



Mass Vaccination Programme

Advisory Review Final Report

2020/21

Hywel Dda University Health Board

Audit and Assurance Services

Private and Confidential

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Please note:

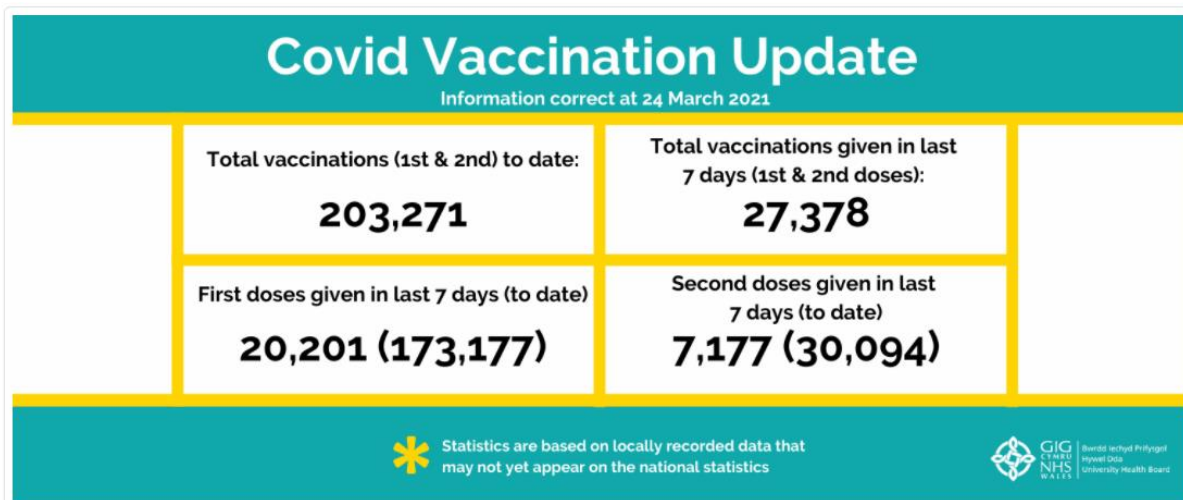
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1. INTRODUCTION AND BACKGROUND

Introduction

During the last twelve months, the COVID-19 pandemic has brought unprecedented pressures and challenges to the NHS in Wales. At the time of this review, the country continues to be under alert level four restrictions having entered its third lockdown on 19th December 2020. The 'second wave' saw a rapid acceleration of cases towards the end of 2020, which was deemed to be "a pandemic within a pandemic, a crisis within a crisis" by the Welsh Government (WG).

Simultaneously, NHS Wales had been actively planning to undertake the biggest mass vaccination programme in history. The rollout of the COVID-19 vaccine started on 8th December 2020. It is pleasing to highlight that 15 weeks later, approximately 45% of Hywel Dda residents have received a first dose of a vaccine and approximately 8% have received the full course.



Background and Context

By mid-summer 2020, positive news had emerged that COVID-19 vaccines were in development. In response, an *All-Wales COVID-19 Vaccine Delivery Programme Board (CVB)* was established on 4th June 2020, led by WG and included representatives from across the Welsh health and care sectors. The CVB identified 'Once for Wales' workstreams including but not limited to: planning and delivery, workforce surge recruitment, vaccine storage, distribution and safety monitoring, communications and marketing; infection prevention and control (including personal protective equipment), digital solutions, consumables and vaccine efficacy.

As part of preparations in Wales, on 13th July 2020, the Chief Medical Officer (CMO) wrote to all Health Boards and Trusts requesting to rapidly progress local plans for delivery of a potential COVID-19 vaccine, supported at a national level by the CVB. In response, Hywel Dda University Health Board established a COVID-19 Vaccination Delivery Group, linked to its COVID-19 Command and Control Structure, in order to utilise all organisational resources and enable support from key partner agencies. Four workstreams were assigned to the Group and the first table-top exercise was undertaken on 27th July 2020 to explore the requirements of a mass vaccination programme.

The CMO wrote again to all Health Boards on 13th August 2020 requesting an initial draft local plan by 3rd September 2020. The Health Board met this target and submitted the initial framework for a mass vaccination plan. As further information on potential vaccines was received, planning was geared up and the Wales CVB requested a first draft *Covid-19 Vaccine Operating Plan* by 20th November 2020, which the Health Board achieved.

