

Mass Vaccination Programme

Final Internal Audit Report

July 2021

Cwm Taf Morgannwg University Health Board

NWSSP Audit and Assurance Services



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1. Introduction and Background

The review of the mass vaccination programme was completed in line with the 2021/22 Internal Audit Plan. The review assessed the effectiveness of Cwm Taf Morgannwg University Health Board's (the 'Health Board') plan to manage the key risks associated with the roll out and implementation of the mass vaccination programme (the 'Programme').

Since the summer of 2020, the Health Board has been preparing the delivery of vaccination services for health and social care frontline staff and its local population based on a priority rating. The aim being to implement swift activation of the plan when vaccines became available. A Covid-19 Vaccination Programme Board and a wider Stakeholder Group were established, and the Health Board's draft plan was sent to Welsh Government (WG) in September 2020.

On 2 December 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) granted the Pfizer / BioNTech vaccine temporary authorisation for use based on evidence of safety and effectiveness. The Oxford/AstraZeneca vaccine was approved for use later in December, followed by the Moderna vaccine in January 2021. The Health Board started rolling out its mass vaccination programme using the Pfizer / BioNTech vaccine on 7 December 2020.

The Joint Committee for Vaccination and Immunisations (JCVI) has provided an order of priority to vaccinate the population, which is detailed below:

1. residents in a care home for older adults and their carers;
2. all those 80 years of age and over and frontline health and social care workers;
3. all those 75 years of age and over;
4. all those 70 years of age and over and clinically extremely vulnerable individuals;
5. all those 65 years of age and over;
6. all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality;
7. all those 60 years of age and over;
8. all those 55 years of age and over; and
9. all those 50 years of age and over.

The Welsh Government Vaccination Strategy sets out three key milestones in which they planned to have offered a vaccine to each of the above priority groups. The guidelines stated that each health board should start with priority group 1 and work their way through each group in order of sequence. Health boards were able to move onto the next priority group once they had offered vaccines to 50% of the current group.

The initial milestone target for the Health Board was to offer first doses of vaccines to those in priority groups 1 to 4 by 14 February 2021. For the Health Board, this amounted to 110,000 people. To ensure this was achievable, an operational model

using a mobile vaccine team for those based in care homes, hospital vaccination sites for frontline health care staff, and GP practices and community vaccination centres for all others was developed. By the end of January 2021 51 GP Practices were vaccinating their patients and four Community Vaccination Centres (CVCs) had been set up, though this later grew to seven CVCs. The target associated with priority groups 1 to 4 was achieved.

The second milestone related to priority groups 5 to 9 was initially less prescriptive as it required health boards to have made vaccination offers by spring 2021. However, this was later defined as the end of April 2021. The Health Board identified approximately 148,000 residents that fell into these priority groups. Alongside offering a first vaccination these residents the Health Board aimed to offer all those in priority groups 1 to 4 with their second dose of the vaccine. Again, this target was achieved.

The final milestone related to offering the rest of the adult population a first dose of the vaccine by autumn 2021, however this was brought forward by WG to the end of July 2021.

As at 5 July 2021, 569,675 people had been vaccinated by the Health Board, of which 324,810 people had received their first jab and 244,865 had received both jabs.

2. Scope and Objectives

We assessed the adequacy and effectiveness of the internal controls in operation. Any weaknesses will then be brought to the attention of management and advice issued on how particular problems may be resolved and control improved to minimise future occurrence.

The specific objectives that we reviewed were:

- To ensure that an effective plan is in place detailing the delivery of vaccinations for each priority group and in particular:
 - sufficient trained resource to support delivery;
 - all potential patients are identified within each priority group, including individuals not registered with the Health Board;
 - arrangements to ensure patients are offered a vaccination and follow-ups where appointments are missed;
 - the selection of an appropriate vaccine, taking into consideration storage facilities, patient factors (e.g. allergies) and availability;
 - the management and scheduling of second doses, where required;
 - ongoing communication with the population of the Cwm Taf Morgannwg area, to provide assurance over the vaccinations and to answer frequently asked questions;
 - communication with relevant staff to keep them updated of changes that occur (external and internal to the Health Board);
 - key milestones are documented.

