Commission: What are the appropriate layers of mitigation to deploy for care homes in the context of post vaccination risk landscape?

Executive summary

Purpose of report in assessing post vaccination risks in the current context.

This report examines the evidence of the impact of interventions to mitigate COVID-19 that have been put in place in residential care and nursing homes and considers scenarios for future mitigation provision. During the vaccination campaign a very small number of outbreaks have been observed though mortality rates are low at present, meaning that there is some ongoing risk but that it is challenging to state due to small numbers.

Care homes have experienced large outbreaks and high mortality, due to the extreme vulnerability of residents and dense contact patterns contributing to transmission. However it should be noted that older adults receiving social care services in their home (home care, domiciliary care) have similar personal vulnerability to severe outcomes from COVID-19. Outbreaks in domiciliary care appear less common, but are likely to be under-ascertained by comparison with care homes. This paper addresses care homes specifically, but may inform future guidance for post-vaccine mitigations in domiciliary social care more generally.

Hazard environment

Care home settings have multiple potential hazards from infectious diseases. These are summarised as a strong connection between a care home setting and the external community. For a respiratory infectious disease close and regular contact (such as required for care) enhances transmission. Transmission hazard can cause chains of transmission and so, in a closed and relatively large population, large outbreaks. Older people have higher chance of severe outcomes than younger people from COVID-19 so residents are particularly vulnerable (Residents of care homes will be frailer and have more co-morbidity than the general age matched population).

Using the outcomes of those with prior infection to predict future vaccine impact

The Vivaldi study found that prior infection in the care home population provided 85% protection for up to 10 months (high confidence). The vaccine efficacy studies appear to suggest that second dose will provide 80-90% protection in this population (high confidence). While data doesn't allow us to produce exact estimates, the wave two mortality patterns in the homes that we know were significantly impacted by COVID-19 in wave one were more akin (albeit slightly higher) to seasonal mortality patterns. Therefore, keeping all things equal and not removing any interventions, it is possible to anticipate the residual mortality risk in a vaccinated set of residents to be of the same order as pre-pandemic seasonal flu (medium confidence). If the premise is accepted that prior immunity is equivalent to vaccination, we can conclude that the key transformational intervention will be vaccination noting that it acts to mitigate all hazards described above.

Easing restrictions – the case for caution

The decision to suspend any intervention, given expected protection by vaccination, is contingent on the number of cases society is willing to observe in future as no intervention or combination of interventions is certain to stop all future cases. Further to this a care home is the home of an individual resident but decisions also affect all other residents. Therefore the risk perception of all residents and their relatives (particularly for people who may lack capacity) should be considered as part of the social contract within the home.

This context allows us to look again at the balance of risks. Most interventions come with at least some cost. For instance wearing facemasks can hinder communication. Restricting visitors, as has been noted in a previous SCWG paper, has an obvious detrimental effect on the quality of life of residents in their final years and loved ones. It is therefore recognised that some measures should be relaxed to give quality of life back to residents and ease any disproportionate burden on care homes. As we know that all the interventions have probably had some incremental effect, but we don't know the specific contribution of each measure, it is recommended that any mitigations / restrictions that are eased are done so in a measured manner and if possible in a way that allows for evaluation of the individual impact before further easing of restrictions. The case for this cautious approach is also underlined by the fact that the impact of new variants in the context of a general easing of societal restrictions is still to be seen.

A strategy for employing interventions, based on three different categories of risk (**baseline**, **defend**, **outbreak**) of threat is provided in the report. A framework for use by policy makers is suggested in the paper to be used when considering how to assess / prioritise easing of restrictions as more information becomes known about future threats. Consideration should also be given to employing new interventions and technology that has become available. Whilst infection control is the major focus when easing current restrictions, there is clearly need to balance these risks with the other benefits residents may obtain from eased restrictions, i.e. in terms of other benefits to physical and mental health, and quality of life etc., given the evidence that lockdown restrictions have had adverse effects on health.

Further analysis

Further exploitation of linked datasets is recommended to understand more about the different risks that were presented in wave two. Work is underway at the moment to understand the extent to which the new variant impacted the mitigations that were put in place. We know that rapid testing helped prevent thousands of members of staff from working in care homes while infectious, but we don't know at an individual care home level, the extent to which this delayed rather than prevented outbreaks. Linking the data and undertaking analysis of this kind, this will in turn help build capability for rapid surveillance. At the present time data on care home visits is extremely poor and, as a result, the risks and benefits posed by different visiting policies cannot be adequately assessed leaving a vulnerability in the system.

Recommendations

The review of interventions deployed in care homes by SCWG has highlighted the unique position of vaccination in acting across the hazards of COVID-19 to care homes. There is medium empirical evidence that the suite of interventions prior to vaccination had an effect on reducing morbidity and mortality, particularly when community prevalence was low. There is very limited data (and thus weaker evidence) on impact of specific interventions and on proving causality. *Careful risk assessment should be undertaken based on evaluation of the consequences of standing down interventions in terms of infection control and general wellbeing and the threats from new variants and prevalence in the community which SCWG will review.*

Risk scenarios

We recommend that risk is managed in 3 categories (baseline, defend and outbreak: Table 1) once vaccine campaign targets are achieved this can be reviewed over time and possibly relaxed or surged dynamically as evidence emerges in future. None of the categories described below should be considered as static and flexibility is needed to increase and decrease capacity as the epidemiological situation dictates.

For example the external force of infection to care homes is potentially lowering as more of the general population is being vaccinated. However, we must beware of complacency since there are also hazards as younger care workers may be hesitant to be vaccinated because of anti-vaccination misinformation or because of specific cultural or religious beliefs. This may vary enormously between care homes, some may have nearly all staff/regular visitors vaccinated and some may have lower levels, NHS England data from April show 53% of care homes have at least 80% of staff and 90% of residents with at least one dose whilst PHE data shows about 20% of homes have not received a second dose yet. There is also risk associated with changes in behaviour as vaccine is rolled out and societal lockdown measures are relaxed.

In the baseline and defend categories below we do not make explicit mention of infection prevention and control measures within the home (i.e. use of PPE such as masks, social distancing, cohorting of staff and residents). This is because specific scientific evidence on the effectiveness of individual interventions in care home settings is hard to find, given the way they were implemented together and at pace during the early pandemic period. It is therefore difficult to provide a steer at this stage other than to state such interventions have an important role. If such interventions are to be relaxed this must be done in a proportionate and sequential manner so as to monitor the impact of change, rather than removing all such measures in one go.

Baseline: In areas with **low incidence** (measured as no outbreaks in homes nearby **or** low community incidence) **and** no reports of **VOC** in local community: weekly PCR testing for staff, LFD testing for visitors up to a maximum of twice per week, no testing of residents unless returning from external setting as per current advice, and monitor vaccine coverage rates at individual home level to ensure consistently high level of vaccine in staff and residents (see below for evidence on effective levels).

Defend: In areas where there are **either** consistently rising levels of infection (measured through number of outbreaks in nearby care homes or community incidence) **or** VOC in community then move to more **defensive** posture. If community transmission of VOC, trigger whole home care home testing as part of surge testing (ahead of any detected cases or outbreaks in care homes); otherwise, implement weekly PCR testing and twice weekly LFD testing of staff; threshold testing for visitors to maximum of twice per week; no resident testing unless returning from external setting. All suitable

PCR test positive cases (staff, residents and visitors) to be sent for whole genome sequencing. Push vaccine coverage to desirable levels for staff and residents (especially new staff and residents) at home level. Advise all visitors to take up offer of vaccine. Cohort staff and residents and limit cross-deployment of staff.

<u>Outbreak:</u> If confirmed case(s) in home then trigger whole home testing as per current outbreak protocol including daily LFD testing of staff; for duration stated in protocol restrict visiting to essential only and threshold test on every visit; stand up all IPC measures as per protocol.

Risk	Testing and Vaccine Mitigation	Impact
Baseline (No outbreaks nearby and No VOC in community)	Weekly PCR staff, LFD for visitors & returning residents, monitor vaccine coverage and encourage and facilitate vaccine uptake where needed.	Low infections, rare deaths due to low transmission / severity provided by vaccine. Residual testing monitors VOCs and ingress.
Defend (Outbreaks nearby but not VOC or VOC in community)	Actively boost vaccination coverage in staff and residents. If community transmission of VOC, surge test whole home care home; otherwise, weekly PCR testing + twice weekly LFD testing of staff; LFD testing for visitors to max of twice per week; no further resident testing. All suitable PCR test positive cases (staff, residents and visitors) to be sent for WGS.	Community infections may increase ingress rate, rare deaths due to low transmission / severity provided by vaccine. Testing monitors VOCs and reduces ingress of infectious staff and visitors.
Outbreak	Testing policy and targeted interventions within home as per current outbreak protocol. Ensure all resident and staff vaccine rates are high (noting it will take 3 weeks for protection to be achieved post- vaccination).	Increased ability to detect and respond to the raised threat level to care home residents. Could potentially be more risk of transmission and deaths within care home depending on nature of variant driving outbreak.

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Data needs and gaps

As numbers of outbreaks are currently low this is a perfect opportunity to refine data needs and collection processes. We make the following recommendations:

• There are clear fundamental evidence gaps on the impact of interventions to reduce transmission and outbreaks. Eliciting such evidence will be key in order to decide on effective control processes. Simulation modelling is part of this but relies on assumptions of effectiveness that may not be evidence based of the range of settings modelled.

- There should be a review of data collection systems to make them less burdensome to care home providers and improve quality of data (helping to increase adherence with policy).
- New efficient and reliable mechanisms are needed to measure the number, frequency and pattern of visitation for all the different *types* of visitors (family, professional). It is critical that data are collected at a resident level to assess risk of clustering of infection as well as similar quality data on outings and external trips by residents. As part of this data provision tracking vaccine status of visitors may be useful. This will be critical as visiting in and out is relaxed and monthly screening of residents removed.
- The opportunity should be taken to improve data linkage for specific purposes, for example tracking individual (staff and resident) level testing, vaccination, hospitalisation and other outcome data. A timely provision of individually linked data would substantially improve the ability to monitor the impact of interventions and outcomes.
- Major lessons identified from pandemic are that better understanding of the number of
 residents and staff in care homes is essential. Therefore resourcing and expediting work on
 'social care episode statistics' is critical as well as occupational health and support to staff.
 There is no reliable or consistent data source to monitor the number of residents in a given
 care home, which changes constantly due to high resident mortality and new admissions
 and discharges to/from the home. Monthly resident testing data has been a proxy for this,
 and has made it possible to evaluate vaccine coverage and effectiveness and mortality and
 case-attack ratios all of which require accurate denominators. However, when monthly
 testing of residents is stopped the ability to monitor infection and related outcomes in
 residents will cease. A reliable alternative will be required to ensure long-term surveillance
 of the care home population.
- Existing systems, such as the Palantir Foundry, provides part of the solution on data capture, but its use could be improved by facilitating access in a manner that allows modellers to perform analyses within their own workflows locally by permitting download access.

Resident Testing

Monthly resident testing (when no outbreak is ongoing) was found in previous modelling to have minimal benefit in reducing morbidity or detecting outbreaks in all modelling given testing of staff is in place. Continuation of policy was recommended in January 2021 as the vaccine campaign started to enable further insights into vaccine effectiveness. Vaccine effectiveness is better understood now and so monthly screening of residents may serve limited purpose given distress and challenges caused. However, it may be valuable for monthly testing of a subset of residents to continue in a research context. Should variants be detected, vaccine effectiveness against the specific variant would need to be measured and so well designed studies that can deliver timely data are essential. A review of data on whether outbreaks were triggered by resident screening should be completed to quantify the benefit of resident screening to compare with modelling estimates.

Interventions associated with care homes

Assessing the utility of interventions post vaccination.

With high vaccine coverage achieved (see ¹ for SCWG previous advice on suitable coverage levels) and with low community prevalence it is natural to consider whether it is time to reduce the level of IPC, PPE etc interventions in social care settings so as to allow a return to "normal". To assess the wisdom of reducing such interventions, the interventions that have been put in place must be reviewed to assess how each is working as integral part of the overall package of mitigations.

It is imperative that interventions are considered holistically rather than in a piecemeal manner. The mitigations in place are interconnected and relaxing or removing multiple interventions at similar times may have greater impact than their individual contributions (as they may act against multiple hazards and onward transmission is naturally non-linear process in outbreaks). This interconnectedness is a potential strength but a challenge to evaluate and generalise to all care home settings.

In closed settings even at times when there are low levels of infection in the community, there can still be outbreaks of infectious diseases (as experienced with flu in prisons and care homes in previous years). So even if low levels of infection, we need to be mindful that protections are required, and this may include more mitigation than provided by vaccination.

In order to understand the effectiveness of interventions specifically implemented within care homes we need to view them in the context of changes in prevalence of COVID-19 in the community they are part of. This includes assessing the impact of vaccination given the coverage levels of staff and residents and the effectiveness of the vaccine against variants of concern circulating nearby. Waning natural immunity and potential waning protection from vaccine as well as impact of variants on transmissibility and severity should also be part of risk assessment for the future.

The decision to suspend any intervention, given expected protection by vaccination is contingent on the number of cases society is willing to observe in future as no intervention or combination of interventions is certain to stop all future cases. Thus to fully evaluate and compare interventions with any modelling framework the tolerance of risk (i.e. the number of cases or number of deaths) and the objective (reducing deaths, cases or cost) needs to be stated to assess the sufficient level of intervention.

