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Subject: Official Sensitive - SG C-19 Advisory Group - Advice on Certification
Date: 22 June 2021 14:19:36
Attachments: [SG C-19 Advisory Group - Advice on Certification.pdf](#)

To: [NR] Liz Sadler, Marion McCormack and [Name Redacted]

Copy list: as above

Please find attached the advice on the scientific basis for covid-19 certification which you commissioned from the C-19 Advisory Group.

Kind regards,

[NR]

[NR]

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**Scottish Government Covid-19 Advisory Group
Advice on Certification
22 June 2021**

Key Points:

1. The Scottish Government Covid-19 Advisory Group has been commissioned for advice on the strength of the scientific case for using vaccine certification in the context of large scale events.
2. Vaccination provides very effective protection against acquiring both symptomatic and asymptomatic infection. Two doses of either of the most used vaccines are more effective than one dose.
3. Testing provides some indication of likely infectiousness at the time of an event, although its effectiveness is less than vaccination.
4. Community prevalence on its own might provide as good an indication of likely transmission at a larger scale event.
5. The results from pilot studies of testing before attending mass events suggest community prevalence could be an effective measure to limit transmission, without vaccine certification. Some caution is needed around this approach, as its effectiveness would depend on low community prevalence. Increased transmissibility of the Delta variant would increase the risk of significant transmission.

1. Introduction

The Scottish Government Covid-19 Advisory Group has been commissioned for advice on the strength of the scientific case for using covid-19 certification in response to recent policy developments by the UK Government in this area.

These UK Government proposals were for certification to be used in large scale events, with certification available for those with:

- one dose of vaccination – at least 3 weeks earlier than the event, but no more than 9 weeks earlier.
- both doses of vaccination.

- A negative LFD or PCR test taken within 72h of the event either at a testing site or at home and self-reported
- a positive PCR test at least 10 days earlier than, but within 180 days of, the event

Details of this proposal and the rationale underpinning it are available in Annex A. This area of policy is fast moving and the advice below considered certification proposals at the time this advice was commissioned.

2. Potential Aims of Certification

1. Protect an individual from infection
2. Limit potential spread of SARS-CoV-2

Mixing with larger groups of people will increase the risk of exposure to somebody with SARS-CoV-2 infection. The risk of acquiring infection is greater in an indoor environment, with relatively poor ventilation. In addition, for certain events it may not be possible or desirable to maintain other mitigating measures, such as physical distancing or mask/face coverings. Vaccination can provide protection for an individual against acquiring and spreading infection¹. Testing is a measure to limit possible spread of infection. Certification of either vaccination or recent testing could provide a means to stage larger scale events both indoors and outside with a greater degree of security. There are numerous practical difficulties associated with such certification. The sections below do not treat those but are confined to the underpinning scientific rationale that could support such a measure.

3. Vaccination

Data from Public Health England on the effectiveness of vaccination against the now dominant circulating strain B.1.617.2 (henceforth known as Delta) demonstrated the following effectiveness against symptomatic disease²:

1 dose Pfizer 21 day effect	33.2%
2 dose Pfizer 14 day effect	87.9%
1 dose Astra Zeneca 21 day effect	32.9%
2 dose Astra Zeneca 14 day effect	59.8%

¹ One dose of COVID-19 vaccine can cut household transmission by up to half, UK Government, Public Health England. 28 April 2021. <https://www.gov.uk/government/news/one-dose-of-covid-19-vaccine-can-cut-household-transmission-by-up-to-half>

² Vaccines highly effective against B.1.617.2 variant after 2 doses, UK Government, Public Health England. 22 May 2021. <https://www.gov.uk/government/news/vaccines-highly-effective-against-b-1-617-2-variant-after-2-doses>

For serious infection, the figures will be higher but the exact number is not yet clear. Preliminary data suggests that either vaccine offers significant additional protection against serious disease.

Comparable data of protection against *asymptomatic* infection with the Delta variant are not available. Data from population surveys in Israel showed that after 2 doses of the Pfizer Vaccine, the estimated efficacy against asymptomatic infection at 7 days after the second dose was 91.5%, compared to 95.3% for symptomatic infection³. The majority (>90%) of isolated virus in this study was Alpha (B.1.1.7). For the AstraZeneca vaccine, overall reduction in PCR positivity (both symptomatic and asymptomatic) after 2 doses of the vaccine 14 days after the 2nd dose was ~ 50%⁴. This was when the 'wild type' virus was circulating in the UK.

