Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

CYFARFOD BWRDD PRIFYSGOL IECHYD UNIVERSITY HEALTH BOARD MEETING

DYDDIAD Y CYFARFOD: DATE OF MEETING:	10 June 2021
TEITL YR ADRODDIAD: TITLE OF REPORT:	Quality, Safety & Experience Assurance Committee Annual Report 2020/21
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Anna Lewis, Chair, Quality, Safety & Experience Assurance Committee
SWYDDOG ADRODD: REPORTING OFFICER:	Mandy Rayani, Director of Nursing, Quality and Patient Experience

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 Quality, Safety & Experience Assurance Committee (QSEAC) Annual Report 2020/21 to the Board.

The QSEAC Annual Report provides assurances in respect of the work that has been undertaken by the 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 QSEAC require the submission of an Annual Report to the Board to summarise the work of the Committee and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Committee is to provide assurance to the Board around the organisation's strategy and delivery plans for quality and safety.

This QSEAC Annual Report specifically comments on the key issues considered by the Committee in terms of quality, safety and experience, and the adequacy of the response, systems and processes in place during 2020/21.

Asesiad / Assessment

The Health Board established QSEAC, under the Board's Scheme of Delegation, in 2015. Since then, the terms of reference have been subject to an annual review and were most recently approved by the Board at its meeting on 25th March 2021.

These terms of reference clearly articulate that the Committee's purpose is to provide assurance to the Board that the organisation's strategy and delivery plans for quality and safety are appropriate and that it can provide evidence based and timely advice to the Board to assist it in discharging its responsibilities.

The Committee provides leadership and ensures that the appropriate enablers are in place to promote a positive culture of quality improvement based on best evidence.

As identified within the most recently revised terms of reference, the Sub-Committees directly reporting to QSEAC during 2020/21 are as follows:

- Operational Quality, Safety and Experience Sub-Committee
- Listening and Learning Sub-Committee
- Research and Development Sub-Committee

The terms of reference for the above Sub-Committees have all been reviewed and approved during 2020/21.

CONSTITUTION

From the terms of reference approved by the Board in March 2021, the membership of the Committee has been agreed as the following:

Full Members

- Independent Member (Chair)
- 5 x Independent Members (including the Audit and Risk Assurance Committee Chair and the People, Planning and Performance Assurance Committee Chair)

In attendance Members:

- Director of Operations
- Medical Director and Deputy Chief Executive Officer
- Director of Nursing, Quality and Patient Experience (Lead Executive)
- Director of Therapies and Health Science (Chair of Operational Quality, Safety & Experience Sub-Committee)
- Assistant Director of Therapies and Health Science
- Director of Public Health
- Director of Primary Care, Community and Long Term Care
- Associate Medical Director Quality and Safety
- Assistant Director of Nursing, Assurance and Safeguarding
- Assistant Director, Legal Services/Patient Experience
- Hywel Dda Community Health Council (CHC) Representative (not counted for quoracy purposes)

MEETINGS

QSEAC meetings have been held on a monthly basis throughout the year, with the exception of September 2020, and all were quorate as follows:

- 7th April 2020*
- 7th May 2020
- 9th June 2020*
- 7th July 2020
- 13th August 2020*
- 6th October 2020
- 13th November 2020*
- 1st December 2020
- 14th January 2021*
- 2nd February 2021
- 16th March 2021*

*COVID-19 specific QSEAC meetings.

In-Committee sessions have been held during 2020/21 as necessary, to discuss either potentially sensitive matters or identifiable patient data, including the following:

- Accessing Specialist Spinal Services
- Commissioned Services: Long Term Agreements and Quality Assurance
- Complex Mental Health Case

As QSEAC is directly accountable to the Board for its performance, the Chair of QSEAC has provided assurance or escalated matters to the Board through a formal written update report following each Committee meeting.

Outcome of QSEAC Self-Assessment of Effectiveness 2019/20 – at its April 2020 meeting, the Committee received notice of the QSEAC self-assessment of effectiveness exercise for 2019/20. Members were advised that following discussions with the QSEAC Chair, 5 key questions would be posed to self-assess the Committee's effectiveness during 2019/20 to elicit broader feedback than the previous questionnaire to influence the agenda going forward. In June 2020, QSEAC received the Outcome of the Committee's Self-Assessment Process for 2019/20, noting the resulting enriched narrative in comparison to the previous methodology, and suggesting a similar approach be considered for other Board level Committees for 2020/21. It was agreed that confirmation of the agreed themes from the process would be included within the QSEAC forward work programme.

Annual Reports - the Committee received and approved the following Annual Reports in 2020/21:

- QSEAC Annual Report 2019/20
- QSEAC Sub-Committees Annual Reports 2019/20
- Draft Annual Quality Statement 2019/20 prior to its approval at the June 2020 Board

Operational and Strategic Delivery Reports – COVID-19 Specific
During the year, the Committee received numerous presentations, reports and updates in relation to operational services delivery and performance issues including the following COVID-19 specific items:

- **Policy/Guidance Updates** - in May 2020, the Committee received the Policy/Guidance Updates - COVID-19 National and Local Approved and Published Guidance report, outlining the approach taken by HDdUHB in recognition that all COVID-19 guidance would require a robust process for approval and dissemination within the Health Board. Members were advised that the new procedures are embedded, approved and published on the Health Board's COVID-19 Patient Management webpages, and that learning from COVID-19 would be taken forward for future engagement with clinical teams. The Committee received an assurance that for any variations in guidance, the Health Board would engage with key individuals who may be impacted by the guidance, and for any cases where significant discrepancies occur, a report would be presented to Gold Command for approval.
- **Incident Reporting During COVID-19** - also in May 2020, the Committee received a verbal update in relation to incident reporting during COVID-19, highlighting that up to this point in time, the total reported incidents on Datix which now has additional fields for COVID-19 related incidents, is comparable to the previous year. 9 reported incidents related to communication issues which were the subject of review, and up to the end of March 2020, 5 incidents in relation to PPE had been reported, in the main regarding fit testing, however no further issues in regard to PPE had been reported since. In relation to the potential for a possible reduction in Hospital Acquired Infections (HAIs) due to COVID-19, Members were advised that Infection Prevention meetings were being reinstated which would review the available data to establish any emerging themes, in particular, whether following improved hand hygiene during the COVID-19 period, a

reduction in community infections may result. In July 2020, the Committee received the Incident Reporting During COVID-19 report, noting that whilst the number of reported safety incidents had reduced, there had been a rise in the number of incidents per 1,000 patients during the COVID-19 period. Whilst challenging to identify why, QSEAC acknowledged this could be linked to the acuity of patients being treated and received an assurance that the Assurance, Safety & Improvement (ASI) Team would continue to monitor in order to identify any themes involved. QSEAC received confirmation that following a review undertaken into previous concerns raised by the Committee, no significant increase in hip fractures has been identified during the COVID-19 pandemic, however as changes to data collection made since April 2020 now included fractures to the shaft of the femur, it would be difficult to determine whether COVID-19 has had an impact to date. QSEAC received an assurance from the processes in place to monitor incident reporting during the COVID-19 pandemic and that appropriate action is subsequently taken.

