Department of Health & Social Care

Making vaccination a condition of deployment in health and wider social care sector

Government response to public consultation

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Contents

Introduction

Background and objectives

The government has set out in its consultation the importance of protecting people receiving care in all health and social care settings. It has also set out the importance of protecting our valuable health and social care workforce. COVID-19 continues to pose a threat to people's health across the country. In winter months, we can expect COVID-19 and respiratory viruses to spread more easily, increasing risks to health, particularly for those who are elderly or who have health conditions. Vaccination is a safe, effective way of preventing the spread of viruses.

Following a public consultation, the government recently announced COVID-19 vaccination would be required of people entering a Care Quality Commission (CQC)-registered adult care home, unless exempt, to protect vulnerable residents. While residents in care homes are some of the most at risk from COVID-19, the responses to the care home consultation made a clear case for extending this policy beyond care homes to other settings where vulnerable people receive care and treatment.

There has already been an incredible roll-out of COVID-19 vaccination to health and social care staff, thanks to effective leadership and collaboration across the NHS and health and care sector. As of 31 October 2021, more than 2.6 million health and social care workers have now taken up the COVID-19 vaccination. Workers have taken important steps to protect themselves, their loved ones, and the people they care for.

However, there is still more to do. Evidence suggests some areas of the country are less protected than others against COVID-19. It is right that the government acts now to ensure that those who are deployed to deliver healthcare and social care are fully vaccinated, to help protect the people they care for, as well as themselves and their colleagues.

The aim of this consultation was to seek views on whether or not the government should extend the existing statutory requirement, for those responsible for care homes to ensure that they have evidence that those working or volunteering in a care home have been vaccinated against COVID-19, to other health and care settings, as a condition of deployment. The consultation also asked for views on whether or not the government should introduce a statutory requirement for registered providers to have evidence that their workers have been vaccinated against flu as a condition of deployment.

Clinical rationale

As set out in the consultation document, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that in winter 2021 to 2022, seasonal flu and SARS-CoV-2 viruses have the potential to contribute substantially to the 'winter pressures' faced by the NHS. Vaccination is a critical step in protecting vulnerable people, and the wider health and social care system, against a tough winter this year, and in future.

The government's Green Book, Chapter 14a - COVID-19 - SARS-CoV-2, and Chapter 19: Influenza, sets out clear advice that vaccination should be provided to healthcare and social care workers to:

- protect them and to reduce transmission within health and social care premises
- contribute to the protection of individuals who may have a suboptimal response to their own immunisations
- avoid disruption to services that provide their care

The Scientific Advisory Group for Emergencies (SAGE) has advised vaccination as a tool in preventing the transmission of COVID-19 and flu in settings where vulnerable people receive care.

The SAGE Social Care Working Group has made a strong scientific case for parity of approaches in vaccination between NHS inpatient settings and care homes, given the close and overlapping networks between residents or patients and workers. Ensuring and sustaining very high levels of vaccination of people working in settings with vulnerable people is an essential public health intervention for serious vaccine-preventable disease.

COVID-19 vaccination

Analysis from PHE indicates that the COVID-19 vaccination programme has directly prevented an estimated 24.1 million infections, over 261,500 hospitalisations, and 127,500 deaths.

Studies have now reported on vaccine effectiveness against infection of the COVID-19 Alpha variant in healthcare workers, care home residents and the general population. For the Pfizer-BioNTech vaccine, estimates of effectiveness against infection range from around 55 to 70%, for the Oxford-AstraZeneca vaccine from

around 60 to 70%[1,2,3,4]. With 2 of 2 doses of either vaccine effectiveness against infection is estimated at around 65 to 90%[Error! Bookmark not defined.,Error! Bookmark not defined.].

For the COVID-19 Delta variant vaccine effectiveness against infection has been estimated at around 65% with Oxford-AstraZeneca vaccine and 80% with Pfizer-BioNTech vaccine. Studies have reported 65% to 70% effectiveness against symptomatic disease with Oxford-AstraZeneca vaccine, and 80 to 95% with Pfizer-BioNTech. Effectiveness against hospitalisation of over 90% is observed with the Delta variant with both vaccines.

There is clear evidence that vaccines are effective at preventing infection. Uninfected individuals cannot transmit, which means the vaccines are also effective at preventing transmission. Beyond preventing infection, there may also be the additional benefit of reduced transmission by those individuals who become infected despite vaccination, because of reduced duration or level of viral shedding.

Principles

The overarching principles we have considered in developing this policy are:

- **building on what's been done to date** – recognising the impact vaccinations have had so far and building on these strong foundations

- **the need to protect people receiving care** – acknowledging our duty of care to all those receiving health and social care in this country, who may include the most vulnerable, the elderly, and those with ongoing health conditions

- **the need to protect our workforce** – accepting the government's duty to protect health and social care workers, both for their own health and wellbeing, and to ensure our health and social care sector can continue to deliver services.

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[1] Pritchard E, Matthews PC, Stoesser N, Eyre DW, Gethings O, Vihta K-D, and others. 'Impact of vaccination on SARS-CoV-2 cases in the community: a population-based study using the UK's COVID-19 Infection Survey.' medRxiv 2021: 2021.04.22.21255913

[2] Hall VJ, Foulkes S, Saei A, Andrews N, Oguti B, Charlett A and others. 'COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study.' Lancet 2021

[3] Shrotri M, Krutikov M, Palmer T, Giddings R, Azmi B, Subbarao S and others. 'Vaccine effectiveness of the first dose of ChAdOx1 nCoV-19 and BNT162b2 against SARS-CoV-2 infection in residents of long-term care facilities in England (VIVALDI): a prospective cohort study.' Lancet Infectious Diseases 2021

[4] Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P and others. 'Vaccine side effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study.' The Lancet Infectious Diseases 2021

Our consultation

The Department of Health and Social Care (DHSC) conducted a public consultation seeking views on whether or not to extend vaccination requirements to other health and care settings for COVID-19 and also for flu. The consultation proposed an amendment to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which would require the CQC-registered person (that is the service provider or registered manager) to deploy only those workers who have received their COVID-19 and flu vaccinations (unless medically exempt). The consultation was live from 9 September to 22 October 2021 and the full consultation document is available online. This is the formal government response to that consultation.

The consultation posed a series of questions about the government's proposals, which covered the following areas:

- proposed legislative change
- policy scope
- who should be exempt
- implementation
- the impact and implications on the workforce and on those with protected characteristics

The consultation was available through an online survey hosted on GOV.UK and 34,929 responses were submitted. A total of 42 responses to the consultation were received outside the online platform, which were also accepted and analysed. The government is grateful for the responses received from individuals and organisations, and values the comments and views submitted.

This document summarises the responses to that consultation and sets out the government's response to the issues raised in each section. In the government response sections, 'we' refers to the UK government.

Stakeholder engagement

To supplement the views provided in the consultation, DHSC conducted extensive engagement with stakeholders. We are grateful to all those who joined our round table events comprising health and social care providers, representative organisations, local government and regulators. In addition, adult social care

stakeholder sessions were held on 12, 21 and 22 October. The topics discussed included: the rationale behind the policy proposal, proposed scope of the regulations, equality issues, workforce impacts, and impacts on providing a safe service.

We have raised awareness of, and encouraged participation in, the consultation through our DHSC communications channels and through targeted communications delivered directly to health and care stakeholder organisations.

Executive summary

The overarching principles we have considered when developing this policy and analysing responses are:

- building on what's been done to date
- the need to protect people receiving care
- the need to protect our workforce, to ensure our health and social care sector can continue to deliver services

Building on what's been done to date

During the pandemic, the overriding concern for government, the National Health Service (NHS) and the care sector has been to protect the workforce, patients, and the users of services. Whether in care homes, at home, in hospitals or in general practice, everyone working in health and social care would accept responsibility to avoid preventable harm to the people whom they are there to care for.

Following the development of COVID-19 vaccines, the government led a rapid programme of vaccination development and deployment. On 13 February 2021, the government published the UK COVID-19 vaccines delivery plan, setting out the significant programme of work underway to drive vaccine uptake, including actions to improve access and to address the concerns of those hesitant to receive the vaccine. To date, over 45 million people have received two doses of COVID-19 vaccination in the UK (6 November 2021), protecting them and their loved ones from the virus.

There is already a requirement placed on registered persons in care homes to secure that, subject to limited exceptions, only those persons who can provide evidence that they have been vaccinated against COVID-19 or that they are clinically exempt can enter the care home premises. Residents in care homes are particularly vulnerable to severe illness and death from COVID-19. This requirement will come into force on 11 November 2021. Approximately 1.3 million social care workers in England have now taken up the vaccination. Responses to the care homes consultation also made a clear case for extending the policy beyond care homes, to other settings where vulnerable people receive care and treatment, such as hospitals, hospices, and also in a person's home.

There has already been incredible work to vaccinate our health and care staff. In our consultation document, we set out the targeted programmes of work that have been delivered to support vaccine uptake. This has involved bespoke communications materials, paid advertising, stakeholder toolkits, positive messaging using influencers and leaders, content in different languages, briefings with different faith groups, engagement sessions, webinars with clinical experts, vaccine champions, and practical support including vaccination at places of work, flexible access to vaccine hubs, digital booking support, and monitoring and support from NHS England.

Yet there is still further to go. Nationally, 93% of NHS workers have received at least one dose of COVID-19 vaccination, but if we look at the regional picture, this is as low as 84% in some trusts. Similarly, in social care, 83% of domiciliary care staff and 75% of staff in other settings had received one dose of COVID-19.

While it is encouraging that a high proportion of those delivering health and care are now vaccinated, it remains the case that despite the significant efforts to increase vaccination uptake, many health and care workers may remain unprotected.

The need to protect people receiving care

People receiving care include the most vulnerable in our society, whether due to their age, underlying health conditions, disability or other needs. At present there remains uncertainty as to whether they are afforded the added protection of being cared for by vaccinated health or care workers. There is a clear public health rationale for ensuring that people who provide health and care services only deploy those people that have been vaccinated in order to protect those who are most at risk.

As at 4 November 2021, there were 30,139 new COVID-19 cases and 9,160 COVID-19 patients in hospital. Since the start of the pandemic, 141,735 lives have been lost.

The variation of vaccination rates amongst health and social care workers that we know exists across the country means that some of the people being cared for are at greater risk. To fail to act now, when we have effective vaccination available, risks undermining public confidence in our health and care services.

The need to protect our workforce

Our workforce has worked heroically to deliver services throughout the pandemic, for people with COVID-19, for people with urgent and emergency care needs, for people with ongoing care needs, and for people waiting for planned care or treatment. The pressures that the workforce have faced cannot be overstated.

COVID-19 continues to put pressure on health and care services, and it is imperative that we take action to protect our workforce. Our consultation proposal aimed to ensure high workforce vaccination levels are maximised and maintained. The intention is to protect workers and their colleagues, to safeguard their own health, and to ensure that the health and social care sector can continue to help people and deliver important services.

A higher level of vaccination uptake is likely to reduce sickness absence. Pre-pandemic, absence levels were 4.1%, but reached over 12% in the first COVID-19 wave in April 2020. As of 6 October 2021, the number of sickness absences (7-day average) was 74,863 in NHS trusts, of which around 15,500 staff were absent for COVID-19 reasons, including the need to self-isolate. The NHS cannot sustain such high levels of absence. As well as ongoing COVID-19 care, there is significant urgent and emergency care demand, and elective care waiting lists have reached a record high of 5.7 million, with 292,000 patients waiting over one year for treatment. Now more than ever, we need health and social care staff in good health and delivering services.

What we proposed

The consultation asked for views on whether people supported the proposed legislative change, the scope of the policy, proposed exemptions, implementation methods; and sought views on equality impacts and impact on maintaining safe levels of staffing and the workforce.

It proposed applying vaccination as a condition of deployment to those frontline workers who provide face-to-face care for patients and clients. This was defined as those deployed to undertake direct treatment or personal care as part of a Care Quality Commission (CQC) regulated activity.

What we heard

DHSC undertook thorough analysis of the more than 34,900 consultation responses and considered the feedback received. Overall, the consultation showed that, while a majority of respondents (65%) did not support the proposal, the responses from the health and social care sector were mixed, with some groups (for example managers of healthcare or social care services) mostly supporting the proposed legislative change while others (for example service users and relatives of service users) were mostly opposed.

Regarding policy scope, the consultation showed some support for the proposed scope of those deployed to undertake direct treatment or personal care as part of a CQC-regulated activity in a healthcare or social care setting.

One of the main areas of concern was the impact on workforce capacity and the timing of implementation. Many representative bodies called for a longer period of preparation and implementation, to take effect after winter with some stakeholders pointing to current vacancy rates being high.

The majority of respondents agreed with our proposal to provide exemptions based on medical grounds, as outlined in the proposal. There was a call for ensuring that the system for demonstrating vaccination status or exemption from vaccination is simple and clear.

A majority of respondents (61% for healthcare settings and 62% for social care settings) did not support flu vaccination requirements. Apart from managers of healthcare and or social care services, of whom a small majority (51% for healthcare settings and 50% for social care settings) supported, the majority of all other respondent groups did not support flu vaccination requirements. The proportion of respondents selecting ‘neither supportive nor unsupportive’ was almost twice as high for flu as for COVID-19. Differences were raised by stakeholders in relation to virus transmissibility and impact and the different efficacy of the vaccines as well as lower uptake rates compared to COVID-19 vaccination.

The consultation showed that respondents were concerned about the potential for disproportionate impact on those with protected characteristics, such as pregnant women and people from particular ethnic minority backgrounds.

Our response and plan for the future

The government is grateful to those that took the time to provide their views as part of the consultation and has considered these carefully. In response to the consultation, and in order to help protect people receiving health and social care, who may be more clinically vulnerable to COVID-19, the government will be introducing regulations to only allow providers of CQC-regulated activities to deploy individuals who have been vaccinated against COVID-19 to roles where they interact with patients and service users.

These regulations will require workers who have direct, face to face contact with service users to provide evidence that they have been vaccinated, subject to limited exceptions. This will include front-line workers, as well as non-clinical workers not directly involved in patient care but who nevertheless may have direct, face to-face contact with patients, such as receptionists, ward clerks, porters and cleaners.

These regulations will protect vulnerable people and individual workers in health and social care settings, including hospitals, GP practices, and where care is delivered in a person's home. The requirements will apply to CQC-regulated activities whether they are publicly or privately funded. They will also apply where a regulated activity is delivered through agency workers, volunteers or trainees, or contracted to another provider.

This means health and care workers will need to have received a full course of COVID-19 vaccination in line with the UK Health Security Agency (UKHSA) guidance in order to continue to be deployed. Some individuals will be exempt from the regulations:

- those under the age of 18
- those who are clinically exempt from COVID-19 vaccination
- those who have taken part or are currently taking part in a clinical trial for a COVID-19 vaccine
- those who do not have direct, face to face contact with a service user, for example, those providing care remotely, such as through triage or telephone consultations or managerial staff working in sites apart from patient areas
- those providing care as part of a shared lives agreement

Shared Lives caring arrangements are excluded from the requirements because the Shared Lives caring model is different from other forms of care as it involves the care recipient living in the home of the carer. In many cases, care recipients have lived in their homes for decades with people they view as their extended families. We would nevertheless urge all Shared Lives carers to take up the offer of vaccination.

Those newly joining the workforce will also need to be vaccinated in order to be deployed by a CQC registered person. The registered person must only deploy those who have had their first dose of vaccination, with a second dose within 10 weeks. This approach is intended to help balance the requirements of the policy with workforce pressures in health and care services.

It will be the responsibility of the CQC-registered person, either the service provider or registered manager, to ensure that they only deploy those who have provided evidence that they have been vaccinated against COVID-19. For health and care workers who may be exempt, the CQC-registered person must have seen evidence of their medical exemption before they can deliver care.

It is important to balance the risk of COVID-19 this winter with the need for time for employers to put in place processes and communications with workers, as well as provide sufficient time for workers to get COVID-19 vaccinations. Our approach, therefore, is to provide a twelve-week grace period to allow time for providers to engage with workers, while still moving quickly enough to protect patients and service users as soon as possible.

We fully recognise there are concerns about the impact of implementing vaccination requirements at a time of significant pressure on services this winter. Therefore, subject to parliamentary passage, these regulations will not come into force until 1st April 2022 in order to provide the health and care sector with enough time to implement the requirement and help minimise risks to workforce capacity over the winter period.

