From: Derek Grieve
Vaccines Division
Covid Public Health Directorate
17 November 2020

Cabinet Secretary for Health and Sport

**DECISIONS TO AID URGENT PLANNING ACTIVITY FOR EARLY VACCINE DEPLOYMENT**

**Purpose**

1. To seek your views on critical operational decisions to assist the programme team to further develop their plans, recognising that some of these may change once we have clarity from JCVI and more information on the vaccine characteristics.

**Priority**

2. Routine, although an early steer would be really appreciated to help the operational planning team and ensure the Parliamentary statement addresses these issues.

**Background**

3. As you know the vaccine characteristics for the Pfizer / BioNTech vaccine are complicated and are posing real logistical challenges. Although deployment will only start when there is a safe, effective, high quality vaccine available, which is authorised by the MHRA, we need to make decisions in advance to ensure any time lag between delivery of a vaccine and deployment is minimised.

4. Yesterday I attended the UK Covid-19 Vaccine Deployment Board and was made aware, that it is not yet known if it will be possible to transport the vaccine once it is defrosted as the clinical trials have not tested the impact of significant movement on the stability of the Pfizer BioNTech vaccine at 2-8C. We understand that the Licensing Division within the MHRA are concerned that the physical properties of this product mean that it is fragile and therefore Pfizer/BioNTech is being asked to provide stability data on chemical, microbiological, biological and physical attributes in order to deploy satisfactorily.

5. Current stability data indicate it can accept some movement at this stage (i.e. movement within a mass vaccination site). However, this data may not be sufficient to support MHRA approval of deployment of the vaccine through delivery channels that require transport of the vaccine at 2-8C. We understand that stability studies are being carried out to confirm whether the vaccine can be moved through the supply chain at 2-8C, but we do not expect to receive this data in sufficient time to inform deployment as it may be available as late as the beginning of December. The interim Chief Pharmaceutical Officer is engaging with Pfizer as a matter of urgency to validate this information.

<u>Challenges of the Vaccine</u>

6. There are a number of issues of which we are already aware that are acting as constraints to the delivery planning. Namely:

- The Pfizer BioNTech vaccine will be delivered from the manufacturer in ultra-low temperature (ULT) freezer storage at -70C, and it can be transitioned in an out of ULT storage a maximum of 4 times, after which it must be thawed.
- Once thawed, the Pfizer BioNTech vaccine shelf life is 5 days (120 hours) at 2 – 8 degrees Celsius.
- There are a minimum 195 vials / 975 doses (or multiples thereof) in each delivery, requiring administration of these volumes within 5 days to prevent wastage.
- The Pfizer BioNTech vaccine cannot be moved once diluted, therefore it has to be diluted at the site of administration. There are 5 doses in one vial, which means we cannot use one dose at a time, as this would result in 80% waste.

Potential implications of this on priority groups

7. As you are aware, we have received the interim advice from the JCVI and it is likely that their final recommendation will be broadly in line with this for the first cohort in that the following would be prioritised (in order);

- Residents in care homes for the older adults and staff in care homes for the older adults ; then
- Over 80s ; then
- Health and social care staff.

8. Although any prioritisation will be informed by the JCVI recommendations, there will be a need to balance that prioritisation alongside the practicalities of vaccine packing down, distribution, storage conditions and deliverability in different clinical settings and via different delivery models to minimise wastage. This is particularly relevant in the very early stages of deployment given we may not have all of the information we need to inform delivery given the compressed timeframe we are working to. We also understand that the JCVI were not aware of this stability issue when they met last week and this may have a bearing on their recommendations when they meet on Thursday (and potentially on Saturday to provide their final recommendations assuming they receive the clinical data from Pfizer as anticipated on Friday).

9. The issues set out above would have a fundamental impact of how we would propose to vaccinate residents in care homes and those over 80 years of age. For both residents and staff within a care home it would be impractical and disturbing to transfer them to a mass vaccination centre. We are exploring options to maintain the ULT supply chain up to care homes, but there are challenges with this given the product can only have four frozen transitions and we will have used them all by the time the vaccine gets delivered to NHS Boards. We are however urgently exploring potential solutions to this. For those aged over 80 years old, it may be possible to invite some to a mass vaccination centre, but this clearly wouldn't be an option for those that are housebound. However, the delivery model for Health Care workers (and some social care workers) is different and is based on the vaccine being administered in a central vaccination centre managed through occupational health delivered by NHS Boards themselves.

10. However, even if it is established that the vaccine is stable and therefore could be transferred, the vial size has a bearing for delivering individual outreach to over 80 year olds housebound patients given this would result in a high level of wastage (for one person - 4 vaccines would be spoiled resulting in 80% wastage). However, it would enable us to deliver to care homes in line with our current planning assumptions and to mobile 80+ year olds through locally accessible GP and/or community clinics.

Next steps

11. Given the challenges set out above and the need for us to communicate now to the likely priority groups in order to start vaccinations as soon as the Pfizer / BioNTech vaccine receives a license in early December, we need to make decisions on the operating model that would support this. We have considered how best to proceed and engaged with clinicians and the interim chief pharmaceutical officer to provide you with advice on this.