Transmission of SARS-CoV-2 from an asymptomatic individual can occur but is less likely than for a person with symptomatic infection. A study in Luxembourg found the secondary attack rate from asymptomatic individuals was about half that from those with symptoms⁵. A meta-analysis from Imperial College found secondary attack rates from asymptomatic individuals were about 14% of those who were symptomatic⁶. However, from those who were pre-symptomatic, transmission rates were higher, about 2/3 of the symptomatic secondary attack rate.

4. Testing

Detection of the viral RNA in nasopharyngeal samples will act as a marker of risk of transmitting the virus at the time of the test. PCR based technology is the 'gold standard', and has a sensitivity of detecting actual infection of above ~90%⁷. In contrast, detection by LFTs has a lower sensitivity - estimates vary but is probably about 75%⁸. These LFTs have a higher sensitivity against symptomatic versus asymptomatic infection, thus will better identify those who are more likely to transmit the infection. Both tests have high specificity, of about 99.9% (very few false positives).

³ Eric J Haas, et al Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data, *The Lancet*, Volume 397, Issue 10287, 2021, Pages 1819-1829.

⁴ Voysey, Merryn et al Single Dose Administration, And The Influence Of The Timing Of The Booster Dose On Immunogenicity and Efficacy Of ChAdOx1 nCoV-19 (AZD1222) Vaccine. Available at SSRN: <https://ssrn.com/abstract=3777268> or <http://dx.doi.org/10.2139/ssrn.3777268>

⁵ Paul Wilmes, et al, SARS-CoV-2 transmission risk from asymptomatic carriers: Results from a mass screening programme in Luxembourg, *The Lancet Regional Health - Europe*, Volume 4, 2021, 100056

⁶ Thompson, H.A. et al, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Setting-specific Transmission Rates: A Systematic Review and Meta-analysis. *Clin Infect Dis*. 2021 DO 10.1093/cid/ciab100

⁷ Covid-19 Infection Survey: methods and further information, Test sensitivity and specificity, Office for National Statistics. 26 March 2021.

<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/methodologies/covid19infectionsurveyspilotmethodsandfurtherinformation#test-sensitivity-and-specificity>

⁸ Mass testing for COVID-19: January update on lateral flow tests, UK Parliament. 29 January 2021.

<https://post.parliament.uk/mass-testing-for-covid-19-january-update-on-lateral-flow-tests/>

There are a number of caveats around the timing of tests and their interpretation. Testing 72 hours prior to an event would not pick up those at an early stage of infection who may have very low levels of viral RNA at the time of testing but who become symptomatic or have higher viral loads at the time of the event itself. Given the incubation period is about 5 days, there will be infections that are undetected 72 hours before an event. If the test is self-administered, the test result will depend on individuals' ability to self-test and truthful reporting. Certification from a testing centre would be much more reliable. Secondly, the value of a test result will depend on prevailing community prevalence of COVID-19 at the time of the test. If this is low, the negative predictive value of a test will be correspondingly high (few false negatives), but the positive predictive value less (there will be a significant number of false positives). In the context of only allowing those without infection to attend an event, this would enhance the utility of a test, although some individuals may be asked to self-isolate who are in fact not infected.

Pilot studies of the role of testing prior to mass events which have no mask wearing or distancing measures have been performed as part of the UK Government sponsored Events Research programme. Preliminary results of the pilot schemes run in Liverpool of a number of mass events with testing before the event have been reported⁹. The numbers of onward transmission events that resulted from these events were very small – from 13,258 attendees, between 25 – 43% completed a follow up test by PCR after the event which identified 7 infections. Of course the point at which they acquired the infection could have been at the event or with another contact thereafter. The events occurred before the current increased circulation of the Delta variant. Of note, only 5 people were identified as having a positive test before the event and they were excluded.

Testing remains important – certification should not permit the relaxation or avoidance of self-isolation and testing if symptoms develop or individuals test positive LFT/PCR (acknowledging when community prevalence is low LFT testing will have a higher false positive rate).

5. Behavioural Science

If certification is viewed by the public as a means to encourage vaccination, there is potential for at least some sections of the community to regard the process as coercive and undermine trust (once lost, hard to rebuild). A recent study in this area found: “when we remove those participants who express certainty (they either definitely will or definitely will not get a jab) and an unchanged inclination to vaccinate were passports introduced, and focus on the remaining doubters, a very different picture emerges. Overall, this remaining group expresses lower intentions to get vaccinated

⁹ Liverpool pilot events had no impact on Covid spread in region, University of Liverpool. 25 May 2021. <https://news.liverpool.ac.uk/2021/05/25/liverpool-pilot-events-have-no-impact-on-covid-spread-in-region/>

when vaccine passports are mentioned, especially when these passports cover domestic activities as opposed to international travel.” Such perception may be particularly likely amongst communities who experience other aspects of their interaction with authority as involving coercion. This study also found that “among the groups with lower observed uptake—such as the Black community and those who are economically deprived (unemployed)—the effects of domestic use vaccine passports on stated vaccination inclination (without controlling for baseline intent) are most negative”¹⁰.

