings. In addition, the authors of the review noted that some studies had discrepancies in reported data and did not account for **confounding variables** in their analyses. The **included RCT** was judged as good quality but was reliant on face coverings providing protection to the wearer, as opposed to providing source control, and was **underpowered** to detect a difference in infection rate.

Evidence gaps

We aimed to report the effectiveness of face coverings for different community settings, for children and adolescents, or according to seasonality as specified in our review protocol. Some studies included children and adolescents, and adults in the samples. However, **no studies** that report**ed outcomes specific to children and adolescents** for SARS-CoV-2 were identified on these issues. No studies relating to SARS-CoV-2 and **different community settings, or seasonality** were identified.

2.1.2 Evidence from primary studies on transmission of SARS-CoV-2

Kwon et al. (2021) conducted a prospective cohort study in the United States and included participants who were registered on a COVID-19 symptom-monitoring app. The study did include people working in health care settings, but this accounted for only 7.9% of the sample, meaning the results are still broadly applicable to the scope of this review. In the absence of testing data, Kwon et al. (2021) combined data on symptoms and individual characteristics to model predicted cases of COVID-19 and examined the association with self-reported mask use. The authors reported that use of **face coverings was associated with a reduced risk** of predicted COVID-19 for those who wore them always (hazard ratio [HR], 0.36; 95% confidence interval [CI] 0.30 to 0.44), most of the time (HR, 0.34; 95%CI 0.27 to 0.43, and sometimes (HR, 0.27; 95%CI 0.19 to 0.39). Similar results were found when accounting for poor social distancing and high incidence in the community. The study suggests that always wearing a face covering is not more beneficial than wearing a face covering sometimes. The study did not explore the settings in which people wore face coverings, but it is possible that people who wore them sometimes chose to do so in higher risk settings and this was sufficient to reduce risk.

The study has significant **limitations**. The outcome was predicted COVID-19 based on modelling of self-reported symptoms and individual characteristics. This model was based on participants of a UK COVID-19 monitoring app and was reported to have a sensitivity and specificity of 0.66 (95% CI 0.62 to 0.69) and 0.83 (95% CI 0.82 to 0.85) when validated with participants in the US. The approach means that **asymptomatic cases were not detected,** and mild cases were less likely to be detected. This introduces significant imprecision into all analyses. Furthermore, there appear to be baseline differences across groups with differing levels of mask use. Analyses were adjusted for a series of **confounding variables**, but there were other important variables that could not be captured by the app and were therefore not accounted for. For example, if people who wore face coverings made additional changes to their behaviour, the effectiveness of face coverings could be substantially overstated in this study.

Gonçalves et al. (2021) conducted a case-control study with the cases recruited after attending primary or secondary care seeking treatment and the controls recruited from a community serology study. Information on use of face coverings and other characteristics were recorded. However, **response rates were notably low** in both groups, with around half of eligible participants taking part. The study reported that in adjusted analyses, **face covering use was associated with a large reduction** in risk of COVID-19 (odds ratio [OR], 0.10; 95% CI, 0.04 to 0.30). Removing participants who did not leave home showed a similar association, and no interaction between use of face coverings and social distancing was found.

This study also has significant **limitations**. Only people who presented to seek care with COVID-19 were identified, meaning that **mild or symptomatic cases were not included**. There were also important differences between the case and control groups, including differences in sociodemographic characteristics (the cases were more frequently men, Black and younger), alongside lower use of face coverings in the cases group, which would make them at higher risk of transmission. In addition, healthcare workers were excluded from cases but could not be excluded from the controls. Despite attempting to adjust for these factors in analysis, this introduces a high **risk of bias**.

2.1.3 Evidence from studies on transmission of other viral respiratory infections

The review by Chou et al. (2020c) also reported on transmission of other respiratory viruses in the community. It identified evidence relating to SARS-1 (three observational studies) and influenza-type infections (12 RCTs); no studies on MERS-CoV were identified. Studies that examine other viral respiratory infections may not be generalisable to the present situation. However, they may provide useful information in the absence of wide-ranging research on face coverings and COVID-19.

For these other viral respiratory infections, Chou et al. (2020c) report that use of face coverings do not appear to reduce risk of infection in the community during influenza seasons but do appear to reduce risks for SARS-1 infection. The observed differences may be due to study design and confounding, or they may reflect real differences based on increased compliance during a more severe pandemic or characteristics of the viruses. This means that it is **difficult to interpret how generalisable** these studies are to the present situation.