The adult social care hazard environment

A hazard is considered here to be an event that can cause harm. Care home settings have multiple potential hazards from infectious diseases as shown in Figure 1, below. Strong connection between a care home setting and the external community increases chance of *ingress* of disease and this may be amplified if the external connections are to areas of persistent infection (for care homes, say, through staff interactions in the community and possibly between care settings too). A threat remains of high epidemic/endemic prevalence in care homes driven by transmission within the social care and health care system by cross-deploying staff. For a respiratory infectious disease close and regular contact, such as that required during care provision, enhances *transmission*. This is almost independent of mode because whilst droplet and fomite transmission are clearly impacted by close contact, the likelihood of exposure to infectious aerosols may be increased by regular close contact with others outside of your family or care bubble [whilst not specific to social care settings

¹ SCWG Consensus note: Estimating the minimum level of vaccine coverage in care home settings

infection risk increased with social contact² and household contacts³]. Transmission hazard can cause chains of transmission and potentially large *outbreaks* especially if the population is closed and relatively large. Previous work (pre-pandemic on flu [Finnie, Copley, Leach and Hall ⁴]) suggests closed societies have higher attack rates than community or national average. Older people have higher chance of *severe outcomes* than younger people from COVID-19 (for example hospitalisation and deaths) and so care homes for older people have a vulnerable resident base [Barker, Hanratty, et al 2021⁵].

In the language of epidemic modelling then the ingress hazard provides the initial seeding of virus, transmission hazard relates to the probability of causing infection at each contact, outbreak hazard relates to the number of contacts and severe outcome hazard applies to all infections.

Evaluating the risk of these hazards requires consideration of the impact and likelihood of the hazard. When considering the package of interventions in the future it will be important to frame the policy decisions in the context of the hazards presented in Figure 1. Also note that care homes are part of the community they are geographically situated within, mainly characterised in terms of ingress risk (commuting needs of staff and visitors) but care homes should be factored specifically into mitigations affecting the whole community.

Care homes have experienced large outbreaks and high mortality, due to the extreme vulnerability of residents and dense contact patterns contributing to transmission. However it should be noted that older adults receiving social care services in their home (home care, domiciliary care) have similar personal vulnerability to severe outcomes from Covid-19. Outbreaks in domiciliary care appear less common, but are likely to be under-ascertained by comparison with care homes [Phipps et al, scabies). This paper addresses care homes specifically, but may inform future guidance for post-vaccine mitigations in domiciliary social care.

² <u>https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a5.htm</u>

³ <u>https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3566149</u>

⁴ An analysis of influenza outbreaks in institutions and enclosed societies - PubMed (nih.gov)

⁵ <u>https://doi.org/10.1093/ageing/afaa227</u>



Figure 1: Schematic showing the main hazards to care homes from infectious diseases such as COVID-19, illustrative mitigations are included in adjacent bullet list that may reduce the impact of the risk of the relevant hazard.

Evaluation challenges

To determine effective interventions going forward it is helpful to consider the following principles:

- Modes of transmission: The virus is known to spread through close range interactions (may be aerosols, droplets or direct physical contact), via the air over distances greater than ~2m and via contaminated surfaces. Evidence suggests that inhalation may pose more risk than surface transmission. It is important that interventions consider all modes of transmission.
- Risk Assessment: assessing risk for all work activities is critical to identify the controls needed to protect workers and others from SARS-CoV-2 (ref: <u>https://www.hse.gov.uk/coronavirus/working-safely/risk-assessment.htm</u>). The framework provided by HSE requires that:
 - o work activity or situations that might cause transmission of the virus are identified
 - o you think about who could be at risk
 - o you decide how likely it is that someone could be exposed
 - you act to remove the activity or situation, or if this isn't possible, control the risk using the hierarchy of risk control (as shown below)
- *Hierarchy of risk controls:* This is a well known principle of risk assessment that recognises that some interventions are more effective than others, and that those that rely very heavily on the behaviour of individuals are likely to be less effective than those that are structural. This is often shown in the form of an inverted pyramid (Figure 2 below) with those at the top, more effective than those at the bottom. Measures which prevent the virus from being present in the environment are more effective than those to limit its spread once it is present.
- Inequalities and harms: Some measures have very limited downsides, while others will have significant consequences whether it is social, cost, time or impact on other activities. This is particular the case in care home settings where measures can have a significant impact on the wellbeing of residents.

• Individual vs collective/population risks: Consider how measures may influence 1-to-1 transmission or 1-to-many transmission. Those that limit the chances of a large outbreak are likely to be more important to retain over those that focus on individual risks.



Figure 2: Illustration of a hierarchy of risk controls principles from a context outside of social care, further work could develop this for social care.

Another framework that could be considered for evaluating inequality or harm of interventions is the APEASE framework⁶, which looks at the following areas:

- **Acceptability**: How far is it acceptable to key stakeholders? This includes the target group, potential funders, practitioners delivering the interventions and relevant community and commercial groups.
- **Practicability**: Can it be implemented at scale within the intended context, material and human resources? What would need to be done to ensure that the resources and personnel were in place, and is the intervention sustainable?
- *Effectiveness*: How effective is the intervention in achieving the policy objective(s)? How far will it reach the intended target group and how large an effect will it have on those who are reached?
- **Affordability**: How far can it be afforded when delivered at the scale intended? Can the necessary budget be found for it? Will it provide a good return on investment?
- *Side-effects*: What are the chances that it will lead to unintended adverse or beneficial outcomes?
- *Equity*: How far will it increase or decrease differences between advantaged and disadvantaged sectors of society?

Traditional epidemiological evaluation methods based on health economics and reliant on measures such as QALYs provide an effective means to assess interventions and consider affordability, equity

⁶ <u>https://www.ucl.ac.uk/behaviour-change/sites/behaviour-</u>

change/files/phebi_achieving_behaviour_change_local_government.pdf

and acceptability (or specifically inequality/harm and collective v individual harms). Some of the challenges of such approaches for care homes and adult social care were discussed in previous SCWG work⁷. These challenges include methodological ones of who defines the objective and around how to compare the wellbeing lost from isolation against the impact of disease but also practical ones around say residents with cognitive impairment or near end of life. The Adult Social Care Outcomes Toolkit (ASCOT) is designed to measure the domains of quality of life affected by social care⁸. However, although often well developed, these measures are less well established as a utility measure than the EQ5D health-related quality of life for the QALY.

During the pandemic, multiple measures have been introduced at pace, representing challenges for taking a 'gold standard' approach to evaluation.⁹ Interventions associated with care homes are multi-layered and dynamic, and by definition complex¹⁰. As such it is hard to objectively measure individual components and generalise impacts to other settings. The international evidence base on measures taken in response to the pandemic in social care has mostly consisted of descriptive case studies and outbreak reports¹¹. It is challenging to use the traditional epidemiological tools of case control studies and operationally impractical to recruit people during an outbreak (so recruitment would have to be ahead of time but at present case numbers are small) or be clear on implemented interventions locally given observation will be remote. Some 'natural' experiments may occur where other countries or regional differences mean policies vary between homes but generalising these will be challenging as data generated is observational and pragmatically collected.

Data challenges

Firstly there is a challenge with terminology. Vaccine efficacy is measured in a randomised control trial, effectiveness is a real world measure, and is naturally more uncertain than formal efficacy. The measurements that are derived from UK settings are all vaccine effectiveness. Other interventions described in this report will have similar differences between evaluation in a carefully controlled study and pragmatic real world evaluation.

Analytical quantitative results are challenging at this time due to the small numbers of cases observed at present. This is a wholly positive situation due to vaccination campaign and societal sacrifices but make concrete advice difficult to frame.

⁷ Social Care Working Group Consensus statement on family or friend visitor policy into care home settings, SAGE, November 2020.

⁸ https://www.pssru.ac.uk/ascot/

⁹ <u>https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003266</u> "In a complex system, the question driving scientific inquiry is not "what is the effect size and is it statistically significant once other variables have been controlled for?" but "does this intervention contribute, along with other factors, to a desirable outcome?". Multiple interventions might each contribute to an overall beneficial effect through heterogeneous effects on disparate causal pathways, even though none would have a statistically significant impact on any predefined variable"

¹⁰ https://mrc.ukri.org/documents/pdf/developing-and-evaluating-complex-interventions/

¹¹ Byrd W., Salcher-Konrad M., Smith S. and Comas-Herrera A. (2021) *What long-term care interventions and policy measures have been studied during the Covid-19 pandemic? Findings from a rapid mapping review of the scientific evidence published during 2020.* Preprint under review, available

at <u>https://ltccovid.org/2021/05/19/preprint-what-long-term-care-interventions-and-policy-measures-have-been-studied-during-the-covid-19-pandemic-findings-from-a-rapid-mapping-review-of-the-scientific-evidence-published-during-2020/</u>

Data collection processes should be improved with some urgency, both to make data collection less burdensome and improve quality of data (possibly also helping to increase adherence with policy). For example the reporting of negative LFD test results is time consuming and not straightforward and submission of Capacity Tracker data is seen by some as placing a burden on care home managers (From stakeholder engagement it seems that this is in part because care homes do not see the benefits of providing the data and if useful information was fed back to them, this may help change the perception that this is a "one way" exercise).

As numbers of outbreaks are currently low this is a perfect opportunity to refine data collection practice. Key emerging question relate to the density of visitors and pattern of visitation so having data capture on all the different *types* of visitors (family, professional) and their frequency is critical at a resident level to assess risk of clustering of infection as well as similar quality data on outings and external trips by residents. Vaccine status of visitors may be hard to curate but could be considered.

Given the lower numbers of cases being observed this is the time to consider a much fuller revision of data issues and review the broader picture around data collection and processing. The opportunity should be taken to improve data linkage for specific purposes, for example tracking individual level testing, vaccination, hospitalisation and other outcome data. A timely provision of individually linked data would substantially improve the ability to monitor the impact of interventions and outcomes.

Existing systems, such as Palantir Foundry, provides part of the solution, but its use could be improved by facilitating access in a manner that allows modellers to perform analyses within their own workflows locally by permitting download access.

Community infection scenarios

SAGE recently (5th May 2021) published advice¹² which showed the impact on the national curve of relaxation of national mitigation measures through modelling scenarios.

The report emphasises that there is considerable uncertainty about behaviour as measures relax, which impacts on transmission, at each step of the Roadmap. The simulations presented do not account for waning immunity nor do they consider dominance of variants of concern. Given the assumptions then whilst it is likely that steps 3 and 4 of the roadmap will increase R and so see increases in community incidence and hospital admissions and deaths it is unlikely to put unsustainable pressure on the NHS.

Scenarios simulated suggest that there will be a wave of infection over the summer peaking during August, as a result of relaxation of social mitigations in the community, but this is likely to be in younger aged people due to high vaccination rates in older age groups and so have lower impact on primary care.

Figure 3 (copied from appendix 1 of the SPIM-O consensus statement) below shows the number of hospitalisations arising from given scenarios over roughly the next year from one of the modelling groups involved but note that model outputs depend on assumed use of NPIs and transmission.

The SPIM-O body of work suggests that the impact of future waves on care home residents and social care clients should be reduced due to vaccination. However, staff age groups may remain at risk if vaccination uptake is lower and visitors to care homes may come from ages that are not currently vaccinated, so caution is still warranted.

¹² <u>SPI-M-O: Summary of further modelling of easing restrictions – roadmap step 3, 5 May 2021 - GOV.UK</u> (www.gov.uk)

OFFICIAL SENSITIVE

Appendix 1: Sensitivity analyses comparison



Comparison of all the uncertainties investigated by University of Warwick, impact on hospital admissions from 17th May to end of June 2022

Figure 3: Comparison of hospital admissions under given potential scenarios, image taken from SPIM roadmap work

Summary of interventions used to date

Table 2 below lists the common interventions, summarising expected impact and potential issues arising from implementation. Ideally an evaluation via a hierarchy of control framework would be useful, but given the way interventions were implemented at pace and together it is difficult to disentangle individual intervention contributions from the data available. Therefore the order in the list is indicative and where effectiveness is unknown the interventions are grouped by hazard. This may need an expert elicitation event in future. In order to evaluate the relative harms and benefits of interventions then a fuller evaluation would be useful possibly using APEASE, health economics or combination. Should this analysis be available SCWG is willing to assist and review work.

Only vaccine is reported as affecting severe outcome. Each row in Table 2 has a fuller review in the appendices of this report.

Table 2: Interventions used in residential care, broad aim of intervention, expected impact of these measures and potential issues arising from implementation.