COVID-19 continues to be a reality across the country. Now we have effective COVID-19 vaccination, we have a duty to ensure it is taken up to protect all patients and service users.

The government has considered the concerns raised in relation to introducing flu vaccination requirements. The flu programme runs between October and March with most flu vaccinations happening October and January. Due to the need to balance this with the time necessary for health and social care to implement the regulations, the government has decided not to introduce vaccination requirements for flu at this time.

The government will keep this under review following this winter and ahead of winter 2022/23.

Methodology

The survey hosted on GOV.UK comprised of closed-ended (quantitative) and open-ended (qualitative) questions. We also received a number of off-platform responses via email which, unless they specifically referred to any of the closed-format consultation questions, were analysed alongside the open-ended responses.

Descriptive statistics of the quantitative responses were produced, which are used to describe and summarise the characteristics of the consultation responses, not to make inference or prediction, or assess the interaction between variables. For each question, distributions of responses were calculated as percentages of those who provided an answer to that question. Responses were also broken down by:

- type of respondent (for example, members of the public, a representative organisation or body, current service users or their friends/family/carers)
- age
- ethnic group
- sex
- religion
- area of the UK and/or English region

Responses to the consultation are not representative of the groups referenced, but only of those who chose to respond to the consultation. Where particular groups are referred to or compared for example, *members of the public are most likely to say…* this refers only to members of the public responding to the consultation and cannot be taken to represent the views of the public more generally. As such, statistical significance testing has not been used to analyse results. Differences between responding groups have been highlighted using judgement.

We have assumed in analysis that respondents submitted responses in good faith which, if given, accurately represent their characteristics and their view. For example, we take at face value those selecting ‘member of health workforce – registered nurse’ are indeed from this group, as verification was not sought.

For ease of reading and consistency with the care home vaccination consultation, unless specified otherwise, we have aggregated positive or negative responses. For example, if 28% were unsupportive and 5% slightly unsupportive, we have written this as ‘33% unsupportive’. These aggregated figures are derived from the

frequencies rather than the rounded percentages. In most cases, this would result in the same figure, but may in some cases result in a one or two percentage point difference from adding together rounded percentages.

Accompanying data tables for COVID-19 and flu have been published alongside the consultation response. These data tables present full breakdowns for each quantitative question in the consultation and provide the data used in the analysis section. We have also published a set of data comparing the demographics of the responses to the consultation to the English population and English workforce demographics.

The number of respondents in each of the categories is set out in the accompanying Excel tables.

The consultation also included 20 open-ended questions where respondents could provide free text responses. Across all these questions, around 8.3 million words were received in approximately 250,000 free text responses. This was in addition to ‘other please specify’ responses which were given to add to pre-defined options shown to respondents.

Responses from key health and social care organisations were identified for manual review in their entirety (including those submitted via email) using thematic analysis to code into themes via an iterative process with a team of seven analysts. These are referred to in the analysis as ‘stakeholders’ or ‘stakeholder organisations’. A random sample of all respondents’ free text responses for each of the open format questions was also taken and reviewed via the same approach to identify any further themes raised in the responses. Where free text questions followed a quantitative question (for example, *please explain your answer [to the previous question]*), these responses were understood and analysed in context of their preceding quantitative response.

Whilst qualitative analysis is not intended to show exactly how many people held a certain view, we have endeavoured to provide an indication of the weight of opinion in responses, using words such as ‘many’, ‘some’, ‘several’, or ‘a few’.

Individual quotes have been used, where appropriate, to help illustrate themes. These were selected either as being typical of the responses received, or that they were particularly clear examples of the theme. Quotes are presented anonymously by removing information that could potentially identify them.

Detailed government response to the issues raised

Flu

Overall, in the consultation responses and in the stakeholder roundtables, there was less support for proposals to make flu vaccination a condition of deployment. Differences were raised by stakeholders in relation to virus transmissibility and impact and the different efficacy of the vaccines. We also recognise the different emphasis in COVID-19 and flu national vaccination programmes to date.

Given these concerns, and the practical seasonal timing of flu supply, with the vast majority of flu doses administered by January, the government has decided not to take forward regulation making flu vaccination a condition of deployment.

The government will keep this decision under review following this winter and will act to protect those who are vulnerable if necessary.

This consultation response below therefore focuses on COVID-19 vaccination as a condition of deployment in health and social care.

Change 1: We are limiting the scope of the policy to focus on COVID-19 vaccination only.

Proposed legislative change

Respondents were asked about their preference on the vaccination status of the people providing health and social care. The responses showed a range of opinions, as reflected in the care home consultation and in stakeholder engagement. Overall, 29% of respondents were supportive of the recommendations on COVID-19 vaccination, while 65% were not supportive. This is similar to responses seen in the care homes consultation (57% not supportive).

Support varied by type of respondent, but managers of healthcare or social care services were most likely to support the policy (56% supportive in both healthcare and social care, compared to 37% not supportive in healthcare and 38% not supportive in social care). This is significant as these are the people most likely to face implementation challenges through the proposed changes, but who can also

balance this against the rationale and benefits. Organisations providing health or care services were fairly split in their support.

Some stakeholders, the majority being in the social care sector, acknowledged the importance of parity between healthcare and social care. This was not only for parity of esteem between health and social care, but also to avoid the potential for workers to seek to move between sectors or roles, purely on the basis of vaccination requirements.

When looking at responses from the workforce, 41% felt strongly that they and their colleagues should be vaccinated against COVID-19, which was the highest proportion. Medical practitioners were the most supportive of the proposals in both healthcare and social care (52% supportive).

A majority of the responses from the public (81%) were unsupportive of the policy, however, other earlier data including a survey from Ipsos MORI, has shown support (79%) for introducing vaccination requirements for health and care workers.

A number of respondents raised concerns about vaccine safety, efficacy and potential side effects. They suggested we could do more to inform and reassure the workforce on these points. In response, we want to emphasise that vaccines are the best way to protect people from COVID-19 and have saved thousands of lives. Any vaccine available in the UK has been approved by the independent regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), only when it has met robust standards of effectiveness, safety and quality. Approved COVID-19 vaccines are monitored continuously after roll-out, by the MHRA and UKHSA, to ensure that the benefit of the vaccines continues to outweigh any risk, and to review vaccine effectiveness in response to new variants of concern. We have already delivered a huge programme of support to workers across the country regarding the benefits of COVID-19 vaccination and will continue to deliver this to ensure workers remain informed and supported. Further details are set out in the section on implementation and impacts.

Some respondents who did not support the proposed policy had strongly held beliefs that workers should have freedom of choice in relation to vaccination. The government recognises those concerns. Workers will retain autonomy over their decisions about vaccination. The regulations will put a duty on registered providers or managers to ensure that they provide care that is safe, including by having evidence that the workers they deploy have been vaccinated. We never again want to return to a position of widespread COVID-19 outbreaks in the health and social care sector. Vaccination is a safe and effective way of preventing the spread of COVID-19. It is essential that all those who can have the vaccine do so, in order to protect people in their care who are at risk from COVID-19.

In considering the evidence of the impact of vaccination on COVID-19 infection, we see a clear public health rationale to protect those receiving health and social care, who may be most at risk from COVID-19 and its complications, by driving vaccination uptake in those deployed to deliver CQC-regulated activity. We also note that significant parts of the health and social care sector (providers and workforce) do support the proposal.

It is the government's view that the clear public health evidence provides a strong foundation on which to proceed with the policy. In light of the consultation responses we have also carefully considered how to ensure that the policy is proportionate and have provided exemptions where appropriate, including medical exemptions.

Policy scope

Who is in scope

We proposed that a requirement to be vaccinated would apply to all those that are deployed in respect of a CQC regulated activity, who have direct, face-to-face contact with service users.

These workers would be most likely to interact with vulnerable people receiving care in health and social care settings including, but not limited to, hospitals, GP practices and also in a person’s home.

The consultation sought views on this scope and asked whether there were other workers who should be included within the scope of the vaccination requirements.

Almost half of respondents (49%) considered that there are other people deployed in healthcare or social care settings, in addition to those undertaking direct treatment or personal care, that should be included within the scope of a requirement to have a COVID-19 vaccine.

Managers of healthcare or social care services were most likely to agree (64%), followed by organisations providing health or care services (59%).

Stakeholders also raised the benefits of a single approach across clinical and non-clinical staff and questioned the rationale of excluding some workers who also have contact with service users.

“the COVID-19 pandemic has challenged previously defined definitions of front line and corporate/office staff. People in all roles have been required to support and enable front line delivery in a variety of ways and there is concern that a two-tier

approach may not support the practical operation of services which require increased flexibility. It is also difficult to communicate a clear rationale to staff as to why those who do not undertake direct treatment or personal care as part of a CQC regulated activity but still have contact with patients and other staff do not require vaccination"

We agree with these concerns and have therefore will include non-clinical workers who come into social contact with patients and service users as part of a CQC-regulated activity within scope of the requirements. This includes, but is not limited to receptionists, ward clerks, porters and cleaners.

As set out during consultation, these requirements will apply to CQC-regulated activities whether they are publicly or privately funded. The intention is for the requirement to apply equally where a regulated activity is delivered through agency workers, volunteers or trainees, or contracted to another provider.

We have considered whether any regulated activities should be out of scope of the regulations. Based on stakeholder feedback we have decided that Shared Lives caring arrangements will not be in scope of the regulations. The Shared Lives caring model is different from other forms of care as it involves the care recipient living in the home of the carer. In many cases, care recipients have lived in their homes for decades with people they view as their extended families. This means that vaccination requirements will not apply where the provision of a CQC-regulated activity is part of a shared lives agreement.

We would nevertheless urge all Shared Lives carers to take up the offer of vaccination.

We have also considered whether some CQC-regulated activities carried on in residential or inpatient settings (for example, residential recovery services for drugs and alcohol, hospices, and registered extra care and supported living services) should be in scope of the care home requirements (all those that enter the setting are required to be vaccinated). While there was some support for this approach, we have at this time chosen not to include other settings within the care home requirements, given the expanded approach set out above but government will keep this decision under review. We have also given careful thought to the role of 'essential care givers' – those friends or family who have agreed with the registered person that they will visit regularly and provide personal care. Some respondents felt that the most important criterion determining whether vaccination should be required was the closeness of contact and the length of the interaction, which might apply to this group. However, our intention is to follow the policy set out in response to the previous consultation in relation to care homes, where these people were not in scope. We do not want to cause challenges where friends and family no longer feel

able to support their loved ones. We are therefore not extending this policy to essential care givers.

We will also not be extending this policy to friends and family members who visit people in health and social care settings or a person's home. While we would still strongly encourage friends and family members who are visiting health and social care settings to get there COVID-19 vaccination as soon as possible if they haven't already, introducing this requirement could again cause distress to those patients or service users in need of visits, comfort and support.

Change 2: We will include within scope of the policy those non-clinical ancillary workers who may have direct, face to face contact with patients but are not directly involved in patient care.

Change 3: Where the provision of a CQC-regulated activity is part of a Shared Lives agreement the vaccination requirements will not apply.

International workers

Our health and social care workforce in England is already facing significant pressures, with recruitment and retention a priority to ensure our services can continue to deliver high quality care for patients and service users. The government has committed to increasing health and social care workforce, including a commitment to deliver 50,000 more nurses by the end of this Parliament.

An important element of recruitment remains recruiting workers from overseas. While this is important in boosting our resources, it is also important to ensure that these workers have protection against COVID-19, for their own protection and for the people they will be caring for.

Our approach, therefore, will be to require those who have been vaccinated abroad to provide evidence of their vaccination status and, where necessary, have a top-up dose with a UK authorised vaccine consistent with the UKHSA's guidance on vaccines. We will update requirements for those entering care homes to align with this approach. To avoid doubt, mixed doses (that is, where different vaccines have been administered to complete the dose schedule), will be accepted for the purposes of the vaccination requirements.

Further guidance on this point will be provided within implementation guidance.

Change 4: We will set out specific requirements for those vaccinated abroad, including where necessary, a top-up dose with a UK authorised vaccine, consistent with UKHSA's guidance on vaccination doses and mixed vaccines.

Booster vaccines

Our approach will not require boosters in addition to the full course of vaccination. All health and social care providers and the workers those providers deploy are encouraged to follow national guidance regarding boosters and the need for ongoing protection.

We will keep this decision under review during 2022/23.

Exemptions

We note that the majority of respondents (61%) agreed with our proposal in the consultation to grant exemptions from COVID-19 vaccination only on medical grounds. We also recognise that a significant proportion of all respondents feel that there should be a broader list of exemptions (for example to those who are pregnant, breastfeeding or hoping to conceive; and on religious grounds).

We have carefully considered the different options, to strike a balance between the range of views submitted, on what is a complex issue. Permitting limited exemptions will help to ensure that the requirement does not exclude, or impose a disproportionate burden on, certain individuals. It is also important to ensure that the scope of exemptions does not undermine the public health benefits of the policy or create a system that can be used by individuals to circumvent the requirement.

We will provide exemptions allowing registered persons to continue to use workers for whom vaccination is not clinically appropriate (for example a pre-existing diagnosis of anaphylaxis). We will publish guidance giving more detail about exemptions, which will reflect the Green Book on Immunisation against infectious (COVID-19: the green book, chapter 14a) and clinical advice from the Joint Committee on Vaccination and Immunisation (JCVI). For those who are medically exempt, who can still be deployed, we will work with stakeholders to produce guidance on steps that should be taken to mitigate the risk of COVID-19 transmission to vulnerable patients and service users.

We have considered exemptions for those who refuse the vaccine due to religious beliefs and have decided not to provide this exemption. This type of exemption would be difficult to implement or prove and would likely significantly reduce the

impact of the policy in achieving its aims of increasing levels of protection for both the workforce and patients. It may also cause tension between those who have been exempted and other workers who have been required to be vaccinated as a condition of deployment.

Clinical trials

In line with clinical advice, those who are taking part or have previously taken part in a clinical trial for a COVID-19 vaccine will be exempt from the requirement. Regulations and the accompanying guidance will set out in more detail on which clinical trials will be recognised in order to be granted an exemption.

Under 18s

As part of the consultation we asked whether vaccination as a condition of deployment should apply to workers who are under the age of 18. Earlier in the pandemic, the evidence of the benefits compared to risks of harm involved in vaccination for people aged 15 to 18 was not conclusive. However, in August 2021, the Joint Committee on Vaccination and Immunisation (JCVI) recommended that all 16 to 17-year-olds should be offered a first dose of the Pfizer-BNT162b2 vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17-year-olds who are in 'at-risk' groups.

The responses to the consultation on the question of COVID-19 vaccination for under 18s showed 26% of respondents were supportive, while 68% were not supportive. There was greater support from managers at 50% and organisations at 39%, while there was most opposition from members of the public at 84%.

At this point in time we have decided not to make it a requirement for those under the age of 18 to be vaccinated in order to undertake a CQC regulated activity. However, this decision will be kept under review.

Pregnancy and fertility

We have considered the concerns raised by respondents about pregnancy and fertility in relation to vaccination. The scientific advice is that you can be vaccinated against COVID-19 if you are pregnant, breastfeeding, trying for a baby or might get pregnant in the future. COVID-19 vaccines offer pregnant women the best protection against COVID-19 disease which can be serious in later pregnancy for some women. There is no evidence that COVID-19 vaccines have any effect on fertility or chances of becoming pregnant. The Royal College of Obstetricians, Royal College of

Midwives and the UK Tetralogy Service consider COVID vaccination to be safe. They recommend that pregnant women get vaccinated against COVID-19.

The JCVI has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. In the USA, around 90,000 pregnant women have been vaccinated mainly with Pfizer and Moderna vaccines and no safety concerns have been identified.

Although the overall risk from COVID-19 disease in pregnant women and their new babies is low, in later pregnancy some women may become seriously unwell and need hospital treatment. This is why it is important that pregnant women have their vaccination as soon as they are invited.

The JCVI has recommended that the vaccines can be received whilst breastfeeding, in line with recommendations from the USA and the World Health Organization.

Clinicians have been clear that vaccines are safe for the majority of pregnant women, however we recognise that in some circumstances, vaccination may not be appropriate during pregnancy.

There are already arrangements in place for demonstrating COVID-19 vaccination status with short-term exemptions available for those with short-term medical conditions and as an option that some pregnant women may choose to take. For pregnant women the exemption expires 16 weeks post-partum. This will allow them to become fully vaccinated after birth. We will set these arrangements out in the guidance on exemptions supporting implementation of the policy.