The Medicines and Healthcare products Regulatory Agency (MHRA) gave regulatory approval to the Pfizer-BioNTech vaccine on 2nd December 2020 and the Health Board received its first supply week commencing 7th December 2020, with the first dose being administered on 8th December 2020.

The Oxford/AstraZeneca vaccine received regulatory approval on 30th December 2020 and the Health Board received its first supply on 2nd January 2021 and rolled out on 4th January 2021. The Moderna vaccine received its regulatory approval on 8th January 2021 and are awaiting its arrival into Wales for deployment which is anticipated for April 2021. In response, WG published its *Vaccination Strategy for Wales* on 11th January 2021, which set out the priority groups as endorsed by the independent Joint Committee on Vaccination and Immunisation (JCVI) together with target milestones and markers in order to drive efforts across Wales.

The Health Board had already established a Command and Control Structure in response to the COVID-19 pandemic, and changes were adopted to allow for the establishment of a Bronze-level Vaccination Delivery Group to report into Tactical (Silver) and subsequently to Strategic (Gold) with the purpose of taking the plan forward.

This advisory review was completed in line with the Health Board's Internal Audit Plan 2020/21 and the relevant Executive Director was the Director of Public Health. We have assessed the adequacy of the systems and controls in place within the Health Board for the management of the mass vaccination programme, in order to provide assurance to the Audit & Risk

Assurance Committee that risks material to the achievement of the system's objectives are managed appropriately.

Our review was undertaken during February and March 2021 and involved attending the Bronze Vaccination Delivery Group (BVDG) virtual meetings, an interview with the Director of Public Health and reviewing iterations of the Health Board's vaccine delivery plan in line with WG and other official guidance.

Further detail regarding the scope of the review and the review work undertaken is included in the appendices to this report.

2. EXECUTIVE SUMMARY

Main Observations

The Health Board was required to submit its first initial draft plan to the CMO by 3rd September 2020, several weeks before regulatory approval was given to any vaccine. From our meeting with the Director of Public Health during this review, it was noted that much of the initial planning took place in a vacuum with more unknowns than knowns at that time and the plan was developed in alignment to the Health Board's Influenza Vaccination Plan 2020/21 and JCVI guidance. Several iterations of the plan were developed over the following months when new information was received through the CVB and WG.

In January 2021, the Strategic (Gold) Command Group gave the approved instruction to establish a tactical level delivery task & finish group to develop a plan by 15th January to give first dose vaccination to all priority groups in order, and second doses where due, by 4th April 2021. The deadline was met and the *COVID-19 Mass Vaccination Delivery Programme Plan* (the Delivery Plan) was presented and noted by its members and subsequently by the In-Committee Board and the People on 28th January 2021 and Planning and Performance Assurance Committee (PPPAC) on 10th February 2021.

The Health Board's vaccination programme is governed by the Command and Control Structure, which was implemented during the early stages of the COVID-19 pandemic. The governance structure has allowed effective and agile decision-making, whilst maintaining overall control of the Delivery Plan.

The Health Board's Mass Vaccination Delivery Programme was launched in December 2020 and was aligned to guidance released by the independent Joint Committee on Vaccination and Immunisation (JCVI) and WG.

Management recognised the lack of a dedicated mass vaccination group and in January 2021 governance arrangements were strengthened with the establishment of the Bronze Vaccination Delivery Group (BVDG) within the Command and Control structure to ensure the planning, monitoring and delivery of the mass vaccination programme.

The Delivery Plan contained comprehensive strategic and operational detail and presents a clear, well-defined approach to the vaccination programme in line with the strategy set out by the WG and JCVI. Key information is presented in a candid and transparent manner;

- Outline of the Delivery Plan's purpose;
- Governance arrangements, including reporting and data control;
- Explanation of eligibility criteria for the vaccine and order of priority;
- Vaccine characteristics; where and how they will be administered;
- Emphasis given to the fluid nature of the plan given the fast pace of emerging information;
- Modelling (workforce and capacity); and
- Finance and budgeting.

Delivery progress was monitored through the BVDG and the Delivery Plan was subject to robust project management practices by use of detailed timelines, weekly plans, Gantt charts in addition to live delivery planning documents. Each plan had an identified Source Data Owner with the responsibility to update, which was supported by a process cycle to ensure continuous delivery of the programme with the adoption of any required updates.

A Health Board produced dashboard has been developed that provides a breakdown of the mass vaccination programme including first and second dose appointments. However, we were unable to establish information relating to vaccination wastage, number of patients that did not attend (DNA's) and reserve lists within the planning activity and therefore, could not determine if this data was appropriately monitored.