Intervention	Hazard affected	Effectiveness	Potential Benefit	Potential Harm/issues
Vaccine	• All	 See table 4, >80% for second dose, and 80% coverage suggest 64% combined effect 	 Reduces severity of infection Reduces susceptibility to infection Reduces transmission Reduces ingress by reducing community transmission 	 Some adverse reactions¹³ Vaccine escape may mean protection is weakened. There may be vaccine hesitancy among staff¹⁴ Staff may have other barriers to vaccination through mix of supply and demand issues. Low uptake in staff may mean outbreaks arise. Confidence of protection may lead to behaviour changes that reduce the effectiveness of other interventions Not everyone can be vaccinated
Lockdown of community	Ingress	 Unknown, if longer than 1 month turns growth rate from +ve to –ve 	 Clear reduction in mortality observed 2-3 weeks after lockdown starts (it takes about 10 days to die post infection and generation time is a week) Reduces force of infection onto care homes. 	 Economic impact on wider society, assessment not in scope of SCWG
Testing	 Ingress and 	• At most 70%,	Currently done via regular LFD	 Much LFD testing done at home and so no
	transmission	lower if	testing.	independent assessment of adherence or
		noor	Assuming virai load is correlated with infectiousness then a positive	• LED has relatively low sensitivity (70-80%)
		, poor	test is currently infectious and so	to infection (compared with PCR)

 ¹³ <u>https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting</u>
 ¹⁴ <u>https://www.medrxiv.org/content/10.1101/2021.03.07.21252972v1.external-links.html</u>

			 detection removes individual from force of infection onto others Turnaround time is fast (< 1 hr) so can be done whilst waiting High specificity (>99.5%) Reduces force of infection both onto and into care homes 	 It is better at detecting infectiousness but given short infectious window this means frequent testing is needed. False negatives may cause secondary infection (and thus outbreaks). Testing will detect positive cases and these will require isolation for 10 days. This may reduce staff pool and require agency staff (working in multiple homes) or reduce general care resources. PCR confirmation of LFD positives would act to reduce false positives Testing can be distressing and confusing for some residents. Testing is uncomfortable for staff and there have been concerns about staff adherence to home testing
Testing infection/variants	• Ingress and transmission	 Weekly test may only be 30% effective at reducing infectiousness (see modelling below) but nearer 90% for detecting variants 	 Current test is laboratory based PCR High sensitivity (~90%) High specificity (>99.5%) Samples may be sent for genomic analysis and so detect variants of concern in terms of vaccine escape. 	 Turnaround time is relatively slow (days) and so individuals may remain in setting causing infections during turnaround time May detect residual infection rather than current infectiousness meaning force of infection from a case is not reduced PCR may detect the early stages of infection before infectiousness which LFD would not but may depend on viral load. Testing will detect positive cases and these will require isolation for 10 days. This may reduce staff pool and require agency staff (working in multiple homes) or reduce general care resources. PCR testing is more costly that LFD testing

Reducing cross- deployment of	Ingress	Unknown	 Limits in working in multiple places and transmission between homes. 	 Testing can be distressing and confusing for some residents. Testing is uncomfortable for staff, but laboratory processing may reduce concern about staff adherence to procedure. Equitable pay for reducing opportunity to work.
staff across multiple locations				 Restricting agency staff may have knock on effects in terms of fatigue, burnout, non- COVID sickness – to reduce the risk.
Providing accommodation for staff who proactively choose to stay separate from their families in order to limit social interaction outside work	• Ingress	• Unknown	Reduces contact with community	 Difficult for staff with familial obligations. Identification of suitable alternative accommodation. May be a policy of last recourse but after ingress too late to be effective so stand up trigger will be very hard to define. Perhaps a policy for high transmission/low effect VOCs
Limiting entry to home	 Ingress 	 Unknown 	 Reduces force of infection from community onto homes 	 Residents cannot meet family and friends and so increases isolation with concomitant adverse effects. Distressing to families, friends and residents alike.
Steps to limit the use of public transport by members of staff	Ingress	• Unknown	 Reduces contact on commute and hence risk of infection 	 Transmission likely to be at home or work. Commute may be with co-workers or co- habitees Synchronised pick-ups in larger vehicles provides opportunity for greater mixing and transmission

				Costs and potential lack of alternatives to public transport for many care staff.
Cohorting of staff	Outbreak	• Unknown	 Reduces contact within the home and effectively forms smaller networks. 	 May be hard to implement given care needs. Could be expensive – possible duplication of care staffing, laundry, catering services so groups can be kept apart. It may be difficult to ensure agency staff cohort effectively
Cohorting of residents	Outbreak	• Unknown	 Reduces contact within the home and effectively forms smaller networks. 	 Reduces social contact between residents and opportunity for group activities. May prohibit exercise and activity groups with resultant deconditioning. May adversely affect mental health and wellbeing of residents. Difficult to implement with small common areas such as lifts.
Isolation	Outbreak	• Unknown	Limits contact between residents.	 Distressing for residents Isolation is detrimental to mental health, wellbeing and physical health. Staff remain a vector May be hard to arrange within homes due to layout and care needs. May be expensive.
Social distancing	 Transmission and outbreak 	• Unknown	Reduces contact within the home	 Hard to implement in smaller, older fabric homes Less effective against aerosol spread Physical contact is necessary for care provision
Quarantining equipment and material	Transmission and ingress	• Unknown	Reduces fomite transmission	• Virus survival is relatively short lived so may have low impact on transmission.

Ventilation	Transmission	• Unknown	 Improved airflow reduces viral load inside homes by removing aerosol contamination¹⁵¹⁶. Use of CO2 monitoring may help balance ventilation vs temperature Air cleaning devices may be beneficial in spaces where ventilation is hard to improve 	 Short term approaches like opening windows is not a long term solution and may be too cold for residents Building design/layout in some homes a barrier to implementation Cost of retrofitting systems to improve airflow and filtration may be high.
Hand hygiene	Transmission	Unknown	Reduce transmission by removing contamination from hands	Standard IPC intervention but may cause skin irritation
Mask use	Transmission and outbreak	• Unknown	 Physical barrier on infectious case reduces amount of infectious material released to environment Physical barrier on susceptible person reduces inhaled doses 	 Masks are a barrier to effective communication with residents with special needs/risk factors. Mask are a barrier to communication for persons with hearing impairments. Masks are a barrier to recognition Some residents may not tolerate mask wearing
Other PPE: gloves, aprons etc.	Transmission	• Unknown	 Physical barrier can reduce contact with surfaces and skin and droplet settling on skin. 	 Donning and doffing may be an issue (cross-contamination). Disposal of PPE Adherence by untrained individuals Time critical and acute care needs may not allow time for full adherence. Challenge for people with specific conditions such as dementia. Visors are a barrier to communication, especially for those with hearing impairments.

 ¹⁵ <u>https://jamanetwork.com/journals/jama/fullarticle/2779062</u>
 ¹⁶ <u>https://www.who.int/publications/i/item/9789240021280</u>

				Mask effectiveness depends on quality and fit
Homes with dedicated resources such as laundries	Transmission	Unknown	 Single use garments may reduce contamination 	Increasing staffing pool
Financial support for staff to take leave to isolate	 Transmission, outbreak and ingress 	• Unknown	 Limits working in multiple places. 	 Staff routinely not paid to be off work. No relevant data available. Staff members that work at multiple care home settings would have different testing regimes and system may not keep track of this effectively

Appendices

Interventions

Wave Two: Five lines of defence



Figure 3 Hierarchy of control of COVID-19 measures

Figure 3 recasts the hazards presented in Figure 1 in terms of the control principles. The questions included are indicative questions for consideration but not necessarily answered in this report. Considering a hierarchy of control approach to evaluation of interventions one needs to consider the effectiveness of each. This is hard in the care home setting as they have been risk adverse in terms of transmission and so interventions have been applied without formal evaluation in mind.

As shown in Figure 3 limiting ingress is most effective as there can be no outbreak without entry. Societal measures external to care home will reduce prevalence and so lower chance of disease ingress, but the link between care homes and community cannot be fully broken since staff live in the community. Similarly vaccination of staff reduces prevalence in staff and lowers chance of ingress. Testing staff and visitors then provides an early warning and limits ingress. Arguably testing as part of a screening programme is essentially a mitigation that has a significant 'failure point' when community prevalence rises and/or new VOCs gain ingress that have more effective transmission dynamics. Once in the home, interventions such as IPC measures, PPE use, isolation, cohorting, and social distancing when possible limit contact and so reduce the inherent transmission potential of infectious cases. Testing to detect outbreaks and monitor effectiveness will be necessary. Care homes with outbreaks will require specific operational advice. Vaccination of residents and staff also acts to reduce transmission potential.





Adherence to IPC	 Among 360 facilities in Massachusetts (US), higher scores on weekly IPC audits were associated with lower infection rates (in particular: cohorting and PPE). [1] Among 24 facilities in Georgia (US), those adhering to IPC protocols had lowest prevalence (in particular: social distancing measures and PPE). [2]
Preventing transmission from staff to residents	 France: better outcomes (cases & deaths) in 17 nursing homes where staff voluntarily confined themselves to the home for at least 7 days. [3] UK: better outcomes (cases & outbreaks) in care homes where staff were cohorted with infected or uninfected residents [4]; higher risk of infection in those working across several homes. [5]
Testing approaches	 Several studies report on large proportions of asymptomatic residents or staff. Universal testing may be associated with better outcomes. [6-9] Resource implications during periods of low community prevalence? [10]
Outbreak responses	 Multifaceted outbreak responses typically included testing, cohorting and isolation, visitor policies, staff cohorting. Multidisciplinary strike teams were deployed to control outbreaks. These are case reports: empirical evidence on these responses is difficult to gauge.

Figure 4: Overview of evidence on preventing and controlling infection

LSE are running the COVID recovery project (Social Care COVID Recovery & Resilience: Learning lessons from international responses to the COVID-19 pandemic in long-term care systems) which aims to learn from scientific evidence and from relevant international context, to inform policies to improve the resilience of the English social care sector, prepare for ongoing and future COVID-19 outbreaks and future pandemics and shocks, and support recovery of the sector. This has generated the pragmatic literature search summarised in the graphic above¹⁷. (Figure 4).

10.1001/jamanetworkopen.2020.17533.

¹⁷ References from table 4 (full review found here, <u>https://ltccovid.org/2021/05/19/preprint-what-long-term-care-interventions-and-policy-measures-have-been-studied-during-the-covid-19-pandemic-findings-from-a-rapid-mapping-review-of-the-scientific-evidence-published-during-2020/):</u>

^[1] Lipsitz, L. A. *et al.* (2020) 'Stemming the Tide of COVID-19 Infections in Massachusetts Nursing Homes.', *Journal of the American Geriatrics Society*. doi: 10.1111/jgs.16832.

^[2] Telford, C. T. *et al.* (2020) 'COVID -19 Infection Prevention and Control Adherence in Long-term Care Facilities, Atlanta, Georgia', *Journal of the American Geriatrics Society*. doi: 10.1111/jgs.17001.

^[3] Belmin, J. *et al.* (2020) 'Coronavirus Disease 2019 Outcomes in French Nursing Homes That Implemented Staff Confinement With Residents.', *JAMA network open*, 3(8), pp. e2017533–e2017533. doi:

^[4] Shallcross, L. *et al.* (2021) 'Factors associated with SARS-CoV-2 infection and outbreaks in long-term care facilities in England: a national cross-sectional survey', *The Lancet Healthy Longevity*. doi: 10.1016/S2666-7568(20)30065-9.
[5] Ladhani, S. N. *et al.* (2020) 'Increased risk of SARS-CoV-2 infection in staff working across different care homes: enhanced CoVID-19 outbreak investigations in London care Homes.', *The Journal of infection*, 81(4), pp. 621–624. doi: 10.1016/j.jinf.2020.07.027.

^[6] Louie, J. K. *et al.* (2020) 'Early COVID-19 Successes in Skilled Nursing Facilities in San Francisco', *Journal of the American Geriatrics Society*. doi: 10.1111/jgs.16765.

^[7] Ly, T. D. A. *et al.* (2020) 'Pattern of SARS-CoV-2 infection among dependant elderly residents living in long-term care facilities in Marseille, France, March-June 2020.', *International journal of antimicrobial agents*, p. 106219. doi: 10.1016/j.ijantimicag.2020.106219.

^[8] McBee, S. M. *et al.* (2020) 'Notes from the Field: Universal Statewide Laboratory Testing for SARS-CoV-2 in Nursing Homes - West Virginia, April 21-May 8, 2020.', *MMWR. Morbidity and mortality weekly report*. 69(34), pp. 1177–1179. doi: 10.15585/mmwr.mm6934a4.

While not within the scientific expertise of the SCWG, content, style, and volume of guidance to social care providers will influence the quality and extent of implementation. Research during the pandemic revealed confusion and frustration among social care staff at all levels with the complexity and volume of emerging guidance, often published outside working hours (Cassell et al, personal communication, not yet published). Maximising the effectiveness of all remaining mitigations will require the contribution of behavioural scientists to communication strategies to ensure clarity, and maximise acceptability within the context of wider societal messaging where social care staff experience stigmatising reporting

Vaccine

Vaccination is unique amongst the interventions deployed in care homes as it impacts all four identified hazards. It reduces the susceptibility of staff and visitors to reduce ingress rates, it has a reported reduction on transmission, reduces susceptibility of residents to limit outbreaks and reduces severity of infection. Table 4 summarises current evidence of measure of vaccine impact relevant to social care settings, for a more comprehensive overview of effectiveness measures see for example¹⁸.

Vaccination is a highly effective intervention and so ensuring high levels of coverage in staff and residents is critical as previously advised by SCWG¹⁹. As part of this it is essential to ensure relevant vaccine are available and accessible to staff and residents as and when necessary and appropriate support is provided to reduce hesitancy directly.

If effective against transmission then vaccine will reduce attack rates within care homes assuming it is provided sufficiently ahead of the introduction of disease for those vaccinated to be protected. This is a nonlinear process (by having fewer cross-transmissions in a disease generation means there are fewer events likely in later generations but also leaves a population at risk) but was the basis of previous advice that 80% coverage in staff is a minimum sufficient target given 90% coverage in residents.