Chou et al. (2020c) reported results from two randomised controlled studies on the prevention of influenza and influenza-type illness in university halls of residence. In both studies, students were asked to wear medical masks as much as possible in their halls during a six-week intervention period and were compared to a control group who did not use medical masks. No differences in risk of infection between the groups were found (Aiello et al. 2010, Aiello et al. 2012). Chou et al. (2020c) also reported findings from studies relating to the Hajj pilgrimage. It was felt that this community setting was not generalisable to the context of this report and these studies are not reported separately here.

2.2 Efficacy of different types of face coverings designed for use in community settings

2.2.1 Evidence from previous reviews

The **PHE review** also examined the efficacy of different types of face coverings designed for use in community settings (Public Health England 2021) and included **14 laboratory studies** that examined this question.

The review reported that different face covering materials varied in their ability to filter droplets of differing sizes. **Most studies reported that medical masks offered better filtration efficiency** than masks made of fabric, although some reported no difference. One study suggested that cone-shaped medical masks are superior to conventional medical masks. Despite these differences, **all materials were judged to offer benefits compared to no face covering**. There appeared to be some evidence that the use of differing materials in layers improved the filtration of face coverings. Some studies suggested that poor mask fit and repeated washing and wearing of masks can reduce their filtration efficiency. These factors may have a bearing on translation of findings to the community where masks are likely to be used sub-optimally.

The review by Chou et al. (2020c) also examined the comparative effectiveness of different types of face coverings when used in the community outside of laboratory settings. It included one study which compared P2 (equivalent to N95) masks to medical masks for prevention of influenza-like illness in real world settings. This study found no difference between the mask types, though there was a lack of precision in estimates due to low numbers of events.

The included studies have limitations that may limit the generalisability of their findings to the use of face coverings by the general population in the community. For example, none of the studies examined the ability of face coverings to filter SARS-CoV-2 from a person who is currently infected. In addition, studies were mostly conducted in laboratory conditions and face coverings were positioned in an optimal way.

2.2.2 Evidence from primary studies

We did not identify any additional primary studies published after the PHE and Chou et al. (2020c, 2021) reviews that evaluated efficacy of different types of face coverings

Table 1. Summary of the Public Health England (2021) rapid review

Included studies	Inclusion criteria	Quality	Observation/notes
Number of included studies: **Total: 31 studies** **17 observational studies on effectiveness in reducing SARS-CoV-2 transmission in the community** **14 laboratory studies on the efficacy of different types of face coverings** **Publication date of included studies:** **From 25 March 2020 to 22 September 2020**	**Review period:** up to 22 September 2020 **Review purpose:** To identify and assess evidence on 1) the effectiveness of face coverings when used in the community, and 2) the efficacy of different types of face coverings **Included study designs:** Experimental and observational studies **Included outcome measures:** Effectiveness of face coverings, transmission of SARS-CoV-2, SARS-CoV-2 infection, basic reproduction number, mask filtration capacity/droplet transmissions	Due to the use of rapid review methods, a formal quality assessment was not conducted.	Included studies have methodological limitations that impact their ability to identify the effect of face coverings, as opposed to other co-occurring interventions. Included studies may have issues with generalisability due to being conducted in the early stages of the pandemic. 8 included studies were based on preprints. These studies are published prior to peer-review and should be considered of uncertain value.
SARS-CoV-2: severe acute respiratory syndrome coronavirus 2			

Table 2. Summary of the Chou et al. (2020) rapid living review

Included studies	Inclusion criteria	Quality	Observation/notes
Number of included studies: **Total: 39 studies** **1 RCT and 3 observational studies on effectiveness in reducing transmission of SARS-CoV-2 in the community** **12 RCTs and 3 observational studies on effectiveness in reducing transmission in other viral respiratory conditions** **Publication date of included studies:** **Not reported**	**Review period:** up to 2 June 2021 **Review purpose:** To examine the effectiveness of N95, surgical, and cloth masks in community and health care settings for preventing respiratory virus infections **Included study designs:** RCTs and observational studies **Included outcome measures:** Infection based on clinical respiratory illness, influenza like illness, and laboratory confirmation	Randomised trials were assessed using adapted USPSTF criteria. Key limitations for observational studies were noted. Observational studies were retrospective and relied on self-report and confounding was poorly accounted for in analyses. RCTs were rated as good to fair quality.	The review included evidence from other viral respiratory conditions (i.e. SARS-1, MERS-CoV, influenza). The initial publication is supplemented by six updates. Adherence to use of face coverings was found to be low in randomised studies. This may lead to poor generalisability if face coverings are required in certain settings and adherence is therefore higher. The review authors state that due to few new studies and little change to conclusions, updates will be paused for six months.
MERS-CoV: Middle East respiratory syndrome coronavirus; RCT: randomised controlled trial; SARS-1: severe acute respiratory syndrome 1; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; USPSTF: United States Preventive Services Task Force			