- To confirm that appropriate governance / oversight over the delivery of the plan is in place, including:
 - the progress of delivery in line with the JCVI priority list, through regular reporting;
 - lessons learnt and continual improvement; and
 - appropriate approval and monitoring of the plan, including action taken to address shortfalls in delivery or where milestones are not met.

Whilst undertaking the review and testing the controls that are in place, we were mindful that the mass vaccination programme has been set up as an emergency response to the situation NHS Wales finds itself in, and our reported finding and recommendation reflects this.

3. Associated Risks

The risks considered in the review were as follows:


- The plan in place for mass vaccination is not efficient leading to wastage of the vaccine and delays to the delivery of the vaccination programme.
- Insufficient training for staff, resulting in delays to vaccinations being delivered and / or an increased risk of patient harm.
- Reputational damage as a result of a delayed delivery of vaccinations or insufficient information provided.
- Risk of the public not being vaccinated in a timely manner.
- Members of the population are omitted from the vaccination programme.
- Insufficient monitoring of the vaccination programme, resulting in an inefficient delivery.
- A lack of accountability for the implementation of the mass vaccination programme.

OPINION AND KEY FINDINGS

4. Overall Assurance Opinion

We are required to provide an opinion as to the adequacy and effectiveness of the system of internal control under review. The opinion is based on the work performed as set out in the scope and objectives within this report. An overall assurance rating is provided describing the effectiveness of the system of internal control in place to manage the identified risks associated with the objectives covered in this review.





The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with the Mass Vaccination Programme review is *substantial* assurance.

Rating	Indicator	Definition
<p style="text-align: center;">SUBSTANTIAL ASSURANCE</p>		<p>The Board can take substantial assurance that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with low impact on residual risk exposure.</p>

The overall level of assurance that can be assigned to a review is dependent on the severity of the findings as applied against the specific review objectives and should therefore be considered in that context.

5. Assurance Summary

The summary of assurance given against the individual objectives is described in the table below:

Assurance Summary					
1	Effective delivery plan				✓
2	Appropriate governance and oversight				✓

The above ratings are not necessarily given equal weighting when generating the audit opinion.

Design of Systems/Controls

The findings from the review have not highlighted any issue that are classified as a weakness in the system control/design for the vaccinations programme.

Operation of System/Controls

The findings from the review have highlighted one issue that is classified as weaknesses in the operation of the designed system/control for the vaccinations programme.

6. Summary of Audit Findings

By early July 2021, 569,675 first and second doses have been delivered across Cwm Taf Morgannwg area. This means that 88% of adults have had at least one dose of the vaccine and 67% of adults are now fully vaccinated.

In June, to encourage further uptake, the Health Board trialled a walk-in clinic at their Mountain Ash CVC. This allowed anyone over the age of 18 to 'walk-in' with no appointment for their first dose. After an evaluation of how well the trial worked, walk-in appointments are now available most days at five of the CVC.

The governance arrangements and internal controls in place help to ensure that planning, monitoring and delivery of a successful mass vaccination programme which is aligned to JCVI requirements. Detailed below are our observations for each of the areas that we reviewed. What has been clear through the meetings that we held and the documentation we sighted, is the dedication and commitment of staff in delivering a programme of work that was almost constantly changing. At times this will inevitably have placed members of staff under immense pressure and potentially has been an ongoing risk to the Health Board where there has been reliance on a few key individuals. We have made a recommendation in relation to this.

As the current phases of the vaccination programme roll out draw to a close, a report to capture the lessons learnt is being produced. The Health Board undertook a similar exercise in February 2021 between phases one and two of the roll out and implemented a number of changes, though the current 'lessons learnt' report is more likely to influence future projects.