The impact of vaccination can be shown with a simple illustration. Assume there is a chance of infection during a contact between two people A and B. If person A is vaccinated and protected but person B is not, with vaccine effectiveness against infection of θ , due to reduced susceptibility then the infection chance is reduced by factor (1- θ). If person B is vaccinated but person A is not then the vaccine effect is in transmission reduction with chance ϕ . If both are vaccinated then the infection chance is $\phi(1 - \theta)$. Given $\phi \approx 0.5$ and $\theta \approx 0.8$ in table 4 then the relative risk of transmission drops by factor of 0.1 with both people vaccinated. Vaccination is likely to have a major impact on outbreak size as in a highly vaccinated population this tenfold reduction at each contact will stop long chains of transmission and so reduce outbreak size by more than 10%. This is discussed further in the modelling section below.

Vaccine modifies disease progression and so reduces severity at individual levels. Figure 6 shows the case fatality ratio over time. Estimates from wave 1 are unreliable as access to testing was not universal or systematic. Then in summer the estimate is low due to regular widespread testing

^[9] Sanchez, G. V *et al.* (2020) 'Initial and Repeated Point Prevalence Surveys to Inform SARS-CoV-2 Infection Prevention in 26 Skilled Nursing Facilities - Detroit, Michigan, March-May 2020.', *MMWR. Morbidity and mortality weekly report.* 69(27), pp. 882–886. doi: 10.15585/mmwr.mm6927e1.

 ^[10] Ladhani, S. N. *et al.* (2020) 'Regular mass screening for SARS-CoV-2 infection in care homes already affected by COVID-19 outbreaks: Implications of false positive test results.', *The Journal of infection*, p. 4840. doi: 10.1016/j.jinf.2020.09.008.
 ¹⁸ Efficacy of Covid 19 Vaccines Table – 19th May, 2021,

¹⁹ SCWG Consensus note: Estimating the minimum level of vaccine coverage in care home settings

detecting residual infection (PCR can detection virus up to 90 days post infection). The estimated case fatality ratio then stabilises in autumn to about 20%, increasing slightly in December to 25% (perhaps linked to Kent variant becoming dominant). Since January the case fatality ratio has reduced to about 12% (halved at central estimate) but with greater variation due to reduced overall number of deaths at this time. This may be due to the impact of single dose vaccine (delivered late December to mid-February with protective effect expected 3 weeks after dose received). We cannot rule out an impact of reducing prevalence due to false positives affecting the denominator in calculation. The impact of current second dose regime will be monitored moving forwards. The case fatality ratios may have been affected by frailer residents dying in earlier waves.



Figure 6: Estimated case fatality ratio over time from care home settings

	Vaccine effectiveness				
Outcome	Pfizer-BioNTec	h	Oxford-AstraZ	eneca	
	1 dose	2 doses	1 dose	2 doses	
Symptomatic disease	55-70%	85-90%	55-70%	65-90%	
Hospitalisation	75-85%	90-95%	75-85%	No data	
Mortality	75-80%	95-99%	75-80%	No data	
Infection	55-70%	70-90%	60-70%	No data	
Transmission (secondary cases)*	45-50%	No data	35-50%	No data	

Table 4:Overview o	of studies	of vaccine	effectiveness
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High	Evidence from multiple studies which is consistent
Confidence	and comprehensive
Medium Confidence	Evidence is emerging from a limited number of studies or with a moderately level of uncertainty
Low	Little evidence is available at present and results
Confidence	are inconclusive

Table 4 shows PHE analysis of the efficacy of the two main vaccines²⁰. It shows the vaccines are highly effective, particularly after the second dose. The reported mortality reduction of 95% may seem at variance with observed case fatality ratio in Figure 6 showing around 50% reduction. This is because the tabulated value is protective effect against mortality (including the protection effect against infection) whilst the figure shows the case fatality ratio (so is conditional on a person being infected) and at present the vaccine protective effects are dominated by single doses, the current second dose campaign is near completion of delivery at the time of writing this report but will be a few weeks away from full protection being achieved.

There is no certainty that a vaccinated individual will be protected against variants of concern as they emerge and so it is absolutely critical to maintain surveillance and detection schemes and have agile responses (with fast scale up) in place to support worsening epidemiological situations in care homes.

The Vivaldi study is critical evidence as it is specific to care homes. At 35-48 days post dose 1 they estimated 68% for AZ and 65% Pfizer. At 28-34 days post dose 1 they estimated 67% for AZ and 53% Pfizer with wide confidence intervals. Mean PCR cycle threshold values were higher, implying lower infectivity, for infections \geq 28 days post-vaccination compared with those prior to vaccination (31-3 vs 26-6, p<0.001).²¹

Putting effectiveness of <100% in context, there have been reports of breakthrough infections leading to outbreaks in care homes. There were reports from Germany, Northern Ireland, and the US of substantial outbreaks (attack rates between 18% and 34% of all residents in those homes) despite the vast majority of residents having received their first dose. Breakthrough infections have also been documented in fully vaccinated residents (i.e., infection occurred more than two weeks after administration of the second dose)²², ²³, ²⁴, ²⁵, ²⁶, ²⁷. Thus continued monitoring, testing and targeted interventions are necessary moving forward whilst evidence is further evaluated.

20

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/992741/ Vaccine_surveillance_report_-_week_23.pdf

²¹ <u>https://www.medrxiv.org/content/10.1101/2021.03.26.21254391v1</u>

²² Smith S., Salcher-Konrad M. and Comas-Herrera A. (2021) *COVID-19 outbreaks during or shortly after vaccination of care home residents: summary of three studies from the US and Germany*. LTCcovid.org, International Long-Term Care Policy Network, CPEC-LSE, 4th May 2021.

²³ Britton A, Slifka KMJ, Edens C, *et al.* Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020-February 2021. *MMWR Recomm Reports* 2021; **70**: 396–401

²⁴ Cavanaugh AM, Fortier S, Lewis P, *et al.* COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program - Kentucky, March 2021. *MMWR Morb Mortal Wkly Rep* 2021; **70**: 639–43.

²⁵ Teran RA, Walblay KA, Shane EL, *et al.* Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021. *MMWR Morb Mortal Wkly Rep* 2021; **70**: 632–8.

²⁶ Westhölter D, Taube C. SARS-CoV-2 outbreak in a long-term care facility after vaccination with BNT162b2. *Clin Infect Dis* 2021; : ciab299.

²⁷ McConaghy M, Sartaj M, Conway BR, Aldeyab MA. An assessment of the impact of the vaccination program on coronavirus disease 2019 (COVID-19) outbreaks in care homes in Northern Ireland-A pilot study. *Infect Control Hosp Epidemiol* 2021; : 1–2.

Vaccine coverage rates in staff may be low for a complex range of reasons based on supply and demand factors. These are reviewed in a recent report from CPEC²⁸ and policies to improve coverage need to consider the complex mix of drivers.

Prior Exposure to Covid

There have been various studies that have looked at estimating the impact of prior exposure. This is likely to have had a significant impact on care home mortality in wave two. One study suggested that prior immunity in care home residents gives 85% protection for up to 10 months.²⁹

Another study from Vivaldi found that a single dose of vaccine had little additional impact, which in turn suggests that prior exposure offers strong protection in itself. Prior exposure has also been reported as protective for healthcare staff.³⁰ Small-scale studies of vaccine immune response in care home residents consistently show higher antibody levels in residents with prior infections compared to those without prior infection ³¹. After the first dose, immune response may be insufficient for approximately half of residents who did not have a prior infection ³², ³³, ³⁴.

This is important to measure as it enables the overall outcome of any interventions to be separated out from the effects of natural immunity. For instance, although a much smaller percentage of the overall number of Covid deaths occurred amongst care home residents than in the community in wave two, it wouldn't be fair to conclude that this was due to the impact of the measures that have been put in place alone. Levels of natural immunity in the most vulnerable groups in the community is more likely to have stayed relatively static, in comparison to the care home population, where it would be higher due to residents having been exposed to Covid in the care homes that had outbreaks in the first wave.

Estimating the impact of vaccination (after attainment of high uptake of two doses) as a solo effective intervention on the care home population is challenging because of the fact that we haven't yet seen another wave, where care homes have been subject to long periods of exposure to community infection. Imminent threats may also be of a different nature, where increasing prevalence amongst unvaccinated younger people and more transmissible or severe VOCs may present particular challenges. Therefore monitoring the impact of societal relaxations in step 3 and 4 on high risk social care settings will be important.

 ²⁸ International evidence briefing: mandatory Covid-19 vaccination of staff deployed in social care settings
 ²⁹ https://www.gov.uk/government/publications/vivaldi-2-coronavirus-covid-19-reinfections-in-care-homes-study-report/vivaldi-2-covid-19-reinfection-in-care-homes-study-report
 ³⁰ https://www.medrxiv.org/content/10.1101/2021.01.13.21249642v1

³¹ Blain H, Tuaillon E, Gamon L, *et al.* Spike Antibody Levels of Nursing Home Residents With or Without Prior COVID-19 3 Weeks After a Single BNT162b2 Vaccine Dose. *Jama* 2021; published online April 15. DOI:10.1001/jama.2021.6042.

³² Van Praet JT, Vandecasteele S, De Roo A, De Vriese AS, Reynders M. Humoral and cellular immunogenicity of the BNT162b2 mRNA Covid-19 Vaccine in nursing home residents. *Clin Infect Dis an Off Publ Infect Dis Soc Am* 2021; published online April 7. DOI:10.1093/cid/ciab300.

³³ Brockman MA, Mwimanzi F, Sang Y, *et al.* Weak humoral immune reactivity among residents of long-term care facilities following one dose of the BNT162b2 mRNA COVID-19 vaccine. *medRxiv Prepr Serv Heal Sci* 2021. DOI:10.1101/2021.03.17.21253773.

³⁴ Canaday DH, Carias L, Oyebanji O, *et al.* Reduced BNT162b2 mRNA vaccine response in SARS-CoV-2-naive nursing home residents. *medRxiv* 2021; : 2021.03.19.21253920.

One indication of the potential future impact of another wave can be seen by examining the Covid mortality patterns observed in care homes that approached the second wave with prior exposure to Covid. The Vivaldi study cited above indicated that previous infection will have given residents a broadly comparable degree of protection to the anticipated effect of second dose of the vaccine.

The graphs below (Figures 7-9) show weekly deaths in three different cohorts:

- A) Homes that reported deaths in wave 1.
- B) Homes that reported deaths in wave 2
- C) Homes that didn't report any Covid deaths.

Figure 7 demonstrates that the impact of the second wave on care homes that had previously reported Covid was possibly more akin to previous winter peaks, albeit slightly higher. It should be taken into account that new residents will have entered the homes with higher levels of susceptibility, plus not all residents would have been exposed to Covid. It is anticipated that care homes will achieve much higher levels of vaccination in staff and residents than the degree of prior exposure that they had approaching wave 2. Therefore, it may be reasonable to assume that the impact of any future wave, if IPC processes are kept in place and no vaccine- resistant variants emerge, will be the same as the impact of flu in previous years.

Further work should take place to estimate the level of prior immunity that care home staff and residents had in wave 2. This could be possible by examining linked data. Further evidence on the extent of prior exposure could be found by looking at the number of positive results in the staff population over the second wave, comparing those who had worked in care homes with prior outbreaks / deaths to those without.



Figure 7: Weekly deaths in homes that reported deaths in wave 1.

The cohort of homes that had reported deaths for the first time in wave two showed a marked increase.



Figure 8: Weekly deaths in homes that reported deaths in wave 2



A third cohort shows a relatively flat level of mortality in the care homes that hadn't reported any Covid deaths.

Figure 9 Weekly deaths in homes that didn't report any Covid deaths

Lockdowns and Societal Measures outside of residential care home

Figure 5 (top panel) shows the daily *confirmed* COVID-19 death notifications in care home residents from CQC (red points) with a generalised additive model fitted to the data (with a spline fitted over time and additional fixed effect explanatory variable of day of week, which allows for reduced reporting at weekends and increase early in working week to compensate for this reduction).

The bottom panel then shows the derivative of the spline to estimate the instantaneous growth rate (further explanation can be found in Overton, Stage et al, 2020³⁵]). When positive the number of deaths are growing, when negative deaths are decreasing and when the growth rate is crossing zero the mortality has reached a minimum or maximum. Confidence intervals derived from the additive model allows a degree of confidence in whether data is currently plateauing. Grey boxes on this plot show periods of national lockdown and light pink period of first vaccine dose delivery and darker pink the second phase of vaccine delivery in care home population.

Whilst a complex operation with many drivers including other interventions, it is noteworthy that during periods of lockdown the growth rate of mortality starts to decrease with decay a few weeks after start of lockdown. This lag is expected as the generation time is about 1 week and following infection it takes people about 10 days to die and then a couple of days delay of that death being notified to CQC, so 3 weeks is reasonable for a response to be observable. Without lockdowns in place the growth rate starts to increase. It is noteworthy that the second lockdown in November was fairly short and so was insufficient to actually lead to decrease in growth rate (so deaths themselves only plateaued). Also complicating this period (December 2020) the Kent variant started to dominate with potentially higher case fatality ratio (increase in CFR during January 2021, see figure 6 below).

Figure 5 show the deaths in England as a whole and the growth rate inferred is then a national composite. In January the mortality in southern regions was growing faster than in northern regions. Indeed there is a noticeable north-south difference with Northern regions reporting most of the deaths in September to November and Southern regions reporting most of the deaths in December and January (for example, Yorkshire and Humber and the North East had almost no increase in mortality over the new year period). However, periods of decay are more synchronised and with only lockdown in spring 2020 the peak decay rate observed was 0.05 (a 2 week halving time) whilst in January with lockdown AND first dose vaccine effect the peak decay rate was 0.07 (a 10 day halving time). This suggests that the additive value of vaccine increases effect of lockdown. Actual causality is challenging due to behavioural changes.

