Hywel Dda University Health Board

Local Deployment of the

Welsh Immunisation System (WIS)

Final Internal Audit Report

May 2021

Private and Confidential

NHS Wales Shared Services Partnership

Audit and Assurance Services

Contents

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1. Introduction and Background

In line with the revised 2020/21 Internal Audit Plan for Hywel Dda University Health Board (the Health Board) a review of the local deployment of the Welsh Immunisation System (WIS) was undertaken. The relevant Executive Director for this review is the Director of Finance.

The Welsh Immunisation System supports the roll out of the Pfizer/BioNTech and AstraZeneca vaccines (and others as they become available) across the Health Board. The system uses information on patient demographics, occupation groups and agreed priority levels for receiving the vaccination, to allow healthcare professionals to schedule appointments for patients.

2. Scope and Objectives

The overall objective of the review was to evaluate and determine the adequacy of the systems and controls in place within the Health Board for the deployment of the Welsh Immunisation System, in order to provide assurance to the Audit & Risk Assurance Committee that risks material to the deployment are managed appropriately. Our scope for this review was limited to system sessions created by the Health Board only and not from GP practices.

The areas reviewed during the audit were:

- The deployment of WIS enables booking of vaccinations and tracking of all patients and provision of key management information;
- Deployment was under control of a formal plan and appropriate resourcing;
- Issues identified as part of the deployment are resolved;
- Lessons are learned from the deployment and collated to enable feed into future deployments/programmes;
- Data used by the system is complete, accurate, timely and input once only;
- Appropriate controls are in place for access to resources and information within the system; and
- Appropriate local continuity measures are in place for the system.

3. Associated Risks

The potential risks considered in this review were as follows:

- Inappropriate access to system / information.
- Inaccurate data held in system or reported from the system;
- 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.

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 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.

The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with the Local Deployment of the Welsh Immunisation System is **Reasonable** assurance.

RATING	INDICATOR	DEFINITION
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.

Under instruction and guidance from Welsh Government and Public Health Wales, NHS Wales Informatics Services, presently known as Digital Health and Care Wales (DHCW), undertook significant work to deliver the Welsh Immunisation System to all Health Boards in Wales.

Our review recognised the magnitude and pace of the undertaking and it is pleasing to highlight positive feedback received from DHCW regarding the level of engagement and communication from the key contacts within the local implementation team.

Whilst recognising that the deployment of WIS was delivered at speed and under the control of a national implementation plan, we identified four medium priority findings with regards to resolution of issues from early deployment, post-implementation review, active user monitoring and user acceptance testing arrangements.
We also identified two low priority findings with regards to resource contingency planning and rectification of patient records.

5. Assurance Summary

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

Audit Objective		Assurance Summary*			
1	The deployment of WIS enables booking of vaccinations and tracking of all patients and provision of key management information				✔
2	Deployment was under control of a formal plan and appropriate resourcing			✔	
3	Issues identified as part of the deployment are resolved			✔	
4	Lessons are learned from the deployment and collated to enable feed into future deployments/ programmes		✔		
5	Data used by the system is complete, accurate, timely and input once only			✔	
6	Appropriate controls are in place for access to resources and information within the system			✔	
7	Appropriate local continuity measures are in place for the system			✔	

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

6/20

Design of Systems/Controls

There were no issues that are classified as weaknesses in the system control/design for Local Deployment of WIS.

Operation of System/Controls

There were **six** issues that are classified as weaknesses in the operation of the designed system/control for Local Deployment of WIS. These are identified in the Management Action Plan as (O).

6.   Summary of Audit Findings

OBJECTIVE 1: The deployment of WIS enables booking of vaccinations, tracking of all patients and provision of key management information.

During the initial stages of deployment, paper patient consent forms were used, and data entry of vaccination information was manually entered into WIS retrospectively by deployed administration staff and military personnel. Due to the considerable number of vaccinations administered during the first few weeks and accompanying paperwork, it was noted that a backlog accumulated quickly due to insufficient resources to undertake data entry into WIS.

The risk of untimely and inaccurate information within WIS was promptly recognised by the Assistant Director of Digital Services as this data was crucial to the recall function of the system. We can confirm as part of fieldwork undertaken for the review of the *COVID-19 Mass Vaccination Programme* (HDUHB-2021-05), that issues around Workforce planning were continuously being escalated through the Health Board's Command and Control Structure and many recruitment drives took place.