- **Patient Feedback during COVID-19** - in May 2020, the Committee received a verbal update in relation to patient feedback during COVID-19, highlighting that between January and March 2020, the Health Board received 55 formal complaints, a reduction of 50% from April 2020, with the numbers continuing to fall on a weekly basis by approximately 5% per week. Whilst the complaints received generally related to patient appointments, the most significant area of concern related to communication from wards to patient's families. In response to this concern, Members were provided with details of the newly established family liaison role which it is anticipated would be ward based for 2 shifts per day, 7 days per week, to facilitate communication and patient experience. Recognising the Committee's role in advocating the patient's voice, Members welcomed the work of the Patient Advisory Liaison Service (PALS) team who have been supporting the operational site teams with a range of duties. In response to a query regarding end of life visits during COVID-19, the Committee received an assurance that wards have received guidance that risk assessments should be undertaken on a ward by ward basis, and that where appropriate, visits by a relative should take place. On occasions where this has not been possible, wards have used digital based facilities. The Committee was also presented with the draft Ombudsman year end position, demonstrating the significant improvements made by the Health Board at the initial stage of investigations, resulting in no public interest reports being issued during the year. Members welcomed the improvement, noting the positive foundation this would provide to take forward future work.
- **COVID-19 Response Update** – in June 2020, QSEAC received the COVID-19 Response Update following its presentation to Public Board, where it was suggested that a report which focused on quality and safety as opposed to performance, would have enabled QSEAC to provide further assurance to the Board. Caution was expressed that field hospitals do not become the default route when acute hospitals lack capacity, and assurance was provided that a balanced approach would be taken, with plans being established in the escalation process to mitigate against this, which would be regularly monitored. In response to queries regarding any emerging quality and safety concerns arising from non-face to face outpatient clinics, Members were advised that a patient experience review is taking place in conjunction with the work being undertaken by Hywel Dda CHC, and that Welsh Government (WG) is undertaking a national evaluation to inform the most appropriate platforms for future patient contact. In November 2020, QSEAC received a verbal COVID-19 update together with the Learning from COVID-19 Outbreaks Report, following the three COVID-19 outbreaks experienced by the Health Board up until this point in time. QSEAC noted this is an extremely challenging time for both the Infection, Prevention and Control Team (IP&C) and the Operational Teams in terms of managing these outbreaks. Members were assured that following each Outbreak Control Team (OCT)

meeting, findings are quickly shared with all teams involved in order to facilitate rapid learning across the Health Board. In addition, daily situation reports are undertaken, with a new streamlined process having been developed. It was noted that WG has also issued a 16 point plan for transmissions, which is being supported by Executive Directors to ensure oversight of infections; it is anticipated that intra-hospital transfers and transfers between other Health Boards will now be more robust. QSEAC noted that discussions have taken place in a number of fora regarding the appropriateness of the COVID-19 testing regime and received assurance that the Health Board is following guidance issued by Public Health Wales (PHW). QSEAC further noted that regular conversations are taking place to thank staff for all their hard work during these challenging times and added their thanks to all involved in managing the current outbreaks.

- **Field Hospitals** – in July 2020, QSEAC received the Field Hospital Update report, identifying that the temporary field hospital in Carmarthen, Ysbyty Enfys Caerfyrddin, had recently opened for two cohorts of patients. Whilst feedback from the first cohort of patients had been positive, QSEAC recognised that the experience received would require further analysis once capacity within the field hospital is increased. QSEAC received an assurance that the Health Board has been proactive in issuing press releases ahead of opening the Carmarthen field hospital facility, in addition to providing leaflets for patients and families utilising the service. QSEAC expressed their thanks to all involved for the significant work undertaken in establishing Hywel Dda's field hospitals. In November 2020, QSEAC received a verbal update regarding Field Hospital Utilisation and Outcomes from the Healthcare Inspectorate Wales (HIW) Inspections, following HIW's visit to both Ysbyty Enfys Carreg Las at Pembrokeshire's Bluestone site, and Ysbyty Enfys Selwyn Samuel in Llanelli, on 8th November 2020. Noting that the formal report should be received by 21st November 2020, Members were advised that HIW had verbally commended the clinical environment and robust governance structures in place, welcomed the consideration offered in respect of patients' dignity and noted that staff were enthusiastic and engaged. However, concern was expressed regarding security at Ysbyty Enfys Carreg Las, given the multiple access points in place. For assurance, it was agreed that any areas not being utilised would be locked to increase security. In terms of Ysbyty Enfys Selwyn Samuel, HIW provided positive feedback relating to site access, signage and security. QSEAC welcomed the fact that the Health Board's governance structures and underpinning processes had been noted as an exemplar and as such would be shared with other Health Boards in Wales. Members were advised that Ysbyty Enfys Selwyn Samuel should become operational from 16.11.2020, with patient transfers from Glangwili General Hospital (GGH_ and Prince Philip Hospital (PPH). QSEAC welcomed the verbal update, acknowledging the work undertaken to operationalise the two field hospitals and expressed thanks to the teams involved for the comprehensive and professional manner of the Health Board during the COVID-19 pandemic. In January 2021, QSEAC received the Field Hospital Utilisation and Outcomes report from the Healthcare Inspectorate Wales (HIW) Inspections, following HIW's visit to both Ysbyty Enfys Carreg Las at Pembrokeshire's Bluestone site, and Ysbyty Enfys Selwyn Samuel in Llanelli, on 8th November 2020. Members commended the report as testament to the excellent work undertaken, representing the first HIW report received by the Health Board with no requirement to submit an improvement plan. Members were assured that the 3 recommendations made by HIW had been completed and again welcomed the fact that the Health Board's governance structure and underpinning processes had been noted as exemplary.
- **Personal Protective Equipment (PPE**) – in May 2020, the Committee received the Personal Protective Equipment update report to provide assurance on the work undertaken following the regular reports presented to Gold Command. Members

were advised that a healthcare model has been operating in parallel with a Local Authority (LA) model, and that following discussions with the Director of Finance to improve PPE ordering going forward, the Procurement Team has been embedding new systems in order to manage concerns regarding availability and distribution. Members expressed their thanks to the team involved in progressing adequate PPE supplies, recognising the importance of providing a level of assurance to staff following the concerns raised. In July 2020, the Committee received a verbal update in regard to PPE, and noting the current delay involved with supplies due from overseas suppliers, received an assurance that mitigations are in place, specifically mask fit testing on a range of alternative products, with additional hoods also being sourced. To further ensure adequate supplies are available, Members were assured that PPE is transferred to where it is required across the organisation, as and when necessary. QSEAC also received confirmation that in addition to the Hywel Dda PPE Cell which meets fortnightly to discuss Health Board supplies, Hywel Dda is represented on the National PPE Cell to support the supply of PPE on an all Wales basis. In March 2021, the Committee noted that, although national issues remain, there had been no locally reported issues around PPE with 3 weeks supply held centrally. Whilst a mass delivery of gloves into Wales is anticipated in the coming months, supplies of the FFP3 masks are at a lower level, with the Health Board needing to utilise all the masks that have been made available. It was noted that sourcing FFP3 masks has been a challenge since the start of the COVID-19 pandemic.