Table 3. Summary of included primary studies (Gonçalves et al. 2021, Kwon et al. 2021)

Study reference	Methods, setting	Key outcomes	Comments
Kwon et al. (2021)	**Study design:** Prospective cohort study **Participants:** 198,077 participants available via the app (of which 134,597 included data on face covering use) **Setting:** United States **Dates of data collection** March to July 2020 **Type of face covering:** Any, frequency of type not reported **Data collection methods:** Self-reporting via a Smartphone-based COVID-19 symptom monitoring app. Information collected on COVID-19 symptoms, frequency of face covering use, and other personal risk factors/ Information Community level characteristics also collected, including social distancing measures, incidence of COVID-19, population density. **Analysis:** Analysed at the individual level with community level information assigned to participants according to their zip code.	**Primary Findings:** Compared to individuals who did not wear face coverings at any time, the adjusted HRs for predicted COVID-19 were 0.27 (95% CI 0.19 to 0.39) for individuals who wore face coverings sometimes, 0.34 (95% CI 0.27 to 0.43) for individuals who wore face coverings most of the time, and 0.36 (95% CI 0.30 to 0.44) for individuals who wore face coverings always. **Additional Findings:** Findings were found to be similar after analysed accounted for communities with poor social distancing, communities with high incidence, and high reproductive rates. Subgroup analyses did not find statistical differences according to individual characteristics. However, the authors report the following groups trended towards a lower risk of predicted COVID-19: if they were younger, had interacted with suspected or documented COVID-19 patients, regularly use a mobility aid, or had health problems that limited activities of daily living. Sensitivity analyses that used positive COVID-19 tests rather than predicted COVID-19 reported that mask use was associated with reduced transmission but not to the extent of primary analyses (Always vs None; HR 0.37, 95% CI, 0.24 to 0.57).	The primary outcome variable was predicted COVID-19 that was modelled based on self-reported COVID-19 symptoms and individual characteristics. This was reportedly due to a small number of COVID-19 test-positive app users during the study period. This approach may be less accurate and reliable than using test data. However, it may also reduce problems with geographic variations in access to testing. Sensitivity analyses using positive COVID-19 tests were also presented. The study relied on data from participants who had chosen to sign up to and provide information to a COVID-19 symptom-monitoring app. This may mean the sample is not representative of the general population. It may also introduce selection biases with people who have had a COVID-19 contact or with higher awareness of COVID-19 more likely to be included. The study included frontline healthcare workers and they made up 7.9% of the sample. This may influence findings and the scope of this review was on community transmission. A limited amount of information could be collected via the app meaning there may be unobserved confounding. This may include other individual level strategies to avoid transmission. In addition, the study did not record details on the types of face coverings used or the settings that participants used them in.

Study reference	Methods, setting	Key outcomes	Comments
Gonçalves et al. (2021)	**Study design:** Case control study **Participants:** 271 case-patients recruited from hospital and primary care via Municipal Health Department 1,396 controls identified from representative household surveys (of which 464 included data on face covering use) **Setting:** Porto Alegre, Brazil **Dates of data collection** April to June 2020 **Type of face covering:** Any, frequency of type not reported **Data collection methods:** Self-reporting after being identified as a positive case or via a community serology survey. Information on face covering use and individual characteristics were collected **Analysis:** Analysed at the individual level	**Primary Findings:** Use of face coverings reduced odds of infection (OR 0.12, 95% CI 0.04 to 0.30) in adjusted analyses. **Additional Findings:** No interaction between mask use and social distancing was found (OR 0.96, 95% CI 0.60 to 1.58). In a sensitivity analysis, findings were similar if those staying at home all the time were excluded from analyses. Where use of face coverings was dichotomised to always, or sometimes/never, mask use was associated with a lower reduction in risk (OR 0.36, 95% CI 0.17 to 0.74).	The study relied on presentation of positive cases to primary or hospital care to seek care. Failure to identify mild and asymptomatic cases would result in underestimation of COVID-19 infection and likely impact the reported effectiveness of face covering use. The study excluded cases who were healthcare workers, but controls were taken from a serology study that did not include occupation and could not exclude healthcare workers. The authors highlight that only around 5% of the workforce in Brazil are healthcare workers and they anticipate a similar proportion within the study. This may introduce important bias as the scope of this review was on community transmission. The study reported important differences between groups and those with positive COVID-19 tests were more frequently men, Black, younger, had a lower level of education, and lived in larger households. It also reported that these groups were less likely to adhere to social distancing. In addition, the study reported that the control group were older and more frequently female than the general population of the study setting. Participants in the case and control groups were also recruited at different stages of the pandemic. A limited amount of information could be collected via the serology survey and questions that were asked different from those asked of cases. Response rates were also low in both groups (between 46 and 56%).

