NCF Briefing: VCOD in wider social care and health settings

The government has published its response to the consultation on vaccination as a condition of deployment (VCOD) in NHS and wider social care settings alongside an impact statement for the policy. The draft regulations have also been published. Below we have created a briefing based on these documents. At the outset, let me say that the draft Code of Practice at the bottom of the government response document is a very confusing read and doesn't appear to align completely with what is written in the actual regulations. We have raised out concerns with DHSC and are seeking further clarity. We have indicated this in the briefing below. Be aware that some elements of the new regulations are likely to come into force for care homes when they are passed by parliament (likely in January 2022).

Do also see Anthony Collin's blog post highlighting key points and concerns.

Summary of Key Points

- The law will require vaccination (or exemption) and will apply to providers of CQC regulated activities (such as home care) and will be in respect of any person they 'employ or otherwise engage' who has direct face-to-face interactions with patients or care service users 'for the purposes of the provision of' the regulated activity'. This is very broad wording which we are seeking clarity on. In short it will apply to staff carrying out a CQC regulated activity which involves face to face contact with patients or service users. But the consultation response takes this further and states that it would also cover *'non-clinical ancillary workers who may have direct, face to face contact with patients but are not directly involved in patient care'* – This is very vague and we need to understand what is meant by 'ancillary' and how this regulation can possibly apply to them considering they are not typically carrying out CQC regulated activity.
- Covid-19 boosters and flu vaccinations are not included in the policy scope.
- Once the regulations have been laid and approved in Parliament, there will be a 12-week grace period before the regulations come into force. Therefore, the policy is expected to come into force in April 2022.

The regulations that introduce VCOD across health and wider social care settings will also include some amendments to the existing care home regulations. Once approved by Parliament, these amendments will take effect in the coming months (possibly in January 2022 for care homes and everyone else from April 2022) and include:

- An unvaccinated new starter can be deployed in a care home 21 days after receiving one dose of an authorised COVID-19 vaccine. More details below.
- Staff vaccinated overseas can be deployed but may need to receive a top-up vaccine dose, as per UKHSA advice. The government intends to run the self-certification process for people vaccinated in care homes until the end of the proposed grace period which is expected to be April 2022. More details below.
- Clinical trial participants will need to evidence their participation in order to be exempt from the requirement
- The definition of authorised vaccine will be aligned across the two policies

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Response to the Government's Consultation

The consultation saw 34,929 responses and an additional 42 received outside the online platform. Only 29% of respondents supported the proposal to mandate COVID-19 vaccination in health and wider social care settings, while 65% of respondents did not support the proposal. It is noticeable that service users and relatives of service users tended to be the most opposed to elements of this policy. 62% of social care and 61% of health care settings did not want flu mandated.

In terms of the workforce response, 41% felt strongly that they and their colleagues should be vaccinated against COVID-19.

81% of public responses were unsupportive of the policy.

It would appear the government has largely ignored the opposition to the policy.

Overview of policy

Flu and COVID-19 Booster vaccinations will not be included in the regulations but will be kept under review.

The government is proposing to introduce regulations to only allow providers of CQC-regulated activities in health and social care to deploy individuals who have been vaccinated against COVID-19 to roles where they have direct, face-to-face contact with people who draw on care and support. The wording of the actual regulations is vague and we are seeking clarity on it. The law will require vaccination (or exemption) and will apply to providers of CQC regulated activities (such as home care) and will be in respect of any person they *'employ or otherwise engage'* who has direct face-to-face interactions with patients or care service users *'for the purposes of the provision of' the regulated activity'*

The DHSC's consultation response, as a result, goes beyond staff employed carrying out CQC-regulated activities and includes:

- non-clinical ancillary workers (such as receptionists, porters and cleaners) who may have direct, face-to-face contact with people but who are not directly involved in their care. approach
- Agency workers carrying out a regulated activity
- Where a regulated activity is delivery through agency workers, volunteers or trainees, or contracted to another provider

Please note that the DHSC acknowledges that there a lot of work to be done to clarify the approach to ancillary staff and to define what is meant by direct, face to face contact. The regulations themselves do not reference ancillary workers, so this will likely be included in guidance.

Do also note that settings such as extra care housing or supported living will be covered by this wider scope, and **not** the care home regulations. DHSC has listened to feedback on that issue. To clarify, this means that the care home threshold regulations are not being extended to extra care housing and supported living settings but there will still be implications for them from this policy as it evolves.

There also some additional nuance for new starters – see below.

People vaccinated abroad

DHSC is currently working to set out specific requirements for those who are vaccinated abroad for both the new policy and the existing care home policy. This may include a top-up dose of a MHRA approved vaccine (see Annex A of draft Code of Practice - page 69), consistent with UKHSA's guidance on vaccination doses and mixed vaccines. This will also apply to care homes.