From interviews conducted with the Health Board's Assistant Director of Digital Services, Head of Systems and Informatics Projects and Application Support Trainers, it was confirmed that the initial backlog has been fully cleared. We were also informed that data quality has improved dramatically since initial rollout as users have become trained and more familiar with the system.

We are satisfied that the Health Board has taken adequate steps to resolve these initial issues to enable appointment booking, patient tracking and management information reporting. Evidence of this was found within the Health Board's COVID-19 Vaccination Dashboard, which is driven by data output from WIS. The internal dashboard allows clear surveillance of all crucial information relating to the vaccination programme.
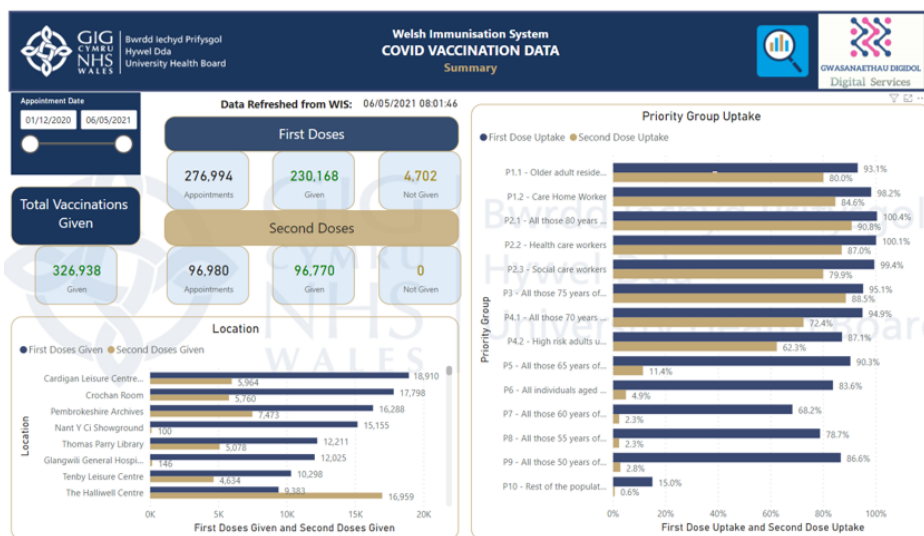
See Finding 5 at Appendix A.

OBJECTIVE 2: Deployment was under control of a formal plan and appropriate resourcing.

WIS is a national product and as such, is under the control of a national plan developed by DHCW and adopted by all Health Boards across Wales.

The WIS Implementation Plan was governed by the *All-Wales COVID-19 Vaccine Programme*, led by Wales' Deputy Chief Medical Officer. The plan set out the key tasks required to be performed by Health Boards in conjunction with DHCW when implementing the system.

DHCW prescribed documentation such as User Acceptance Testing scripts to be completed and returned. Whilst we were informed by both the Health Board and DHCW that User Acceptance Testing was undertaken, we were unable to find evidence of the full test scripts being used. Investigations indicate that it was a consequence of time constraints and staff shortages within the Health Board.

See Finding 4 at Appendix A

OBJECTIVE 3: Issues identified as part of the deployment are resolved.

As part of this review, we conducted interviews with key deployment personnel and noted that although no formal issue log was kept by the Health Board, a central record of implementation issues was retained by the DHCW ICT Team.

We noted that the main method of communication and documentation storage in relation to deployment was through Microsoft Teams. DHCW set up Teams Channels for each Health Board which allowed for real-time monitoring and swift resolution of arising queries and issues by both parties.

We were informed by the local implementation team of issues such as demographic data on vaccination session spreadsheets not corresponding with provided details on patient consent forms due to care workers using their place of work address instead of personal address. Due to the lack of local administrative resources and resulting backlogs of data entry into WIS, the patient had often left the Mass Vaccination Centre (MVC) resulting in discrepancies in need of retrospective correction by follow-up calls to patients.

During early deployment, the Application Support Team often received requests to add Vaccinators to WIS with little notice and out of hours. To avoid any delays in vaccine administration, when this occurred one of the WIS Supervisors would be selected as the named Vaccinator. The decision was taken to avoid any ambiguity within the dataset, as the WIS Supervisors can be easily be identified. This issue is confirmed as ongoing with retrospective action being taken to amend the approximate 100 remaining records to the correct Vaccinator.