Implementation and impacts

While, overall, respondents were split in their views on whether the policy would be easy or difficult for managers to implement, we recognise the concerns that small providers will find the policy much more challenging to implement. We are exploring steps to mitigate this risk, including working with NHS England and other partners to ensure that providers will have access to guidance and resources to support implementation.

We also recognise the need for a suitable grace period for implementation. Our approach will be to provide for a 12-week grace period from when the regulations are made to when the regulations enter into force, in order to give employers and workers time to meet the new regulatory requirements.

We note that there is very strong support among managers and workers for the use of a digital solution or app to demonstrate vaccination status. We have recognised

this and are exploring the option to evidence vaccination status via the NHS App. We are also working on a simple process to allow people to prove their exemption status. We intend to provide a web-based solution for people who do not have access to the app, as well as a non-digital solution, in the form of a letter.

DHSC will continue to liaise with NHS England, local authorities and stakeholders to inform the guidance needed to smooth the processes for implementation.

Impacts

Despite COVID-19 vaccines undergoing strict safety assurances before they are authorised, it is clear that vaccine hesitancy exists as a real concern for some, particularly within certain groups of our society. As such, there is a risk that some health and social care workers who have direct, face-to-face contact with service users may continue to decide not to be vaccinated and therefore, the registered person would not be able to deploy the worker in respect of a regulated activity. A reduction in the number of health and social care workers could, in turn, put additional pressures on the social and healthcare sectors. However, this risk needs to be weighed up against the risk of COVID-19 being transmitted from health and social care workers to the most vulnerable as they receive care, which could endanger their lives.

We have published an impact statement which provides further an analytical assessment of the estimated impacts of this policy. The government intends to publish a full Impact Assessment as soon as possible.

To help mitigate the risk of an impact on capacity during the winter period, the regulations, subject to parliamentary passage, will not come into force until 1st April 2022. However, it remains that the best mitigation will be to further encourage the uptake of vaccination by health and care workers ahead of this.

We will continue to promote access for health and care workers and other people who are within scope of the policy to make it as easy as possible to take up the offer of vaccination.

The NHS has focused in recent months on a targeted approach to improve uptake in hesitant groups by undertaking campaigns directed towards midwifery workers, black, Asian, and minority ethnic (BAME) groups and students, as well as using the booster campaign as an opportunity to reengage workers. In order to maximise uptake over the winter months, the NHS's plan includes the following:

- further increase engagement with targeted communities where uptake is the lowest, including extensive work with BAME and faith networks to encourage workers to receive the vaccine

- use Chief Professional Officers to encourage staff vaccination uptake for all NHS staff in a communications push

- the use of 1-2-1 conversations for all unvaccinated NHS staff with their line manager, with clear guidance on how to do this. This was associated with an increase in vaccine uptake by 10% in phase 1

- increasing number and diversity of opportunities to receive the vaccine. Using the booster campaign to make the most of walk-ins, pop-ups, and other ways to make getting the vaccine as easy as possible

In order to build confidence in the vaccine within the social care workforce, we have delivered an extensive communications programme which includes:

- bespoke communications materials (posters, videos, leaflets, and shareable social media assets) shared across our CARE App, a weekly newsletter, and Adult Social Care and Department of Health and Social Care social channels

- a paid advertising campaign targeting social care workers with digital advertising to build vaccine confidence and encourage booking via the National Booking Service

- a stakeholder toolkit (Q&As, guidance and communications materials) which is updated weekly

- positive messaging using influencers, leaders and care home workers who have already been vaccinated to boost confidence and tackle misinformation

- content in different languages and briefings with different faith groups who have expressed interest in co-creating vaccine content and acting as ambassadors

We continue to work closely with partners and stakeholders to identify and progress further actions at local, regional and national level to increase vaccine uptake among social care staff.

We will also continue to work closely with health and care providers and their representative organisations to keep workforce capacity under review, and to ensure that pressures on health and social care sectors are mitigated.

We have also published an Equality Impact Assessment alongside this response and will carefully track the impact of the policy on vaccine uptake.

Data protection

To address questions raised by providers regarding the interaction with data protection law, we will ensure that nothing in the regulations authorises the processing of personal data in a manner inconsistent with the Data Protection Act 2018.

Analysis

The full data used in this section can be found in the accompanying Excel tables.

Over 34,900 responses were received to the consultation. Those identifying as a member of the health and care workforce delivery services to patients or clients made up the largest proportion of respondents (45%). Members of the public were the second largest group responding (33%).

Proposed legislative change

***Question**: Those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a healthcare or social care setting (including in someone's home) must have a COVID-19 and flu vaccination?*

COVID-19 vaccination in healthcare

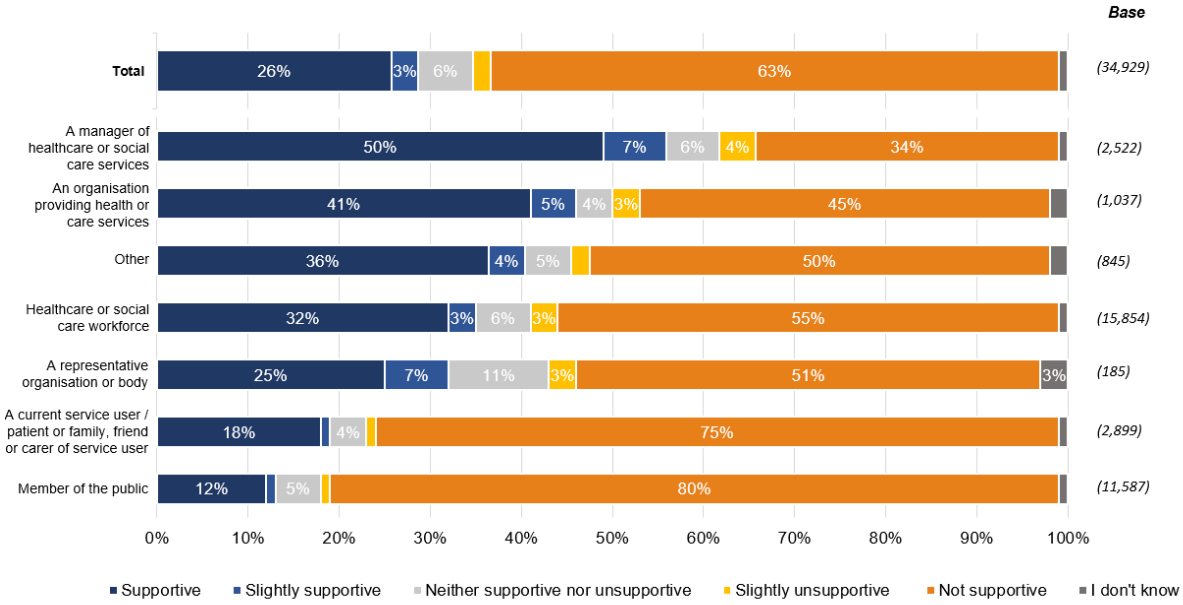
When considering if those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a healthcare setting must have a COVID-19 vaccination, just under two in three respondents did not support the proposed policy (65% not supportive or slightly unsupportive), and just under three in ten (29%) said they were supportive or slightly supportive.

Support differed by type of respondent. Managers of healthcare or social care services were the most likely to support the policy and were the only respondent group to be more supportive of the policy compared to unsupportive (56% supportive or slightly supportive; 37% not supportive or slightly unsupportive). Members of the public were least likely to express support, with one in ten in support (13% supportive or slightly supportive) compared to four in five (81% not supportive or slightly unsupportive) who were not supportive. Members of the health and care workforce were more likely to be unsupportive (58% not supportive or slightly unsupportive) than supportive (35% supportive or slightly supportive). Organisations providing health or care services were fairly split in their support, with 46% supportive or slightly supportive and 48% not supportive or slightly unsupportive. The variation in support by type of respondents was similar for COVID-19 vaccination if providing social care services.

Respondents to the consultation expressed strong feelings on this subject, with the proportion who were supportive or not supportive being substantially greater than the

proportion who were slightly supportive or slightly unsupportive. This was the case for both COVID-19 and flu vaccinations in both healthcare and social care settings.

Figure 1: Which of the following best describes your opinion of the requirement: Those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a healthcare setting (including in someone's home) must have a COVID-19 vaccination?

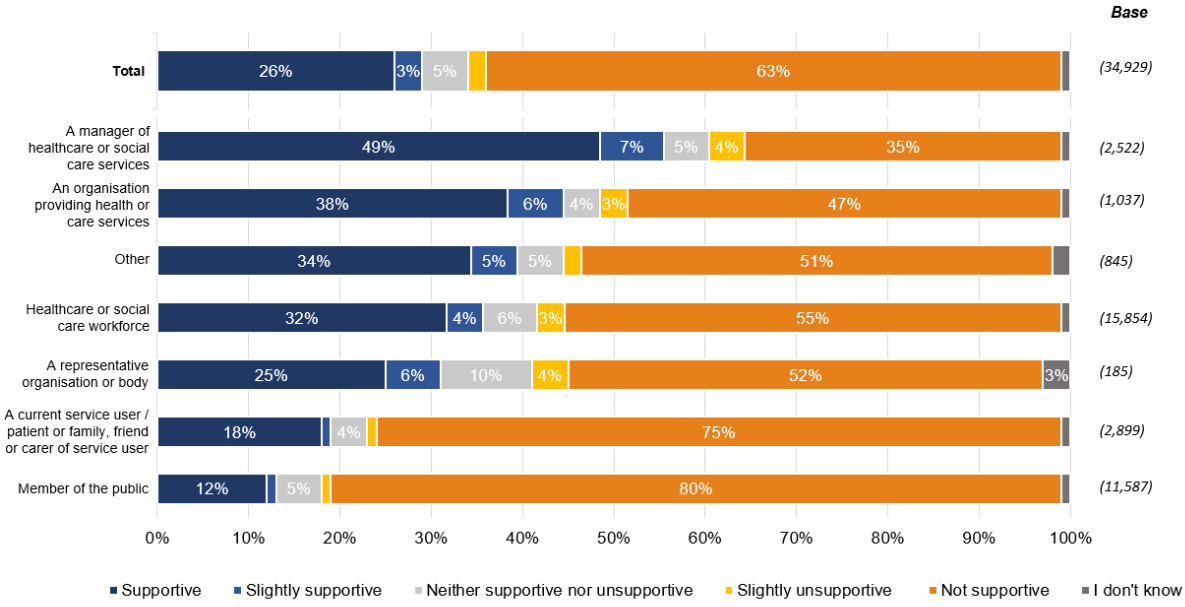


Data labels suppressed for categories of 2% or less, where %s do not add to 100 this is due to rounding.

COVID-19 vaccination in social care

When considering if those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a social care setting must have a COVID-19 vaccination, just under two in three respondents did not support the proposed policy (65% not supportive or slightly unsupportive), and just under three in ten (29%) said they were supportive or slightly supportive.

Figure 2: Which of the following best describes your opinion of the requirement: Those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a social care setting (including in someone's home) must have a COVID-19 vaccination?

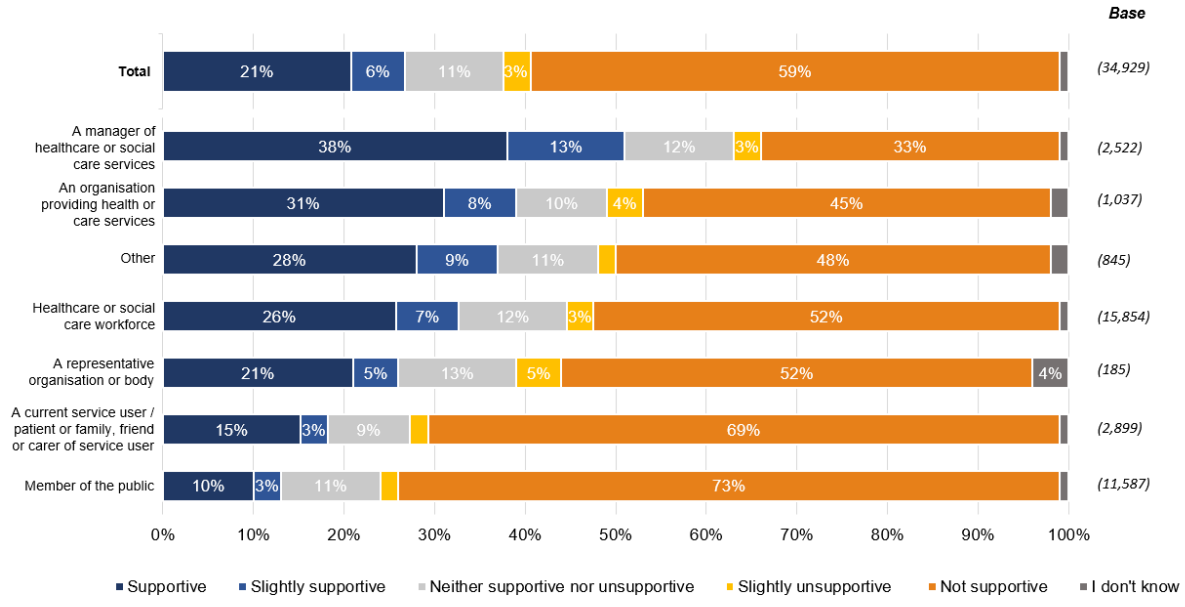


Data labels suppressed for categories of 2% or less, where %s do not add to 100 this is due to rounding.

Flu vaccination in healthcare

When considering if those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a healthcare setting must have a flu vaccination, around three in five respondents did not support the proposed policy (61% not supportive or slightly unsupportive), and one in four (27%) said they were supportive or slightly supportive.

Figure 3: Which of the following best describes your opinion of the requirement: Those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a healthcare setting (including in someone's home) must have a Flu vaccination?

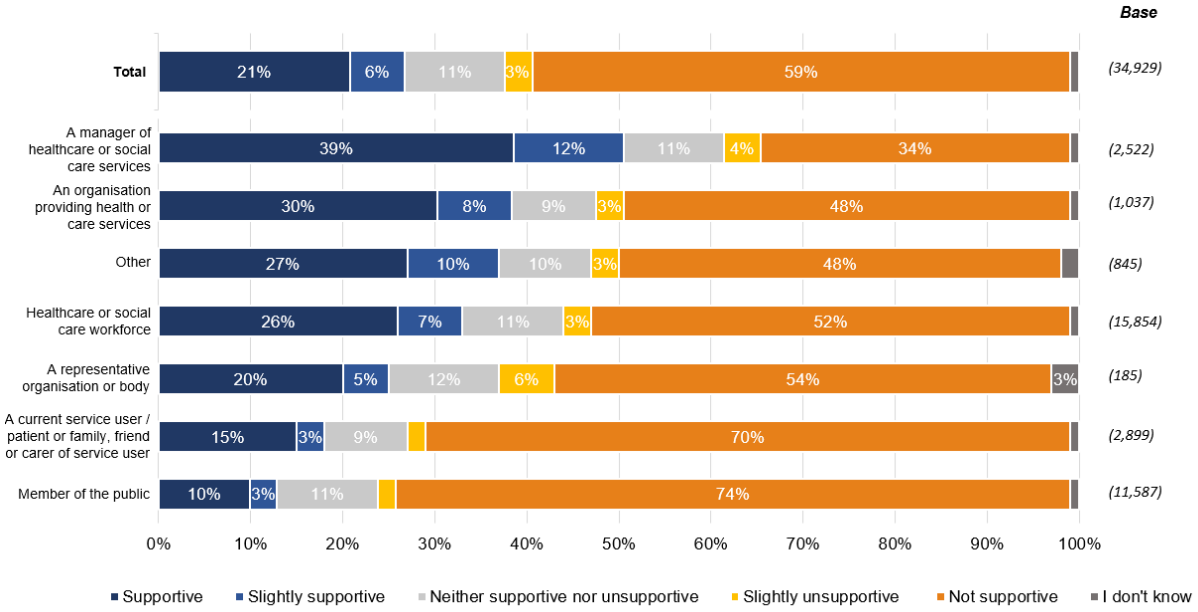


Data labels suppressed for categories of 2% or less, where %s do not add to 100 this is due to rounding.