The proposed regulations allow a person who provides evidence that they have 'otherwise been vaccinated against coronavirus' (i.e. vaccinated abroad) to continue working temporarily once the regulations come into force. A person is considered to be 'otherwise vaccinated against coronavirus' if they provide evidence they have received a complete or partial primary course of a vaccine listed here: https://www.gov.uk/government/publications/covid-19-vaccinations-received-overseas

Note, this is a temporary provision and **stops applying 10 weeks after the date of the first vaccine**, unless that person can demonstrate that they satisfy additional conditions – specifically, that they have been vaccinated with an additional dose of an authorised vaccine if they only have a partial course of vaccination, or been vaccinated with a vaccine listed in Schedule 4A (page 7 of draft regulations) with the corresponding number of doses.

Recognised Evidence

The proposed regulations list a number of recognised evidence which helpfully expands what was in the original regulations made for VCOD in care homes. These will apply to care homes as well.

- Vaccination record within NHS COVID App, or equivalent from NHS Scotland, NHS Wales or Department of Health Northern Ireland
- The vaccination record within the NHS COVID app accessed via the NHS website
- NHS COVID Pass Letter
- EU Digital COVID Certificate
- Centres for Disease Control and Prevention vaccination care
- A certificate in English, French, or Spanish issued b the competent health authority which contains
    - The full name

- Date of birth
- The name and manufacturers of the vaccine received
- The date each dose was received
- Details of either the identity of the issuer of the certificate or the country of vaccination, or both

Providers will need to be able to show that they have systems in place to confirm that evidence has been provided. The provider does not need to keep evidence itself.

Exemptions for new expanded scope

Those that are exempt from the new policy expanded (excluding care homes) include:

- Those under 18
- Those who are clinically exempt from COVID-19 vaccination on the basis of Green Book Chapter 14a – this will involve a formal exemption process
- Those who have taken part or are currently taking part in a clinical trial for 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 from patient areas
- Those providing care as part of a shared lives agreement
- Visitors or essential care givers will not be added to the existing scope

Please note that the above is for wider social care and NHS settings only. Not care homes

People are only permitted to enter a care home if one of the following applies:

- Residents
- Evidence of a complete course of vaccination or medical exemption
- It is reasonably necessary for the person to provide emergency assistance in the care home
- It is reasonably necessary for the person to provide urgent maintenance assistance with respect to the premises of the care home
- The person is attending the premises in the execution of their duties as a member of the emergency services
- The person is a friend or relative of a current or former service user
- The person is visiting a service user who is dying
- 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
- The person is under 18
- The person is participating or has participated in a clinical trial (this should apply once the new regulations are passed by parliament in January 2022)

Evidence for medical exemption

- NHS COVID pass or equivalent from NHS Scotland, NHS Wales or Department of Health Northern Ireland
- Non-digital equivalent of above
- Where the person is not registered with a GP in the UK, confirmation in writing from the clinician responsible for the individual's treatment, or with direct knowledge of the individual's treatment, that they should not be vaccinated with an authorised vaccine

- Individuals who have a GP in the UK and are applying via the formal process will automatically get the results of their application by post 2 to 3 weeks after applying. This notification letter can be used to prove status.
- Pregnant women can also use a MAT B1 certificate to prove their exemption status.

While DHSC emphasises that vaccination is safe for pregnant women, it looks like there will be the option for short-term exemption for them. For pregnant women the exemption will expire 16 weeks post-partum. Pregnant women can also use a MAT B1 certificate to prove their exemption status.

Formal medical exemptions can be applied for by following the instructions on this page: https://www.gov.uk/guidance/covid-19-medical-exemptions-proving-you-are-unable-to-get-vaccinated

Clinical Trials

Evidence to demonstrate exemption from policy due to participation in clinical trial includes:

- Confirmation in writing to registered person from the organiser of the clinical trial that the trial is:
    - For a vaccine against coronavirus
    - Regulated by one of the regulatory bodies in Annex B of draft Code of Practice (page 69)

New Starters

The regulations contain a number of measures for new starters which allow a person to be employed after the regulations come into force for a limited time when that potential employee:

- Has been 'otherwise vaccinated' but not had a top up dose (see information about people vaccinated abroad above); Or
- Has only had a single dose of an authorised vaccine.

Note that the scenarios in the DHSC's Code of Practice (see bottom of consultation response) do not seem to entirely align with the draft regulations and so we are awaiting further clarity and detail. The aim of these changes by DHSC is to offer flexibility for care homes sooner than April 2022 and flexibility for other settings from the date the wider regulations go live in April 2022.

For care homes, the flexibilities are intended to take effect as soon as the regulations are made, possibly in January 2022, and for other regulated health and care services from April 2022.