³⁵ <u>https://doi.org/10.1016/j.idm.2020.06.008</u>



Plateauing recent trend, may be decreasing Projected new deaths in next 14 days: 43 (10,137) Projected new deaths in next 2 weeks from regional models:50(11,271)



Figure 5: Daily mortality notified to CQC up to 10th May 2021 from residential and nursing care home settings (red dots, top plot) and GAM model fit (solid line, top plot). Bottom panel shows the derivative of the spline arising from GAM as a measure of the instantaneous growth rate. Grey lockdown periods: Pink 1st and 2nd vaccination roll out.

Testing strategies.

Purpose of Testing and Implications for Deployment

The purpose of testing is critical to define within the policy framework. The purpose of testing to date in high risk adult social care settings, such as care homes, has essentially been to provide a practicable and effective screening programming to rapidly identify and control ingress of infection and hence reduce mortality and morbidity. The effectiveness of the UK covid-19 vaccination programme and the decrease in community prevalence now allows a switch to the use of testing as a surveillance tool, especially if coupled with sufficient capability and capacity for 'real time' phylogenectic epidemiology to monitor the impact of variants of concern on the state of protection of residents and staff. The advent of VOCs in a locality may mean switching back and forth to screening strategies again with different testing frequencies and modalities. Investigation of a

reactive approach where testing policy moves from national testing to local geographical areas including more high frequency testing should the situation demand. It is important to be proportionate – so key questions are about what and why should we continue the measures and needs to consider all interventions not just testing strategy. It may be that other interventions are more effective in care home settings for equivalent cost. But should metrics in the community be increasing, the ability to ramp measures back up at pace is critical.

This gives rise to questions of the minimum level of testing in the future for other infectious diseases, what should be the new normal in social care settings? Addressing such questions will involve public engagement and policy decisions.

Using Testing Data for Surveillance

The system is currently contingent on testing to understand case numbers. If testing is reduced there is a risk of central government being blind to the epidemiological reality until too late. Further work is needed to process genomic evidence to assess transmission building on the PHE Easter studies³⁶. These studies and other investigations within care homes give an opportunity to study transmission and control, as well as detection of variants with genomic analysis. Such research should be prioritised and setting up new prospective studies is important to characterise transmission networks (as has been done in prisons). As case numbers are low this may be a good opportunity for Test and Trace to investigate transmission episodes in detail.

Challenges around sampling in care home settings

The current approach to testing (through LFT and PCR) involves taking nasopharyngeal swabs which can be uncomfortable, particularly for frail care home residents, but also for staff. Saliva testing is a less invasive means of sampling³⁷, though trials were in children³⁸ and care home residents may struggle to provide sufficient sample. Point of care technology may offer a 12 minute test which may have advantages over home LFD, but this remains to be demonstrated.

Understanding Outbreaks

At present outbreaks are effectively a series of natural experiments and refined data on the contextual information in the homes at time of outbreak and location of cases within homes would be useful. While reports of outbreaks have been widely published throughout the first year of the pandemic, the multifaceted nature of responses meant that the effectiveness of specific components (typically including testing, cohorting and isolation of residents, visitor policies, staff cohorting, and in some cases deployment of public health strike teams) remains unclear³⁹. Thus better data about outbreaks is required to contrast different provider approaches and community infection rates. Post vaccination less severe forms of infection should reduce symptomatic presentation and mortality. However, new members of staff will join the care home workforce due to historically low retention of staff in the social care sector and represent an emerging risk if they are not vaccinated and well trained in IPC procedures etc.

Agility of interventions to respond to the changing pandemic landscape and adherence to specific interventions is critical. If testing is reduced it is essential to ensure detection of variants is possible

³⁶ Ladhani et al, <u>High prevalence of SARS-CoV-2 antibodies in care homes affected by COVID-19; prospective</u> <u>cohort study, England | medRxiv</u>

³⁷ <u>New saliva test for coronavirus piloted in Southampton - GOV.UK (www.gov.uk)</u> 38

https://eprints.soton.ac.uk/445622/1/Evaluation_of_the_expanded_Southampton_pilot_study_Phase_2_for_ use_of_saliva_based_lamp_testing_in_asymptomatic_populations_eprints.pdf

³⁹ <u>https://ltccovid.org/2021/05/19/preprint-what-long-term-care-interventions-and-policy-measures-have-been-studied-during-the-covid-19-pandemic-findings-from-a-rapid-mapping-review-of-the-scientific-evidence-published-during-2020/</u>

and that testing can be ramped back up at pace locally, regionally or nationally to monitor care settings. Quantifying vaccine effectiveness in this population and in particular against the different variants circulating will be important to determine risk. This, coupled with knowing which variants are circulating in as close as possible to real time (surveillance) and if possible some forecast of dominance in the general population should give a clearer picture of risk. It is also important to investigate the behavioural effect that vaccination will have on interventions in place.

Testing infectiousness

Testing encompasses a range of activities with different goals that may become conflated. *Since LFDs were introduced to care homes, over 24,000 LFD positives have been found in care homes using this method, enabling action to be taken quickly to stop the spread by isolating these individuals⁴⁰. Further analysis by DHSC analysts is being conducted. LFDs help to identify individuals quickly with high viral load and who are likely currently infectious, meaning they are able to transmit the virus to others. LFDs can help to give an earlier warning of infection in the care home than a PCR test carried out at the same time, as the time to test return is faster for LFD than PCR, (82% of PCR positive cases were detected by an LFD test with result on average 40 hours earlier) helping to contain the infection as quickly as possible. US study (Georgia): Infection prevalence and 4-week incidence was statistically significantly lower in 13 long-term care facilities (LTCFs) that used preventative (routine) testing compared to 15 LTCFs that employed reactive testing only after an index case was identified⁴¹. Access to testing by LFD is easier so tests can be conducted more often but it is possible that regular self-administered home testing may affect adherence with the regime. Specificity of LFD testing is relatively high 99.68% (a false-positive rate of 0.32%)⁴² but false positives do risk undermining confidence in strategy and effective communication is needed to mitigate this⁴³.*

During the Liverpool mass testing pilot, 407 care home staff members were tested (out of 498 total staff) as part of the protocol, 1638 LFD tests were performed, of which 828 had matched PCR tests⁴⁴. All five positive LFD test results were subsequently confirmed positive by PCR. No false negative LFD test results were identified. The proportion of staff achieving a minimum of 50% (0-80.0%) and 75% (0-36.7%) protocol adherence varied considerably between homes. The Liverpool study found that human factors not technology were the main barrier to successful implementation of enhanced testing of staff, specifically staff workload, morale and conflicting communications over protocols for testing in care homes. For visitor testing, staff workload was a key barrier as the additional infection prevention and control measures consume 2-3 hours of person time for each visit. The report of the trial states "Further work is needed to evaluate serial LFT visiting protocols in the post-vaccination context, including consideration of the resources care homes need to support visits while Covid safety measures are still needed.".

⁴² <u>https://www.gov.uk/government/publications/evidence-on-the-accuracy-of-lateral-flow-device-testing/evidence-summary-for-lateral-flow-devices-lfd-in-relation-to-care-homes</u>

⁴⁰ Weekly statistics for NHS Test and Trace (England): 27 May to 2 June 2021 - GOV.UK (www.gov.uk) (Tests conducted: 28 May 2020 to 2 June 2021)

⁴¹ Telford CT, Onwubiko U, Holland DP, et al. Preventing COVID-19 Outbreaks in Long-Term Care Facilities Through Preemptive Testing of Residents and Staff Members - Fulton County, Georgia, March-May 2020. MMWR Morb Mortal Wkly Rep. 2020;69(37):1296-1299. doi:10.15585/mmwr.mm6937a4

⁴³ <u>SARS-CoV-2 antigen testing: weighing the false positives against the costs of failing to control transmission -</u> <u>The Lancet Respiratory Medicine</u>

⁴⁴ Liverpool Covid-SMART Community Testing Pilot. Evaluation Report I 21 May 2020 (Draft 17)

Two additional testing technologies have now been validated in the care home setting^{45 46}, Horiba POCKIT Point-of-Care PCR testing, and the LumiraDx automated antigen assay. An evaluation of SAMBA-II Point-of-Care PCR is near completion. These mean that an array of technologies, with differing sensitivities, specificities and costs are now available for deployment in the sector. Process analysis conducted as part of the CONDOR platform to evaluate these technologies suggested that they could be integrated into workflow to support batch-testing (POCKIT/SAMBA-II) or threshold testing of staff and/or visitors (LumiraDx). There are concerns raised by the Liverpool Care Home LFD testing pilot that staff adherence to LFD testing at home may be suboptimal⁴⁷. Thus introducing some of these alternative technologies, which are more quickly completed and can take place at the start of shift, may overcome such staff adherence problems.

Particularly at low prevalence in community removing LFD and PCR testing of residents could be considered but sufficiently regular screening of staff should be maintained to survey for variants of concern (different tests have different costs, and sensitivity and specificity rates – see Table 3). Once cases (and the number of cases will have to be a clinical judgement) are detected in a care home the testing strategy should be re-escalated as per the contemporaneous outbreak protocols. The turnaround time of a VOC sample is about 7 days which is similar to the generation time of COVID-19 and so cross-transmission during wait for VOC sampling is likely and a presumptive or risk based approach should be considered for escalation.

The costs of PCR testing is higher that LFD but evaluation of point of care PCR testing and improved adherence from being in at a care home rather than individuals home should be considered. Costs include ensuring that staff who need to attend work at another location for the purposes of being tested for COVID-19 are paid their usual wages to do so, any costs associated with reaching a testing facility, and any reasonable administrative costs associated with organising and recording outcomes of COVID-19 tests.

Testing technology	Sensitivity	Specificity	Indicative cost/test*
Horiba POCKIT	96.4%	97.7%	£45
Samba-II ⁴⁸	98.8%	100%	£45
LumiraDx ⁴⁹	92.3%	98.7%	£5
Innova LFD ⁵⁰	77.8%	95.6%	£5

Table 3: Sensitivity, specificity and costs of different testing technologies.

*Against laboratory based PCR using a CT value of 25, to enable direct comparison with the Porton Down evaluation of the Innova LFD

**DHSC procurement have secured preferential rates for some of these technologies which may not be reflected in the price stated here

⁴⁷ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3822257

⁴⁵ <u>https://www.medrxiv.org/content/10.1101/2021.04.22.21255948v2</u>

⁴⁶ Micocci, M., Gordon, A. L., Seo, M. K et al. (2021). Is Point-of-Care testing feasible and safe in care homes in England? An exploratory usability and accuracy evaluation of a Point-of-Care Polymerase Chain Reaction test for SARS-COV-2. *Age and Ageing*. <u>https://doi.org/10.1093/ageing/afab072</u>

⁴⁸<u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/941767/technical-validation-report-SAMBA-II.pdf</u>

⁴⁹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/970905/TVG_Repor_ t_LumiraDx-v2.pdf

⁵⁰<u>https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University</u> %20of%20Oxford_final.pdf

Testing infection and for variants

Some people may be infected but unable to transmit the virus to others, for example people who have lower amounts of the virus in their body because they may be at the start of their infection or are recovering from infection. Studies to evaluate the link between the frailty of the susceptible individual and infecting dose are welcomed, ie it is uncertain if borderline infectious people in care home settings may transmit because of lower infectious dose. PCR tests detect almost all infected people, including some that are unable to transmit the virus to others. LFTs will not identify everyone who is infected but will detect people who are able to transmit the virus to others^{51,52}. PCR testing can detect the variant causing the infection which may be critical to assess vaccine escape potential. When LFTs and PCR are used in combination, LFTs rapidly identify some individuals who are highly infectious, and PCR tests find those who were not identified by LFT and provide information about the variant. Using the LFTs midweek and on the same day as the PCR (so per week 2 LFTs and 1 PCR test) is the best way to identify people who transmit the virus given a logistical constraint of 3 tests per week per staff member though this has not been formally evaluated (and a 4th test may be required for some if the midweek LFD was positive). The LFTs help to identify some people who have become infectious since the last PCR was taken and therefore taking one LFT on the same day as the PCR and one midweek is better than spreading the three tests out evenly through the week.

We are assuming that symptomatic individuals will be PCR tested for some time to come. Where this and further testing impacts on staff working ability suitable support to ensure avoidance of presenteeism (and adherence to testing in general) is critical.

Continuing regular PCR testing will enable samples to be collected for genome sequencing provided low CT counts and timely and effective dispatch for processing.. This will allow for the identification of variants which are more transmissible, cause more serious disease or where vaccines are ineffective. As there are high levels of vaccine coverage within care homes, mutations causing vaccine escape will be most evident within this cohort compared to the general population. All variants of concern so far have been identified by sequencing prospective surveillance samples, combined with retrospective lineage and mutation analysis. Rapid turn-around of sequencing data and analysis will enable trends to be identified earlier. When mutations are identified as being associated with concerning changes, such as E484K or N501Y, PCR assays can be employed to further reduce the turn-around time, but are not a replacement for genome sequencing.

Genomic Epidemiology

Genome sequences from care homes should be routinely analysed to understand the transmission characteristics within the setting, and to understand the routes of ingress. It also allows for different clusters to be linked together, however a lack of metadata, or incomplete metadata, on the samples can hinder this analysis. Whilst some of this analysis can be undertaken programmatically to look for trends and patterns, ultimately it requires an epidemiologist to pull together the whole picture to understand the dynamics of an outbreak, and this can be a slow and time consuming task. It has been difficult to use very fine-scaled phylogenetic information because the rate of mutation is not high and/or transmission occurs early in infection.

