Delivering Mass Vaccinations During COVID-19

A Logistical Guide for General Practice

This document has been written by a number of clinicians with experience of delivering vaccinations at scale. It is written with the understanding that a number of mass vaccination programmes may need to be delivered during mid-2020 to 2021, while COVID-19 continues to be in general circulation; it will address approaches to delivering large-scale vaccination programmes in this context.

This document will not cover clinical aspects of immunisations.

Acknowledgements

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Scope

This document has been produced to assist GPs, lead practice nurses, Practice Managers, Clinical Directors, GP Federations, PCNs and CCGs/Health Boards in understanding the practicalities and challenges of delivering mass vaccination programmes in a context when COVID-19 remains in general circulation. It sets out key areas that will need to be considered, offers possible solutions and highlights areas where risk assessments are required, particularly where these may differ from normal practice. This document focuses on the needs of general practice but may also be of relevance to other vaccinators, local directors of public health, and colleagues operating in international contexts. The guidance is intended to be generic, and applicable to various potential vaccines which may need to be delivered to a large population in a short time frame.

This document should be read in conjunction with other relevant guidance from the RCGP, national organisations (such as NHS England, Public Health England and equivalent bodies across the devolved nations), and other medical bodies (such as the Royal College of Nursing and Royal Pharmaceutical Society and the BMA).
Introduction and Context

General practice and the delivery of large-scale vaccination programmes
The UK has a long-established system for vaccinating people against infectious disease. As well as programmes of childhood vaccination, the UK delivers a large-scale seasonal influenza (flu) vaccine programme on an annual basis. This is principally delivered in general practice, pharmacies, maternity departments, occupational and school vaccination services. In typical years, this programme is delivered to over 15 million people in the UK (see Table 1., below). All four nations of the UK consistently achieve some of the highest vaccination rates in the EU among the over-65s group (see Figure 1., below).

Table 1. UK Seasonal Flu Vaccination Coverage, 2019-20 season - Number of patients vaccinated and target population by cohort and nation

<table>
<thead>
<tr>
<th></th>
<th>General Practice†</th>
<th>Schools</th>
<th>Employers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>65+ years</td>
<td>Under 65 at-risk</td>
<td>Pregnant Women§</td>
</tr>
<tr>
<td>England</td>
<td>7,621,505 (10,523,854)</td>
<td>3,182,752 (7,086,331)</td>
<td>242,024 (574,918)</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>241879 (323,475)</td>
<td>156,943 (266,401)</td>
<td>No data</td>
</tr>
<tr>
<td>Scotland</td>
<td>787,766 (1,064,075)</td>
<td>331,162 (787,711)</td>
<td>14,962 (34,871)</td>
</tr>
<tr>
<td>Wales</td>
<td>469,497 (676,939)</td>
<td>197,481 (448,018)</td>
<td>10,618 (23,085)</td>
</tr>
</tbody>
</table>

† Responsibility for provision of vaccinations to pregnant women is shared between general practice and antenatal services, depending on local arrangements.
§ This excludes those pregnant women already counted in the Under 65 at-risk group.
* In England and Scotland, this includes children aged 2-3, in Wales and Northern Ireland, aged 2-4.
^ Raw data for Northern Ireland, Scotland and Wales has not been published, however percentage coverage has been, and is provided here.

Figure 1. Seasonal influenza vaccination coverage rates in older age groups, 29 EU/EEA Member States, 2007–08 to 2014–15 influenza seasons

Source: National seasonal influenza vaccination surveys, July 2009–December 2015
*Age groups of over 65 years of age and clinical risk groups combined
†Sweden: For the 2009–10 influenza season, reports were received for around 60% of the population.

While this programme is delivered in a variety of locations including pharmacy branches, people’s homes, workplace and schools, the majority of the programme is delivered in general practice. General practice is particularly well prepared for such large-scale vaccination programmes, with the capacity to effectively reach large numbers of patients quickly and the appropriate physical and digital infrastructure to deliver the programme (such as reliable cold chains, appropriate stocks of equipment, medical waste disposal facilities and access to patient records). Furthermore, the dispersed nature of general practice means that there is less reliance on any one provider.