Flu vaccination in social care

When considering if those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a social care setting must have a flu vaccination, around three in five respondents did not support the proposed policy (62% not supportive or slightly unsupportive), and one in four (26%) said they were supportive or slightly supportive.

Figure 4: Which of the following best describes your opinion of the requirement: Those deployed to undertake direct treatment or personal care as part of a CQC regulated activity in a social care setting (including in someone's home) must have a Flu vaccination?



Data labels suppressed for categories of 2% or less, where %s do not add to 100 this is due to rounding.

Respondents were provided with a free text box in conjunction with the closed questions above, so that they were able to explain their responses in more detail. Among those who did not support the policy relating to the COVID-19 vaccine, reasons mentioned were that the policy is potentially an infringement on the human rights of workers and that workers should be free to choose whether to have the vaccine, together with concerns about its morality, legality and impact on people's bodily autonomy. A notable number of respondents expressed concerns about the safety of the vaccine.

Other concerns related to the vaccine's effectiveness in preventing the spread of COVID-19. A notable number of respondents mentioned concerns that the legislation could exacerbate health and social care pressures, such as staffing levels and resourcing demands.

Those who supported the policy tended to mention the protection of vulnerable people and the belief that health and social care workers have a duty of care to patients as reasons for their support.

Reasons for support of the policy and reasons for not supporting the policy were similar for flu vaccination, with some specific flu-specific comments. Some respondents questioned how proportionate making flu vaccination a condition of deployment would be, relating to costs versus benefits when considering severity of the virus. Others questioned why making flu vaccination a condition of deployment would be necessary now, considering that flu has been present for a long time but there has never been a regulatory condition in relation to it.

Views from stakeholders that responded to the consultation

Stakeholder responses tended to either focus on COVID-19 vaccination, or did not make a distinction between COVID-19 vaccination and flu vaccination. The analysis below focuses on COVID-19 vaccination, unless flu is expressed explicitly.

The benefits of COVID-19 and flu vaccination were universally acknowledged by stakeholders and there was support for maximising vaccination rates irrespective of overall views of the policy. The majority of stakeholders said they encourage their staff to get vaccinated.

> *"There is broad agreement that ensuring a high level of vaccination among health and social workers is important in order to protect patients and members of the staff."*

However, some questioned whether making vaccination a condition of deployment would be a proportionate, fair or effective strategy to achieve greater protection from COVID-19.

Responses from stakeholders who were unsupportive of the requirement fell broadly into three themes:

i. Concerns about workforce impact/service delivery

Many stakeholders expressed concerns that the policy would exacerbate existing sector pressures in healthcare and social, regardless of their support towards the policy. The majority of stakeholders cited concern that the policy would negatively impact on staffing levels. Concerns included staff leaving due to the requirement to be vaccinated, as well as the policy making the recruitment of staff difficult in the future. Stakeholders also highlighted the potential loss of skilled and experienced specialised staff, of which it would be hard to replace.

Some stakeholders suggested that the policy could cause difficulties and unnecessary disputes at local and national level. Concern of higher administrative burden was also noted, as resource for tracking staff vaccination status would need to be accounted for.

Many stakeholders noted concerns about the implementation of the policy during the winter period, with concerns that the unintended consequences of the policy would further exacerbate projected winter pressures. Some stakeholders suggested that if a decision were to be made to take the proposal forward, then the policy should be delayed until the latter half of 2022, or at least after winter, to account for these pressures, as well as other factors.

> *“If government were to proceed and implement the policy over the winter period, there is a significant risk that it will exacerbate existing workforce shortages, as well as divert management time away from the response to winter pressures and the recovery of services.”*

It was also noted by stakeholders that the policy in the context of existing sector pressures could impact on patient care if it were to impact on workforce levels, as well as risk widening inequality.

ii. Ethical, moral, and legal questions

Many stakeholders expressed unease over the ethical implications of the policy, highlighting issues relating to freedom of choice, and the principle of voluntary consent to medical treatment. The legal implications of the policy for organisations were also raised, and the potential for contractual disputes with employees. A few had concerns about data privacy and GDPR with respect to medical records and proof of vaccination.

> *"All those working in health and social care with vulnerable people should accept a primary responsibility to avoid preventable harm to the people whom they are there to care for. Such moral duty, however, does not necessarily justify a legal obligation to have a vaccination."*

Some stakeholders highlighted the potentially disproportionate impact the policy may have on some ethnic minorities.

> *“…vaccination as a condition of employment may further marginalise those who are currently vaccine hesitant – such as Black and Minority Ethnic staff.”*

However, distinct from the non-stakeholder responses, stakeholders did not generally raise questions about the use of the vaccines themselves.

iii. Effectiveness and proportionality

Many stakeholders noted that vaccination is not entirely effective against transmission and infection, therefore questioning the proportionality of making vaccination a condition of deployment and the impact the policy would have on improving health outcomes.

> *"As the delta variant has emerged as the prevailing variant, so the science has confirmed that vaccination of an individual is less effective in preventing transmission to others. This being the case, the argument for compelling staff to take the jab to protect others is significantly diminished."*

Some highlighted that other measures are needed alongside vaccination for infection control. Reducing the impact of COVID-19 with other measures in conjunction with voluntary vaccination was an alternative approach mentioned by some responding stakeholders, such as regular testing.

> *"A further concern that we have with these proposals – which is informed more generally by other UK Government policies - is that vaccination is sometimes viewed as a silver bullet in the effort to curb infection rates both in hospitals and in the community, rather than as an extremely effective intervention to be employed alongside others."*

Several responses questioned the proportionality of the policy as voluntary vaccination amongst staff in the health and social care sectors is high. Suggestions of less intrusive means of increasing vaccination uptake were offered and were suggested to be more effective at increasing vaccination uptake.

Examples of such interventions included providing more education, encouraging communication, support from experienced peers, and easing access to the vaccine for example making the vaccine easily accessible during working hours. It was noted by some stakeholders that the consultation proposal required more evidence that it would be more effective than approaches to encourage further voluntary vaccination.

There were concerns that the policy could undermine trust in vaccination and have the unintended consequence of increasing vaccine hesitancy.

"The risk that the policy might result an embedding or worsening of vaccine hesitancy and loss of trust needs consideration."

Some stakeholders were mixed about the proposal. Two main themes emerged from their responses:

i. Lack of consensus amongst membership

Several stakeholders canvassed opinion from their members, and these suggested that individuals even within the same organisation often held different views towards the policy. Stakeholders that were mixed or ambivalent in their support/opposition generally reflected on a lack of consensus on the policy within their own organisation.

They reflected on a tension between their central organisational objective to improve patient care and safety, and recognition of the potential for the policy to divide the workforce, and possibly be counterproductive if leading to retention challenges.

ii. Parity between care homes, wider adult social care, and healthcare

Some stakeholders, the majority being in the social care sector, acknowledged the importance of parity between healthcare and social care. These organisations who even expressed disagreement with the policy or lukewarm support often expressed support for unifying approaches across the healthcare and social care sectors. This was not only for parity of esteem between health and social care, but also to avoid potential for people to move into parts of the sector which are not subject to the regulations.

From 11 November 2021, anyone working or volunteering in a care home must provide evidence which satisfies the registered person that they have been vaccinated against COVID-19, subject to limited exceptions. Respondents stated that the rest of the healthcare and social care sector should also have a comparable condition in order to achieve parity.

> *“Legislating vaccination as a condition of deployment across healthcare would place health and social [care] on an equal footing.”*

Responses from stakeholders who were supportive about the requirement often cited the duty of care owed to patients and the safety of staff, reflecting their organisations’ objectives.

> *“We are supportive of this principle as a way of achieving the key benefits of protecting patients and staff, reducing the risk of Covid-19 transmission in*

independent healthcare facilities, and potentially lowering levels of staff sickness absence."

Similar comments and concerns were raised for flu vaccination. Some additional concerns were raised specifically relevant for flu vaccination, which included prolonged staff scepticism of flu vaccine efficacy. It was noted that flu vaccine uptake has been increasing and the proportionality of including the flu vaccine was called into question.

Question: *Which of the following best describes your opinion of the requirement: Those under the age of 18, undertaking direct treatment or personal care as part of a CQC regulated activity (in a healthcare or social care setting, including in someone's home), must have a COVID-19 and flu vaccination?*

For COVID-19 and flu vaccinations in both health care and social care settings, respondents were more likely to be unsupportive of introducing a condition of deployment for under 18-year olds than supportive. Respondents broadly had similar views on introducing vaccination as a condition of deployment for under 18-year olds as they did on the health and social care workforce in general.

Overall, two thirds of respondents (68% not supportive or slightly unsupportive) did not support that those under the age of 18, who undertake direct treatment or personal care as part of CQC regulated activity in a healthcare setting, must have a COVID-19 vaccination. One in four were supportive of this requirement (26% supportive or slightly supportive). Of those who were supportive or slightly supportive of the policy for all healthcare staff, nearly nine in ten (89%) were supportive or slightly supportive of this policy for under 18-year olds.

Similarly, when asked about the requirement for under 18-year olds for COVID-19 vaccination in social care settings, 26% were either supportive or slightly supportive and 68% were not supportive or slightly unsupportive.

When considering this requirement for flu vaccination in healthcare settings for those under 18 years of age, 25% were either supportive or slightly supportive. In comparison, 65% were not supportive or slightly unsupportive.

Similarly, when asked about the requirement for under 18-year olds for flu vaccination in social care settings, 25% were either supportive or slightly supportive and 65% were not supportive or slightly unsupportive.

For COVID-19 and flu vaccinations in both health care and social care settings, members of the public were the least likely to support the requirement for those

under the age of 18 years old. Managers of healthcare or social care services were the most supportive of the requirement for under 18s.

Views from stakeholders that responded to the consultation

The majority of stakeholders did not make a distinction between their stance on the policy for all healthcare and social care staff and those staff who are under 18 years old.

Some stakeholders identified that any condition that is applied to under 18-year olds should reflect what is approved and available for under 18-year olds in the general population.

> *"If vaccination is introduced as a condition of deployment but only one dose is recommended for under 18s (that is the second dose recommended by JCVI is not offered) then the number of doses required in legislation should reflect this. Similarly, if in future a particular type of vaccine is considered safer for younger people, this should be taken into account."*

However, a few stakeholders did have concerns about implementing the policy for those under 18 years of age. It was suggested that the policy could have an impact on future recruitment and staffing levels.

> *"Mandating either vaccine in the health and care sector might put off the under 18 group who represent the next generation workforce, therefore making future recruitment and retention more difficult for employers."*

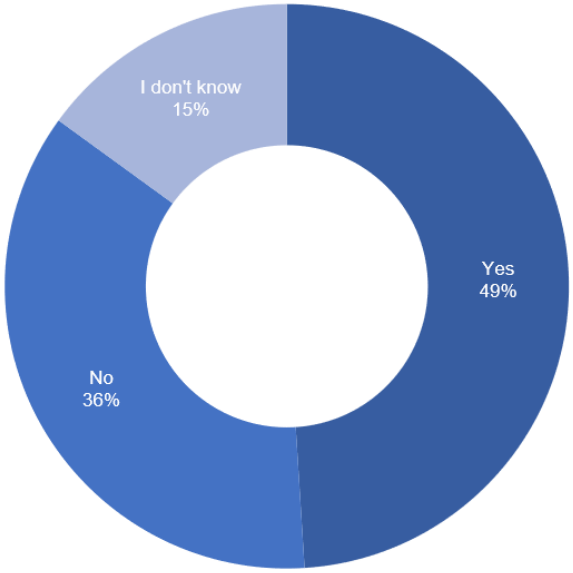
Policy scope

Question: *Do you think there are people deployed in or visiting a healthcare or social care setting (including someone's home) who do not undertake direct treatment or personal care as part of a CQC regulated activity but should also be included within the scope of a requirement to have a COVID-19 and flu vaccine?*

Almost half of respondents (49%) said that they think there are people deployed in or visiting a healthcare or social care setting (including someone's home), who do not undertake direct treatment or personal care as part of a CQC regulated activity, but should also be included within the scope of a requirement to have a COVID-19 and flu vaccine. Over a third (36%) did not think this is the case.

Managers of healthcare or social care services were most likely to agree (64%), followed by organisations providing health or care services (59%). In contrast, members of the public were the least likely to agree (36%).

Figure 5: Do you think there are people deployed in or visiting a healthcare or social care setting (including someone's home) who do not undertake direct treatment or personal care as part of a CQC regulated activity but should also be included within the scope of a requirement to have a COVID-19 and flu vaccine?

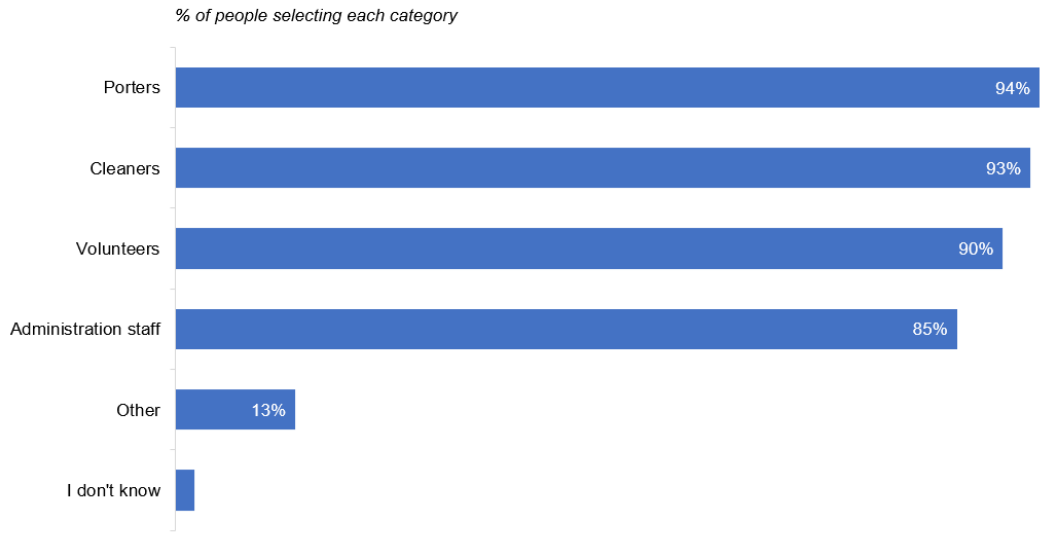


Base: All answering [Excluding those 'not supportive' of policy for both flu and COVID-19 in both healthcare and social care settings] (15,668)

Question: *Which people do you think should be covered by the scope of the requirement to have a COVID-19 vaccination and flu vaccination?*

The majority of respondents who agreed that other people should also be included within the scope of a requirement to have a COVID-19 and flu vaccine believe porters (94%) and cleaners (93%) should be in scope. A considerable number of respondents also believe volunteers (90%) and administration staff (85%) should be in scope.

Figure 6: Which people do you think should be covered by the scope of the requirement to have a COVID-19 vaccination and flu vaccination?



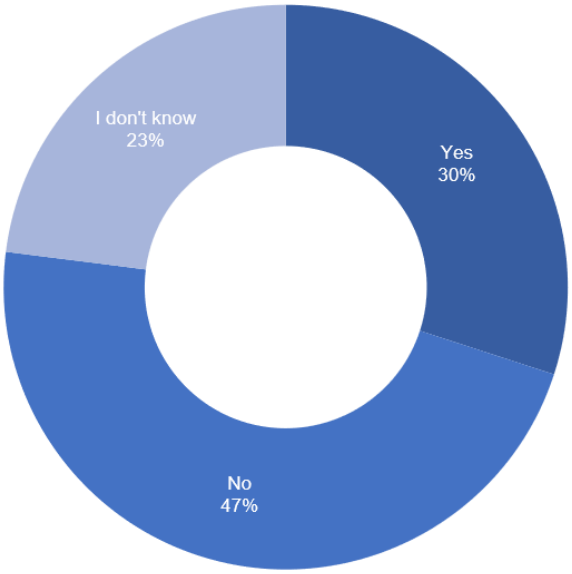
Base: All answering [Answered 'Yes' at previous question regarding if anyone else should be included in the scope of the requirement] (7,727). Data labels suppressed for categories of 2% or less.

Question: *For COVID-19 and flu vaccination are there people deployed to undertake direct treatment or personal care as part of a CQC regulated activity that should not be in scope of the policy?*

Three in ten respondents (30%) said that for COVID-19 vaccination there are people deployed to undertake direct treatment or personal care as part of a CQC regulated activity that should not be in scope of the policy. Almost half of respondents (47%) did not think this is the case. 23% said that they don't know.