The BVDG has a diverse membership from across the Health Board and the outcome of our attendance at their meetings was that the expertise within the group allowed for inclusive discussions and management of the response around emerging issues and guidance within the strategic direction of the Tactical (Silver) Group.

The Delivery Plan was presented to and noted by the Board and relevant committees, in addition to the Command and Control groups. The Board received papers and verbal updates at each meeting on the vaccination programme and decisions deployed through the Command and Control Structure were recorded and ratified in the public domain.

Overall, we identified satisfactory governance arrangements and internal controls in place to ensure the planning, monitoring and delivery of the mass vaccination programme through the development and delivery of the Delivery Plan aligned to JVICI and WG requirements and the establishment of a dedicated BVDG, following the encompassing of the group within the Command and Control structure, that meets on a weekly basis to scrutinise and promptly respond to the live events and changes/risks occurring locally and nationally affecting the delivery of vaccine.

Priority considerations for the future

We have not assigned priority ratings to considerations, but we believe the following to be key priorities (management responses provided in *italic font*):

- **Consider whether data relating to vaccine wastage, DNAs and reserve lists is included within current planning activity, appropriately monitored and reported.** – *Some DNA data is available via HD Dashboard and we are working on a process whereby wastage could be displayed on dashboard but this is not an easy fix. National data is provided regarding DNA rate and wastage and will be introduced and shared at BVDG in future meetings. Reserve lists and the need to ensure nobody is left behind as per National plan is discussed in the BVDG regularly but again will be brought into meeting agenda in a more formal way.*
- **Establish arrangements to ensure minutes of the Bronze Vaccine Delivery Group are retained as an accurate record and audit trail** – *Due to pace and scale of delivery programme it was agreed to have archived recordings of the meeting and agreed actions within an action log. There is a plan in place and already underway to record meeting notes to sit as a reflection of the meeting but not formal minutes in the event of a failure or loss of recording.*
- **Develop standard risk log templates for use by operational project groups with guidance on risk management which are aligned to the Health Board's Risk Management Strategy & Policy** – *Chair has met with Assurance and Risk Team. Datix risk in process of being populated after meeting and system built for programme. Agreed process for monitoring and reviewing on monthly basis.*
- **Assess aspects of the COVID-19 vaccination rollout that have worked particularly well and consider whether they can form part of future vaccination and immunisation arrangements, for example, the Influenza Vaccination Campaign** – *We have a process of 'recording history in the making' by archiving the delivery*

plans, at that point in time, on a regular basis. All learning will be brought into the future influenza campaigns and any other relevant campaigns going forward.

