Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

PWYLLGOR ANSAWDD, DIOGELWCH A SICRHAU PROFIOD
QUALITY, SAFETY AND EXPERIENCE ASSURANCE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	13 April 2021
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research and Development Sub-Committee Annual Report 2020/21
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Philip Kloer, Medical Director/Deputy Chief Executive
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Leighton Phillips, Director of Research, Innovation and University Partnerships

Pwrpas yr Adroddiad (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate)
Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

The purpose of this paper is to present the Research and Development (R&D) Sub-Committee Annual Report 2020/21 to the Quality, Safety & Experience Assurance Committee (QSEAC). The R&D Sub-Committee Annual Report provides assurances in respect of the work that has been undertaken by the Sub-Committee during 2020/21 and outlines the main achievements which have contributed to robust integrated governance across the University Health Board (UHB).

Cefndir / Background

The UHB's Standing Orders and the terms of reference for the R&D Sub-Committee require the submission of an Annual Report to QSEAC to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it.

The purpose of the Sub-Committee is to

a) assure the Board, via QSEAC, that it is discharging its functions and meeting its responsibilities with regards to the quality and safety of research activity carried out within the organisation.
b) promote and support involvement in high quality, multi-disciplinary and multi-agency healthcare research, promote evidence-based healthcare, build research capacity and foster a research culture, including patient/public involvement
c) facilitate collaboration with the research and academic community to maximise outcome and impact for the Health Board and the patients it serves.

The Annual Report specifically comments on the key issues considered by the Sub-Committee in terms of quality, safety and performance management of research activities, and the adequacy of the research governance and quality assurance systems and processes in place.

Asesiad / Assessment

The R&D Sub-Committee has been established under Board delegation with the Health Board approving terms of reference for QSEAC most recently at its Board meeting on 28th May 2020. The terms of reference of the R&D Sub-Committee (Version 0.9) were approved by the Sub-Committee on 14th September 2020 and subsequently ratified at the QSEAC meeting on 6th October 2020.

These terms of reference clearly detail the Sub-Committee's purpose to provide assurance to QSEAC around the organisation's research activities, ensuring that there is an accurate reflection of quality, safety, and performance management to deliver against gaps in assurance.

In discharging this role, the Sub-Committee is required to oversee and monitor the research agenda for QSEAC in respect of its provision of advice to the Board, and ensure the implementation of the research agenda against the following areas of responsibility:

Assure the Board in relation to arrangements for ensuring compliance with all relevant frameworks, standards, legal and reporting requirements

- The UK Policy Framework for Health and Social Care Research (2017).
- The Medicines for Human Use (Clinical Trials) Regulations (2004) as amended.
- The Medical Devices Regulations (2002) as amended.
- The General Data Protection Regulations (2018).
- International Conference for Harmonisation of Good Clinical Practice (ICH-GCP) standards (1996).
- Human Tissue Act (2004).

Consider the implications for the Board of the outcomes arising from relevant external Regulatory Agency Inspections, reviewing progress with resulting Corrective And Preventative Action plans (CAPAs) and authorising their completion

- The Medicines and Healthcare products Regulatory Agency (MHRA).
- The Human Tissue Authority (HTA).

Oversee the development of the Board's R&D documentation in line with local and national priorities and guidance, for sign off by the Board after scrutiny by the Quality, Safety & Experience Assurance Committee

- R&D Strategy.
- R&D Strategic Objectives.
- R&D Annual Plan.
- R&D Policies.
- R&D Standard Operating Procedures (SOPs).
- R&D Guidelines for Researchers.

The R&D Sub-Committee will endeavour to ensure the Health Board maintains its University status by monitoring and driving improvement in those metrics associated with University status against which it will be judged by Welsh Government

- Establishing and maintaining University Links.
- Contribution to Health Education and Training.
- Contribution to Quality Care.

- Contribution to Healthcare Research.
- Contribution to other Health related activities.