- **Thematic Review of Never Events During COVID-19** - in November 2020, the Committee received the Thematic Review of Never Events During COVID-19 report, providing an overview of the incidents, and the learning identified through Root Cause Analysis (RCA) review. Members were assured that following each never event, a Control Group is established, which works with operational teams to identify any themes arising from the incidents. Further to this, discussions have taken place with the WG Delivery Unit (DU), in order to establish whether these are comparable with the rest of Wales. For assurance purposes, and to ensure wider Health Board learning is possible, all never events are presented to the Listening and Learning Sub-Committee (L&LSC) to identify themes. Given that the review identified that a number of the never events took place during the evening and weekends, to mitigate this, shift patterns have been changed, with additional capacity available since the beginning of the COVID-19 pandemic. QSEAC noted that the review had not found evidence that suggests an escalating trend of never events, but rather a spike that is associated with changes in the working environment due to COVID-19, alongside a greater risk of staff fatigue. As this situation requires ongoing vigilance, QSEAC would maintain close oversight of the position. The importance of maintaining an open approach to reporting of serious incidents was emphasised.
- **COVID-19 Risk Assessments** - in December 2020, the Committee received the COVID-19 Risk Assessments noting that these had previously been discussed at both Gold Command and Tactical Group meetings, with the agreement that these Risk Assessments be presented to QSEAC for assurance purposes. Members were advised that the Risk Assessments outline the change in process for field hospitals and outbreak management in order to manage the flow from acute settings, following on from an extremely challenging period of time where pragmatic decisions had needed to be made. It was understood that all Health Boards are experiencing similar challenges and have established similar approaches to mitigate the associated risks. Members were informed of staffing challenges at both Llandovery Cottage Hospital and Amman Valley Hospital, with the Health Board currently working on the most appropriate resolution. QSEAC noted that any

actions taken would be clinically-led to ensure the safety of all patients in both facilities, and that the Hywel Dda CHC would receive a further briefing once the changes had been agreed, emphasising that these changes would be made on a temporary basis only. QSEAC received assurance that the patients involved, their families and other professionals would be informed of the proposed plans. QSEAC acknowledged the evolving situation and that Members would be supportive of the actions taken to ensure patient safety.

- **COVID-19 Impact on Essential Services Report** - in January 2021, the Committee received the COVID-19 Impact on Essential Services slide-set, providing a system-wide overview of the impact of COVID-19 and offering a level of assurance on the governance and decision-making processes at an operational and organisational level. QSEAC acknowledged the impact of COVID-19 on each part of the system and the organisational response to any resulting potential harm, with decisions made and monitored in line with national guidance. Members were assured that all organisational decisions are made through a clear Command and Control governance framework, with decisions subsequently ratified at Board as appropriate. Members were assured that all operational decisions are made utilising a national risk stratification framework, which sets out a level of immediacy to assess and review patients and to determine their prioritisation. Members were further assured that the assessment of individual patient status is a dynamic process and repeated continuously on at least a 3 months basis, with a range of actions undertaken by the Health Board to ensure appropriate and effective communication is in place. Members were informed that the Command Centre is working to develop a more structured point of contact system for patients, with good progress made using digital resources to maintain contact, recognising the need to be clear both from a governance perspective and more importantly from the public's perspective, on how they can expect to receive communication relating to their care.
- **Hospital COVID-19 Outbreak Update Report** - also in January 2021, the Committee received the Hospital COVID-19 Outbreak Update slide-set, detailing the number of outbreaks and their location across the Health Board together with the duration of ward closures. Members were assured that much learning had been taken from the first outbreak experienced within HDdUHB, with an Outbreak Control Team established to manage outbreaks going forward. Members were assured by the subsequent improvements made to practice following reviews by the Outbreak Control Team including the mandatory use of visors for staff on outbreak wards together with enhanced cleaning in these areas, changes introduced to screen all admissions into hospital, Point of Care testing introduced in Accident & Emergency departments which has been rolled out effectively across the Health Board, and in terms of staff wellbeing, psychological support provided. Members were further assured that communication with patients has been acknowledged as important, with families of patients having been supported by the recently recruited Family Liaison Officers. QSEAC noted the work undertaken to reopen Llandovery Hospital and received assurance that criteria had been developed to avoid further outbreaks in community hospitals, with community settings across the Health Board receiving support from Infection Prevention nurses. QSEAC also noted the ongoing issues in respect of patient discharge to partner organisations, and care packages and domiciliary support, exacerbated by the COVID-19 pandemic, and received assurance that weekly discussions are held with Local Authority colleagues and Directors of Social Care to address any obstacles in place. It was noted that this issue is being strategically influenced by the national Nosocomial Transmission Group and at Regional Partnership Board. QSEAC expressed thanks to all staff involved in managing the current outbreaks. In March 2021, the Committee was informed that,

between 1st October 2020 and 28th February 2021, HDdUHB had experienced 44 COVID-19 outbreaks of varying lengths with affected staff having to work longer hours to manage the situation. However, since the most recent outbreak closed week ending 18th March 2021 the Health Board has not experienced any further outbreaks of COVID-19. It was noted that during the outbreaks, the Health Board had managed and mitigated a number of risks due to operational pressures, with PPE, patient flow and social distancing examples cited. Due to a number of contributing factors such as lateral flow device (LFD) testing, the rollout and uptake of the mass vaccination programme and in-patient testing taking place at day 5, the Health Board is confident that great strides are being made in overcoming outbreak situations. The Committee was advised that the Health Board is taking learning opportunities post COVID-19 from a number of organisations noting that the Grange Hospital, a new hospital within Aneurin Bevan University Health Board, had experienced no outbreaks of COVID-19 since its opening, despite experiencing patient flow and delay challenges. The Committee was advised that in-patient testing is now confirmed to be completed every 5 days for the duration of an in-patient's stay whereas previously in-patients were to be tested on day 5; this includes all in-patients including Community Hospitals and Mental Health and Learning Disability facilities.