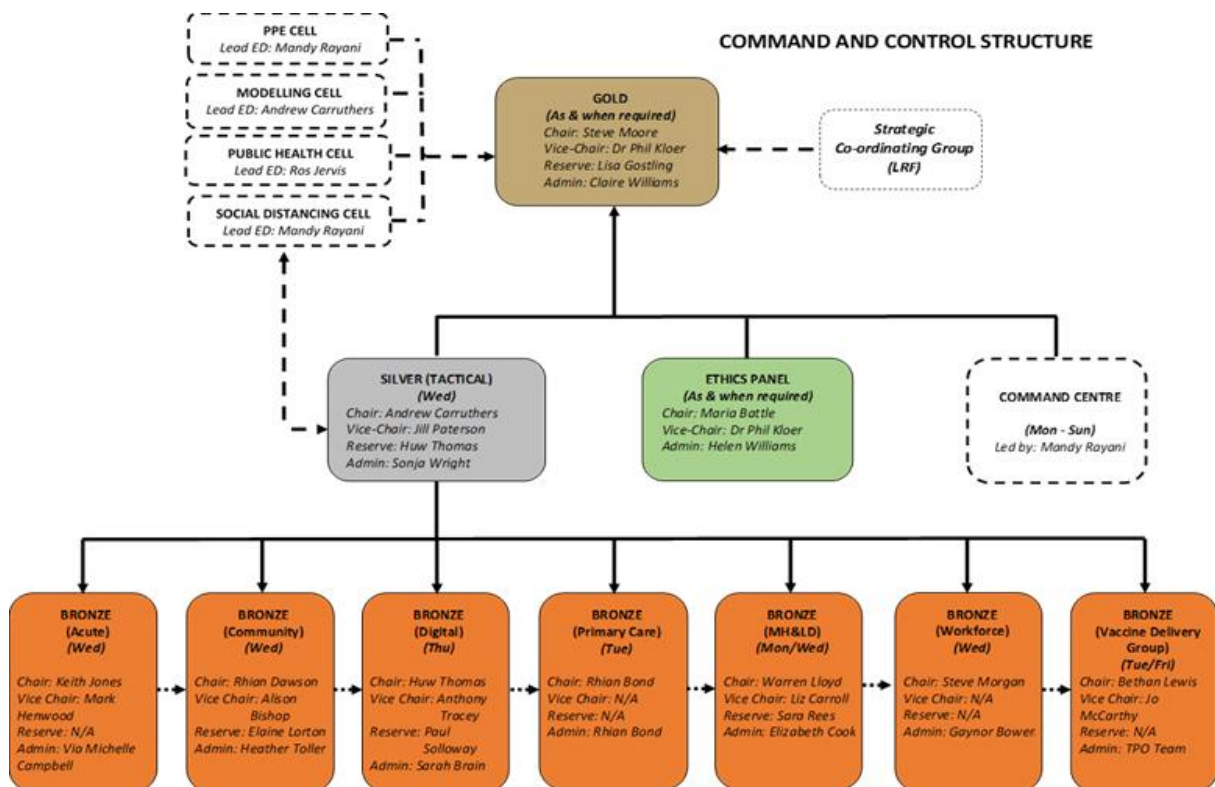
3. DETAILED REPORT

3.1 Organisational Structure for the Vaccination Programme

The Health Board established a hierarchy of command and control during March 2020 to progress actions and decisions during the pandemic. The structure was subject to ongoing review, with amendments made to ensure it continued to meet the needs of the Health Board in responding to the pandemic and mass vaccination programme.

In January 2021, governance arrangements were strengthened with the establishment of a dedicated mass vaccination group – the Bronze Vaccination Delivery Group (BVDG) – within the Command and Control structure to ensure the planning, monitoring and delivery of the mass vaccination programme.

The latest version of the Command and Control structure, as included within the Delivery Plan, is shown below.



3.2 Operational Detail and Resourcing

Our review confirmed that the Health Board's Mass Vaccination Delivery Plan is aligned with JCVI guidance and WG's *Vaccination Strategy for Wales* (January 2021). We can confirm that eligibility criteria, milestones and target completion dates set by the JCVI and WG was accurately reflected in the Health Board's Plan, in addition to a detailed table identifying approximate population numbers per priority group to assist in the delivery planning.

The plan states that *"Hywel Dda is using a blended approach in order to deliver the COVID Vaccination Programme at pace, and accommodate the logistical issues caused by the vaccine characteristics, vaccine supplies, our demographics and rurality and changing national policy and advice."*

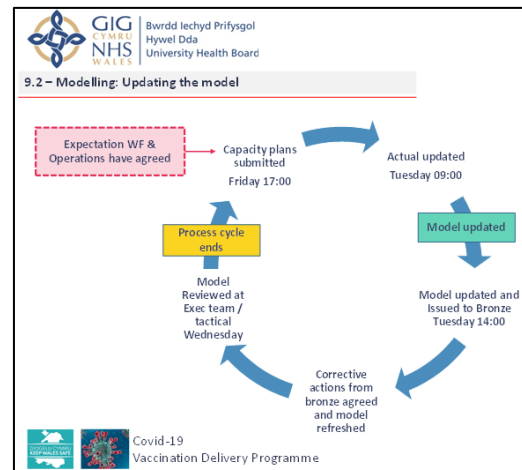
The approach taken was to use five delivery arms as below:

- Primary Care Vaccination Services
- Primary Mass Vaccination Centres
- Secondary Mass Vaccination Centres
- Supplementary Clinics
- In-reach/out-reach vaccination services

At the time of the plan being written (28th January 2021) the Health Board had identified and scoped eight Primary Mass Vaccination Centres and four Secondary Mass Vaccination Centres (one per acute hospital site) based across the three counties of Ceredigion, Pembrokeshire and Carmarthenshire. Community venues across the region had also been identified for use as pop-up style clinics to target specific groups in local communities and planning was underway to develop agile and bespoke clinics to facilitate the vaccination of vulnerable individuals.

The Delivery Plan included information on Workforce Demand Modelling, which set out the weekly workforce whole-time equivalent (WTE) estimates and implications from 18th January– 5th April 2021 and identified the staff groups required per week based on assumed vaccine supply. There was recognition within the Delivery Plan that further work was required to develop a full workforce plan, including workforce gap analysis, resourcing and training activity and alignment of workforce groups to capacity planning assumptions.