The proposal to access certification via testing may help address this issue, in part as this would be less intrusive. However, it means any certification based on a negative test would be time limited (72 hours). This raises a number of questions including:

- What form the test-based certification would take?
- How would a self-administered test result be authenticated and feature on a certificate?
- Would it be based on self-report?
- Is there independent validation of a claim to be negative?
- As people may go to a number of events requiring certification, the number of certificate issuances could be significant (adding to the logistical burden).
- For the testing to have value it would need to be conducted properly. How good are people at self-testing?
- People’s motivation to do the test properly may be diminished if they want the test to be negative. Are there data on self-testing that speak to the issue of how fully people comply with the recommended procedure?
- If self-testing is involved there would need to be significant public health messaging on how it is to be done properly and people’s responsibilities (to others) to take the text seriously?

In order to avoid concerns that certification for large-scale events is the ‘thin end of the wedge’ (with the Government seeking to broaden the range of events for which certification is required) it would be important to have very clear statements on the limited range of contexts for which certification is required. Messaging will be key and would need to anticipate various anxieties.

Further research and evaluation is needed to better understand the impact of immunity certificates – inclusive of impact on outcome and behavioural considerations outlined above.

¹⁰ The potential impact of vaccine passports on inclination to accept COVID-19 vaccinations in the United Kingdom: evidence from a large cross-sectional survey and modelling study
Alexandre de Figueiredo, Heidi J. Larson, Stephen Reicher
medRxiv 2021.05.31.21258122; doi: <https://doi.org/10.1101/2021.05.31.21258122>.

6. Additional Considerations

The NERVTAG position is that immunity certification could be used as an adjunct to other measures to control transmission and/or to enable relaxation of certain measures, however a risk-based approach should be adopted using the hierarchy of controls in a context specific way, inclusive of consideration of community prevalence.

The full summary of SAGE information on certification can be found in the paper SAGE greatest hits on upcoming reviews Certification, circulated for SAGE 87. Due to the large number of attachments embedded this has not been included in an Annex but can be made available upon request.

An overview of certification schemes from Israel, Denmark, France, Germany and New York from a recent ICJU comparison has been included in Annex B.

Differences in the level of social trust in countries should also be recognised, for instance Denmark has higher social trust compared to the UK. The level of social trust may affect perceptions that certification is an imposition. In the case of Denmark, a 'sunset clause' has been announced for their 'Coronapas' certification scheme. Using a fixed end date can provide some reassurance that this scheme will not raise long term issues of civil liberties.

7. Conclusions

Setting aside practical and ethical concerns around nature of certification, equality issues etc., the following conclusions can be drawn:

1. Vaccination provides very effective protection against symptomatic and asymptomatic disease. Two doses of either of the most used vaccines are more effective than one dose.
2. Testing provides some indication of likely infectiousness at the time of an event, although its effectiveness is less than vaccination.
3. Community prevalence on its own might provide as good an indication of likely transmission at a larger scale event. Current estimates from the Office of National Statistics are that 1 in every 630 people have COVID-19 (data from week ending 22 May 2021)¹¹. In an event of say 1,000 people, then on average

¹¹Coronavirus (COVID-19) Infection Survey, UK: 28 May 2021, Percentage of people who had COVID-19 in England, Wales, Northern Ireland and Scotland. 28 May 2021.
<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronaviruscovid19infectionsurvey/pilot/latest#percentage-of-people-who-had-covid-19-in-england-wales-northern-ireland-and-scotland>

there will only be 1.6 people with COVID-19. Secondary attack rates from these individuals will depend on the length and intensity of contact. Furthermore, actual contacts in a larger event will depend on the nature of the event – high for a wedding but lower for a music festival for example. The Imperial meta-analysis cited above found secondary attack rates of about 1.2% for casual contacts, rising to 5.9% in social gatherings of family or friends. This contrast with the much higher secondary attack rates within households (21.1%). These figures do not factor in any effect of vaccination.

4. The results from pilot studies of testing before attending mass events suggest this could be an effective measure to limit transmission, without vaccine certification. Some caution is needed around this approach, as its effectiveness would depend on low community prevalence and the increased transmissibility of the Delta variant would increase the risk of significant transmission. A further pilot where this variant is now dominant would be helpful.
5. A risk-based approach should be adopted using the hierarchy of controls in a context specific way, inclusive of consideration of community prevalence.