These factors together mean that general practice can easily deliver large-scale vaccination programmes, with high throughput in a short space of time. This improves productivity, reduces vaccine wastage and minimises impact upon other clinical services, while maximising vaccination coverage.

The challenges posed by COVID-19
In the past primary care has provided emergency vaccination to reduce the spread of disease, notably in 1960s (smallpox) and 2010 (swine flu pandemic). It is apparent that a similar scale of emergency vaccination will be needed from primary care, because of the COVID-19 pandemic. This includes significantly expanding the seasonal flu vaccination programme and potentially delivering mass vaccination against COVID-19.

However, the COVID-19 pandemic poses a specific set of challenges to achieving high volume throughput. For example, it is likely that enhanced standards of infection prevention and control will be needed, and larger spaces may be necessary to maintain safe social distancing. Premises normally used to undertake vaccination (GP surgeries, pharmacies, schools) are likely to be impacted by any restrictions of social distancing, if in place. Creating a safe flow of patients to achieve the high throughput to vaccinate large numbers may be difficult in many locations and impossible in some.

In the context of social distancing, use of personal protective equipment and increased time necessary for immunisers to prepare for each patient, it is likely that additional time will be required. Under normal circumstances, well-organised, properly supported flu clinics may be able to vaccinate patients at rates as high as one patient per vaccinator every one to three minutes, as part of a patient journey around 15 minutes in length.

In these altered circumstances, we estimate that the actual vaccination process may take at least four minutes, and potentially five to six minutes depending on the PPE requirements. Unless the number of vaccinators is also increased, this will have significant implications for the time taken to vaccinate a population (see Table 2., below). Additional time will be needed to allow for staff breaks. Other elements of the process (registration, queuing etc.) will add to the length of the patient journey, but it likely that the vaccination itself will be the limiting factor.
High throughput of patients will also require adequate, reliable supplies of the vaccine itself. Local refrigeration capacity for vaccines and vaccine delivery schedules are crucial components in the seamless steady administration of vaccines to patients.

Furthermore, government has now announced a substantial expansion of the seasonal flu programme for 2020-21 (though full details have yet to be published).⁴ Priority will be given to the ‘regular’ cohorts (as detailed in Table 1), but to mitigate pressures from a heavy flu season, and protect at-risk groups, free vaccinations will also be offered to those aged 50-65 years, and to the households of patients identified as extremely clinically vulnerable (shielded patients). Government estimates this will mean vaccinating over 30 million people, twice the usual programme scale. It remains the case that general practice will deliver the majority of this expanded programme. Additional locality vaccination may be required for outbreak control purposes, and a similar population may need priority vaccination against COVID-19 in the first instance.

This vaccination programme will need to be delivered by a workforce which is facing additional demand due to the longer-term impacts of the COVID-19 pandemic and lockdown, and which may have reduced capacity, due to the need to protect vulnerable staff from frontline work and for potentially infected staff to self-isolate.

These factors, taken together, suggest that services, facilities and delivery models may need to be altered or enhanced to ensure that vaccination programmes are successful. Furthermore, specific requirements, such as social distancing measures, may be subject to rapid change. Plans should therefore be based around a reasonable worst-case scenario for delivering the vaccine.

With sufficiently detailed planning and preparation, however, it will be possible to mitigate these risks and deliver effective vaccination programmes which protect patients without impacting unduly on delivery of other services.

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Table 2. Time taken to vaccinate 100 people

<table>
<thead>
<tr>
<th>Number of Vaccinators</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
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<tr>
<td>1</td>
<td>200</td>
<td>300</td>
<td>400</td>
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<td>150</td>
<td>175</td>
<td>200</td>
<td>225</td>
<td>250</td>
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</tbody>
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Prior Planning and Leadership

Detailed planning is essential to effectively delivering any large-scale vaccination programme, particularly where this departs from routine practice. This planning should be undertaken well in advance of the likely date of roll-out, to allow time for any challenges to be identified and mitigated.

Planning and delivery should be undertaken across a consistent, pre-agreed footprint. It may be more efficient and cost effective to provide immunisation across a number of providers, pooling resources and sites to deliver the best service possible, and working in coordination with other local stakeholders such as directors of public health and local government. For example, a grouping of GP surgeries/providers (such as a GP federation or Primary Care Network), may work together to jointly immunise a given population. If the footprint is not based on a pre-existing organisational structure, but is created on an ad hoc basis, this may create additional challenges for the governance and management of the vaccination programme, which should be fully considered from the outset.