Views were similar across all respondent types. Those who identified as a current service user/patient or family, friend or carer of current service user/patient were the most likely to think there are people who should not be in scope (35%), while members of the health and care workforce were the least likely to think this (29%).

Figure 7: For COVID-19 vaccination are there people deployed to undertake direct treatment or personal care as part of a CQC regulated activity that should not be in scope of the policy?



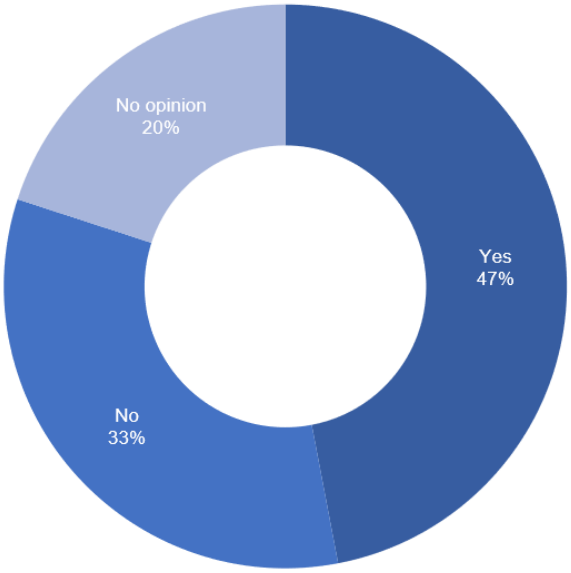
Base: All answering [Excluding those 'not supportive' of policy for both flu and COVID-19 in both healthcare and social care settings] (15,723)

Three in ten respondents (30%) said that for flu vaccination there are people deployed to undertake direct treatment or personal care as part of a CQC regulated activity that should not be in scope of the policy. Over two in five respondents (44%) did not think this is the case. (26%) said that they don't know.

Question: *Are there any other health and social care settings where an approach similar to adult care homes should be taken? (that is, all those working or volunteering in the care home must have a COVID-19 vaccination or have an exemption)*

Almost half of respondents (47%) said that there are other health and social care settings where an approach similar to adult care homes should be taken. A third of respondents do not believe this to be the case (33%).

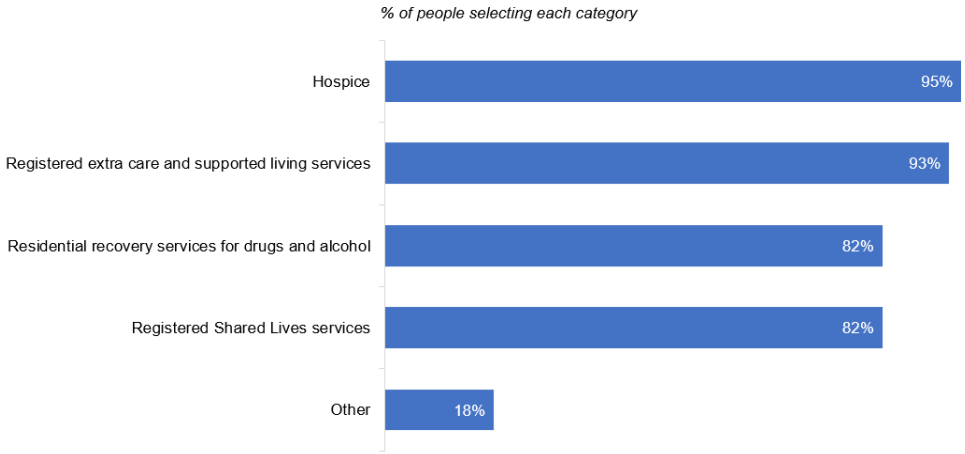
Figure 8: Are there any other health and social care settings where an approach similar to adult care homes should be taken? (that is, all those working or volunteering in the care home must have a COVID-19 vaccination or have an exemption)



Base: All answering [Excluding those 'not supportive' of policy for both flu and COVID-19 in both healthcare and social care settings] (15,653)

Of those who said that there are other health and social care settings where an approach similar to adult care homes should be taken, the majority of these respondents believe hospices (95%) is a setting for such an approach. Over nine in ten selected supported living services (93%). Over four in five believed residential recovery services for drugs and alcohol (82%) and registered shared lives services (82%) are settings for such an approach.

Figure 9: You said there are other health and social care settings where an approach similar to adult care homes should be taken (that is, all those working or volunteering in the care home must have a COVID-19 vaccination or have an exemption). Please select all that apply.



Base: All answering [question asked to those who selected 'Yes' at previous question, 'are there any other health and social care settings where an approach similar to adult care homes should be taken?'] (7404)

Exemptions

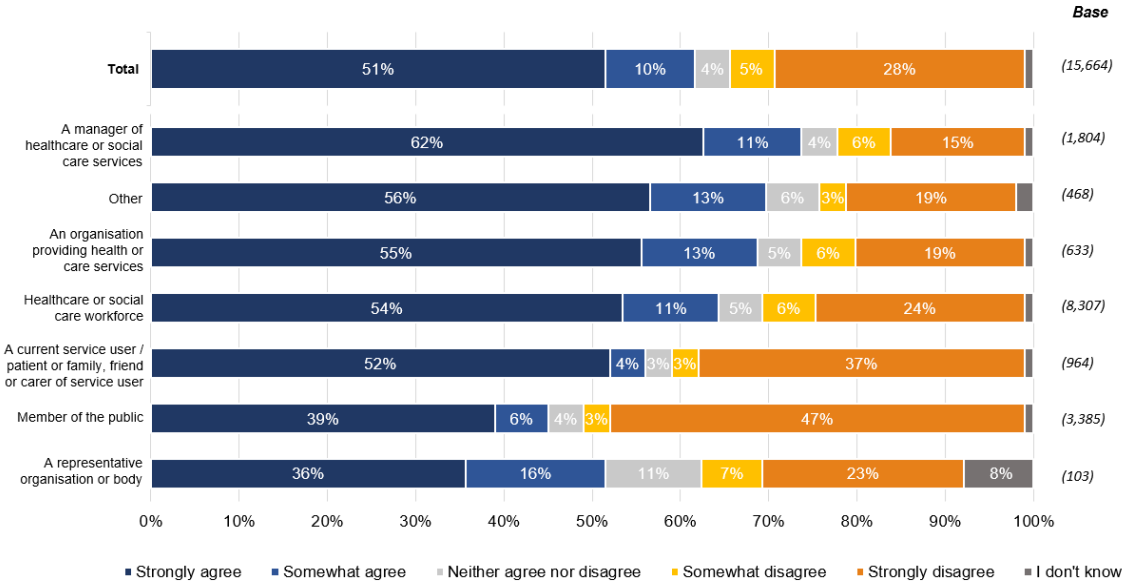
Question: *Do you agree or disagree that exemption from COVID-19 vaccination and flu vaccination should only be based on medical grounds?*

Three in five (61%) respondents agreed that exemption from COVID-19 vaccination should only be based on medical grounds. One in three (33%) respondents disagreed. Managers of healthcare or social care services were the most likely to agree (74%), whilst members of the public were least likely to agree (45%) and the most likely to disagree (51%).

When asked on what other basis, if any, should a person be exempt from COVID-19 vaccination requirements, a significant number felt that vaccination as a condition of deployment should not be introduced. Reasons for this often related to concerns of a violation of human rights and people's freedom of choice about their body.

A number of respondents mentioned other groups which they believed should be exempt. For example, these included those seeking exemption on religious, cultural or ethical grounds.

Figure 10: Do you agree or disagree that exemption from COVID-19 vaccination should only be based on medical grounds?



Data labels suppressed for categories of 2% or less, where %s do not add to 100 this is due to rounding.

For flu vaccination, almost three in five (57%) respondents agreed that exemption should only be based on medical grounds. One in three (33%) disagreed. Managers of healthcare or social care services were the most likely to agree (67%), whilst members of the public were least likely to agree (43%) and the most likely to disagree (46%).

Views from stakeholders that responded to the consultation

Generally, specific exemptions from the policy were not discussed by stakeholders. However, a notable number of stakeholders did highlight the need for exemption based on pregnancy. Some stakeholders mentioned the need for exemption from the requirement relating to particular religious, faith based or personal beliefs.

> *"Exemptions must take into account people's personal and religious beliefs as well as their mental and physical health."*

Implementation

Question: *How would you prefer to show that you have been vaccinated for both flu and COVID-19 or that you are exempt from vaccination?*

Question: *The people you deploy would need to be able to show that they had been vaccinated for both flu and COVID-19 or are exempt from vaccination. How would you prefer that they do this?*

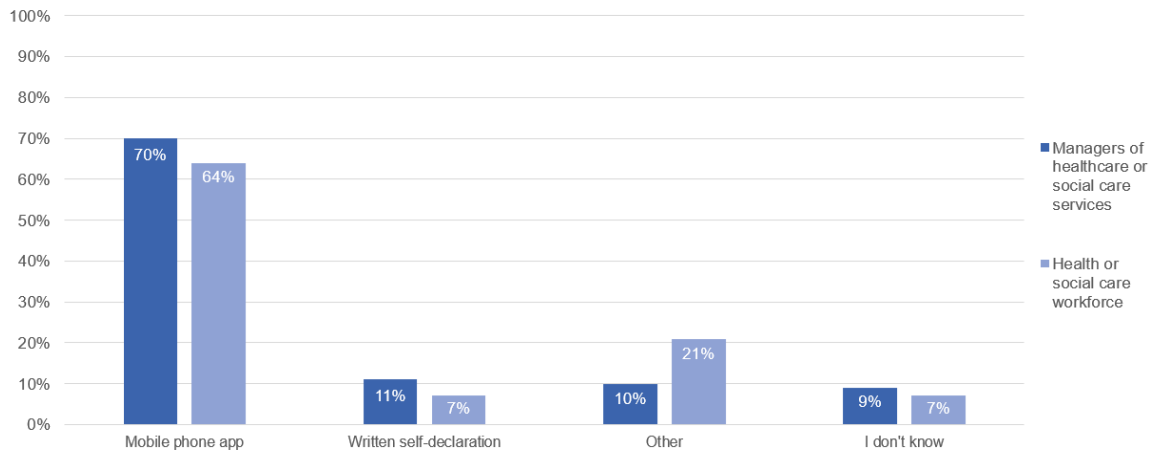
Nearly two in three (64%) health or social care staff and over two in three (70%) managers of health and social care services said they would prefer to use a mobile app to show vaccination status. Although the app was by far the most popular option, some respondents highlighted that not everyone covered by the policy would have access to a smart phone, and therefore if a mobile app were to be used, another option would also need to be available.

Under one in ten (7%) health or social care staff would prefer a written self-declaration to show their vaccination status. Just over one in ten (11%) managers of health or social care services would prefer a written declaration for the people they deploy to show their vaccination status.

Several respondents mentioned that they would prefer a physical card or ‘passport’ which could be shown to prove vaccination status.

Some respondents who identified themselves as members of the health and social care workforce stated that they believed their vaccination status was private and should not be required to be shared.

Figure 11: How would you prefer to show that you have been vaccinated for both flu and COVID-19 or that you are exempt from vaccination? The people you deploy would need to be able to show that they had been vaccinated for both flu and COVID-19 or are exempt from vaccination. How would you prefer that they do this?

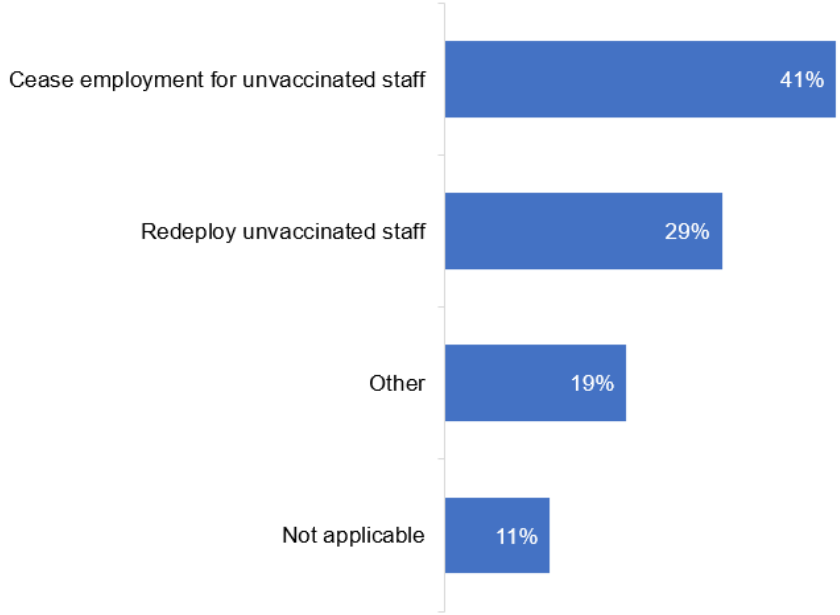


Base: All answering – Healthcare or social care workforce (7285); A manager of healthcare or social care services (1541)

Question: *Thinking about circumstances in which staff fall within a requirement to be vaccinated but remain unvaccinated, how do you anticipate you would respond?*

Managers of healthcare or social care services and organisations providing health or care services were asked how they anticipate they would respond to unvaccinated staff which fall within the requirement to be vaccinated. Two in five (41%) said that they would cease employment of unvaccinated staff. Almost three in ten (29%) said that they would redeploy unvaccinated staff.

Figure 12: Thinking about circumstances in which staff fall within a requirement to be vaccinated but remain unvaccinated, how do you anticipate you would respond?



Base: An organisation providing health or care services & A manager of healthcare or social care services (3,929)

Views from stakeholders that responded to the consultation

A number of stakeholders noted that they would want to try and redeploy staff, even when difficult. However, concerns were raised about the feasibility of this, especially considering the volume of staff the policy would affect.

> *"We will of course redeploy staff where possible, but opportunities for doing so are limited and dwarfed in scale by the number of colleagues who would be impacted by the proposed vaccine deployment policy."*

Question: *What could the government do to encourage those working in unregulated roles to have the COVID-19 and flu vaccination?*

Views from stakeholders that responded to the consultation

Many stakeholders suggested that advertisement and communications to the wider population could encourage vaccination uptake. The importance of education and increasing understanding about the vaccines was highlighted. A few stakeholders suggested that more data about the vaccines made available to the public could help in increasing vaccination uptake.

> *"The government should continue to educate the public about the benefits and safety of the COVID-19 and flu vaccines. In particular, they should work to dispel some of the misinformation that exists about vaccines."*

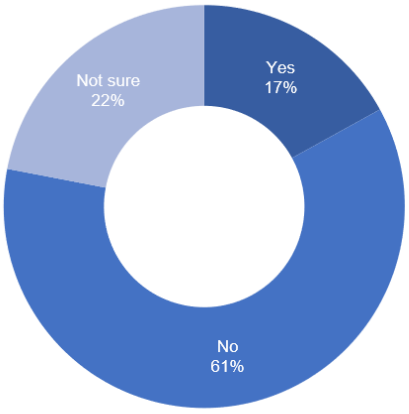
Considerations of potential impacts

Question: *Are there particular groups of people, such as those with protected characteristics, who would particularly benefit from or who would be particularly negatively affected by COVID-19 vaccination and flu vaccination being a condition of deployment in healthcare and social care?*

Under one in five (17%) of respondents thought that particular groups of people would benefit from the policy. A much larger proportion (40%) thought that particular groups would be negatively affected.

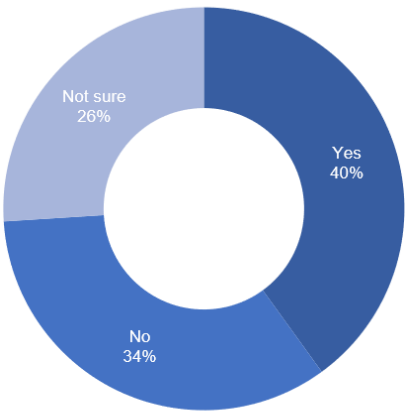
Figure 13: Are there particular groups of people, such as those with protected characteristics, who would…

…particularly benefit from COVID-19 vaccination and flu vaccination being a condition of deployment in healthcare and social care?



Base: All answering (34,929)

…be particularly negatively affected by COVID-19 and flu vaccination being a condition of deployment in healthcare and social care?