Annex A. UK Government Proposals.

Note: these draft policy proposals were the latest UK Government position on 3 June 2021. This area of policy is fast moving and these may no longer represent the most recent position of the UK Government.

The UK Government proposals which the Scottish Government Covid-19 Advisory group were asked for advice on were the following.

UK Government Proposals

- The rationale for using certification would be that restricting entry to those who are less likely to infect others and less likely to become seriously ill, the public health risk posed by the event would be reduced to a manageable and tolerable level.
- The type of events and settings being proposed for mandatory certification are:
 - all indoor unseated events of over 500 people
 - all events of over 20,000 people (outdoors or indoors, including seated venues)
 - any event of more than 4,000 people outdoors, where there is likely to be a high degree of mingling and interaction in shared communal spaces (for example music festivals)
- For illustrative purposes, this proposal would include the use of certification in settings like large sports stadiums, music festivals, large business conferences and large nightclubs. Large weddings and other life events with over 500 people would be in scope, given the public health implications.
- Employees at the event would not be required in law to demonstrate COVID status.

UKG certification standards

The proposal is that a person would be able to gain entry to a qualifying event by presenting a certificate (on an app or a paper copy) that proved one of the following:

- one dose of vaccination – at least 3 weeks earlier than the event, but no more than 9 weeks earlier.
- both doses of vaccination.
- A negative LFD or PCR test taken within 72h of the event either at a testing site or at home and self-reported
- a positive PCR test at least 10 days earlier than, but within 180 days of, the event

There would be exemptions from the requirement to prove Covid Status, based on:

- Those taking part in COVID-19 vaccine clinical trials.
- Those with a pre-existing diagnosis of anaphylaxis, for whom none of the COVID-19 vaccines are suitable, as outlined in The Green Book chapter 14a. Exceptional circumstances for individuals where a clinician recommends vaccine deferral or that vaccination is not appropriate
- Age-based exemptions (for example under 18s or under 12s)

Annex B – ICJU – Certification¹²

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4 – Certification

Germany will use certification app from June in the hospitality sector; France extends use of certification to ‘risk’ sectors including sports events and festivals

Note: This slide does not include apps for track and trace which are used by all comparators
Comparators that do not currently have certification apps are not featured on this slide

Key: Bold text represents changes since last version of this paper on 27 April

Comparators use of ‘Covid health certificates’

Country	Format	Certificate availability and validity	Sectors					Observations
			Hospitality	Exercise and sports	Public transport	Non-essential retail	Mass gatherings or events	
 Denmark	‘Corona pass’ App or paper version	<ul style="list-style-type: none"> Full vaccine – valid until 31 July Positive test – valid until 31 July Negative test – valid for 72hrs 	✓	✓	X	X	✓	<ul style="list-style-type: none"> Government set August 2021 ‘sunset clause’ for its use Compulsory for entry in a number of sectors
 France	App or paper version	<ul style="list-style-type: none"> Full vaccine – valid for 6 months Positive test – valid for 6 months Negative test – valid for 72hrs 	X	X	X	X	✓	<ul style="list-style-type: none"> Initially only used to allow travel to and from overseas territories Has now been extended for use in certain ‘risk’ sectors e.g. large spectator sporting events and festivals
 Germany	‘CovPass’ App or paper version (regional)	<ul style="list-style-type: none"> Full vaccine – valid for 6 months Positive test – valid for 6 months Negative test – valid for 72hrs 	✓	X	X	X	X	<ul style="list-style-type: none"> ‘CovPass’ to be launched in June Designed to be compatible with the certificate being developed by the EU
 Israel	‘Green Pass’ App or paper version	<ul style="list-style-type: none"> Full vaccine – valid until 31 Dec Positive test – valid until 31 Dec Negative test – valid for 72 hours 	✓	✓	X	X	✓	<ul style="list-style-type: none"> Rapid on the spot testing at premises offered as an alternative to certification children under 18 included on parents’ pass
 Italy	‘Green Pass’ App or paper version	<ul style="list-style-type: none"> Full vaccine – valid for 9 months Positive test – valid for 6 months Negative test – valid for 48hrs 	✓	✓	X	X	✓	<ul style="list-style-type: none"> Certificates from countries with EU recognised vaccinations can also be used
 New York	‘Excelsior’ App or paper version	<ul style="list-style-type: none"> Full vaccine – valid for 365 days Negative test – valid for 72hrs 	✓	✓	X	X	✓	<ul style="list-style-type: none"> Use of certification is voluntary for businesses and individuals It does not currently reduce restrictions for settings or for individuals using it

¹² ICJU – Covid-19 International Comparators: Social Distancing, 27 May 2021