COVID-19: coronavirus disease 19, CI: confidence interval, HR: hazard ratio; OR: odds ratio

3. DISCUSSION

3.1 Effectiveness of face coverings to reduce the spread of SARS-CoV-2 in the community

There is a developing body of evidence on the effectiveness of face coverings to reduce the spread of SARS-CoV-2. A major limitation of the evidence is that studies largely rely on **low-quality observational methods** that have serious flaws. Findings do consistently suggest that face coverings are associated with a **reduction in transmission at both the population and individual levels**. However, there is **low certainty** around the scale of benefit that face coverings may provide due to limitations. The higher quality observational studies that provide more robust analyses and a single good quality RCT suggest that the **effect may be modest.**

Further studies are available on the effectiveness of face coverings to reduce the spread of other viral respiratory infections. The evidence base for these other conditions is mixed. RCTs on transmission of influenza or influenza-like illness suggest that medical masks do not reduce transmission, whereas observational studies suggested there may be some reduction in transmission for SARS-1. It is difficult to assess whether this is due a real difference stemming from different virus characteristics or due to methodological differences.

3.2 Efficacy of different types of face coverings designed for use in community settings

Evidence on the efficacy of different types of face coverings is limited and relies on methods that are not generalisable to the community. Studies have mostly evaluated simulations in **laboratory studies,** and few have used human participants or droplets including SARS-CoV-2. Findings suggest that commonly used face coverings have at least some ability to filter droplets and it **appears that medical masks are superior** to fabric masks, although some evidence suggests there is no difference. Other characteristics of face coverings, such as **multiple layers**, are also thought to provide additional benefit.

3.3 Areas of uncertainty

We identified no studies that examined the effectiveness of face coverings to reduce transmission of SARS-CoV-2 in specific settings of interest in the community. This means it is highly uncertain whether limiting use of face coverings to specific settings of interest is effective. Studies on other viral respiratory illnesses suggest that targeting specific settings may not have an impact on transmission. We identified no studies that examined effectiveness of face coverings for **children and adolescents** specifically. Studies examined either use of face coverings by children, adolescents and adults, or they used only adult samples. Further, we identified no studies on whether **seasonality** has an impact on the effectiveness of face coverings. Finally, there remains uncertainty about the mechanism of action of face coverings and the extent to which they **protect the wearer or provide source control**.

Further studies may be able to address some of these areas of uncertainty. However, higher quality studies that address the limitations of studies included in this review may have limited feasibility. Cluster randomised controlled trials could provide evidence on effectiveness of face coverings in specific settings. More feasibly, observational studies could be significantly improved if they were analysed using higher quality methods that have a greater ability to assess whether a causal effect is present. For example, if cohort or case control studies were analysed with propensity-score matching or instrumental variables approaches, they may be able to better account for unobserved confounding. Finally, laboratory studies that examine the efficacy of face coverings in containing SARS-CoV-2 and preventing it entering the environment may provide additional understanding of their likely impact. These studies should examine face coverings as worn in real life to enhance their generalisability.

3.4 Implications for policy and practice

Face coverings **may play a role in preventing transmission** of SARS-CoV-2 over the next phases of the pandemic. However, **higher quality studies found a more limited effectiveness** of face coverings in preventing transmission of SARS-CoV-2 and the impact of this should be considered. As a result, face coverings may be able to slow the growth of increasing cases or accelerate the reduction of incidence, but they **would not be expected to prevent growth unless the effective reproductive rate was close to one**, based on other pharmaceutical and non-pharmaceutical interventions.