The outcome of our review of BVDG meetings and papers confirmed that work had been progressed and continuously addressed by means of discussions and data analysis of submitted reports, such as the Mass Recruitment On-Boarding Progress and Vaccinator Update Reports. The Delivery Plan and specifically, the Modelling, is continuously updated and adjusted as per the process cycle and evidenced within the Health Board's *Vaccinations: Weekly Command Updates*.



The BDVG was kept informed of the latest staffing developments to enable planning against vaccine supply and our review highlighted the working relationship between the Bronze groups, with Bronze Workforce feeding into the BVDG on any agreed actions and relevant information to facilitate planning activity.

3.3 Deliverability of the Vaccination Programme

WG's *Vaccination Strategy for Wales* (January 2021) recognised that if Wales were to deviate away from the recommended priority approach of the JCVI, residents would be vulnerable to harm and be at greater risk of exposure to the virus. Therefore, all Health Boards were required to follow and implement JCVI guidance as part of their local plans. Our assessment of the plan confirms that the guidance played a vital role in shaping the Delivery Plan and no deviation from the guidance was noted. We can confirm that the Delivery Plan was reviewed and scrutinised by the Health Board's Gold and Silver Command Groups, In-Committee Board and PPPAC.

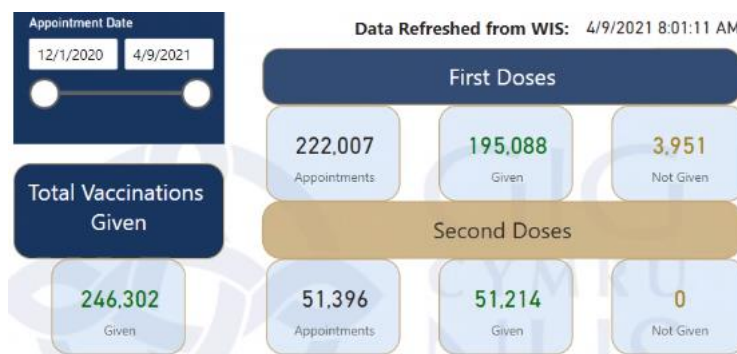
Our review highlighted that assessing the plan's deliverability was a continual process that can be linked to delivery progress and planning work undertaken since December 2020 by the BVDG through the consistent scrutiny of emerging national and local information and issues.

3.4 Programme Delivery Progress Monitoring and Reporting

Our review highlighted the continuous monitoring of the delivery programme at all levels. The Health Board's established governance arrangements has allowed for the Chief Executive to deploy decision making through the Command and Control structure with the Board receiving notifications of all changes via reports such as '*Maintaining Good Governance COVID-19*', '*COVID-19 Reports*' and '*Report of the Chief Executive*'.

The BVDG is responsible for making operational decisions to ensure the effective and timely delivery of the vaccination programme under the strategic direction of the Tactical (Silver) Group. A review of the agendas and papers submitted to the BVDG highlighted the speed at which the programme was going, and the continuous changes being adopted. Weekly command updates were circulated and discussed at the BVDG that provided concise information in the form of key messages, planned versus actual vaccinations to date, vaccinations by Delivery Arm, on/off delivery plan and vaccine supply.

Progress of the vaccination rollout was being captured on a Health Board dashboard produced by the Informatics Team. The dashboard provides a breakdown of the mass vaccination programme, including first and second dose appointments (see below). We were unable to locate any reference to other information such as vaccination wastage, number of patients that did not attend (DNA) and reserve list numbers.



The BVDG does not produce official minutes, referencing the recorded meetings as such, however it was noted that this was identified as a potential concern by the project support team in the event of the recordings not being accessible at a later date and will mitigate the risk by producing meetings notes going forward.

We noted that the BVDG's risks and actions were logged and circulated amongst members on a weekly basis. Our review established that risks had been identified by the group and were noted within a risk log, dated, referenced and assigned a risk category. Actions from each meeting were captured in an Action Log, which were dated, referenced and assigned an owner. However, we also noted the following:

Risk Log

- Risks not logged on DATIX system.
- Risk owners not identified.
- Post-risk mitigation for risks marked with a risk response of "mitigate" not completed.
- Risks passed to other groups not dated.

- Overall risk status not complete.
- No weekly updates/notes by group members.
- Risk scoring not in line with the Health Board's *Risk Management Strategy & Policy* document.