The R&D Sub-Committee will provide general assurance to the Board by:

- Ensuring strong relationships and effective communication with associated Higher Education Institutions and other external organisations.
- Reviewing new research applications pertaining to a member's specialist field / management responsibilities when requested by the R&D Manager.
- Promoting increased staff involvement in research activity, including facilitating access to relevant training to enhance research capacity and capability.
- Encouraging multi-disciplinary and multi-agency R&D, including patient/public involvement where appropriate.
- Reporting on R&D activity to relevant health community Committees and Health Board via the R&D Director or their nominated person.
- Promoting the dissemination of research findings in order to contribute to clinical effectiveness and evidence-based healthcare delivery, Value Based Health Care and to demonstrate the impact of research outcomes.
- Agreeing issues reported via the Research Quality Management Group (RQMG) to be escalated to the Quality, Safety & Experience Assurance Committee (QSEAC) with recommendations for action.
- Providing assurance that the ring-fenced NHS R&D Funding from Health and Care Research Wales is spent according to Welsh Government guidelines and requirements.

Research and Development Sub-Committee Reporting Group

The Research Quality Management Group reported into the R&D Sub-Committee during 2020/21. The Group was established to:

- Oversee the quality and safety of research activity carried out within the organisation.
- Monitor the production of research SOPs and associated documentation.
- Oversee routine and triggered audits and monitoring visits for research studies.
- Oversee the delivery of essential Good Clinical Practice (GCP) and other research governance training.
- Manage and oversee the Hywel Dda University Health Board's Biobank.
- Oversee research study Set-up and data quality assurance, and risk monitoring.
- Receive and discuss concerns from the research community regarding compliance with GCP and research study protocols, and direct investigation as appropriate.

The R&D Sub-Committee Annual Report 2020/21 is intended to outline how the Sub-Committee and its Group have complied with the duties delegated by QSEAC through the terms of reference set, and also to identify key actions that have been taken to address issues within the Sub-Committee's remit.

Constitution

From the terms of reference approved on 14th September 2020, the membership of the Sub-Committee was agreed as the following:

- Medical Director & Deputy Chief Executive (Chair)
- Deputy Director Research & Innovation (Vice Chair)
- R&D Director

- Deputy R&D Director
- Senior R&D Operations Manager
- Independent Member
- Assistant Director of Nursing (with a responsibility for research)
- Assistant Director of Therapies and Health Science (with a responsibility for research)
- Research active representatives – acute sector, primary care, mental health
- A representative from Aberystwyth University
- A representative from Swansea University
- A representative from the University of Wales Trinity Saint David
- Director of Finance or deputy
- Head of Clinical Engineering
- Head of Medical Education and Knowledge
- Representative from the Division for Social Care and Health Research (DSCHR) Welsh Government – Health and Care Research Wales Workforce
- Representative from 3rd Sector Organisation
- Head of Research, Innovation & Improvement, Regional Partnership Board

Meetings

Between March and July 2020, R&D Sub-Committee meetings were stood down due to the COVID-19 pandemic. For 20th April 2020 and 27th July 2020 when there were no Sub-Committee meetings, the Chair presented an update of R&D department activity to QSEAC at its meetings in June and August 2020.

From the R&D activity report to QSEAC in June 2020, Members were asked to note the current research activity being advanced by Hywel Dda University Health Board to support the national and international drive towards tackling the COVID-19 disease.

From the R&D activity report to QSEAC in August 2020, Members were asked to note that Health and Care Research Wales, Welsh Government, had requested that all R&D Departments put in place arrangements for restarting non COVID-19 research studies in view of the marked decrease in patients with the disease and the requirement to ensure all patients and staff are able to benefit from research. QSEAC was asked to receive an assurance from the R&D Restart Activity Report.

During 2020/21, the Sub-Committee met on 3 occasions and was quorate at all meetings.

R&D Sub-Committee meetings have been held on a bi-monthly basis as follows:

- 14th September 2020
- 9th November 2020
- 8th March 2021

The meeting scheduled for 11th January 2021 was cancelled due to the extreme pressures impacting on the R&D Department and acute hospital sites due to the second wave of the COVID-19 pandemic. The RQMG's updated Terms of Reference were approved by the R&D Sub-Committee via Chair's Action.