- **Vaccination Programme and Prioritisation Framework** - in January 2021, the Committee received the Hywel Dda UHB Vaccination Prioritisation Framework and the COVID-19 Vaccination Programme report, noting the constant changes to the challenges associated with the rollout of the vaccines. Members were assured on how frontline health and care staff are prioritised utilising the guidance issued by the Joint Committee of Vaccination and Immunisation (JCVI), and that vaccination for staff in priority group 1, consisting of care home residents and staff, and group 2, consisting of frontline health and social care staff, had been rolled out with the anticipation that first dose vaccination of the 2 groups would be complete by the end of January 2021. It was noted that vaccination had commenced with care home staff and those identified at risk of greater exposure due to daily work, i.e. staff working in COVID-19 red areas as identified by Bronze Groups. Members were assured that concerns that staff from care homes with red status had not been able to attend for vaccination had been rectified with the revision of Public Health Wales guidance. It was noted that a Task & Finish Group has been established to look at sub-prioritisation within the JCVI priority groups which, as a result, would provide further assurance that the Health Board is in line with the all Wales position regarding the development of the 10 sub-groups for prioritisation. Members were assured that instances of non-attenders are being addressed by the Communications team and that a cancellation booking contact number had been recently introduced. A reserve list is also held to ensure non-attender slots are covered. Members noted the technical issues associated with the interim booking system in place whilst awaiting the national online booking system, and were assured that learning had been taken from these logistical challenges, with the anticipation to transfer to call and recall via the Welsh Immunisation System (WIS) eventually. Members commended the collaborative approach undertaken to this work with the RAF and volunteers, and noted the excellent work being undertaken in producing a weekly vaccine bulletin for the public. QSEAC received assurance from the progress made to date with the Hywel Dda UHB COVID-19 Vaccination Prioritisation Framework, noting that plans and mitigation measures are in place for dealing with risks around delivery of the COVID-19 vaccines across Hywel Dda UHB. QSEAC expressed thanks to all staff involved for the sterling work undertaken. In March 2021, the Committee was advised that milestone 1 i.e. vaccination of Priority Groups 1-4 by the middle of February 2021 had been achieved, with the Health Board now undertaking milestone 2 i.e. vaccination of Priority Groups 5-9 to be undertaken by mid April 2021. The Committee was further

advised that the Health Board received confirmation week ending 12th March 2021 that sufficient doses of the AstraZeneca Oxford vaccine would be received to achieve the targets set. The Health Board will therefore endeavour to rollout the vaccine to the remaining population as described by the JCVI by the end of July 2021. The Committee was assured that the Health Board is satisfied there are sufficient doses of vaccine to meet the mid April 2021 deadline with the ability to deliver as planned at Mass Vaccination Centres for Priority Groups 7-9 and for GP Practices to deliver to Priority Groups 5 and 6.

- **COVID-19 Learning Disability Patient Story** - in August 2020, the Committee received an account from a patient's perspective of the care received for their condition known as Spastic Cerebral Palsy from the Community Team Learning Disabilities during COVID-19. It was noted that prior to COVID-19, the patient would routinely attend a spasticity management clinic to receive botulinum toxin injections which relax the neck muscles to improve head posture, however as these clinics have not taken place, the patient had been referred to the Community Team Learning Disabilities in order to receive physiotherapy intervention. QSEAC was advised that the team followed the guidance introduced to support a COVID-19 pathway for safe intervention on a face to face basis, prior to visiting the patient. The patient confirmed that following the visit, their non-verbal communication had improved, they were less fatigued, and more engaged. The patient story provided QSEAC with an excellent example of the positive impact of person-centred care. QSEAC welcomed the presentation, noting the life changing work of the team which has continued during the COVID-19 pandemic.
- **Health Response to the use of the MOD Training Camp at Penally for Men Seeking Asylum in the UK** - in November 2020, the Committee received the Health Response to the Use of the MOD Training Camp at Penally for Men Seeking Asylum in the UK report, acknowledging the work undertaken by the Health Board and stakeholders to provide support, particularly in light of the challenges due to the COVID-19 pandemic. As a result, 156 residents had been offered a core service for primary care needs out of South Pembrokeshire Hospital, in addition to an enhanced service, which is over and above that which the Home Office had requested. Members noted that the identified quality and safety concerns relating to the Penally site had been expressed in correspondence to the Home Office, with it emphasised that the Health Board is not in a position to be the regulators of the site. Furthermore, stakeholders had expressed concerns that they do not have the infrastructure to provide appropriate services for this cohort of patients. It was acknowledged that even with the significant amount of work that has been undertaken, risks still remain, which had been referenced within correspondence to the Home Office on 4th November 2020. In addition to this, Members were advised that the Health Board has provided clarity on the assurance required from the Home Office in order to continue to provide the care and support to this cohort of patients, with a response currently awaited. In terms of support for Health Board staff, QSEAC received assurance that this is being provided by the Health Response Team. Whilst recognising that the challenges for the Health Board and stakeholders are multi-faceted, QSEAC expressed thanks to all involved for the professional and compassionate manner in which the work undertaken has been progressed. Given the significant concerns cited within the correspondence to the Home Office, it was agreed to escalate these via the QSEAC update report to Board. In February 2021, the Committee received a presentation regarding the continuing challenges experienced in providing primary care services to residents of Penally camp. QSEAC received assurance surrounding the provision of services, noting that concerns regarding the suitability of the camp remain on the Board's agenda in a clear and transparent way.

- **Delayed Transfers of Care** – in March 2021, the Committee received a presentation on the impact on delayed transfers of care due to the COVID-19 pandemic. Whilst the formal report that had been required to be submitted to WG had been stood down, Discharge to Assess reporting standards are included in the report covering both Acute and Community Hospitals. A rapid reduction has been noted in the number of individuals 'stranded' over 7 days with the percentage of those stranded and super stranded patients having reduced in comparison to the preceding two years. Whilst there are more individuals being cared for in the Community, those individuals noted as stranded for longer tended to be patients with complex care needs. The Committee was advised of challenges in securing appropriate packages of care in care homes during the COVID-19 pandemic, with domiciliary care capacity challenges also experienced in Pembrokeshire. The Committee was advised of only one care home currently classified as Red, compared to the position 6 weeks previously where approximately 74 care homes had been categorised as such. The Committee noted there is no deterioration with regard to the long term pathway case numbers for 2020/21. The Committee received assurance that actions had been implemented to work towards the Discharge to Recover and Assess pathways, with the Health Board working with both care homes and the domiciliary care sector to maximise capacity, should a third wave of the COVID-19 pandemic occur.
- **Colorectal Green Pathway** – in March 2021, the Committee received assurance that the success of the pathway introduced to provide continuing cancer care and urgent surgery throughout the pandemic, ensuring patients are protected from COVID-19 while receiving the surgery they required by adapting care pathways, had instilled confidence within Scheduled Care to resume surgery going forward. The data presented illustrated a 1.5% mortality rate within this patient group, which compared to a 9.3% mortality rate in Wales. There was also a 1.5% readmission rate within this group as opposed to a national rate of 11.6%. However, there had been an increase in the length of stay for this group of patients, from 6 days (compared nationally) to 8 days. This increased length of stay had been due to geographical considerations and the fact that PPH has not undertaken this type of surgery for 10 years. The Committee was assured that the application of vaccines and lower COVID-19 prevalence would provide greater confidence to progress the treatment of urgent and subsequently routine patients in the near future.
- **Programme For Asymptomatic Staff Testing For Covid-19 Utilising Lateral Flow Devices (LFD)** - in March 2021, the Committee was informed that LFD testing had been rolled out to 2,200 staff (25%), and supported the Executive Team decision to implement the phased approach to offer routine asymptomatic testing of Health Board patient-facing staff with LFDs by 31st May 2021.