Objective 1: An effective plan was in place for the delivery of vaccinations for each priority group.

Training to support delivery

The Specialist Immunisation Team were responsible for developing the clinical delivery of the Community Vaccination Centres (CVCs). This included recruitment of staff, identifying equipment needs, administering training and managing rotas. Staff are trained using the recognised standards, which includes CPR and anaphylaxis training and the infection control e-learning module.

The core staff that were recruited and trained to work in the first two CVCs, have since split, so that every CVC team now has an element of the original cohort of staff. Workshop training sessions for the senior team within the CVCs also took place to ensure that the standards continue to be maintained. The Specialist Immunisation Team are still present in the CVCs and can address training needs or identify any failings.

The Health Board has to date recruited approximately 40 WTEs with a wide skill mix. Innovative approaches were adopted when creating the job descriptions that has allowed Allied Healthcare Professionals to also apply, therefore widening the scope of applicants.

Staff absence and annual leave has been covered using Bank staff or with staff from other CVCs where necessary. Furthermore, the Specialist Immunisation Team and some of the community teams are trained to vaccinate should there be a significant staffing shortage. To date, the Health Board has not had to utilise any agency staff within the CVCs

Potential patients are identified

The Welsh Immunisation System (WIS) has been developed by NHS Wales Informatics Service (now Digital Health and Care Wales, 'DHCW') for the roll-out of the mass vaccination programme. Patient data is refreshed daily, which ensures that changes to priority codes are quickly actioned in line with JVICI requirements.

DHCW produced an automated appointment run in WIS. The priority groups were loaded onto WIS based on data extracted from primary care records and appointments were allocated to patients in line with planning and progress through the cohorts. Each automated appointment run included individuals from previous priority groups that had not had an appointment. Daily internal reports were produced to identify anyone who has not had their vaccine within a 12-week period.

Vaccine appointments were generated from information held on primary care records. Local authorities provided information for patients who may not be registered with a GP, such as homeless people or gypsy and traveller communities. Booking appointments, especially for the homeless, proved difficult and the team

have relied heavily on third parties, such as charities and Local Authority homeless groups to co-ordinate their vaccine appointments. The Health Board 'ring-fenced' 10 appointments per day at each CVC to accommodate these groups of people.

Individuals who temporarily work in the area or are home from university were asked to temporarily register with a local GP otherwise their appointment letters would be generated by the Health Board where they are registered.

In care homes where positive cases prevented vaccinations taking place, a RAG monitoring status was introduced to help manage the situation and ensure later visits were planned. This was monitored by the Lead Nurse responsible for the care home campaign. Once 28-days had passed, and there are no more positive cases, the Vaccination Team could visit the care home and carry out the vaccinations.

Missed appointments

Patients can 'suspend' their appointment and should complete an online 'Mop up Clinic' form when they were ready to reschedule. Individuals that do not attend an appointment without an explanation are recorded as 'DNA' (Did Not Attend).

Daily DNA reports are reviewed by the Project Team's admin support and the Contact Trace Team. Patients are contacted by phone or text offering an appointment. If there is no response after three attempts, or if they do not wish to have the vaccine, their status within WIS is changed to 'opt out'. This does not mean that they cannot 'opt back in' at a later date. The Health Board's policy is 'no one is left behind', and this information is made clear to the individual at the time.

To tackle any potential vaccine wastage caused by the DNAs, a reserve list was created for people who could attend a clinic at short notice. The use of reserve lists and the extended life span of the Pfizer vaccine has helped the Health Board to minimise wastage.

Selection of appropriate vaccine

The process for storing and distributing the vaccine to care homes, GPs, ILGs and CVCs is tightly controlled. A vaccine schedule is produced and shared with Pharmacy, that identifies the type of vaccine that will be used in each area on separate days. The Admin Support Team and the Booking Office also receive a copy, so they know when booking appointments, what vaccines will be available to allow appropriate appointments for specific groups to be made.