Base: All answering (34,657)

On occasion some groups were identified as potentially benefiting as well as potentially being negatively impacted by the policy. Notably, this was the case for ethnic minorities.

Of those who said that the policy would benefit particular groups, reasons often related to enhanced protection for groups perceived to be more susceptible to severe illness and death due to contracting COVID-19. Many respondents mentioned people with vulnerabilities as potentially benefiting, for example people who are immunocompromised, people who have disabilities, and people with underlying health conditions. A number of respondents mentioned older people and

ethnic minorities who have been more vulnerable to COVID-19 as groups who may benefit from the policy due to increased protection. Some respondents identified people who are unable to be vaccinated themselves as potential beneficiaries of the policy, as they'd gain access to protection against the virus, that they might not otherwise have had.

Of those who said the policy would negatively affect particular groups, many respondents expressed general disagreement with the policy, suggesting that vaccination should not be mandatory. In terms of specific groups who might be negatively affected, staff who refuse the vaccination were identified as potentially facing unemployment and associated difficulties. Some respondents felt that ethnic minorities would be disproportionally affected, as groups who generally have lower vaccine uptake. Women who are pregnant or hoping to become pregnant, and people with religious or cultural beliefs which would oppose being vaccinated against the virus, were also cited as being at risk of negative impact.

Views from stakeholders that responded to the consultation

Some stakeholders noted that the policy could benefit people with vulnerabilities.

> *"Disabled and older people who are clinically vulnerable and who live in areas where vaccine hesitancy levels are low. In these cases, vaccination as a condition of deployment might make services slightly safer, but without impacting staffing levels or capacity. Staff members who are clinically vulnerable, may be safer if colleagues are vaccinated."*

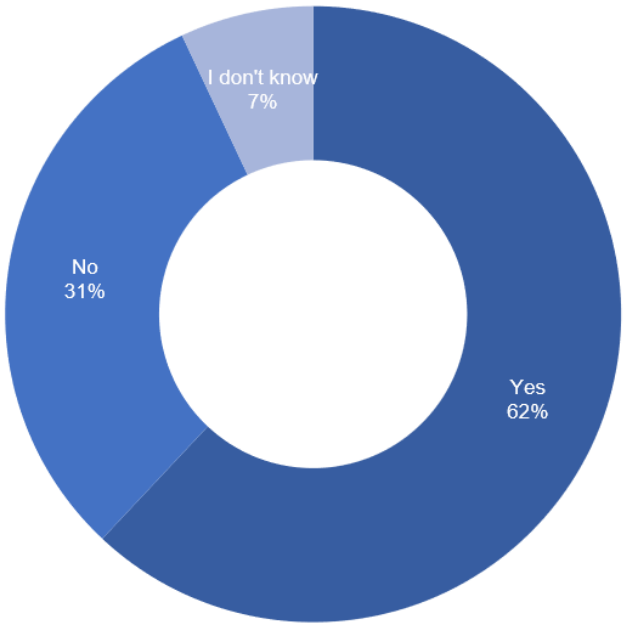
However, the potential negative impact and discrimination across groups with protected characteristics was a frequent concern amongst organisations. Most commonly, the potential negative impact on ethnic minorities was highlighted, as well as for those who are pregnant, trying to get pregnant, or breastfeeding. Some stakeholders identified women (beyond pregnancy) as being disproportionally impacted by the policy. Groups with certain religious, cultural or ethical beliefs were also identified as groups which could be negatively impacted.

> *"Staff groups where vaccine uptake is lower (that is young women, pregnant women and those from a BAME background) are at greater risk of redeployment or loss of employment and therefore could be disproportionately affected by this policy."*

Question: *Do you have concerns about the impact of a vaccination requirement policy on the ability of your organisation to deliver safe services?*

Managers of healthcare or social care services and organisations providing health or care services were asked if they have concerns about the impact of the policy on the ability of their organisation to deliver safe services. Six in ten (62%) said that they had concerns, compared to three in ten (31%) who said that they had no concerns.

Figure 14: Do you have concerns about the impact of a vaccination requirement policy on the ability of your organisation to deliver safe services?

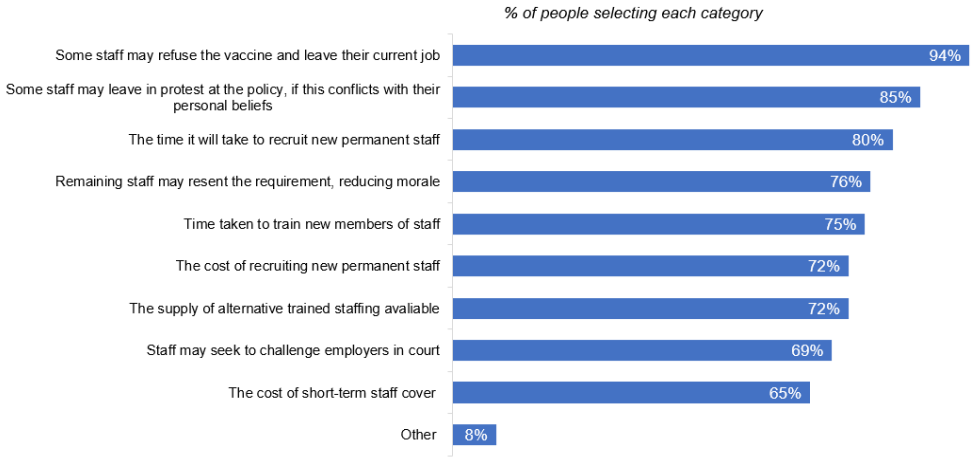


Base: An organisation providing health or care services & A manager of healthcare or social care services (3562)

Question: *Which of the following are concerns that you have about the impact of a vaccination requirement policy on your organisation?*

Amongst the organisations and managers of healthcare or social care services who have concerns, the most common was about the impact of the policy was that some staff may refuse the vaccine and leave their current job (94%). Over four in five (85%) had a similar concern, that some staff may leave in protest at the policy, if this conflicts with their personal beliefs. Four in five (80%) cited the time it will take to recruit new permanent staff as a concern.

Figure 15: Which of the following are concerns that you have about the impact of a vaccination requirement policy on your organisation?

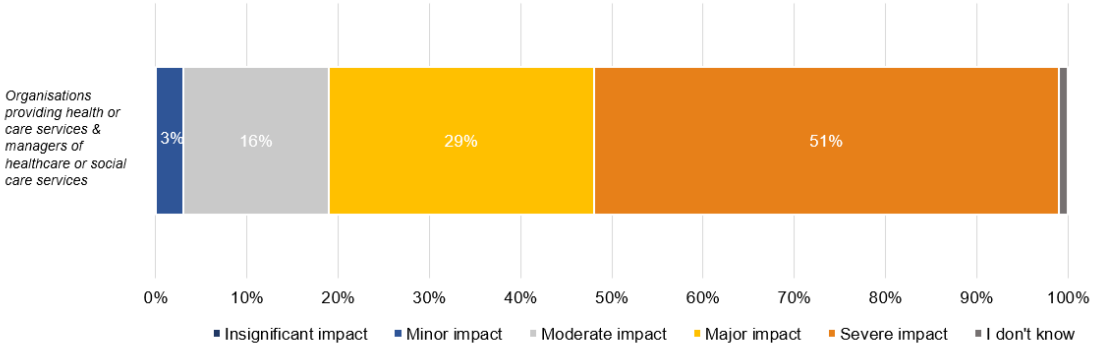


Base: An organisation providing health or care services & A manager of healthcare or social care services [Answered 'Yes' to having concerns about policy on ability for organisation deliver safe services] (15,522)

Question: *Please provide an estimate of the scale of potential impact.*

Amongst the organisations and managers of healthcare or social care services who have concerns, almost four in five (79%) respondents think that their concerns could have severe or major impact. In comparison, under one in twenty (4%) think their concerns could have minor or insignificant impact.

Figure 16: Please provide an estimate of the scale of potential impact.

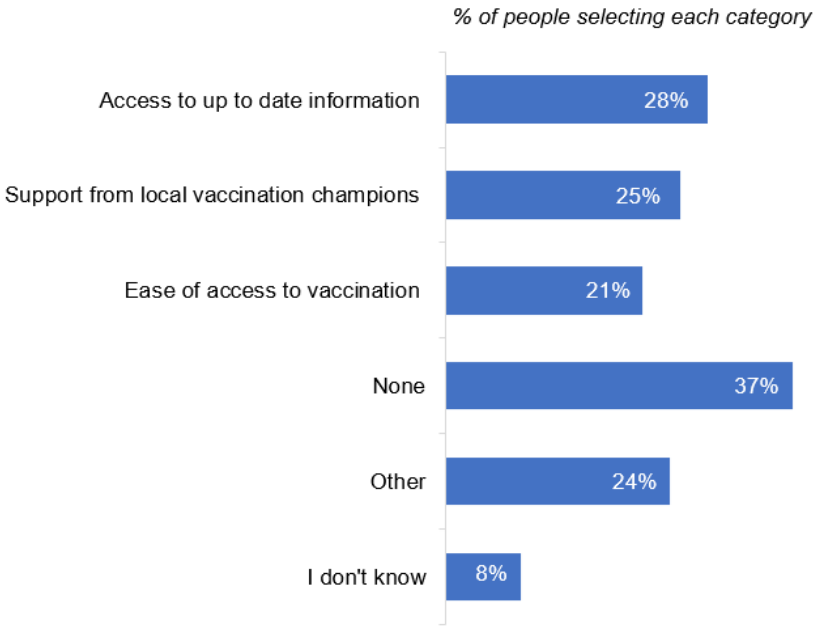


Base: An organisation providing health or care services & A manager of healthcare or social care services [question asked to those who selected 'Yes' to having concerns] (2,226).
Data labels suppressed for categories of 2% or less.

Question: *What, if anything, do you think could minimise any negative impact of a vaccination requirement policy on the healthcare and social care workforce?*

Amongst the organisations and managers of healthcare or social care services who have concerns, over one in four (28%) selected that access to up to date information could minimise any negative impact of the policy. One in four (25%) think that support from local vaccination champions could minimise impact, while one in five (21%) think that ease of access to vaccination could help. Over one in three (37%) thought nothing could minimise any negative impact caused by the policy.

Figure 17: What, if anything, do you think could minimise any negative impact of a vaccination requirement policy on the healthcare and social care workforce?



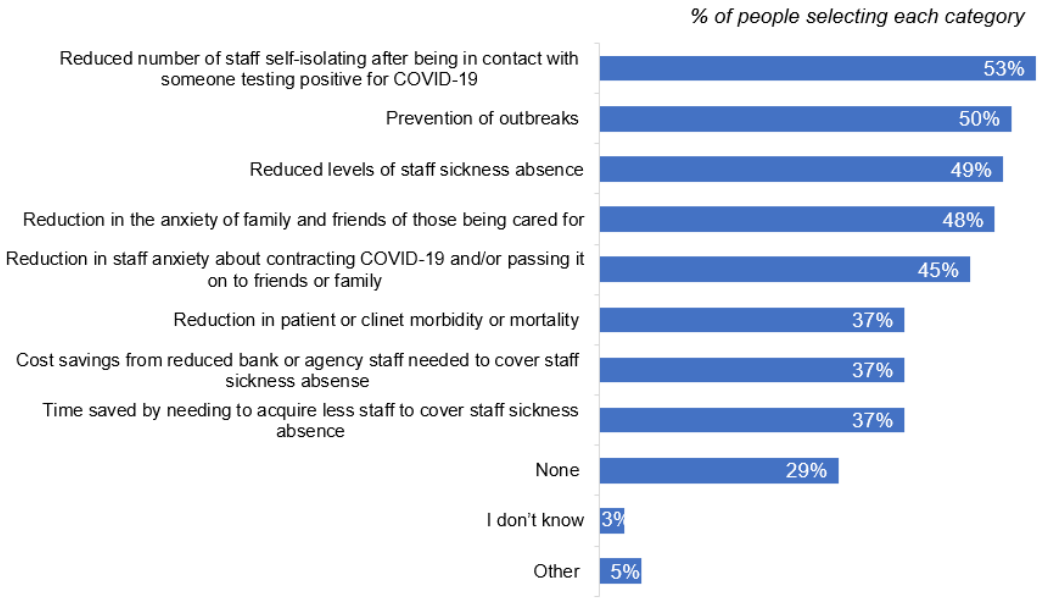
Base: An organisation providing health or care services & A manager of healthcare or social care services [question asked to those who selected 'Yes' to having concerns] (3,192)

Question: *Which of the following, if any, do you think your organisation could benefit from as a result of a vaccination requirement policy?*

Organisations and managers of healthcare or social care services were asked about potential benefits to their organisation as a result of the policy. Over half (53%) think that a reduced number of staff self-isolating after being in contact with someone testing positive for COVID-19 could be a benefit as a result of the policy. Half (50%)

cited prevention of outbreaks as a potential benefit. Almost three in ten (29%) think there would likely be no benefit to their organisation as a result of the policy.

Figure 18: Which of the following, if any, do you think your organisation could benefit from as a result of a vaccination requirement policy?

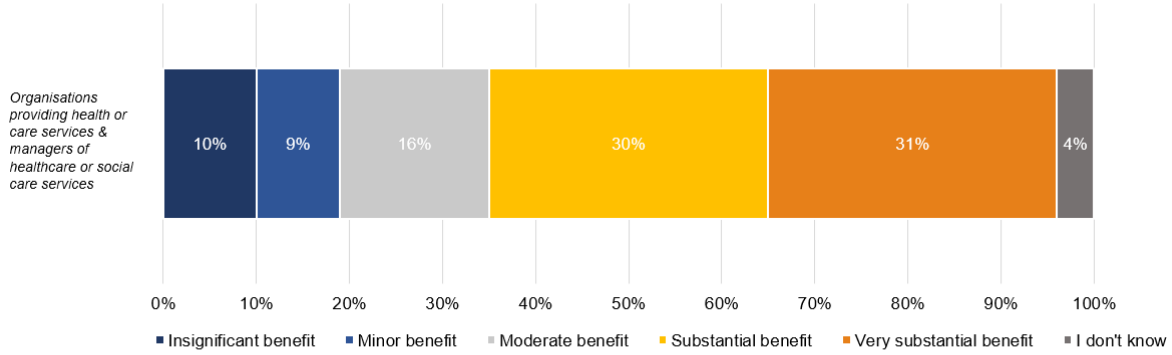


Base: An organisation providing health or care services & A manager of healthcare or social care services (3,562)

Question: *Please provide an estimate of the scale of potential benefit.*

Three in five (62%) respondents (organisations and managers of healthcare or social care services) think that potential benefits of the policy could have very substantial or substantial benefit for their organisation. In comparison, under one in five (19%) think the policy could have minor or insignificant benefit.

Figure 19: Please provide an estimate of the scale of potential benefit.

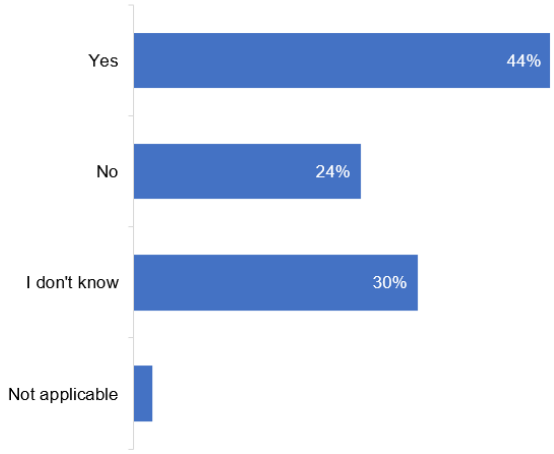


Base: An organisation providing health or care services & A manager of healthcare or social care services
[Question not asked to those who selected that they do not think there would be a benefit at prior question] (2,423)

Question: *Do you think a vaccination requirement policy could cause any conflict with other statutory requirements that healthcare or social care providers must meet?*

Representative organisations or bodies, organisations providing health or care services, and managers of healthcare or social care services were asked if the policy could conflict with other statutory requirements that providers must meet. Over two in five (44%) said yes. Almost one in four (24%) said no.

Figure 20: Do you think a vaccination requirement policy could cause any conflict with other statutory requirements that healthcare or social care providers must meet?