As the R&D Sub-Committee is directly accountable to QSEAC for its performance, assurance to the Committee is provided via a formal written update report following each Sub-Committee meeting, which is received at the subsequent QSEAC meeting.

Sub-Committee Terms of Reference and Principal Duties
In discharging its duties, the R&D Sub-Committee has undertaken work during 2020/21 against the following areas of responsibility in relation to its terms of reference:

Feedback from Research Quality Management Group – written update reports from the RQMG highlighting the key areas of work scrutinised and identifying key risks and issues and matters of concern, have been regularly received by the R&D Sub-Committee during 2020/21, including the following:

- The risk-based Research Governance Audit programme (Routine Audits and Monitoring Visits) was suspended in March 2020 due to COVID-19.
- Corrective And Preventative Action (CAPA) plans following Triggered (for cause) Audits were agreed and authorised on completion.
- Key risks, issues and matters of concern were scrutinised, and action plans to address these agreed via the Research Quality Assurance (QA) Team in liaison with other R&D Teams and the Health Board's research community.
- The Breast Cancer 'Oncotype Dx' trial handover was facilitated by the Quality Assurance Officer (Research) before the Study Coordinator left the Health Board.
- The Respiratory 'Fourier Transform Infrared (FTIR)' study Triggered Audit report was approved by RQMG Chair's Action and submitted to the Wales Research Ethics Committee 7 on 17th July 2020.
- Destruction of the 'FTIR' study human tissue samples was approved in compliance with both the Health Board's Biobank Policy (466) and the Human Tissue Authority License for Research.
- Progress updates received for the Health Board's Biobank Database development project with Aberystwyth University, and delays managed by the Biobank Database Project Group with appropriate escalation.
- Reviewed applications from internal and external researchers to receive surplus human tissue samples held in the Health Board's Biobank for their own research.
- Discussions held relating to establishing an independent Biobank Access Committee to consider requests for, and approve the release of, human tissue samples from the Health Board's Biobank.
- Guidance on preparing for Statutory Inspections by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Tissue Authority (HTA) was developed for R&D staff and the research community.
- Continued progress on producing the UHB's portfolio of core R&D written controlled documents, with 14 documents approved by RQMG in August 2020, 20 documents approved in December 2020 and a further 5 documents approved in February 2021.
- Plans to develop a Research Quality Assurance metrics dashboard, for presentation to the R&D Strategic Management Team and R&D Sub-Committee to provide further assurance that research activities are being closely monitored and are conducted in line with recognised quality standards.

- Agreed mechanisms to share lessons learned from adverse events and audit findings by incorporating learning into ongoing research training provision across the Health Board and its research partners, and when providing Research QA advice, mentoring, ad hoc training and guidance to novice and experienced researchers.
- Managed any research-related Adverse Events, Serious Adverse Events, Suspected Unexpected Serious Adverse Reactions (Clinical Trials of Investigational Medicinal Products) or Unanticipated Serious Adverse Device Effects (Clinical Investigations of Medical Devices) reported to the R&D Department via the R&D safety reporting process and/or the UHB's DATIX system.
- Prioritised and monitored progress with R&D written controlled documents including Policies, Procedures, Guidelines, Checklists, Templates and Forms, consulting on and approving final versions.