⁵¹ https://www.medrxiv.org/content/10.1101/2021.01.13.21249563v1.full

⁵² <u>https://www.bmj.com/content/372/bmj.n287</u>

Alternative approaches to surveillance

Environmental surveillance, for example monitoring care home effluent (wastewater), surfaces or room air for presence of SARS-CoV-2 genetic material (RNA), could in theory supplement case-based surveillance to detect asymptomatic infections and provide early warning of outbreaks.

Challenges to implementing 'near source tracking' (NST) in care home effluent include a lack of standardised sampling frameworks and laboratory protocols, difficulty defining the source population (which may include visitors and exclude residents with incontinence), and degradation of viral RNA within the environment.⁵³ These factors may limit the extent to which the data can be interpreted and acted upon. A pilot study of surface swabbing during three care home outbreaks of COVID-19 found the proportion of sample sites contaminated with SARS-CoV-2 was highest in rooms occupied by infected residents and that elevated surfaces, particularly those that accumulated dust, were more likely to test positive for SARS-CoV-2 than common touch-points.⁵⁴

More work is needed to assess the feasibility and utility of environmental surveillance in care homes.

Utility of Resident Testing

Monthly resident testing was found in previous modelling to have minimal benefit in reducing morbidity or detecting outbreaks in all modelling given testing of staff is in place. It was recommended in January 2021 as the vaccine campaign started, but has been advocated to enable further insights into vaccine effectiveness. Vaccine effectiveness is better understood now and so monthly screening of residents may serve limited purpose. Before suspension a full review of data on trigger events is critical to quantify the benefit of resident screening (but, should variants be detected, vaccine effectiveness against the specific variant would need to be measured and so studies that can deliver timely data are essential).

⁵³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940919/ S0908 Wastewater C19 monitoring SAGE.pdf

⁵⁴ Kwiatkowska RM, Yaxley N, Moore G et al. Environmental screening for SARS-CoV-2 in long term care facilities: lessons from a pilot study. In submission: Wellcome Open.

Outbreak mitigation

Interventions to limit or modify contact rates such as cohorting and financial support have not been systematically evaluated. General points arising from a recent clinical summit (09/2020) include the challenges in evaluating measures is that we are in effect analysing policies – which will potentially be interpreted in different ways, have different levels of adherence and be applied in a multitude of settings. Although data collections have been set up to track IPC activity, this may tell us more about what was done as opposed to how it was done. Further fieldwork may be necessary to examine how some of the IPC policies were carried out.

Cohorting of staff and residents

Cohorting acts to reduce contact so dedicated staff are assigned to specific residents (staff cohorting) or residents assigned to specific areas in care home (resident cohorting). The physical layout of homes likely prohibits widespread uptake of resident cohorting (older buildings less amenable to separation) and that moving frail residents is itself harmful to them.

Staff cohorting logically is both easier to achieve and should act to reduce contact between cases (but increase chance of infection within cohorts due to repeated contacts) but has limited investigation.

Financial support

The Vivaldi study surveyed 5,126 care homes⁵⁵ and found better outcomes in care homes that paid staff statutory sick pay compared with those that did not:

- Less likely for residents to have infection (adjusted OR 0.80 [95% CI 0.75–0.86], p<0.0001)
- Less likely for staff to get infected (aOR 0.70 [0.65–0.77], p<0.0001)
- Less likely to have large outbreaks (aOR 0.59 [0.38–0.93], p=0.024).

Steps to limit the use of public transport by members of staff

The implementation will be sensitive to the outcome where if staff buddy up with colleagues to share non-public transport they are effectively spending more time together. So smaller vehicles are likely less risk than minibuses and such vehicles.

This was done in Singapore, where they also offered accommodation to staff whose commute or living accommodation put them at increased risk of infection (but that's because a high proportion of staff are migrants living in shared dormitories)

Providing accommodation for staff who proactively choose to stay separate from their families in order to limit social interaction outside work

A French retrospective cohort study found that there were significantly fewer infections and severe outcomes (including symptomatic COVID and death) in 17 nursing homes where staff voluntarily self-confined themselves to the home compared to 9,513 other nursing homes throughout France⁵⁶.

This seems a measure to deploy in very acute situations and requiring adequate compensation and support for the staff involved, it has been done a lot in Asian countries and some countries in the

⁵⁵ Shallcross L, Burke D, Abbott O, et al. Factors associated with SARS-CoV-2 infection and outbreaks in longterm care facilities in England: a national cross-sectional survey. *Lancet Heal Longev*. 2021;0(0). doi:10.1016/S2666-7568(20)30065-9

⁵⁶ Belmin J, Um-Din N, Donadio C, et al. Coronavirus Disease 2019 Outcomes in French Nursing Homes That Implemented Staff Confinement With Residents. *JAMA Netw open*. 2020;3(8):e2017533-e2017533. doi:10.1001/jamanetworkopen.2020.17533dinin

Middle East but these countries tend to rely on migrant workers who are away from home anyway. This seems an unlikely measure for a situation of low levels of community transmission and high vaccination rates, but could be considered in situations where vaccination rates are very low and community transmission is high

Reducing cross-deployment

English study of 5,126 care homes found that residents and staff were significantly less likely to get infected, and care homes were significantly less likely to experience an outbreak in care homes that used agency staff compared with those that did not⁵⁷. In care homes that used agency staff compared with those that did not:

- More likely for residents to have infection (adjusted OR 1.65 [1.56–1.74], p<0.0001)
- More likely for staff to get infected (aOR 1.85 [1.72–1.98], p<0.0001)

- More likely to have any outbreak (aOR 2·33 [1·72–3·16], p<0·0001) and large outbreaks (aOR 2·42 [1·67–3·51], p<0·0001).

Resident Isolation

Physical isolation is hard in some homes for some residents. For example it is particularly challenging for residents with dementia. The care home is a person's home and isolation becomes an ethical rather than scientific issue..

Limiting entry to home

Similar to physical isolation to limit contact within home reducing visitors isolates residents whilst is may reduce ingress. In previous analysis the likelihood that disease ingress was caused by visitors given staff numbers was less than 5% ⁵⁸. Distress of limited visitation affects residents and the would be visitors especially if near end of life.

⁵⁷ Shallcross L, Burke D, Abbott O, et al. Factors associated with SARS-CoV-2 infection and outbreaks in longterm care facilities in England: a national cross-sectional survey. Lancet Heal Longev. 2021;0(0). doi:10.1016/S2666-7568(20)30065-9

⁵⁸ Social Care Working Group Consensus statement on family or friend visitor policy into care home settings, SAGE, November 2020.

Transmission mitigation

Ventilation

Spaces in residential homes are often lower occupancy (<20) and occupied for extended periods during the day (>3 hours). Ventilation helps remove aerosols. If ventilation rates are ascribed on a litres per second per person basis and an infectious person is present then the rate of removal will be much lower than in higher occupancy spaces. Consequently, there are benefits to considering higher rates of ventilation per person in lower occupancy spaces – practically this may involve seeking lower carbon dioxide levels in residential home settings than in other settings with higher occupancy levels. Improved airflow reduces viral load inside homes by removing aerosol contamination⁵⁹,⁶⁰. The use of CO2 monitoring may help balance ventilation vs temperature

There is some work, pre-COVID-19, that looked at temperature / humidity and skin conditions in care homes⁶¹ and overall health⁶². There is very little evidence available, particularly on alternatives to increasing ventilation / opening windows and the problems associated with that.

More research is urgently needed on appropriate and economical ventilation in care home settings and perhaps the role of humidity in comfort conditioning.

Effectiveness of PPE in protection against COVID-19 transmission

In September 2020, we performed a rapid literature search to investigate the effectiveness of PPE in reducing the transmission of COVID-19 in unpaid carers, and those delivering care within the same parameters as unpaid carers⁶³. The search did not reveal any direct evidence regarding the use of PPE by unpaid carers, with zero hits related to PPE and unpaid carer search terms, when combined. Thus, we sought to understand the effectiveness of PPE when used by health care workers. Here we present an update of that review. Our rapid literature search (**see below 'Search Strategy'**) revealed that studies reporting on PPE in health care workers are predominantly based in hospital settings with a focus on nurses and physicians.

PPE Use in Healthcare Workers

Recent evidence on the effectiveness of PPE in health care workers is available in the form of a living rapid review of cross-sectional, cohort, and case series studies. Since our initial review in September 2020, the living review has been updated five times, with the latest update (update 8) published in March 2021 (118 studies reviewed to date)⁶⁴. We searched each update for results of new studies in relation to (a) mask use; (b) full vs. partial use of PPE; (c) frequency/consistency of PPE use; and (d) infection control training and education. The review provides a narrative summary of findings in relation to coronavirus exposure and PPE use and results are consistent across all updates.

Masks

The review reports that 16 studies report consistent and robust evidence for the association between mask use and decreased infection risk (from SARS-CoV-2, SARS-CoV-1, or MERS-CoV infection) in healthcare workers (both high-risk and general departments), with Odd Ratios (ORs)

Hygiene and Environmental Health, 221(3), pp. 376–390. doi: 10.1016/j.ijheh.2018.01.015

⁵⁹ <u>https://jamanetwork.com/journals/jama/fullarticle/2779062</u>

⁶⁰ <u>https://www.who.int/publications/i/item/9789240021280</u>

 ⁶¹ Jin, Y. et al. (2020) 'The effect of indoor thermal and humidity condition on the oldest-old people's comfort and skin condition in winter', Building and Environment, 174. doi: 10.1016/j.buildenv.2020.106790
 ⁶² Wolkoff, P. (2018) 'Indoor air humidity, air quality, and health – An overview', International Journal of

⁶³ Reported in <u>Social Care Working Group update paper – 23rd September 2020</u> Tabled at SAGE Meeting 59 24th September 2020

⁶⁴ Chou R, Dana T, Buckley DI, Selph S, Fu R, Totten AM. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. *Ann Intern Med*. 2020;173(2):120-136. doi:10.7326/M20-1632

ranging from 0.002 to 464.82. Five studies suggest that N95 respirators were associated with decreased risk compared with surgical masks, with ORs ranging from 0.12 to 1.05. No meta-analysis was conducted, but summary tables can be found in the original review and the update supplementary material at https://doi.org/10.7326/M20-1632. This evidence extrapolates from results of studies on non-SARS-CoV-2 specific data, and the appropriateness is unknown given the uncertainty over the transmission of SARS-CoV-2⁶⁵. These findings are consistent with research reported to SAGE on 10th September 2020⁶⁶ which reveal that N95⁶⁷ mask (penetration by contaminants <0.01%) is better than medical mask (penetration 44%) which is better than general cloth mask (penetration 97%). The latter thus may offer the wearer reassurance, but little or no real protection. A rapid review by PHE (1st October 2020) of factors associated with COVID-19 in care homes and interventions to prevent ingress and transmission identified only weak observational evidence for universal mask wearing in residential care as part of fuller package of interventions and identifies the need for further research on all interventions including PPE and mask use in residential care settings.

Other PPE – gloves, gowns, eye protection.

The living review also reports associations between use of gloves, gowns, eye protection, shoe covers, and decreased risk of transmission. Five studies found that full PPE use (gloves, mask, gown, and eye protection) was associated with decreased risk of infection compared to partial PPE use. Four studies found a dose-response relationship between frequency/consistency of PPE use and reduced risk of infection, with ORs ranging from 1.79 to 8.85. However, because of methodological differences in studies and as no meta-analysis has been conducted it is not possible to draw strong conclusions about this dose-response relationship and its stability over time. The authors did not find any studies on the association between reuse of PPE and risk of infection.

Cochrane review (15th May 2020 as reported in September 2020) on PPE use⁶⁸ with infectious diseases included 24 studies, (22 simulation studies, 14 randomised). The review evaluates which types of full-body PPE, and which donning and doffing methods, have the least risk of contamination, and which training methods increase compliance. Overall, the authors found low- to very low-certainty evidence that covering larger areas of the body results in better protection. Gowns may provide better protection against contamination than aprons. PPE made of breathable material, which is associated with greater user satisfaction, was not demonstrated to be worse than water repellent material. The evidence is limited, based on small sample simulation studies. The review also highlights low-certainty evidence from one SARS-related study and two simulation studies that more active training (video/computer simulation or face-to-face training) in PPE use decreases noncompliance with donning and doffing guidelines to a greater extent than passive training (lectures only). There has been no update on this review as providing core evidence and concludes that aprons and gowns are suitable, but point to pros and cons during donning, use and

⁶⁵ Ramaraj P, Super J, Doyle R, Aylwin C, Hettiaratchy S. Triaging of respiratory protective equipment on the assumed risk of SARS-CoV-2 aerosol exposure in patient-facing healthcare workers delivering secondary care: a rapid review. BMJ open. 2020 Oct 1;10(10):e040321.

⁶⁶ Processing Methods to Facilitate the Re-Use of Personal Protective Equipment (PPE). Paper presented to <u>SAGE Meeting</u> <u>56</u> 10th September 2020

⁶⁷ HSE *Rapid evidence review: Part 1 Equivalence of N95 and FFP2 masks,* concludes there is no material difference between N95 and FFP2 masks and both would provide comparable protection against coronavirus as long as the wearer was face-fit tested. <u>https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-equivalence-aprons-gowns-eye-protection.htm</u> Accessed 20th May 2021.