Corporate Risks Assigned to QSEAC - the Committee received regular Corporate Risk Reports outlining current and new corporate risks assigned to QSEAC from the Board throughout 2020/21. In May 2020, the Committee received the New Corporate Risks Assigned to QSEAC in Light of COVID-19 report. Members were reminded that it had been agreed at the Board meeting in March 2020 that for assurance purposes, non-COVID-19 risks should be managed through the Executive Team. The Committee received an assurance that Datix reporting now includes reference to COVID-19, and while the number of new risks related to COVID-19 is still being assessed by the services, a significant number of existing risks are impacted by COVID-19 and its consequences, which are being reviewed in order to provide an accurate reflection in the Risk Register for scrutiny by the Board at its next meeting.

In June 2020, the Committee received the Corporate Risk Register report which had been reviewed to ensure that risks now take into account the impact of COVID-19 on patient

safety. Members recognised that Risk 855: Risk that UHB's normal business will not be given sufficient focus, will be significant for all organisations and that the COVID-19 NHS Wales Operating Framework for Quarter 1 (2020/21) identifies the impact on business as usual. In relation to Risk 853: Risk that Hywel Dda's Response to COVID-19 will be insufficient to manage demand, whilst the current score has been reduced to 5, QSEAC acknowledged that as a novel disease with the long term trajectory difficult to predict, there is a likelihood that this will fluctuate during the year. QSEAC agreed that dual capacity (i.e. acute sites and field hospitals) should be included within the risk register as a standalone risk. QSEAC noted that discussions are on-going with Werndale Private Hospital to continue to support cancer and/or more routine cases in the medium term, in addition to discussions with Swansea Bay University Health Board (SBUHB) regarding regional arrangements and field hospitals. QSEAC acknowledged the controls in place providing an assurance to the Committee. Also in June 2020, the Committee received the new COVID-19 Identified Operational Risks assigned to QSEAC, noting in particular Risk 720 and Risk 574, which are linked to concerns regarding staffing levels in Tregaron Hospital and Ceredigion, and the newly identified workforce risk in relation to the Black, Asian and Minority Ethnicity (BAME) risk assessment, with any attendant reduction in the level and/or quality of care for patients needing to be considered by QSEAC. Concerns were expressed at the significant length of time a number of these risks had been on the risk register with the suggestion that once normal business resumes, discussions should take place with operational teams in order to agree how each risk will be managed appropriately going forward, with the outcome reported to a future QSEAC meeting.

In July 2020, the Committee received the Corporate Risk Report (CRR), recognising the synergy between the Corporate Risk Register and the Operational Risks Incorporating COVID-19 report. QSEAC queried the rationale behind the inclusion of a number of risks on the CRR, in particular Risk 733 - Failure to meet its statutory duties under Additional Learning Needs and Education Tribunal (ALNET) Act (Wales) 2018 by September 2020. Whilst QSEAC discussed the potential to include a single risk on the CRR where the Health Board may not comply with legislation, it was acknowledged that similar risks of non-compliance with various legislation would need to be included within other relevant Committees portfolios. QSEAC proposed that responsible leads may require a reminder of the process in regard to the inclusion of risks on the CRR, which will be imperative following COVID-19. QSEAC noted that the WG COVID-19 NHS Wales Operating Framework (2020/21) required the identification of risks since COVID-19, highlighting the need to review the Health Board’s corporate risks. Following a number of queries raised on the clarity of the risks contained within the CRR, and concerns regarding the priority afforded to this work, QSEAC reflected that only limited assurance could be received from the report. In order for the Committee to provide an assurance to the Board, it was agreed that additional narrative would be provided to confirm that the process outlined within the report had been applied. It was agreed that the Director of Nursing, Quality & Patient Experience would liaise with the Board Secretary to review the arrangements in place for the updating of the CRR and operational risk register and seek to identify the key risks facing the organisation as a consequence of COVID-19. A deep dive process into the risks on the CRR would be implemented from the Committee’s next meeting. Also in July 2020, the Committee received the Operational Risks Incorporating COVID-19 report. Whilst noting that the score for Risk 848 relating to critical care medicines had remained static, QSEAC received an assurance that the all Wales agreement to support access to medicines during COVID-19 had been effective, with the Health Board maintaining 4 days of stock at any one time to ensure that adequate supplies are in place. QSEAC received an assurance that operational risks are being reviewed and updated to reflect the impact of COVID-19, noting that work is continuing whilst also acknowledging that additional work would be required.

In August 2020, the Committee received an update on Risk 855 - Risk that UHB's normal business will not be given sufficient focus, and acknowledged the complexities involved in restarting services whilst ensuring that patient safety and experience are taken into consideration. QSEAC noted the steps taken to mitigate harm during COVID-19, and recognised an inherent risk to service delivery for a number of pathways, resulting in additional risks having been identified during the pandemic. Given that early in the pandemic the Cabinet Secretary suspended elective surgery, post COVID-19, QSEAC accepted that an increase in patient numbers on the waiting lists would be inevitable, despite HDdUHB being on course to deliver zero patients waiting over 36 weeks at the point of suspension. QSEAC acknowledged the difficulty in quantifying the qualitative aspect of this impact to patients due to delays in treatment, and suggested that simpler metrics should be made available which the Health Board can review in order to understand patient harm, including both the physical and psychological, to recognise the true extent of the impact of waiting on patients. In addition, QSEAC requested clarity as to which part of the system is responsible for maintaining oversight of the patient's condition while on waiting lists; the referrer or the service referred to, recognising the importance of real time patient contact. QSEAC directed that the Health Board should be proactive in this oversight, rather than relying on patients whose condition is deteriorating to self-report. QSEAC proposed that a plan be formulated, which Gold Command should consider, and that once agreed, be included within the COVID-19 update report to Board and presented to a future QSEAC meeting.

In October 2020, the Committee received the Corporate Risks Assigned to QSEAC report, noting that future such reports to the Committee would be aligned to the Health Board's planning objectives. QSEAC received assurance, following discussions relating to Risk 750, Lack of substantive middle grade doctors affecting Emergency Department (ED) in Withybush General Hospital (WGH), that WGH has more registrars in its ED than previously, and that the risk had been mitigated with support from consultants. Whilst noting that as part of the Health Board's strategy, a business case to support alternative staffing models would be progressed; it was recognised that business continuity also needs to be considered. Following further discussions on the number of risks that have been on the risk register for a significant period of time, QSEAC noted that the interconnection between the Corporate Risk Register (CRR) and the Board's planning objectives has been recognised, and received an assurance that following Board approval, the focus of the Executive Team would be on taking this forward. In February 2020, the Committee received the Corporate Risk Register report and noted that further assurance is required on how Risk 1032, and the impact on patients from delays to assessment and diagnosis for Mental Health and Learning Disabilities could be mitigated. QSEAC also supported the escalation to Board of the deterioration of Risk 684 and the barriers that are preventing progress on the replacement programme for radiology equipment, acknowledging that the Health Board is awaiting funding confirmation from WG. In March 2021, the Committee noted in relation to the Test Trace Protect Programme, that testing capacity is sufficient for the coming year. However, consideration would need to be given should the testing of contacts be introduced which has been highlighted to Welsh Government as a risk.