Across a given delivery footprint, clear structures and lines of accountability are necessary. A single clinical lead (such as a PCN clinical director, a specific GP/nurse partner in a GP federation, or a Senior Practice Nurse) should be appointed to take responsibility for coordinating planning and delivery, ensuring patient safety and where necessary, providing a link to national and subnational governance structures.

It should be noted that there may be additional regulatory requirements if the lead practice or host is delivering vaccinations outside their usual premises. Where the lead practice is delivering vaccinations at an alternative site, that site will need to be added to the statement of purpose of the lead practice. Where the chosen site is the premises of a specific practice (rather than a non-traditional facility), it may be convenient for that practice to act as the lead for the vaccination programme.

It is also likely that mass vaccination may be delivered by multiple organisations and structures working in parallel; significant parts of the seasonal flu vaccination programme are delivered outside general practice (by schools, pharmacies and employers including secondary care). In the event of a programme of COVID-19 vaccination alongside seasonal flu vaccination, it may be necessary for the NHS to develop an additional vaccination infrastructure working with trusts. In these circumstances, coordination will be vital to ensure that vaccines are delivered appropriately, and that the correct patients receive the correct vaccinations in a timely fashion.

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Practical Considerations

There are a wide range of practical considerations which should be borne in mind when planning and delivering large-scale vaccination programme.

The following points should be addressed early in the planning stage.

Governance and leadership

- Is there a clear leader of the process, who has the authority to make necessary on decisions on delivery including regarding financial and governance issues?
- If this is being delivered at an above-practice level does it need its own governance structure (incident reporting), CQC registration and management teams? Such structures may already be in place in certain circumstances.
- What are the financial elements to immunisation delivery?
- Does the chosen location necessitate an alteration to CQC statement of purpose?

Programme scale and eligibility

- Is the scale of the requirement clear? Who should receive the vaccination? If multiple programmes are to be run (seasonal flu, COVID-19), is it clear how these will overlap, and what impact this will have on delivery?
- Has vaccine be ordered in sufficient quantities and when will it arrive?
- What are the required timeframes for delivery of the programme?
- If the programme is particularly large-scale or particularly urgent, is a system of prioritisation in place to ensure that those most at risk receive the vaccine soonest?
- What is the communication plan to ensure that eligible patients are aware of the immunisation? Does this require the involvement of local/national media?
- How will eligible persons be contacted? How will non-attenders be encouraged to attend? Will patients be cohorted based on age, risk factors or other characteristics? Particular consideration should be given to vulnerable or hard to reach groups, which may be more appropriately vaccinated in ‘traditional’ settings.

Vaccination process requirements

- Is the vaccine a single dose or multiple doses? If multiple doses, what implications does this have; how will repeat engagement be ensured? This may be further

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Government has confirmed the expansion of the 2020 flu programme to those aged 50-65 and shielded patients households, however updated guidance has not yet been published.
complicated if multiple large-scale programmes are being delivered in parallel or quick succession (e.g. flu vaccine and possible coronavirus vaccine).

- If multiple vaccines are available, how will patients be cohorted to receive the most appropriate vaccine?
- What are the necessary cold chain requirements and how will they be met?
- What is the format of the vaccine – injectable or nasal? Are there any implications on the format of the vaccine?
- Does the vaccine come in a large vial requiring individual doses to be drawn up or is it in a pre-filled syringe with needle? How does this effect equipment needed, time taken etc? PHE guidance should be considered in this context.

Staffing and delivery
- Do staff understand their roles and responsibilities? It may be beneficial to work in teams of two or more, with at least one administrator and one vaccinator. Additional staff may be able to assist with vaccine preparation, and it may be helpful to have multiple vaccinators to each administrator, who rotate to allow for IPC measures/changing PPE. Multiple teams may be able to work in parallel.
- Are there sufficient members of staff to deliver vaccination, and to prepare vaccinations and provide logistical, administrative and clinical support?
- If additional staff are needed, where will they come from? What legal or regulatory issues may need to be addressed to allow for safe patient care, including the limitations of Patient Group Directions (PGDs)?
- Are staff trained for their roles, or is training required?
- Are staff trained in the immediate identification, support and treatment of any patients who develop difficulties in accordance with Resuscitation Council guidelines? Are appropriate support and resuscitation facilities available? Provision of simple airway support equipment and a defibrillator is strongly recommended in addition to anaphylaxis medication.