⁶⁸ Verbeek JH, Rajamaki B, Ijaz S, et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev. 2020;(5). doi:10.1002/14651858.CD011621.pub5

⁶⁹ HSE Rapid evidence review: Part 2 Aprons, Gowns and eye protection. <u>https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-equivalence-aprons-gowns-eye-protection.htm</u> Accessed 20th May 2021.

doffing. HSE also point out the lack of evidence on the effectiveness of goggles or face shields. No evidence is identified that directly relates to residential social care settings.

Training

There was a consistent association across six studies between infection control training and decreased infection risk, with not being trained being associated with a risk increase between 2.4 and 13.6⁷⁰ The review is limited as risk factor studies were retrospective, with the possibility of recall bias regarding use of PPE. None of the studies used an RCT design, some studies did not control for confounders, and those that did were limited in their ability to control for exposure.

PPE in Social Care Settings

A review by Khunti *et al.*⁷¹ (August 2020) highlights that most of the guidance surrounding PPE use focuses on emergency or inpatient care settings and it is often assumed that primary or community care settings (which may include social care) are at low risk in comparison. The reality is likely much more nuanced, as community care may often expose health care workers and those they care for to a high degree of risk through close prolonged contact. A recent US-based study⁷² (March 2021) investigated COVID-19 seropositivity in healthcare personnel in nursing homes and found that nursing home staff in all occupations had elevated seropositivity compared with hospital counterparts. However, the role of PPE use in transmission was unclear. Similarly, the Khunti *et al*⁶ review found little direct evidence for the effectiveness of PPE in primary or community care. However, indirect evidence from single-centre experimental studies supports the appropriate use of PPE in community and social care settings according to PHE⁷³ and WHO⁷⁴ guidelines in order to protect against COVID-19.

Behaviour

Behavioural measures to support proper doffing and donning and general infection control measures should be promoted in tandem with PPE use⁷⁵. Research from healthcare settings emphasises the importance of training staff in correct donning and doffing procedures and safe disposal of PPE after use⁷⁶.

Hand hygiene

Handwashing was also considered in the living rapid review outlined above⁷⁷ and seven studies found that it was associated with decreased risk of SARS-CoV-1 infection. As a key intervention of

⁷² Akinbami LJ, Chan PA, Nga Vuong SS, Lewis D, Sheridan PE, Lukacs SL, Mackey L, Grohskopf LA, Patel A, Petersen LR. Severe Acute Respiratory Syndrome Coronavirus 2 Seropositivity among Healthcare Personnel in Hospitals and Nursing Homes, Rhode Island, USA, July–August 2020. Emerging infectious diseases. 2021 Mar;27(3):823.

 ⁷⁰ Chou R, Dana T, Buckley DI, Selph S, Fu R, Totten AM. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-136. doi:10.7326/M20-1632
 ⁷¹ Khunti K, Adisesh A, Burton C, et al. The efficacy of PPE for COVID-19-type respiratory illnesses in primary and community care staff. Br J Gen Pract. 2020;70(697):413-416. doi:10.3399/bjgp20X710969

 ⁷³ Public Health England. Coronavirus (COVID-19): personal protective equipment (PPE) hub. Updated July 2020. Accessed May 18, 2021. https://www.gov.uk/government/collections/coronavirus-covid-19-personal-protective-equipment-ppe
 ⁷⁴ World Health Organization. *Prevention, identification and management of health worker infection in the context of COVID-19*; Updated October 2020. Accessed May 18, 2021. https://www.who.int/publications/i/item/10665-336265
 ⁷⁵ Greenhalgh T, Chan XHS, Khunti K, et al. *What Is the Efficacy of Standard Face Masks Compared to Respirator Masks in Preventing COVID-Type Respiratory Illnesses in Primary Care Staff?* Centre for Evidence-Based Medicine; 2020. Accessed May 20, 2021. http://arc-em.nihr.ac.uk/resources/what-efficacy-standard-face-masks-compared-respirator-masks-preventing-covid-type

⁷⁶ Verbeek JH, Rajamaki B, Ijaz S, et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev. 2020;(5). doi:10.1002/14651858.CD011621.pub5

⁷⁷ Chou R, Dana T, Buckley DI, Selph S, Fu R, Totten AM. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-136. doi:10.7326/M20-1632

known effectiveness, handwashing recommendations should be applied across the board for all healthcare workers. Hand hygiene guidelines are generally informed by the WHO's "five moments for hand hygiene"⁷⁸ which recommend that healthcare workers clean their hands 1) before touching a patient; 2) before clean/aseptic procedures; 3) after body fluid exposure/risk; 4) after touching a patient; and 5) after touching patient surroundings.

Use of PPE

It is highly likely that correct and comprehensive use of masks, gloves, gowns, eye protection, etc., together with behavioural infection control measures, such as hand washing and physical distancing, will result in a decreased risk of coronavirus transmission. Handwashing is an intervention available in all healthcare settings. However, a major caveat relating to PPE is that these procedures must be properly instigated (including donning and doffing) and consistently followed if they are to be effective. Standard precautions should be taken where risk is low (e.g. handwashing and use of masks). Contact and droplet precautions should be taken for suspected or confirmed cases of COVID-19 (e.g. handwashing, mask, gown, googles, and gloves).

Another potential factor to consider in relation to frail or older people is the risk of falls from long gowns or other ill-fitting PPE, although currently there is no literature reporting on PPE trip hazards. Providing care for people with communication issues relating to deafness or cognitive impairment can provide additional challenges when it comes to PPE use. For people with hearing loss, mask use results in reduced acoustic transmission and prevents lip reading, and may also be uncomfortable for those wearing hearing devices⁷⁹. Furthermore, mask use is not suitable for those with severely compromised respiratory systems⁸⁰ or those who cannot remove or adjust their own masks⁸¹. Many residents will fall into these categories and hence mask use if more often observed amongst staff and visitors rather than residents.

Apps

In May 2020, an app was launched by the NHS to support social care workers during the COVID-19 pandemic⁸². The app provided care workers in England with guidance and learning resources on crucial areas such as infection control, as well as wellbeing toolkits to support staff through the pandemic. The app was closed down on 31st March 2021. The Social Care Institute for Excellence (SCIE) has set up online hygiene training in response to the COVID-19 pandemic for care providers (<u>https://www.scie.org.uk/e-learning/infection-control</u>). An existing evidence-based digital intervention <u>https://germdefence.org/</u> was adapted for the COVID-19 pandmic with recent evidence for change in intentions to improve infection control behaviours⁸³. Whilst germdefence was

⁷⁸ Sax H, Allegranzi B, Uçkay I, Larson E, Boyce J, Pittet D. "My five moments for hand hygiene": a user-centred design approach to understand, train, monitor and report hand hygiene. J Hosp Infect. 2007;67(1):9-21. doi:10.1016/j.jhin.2007.06.004

⁷⁹ Trecca EMC, Gelardi M, Cassano M. COVID-19 and hearing difficulties. Am J Otolaryngol. 2020;41(4):102496. doi:10.1016/j.amjoto.2020.102496

⁸⁰ Kao T-W, Huang K-C, Huang Y-L, Tsai T-J, Hsieh B-S, Wu M-S. The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease. J Formos Med Assoc Taiwan Yi Zhi. 2004;103(8):624-628.

⁸¹ Desai AN, Aronoff DM. Masks and Coronavirus Disease 2019 (COVID-19). JAMA. 2020;323(20):2103. doi:10.1001/jama.2020.6437

⁸² Department of Health and Social Care. Dedicated app for social care workers launched. Published May 2020. Accessed May 18, 2021. <u>https://www.gov.uk/government/news/dedicated-app-for-social-care-workers-launched</u> The app was closed on 31st March 2021 <u>https://workforce.adultsocialcare.uk/join</u>

⁸³ Ainsworth B, Miller S, Denison-Day J, Stuart B, Groot J, Rice C, Bostock J, Hu X, Morton K, Towler L, Moore M, Willcox M, Chadborn T, Gold N, Amlôt R, Little P, Yardley L

Infection Control Behavior at Home During the COVID-19 Pandemic: Observational Study of a

designed for the public it is relevant to social care workers, both in their home lives and their work lives and should be promoted.

Conclusion

Overall this is a complex issue and there is likely to be an intersection between high risk, high exposure and low resource, which needs to be addressed when considering how best to reduce transmission across different health and social care settings. It is highly likely that the use of masks, gloves, gowns and other PPE together with behavioural infection control measures, such as hand washing, will result in a decreased risk of coronavirus transmission in social care. However the major caveat here is that these procedures must be properly instigated (including donning, doffing, and disposal of used PPE) and consistently followed if they are to be effective. There is no direct evidence for the effectiveness of PPE in social care, but we recommend that infection control measures are implemented based on the WHO risk classification. Standard precautions should be taken where risk is low (e.g. handwashing and use of masks). Contact and droplet precautions should be taken for suspected or confirmed cases of COVID-19 (e.g. handwashing, mask, gown, googles, and gloves).

Web-Based Behavioral Intervention (Germ Defence) J Med Internet Res 2021;23(2):e22197 doi: <u>10.2196/22197</u>

Search Strategy

Search for PPE effectiveness in health and social care

(a) Google Scholar keywords/terms.

Combinations of the following keywords/terms were searched:

- 1. personal protective equipment
- 2. PPE
- 3. effectiveness
- 4. health care professionals
- 5. social care workers
- 6. residential care
- 7. community health services
- 8. COVID-19

(b) MEDLINE (Ovid) Search Strategy Flow Chart:



Summary of modelling work to date

Model A

An agent based simulation examined the impact of reducing routine testing of staff for different vaccination coverages of care home residents and staff to determine the threshold of incidence rate in the community at which routine testing of staff can be reduced/lifted for each vaccination coverage scenario. The model is described elsewhere⁸⁴ with the changes that have been made to the model for the subsequent analysis.

Safe lifting of a routine staff testing strategy is when this does not lead to a statistically significant difference in the cumulative numbers of Covid-19 deaths after 90 days. Each scenario was examined at the average per-contact transmission probability of 0.02 (low, most likely, Ro = 4.02 in care homes) and 0.035 (high, Ro = 7.04). The most likely per-contact transmission probability of 0.02 was based on the studies of transmission risk in different settings.^{85 86} This value corresponded to R_o of 4.02 in care homes, in line with the base case R_o of 4.04 used a study of Covid-19 spread in a long-term care facility in France.⁸⁷

When transmission risk per contact was low (0.02) and at least 50% of residents and staff were vaccinated with two doses of the Covid-19 vaccine, reducing the routine testing of staff had a small impact on the cumulative number of infected residents and Covid-19 deaths. With 50% vaccination coverage of residents and staff, the threshold of incidence rate in the community for the twice weekly LFD testing to be safely lifted was 385 weekly cases per 100,000 population. This threshold was higher than the peak incidence rate of the second wave in Scotland (302 weekly cases per 100,000).

This threshold increased as the vaccination coverages went up. When 90% of residents and staff received two doses of the vaccine, lifting the LFD testing was still safe even if the incident rate reached 95 daily case per 100,000 (just below the peak of second wave in England, approximately 100 daily case per 100,000). An increase in the risk of transmission significantly lowered the incidence rate threshold (from reproduction number of 4 to 7). With at least 50% of residents and staff having received two vaccine doses and a low risk of transmission, the incidence rate threshold of 15 daily case per 100,000 allowed both weekly PCR and LFD testing to be safely halted. When transmission risk increased, the impact of removing both weekly PCR and LFD testing upon the outcomes increased. The analysis is likely to overestimate the impact of lifting weekly testing of staff as the actual compliance of care home staff to the LFD testing is lower than our assumption that all staff comply to a full testing regime

Model B

A stochastic compartmental model to simulate the spread of SARS-CoV-2 within an English care home. This model quantified the outbreak risk under the non-pharmaceutical interventons already in place, the role of community prevalence in driving outbreaks, and the relative contribution of all importation

⁸⁴ Evaluating intervention strategies in controlling coronavirus disease 2019 (COVID-19) spread in care homes: <u>An agent-based model - PubMed (nih.gov)</u>

⁸⁵ Sun K, Wang W, Gao L, et al. Transmission heterogeneities, kinetics, and controllability of SARS-CoV-2. *Science*. 2021;371(6526):eabe2424.

⁸⁶ Knock E, Whittles L, Lees J, et al. Report 41: The 2020 SARS-CoV-2 epidemic in England: key epidemiological drivers and impact of interventions

⁸⁷ Smith DRM, Duval A, Pouwels KB, et al. Optimizing COVID-19 surveillance in long-term care facilities: a modelling study. *BMC medicine*. 2020;18(1):386.

routes into the care home. The model also considered the potential impact of additional control measures, namely: increasing staff and resident testing frequency, using lateral flow antigen testing (LFD) tests instead of PCR, enhancing infection prevention and control (IPC), increasing the proportion of residents isolated, shortening the delay to isolation, improving the effectiveness of isolation, restricting visitors and limiting staff to working in one care home. The model suggests that importation of SARS-CoV-2 by staff, from the community, is the main driver of outbreaks, that importation by visitors or from hospitals is rare, and that the past testing strategy (monthly testing of residents and weekly testing of staff by PCR) likely provides negligible benefit in preventing outbreaks. Daily staff testing by LFD was 39% (95% 18-55%) effective in preventing outbreaks at 30 days compared to no testing.

Model C

Figure 10 shows the outcome from a simple 'toy' stochastic model (Model C1) of a care home outbreak with random introduction of disease from outside. The care home has 40 residents and is designed to illustrate effects.