See Finding 6 at Appendix A

OBJECTIVE 4: Lessons are learned from the deployment and collated to enable feed into future deployments/ programmes.

Our review concluded that lessons learned have not yet been collated. It is anticipated that our report will provide a starting point to enable further discussions and analysis.

See Finding 1 at Appendix A

OBJECTIVE 5: Data used by the system is complete, accurate, timely and input once only.

The two system components considered within this review are WIS Core and WIS Web. WIS Core is used to manage clinic and appointment scheduling, dealing with patient records, sending appointment and cancellation letters and running local reports. WIS Web is a web interface where administrative staff can record consultations and vaccines and view lists of appointments.

WIS uses a combination of data sources as depicted above. During configuration, DHCW bulk-loaded data into WIS in the order determined by the Joint Committee on Vaccination and Immunisation (JCVI) to minimise the need for data input, for example, vaccination details such as vial numbers were pre-populated for administrative staff to select via dropdown.

As noted under objectives one and two, data quality issues ensued due to paper forms being used at MVCs, with demographic and vaccination consultation details being entered into WIS at a later date.

Our investigations indicate that although these initial data quality issues have been resolved, no further work has been undertaken by the Health Board to ensure data accuracy within WIS.

See Finding 2 at Appendix A.

OBJECTIVE 6: Appropriate controls are in place for access to resources and information within the system.

WIS Core employs a two-step approach, transparent to the user. It uses Windows Authentication to confirm that they are a member of the "Domain Users" group in the CYMRU domain. It also uses the NADEX username to authenticate and retrieve WIS credentials. A WIS account with a matching username is required for the application to be available to the user.

The WIS Web application is internet facing and utilises Multi-Factor Authentication (MFA) to help safeguard access to data find the application. A prerequisite is that users have licences for Microsoft Enterprise Mobility and Security (EM&S). EM&S enables users to access several services remotely

without the need for VPN. As with the core application, users require both a NADEX and WIS account to complete authentication.

Data recorded on the web system will automatically update the core system in real time and vice versa.

Each WIS User Account must be assigned one of four predefined User Roles;

- **WIS Supervisor** has access to all screens on both Core and Web applications.
- **Vaccine Administrator** has access to all screens on the Web application.
- **Vaccination Coordinator** has access to all screens on the Core and Web applications except WIS System Supervision (management of User Accounts).
- **Clerical Booking Officer** has access to all screens on the Core application except WIS System Supervision.

Our review confirmed that the WIS Supervisors within the Health Board were of appropriate seniority. The Assistant Director of Digital Services and the Head of Information Services are two of five WIS Supervisors within the Health Board. It was pleasing to note effective segregation of duties and validation of data entry between the two senior users, as one will set up clinics on the system whilst the other will complete letter templates and review the other's work.

The remaining User Roles have basic data entry privileges and are not permitted to amend critical data within the system.

Through conversations with key personnel, we noted that at present, the Health Board does not undertake active user monitoring. Whilst we recognise that staff leaving the organisation would have their access to key systems revoked under the Health Board's ICT Starters and Leavers policy, seconded staff returning to their main roles will still have access to WIS.

See Finding 3 at Appendix A

OBJECTIVE 7: Appropriate local continuity measures are in place for the system.

The main continuity measure in the event of loss of system, is a prescribed paper back-up form produced by DHCW, and is in place within all Health Boards. During the early deployment stages, we were informed that the system went down on two occasions. Staff at MVCs reverted to paper forms, with the Administration Site Leads dedicating time and resource to record in the system retrospectively when back online.

Both the WIS Core application, installed on LHB infrastructure and the internet facing WIS Web application connect to the WIS Oracle database and Services

hosted on DHCW infrastructure, DHCW therefore have the responsibility for backup and recovery of these services.

WIS Supervisors have access to export all future vaccine booking appointments. Downloads are undertaken weekly for review and as a failsafe should a major system failure occur. At the time of this review, future appointments within six weeks could be viewed and downloaded, amounting to approximately 58,000 appointments.

No matters arising.