Data and record keeping
- Is there a requirement for IT access to view and record patient information; how will this be achieved? If WIFI solutions are used can these cope with multiple devices, particularly if all are to be logging on simultaneously? This may affect the preferred location for programme delivery.
- How will immunisation delivery be reported to relevant authorities and by when?

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Location, premises and social distancing

A key consideration when delivering a large-scale vaccination programme will be the most appropriate location for vaccination clinics. Under normal circumstances, vaccinations are routinely delivered in surgeries, pharmacies, schools, places of work and other locations. However, many such 'typical' locations may not lend themselves to ensuring rapid through-put, while maintaining social distancing. Model layouts to allow for high through-put in non-traditional settings are included in Appendix B and C. These models assume multiple teams of vaccinators and parallel queues to maximise through-put, while maintaining social distancing.

Key factors to consider will include the local geography (rural vs urban, and ease of site access), building design, accessibility and occupancy, prevailing social distancing requirements and numbers required to be vaccinated at what speed.

If high through-put is required, indoor and outdoor queuing maybe be considered, however additional consideration may be needed in cold or inclement weather, or when delivering a vaccination to vulnerable groups. It may be appropriate to have a 'fast-track' queue for such patients, perhaps allowing the person to bypass normal queuing arrangements, or to provide specific time-slots (for example 10-15-minute intervals). Other factors include digital infrastructure and record keeping, facilities for infection prevention and control and transport/traffic management.

Delivering a programme at scale across numerous providers may increase the range of available settings. For example, it may be possible to deliver vaccinations in more modern surgery premises (with more capacity for social distancing), while relocating lower through-put routine practice to other settings. Alternatively, operating at scale may facilitate access to other settings such as community centres or schools.

Liaison with local and NHS authorities and potentially local police maybe required to ensure that suitable parking, traffic flow and any site security implications are managed.

Local GP surgery
If suitable flow routes and volumes can be achieved, or this is the most appropriate place for a restricted number who cannot attend elsewhere.

Pharmacy premises
If suitable flow routes and volumes can be achieved, or this is the most appropriate place for a restricted number who cannot attend elsewhere.

Larger community health facility
Larger buildings may offer opportunities for better queueing and circulation of patients but may have multiple occupants whose safe working may be impacted by or limit the numbers of patients who can access a vaccination clinic. These locations offer greater flexibility to individual practices but may provide opportunities for cross-practice (PCN/Federation) working.
Other buildings
These may be made available by schools (such as a school hall/gymnasium) or Local Authorities (council gym or village facilities) to provide larger spaces. They often have reasonable accessibility and transport arrangements, however there may be challenges relating to managing queues, equipment, technical infrastructure and storage. Use of some buildings (e.g. places of worship), may raise additional cultural issues.

Drive-through facilities
These can provide some safety for the patients whilst queueing, however they require large spaces and well-developed traffic management. If weather is adverse, arrangements should be made to protect clinical, administrative and ancillary staff. Adverse weather may also raise additional barriers to patient access, and drive-through facilities may mean patients feel less able to raise questions or concerns.

Patients taken ill within a vehicle, fainting, hyperventilating or anaphylaxis may present a potential issue, particularly if they are the driver of the vehicle. Managing this risk may require additional planning and consideration. It may be appropriate to require all patients to wait onsite post-vaccination before departing.