Studies on the efficacy of face coverings **suggest that medical masks are more beneficial** than fabric masks. Some face covering characteristics (e.g., multiple layers) are associated with higher efficacy, and multiple use and washing of face covering may reduce efficacy. These findings are uncertain but there may be benefits to highlighting this in public health messaging.

3.5 Strengths and limitations of the rapid review

We searched for published studies on the research questions within this review. It is possible that additional unpublished studies have been conducted but are not publicly available. This is often the case for studies that report null results, and this leads to the possibility of publication bias. Due to the rapid review methods used here, we have not been able to evaluate this.

We searched multiple databases to identify primary studies published since the searches of other included reviews (Chou et al. 2020c, Public Health England 2021) and the included reviews also searched multiple sources. It is possible that studies from other disciplines, such as economics, physics, or engineering, were not identified, although this does not appear to be the case.

We are reliant on interpreting the results of **studies that have serious limitations** and this reduces the strength of conclusions. We have made efforts to summarise the key limitations of study designs included in the review. However, formal risk of bias assessment of studies nor grading of our confidence in conclusions were not included due to the rapid nature of the review.

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5. RAPID REVIEW METHODS

5.1 Literature search strategy

We searched for evidence that could be used to answer the review questions:

1) What is the effectiveness of face coverings to reduce the spread of COVID-19 in the community?
2) What is the efficacy of different types of face coverings designed for use in community settings?

A systematic literature search for evidence was carried out on 14 and 15 July 2021. The searches were restricted to studies published after 22 September 2020, as that was the date of the last searches carried out by Public Health England (2021). Table 4 lists all databases searched. The key concepts included in the searches were COVID-19/SARS-CoV-2 and face coverings/masks (including surgical, medical and cloth masks). Study design filters for systematic reviews, meta-analyses, randomised controlled trials and observational studies were applied. Appendix 1 gives the search strategy used for MEDLINE. Search strategies for other databases are available on request. The eligibility criteria used to select evidence for the appraisal are outlined in the protocol in Appendix 2. These criteria were developed with input from the wider Wales COVID-19 Evidence Centre group and consultation with stakeholders. Ongoing trials, comment/editorial, and preprints that duplicated articles published in peer-reviewed journals were not considered for inclusion.

Table 4: resources list

Database	Segment	Date Searched
Ovid MEDLINE and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily	1946 to July 13, 2021	14/07/21
Ovid Embase	1996 to 2021 July 13	14/07/21
Cochrane Library	Issue 7 of 12, July 2021	15/07/21
Cochrane COVID-19 Study Register	-	15/07/21