Base: A representative organisation or body & An organisation providing health or care services & A manager of healthcare or social care services (3,749)
Data labels suppressed for categories of 2% or less

Views from stakeholders that responded to the consultation

A common concern amongst stakeholders was that the policy could impact on delivery of services and quality of care due to insufficient staffing levels for example, retention and recruitment problems. The policy impacting employment rights, data protection and generating legal issues was commented on. Examples mentioned of the potential legal risks as a result of the policy include human rights challenges, personal injury, and industrial action.

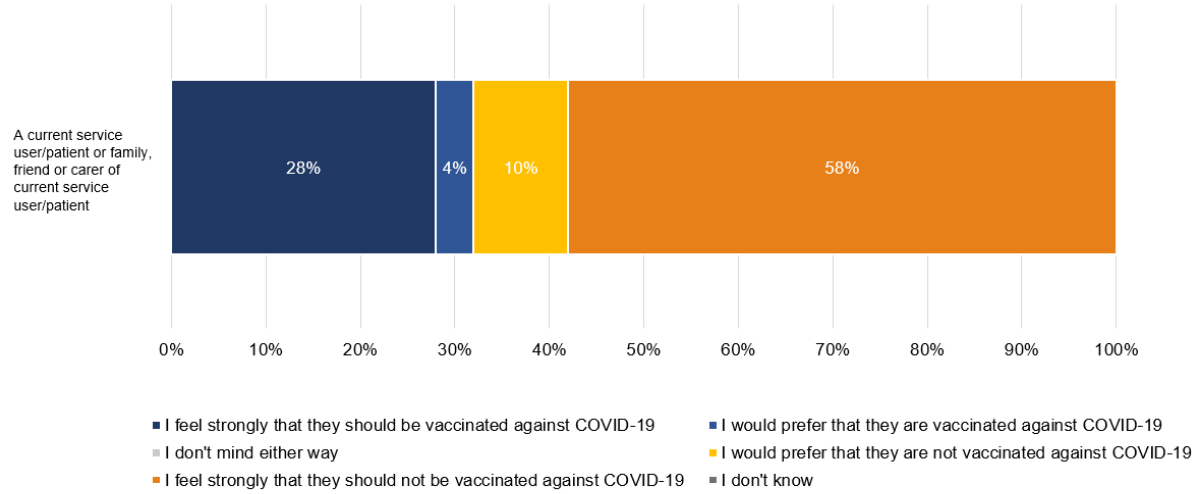
> *"... it could conflict with requirements under employment, equality and other legislation."*

Views on the policy intention

Question: *Which of the following best describes your preference about the COVID-19 and flu vaccination status of the people who provide your care, your family member's care or your friend's care?*

Current service users/patients or family, friends or carers of current service users/patients were asked their preference about the COVID-19 vaccination status of the people who provide their care (or their family member's or friend's care). Three in ten (31%) feel strongly or would prefer that those proving the care be vaccinated against COVID-19. In comparison, over two in three (68%) feel strongly or would prefer that they are not vaccinated against COVID-19.

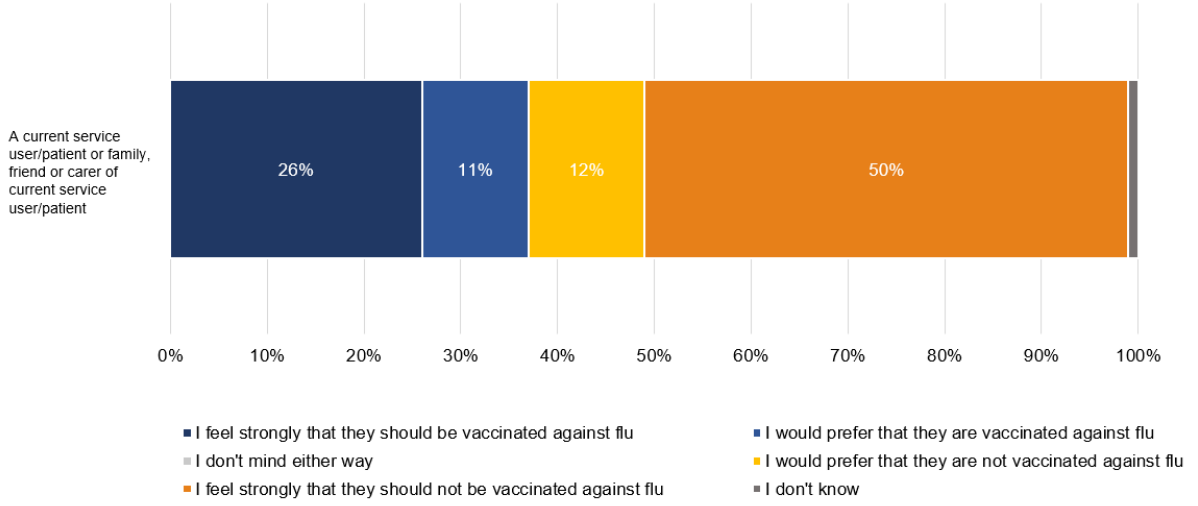
Figure 21: Which of the following best describes your preference about the COVID-19 vaccination status of the people who provide your care, your family member's care or your friend's care?



Base: A current service user/patient or family, friend or carer of current service user/patient *(1,913)*
Data labels suppressed for categories of 2% or less.

Current service users/patients or family, friends or carers of current service users/patients were also asked their preference about the flu vaccination status of the people who provide their care (or their family member's or friend's care). Over one in three (37%) feel strongly or would prefer that those proving the care be vaccinated against flu. Three in five (62%) feel strongly or would prefer that they are not vaccinated against flu.

Figure 22: Which of the following best describes your preference about the flu vaccination status of the people who provide your care, your family member's care or your friend's care?



Base: A current service user/patient or family, friend or carer of current service user/patient *(1,575)*
Data labels suppressed for categories of 2% or less.

Question: *Which of the following best describes your preference about the COVID-19 vaccination being compulsory for the people who provide your care, your family member's care or your friend's care?*

Of those who said that they feel strongly or would prefer the people who provide their care, their family member's care or their friend's care to be vaccinated against COVID-19, all (100%) said that they feel strongly that COVID-19 vaccination should be compulsory.

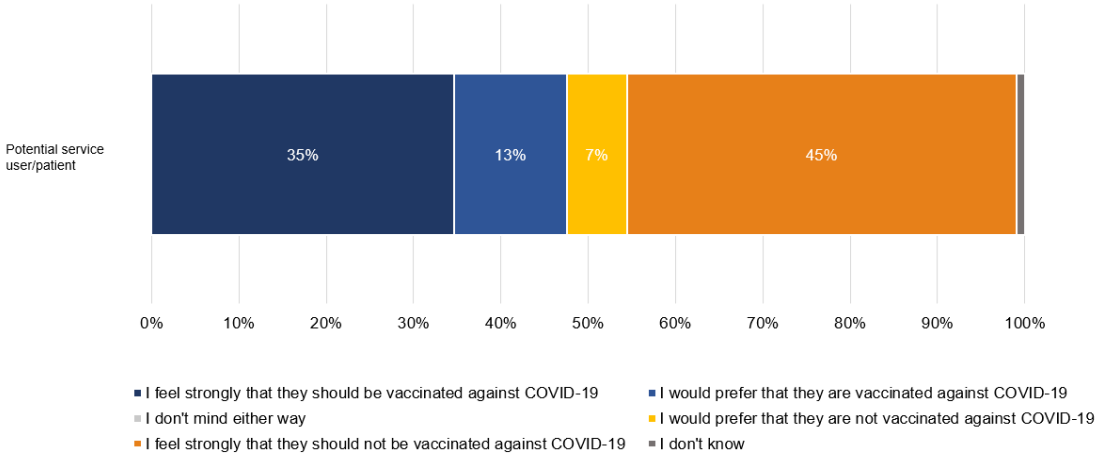
Question: *Which of the following best describes your preference about the flu vaccination being compulsory for the people who provide your care, your family member's care or your friend's care?*

Of those who said that they feel strongly or would prefer the people who provide their care, their family member's care or their friend's care to be vaccinated against flu, nine in ten (90%) said that they feel strongly or would prefer that flu vaccination be compulsory. Under one in ten (9%) feel strongly or would prefer flu vaccination not to be compulsory.

Question: *Which of the following best describes your preference about the COVID-19 and flu vaccination status of the people who would be providing your care?*

Those who are not current service users or patients were asked their preference about the COVID-19 vaccination status of the people who would be providing their care, if they were to need health or social care services in the future. Close to half (48%) feel strongly or would prefer that they be vaccinated against COVID-19. Similarly, slightly more than half (52%) feel strongly or would prefer that they are not vaccinated against COVID-19.

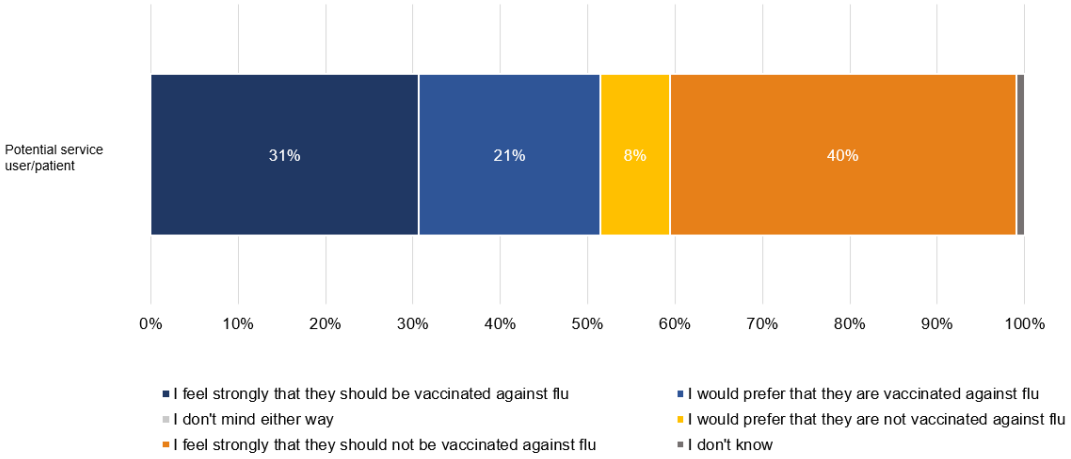
Figure 23: Which of the following best describes your preference about the COVID-19 vaccination status of the people who would be providing your care?



Base: A member of the health and care workforce delivering services to patients or clients & A manager of healthcare or social care services & A member of the public & Other (21,493). Data labels suppressed for categories of 2% or less.

Those who are not current service users or patients were asked their preference about the flu vaccination status of the people who would be providing their care, if they were to need health or social care services in the future. Half (51%) feel strongly or would prefer that they be vaccinated against flu. Similarly, near half (48%) feel strongly or would prefer that they are not vaccinated against flu.

Figure 24: Which of the following best describes your preference about the flu vaccination status of the people who would be providing your care?



Base: A member of the health and care workforce delivering services to patients or clients & A manager of healthcare or social care services & A member of the public & Other (18,100). Data labels suppressed for categories of 2% or less.

Question: *Which of the following best describes your preference about the COVID-19 vaccination being compulsory for the people who would be providing your care?*

Of those who said that they feel strongly or would prefer the people who would be providing their care to be vaccinated against COVID-19, over four in five (83%) said that they feel strongly or would prefer that COVID-19 vaccination be compulsory. Under one in five (17%) feel strongly or would prefer COVID-19 vaccination not to be compulsory.

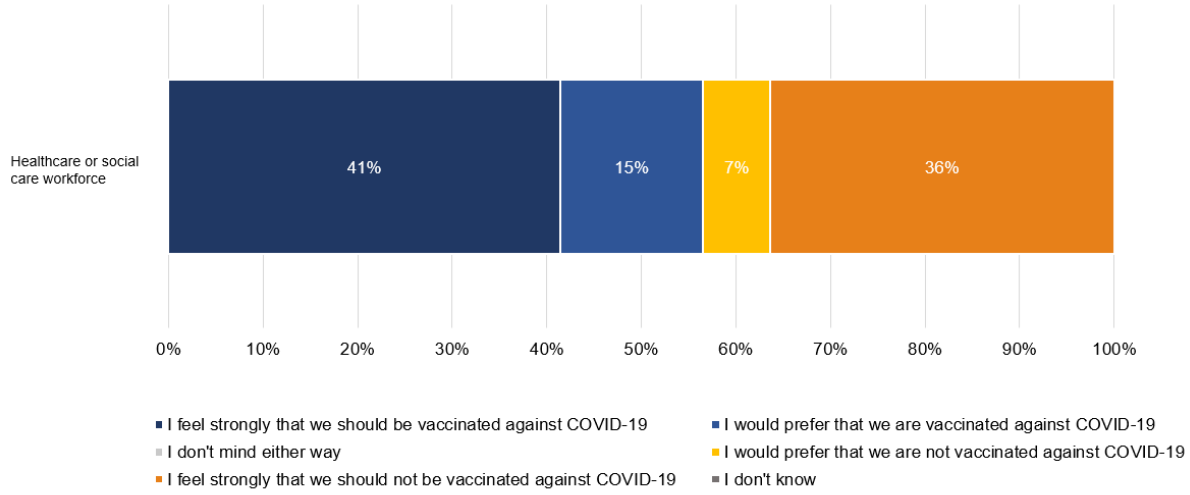
Question: *Which of the following best describes your preference about the flu vaccination being compulsory for the people who would be providing your care?*

Of those who said that they feel strongly or would prefer the people who would be providing their care to be vaccinated against flu, over four in five (83%) said that they feel strongly or would prefer that flu vaccination be compulsory. Under one in five (16%) feel strongly or would prefer flu vaccination not to be compulsory.

Question: *Which of the following best describes your preference about the COVID-19 vaccination status of you and your colleagues who provide care to service users?*

Members of the health and care workforce delivering services to patients or clients were asked their preference about the COVID-19 vaccination status of them and their colleagues who provide care to service users. Over half (56%) feel strongly or would prefer that they be vaccinated against COVID-19. In comparison, over two in five (44%) feel strongly or would prefer that they are not vaccinated against COVID-19.

Figure 24: Which of the following best describes your preference about the COVID-19 vaccination status of you and your colleagues who provide care to service users?



Base: A member of the health and care workforce delivering services to patients (11,965).
Data labels suppressed for categories of 2% or less.

Question: *Which of the following best describes your preference about the COVID-19 vaccination being compulsory for you and your colleagues who provide care to service users?*

Of those who said that they feel strongly or would prefer themselves and their colleagues who provide care to service users to be vaccinated against COVID-19, four in five (80%) said that they feel strongly or would prefer that COVID-19 vaccination be compulsory. Under one in five (19%) feel strongly or would prefer COVID-19 vaccination not to be compulsory.

Amendment of the Code of Practice

As part of the consultation, we have also consulted on a proposed amendment of the Code of Practice on Infection Prevention and Control and its associated guidance, which is issued by the Secretary of State under section 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and to which providers must have regard when complying with their obligations under regulation 125 of the Regulations.

We have received limited feedback on the wording of the proposed amendment during the consultation.

A draft of the text for the Code of Practice is set out below. It provides an explanation of the regulations and reflects the policy decisions being made as a result of the consultation.

The draft text below will be updated prior to the Code of Practice being issued to provide further practical information to assist service providers with the operational aspects of the policy. The text relating to the policy will remain substantively the same.

[5] Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires care and treatment to be provided in a safe way for service users. This includes an obligation on the registered person to assess the risk of, and prevent, detect and control the spread of infections, including those that are health care associated (regulation 12(2)(h)).

Proposed addition to the code of practice – criterion 10

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

1. For the purposes of preventing, detecting and controlling the spread of infections, specifically in response to the effects of the coronavirus pandemic, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") are amended by:

    1.1. The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021 ("**the Care Home Coronavirus Regulations"**); and

    1.2. the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No.2) Regulations 2021 (**"the Health and Social Care Coronavirus Regulations"**).

2. The Care Home Coronavirus Regulations come into force on 11th November 2021 and make provision in relation to the requirements on registered persons registered for the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home.

3. Regulation 3 of the Health and Social Care Coronavirus Regulations makes further provision in relation to the requirements on registered persons registered for the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home. Regulation 3 will come into force on [X date].

4. Regulation 4 of the Health and Social Care Coronavirus Regulations makes provision in relation to the requirements on registered persons registered for any regulated activity including the provision of accommodation for persons who require nursing or personal care carried on in a care home. Regulation 4 comes into force on [x date].

