

Hywel Dda University Health Board

Research & Development Department Governance Review – Follow Up

Final Internal Audit Report

September 2020

Private and Confidential

NHS Wales Shared Services Partnership

Audit and Assurance Services



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Committee:	Audit & Risk Assurance Committee



Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors.

ACKNOWLEDGEMENT

NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

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1. Introduction and Background

The follow-up review of Research & Development (R&D) Department was completed in line with the 2020/21 Internal Audit Plan. The relevant lead Executive Director for the assignment was the Medical Director.

The original internal audit (HDUHB-1920-09) considered the adequacy of arrangements for the management of the R&D Department in order to provide assurance to the Audit & Risk Assurance Committee (ARAC) that risks material to the achievement of system's objectives are managed appropriately. A report rating of limited assurance was derived from this review. This audit has looked at the progress made by management to implement agreed actions to address the key findings identified in the previous report.

2. Scope and Objectives

The overall objective of this audit was to establish progress made by management to implement actions agreed to address key issues identified during the 2019/20 review of the adequacy of arrangements for the management of the R&D Department, in order to provide assurance to the ARAC that risks material to the achievement of system objectives are managed appropriately.

The scope of this audit was limited to the follow up of action taken in response to issues raised in the last report.

3. Associated Risks

The following inherent risks were considered during this audit:

- i. R&D does not deliver work aligned to the overall strategic objectives of the UHB;
- ii. R&D is of poor quality;
- iii. Patient harm due to poor management of trials/ research;
- iv. Lack of governance and management of the R&D Department; and
- v. Recommendations have not been addressed as agreed by management.


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 follow up governance review of R&D Department 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.

Follow up work was undertaken to confirm the progress that the Health Board has made against the agreed management responses from the original audit.





In summary, progress against the seven agreed recommendations that required implementation is as follows: Priority rating	No of management responses to be implemented	Fully actioned	Partially actioned	Not actioned
High	5	4	1	0
Medium	8	6	2	0
Low	0	0	0	0
Total	13	10	3	0

The R&D Department has made significant progress since the original Internal Audit review undertaken in February 2020, including improvements in the financial, local and corporate governance arrangements.

Of the 13 findings identified in the original audit report, 10 findings have been fully actioned. Three findings were noted as being partially addressed, including the delay in submission of individual spending plans, continued administrative discrepancies of sickness absences and the continued progress of updating the standard operating procedures.

5. Assurance Summary

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

Audit Objective		Assurance Summary*			
					
1	There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW			✓	
2	The Health Board produces appropriate guidance and training for the management of research and development studies/trials which is distributed appropriately throughout the Health Board			✓	
3	Approval processes ensure that research is of an appropriate quality and relevant to the Health Board				✓

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

6. Summary of Audit Findings

The progress of management actions against key findings identified in the original report are noted in the main body below.

OBJECTIVE 1: There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW

R&D Strategy Document

We confirmed that the latest version of the *Research and Development Strategy 2016-2020 (V4)*, which sets out the strategic direction for Research and Development (R&D) Department, has been uploaded on the Health Board's internet site.

Management action addressed.

R&D Sub-Committee Annual Report

The R&D Sub-Committee (RDSC) is required to provide regular formal reports of activities and submission of an annual report within six weeks of the end of the financial year to the Quality, Safety & Experience Assurance Committee (QSEAC) as outlined in the term of reference. We can confirm that both the 2018/19 and 2019/20 annual reports were submitted to the QSEAC meeting in June 2020.

Management action addressed.

Declarations on Corporate Registers

A review of the organisational registers published on the Health Board's website (including gifts, hospitality and sponsorship) noted that entries were up to date. We also noted that declarations of interest were now a standing agenda item for departmental meetings, such as the R&D Strategic Management Team meetings.

Management action addressed.

Risk Register

We can confirm that the R&D Department has a current, operational risk register in place, which has been subject to regular review at the Strategic Management Team meetings during 2020.

Management action addressed.

Finance Update Reports

A review of the frequency of Finance update reports due at the RDSC was undertaken to ensure the regular submission of information.

The impact of Covid-19 has meant that the RDSC has been unable to meet to review finance updates – the RDSC due to recommence in September 2020. However, during this period management oversight of the finance position continued with monthly financial reports submitted to the Strategic Management Team.

Individual spending plans were due to be submitted to the RDSC by year-end. However, the impact of the pandemic has resulted in a delay in the production of individual spending plans by Finance – an SBAR paper is due to be submitted to the RDSC in September 2020 to provide an update on the progress of finalising the individual spending plans.

Management action partially addressed.

HCRW Financial Returns

The original finding noted that individual researchers assigned investigation accounts had not promptly completed or submitted their quarterly returns to Health & Care Research Wales (HCRW) via the Finance Department. We can confirm that the latest quarterly returns were submitted to HCRW in May 2020.

Management action addressed.

R&D Director Payments

The former R&D Director has an honorary contract with the Health Board as a Consultant within Respiratory Medicine in addition to the R&D role for one session. We can confirm that monthly internal controls introduced by the Finance Department ensure the R&D Department is accurately recharged for the one session worked by the former R&D Director.

Management action addressed.

Sickness Absence

A follow up sample of four periods of sickness was selected and tested to ensure appropriate actions have been taken and documented in line with the *NHS Wales Managing Attendance at Work Policy*. Concluding testing, we continued to note errors with the sickness documentation reviewed including variances in dates recorded on self-certificates and return to work forms, in addition to a missing self-certificate for an absence period.

We noted the proactive response that management had taken to remind staff of the *NHS Wales Managing Attendance at Work Policy* and the need to attend sickness training. Unfortunately, due to the Covid-19 pandemic, training was suspended at that time.

Management action partially addressed

PADR Forms

A follow up sample of five employee personal appraisal development review (PADR) forms were tested to ensure personal objectives align with the Health Board's Policy referring to the use of SMART objectives. Testing highlighted that the sampled PADRs complied with the *Performance Appraisal & Personal Development Plan Policy*.

Management action addressed.

Travel Claims

All employee calendars were made available to approving officers following an email request by the Senior R&D Operations Manager in February 2020. We reviewed a follow up sample of five travel claim costs to ensure that they reconciled to the corresponding personal electronic diaries. Testing confirmed the sampled travel claims all reconciled to the employee calendars.

Management action addressed.

OBJECTIVE 2: The Health Board produces appropriate guidance and training for the management of research and development studies/ trials which is distributed appropriately throughout the Health Board

Standard Operating Procedures

We can confirm a timetable was in place to ensure a review and update of the 16 extant SOP's with a target date for completion by January 2021. A review of the latest version of the timetable, as of July 2020, confirmed progress was underway in the updating of SOPs, with a number still outstanding.

Management action partially addressed.

OBJECTIVE 3: Approval processes ensure that research is of appropriate quality relevant to the Health Board

Research Application Checklist

The primary source of information for studies is the LPMS system, with the 'Research Application Checklist' only used as an aide memoir for staff working on study set-up on a day to day basis.

Continual monitoring via the LPMS system is used to record progress against study set-up and progress. A review of the LPMS system confirmed that current data completeness within the systems is recorded at 100%.

Management action addressed.


Grant Submissions


A review of four grant submissions were tested to ensure they had been fully approved by an appropriate individual within the R&D Department. We can confirm that the grant submission had been signed off by either the Consultant Physician & Endocrinologist, Senior Researcher Development & Grants Manager or the R&D Manager.


Management action addressed.


Appendix A - 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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