The Health Board does not mix vaccines between doses and uses one vaccine type in a single location on any day. Application of the Pfizer and AstraZeneca vaccines are different, so controls have been put in place and procedures developed to ensure that the change over from one vaccine to another at the CVCs is completed correctly and safely. These form part of the CVCs Standard Operating Procedures.

Pharmacy is responsible for ordering and monitoring the temperature of the vaccine during circulation. Throughout its journey and whilst in storage the vaccines are temperature controlled using monitors, that records the temperature every minute. Visual temperature checks are also made at the beginning and end of each day, which is documented by the Lead Nurses at the CVCs. This information is hyperlinked and recorded on the Pharmacy vaccine database. The more detailed

temperature analysis from the monitors is also uploaded to this system, should further scrutiny of the temperatures be required. The Pharmacy database also records the supply and delivery of each vaccine by date and venue.

Changes to the clinical requirements of the vaccines, such as the use of the AstraZeneca vaccine on younger people has had an impact on the allocation of appointments. Ensuring that the right priority groups was aligned to the appropriate vaccines was an initial challenge for the Health Board, plus the demand for the Pfizer vaccine also increased as a result. Despite these obstacles the Health Board was able to manage the changes effectively.

A specific pathway is in place for patients with allergies. The administration of their vaccine takes place at one of the ILG hospital sites. A vaccination referral form is sent to the relevant ILG, who will arrange the appointment and carry out the relevant pre-assessment checks. There is a Doctor / Resus team on standby during these appointments. Any complex cases are sent directly to the Cardiff and Vale University Health Board allergy specialist.

Management and scheduling of second dose

The time between the first and second dose is set within WIS. A 'second dose' report details the individuals who have reached that target date and the type of vaccine for the first dose.

Communication with the local population and staff

The communication team have used community Facebook groups and Twitter to share information on the vaccination programme. However, key information, such as the process of rearranging an appointment, may not be reaching members of the public who do not have access to the internet or belong to social media groups. The online information encouraged people to share it with others who may not use social media.

The communication team have worked with the three local authorities: Bridgend, Merthyr and Rhondda Cynon Taff. This relationship has helped with the development of the priority lists and for contacting people at short notice to fill vacant appointment slots, especially for the reserve list.

At the start of the programme the Health Board arranged a 'Q&A' session with the Director of Public Health. A sample of questions raised by the public were addressed and short videos were uploaded onto social media to help answer concerns.

The Health Board's website and intranet have a direct link to a dedicated Covid-19 page, providing information regarding the vaccination programme. The website provides useful links to Public Health Wales (PHW) latest updates, social media posts, and information how to access the reserve list. The intranet site provides the key information for staff on the Covid-19 vaccine, links to policies and procedures, and a range of advice for Healthcare Professionals.

A 'Weekly Vaccination Update' newsletter is produced and shared with staff, external stakeholders and the public via the Health Board's website.

An advice line has been set up by the Health Board to help address concerns raised. The advice line provides guidance on how to complete the online forms for those

members of the community that may need assistance, and to answer the most frequently asked questions regarding the vaccination programme. The advice line telephone number is advertised on the Health Board's website and is the number provided by the Switchboard.

The Health Board has its own staff Facebook page, which allows staff to receive quick information from the communications team. The use of Facebook allows staff to access information using their mobile phones, which is particularly useful for staff who work in communities.

At the start of the programme there were a number of Q&A sessions via Teams which involved Health Board staff. The Chief Executive took part, as did the Senior Responsible Officer for the Vaccine Programme.

The Communications and Engagement Manager attends the Strategic and Operational Board and is a member of the Risk Communication and Community Engagement Workstream. This meeting is chaired by the Senior Public Health Practitioner and includes members from local authority communications team and PHW.