See Appendix 1 (to follow) for the Research Quality Management Group's Annual Report 2020/21*.*

Other Areas of Responsibility
During 2020/21, the R&D Sub-Committee also received, and considered the following:

- Activity reports from the Sponsorship Review Panel (SRP) established to consider whether, for in-house research proposals, the Health Board is able and willing to fulfil its responsibilities as Sponsor as laid out in the UK Policy Framework for Health and Social Care Research (2017).
- Details of research proposals considered by the SRP in terms of scientific quality and validity; information use and dissemination, including value and impact of findings; health and safety of researchers and participants; finance, resource use and Intellectual Property Rights.
- A 'Pathway to Portfolio' grant programme was set up in July 2020, with applications assessed by the SRP and a recommendation for award of funding made to the R&D Strategic Management Team. This initiative would run quarterly, with one award made to date.
- Continuing increased oversight of Investigator research accounts to ensure robust financial governance and implementing the recommendations of the All Wales NHS R&D Finance Policy (2017).
- Overseeing the R&D department's financial reporting to Health and Care Research Wales to demonstrate compliance with the 'Purpose and Use of NHS R&D Funding Guidelines'; ensuring that the Annual Spending Plan, Quarterly Financial Returns and Annual Financial Returns were submitted to Welsh Government on time.
- Financial reports, noting that R&D was on track to break even for 2020/21 with no risk to the Health Board despite commercial trial income being reduced due to a decrease in commercial research. A commercial approach would be included as part of the strategy development process. Spending Plans had all been requested and no Investigator research accounts were at risk of being overdrawn.
- An analysis of the strengths and weaknesses in the R&D department's Grant capture history was requested in order to involve the Health Board's University partners and consider future targeting.
- Three R&D written controlled documents were ratified by the Sub-Committee in November 2020: SOP, Flow Chart and Form for Reporting Research-Related

Adverse Events/Serious Adverse Events, which had been expedited for approval in April/May 2020 for a COVID-19 Clinical Investigation of a Medical Device. The RQMG Chair and the R&D Strategic Management Team Chair had granted 6-month interim approval with a requirement to receive full R&D Sub-Committee approval.

- The Sub-Committee noted in November 2020 that 60% of the core R&D SOPs had been completed, and requested details of which SOPs potentially posed a risk if they were not in place in order to prioritise these. The remaining core SOPs were completed by the end of December 2020. The Sub-Committee recognised that this has been an enormous piece of work and the Research Quality Assurance Team were commended for their progress.
- Summary reports from the R&D Operational Leadership Group, established in 2020, to oversee the operational objectives of the R&D department; scrutinise individual team performance, quality and governance issues, financial matters and identify potential risks; address issues escalated from the Researcher Development, Research Delivery, Research Study Set-up and Research Quality Assurance Teams; look forward and advise on developing the service; produce action plans to progress improvement and development and mitigate risks; identify issues to be escalated to the R&D Strategic Management Team for information and decisions.
- Between September 2019 and January 2020, the R&D department had been subject to an internal audit to assess the adequacy of arrangements for the management of R&D to provide assurance to the Audit & Risk Assurance Committee (ARAC) that risks material to the achievement of systems objectives were being managed appropriately. In January 2020, the overall decision of the auditors was that the Board could only take limited assurance that arrangements to secure governance, risk management and internal control were suitably designed and applied effectively, resulting in a moderate impact on residual risk to exposure until recommendations were implemented. A management response to address the recommendations was submitted to ARAC and a re-audit took place in August 2020 to establish the progress made in implementing the agreed actions. The re-audit concluded that the level of assurance as to the effectiveness of the system of internal control in place was reasonable assurance. A full report was submitted to ARAC in October 2020.
- Reports from the R&D Strategic Management Team, established to oversee the strategic objectives of the R&D department; the management of staff, prioritising and appointing new posts and making temporary posts permanent; ensuring compliance with the NHS R&D Finance Policy, and advising the research community on the Terms and Conditions affecting management of their Investigator research accounts.
- As the current R&D Strategy concludes in March 2021, work has been progressed to develop a new 3-5 year R&D strategy to cover innovation in addition to research. A discussion took place with active involvement of the three University representatives and a work plan was produced to develop the new strategy. Key issues discussed included the need to increase and diversify the R&D financial allocation focussing on areas to target for growth; the development of Clinical Engineering and Innovation Research; collaborations with three University partners and the two neighbouring Health Boards; the growth plan in Primary Care; the need for the new hospital to be considered; the need to consult Health and Care Research Wales, Welsh Government, to ensure the strategy is following the same trends. A final draft of the R&D Strategy was considered and approved by the Sub-Committee on 8th March 2021, to be submitted to QSEAC in April 2021 for final ratification.