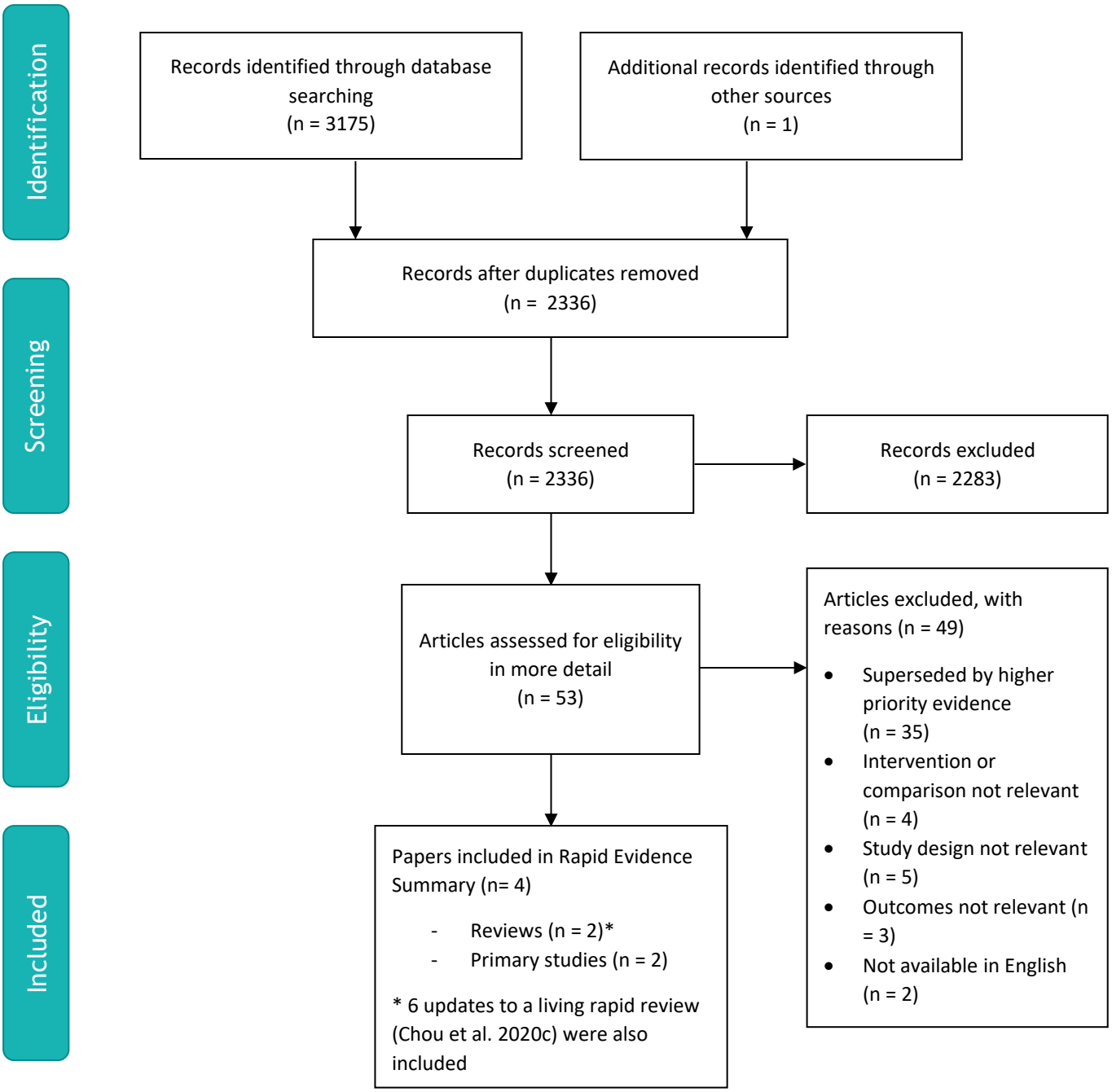
5.2 Study selection process

A rapid review by Public Health England was identified during scoping and includes evidence up to 22 September 2020 (Public Health England 2021). As this review aligns closely with the research questions in this report, we searched only for new evidence published since the PHE search was completed (i.e., from 22 September 2020). Studies were then selected according to the order of priority of study types outlined in the protocol. A

more recent review was identified during searches (Chou et al. 2020c). This is a living rapid review and discussion with stakeholders highlighted that updates to this review should be manually retrieved. All six updates were reviewed for relevant new information and the most recent was updated to include evidence up to 2 June 2021 (Chou et al. 2021a, Chou et al. 2020a, Chou et al. 2020b, Chou et al. 2021b, Chou et al. 2020d, Chou et al. 2020e). Primary studies were only considered for inclusion if they were published more recently than this. Two primary studies met these criteria (Gonçalves et al. 2021, Kwon et al. 2021).

The protocol for this report initially excluded studies on N95 masks, as based on scoping work it was anticipated that these would be used exclusively in healthcare settings and not in the community. However, one of the previous evidence reviews included a single study comparing N95 type masks to other masks in a real-world community setting. This was considered relevant to include in this report.

5.3 Study selection flow chart



5.4 Data extraction

A single researcher checked eligible studies against the inclusion/exclusion criteria. A single researcher extracted data from relevant evidence sources; a sample of these was checked by a second researcher. Extracted data included details of study characteristics and reported outcomes.

5.5 Quality appraisal

There was no formal quality assessment of studies. Where other reviews report quality assessment, this was reported by a single researcher who provided a narrative summary of key limitations of included primary studies.

5.6 Synthesis

Evidence was synthesised narratively.

5.7 Information available on request

The full search strategy for each included database is available on request.

6. ADDITIONAL INFORMATION

6.1 Conflicts of interest

The review team declares no conflicts of interest.