Action Log

- Actions logged as 'on-going' under previous meeting dates had not updated with information on progress.
- Several actions had no deadline date assigned.
- Several actions had no status assigned.
- Administrative errors in version control.

Internal Audit contacted the Health Board's Assurance & Risk Team to clarify the Risk Management Strategy and Policy and it was confirmed that there are no standard risk logs for the Bronze-level groups and that the issue of the risks not being included on DATIX had been raised in the Tactical (Silver) Group meeting on 3rd March 2021. The resulting action for the BDVG Chair to liaise with Assurance & Risk Services on the matter has since been completed.

Wider arrangements were in place to monitor delivery progress such as the *All-Wales Covid-19 Vaccine Delivery Programme Board* meetings. We noted that the Director of Public Health and Mass Vaccination Delivery Programme Lead (Chair of BVDG) attend the national meetings where lessons learned had been shared across Wales and information on emerging issues in real-time were discussed.

Throughout our fieldwork it has been evident that public communications had been determined as critical to the success of the vaccination rollout. The Health Board adopted the communications campaign developed by WG to provide consistent and co-ordinated messaging across Wales and created a public-facing website front page to provide the public with weekly updates on the vaccination statistics within the Hywel Dda region and also signposting links to national information on policy and public health issues.

The Delivery Plan considered the importance of gaining public confidence and demonstrated the significant rollout of the programme. The Health Board used social media as one of the platforms to assure the public, posting regularly on COVID-19 related matters including vaccinations. Photographs of those first to receive the vaccinations were also provided by the Health Board to the local media in order to boost interest and up-take.

Appendix One – Scope and Objectives

Scope of this Advisory Review

The advisory review assessed the adequacy of the systems and controls in place within the Health Board for the management of the mass vaccination programme, with particular regard to the Delivery Plan.

The areas of focus within this review were as follows:

- An adequate organisational structure has been established for the vaccination programme;
- A clear and sound strategy/plan has developed, documented and received an appropriate level of approval;
- Resources have been identified and are available to deliver the plan;
- An assessment of the deliverability of the plan has been undertaken
- The plans contain sufficient operational detail including identifying set eligibility criteria, approach to be taken, staff required, milestones and target completion dates;
- Arrangements are in place to monitor the progress of the delivery of the programme, including lessons learned and any arising issues and;
- Reports are submitted to the appropriate group or committee in respect of the vaccination programme.

The potential risks considered in this review were as follows:

- Poor governance arrangements in the planning and delivery of the vaccination programme;
- 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; and

- Lack of accountability for the implementation of the mass vaccination programme.

As this is an advisory review, the assignment is not allocated an assurance rating, however, we have suggested some considerations for the future to supplement already robustly established delivery plans.

Appendix Two – What we did

We undertook the following review activity:

- Discussed the Delivery Plan roadmap from initial planning through to the latest iteration with the Director of Public Health.
- Attended Bronze Vaccination Delivery Group meetings and reviewed recordings of previous meetings.
- Reviewed papers submitted to the Bronze Vaccination Delivery Group
- Reviewed papers presented to the Board on Maintaining Good Governance during the pandemic, including Board and Committee arrangements as well as the Command and Control Structure.
- Reviewed agendas, papers and minutes of the:
 - Board
 - In-Committee Board (28th January 2021 meeting)
 - People Planning Performance Committee (10th February 2021 meeting)
- Reviewed the COVID-19 Vaccination Bulletins on the Health Board's website.
- Reviewed papers to Board on Responding to the Pandemic.
- Reviewed the initial draft of the Delivery Plan as submitted to the Chief Medical Officer for Wales on 3rd September 2020.
- Reviewed the initial draft of the Operating Plan for Delivery of Pfizer-BioNTech as submitted to the All-Wales Covid-19 Vaccine Delivery Programme Board on 20th November 2020.
- Reviewed the interim advice and subsequent updates on the priority groups for COVID-19 vaccination from the Joint Committee on Vaccination and Immunisation (JCVI) dated 18th June, 25th September, 2nd and 30th of December 2020 and 6th January 2021.
- Reviewed Welsh Government's COVID-19 Planning Parameters for Wales dated 26th August, 1st September and 29th September 2020.
- Reviewed Welsh Government's Vaccination Strategy for Wales dated 11th and 26th February 2021.
- Reviewed minutes from the Strategic (Gold) Group meeting on 15th January 2021.
- Reviewed minutes and action log from the Tactical (Silver) Group meeting on 3rd March 2021.
- Reviewed local Coronavirus (COVID-19) Prevention and Response Plans (2020/21).

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