Equipment and layout requirements

Equipment requirements
- Furniture (chairs, tables, screens)
- Crowd barriers
- Refrigeration
- IT (computers, broadband), power supply
- Waste disposal (general, clinical, sharps)
- Personal protective equipment
- Welfare (rest area, catering/refreshments including beverages and lunch provision)
- Vaccination equipment and supplies
- Additional medical equipment (couch, resuscitation and diagnostic)
- Screening and lighting for staff rest areas and for patients taken ill.
- Clear signage both outside a venue and inside, directing patients where to go

Layout requirements for at-scale provision
- Flow of patients (separation of entrance and exits)
- Reception & triage space (to identify patients and assess any who are unwell)
- Queueing space (maintaining social distancing as far as possible)
- Fast-track route (for patients with limited mobility or additional requirements)
- Toilets
- Hand washing facilities for both patients and staff
- Emergency / first aid area
- Secure equipment storage, including for vaccine stocks, PPE and IT equipment.
- Cold chain for supply and storage of vaccine
- Waste disposal (requirements will depend upon how PPE is used)
- Rest area
- Transport and traffic management capacity.

Layouts for indoor and drive-through facilities are provided in Appendices B and C.

**Personal protective equipment and infection prevention and control**

Personal protective equipment and infection prevention and control procedures should follow current guidance from Public Health England and devolved nations bodies.\(^8\) Plans should take in to account the possibility that guidance may change, and specific guidance for vaccination processes may be published in due course.

Matters to consider include:

- PPE requirements for both immuniser and administrative staff. Requirements for child immunisation, which may entail closer contact and use of nasal vaccines, should be considered separately from the needs of adults;
- PPE requirements for patients and how this will be communicated in advance. Current RCGP guidance recommends that where possible, patients wear face coverings.\(^9\) If patients arrive without a face covering, will it be provided?
- Ensuring sufficient supply of PPE for an immunisation session;
- Cleaning requirements, where appropriate;
- Disposal of clinical waste, including PPE and sharps containers, particularly if operating in a non-typical setting.

**Other practical considerations irrespective of location**

**Design error out**

If multiple types of vaccine are available for an individual disease, it is recommended that where possible, only one type is used in a particular session. This is to reduce the potential for error and will require cohorting of patients in advance. If two vaccines are to be administered, for example seasonal flu and COVID-19, ensure that they are clearly labelled and separated.

**Risk Assessment**

Has a thorough risk assessment been conducted for the programme as a whole, and for specific vaccination sessions? Are risk assessments regularly reviewed and updated? How will identified risks be mitigated?

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\(^8\) Public Health England, *COVID-19 personal protective equipment (PPE)*,

Equalities Impact Assessment
It may be appropriate to conduct an equalities impact assessment against protected characteristics to ensure that specific groups are not disadvantaged through mass vaccination programmes. This should consider how patient concerns may be addressed.

Infection prevention and control
What infection control requirements such as handwashing/masks/face coverings are needed for both staff and patients? How will these be efficiently implemented? Current guidance from Public Health England and devolved nations bodies should be followed.

Patient assessment and record keeping
Confirmation of the patient’s identity may be required. Ensure that that relevant consent has been sought and documented. Ensure that relevant contraindications have been excluded.

If possible enter information into clinical records once and automate the process. GP computer systems allow for the entry of repetitive information using macros and equivalent. Pre-populate macros with relevant vaccine information prior to a session and ensure that vaccinators and administrative staff know how to utilise them. An exemplar patient record form can be found in Appendix A.

Where immediate access to clinical records is not possible, systems should be established to ensure vaccination details are added to patient records and, where necessary, further vaccinations scheduled. It may be necessary to collect information on the reason for vaccination (e.g. over 65, at risk patient, healthcare worker), and on protected characteristics such as ethnicity (particularly given the increased COVID-19 risk for BAME individuals). These should be based on official lists of eligible cohorts and protected characteristics. Systems should also be established to share coverage information with relevant local and national authorities.

Advanced communication
Provide clear information and guidance to the patient in advance. Key information includes:

- Type of vaccination. It may be appropriate to share the patient information leaflet and provide opportunities for patients to ask questions, discuss side-effects etc, in advance;
- Process for vaccination;
- Location and setting (including awareness that vaccine may be delivered in an open plan venue, rather than a private consulting room);
- When to arrive for their designated slot to prevent backlogs (patients should not present early or late);
- What type of clothing to wear;
- What PPE to wear;
• What paperwork to bring;
• To attend alone if possible;
• Not to attend if unwell.

Provide relevant information such as Patient Information Leaflets
In accordance with normal practice patients should be provided with a Patient Information Leaflet of the vaccination(s) they receive. This information could be provided in paper form or electronically by text/email.