Scenario 1 for care homes – new starter employed before the regulations are passed by Parliament

No change to the current position. The registered person must ensure that the new starter is not employed for the purposes of a regulated activity unless the new starter has provided evidence that:

- They have been fully vaccinated with a complete course of authorised vaccine
- They are medically exempt
- They have self-certified for vaccination abroad (we believe this will last until April 2022 when the wider regulations go live)

Scenario 2 for care homes - The new starter is employed after the date the regulations passed by parliament (Likely January 2022)

The registered person must ensure that the new starter is not employed for the purposes of a regulated activity unless:

- They have been fully vaccinated with a complete course of authorised vaccine
- They are medically exempt
- They have self-certified for vaccination abroad (we believe this will last until April 2022 when the wider regulations go live)
- **Note** We're not entirely sure if the following bullet point applies from when the regulations are made (January 2022) or when they go live (April 2022). They are 'otherwise vaccinated against coronavirus' (see information about international workers above)
    - The new starter would have 10 weeks from the date of being 'otherwise vaccinated' to prove that they have been vaccinated with an additional dose of an authorised vaccine or been vaccinated with a vaccine listed in Schedule 4A (page 7 of draft regulations) in accordance with the corresponding number of doses. They cannot be deployed after 10 weeks if no evidence is presented. **
- The new starter 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 of the first dose, the new starter will need to provide evidence that they meet one of the conditions as described above.

Scenario 3 for all other health and care services providing CQC regulated activities from the date the regulations take effect (likely April 2022)

The registered person must ensure that the new starter is not employed for the purposes of a regulated activity unless:

- They have been fully vaccinated with a complete course of authorised vaccine
- They are medically exempt
- They are 'otherwise vaccinated against coronavirus' (see information about international workers above)
    - The new starter would have 10 weeks from the date of being 'otherwise vaccinated' to prove that they have been vaccinated with an additional dose of an authorised vaccine or been vaccinated with a vaccine listed in Schedule 4A (page 7 of draft regulations) in accordance with the corresponding number of doses. They cannot be deployed after 10 weeks if no evidence is presented.
- The new starter 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 of the first dose, the new starter will need to provide evidence that they meet one of the conditions as described above.

Moving from out of scope to an in-scope role

If a person moves from a role where it was not required for the registered person to see evidence of vaccination to one where evidence is required, they will be treated as being a 'new starter' in that role from the date that began. The appropriate requirements and conditions as listed above should be followed.

Implementation

The CQC-registered person, either service provider or manager will have responsibility to check the vaccination or exemption status of those covered by the scope. There will be a 12-week grace period from the point Parliament approves the new regulations to go-live, which will likely be in April 2022.

The government is working on ensuring the NHS App alongside a web-based and non-digital solutions are available for workers to evidence status.

Impact Statement

The government has published an impact statement for this policy.

Page 4 of this document has a table which gives an overview of how many staff DHSC believe will remain unvaccinated in wider health and social care settings. It states that they believe that 7.6% (38,000) of non-care home care workers carrying out regulated activities will remain unvaccinated (and exempt) and will therefore will need to be dismissed. They think 3,000 will leave before then as part of normal turnover and so have calculated costs on the basis of 35,000 leavers due to the policy.

The impact statement raises significant concerns as to why the government is pushing ahead with this policy despite the challenges it acknowledges. The government thinks that there will be a greater impact in domiciliary care and other care settings which may lead to lower quality of care and reduced and delayed services. It lists the challenges of a high turnover rate in the sector and challenges in retaining staff and competing with other sectors for staff. However, they have not actually adjusted the wider VCOD policy to reflect this. The impact statement cites the £162.5m recruitment and retention fund but states**: 'As we cannot quantify the maximum working capacity of the current workforce, however, we cannot be confident that the system – even with additional funding – will be able to absorb the loss of capacity resulting from the implantation of this policy, without further intervention'**. This begs the question, why have they pushed ahead with the policy and, given that they are doing so, what is planned in terms of mitigation and practical & financial support for the system?

We're not entirely sure how they have worked out their numbers but the statements states that 503,000 care staff (excluding care home staff and staff carrying out non-regulated activities) will be impacted by the expanded VCOD scope.

There does not appear to be a real understanding in the impact statement about what the loss of 38,000 staff will have in wider social care settings. Instead, the policy claims that there will be benefits from:

- Increased individual health for health and care works (£6.9m)
- Averting sickness absences and the costs associated (£4.3m)
- Reducing hospitalisation costs (£196,000)

In terms of unmonetized benefits:

- Health benefits to patients and care service users
- Benefits to society from higher vaccination uptake – health, wellbeing and economic)
- Greater reassurance to patients and care users

The cost of replacing unvaccinated care workers will be **£86m** in the central estimate (ranging from £32m to £139m).

The impact statement then outlines additional costs which have not been monetised 'leading to potentially lower quality of care'. It is noticeable that legal and implementation costs haven't even been considered:

- Potential disruption to health and care services from needing to replace unvaccinated workers.
- Productivity losses if new, relatively inexperienced staff are recruited to replace staff who leave.
- Productivity losses from staff absences arising from side effects and potentially lower morale of staff if they feel forced into having vaccination.
- Familiarisation costs to the health and care providers to become aware of the regulation and its guidelines.
- Administrative costs to health and care providers who have to deal with complications arising from the regulation, including the redeployment of workers.
- Costs of vaccinations – which are to a large extent sunk costs given already purchased so already accounted for in terms of administrative capacity.