6.2 Abbreviations

CI: confidence interval
COVID-19: Coronavirus disease 2019
HR: Hazard ratio
MERS-CoV: Middle East respiratory syndrome coronavirus
OR: Odds ratio
PHE: Public Health England
RCT: Randomised controlled trial
SARS-1: Severe acute respiratory syndrome 1
SARS-CoV-2: Severe acute respiratory syndrome Coronavirus 2

6.3 Appendix 1 – MEDLINE search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to July 13, 2021>		
Face coverings		
1	((face or faces or facial or head or heads) adj3 (cover* or mask* or shield* or visor* or guard* or screen*1 or protect* or barrier*)).tw,kw.	12035
2	(facemask* or facecover* or faceshield*).tw,kf.	1654
3	((surgical or medical* or cloth*1 or material* or cotton or fabric* or flannel or fleece or textile* or community or communities) adj3 (mask or masks)).tw,kw.	1812
4	Masks/	5740

5	(mask or masks).ti,kf.	11235
6	(mask or masks).ab. /freq=2	10184
7	(mouth adj2 (cover* or protect*)).tw,kw.	298
8	(nose adj2 (cover* or protect*)).tw,kw.	119
9	Respiratory Protective Devices/	2274
10	N95 Respirators/	154
11	(N95 or N97 or N99).tw,kf.	4141
12	(FFP1 or FFP2 or FFP3).tw,kf.	218
13	(filter* adj2 (facepiece or face piece*)).tw,kw.	450
14	or/1-13	34670
15	limit 14 to covid-19	3697
16	20200923:20211231.(dt).	1285785
17	15 and 16	2408
HTW draft systematic review filter		
18	systematic review.pt.	161550
19	systematic reviews as topic/	6144
20	((systematic$ or evidence$) adj (review$1 or overview$1)).tw,kf,kw.	216728
21	meta-analysis.pt.	137525
22	exp meta-analysis as topic/	22605
23	(meta-analy$ or metaanaly$ or metanaly$).tw,kf,kw.	209129
24	exp review literature as topic/	17218
25	or/18-24	370944
26	(medline or pubmed or medlars).ab.	242930
27	embase.ab.	112115
28	cochrane.ab,jw.	101982
29	(cinahl or cinhal).ab.	33923
30	(psychlit or psyclit or psychinfo or psycinfo).ab.	43794
31	science citation index.ab.	3318
32	cancerlit.ab.	635
33	british nursing index.ab.	394
34	hmic.ab.	299
35	current contents.ab.	1241
36	or/26-35	275297
37	reference list$.ab.	19523
38	bibliograph$.ab.	19687
39	(handsearch$ or hand-search$).ab.	9908
40	relevant journals.ab.	1246
41	manual search$.ab.	4960
42	(search adj (strategy or criteria)).ab.	20709
43	(search$ adj4 literature).ab.	76584
44	or/37-43	131101
45	review.pt.	2829889
46	((selection or inclusion or exclusion) adj criteria).ab.	152547
47	data extraction.ab.	24810
48	45 and (46 or 47)	61557
49	25 or 36 or 44 or 48	510342
50	comment.pt.	918031
51	letter.pt.	1143552
52	editorial.pt.	573492
53	or/50-52	1977380
54	49 not 53	493180
Rapid review add-on		
55	(rapid adj2 review*).tw,kw.	1884
56	(health technology assessment* or HTA).tw,kw.	7052

57	or/55-56	8896
SIGN RCT filter		
58	Randomized Controlled Trials as Topic/	146221
59	randomized controlled trial/	537566
60	Random Allocation/	105593
61	Double-Blind Method/	165857
62	Single-Blind Method/	30514
63	Clinical Trial/	529828
64	clinical trial, phase i.pt.	21960
65	clinical trial, phase ii.pt.	35337
66	clinical trial, phase iii.pt.	18704
67	clinical trial, phase iv.pt.	2137
68	controlled clinical trial.pt.	94293
69	randomized controlled trial.pt.	537566
70	multicenter study.pt.	299044
71	clinical trial.pt.	529828
72	exp Clinical Trials as Topic/	360620
73	or/58-72	1444089
74	(clinical adj trial$).tw.	404590
75	((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.	181480
76	PLACEBOS/	35564
77	placebo$.tw.	226805
78	(random$ adj allocat$).tw.	33836
79	(allocat$ adj2 random$).tw.	38005
80	or/74-79	688123
81	73 or 80	1738474
82	case report.tw.	338959
83	letter/	1143552
84	historical article/	364401
85	or/82-84	1829966
86	81 not 85	1698929
SIGN Observational studies filter		
87	Epidemiologic Studies/	8740
88	exp Case-Control Studies/	1200470
89	exp Cohort Studies/	2175464
90	case control.tw.	135136
91	(cohort adj (study or studies)).tw.	240930
92	cohort analy$.tw.	9239
93	(follow up adj (study or studies)).tw.	51503
94	(observational adj (study or studies)).tw.	124631
95	longitudinal.tw.	269783
96	retrospective.tw.	601466
97	cross sectional.tw.	403983
98	Cross-Sectional Studies/	377258
99	or/87-98	3283679
Set combinations		
100	54 or 57 or 86 or 99 [study design filters]	4847457
101	17 and 100 [face coverings AND SR, RCTs & Obs]	618