Specific Risks

In October 2020, the Committee received a report on Risk 628 Fragility of Therapy Provision across Acute, Community and Primary Care Services, noting the lack of therapy staff historically to deliver the intensity of care patients require. QSEAC noted the three year plan to address workforce shortages, with funding secured for a number of therapy roles, and that further options have included reviewing service provision for specific roles, for example, stroke and COVID-19 patients and on-call rotas, with support from Health

Education and Improvement Wales (HEIW) to improve workforce plans and systems with Local Authority (LA) partners. Whilst welcoming the steps taken to manage Risk 628, given that it is too early to determine the impact of these actions and given that the Committee requires timescales for the agreed actions, it was proposed that this risk should be monitored by the Operational Quality, Safety and Experience Sub-Committee (OQSESC), with an update provided to a future QSEAC meeting. QSEAC noted the proposal made at the previous OQSESC meeting, that given the number of therapy risks that relate to staffing issues, these would be incorporated into a wider risk on staffing. QSEAC welcomed the current positive recruitment benefit derived from the rurality of the Health Board, as evidenced by the successful recruitment to a number of posts which have been vacant for a significant period of time.

Also in October 2020, the Committee received a report on Risk 684 - Lack of agreed replacement programme for radiology equipment across the UHB, noting that radiology equipment has a limited lifespan and should be replaced in line with Royal College of Radiologist guidelines. Given the significant costs associated with replacing radiology equipment, these have previously been replaced from the All Wales Capital Programme. QSEAC noted that WG had agreed to fund four pieces of equipment that had the highest priority, with three of the four now in place. QSEAC further noted that whilst the intention had been to request funding from WG to replace CT scanners, this has not yet been progressed due to COVID-19. For assurance, QSEAC was informed that patients also have access to the Integrated Care Centres (ICCs), in Cardigan and Tregaron which have new radiology equipment. This enables patients to access tests closer to home, which is in line with the Health Board's strategic plan.

In November 2020, the Committee received the Risk Assessments for the Recommencement of Orthopaedic Activity report, following discussions at Board Seminar on 15th October 2020, where the Board had approved in principle the recommencement of Orthopaedic activity. It had been agreed that for assurance purposes, the risk assessments relating to the recommencement of Orthopaedic activity should be presented to QSEAC. This was due to concerns raised by the Health Board's clinical teams at PPH that the plans being proposed would only meet the Bronze standards set by the British Orthopaedic Association, rather than Silver or Gold. Given the complexities of the four acute hospital sites across the Health Board, QSEAC acknowledged that the Orthopaedic Clinical Team would be unable to fully satisfy the principles reflected in guidance issued by the British Orthopaedic Association for the recommencement of urgent elective surgery. However, Members were advised that in order for the Health Board to apply the operating framework of mixed COVID-19 and non-COVID-19 pathways for Quarter 3 and 4, 2020/21, Orthopaedic activity needed to restart on acute sites. Members were assured that an overarching risk assessment had been undertaken, in addition to site specific risk assessments, taking into account the COVID-19 environment and the challenges with other specialities on each acute site. QSEAC noted the risks associated with recommencing Orthopaedic services whilst recognising that on balance, the clinical risk to these patients is greater if they do not receive the procedures, providing the Committee with assurance on the actions taken.

In December 2020, the Committee received a verbal update on Risk 635 - No Deal Brexit Affecting Continuity of Patient Care, confirming that all Wales Brexit Steering Group meetings are currently taking place on a weekly basis, with the group receiving regular updates from the UK Government, with the focus relating to supply chains from 31st December 2020. QSEAC received assurance that no significant concerns had been raised in relation to the supply of Drugs and Medicines for both Primary and Secondary Care and

noted that, given that the UK is still in the negotiation phase, a further update had been planned for Board Seminar on 17th December 2020.

Quality and Safety Assurance Report – the Committee received the Quality and Safety Assurance Report at each of its meetings during 2020/21, providing information and data from a high-level position against the organisation's assurance and improvement activities across the Health Board. Members welcomed the reports noting that these provided greater assurance with regard to data, statistical process control (SPC) charts and planned next steps. In April 2020, the Committee recognised, given the requirement to develop revised quality metrics in light of COVID-19, that it may not be feasible to present the routine Quality and Safety Assurance Reports to subsequent QSEAC meetings. The Committee further recognised that given the current pace of change, any data provided in these reports is quickly out of date. With regard to external inspections, whilst Hywel Dda CHC and HIW inspections had been ceased at this point in time, Members received an assurance that any identified actions from previous inspections would still be progressed. The QSEAC Chair suggested that given the omission of quality metrics from the Delivery Unit which assists Members to interpret the narrative, only limited assurance could be gained from the report; it was agreed that a meeting would be arranged to agree these quality metrics as soon as possible. In June 2020, the Committee received the Quality and Safety Assurance Report, noting that due to the staff resource for quality improvement having been redirected during the COVID-19 pandemic, no quality improvement data was available for this report. However, meetings had recently resumed with the Quality Improvement Team to discuss how quality assurance and safety data can play a greater part in the future planning for quality improvement. QSEAC's attention was drawn to a rise in the number of incidents per 1,000 patients in March and April 2020 compared to the same months in 2018 and 2019, however assurance was provided that this rise is potentially due to the acuity of the patients treated during the COVID-19 period, and primarily linked to pressure damage relating to the use of Continuous Positive Airway Pressure (CPAP) machines and extended mask wearing by patients; a trial of the use of gels to reduce pressure damage has since been undertaken. QSEAC received further assurance that from a recent review of HIW inspection reports across Wales relating to the number of immediate assurance requirements, Hywel Dda is on a par with other areas of Wales.

In August 2020, the Committee received the Quality and Safety Assurance Report noting that the top three reported incidents were consistent with those previously reported to QSEAC. Members were advised that the Health Board wide Falls Improvement Group and the Pressure Damage Working Group would be refreshed with new terms of reference to ensure that system wide learning and improvement is progressed. In relation to never events, QSEAC received assurance that a report had been presented to the Listening & Learning Sub-Committee (L&LSC) where the improvement and learning plans to address the issues identified had been discussed. QSEAC was advised that the majority of complaints received had been in relation to General Practice including access to services and appointments, although during COVID-19, there had been a reduction in formal complaints to the Health Board. Whilst receiving assurance from the report, QSEAC requested that for comparison purposes, trend data over an extended period should be included within future reports to enable the Committee to understand the long term trajectory of incidents. In October 2020, the Committee received the Quality and Safety Assurance Report noting that the top three reported incidents were consistent with those previously reported to QSEAC. Furthermore, a scoping exercise had commenced across the four acute sites to ensure standards are consistent. In relation to medication errors, QSEAC noted that workshops would take place in order to understand why errors are occurring and whether the Management of Nursing and Midwifery Medication Errors/Near