7.   Summary of Recommendations

The audit findings and 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	H	M	L	Total
Number of recommendations	0	4	2	6

Finding 1 (O) – Implementation Issues and Lessons Learned	Risk
Our review concluded that the Health Board has not undertaken a post-implementation review and no formal record of issues and lessons learned from a local perspective has been maintained.	Reputational damage as a result of a delayed delivery of vaccinations or insufficient information provided
Recommendation 1	**Priority level**
Management should ensure the completion of a post-implementation review of local arrangements is undertaken.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
Agree – The Digital Team will work with Digital Health and Care Wales (DHCW) to develop a lessons learned document to be taken through the Health Board assurance and governance process	Assistant Director of Digital Services Timescale: June 2021

Finding 2 (O) – WIS Data Accuracy	Risk
Our review confirmed that regular validation checks of data quality within the Health Board are not undertaken within WIS.	Inaccurate data held in system or reported from the system
Recommendation 2	**Priority level**
Management should consider developing a governance framework with metrics to review WIS data within the Health Board and Primary Care for completeness, consistency, accuracy, validity and timeliness to enable confidence in data reliability.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
Agree – The Welsh Immunisation System (WIS) will be incorporated into the Health Board data quality framework, and will form part of the data quality reporting to the Information Governance Sub-Committee (IGSC)	Assistant Director of Digital Services Timescale: December 2021

Finding 3 (O) – Active User Accounts	Risk
We noted that all user accounts set up in WIS remain active and no work has been undertaken by the Health Board to review their status and current usage.	Inaccurate data held in system or reported from the system
Recommendation 3	**Priority level**
Management should ensure that a review of all active accounts is undertaken, and access is revoked for seconded staff who have returned to normal duties.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
Agree – a full review of user accounts will be undertaken and where access is not required it will be revoked. Access to Welsh Immunisation System (WIS) will also be included within the key clinical systems for inclusion within the new starters, leavers and mover's automation	Assistant Director of Digital Services Timescale: June / July 2021

Finding 4 (O) – User Acceptance Testing	Risk
Whilst we were informed that high-level User Acceptance Testing had been undertaken, due to the speed of implementation the prescribed test scripts from DHCW were not used in full. We were unable to validate if all business requirements were fulfilled prior to go-live.	Inaccurate data held in system or reported from the system.
Recommendation 4	**Priority level**
Management should ensure that the risk of undertaking minimum User Acceptance Testing as part of future iterations or major system changes of WIS, is documented as part of the Directorate's risk register.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
Agree – A new risk (Risk Number 1113) has been added to the directorate risk register, and will be monitored as per Health Board guidelines.	Assistant Director of Digital Services Timescale: Complete

Finding 5 (O) – Resources	Risk
Our investigations highlighted that inadequate local administrative resourcing during initial rollout resulted in system data quality issues and extensive backlogs of patient information being added to WIS. The Assistant Director of Digital Services confirmed the issue was resolved once staffing levels became static and backlogs have been fully cleared.	Inaccurate data held in system or reported from the system.
Recommendation 5	**Priority level**
Management should establish a contingency plan in the event of future rounds of vaccinations.	**LOW**
Management Response	**Responsible Officer/ Deadline**
Agree – During the implementation there was limited resources available, however 2 application support specialists have been appointed to assist with the operational service management of WIS	Assistant Director of Digital Services Timescale: Complete

Finding 6 (O) – Named Vaccinators	Risk
During initial deployment stages, Vaccinators would turn up to local clinics without the prior knowledge of the implementation team, resulting in delays to their WIS User Accounts being set up. We were informed of a workaround where one of the WIS Supervisors was chosen as the Vaccinator to avoid any delays in vaccine administration. This was a considered approach to easily identify records to be retrospectively corrected. Approximately 100 records remain to be amended.	Inaccurate data held in system or reported from the system
Recommendation 6	**Priority level**
Management should ensure all remaining records are amended in a timely manner as an accurate reflection of the patient consultation.	LOW
Management Response	**Responsible Officer/ Deadline**
Agree – The Data Quality Team under the auspices of the Head of Information Services are addressing the remaining records.	Assistant Director of Digital Services Timescale: July / August 2021

Appendix B - Assurance Opinion and Action Plan Risk Rating

2020/21 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 has **no assurance** arrangements in place to secure governance, risk management and internal control, within those areas under review, which 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.

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.

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