In scenario 4 the community prevalence is 1% and transmission within home governed by an R0=3. In this scenario then the disease is almost certain to make ingress and when it does lead to a major outbreak (affecting a median of about 36 cases, but some ingresses do not lead to outbreaks producing a bimodal distribution and hourglass look to the violin plot). Scenario 3 has the same community prevalence but half the R0 to R0=1.5 for outbreaks within the care home. This lowering of the transmission within care homes acts to increase chance of stochastic fade out (larger bell at bottom of distribution) and lower attack rates from ingress, the median value is now much lower at about 4 cases. If instead of halving the transmission (i.e. leave at R0=3) but instead half community prevalence (to 0.5%) we have scenario 2 and we see the median is now zero cases but pronounced hourglass shape so when outbreaks occur they have large impact. Scenario 1 shows impact of halving both prevalence (0.5%) and transmission (R0=1.5).

This suggests that preventing ingress can have larger impact on average than reducing transmission assuming reduction effort is equal, but when ingress occurs outbreaks may be worse.

Simulated Cases



Figure 10: Toy model scenario analysis showing impact of reducing potential transmission and force of infection. See text for detail.

Regular testing: Two generic models of the effect of testing interventions (independent of setting) have been used to compare the relative impact of different testing interventions on an individual's infectious potential.

Model C2 is a population average model, and assumes the following:

• Test positivity for PCR and LFD in an individual follows the median profile predicted in Hellewell et al. 2020⁸⁸, which peaks at 80% for PCR and 65% for LFD.

⁸⁸ Hellewell et al. 2020. Estimating the effectiveness of routine asymptomatic PCR testing at different frequencies for the detection of SARS-CoV-2 infections. *Medrxiv* DOI: 10.1101/2020.11.24.20229948

- Infectivity in an individual over time since infection Is given by a Weibull distribution with mean 5 days and standard deviation 1.92 days⁸⁹.
- Approximately 50% of people develop symptoms⁹⁰⁹¹.
- Symptom onset time, when it occurs, is given by a gamma distribution with mean 4.84 days and standard deviation 2.6 days.⁹²
- An individual has 0 infectivity while isolated (assuming 10-day isolation upon reporting of symptoms or positive test).

We then simply calculated the reduction in total infectivity (i.e. integrated over time) of testing at a given frequency vs. not testing. The results are given in Figure 11, and show that twice weekly testing (with 100% adherence) is likely to reduce infection potential by 40-50% (depending on whether symptomatic individuals were likely to isolate at symptom onset anyway). Furthermore, we see that LFD performs very similarly to PCR with a 24-hour delay. As this is a population average model, this mean effectiveness scales linearly with adherence rate, so e.g. 50% adherence would result in only 20-25% effectiveness.



Figure 11: Predictions of the mean impact of repeat-testing on infectious potential using a population-average model (Model C2). (a) Shows the case where no individuals isolate with symptoms and (b) where 50% of individuals (i.e. all symptomatics) do isolate at symptom onset.

Model C3 addresses the fact that population averages are not representative of individuals, and was described in the previous working papers of the SCWG. Viral load trajectories are generated for each individual and then test positive probabilities are assumed directly related (by sigmoidal relations) to viral load, using the data in Peto et al 2021⁹³. Individuals are assumed infectious when their viral load exceed 6 log₁₀ copies/ml and their infectiousness is assumed linearly proportional to viral load above this threshold⁹⁴ (in log₁₀ copies/ml). Note that individuals who never exceed the

⁸⁹ Ferretti et al. 2020. Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing. *Science* **368**, eabb6936

⁹⁰ Pouwels et al. 2020. Community prevalence of SARS-CoV-2 in England: Results from the ONS coronavirus infection survey pilot. *Medrxiv DOI: 10.1101/2020.07.06.20147348*

⁹¹ Marks et al. 2021. Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study. *The Lancet Infectious Diseases.* **21**(5): 629-636

⁹² Overton et al. 2020. Using statistics and mathematical modelling to understand infectious disease outbreaks: COVID-19 as an example. *Infectious Disease Modelling* **5**: 409-441.

⁹³ Peto et al. 2021. COVID-19: Rapid Antigen detection for SARS-CoV-2 by lateral flow assay: a national systematic evaluation for mass-testing. Medrxiv DOI: 10.1101/2021.01.13.21249563.

⁹⁴Ke et al. 2020. Kinetics of SARS-CoV-2 infection in the human upper and lower respiratory tracts and their relationship with infectiousness. Medrxiv DOI: 10.1101/2020.09.25.20201772

infectiousness threshold are discarded. We assume a maximum test sensitivity of 85% for PCR and 75% for LFD to account for false negatives due to the swabbing process.

In this model, frequent testing is predicted to be much more effective for most individuals, as many are detected prior to becoming infectious. This outcome is more likely than would be predicted by model C2, since each individual's viral load is detectable before they exceed the infectiousness threshold. Thus, there is a median reduction of >80% in infectious potential for twice-weekly LFD testing (figure 12), depending on the baseline assumption regarding symptomatic isolation (see previous SCWG report), and the mean reduction in infectious potential is slightly larger the simple model in figure 11(b) (60% vs. 40% for 4-day testing). Figure 12 also demonstrates the heterogeneity in effectiveness,

It is likely that model C2 and C3 are an under- and over-estimate theoretical effectiveness respectively, since the first assumes no individual variability, and the other perfect correlation between viral load, infectiousness and positivity in an individual. Model C3 also predicts that higher viral load cases are more likely to be detected, e.g. for 4-day testing with 100% compliance, the mean infectious potential reduction is 63% for cases with peak viral load > 8 log₁₀ copies/ml and 56% for those with lower. It is also worth noting that, since staff exposure to residents is not continuous, test-timing relative to shifts can also increase test effectiveness, rather than just occurring at fixed intervals, as in this model. These correlations were modelled in a previous report and confirmed the intuitive result that tests are optimally timed to reduce workplace transmission when the results are received just prior to a shift (or series of consecutive shifts), and least-optimal when received just prior to a non-work day (or series of non-work days).

In summary, these models suggest that twice-weekly testing can make a significant contribution to reducing transmission from staff to patients (with predictions ranging from 40 - 60% in reduction of mean exposure from infected staff). However, Figure 12 also shows that there will necessarily be significant heterogeneity on an individual basis, and that significant levels of non-compliance can mean that the majority of infectious cases are missed. Therefore, setting specific models, as described in the other sections, are required to understand the actual impact on care-home and domiciliary care outbreaks.



Figure 12: Violin plots of reduction in infectious potential in a stochastic model of LFD testing in 50,000 individuals (Model C3), assuming no symptomatic isolation otherwise. The shading shows the probability of compliance with testing (assumed independent for each test). The circles show the mean for each distribution (joined by dotted lines), while the crosses indicate the median (some of these are positioned at 0 and 1 making them difficult to see).

Analysis of risk factors.

This is an extension of framework presented in previous SCWG notes and provides the force of infection used in Model C1 above.

Connectivity

Connectivity *C* is a rate per unit time and would have component rates illustrated by Figure 13, namely: visitors *V*, hospital visits of existing residents *H*, community visits by existing residents *X*, hospital discharge of new entrants *E*, new admissions from general community to the care home *A*, core staff becoming infectious in the community *S* and staff (including from agency) working across multiple locations, *M*. If these rates can be modelled as the mean of a Poisson process then the components may be summed so C=V+X+H+E+A+S+M.



Figure 13: Schematic showing the identified routes of ingress of COVID-19 into care home settings (letters denoted the corresponding rates described in text).

Visit by family and friends of residents will be given by $V = vp_V R$ where R is the number of residents in the care home, v is the rate of visit per resident and p_V is the community prevalence of disease where the visitor is **travelling from**. If visitors are allowed this will add to the rate of introduction of disease but may bring benefits in general wellbeing of residents. Note that p_V may be different to the prevalence in the neighbourhood community of the care home itself (as family may live further away). Similarly residents may leave the care home to meet with friends and make trips for social reasons returning with infection and this rate is given by $X = \xi p_X R$ where p_X is the prevalence in location visited and ξ is the rate of such trips per resident.

Staff will be affected by the community incidence in which they live and so $S = \sigma p_S R$ where σ is the core staff-resident ratio, (so σR is the number of staff in the care home) and p_S is the probability of being infected. Similarly staff working in multiple locations or agency staff will be affected by the community incidence (and infectious risk from the other locations they work in) and so $M = \mu p_M R$ where μ is the visiting staff-resident ratio, (so μR is the number of visiting staff in the care home) and p_M is the probability of being infected.

Visits to hospital may not fluctuate a great deal as: outpatient investigation and assessment is usually limited by advance plans primary care have for the resident; transfer as acute illness to secondary care has reduced markedly since the crisis with many clinicians deciding management at care home most appropriate; greater use of email or phone discussion with specialist teams for complex cases rather than sending for assessment. The hospitalisation rate per care home, $H = \eta p_H R$ where η is the rate of visit to hospital per resident and p_H is the prevalence *in hospital*. This is may be small as testing at discharge from hospital or admission to care home should be mandatory.

Limited data is available at present on new residents as a result of hospital discharges but this would be modelled by $E = \epsilon p_H R$. The admission of new residents from community $A = \alpha p_A R$ may be zero or rather if we assume care homes run at capacity then α will be the natural mortality rate of residents to maintain a steady ambient number of residents.

If any of these contributory routes of introduction were subject to testing (with suitable delays on test result being available before entry), only those cases that are false negatives would enter the care home. This means we can scale the connectivity by a probability $1 - \rho$ where ρ is the probability of reduced load if all ingress routes are tested (assuming similar testing methods on those routes). This may not be the test sensitivity due to repeated testing per week and random effects of ingress. When disease is at low prevalence in a setting, the false positive rate associated with testing will mean that some positive test results will not be actual cases, and this means if testing results lead to shut down there may be consequences of this.

So the connectivity rate under universal testing would be $C = (1 - \rho)(\beta(1 - \delta_V)\nu p_V + \xi p_X + (1 - \delta_S)\sigma p_S + (1 - \delta_M)\mu p_M + \eta p_H + \epsilon p_E + \alpha p_A)R$ per unit time and the probability of no introduction by time *t* is then $P = \exp(-Ct)$ given the Poisson random variable in time and space assumption at the start. Previously unexplained parameters are associated with infection control (a broad family of interventions including PPE, social distancing and mask usage) and so the expected effectiveness of infection control when used by staff, δ_S , visitors, δ_V , and visiting professional δ_M is included. In addition β is a change in risk of transmission from visitors due to indoor or outdoor visits.

If staff have a vaccine effectiveness of γ_S with coverage H_S and residents and older people a vaccine effectiveness of γ_R with coverage H_R for residents and H_C for community older people (and similar notation for visitors) then $C = (1 - \rho)(\beta(1 - \delta_V)(1 - H_V\gamma_V)\nu p_V + (1 - H_R\gamma_R)\xi p_X + (1 - \gamma_S)(1 - H_S\delta_S)\sigma p_S + (1 - H_S\gamma_S)(1 - \delta_M)\mu p_M + (1 - H_R\gamma_R)\eta p_H + (1 - H_R\gamma_R)\epsilon p_E + (1 - H_C\gamma_R)\alpha p_A)R.$

Application

This approach suggests hospital discharges and transfers likely have a limited role (as compared with contact with a member of staff contact for an individual with hospital is relatively rare). Assuming a tolerance of acceptable ingress per week say given in terms of probability P means we can evaluate a $C = -\frac{\log P}{7}$. Alternatively if we change a policy (say reduce interventions) then we can say what equivalent connectivity would need to change. For a specific care home (so R is same) and with equal prevalence π assumed for simplicity during testing with efficiency ρ compared with prevalence p without testing then $p = (1 - \rho)\pi$ so if testing reduces connectivity by 90% then the same risk of ingress occurs when prevalence is 10% of current value.

Similarly we see when there is no testing that

$$C_{\{NT\}} = (\beta(1 - \delta_V)(1 - H_V \gamma_V) \nu p_V + (1 - H_R \gamma_R) \xi p_X + (1 - \gamma_S)(1 - H_S \delta_S) \sigma p_S + (1 - H_S \gamma_S)(1 - \delta_M) \mu p_M + (1 - H_R \gamma_R) \eta p_H + (1 - H_R \gamma_R) \epsilon p_E + (1 - H_C \gamma_R) \alpha p_A) R.$$

Whilst when there is no vaccination

 $C_{NV} = (1 - \rho)(\beta(1 - \delta_V)\nu \, p_V + \xi p_X + (1 - \gamma_S)\sigma \, p_S + (1 - \delta_M)\mu p_M + \eta \, p_H + \epsilon \, p_E + \alpha p_A)R.$

And so if we set $C_{NV} = C_{NT}$ we can derive a value of ρ necessary to be equivalent to the impact of vaccination for example if prevalence is equal and hospitalisation and admission rare then

$$\rho = \frac{\left(\beta(1-\delta_V)(H_V\gamma_V)\nu + (H_R\gamma_R)\xi + (1-\delta_S)(H_S\delta_S)\sigma + (H_S\gamma_S)(1-\delta_M)\mu\right)}{\left(\beta(1-\delta_V)\nu + \xi + (1-\delta_S)\sigma + (1-\delta_M)\mu\right)}$$

In the situation that the coverage is equal and effectiveness does not vary by age then $\rho = \gamma H$. We do not evaluate this formula in detail and leave this as a framework that could be considered to consider relative or compensatory risks. Moreover, if vaccination is in place then this could be used as a crude test (prior to full simulation) of impact of relaxation. For example with an 80% effective vaccine and coverage of 80% then the combined effect is 64% and so other interventions (be they testing or more targeted) could be relaxed to be about 50% less effective for no overall change provided the resulting number of cases was tolerable.