10 2	17 not 101 [face coverings AND lower level evidence]	1790

6.4 Appendix 2 – Eligibility criteria

Research Question	What is the effectiveness of face coverings to reduce the spread of COVID-19 in the community? What is the efficacy of different types of face coverings designed for use in community settings?

	Inclusion criteria	**Exclusion criteria**
Population	Human	Non-humans studies
Intervention	**All types of face covering including (but not limited to) handmade and commercial cloth masks** **We will use PHE's definition of face coverings: defined as any type of face covering that covers the mouth or nose (including medical masks and other types of face covering).**	**Studies comparing effectiveness of surgical masks to N95 respirators: scoping indicates this evidence is almost entirely conducted in healthcare settings.**
Comparison/ Comparators	**Any control/no use of face coverings** **Comparison of different types of face coverings with each other**	**Studies comparing effectiveness of surgical masks to N95 respirators: scoping indicates this evidence is almost entirely conducted in healthcare settings.**
Outcome measures	**• Effectiveness of face coverings in preventing the transmission of COVID-19/SARS-CoV-2 virus** **• Transmission of SARS-CoV-2** **• SARS-CoV-2 infection** **• Basic Reproduction number** **• Mask filtration capacity/droplet transmissions**	
Search limits *dates, language, etc.*	**22 September 2020 onwards. We will use the PHE review (2021) as a source of evidence prior to this date.** **English language only**	
Other factors		
Setting	**We will include all community settings including households. We will exclude healthcare settings.** **We will use PHE's definition of community settings: non-healthcare settings, including (but not limited to) public spaces,**	

	households, shops, and public transport
Study design	**We will prioritise the following study types, in the order listed:** • **Well-conducted sources of secondary evidence, including studies of any design** • **Primary studies of any comparative design** • **Ecological/longitudinal studies (ie studies comparing outcomes before/after introduction of the intervention, but without a control group)** • **Laboratory studies** **We will prioritise the above separately for each research question if required, ie different study types will be included for the two different questions if necessary.** **Where relevant and well-conducted systematic reviews exist we will use these by:** • **Reporting or adapting their reported outcome measures where these are fully relevant to the scope of our review, and appropriate synthesis methods have been used** • **Using these reviews as a source of potentially relevant studies where the review cannot be used as a source of outcome data** **We will prioritise systematic reviews in terms of the sources of evidence they include, using the order described above, and also in terms of their certainty (in terms of methodological conduct and relevance to the research questions of interest).**
Publication status	**We will include evidence from studies that are published in full (whether peer-reviewed, preprints or grey literature sources). We will not include evidence from conference abstracts. We will not report ongoing trials (unless they provide fully published interim findings)**
Subgroup analysis	**Where the evidence allows, we will report outcomes separately according to:** • **Seasonality** • **Different settings within the community** • **Use of face coverings by children/adolescents**

7. ABOUT THE WALES COVID-19 EVIDENCE CENTRE (WC19EC)

The WC19EC integrates with worldwide efforts to synthesise and mobilise knowledge from research.

We operate with a core team as part of Health and Care Research Wales, are hosted in the Wales Centre for Primary and Emergency Care Research (PRIME), and are led by Professor Adrian Edwards of Cardiff University.

The core team of the centre works closely with collaborating partners in Health Technology Wales, Wales Centre for Evidence-Based Care, Specialist Unit for Review Evidence centre, SAIL Databank, Bangor Institute for Medical & Health Research/ Health and Care Economics Cymru, and the Public Health Wales Observatory.

Together we aim to provide around 50 reviews per year, answering the priority questions for policy and practice in Wales as we meet the demands of the pandemic and its impacts.

Director:

Professor Adrian Edwards

Contact Email:

WC19EC@cardiff.ac.uk

Website:

https://healthandcareresearchwales.org/about-research-community/wales-covid-19-evidence-centre