Misses Policy is fit for purpose. QSEAC discussed the increase in never events since the previous report presented and received assurance that the Director of Nursing, Quality & Patient Experience oversees the quality panel reviews, which are then progressed by the service. QSEAC received confirmation that the Welsh Health Specialised Services Committee (WHSSC) Quality and Patient Safety Committee held a workshop in September 2020, which focused on patient outcomes for commissioned services. Members discussed options relating to the data received within future reports to QSEAC to enable a better understanding of where targeted work may be required, which the QSEAC Chair agreed to discuss further with the Assurance and Safety Team. In February 2020, the Committee received the Quality and Safety Assurance Report, with attention drawn to the high volume of under 18 admissions to mental health wards, however assurance was provided that a formal Quality Panel had since been held in which all cases had been reviewed with it confirmed that each admission had been in the best interest of the individual. In relation to concerns around a significant number of pressure ulcer reportings failing to stipulate whether these had been avoidable or unavoidable, assurance was provided that plans are in place to standardise the scrutiny process and that, although there may have been an increase in the number of incidents reported, there had not been an increase in the level of harm incurred. In response to concerns raised about access to specialist beds being severely compromised due to COVID-19 restrictions at facilities, assurance was provided that occupants have stayed the minimum amount of time before a community package of care or more appropriate bed has become available. QSEAC received assurance that monitoring of Putting Things Right, and COVID-19 related complaints, is ongoing, with the use of the all Wales toolkit in the review of complaints.

Quality Management System Approach - in December 2020, the Committee was informed that the Quality Management System (QMS) Approach would dovetail both the Health Board's planning and performance objectives, noting that the focus of recent discussions had been on how this could be embedded within the Health Board. Members were advised that this approach considers the organisation's objectives in relation to quality, patient experience, workforce and finance, and aligns these to the Health Board's strategic objectives in order for the Board to receive assurance from the improvements made. It was noted that this is at the early stages of development, with further meetings planned between Improvement Cymru and the Health Board to progress. The approach also aligns to a number of pieces of work currently being undertaken such as value based healthcare, with the aspiration to improve data collection and analysis to ensure consistency across the Health Board. QSEAC recognised the improvements needed in quality and safety for patients of Hywel Dda given the inherent challenges currently being experienced, and requested assurance that staff at ward level have the capacity to embed this new approach. Members were advised that the Executive Team is supportive of this, and given the success of the Enabling Quality Improvement In Practice (EQIiP) programme which delivered on a number of improvement initiatives to support change at grass-roots level, this approach will expand on these principles. QSEAC supported the QMS approach in principle, and whilst accepting that the support of Improvement Cymru would be pivotal to its success, expressed caution that QMS does not become an initiative that does not reach a conclusion.

Patient Outcomes Associated with the Implementation of the Single Cancer Pathway – in April 2020, the Committee received a verbal update in relation to patient outcomes associated with the implementation of the single cancer pathway, highlighting that currently there is no formal mechanism across Wales to evaluate outcomes for long cancer waits. Members were informed that the cancer team in Hywel Dda has engaged with the Wales Cancer Network in regard to developing a suitable model. A draft proposal is currently in development, which is broadly reflective of the model in England with a

focus on cancer waits in excess of 104 days, to be presented for consideration once normal business resumes. Given the recognition that any delay in cancer treatment could be significant for patients, an evaluation of cancer waits in excess of 104 days is currently being undertaken, which may result in each cancer pathway adopting different target waits. Members queried the continuation of cancer treatments as the pandemic develops and were advised that a detailed assessment would be required to determine the impact on patients, with confirmation that the Health Board would be following guidance issued by the Wales Cancer Network. Members received an assurance from the actions taken by the cancer team and recognised that given the pace of change during COVID-19, good governance would be paramount to support the rapidly changing situation. In June 2020, the Committee received the Cancer Treatments During COVID-19 report providing an assurance on the extent of cancer services being undertaken in Hywel Dda, following guidance from WG. QSEAC noted that urgent cancer treatments have continued on all acute hospital sites, in addition to endoscopy pathways on two sites and that further discussions are planned to consider increasing services, whilst acknowledging the challenges involved given the complexity of the required changes to pathways. QSEAC received an assurance that Hywel Dda compares favourably against other Health Boards in relation to the delivery of cancer treatments, including chemotherapy. QSEAC noted that whilst the Health Board has received a number of enquiries from patients regarding their cancer treatment during COVID-19, complaints to date have been low, which could be as a result of the widely circulated information issued reminding patients to access services if required. In February 2021, the Committee received an update on Risk 633 – Cancer Pathway, advising on the improvement actions that had been implemented to mitigate the risk of the impact of COVID-19 on meeting the 75% Single Cancer Pathway (SCP) target by March 2022. QSEAC received assurance that mitigating actions are in place with progress to be reported back to the Committee in August 2021.

Hospital Acquired Thrombosis (HAT) Action Plan - in April 2020, the Committee received the Hospital Acquired Thrombosis (HAT) Action Plan, developed following concerns previously raised by QSEAC regarding the lack of progress made. Members were advised that a Task & Finish Group had been established to progress the actions required, including consideration of the recommendations on the adoption of the All Wales Thromboprophylaxis Policy. Members were further advised that awareness raising mechanisms for all clinical staff would be included within weekly walk rounds, however given COVID-19, progress may be slower than anticipated. Members welcomed the action plan and accepted that the impact of COVID-19 may affect some of the actions. Given, however, that HAT has been a longstanding concern of QSEAC, the Committee requested that all steps are taken to progress the actions in a timely manner.

Health & Care Standards Fundamentals of Care Audit 2019 - in July 2020, the Committee received the Health & Care Standards Fundamentals of Care (HCSFOC) Audit 2019 report and presentation, and whilst noting the overall patient satisfaction of 93%, recognised that improvement work is required for a number of aspects of care. QSEAC received an assurance that the Quality Improvement team would focus on initiatives to improve a patients rest and sleep; pressure & tissue damage and record keeping. Whilst the HCSFOC Annual Audit focuses on nursing care, QSEAC recognised that in order to ensure improvements take place across all healthcare services, a whole system, multi-disciplinary approach would be required. QSEAC received an assurance that the Senior Nurse Management Team (SNMT) would monitor progress and agreed that an update on progress regarding the identified actions would be presented to QSEAC in December 2020. In December 2020, the Committee received the HCSFoC Audit 2019 report, recognising that progress against these work streams had been delayed due to the diversion of resources to the COVID-19 response. QSEAC noted that the Rest and Sleep

workstream had been prioritised in the first cohort of the EQuIP programme, with improvements relating to this workstream having been implemented to some extent with the use of sleep masks within field hospitals. Work on the second cohort of the EQuIP programme via mini collaboratives would take place during March/April 2021. Despite the pandemic, Medicines Management improvement workshops had been held during October and November 2020, resulting in an increased awareness around medicines management activity. QSEAC noted the development of mini collaboratives, forming part of the Quality Improvement approach as an alternative to a top down approach, to facilitate those directly delivering services to determine how best to address such issues, and assurance was provided that an update would be available in July 2021 regarding the change in approach via mini collaboratives to resolve persistent challenges.