Prepare the patient
If a patient is queuing, encourage them to remove outer layers of clothing/roll up sleeves and fill out necessary paperwork to ensure that they can be immunised speedily.

Cold Chain
Ensure that refrigerators contain sufficient stock of vaccine for a session and that necessary cold chain requirements have been met.

Potentially unwell patients
Patients should be advised in advance not to attend if feeling unwell. Nonetheless, some patients may present to the vaccination location unwell, or may become unwell whilst attending the vaccination location. Facilities must be in place for the assessment and management of patients who are unwell, this must include resources to manage fainting and anaphylaxis/cardiac arrest to a primary care level of skill. Reliance on 999 Paramedics is not appropriate.

Consideration should be given as to how patients who are unwell would be isolated and assessed, and what implications that might have (e.g. five-year-old child with cold symptoms, can they continue to be vaccinated?). Consideration should also be given to ensuring attendance at future session if vaccination is not administered.

Post-vaccination observation
Recipients of any vaccine should be observed for immediate Adverse Drug Reactions. There is no evidence to support the practice of keeping patients under longer observation in the GP surgery. (Green Book Ch 4)

There is a common misconception that individuals should wait 20 minutes after receiving a vaccine. Most reactions will occur within two minutes and some occur hours later. The advice from the RCN is that there is no need to keep patients waiting unless this is specifically indicated in the summary of product characteristics for a given vaccine.10 It is currently unknown whether a potential COVID-19 vaccination will require a period of observation following administration.

Patient groups with additional requirements

Hard to reach groups
When designing services, consider those who may be hard to reach and require additional support or immunising at different times/locations especially given that such patients may be more at risk, and may face barriers in accessing vaccination (for example travel limitations).

Additional requirements
There are several groups who will need specific access arrangements or support to be able to access vaccination. These may include those with limited mobility including wheelchair use but also hidden disabilities such as hearing loss, poor vision or learning difficulties including autism.

Services should consider how these groups will be supported to access vaccination. Consideration may be given to the use of Hidden Disability lanyards and training. Consider implementing a “fast track” route for patients unable to queue and their carers/family, equivalent to an airport whereby they can be immunised quickly.

Home visiting
There will be several groups, including care home residents, who will need domiciliary vaccination and services should consider how this can be achieved (including how cold chain requirements can be maintained).
The Patient Journey

Pre-Vaccination
• Patients stratified by risk, type of vaccination (where applicable), additional needs;
• Patient cohorts contacted to book vaccination slot at one of a number of sessions (if multiple injections for one vaccine, both may be booked at once to ensure full schedule is delivered);
• Patient provided with information on vaccine, guidance on what to wear, what to bring, what to do if feeling unwell;
• Patient given opportunity to address any concerns through follow-up telephone appointment if necessary;
• Patients reminded of booking a few days beforehand.

Arrival at Vaccination Site
• Patients arrive during specified time-slot (with some capacity for early/late arrivals);
• Traffic flows managed by marshal;
• Patients directed to hand-wash station by entrance;
• Patient directed to reception, where they are registered and triaged;
• Patients join socially distant queue (fast-track or seated queue for patients with additional needs).

Vaccination
• Patients reach front of the queue
• Patient confirms details with administrator, while vaccinator prepares vaccine
• Patient vaccinated
• Patient moves to rest area
• Vaccinator changes over with alternate for infection control purposes
• Patients who are taken ill may be moved to a rest area

Post-Vaccination
• Patients provided with information leaflet, either in person or via email
• Patients free to depart
• Follow-up text/call to confirm date of subsequent injection if needed
Further Information


Appendix A: Mass vaccination paper record

It may be appropriate to collect data on reasons for vaccination and protected characteristics, to ensure equitable coverage.
Appendix B: Vaccination centre layout
Appendix C: Drive-through vaccination layout

Drive Through Infographic

IMMUNISER BOOTH TEAM OF 2
Admin and Immuniser

EXIT

A  B  C  D

↑  ↑  ↑  ↑
↑  ↑  ↑  ↑
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DRIVE THROUGH ENTRANCE + VEHICLE RECEPTION

Consider
- Security requirements
- Toilets
- Hand wash facilities
- Vaccine
- Fridge
- PPE dump
+ Hazardous waste store

'IT Required