12. To that end, clinicians are of the strong view that we should ensure as much of the maximum amount of vaccine is used for the priority groups as possible (which should include keeping any wastage to an absolute minimum).

13. We would therefore propose to prioritise all patient facing Health and Social Care workers initially as this has the benefit of delivering vaccines at the site where the vaccine is stored as it would enable the highest volume of the at risk group to be vaccinated with the minimum of wastage. This has the added benefit of being able to invite these individuals easily using email and other forms of direct communication and from a clinical perspective both protects them and the high risk patient groups they will come into contact with as well as providing resilience to health and care services.

14. We would continue to develop our plans around an assumption that the Pfizer BioNTech vaccine will be deemed stable in early December and we would commence vaccinating other groups from mid-December onwards once we have this confirmed by the MHRA. If it is subsequently determined that this vaccine is not proved to be stable for movement at 2-8 degrees, we would need to consider an alternative option, which is likely to include deploying the Astra Zeneca vaccine to these groups given we are likely to have clarity on the delivery schedule for this vaccine at the beginning of December. We also do not believe there are the same constraints to storage and we expect this to be available at the end of December/early January 2021. This would therefore only involve a slight delay to these groups of a few weeks given that we are currently expecting 328k doses to be delivered at the end of December.

Public confidence

15. We are also of the view that should we initiate the invitation process for both the over 80 year olds and care homes based on our current understanding or assumptions on delivery (based on what we know of the characteristics) there is a risk we would need to change these at the same time as we start vaccinating. This has the risk of losing the public's confidence and a further reason why focusing initially on front line health and social care workers is an attractive proposition. We are also conscious that given the JCVI recommendations will also be published, it

will be important if we were to deviate from this (even in the short term) that we are clear about the reasons for doing so.

Other areas of the UK

16. Colleagues in others nations are grappling with this issue too. We have shared our early thinking and encouraged all to adopt a similar position to ensure an element of consistency across the UK. There are a number of options being considered, but as yet no final decision has been taken. We are due to have early meeting with officials, but we may wish to use any Ministerial engagement to explore this issue too.

Summary

17. We understand that JCVI will be meeting on Saturday, assuming they receive the final clinical data from Pfizer/BioNTech to consider their final recommendations. We will of course provide you with advice on the final policy position following this.

18. It would therefore be helpful to have a steer on whether you are content for us to proceed for the purposes of planning to deliver the first batches of Pfizer BioNTech vaccine to patient facing Health and Social Care workers, recognising that this may differ slightly to what JCVI may recommend due to the high level of uncertainty regarding the stability of the vaccine. I can confirm we have engaged with senior SG clinicians and they have confirmed they are content with this approach.

**Conclusion**

19. I would therefore be grateful if you could confirm:

- If you are content for the delivery team to progress their planning activity on the basis of the information as outlined above; &
- Whether you would wish us to set out some of these challenges within your Parliamentary statement.

**Derek Grieve**
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**Irrelevant & Sensitive**

| **Copy List:** | For Action | For Comments | For Information | | |
|---|---|---|---|---|---|
| | | | Portfolio Interest | Constit Interest | General Awareness |
| Minister for Public Health, Sport and Wellbeing<br>First Minister | | | X | | X |

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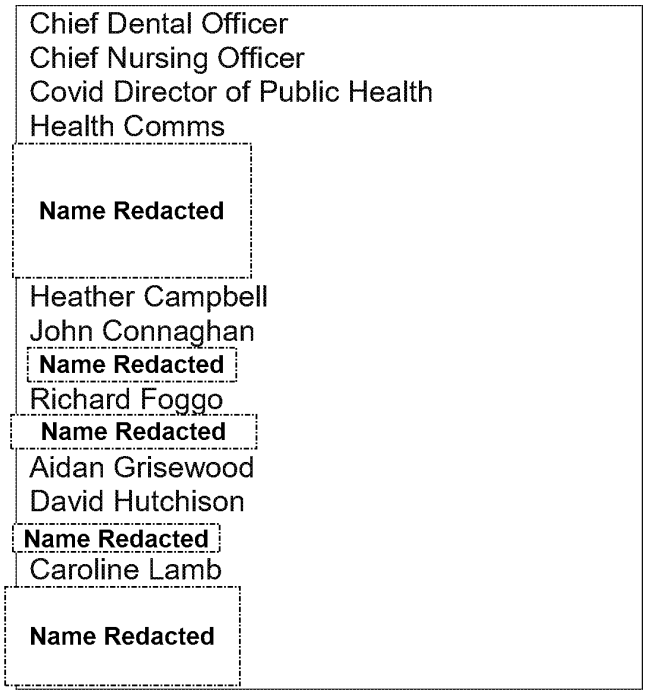
|---|
| Permanent Secretary<br>DG Community Health and Social Care<br>Chief Medical Officer<br>Deputy Chief Medical Officer<br>National Clinical Director<br>Chief Scientist<br>Chief Pharmaceutical Officer |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