Objective 2: Appropriate governance/oversight of the plan

Approval and monitoring of the plan

The Health Board's Covid-19 vaccination plan was submitted to WG in September 2020. The plan incorporated the composition and governance arrangements for the Strategic Programme Board. Phase 1 of the plan, which was for priority groups 1 to 4, was approved by the Board in January 2021, and an update paper was taken to the Board in March 2021, which explained the position of Phase 1 and the plan for the roll out of Phase 2.

A Strategic Board and Operational Board continue to monitor the progress against the plan. Action plans to address any issues raised at these boards are in place and monitored on a fortnightly basis.

Progress of delivery in line with JCVI priority list and milestones is reported

The delivery of the priority list is captured and discussed at the fortnightly Strategic Board and Operational Board. Daily monitoring is undertaken by the Assistant Director of Planning and the Project Team using the databases, schedules and WIS reports.

The performance data looks at each priority group to identify how many have received each dose, what number have 'opt out', or have not received a vaccine. DNA rates are analysed to identify trends. Forward planning of the distribution of the vaccine to the CVCs is also shared at the meeting.

At the Operational Board, workforce, finance, pharmacy and communications are discussed.

Lessons learnt

In February 2021, the Health Board prepared a 'lessons learnt' paper on the vaccination programme, which focused on the mobilisation phase of the project and its aims and key objectives in areas such as governance, communication, ICT and

workforce. The report also discussed the planning and operational phase, booking, data entry and logistics and recommendations were identified under each category. A second 'lessons learnt' paper is currently being prepared that will be used to capture good practice and lessons for future projects.

The Lead Nurse for the CVCs met with other colleagues from other health boards who were also setting up CVCs to benchmark and establish best methods.

The Head of Pharmacy, Community and Integrated Services attends an All Wales Pharmacy group, which is chaired by the Lead Pharmacist for All Wales vaccine. This forum allowed health boards to each Health Board to feedback what they are doing, how they are doing it, and to share information and ideas.

7. Summary of Recommendations

The audit findings, recommendations are detailed in Appendix A together with the management action plan and implementation timetable.

A summary of these recommendations by priority is outlined below.

Priority	High	Medium	Low	Total
Number of recommendations	0	0	1	1

Appendix A: Management Action Plan

Finding -1 Capturing actions for implementation (Control design)	Risk
<p>What has been clear through the meetings that we held and the documentation we sighted, is the dedication and commitment of staff in delivering a programme of work that was almost constantly changing. At times this will inevitably have placed members of staff under immense pressure and potentially this has been an ongoing risk to the Health Board where there has been reliance on a few key individuals to be making strategic decisions on behalf of the Health Board.</p>	<p>Vaccination programme not delivered efficiently where there is over reliance on key individuals.</p> <p>Wellbeing of individuals impacted.</p>
Recommendation	Priority level
<p>Consideration should be given in any future projects to ensuring that there is not over-reliance on a small number of individuals to be managing the programme on a day-to-day basis.</p>	<p>Low</p>
Management Response	Responsible Officer/ Deadline
<p>The COVID vaccination programme has been established as part of the emergency response to COVID and learning from this will feed into the wider COVID learning. The continued requirements for COVID vaccination, mean that the project needs to be converted to 'business as usual'. A business case is being developed to create a core team for 2022/23.</p>	<p>Clare Williams December 2021</p>

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings



Substantial assurance

The Board can take **substantial assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.



Reasonable assurance

The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with low to **moderate impact on residual risk** exposure until resolved.



Limited assurance

The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.



No assurance

The Board can take **no assurance** that arrangements in place to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Action is required to address the whole control framework in this area with **high impact on residual risk** exposure until resolved.



Assurance not applicable

Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are **not appropriate** but which are relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

Priority level	Explanation	Management action
High	Poor key control design OR widespread non-compliance with key controls. PLUS Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in control design OR limited non-compliance with established controls. PLUS Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. These are generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.