- Welsh Government's forthcoming tri-annual review of the Health Board's University status was discussed. Although no report had been produced, it was noted that detailed discussions had taken place with the three local university partners, enabling information to be shared around bi-lateral relationships. The R&D Strategy also covers existing collaborations with partners and future research aspirations to support the Health Board's presentation to Welsh Government. Further examples of collaborations with local and other university partners were requested from the Sub-Committee members to support the presentation.
- The Good Clinical Practice Training Policy (822), approved by the RQMG on 18th February 2021 and by the R&D Strategic Management Team on 22nd February 2021, was ratified by the Sub-Committee on 8th March 2021.

Key Risks and Issues/Matters of Concern

During 2020/21, the following key risks and issues/matters of concern were raised to QSEAC:

- The lack of research facilities in Bronglais and Glangwili General Hospitals hindering their ability to open new portfolio research studies.
- The increase in the number of positive COVID-19 patients in the hospitals impacting on the ability of research delivery staff to keep a variety of studies open alongside the Urgent Public Health COVID-19 studies.
- Space has been allocated for the research facility in Glangwili General Hospital. Plans had been prepared however, the project was more expensive than anticipated and there are constraints on how R&D funding can be utilised. The Director of Finance has been made aware and has agreed to provide support where necessary.
- In August and November 2020, there were nine active risks for R&D on the Risk Register, with the Sub-Committee receiving assurance on the management of these risks.
- In March 2021 there were eight active R&D risks with robust management plans to mitigate and resolve these.

Matters Escalated to Quality, Safety & Experience Assurance Committee

During 2020/21, the following matters requiring QSEAC level consideration or approval were raised:

- In May 2020, QSEAC was asked to note the Urgent Public Health research activity being advanced by the Health Board to support the national and international drive towards tackling the COVID-19 virus.
- In August 2020, QSEAC was asked to note the following risks:
    - Risk 148 Lack of dedicated research space on the acute hospital sites, which was also related to:
    - Risk 556 Failure to increase the number of research studies – a Key Performance Indicator (KPI).
    - Risk 557 Failure to increase the opportunity for people to participate in research – a KPI.
    - Risks 915 and 916 Unsafe working environments in the research laboratory in Prince Philip Hospital and in the laboratory space in Glangwili General Hospital.
    - Risk 952 Lower than expected income from commercial studies and grants.

- In November 2020, given the significance of the R&D Strategy for the R&D Sub-Committee, it was agreed that the draft document would be appended to the R&D Sub-Committee Exception Report to QSEAC, in order to raise awareness of the work of the R&D Sub-Committee and also to provide QSEAC with an opportunity to provide feedback, whist the strategy is still in the development stage.

R&D Sub-Committee Developments for 2021/22

The following developments are planned for the Research and Development Sub-Committee during 2021/22:

- Change of name from the Research and Development Sub-Committee to the Research and Innovation Sub-Committee.
- The Sub-Committee meetings will be structured into two parts: Part 1 – Performance, Quality and Finance; Part 2 – Development and Innovation.
- The new Clinical Engineering, Research and Innovation department will also report regularly into this Sub-Committee as part of standing agenda item reporting.

Argymhelliad / Recommendation

To endorse the Research and Development Sub-Committee Annual Report 2020/21.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	10.4.1 Report formally, regularly and on a timely basis to the Board on the Committee's activities. This includes the submission of a Committee update report, as well as the presentation of an annual report within six weeks of the end of the financial year.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	Not Applicable
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	Governance, Leadership and Accountability

Effaith/Impact:	
Ariannol / Financial: **Ansawdd / Patient Care:** **Gweithlu / Workforce:** **Risg / Risk:** **Cyfreithiol / Legal:** **Enw Da / Reputational:**	Included within the report

Gyfrinachedd / Privacy: **Cydraddoldeb / Equality:**	