5. **<u>The regulated activity of providing accommodation for persons who require nursing or personal care in a care home</u>**

    5.1. This section provides guidance on compliance with respect to the amendments to the 2014 Regulations made by the Care Home Coronavirus Regulations and regulation 3 of the Health and Social Care Coronavirus Regulations.

5.2. Section 6 provides guidance on compliance with respect to the additional amendments to the 2014 Regulations made by regulation 4 of the Health and Social Care Coronavirus Regulations – which includes provisions relating to the regulated activity of providing accommodation for persons who require nursing or personal care in a care home.

5.3. For the purposes of complying with amendments made by the Care Home Coronavirus Regulations to the 2014 Regulations, registered persons in respect of the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home must ensure policies and procedures are in place with regard to COVID-19 vaccination. Specifically, they must secure that a person is only permitted to enter the care home if one of the following applies:

5.3.1. The person is a service user of the regulated activity of providing accommodation for persons who require nursing or personal care in that care home
5.3.2. The person can provide evidence that they have either been vaccinated with the complete course of doses of an authorised COVID-19 vaccine (in this instance, a full course does not include booster vaccines), or evidence that there are clinical reasons why they should not be vaccinated with any authorised COVID-19 vaccine
5.3.3. It is reasonably necessary for the person to provide emergency assistance in the care home
5.3.4. It is reasonably necessary for the person to provide urgent maintenance assistance with respect to the premises of the care home
5.3.5. The person is attending the premises in the execution their duties as a member of the emergency services
5.3.6. The person is a friend or relative of a current or former service user
5.3.7. The person is visiting a service user who is dying
5.3.8. It is reasonably necessary for the person to provide comfort or support to a service user in relation to a service user's bereavement following the death of a friend or relative
5.3.9. The person is under the age of 18
5.3.10. The person has participated, or is participating in a relevant clinical trial (once regulation 3 of the Health and Social Care Coronavirus Regulations comes into force)

5.4. A registered provider will need to apply the above requirements to all persons wishing to enter the premises of the care home including health care professionals, CQC inspectors, tradespeople, hairdressers, beauticians etc.

5.5. Once regulation 3 of the Health and Social Care Coronavirus Regulations comes into force, a registered person will also be required to take account of whether a person has previously been employed or otherwise engaged by

the registered person when considering what conditions to apply with respect to that person.

5.6. Until regulation 4 of the Health and Social Care Coronavirus Regulations comes into force, an authorised vaccine means— a medicinal product—

5.6.1. authorised for supply in the United Kingdom in accordance with a marketing authorisation; or

5.6.2. authorised by the licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc) of the Human Medicines Regulations 2012 for vaccination against coronavirus.

6. **All regulated Activities**

6.1. After regulation 4 of the Health and Social Care Coronavirus Regulations comes into force, a registered person registered in respect of any regulated activity will need to comply with the requirements concerning COVID vaccination in the 2014 Regulations.

6.1.1. *Regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home*

6.1.1.1. A registered person in respect of the regulated activity of providing accommodation for persons who require nursing or personal care in a care home must secure that – subject to certain exceptions— a person is only permitted to enter the care home premises if they provide evidence that they have been vaccinated with a complete course of doses of an authorised vaccine or, for clinical reasons should not be vaccinated against coronavirus.

6.1.1.2. Alternatively a person may provide evidence that they have otherwise been vaccinated against coronavirus (see paragraph 8 for further guidance on being “otherwise vaccinated against coronavirus”). However, this alternative option stops applying after a period of 10 weeks, unless that person can demonstrate that they have satisfies additional conditions – specifically, that they have been vaccinated with one dose of an authorised vaccine or been vaccinated with a vaccine listed in column 1 of the table in Schedule 4A in accordance with the corresponding number of doses listed in column 2 of that table. See annex C for a copy of the Schedule.

6.1.1.3. The 2014 Regulations also provide for alternative conditions in relation to those persons that have not previously been employed or otherwise engaged by the registered person – see section 13.

6.1.2. *Any other regulated activity*

6.1.2.1. A registered person in respect of any other regulated activity (other than a regulated activity (such as the provision of personal care) which forms part of a shared lives agreement) may employ or otherwise engage a person for the purposes of the provision of that regulated activity only if that person provides evidence that they have been vaccinated with a complete course of doses of an authorised vaccine or, for clinical reasons should not be vaccinated against coronavirus.

6.1.2.2. Alternatively a person may provide evidence that they have otherwise been vaccinated against coronavirus (see paragraph 8 for further guidance on being "otherwise vaccinated against coronavirus"). However, this alternative option stops applying after a period of 10 weeks, unless that person can demonstrate that they have satisfies additional conditions – specifically, that they have been vaccinated with one dose of an authorised vaccine or been vaccinated with a vaccine listed in column 1 of the table in Schedule 4A in accordance with the corresponding number of doses listed in column 2 of that table. See annex C for a copy of the Schedule.

6.1.2.3. The 2014 Regulations also provide for alternative conditions in relation to those persons that have not previously been employed or otherwise engaged by the registered person – see section 13.

7. Authorised vaccines

7.1. The definition of an "authorised vaccine" is set out at regulation 3A of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 ("the International Travel Regulations"). The vaccines that currently fall within the scope of this definition is set out at Annex A of this Code of Practice.

7.2. However, it should be noted that the definition of "authorised vaccine" in the International Travel Regulations is reviewed and updated on a regular basis, and it is the definition of "authorised vaccine" in the International Travel Regulations that applies.

8. Otherwise vaccinated against Coronavirus

8.1. There are a number of vaccines that are not currently considered "authorised vaccines" under the International Travel Regulations.

8.2. The UK Health Security Agency COVID-19 vaccination of individuals vaccinated overseas guidance ("UKHSA VOG") lists a number of other vaccines that may have been administered to a person overseas. The UKHSA VOG document provides clinical advice on whether additional doses would be beneficial to enhance protection for those who received coronavirus (COVID-19) vaccinations overseas.

8.3. A person would be considered to be "otherwise vaccinated against coronavirus" if they have provided evidence that they have received a complete or partial primary course of a vaccine listed in the table of that UKHSA VOG in accordance with the manufacturer's authorised schedule (but see paragraph 8.5).

8.4. The 2014 Regulations set out the circumstances in which a registered person needs to have been provided with evidence that the person has received one dose of an authorised vaccine in addition to being otherwise vaccinated against coronavirus

8.5. **Circumstances in which a registered person needs to secure that a person has provided evidence that they have also been vaccinated with a top up of an authorised vaccine**

For the purposes of this section and those that follow, "B"' represents the person employed or engaged by the registered person "A" for the purposes of the provision of a regulated activity

8.5.1. As described in paragraph 8.3, A may employ or otherwise engage B for the purposes of the provision of a regulated activity when B has provided evidence that they have been 'otherwise vaccinated against coronavirus'. In some circumstances, the registered person may not be satisfied that the evidence demonstrates that a person has otherwise been vaccinated against coronavirus (that is because the vaccine is not listed in the UKHSA VOG table). In these circumstances a person would need to provide evidence that they have been vaccinated with a complete course of an authorised vaccine.

8.5.2. Where the evidence that B has provided shows that they have been vaccinated with the specified number of doses of one of the vaccines listed in annex C to the 2014 Regulations, A will not need to secure that B provides evidence of any further vaccination.

8.5.3. However, where the evidence that B has provided shows that they have been "otherwise vaccinated against coronavirus" with a vaccine that is not listed in annex C, or that they have not received the number of doses specified in that Schedule, after a period of 10 weeks from the date of the previous vaccine "A" will need to secure that "B" provides

further evidence of having been vaccinated with one dose of an authorised vaccine.

9. **Vaccinated with two different authorised vaccines**

9.1. For the purposes of the 2014 Regulations, a complete course of doses includes one dose of an authorised vaccine and another dose of a different authorised vaccine.

10. **Recognised evidence of COVID-19 vaccination**

10.1. The Department of Health and Social Care consider that B will have provided a registered person with appropriate evidence to demonstrate that B has been vaccinated with an authorised vaccine or has otherwise been vaccinated against coronavirus if they have provided one of the following types of evidence:

10.1.1. the vaccination record within the NHS COVID App, or equivalent from NHS Scotland, NHS Wales or the Department of Health in Northern Ireland; or
10.1.2. the vaccination record within the NHS COVID App accessed via the NHS website – NHS.uk; or
10.1.3. the NHS COVID Pass letter; or
10.1.4. the EU Digital COVID Certificate; or
10.1.5. the Centers for Disease Control and Prevention vaccination card; or
10.1.6. a certificate in English, French or Spanish issued by the competent health authority which contains:
10.1.6.1. B's full name;
10.1.6.2. B's date of birth;
10.1.6.3. the name and manufacturer of the vaccine that B received;
10.1.6.4. the date that B received each dose of the vaccine; and
10.1.6.5. details of either the identity of the issuer of the certificate or the country of vaccination, or both.

11. **Recognised evidence to demonstrate that for clinical reasons a person should not be vaccinated against coronavirus**

11.1. The Department of Health and Social Care consider that B will have provided a registered person with appropriate evidence to demonstrate that for clinical reasons B should not be vaccinated against coronavirus if they have provided one of the following types of evidence:

11.1.1. NHS COVID pass or equivalent from NHS Scotland, NHS Wales or the Department of Health in Northern Ireland; or

11.1.2. non-digital equivalent of those listed in (a); or

11.1.3. where B is not registered with a GP in the United Kingdom, confirmation in writing from the clinician responsible for B's treatment, or with direct knowledge of B's condition, that B should not be vaccinated with an authorised vaccine.

11.1.4. Individuals who have a GP in the United Kingdom and who are applying for a clinically reviewed medical exemption will automatically get the results of their application by post 2 to 3 weeks after applying. This notification letter can be used by an individual to prove their exemption status. Pregnant women can also use a MAT B1 certificate to prove exemption status.

12. Recognised evidence to demonstrate exemption from COVID-19 vaccination due to participation in clinical trial

12.1. The Department of Health and Social Care consider that B will have provided a registered person with appropriate evidence to demonstrate that B has participated or is participating in a clinical trial, if B provides confirmation in writing, from the organiser of the clinical trial, to the registered person, that the clinical trial that B is participating in / has participated in is:

12.1.1. for a vaccine against coronavirus; and

12.1.2. is regulated by one of the regulatory bodies included in Annex B of this Code of Practice.

13. New starters

13.1. The regulations include provisions which permit a registered person to employ or engage a worker for the first time (new starters) after regulation 4 comes into force, for a limited period, when that worker has been 'otherwise vaccinated' but has not had a top up dose; or has had only a single dose of an authorised vaccine. The effect of the regulations for different workers based on the date that they are first employed or engaged for the purposes of the regulated activity is described below:

13.1.1. ***First employed or engaged for the purposes of the regulated activity before regulations made (date)***

"A" must ensure that "B" is not employed or otherwise engaged for the purposes of a regulated activity after the (date) unless "B" has provided "A" with evidence that either:

13.1.1.1. “B” has been vaccinated with the complete course of doses of an authorised vaccine; or

13.1.1.2. that for clinical reasons “B” should not be vaccinated with any authorised vaccine; or

13.1.1.3. “B” has been “otherwise vaccinated against coronavirus”

13.1.1.3.1. Where “B” provides evidence that they have been “otherwise vaccinated against coronavirus”, “A” must ensure that “B” is not employed or otherwise engaged for the purposes of a regulated activity after the period of 10 weeks from the date of being otherwise vaccinated against coronavirus unless ”B” has provided “A” with evidence that ”B”:

13.1.1.3.1.1. has been vaccinated with one dose of an authorised vaccine in addition to being otherwise vaccinated against coronavirus; or

13.1.1.3.1.2. has been vaccinated with a vaccine listed in column 1 of the table in annex C in accordance with the corresponding number of doses listed in column 2 of that table

13.1.2. ***B is employed or engaged for the purposes of a regulated activity for the first time during grace period (made date –date on which reg 4 comes into force)***

“A” must ensure that “B” is not employed or otherwise engaged for the purposes of a regulated activity after the (the date on which reg 4 comes into force) unless ”B” has provided “A” with evidence that either:

13.1.2.1. “B” meets one of the conditions described above (in paragraph 13.1.1.); or

13.1.2.2. “B” has been vaccinated with one dose of an authorised vaccine. After a period of 10 weeks from the date that the first dose was administered, “A” will need to ensure that “B” has provided evidence that “B” then meets one of the conditions described in paragraph 13.1.1.

13.1.3. ***B is employed or otherwise engaged for the purposes of a regulated activity for the first time on or after (the date on which reg 4 comes into force)***

"A" must ensure that "B" is not employed or otherwise engaged for the purposes of a regulated activity unless "B" has provided "A" with evidence that either:

13.1.3.1. "B" meets one of the conditions described in paragraph 13.1.1;

13.1.3.2. "B" has been vaccinated with one dose of an authorised vaccine at least 21 days before the first day of deployment. After a period of 10 weeks from the date that the first dose was administered, "A" will need to ensure that "B" has provided evidence that "B" then meets one of the conditions described in paragraph 13.1.1.

14. Moving from out of scope role to an in-scope role

14.1. If "B" is moved from a role where "A" was not required to secure evidence of vaccination, to one where such evidence is required, they will be treated as being employed or otherwise engaged for the purposes of the provision of a regulated activity from the date that they begin in the new role. The registered person "A" must follow the appropriate requirement listed in 13.1.2 or 13.1.3 when "B" begins in the new role.

15. When a registered person does not need to secure evidence of vaccination or exemption

Registered persons of the regulated activity of providing accommodation for persons who require nursing or personal care in a care home should refer to paragraph 5.3 instead of this paragraph.

15.1. The requirements on registered providers to ensure that B is not employed or otherwise engaged unless B has provided evidence of vaccination or exemption do not apply where:

15.1.1. "B" will not have direct, face to face contact with a service user; or
15.1.2. "B" is under the age of 18; or
15.1.3. "B" has provided evidence that they are taking part, or have taken part, in a relevant clinical trial, or
15.1.4. the provision of the regulated activity is part of a shared lives agreement.

16. Inspection

16.1. CQC inspectors have a right of entry to the setting in which the regulated activity is being provided and it is an offence for a provider to obstruct entry without reasonable excuse. For care homes only, compliance with the regulations would amount to a reasonable excuse for not giving access to a CQC inspector who could not provide evidence of vaccination or exemption.

16.2. If inspected, the registered provider will need to be able to demonstrate that:

16.2.1. they have systems in place to ensure that they can comply with the requirements of the Regulations and that they can monitor compliance;
16.2.2. there is a record to confirm that satisfactory evidence has been provided. This record must be kept securely by the registered person in compliance with the Data Protection Act 2018;
16.2.3. they have systems in place to review whether they need to secure further evidence in relation to vaccination or exemption status of the people they employ or otherwise engage for the purposes of the provision of the regulated activity, carry out those reviews and secure such further evidence;
16.2.4. there is appropriate information about vaccines and the requirements of regulation 12 available to staff, and that staff receive support in connection with the vaccine; and
16.2.5. staff are provided with the appropriate support to access vaccination.

Annex A – Authorised Vaccines

- Oxford/AstraZeneca
- Pfizer BioNTech
- Moderna
- Janssen

Formulations of these vaccines, such as AstraZeneca Covishield, AstraZeneca Vaxzevria and Moderna Takeda, also qualify as authorised vaccines.

Annex B – Stringent Regulatory Authorities

Australia	Germany	Netherlands
Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Iceland	Romania
Canada	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Japan	Spain
Czech Republic	Latvia	Sweden
Denmark	Liechtenstein	Switzerland
Estonia	Lithuania	United Kingdom
Finland	Luxembourg	United States of America
France	Malta	Norway

Annex C

Vaccine name, manufacturer	***Number of doses***
Sputnik Light, Gamaleva National Centre of Epidemiology & Microbiology	3 doses
Covid 19 vaccine BIBP, Sinopharm	3 doses
BBIBPV-CorV, Sinopharm	3 doses
CoronaVac, Sinovac Biotech	3 doses
Ad5-nCoV, CanSino Biologics	3 doses
Convidecia, CanSino Biologics	3 doses
Covaxin, Bharart Biotech	3 doses
NVX-CoV2373, Novovax	2 doses

Covovax, Novavax	2 doses
Sputnik V, Gamaleva National Centre of Epidemiology & Microbiology	2 doses