Mortality Update - in August 2020, the Committee received the Mortality Update including a position statement in relation to reported mortality indicators. QSEAC acknowledged that as a consequence of COVID-19, the team involved had been redirected which delayed planned improvement work, which may have contributed to a recent decline in Stage 1 compliance. However, for assurance purposes, QSEAC noted that the planned improvement work would re-commence as soon as possible. QSEAC welcomed the benchmarking of data against other Health Boards and that this would be aligned to any learning from COVID-19 related deaths, including confirmation of the development of an all Wales toolkit. QSEAC noted the implementation of the Medical Examiner Service, which should improve the quality of Stage 2 mortality reviews and facilitate learning going forward. QSEAC agreed that in order to ensure learning is shared across the organisation, mortality outcomes should be presented to the L&LSC. In October 2020, the Committee received the Mortality Review of the Impact on Patients Waiting for a Procedure During the COVID-19 Pandemic report, noting this to be a preliminary report to determine whether mortality data had been comparable to non-COVID-19 activity within HDdUHB and also across Wales. On initial analysis, whilst the mortality rate in March 2020, had been significantly higher, over an extended period until July 2020, the average percentage mortality rate had remained significantly lower for Hywel Dda compared to the All Wales average. Recognising that the current analysis does not highlight any immediate concerns, that triangulated data (not yet available) is required to determine the full impact upon those waiting for treatment, and that a formal review requires comprehensive analysis, it was agreed that a further update would be presented to QSEAC in February 2021. However, the Medical Director's team would retain an oversight of data as it becomes available and any concerns would be flagged for immediate attention prior to February 2021, if necessary. In February 2021, the Committee received the Mortality Review of the Impact on Patients Waiting for a Procedure During the COVID-19 Pandemic report, acknowledging that whilst the findings provided a mortality-based review of the impact of COVID-19 on patients waiting at home for treatment, it does not provide any wider findings on the outcomes or experience of patients during the COVID-19 pandemic, recognising it may be too early to draw any conclusions. QSEAC noted that there are currently 197 patients to be reviewed. Assurance was provided that mortality is subject to robust review and the Committee noted the agreement for future reporting to include a breakdown of Referral to Treatment (RTT) waiting times by specialty.

Specialist Children's and Adolescent Mental Health Services (S-CAMHS) - in December 2020, the Committee received the Specialist Children's and Adolescent Mental Health Services (S-CAMHS) report, highlighting the key challenges for the service. Whilst welcoming the work undertaken to clear the historic waiting lists, QSEAC expressed concern regarding the plans in place to reduce waiting times for treatment. Members were advised that the continued demand on the service had been greater than anticipated, noting that a further factor has been the reduced availability of services provided by the

three Local Authorities, due to the COVID-19 pandemic. The need for an in-depth review of the funding streams in collaboration with Local Authority colleagues, through the West Wales Children's Group was acknowledged, and how this is spent through co production. Whilst acknowledging the significant work undertaken operationally to improve access, QSEAC expressed a further concern that there may be a strategic gap in enabling further improvements. Assurance was received that as part of the planning objectives for 2020, an overarching 3 year improvement plan for Children's Services is currently in development, which may provide a resolution. Given the link to patient experience as a consequence of delays in assessment and treatment, QSEAC proposed that for assurance purposes, the plan should be presented to QSEAC once agreed.

Public Health Update - in April 2020, the Committee received a verbal Public Health update outlining the significant amount of progress achieved by the Health Board and stakeholders on COVID-19 preparedness since the Board meeting on 26th March 2020. Members received an assurance that PPE and oxygen supply discussions were taking place at Command & Control meetings. Members were informed that the Health Board is establishing revised staff modelling in order that wards can be staffed appropriately. The Director of Nursing, Quality and Patient Experience advised that following a visit to the field hospitals, assurance could be provided that these nurse staffing ratios are safe and appropriate. Members welcomed the detailed update regarding COVID-19 planning, and on behalf of QSEAC, expressed thanks to all the staff involved. With regard to the Llwynhendy Tuberculosis (TB) Outbreak, Members were advised that following further screening sessions in December 2019 and February 2020, any patients identified as having latent TB are currently being managed. Whilst further sessions have now been paused due to the current government lockdown in place, for Members assurance, further screening sessions would be arranged once the pandemic has ceased. With regard to Flu Vaccinations during 2019/20, Members welcomed the fact that performance indicators for all groups had improved during the period despite the vaccine delays experienced at the beginning of the season and the fact that vaccinations had necessarily been ceased due to the lockdown in place.

Trans-Catheter Aortic Valve Insertion (TAVI) Progress - in June 2020, the Committee received a verbal Trans-Catheter Aortic Valve Insertion (TAVI) progress update, noting that due to the impact of COVID-19, SBUHB had only been undertaking emergency procedures, resulting in an additional number of Hywel Dda patients on the waiting list. QSEAC noted that the Royal College of Physicians (RCP) is due to commence a further review of 51 TAVI patients, 22 of whom are from Hywel Dda, with the final report expected within the next 3-6 months. In October 2020, the Committee received a further Trans-Catheter Aortic Valve Insertion (TAVI) Progress Report from SBUHB, demonstrating significant improvements in service for HDdUHB patients. However, QSEAC recognised that with the combination of the winter period and the expected increase in COVID-19 patients, TAVI patients may experience further delays, and that the outcome of the planned review into the second cohort of patients would determine any further concerns. In February 2021, the Committee received a further TAVI Progress Report Update to SBUHB, noting that an action plan had been developed by SBUHB in response to the 21 recommendations made in the initial external review of the service by the Royal College of Physicians (RCP), which is nearing completion. QSEAC agreed that the final RCP review would be presented to the Committee for completeness.

Nurse Staffing Levels (Wales) Act Updates – the Committee received regular updates in regard to the Nurse Staffing Levels (Wales) Act during 2020/21. In April 2020, QSEAC received the Nurse Staffing Levels (Wales) Act – Annual Report 2019/20, providing an assurance to QSEAC that during 2019/20, the Health Board had complied with the Nurse Staffing Levels (Wales) Act (NSLWA) 2016. During discussions, it was proposed that in order to ensure

Members have a better understanding of the instances where professional judgements are required going forward, additional narrative would be included within further reports to QSEAC and the Board. In relation to staffing levels with COVID-19, Members were appraised of the proposals following discussions with the Chief Nursing Officer, which would be presented to Board in order that Members could understand the expectations and support the approach taken. In May 2020, the Committee received the Nurse Staffing Principles for COVID-19 report, highlighting the significant amount of work that had been undertaken by the team involved to reach this point, and providing assurance that a robust process had been undertaken to determine the revised calculations in regard to the professional to patient ratio models outlined within the report. Members noted that the Health Board had considered alternative professional to patient ratio models for areas outside of 25B (wards that can be defined as medical or surgical wards), given that quality indicators are currently not available for COVID-19 wards, with the calculations based on a worst case scenario following national guidance. In relation to field hospitals, the calculations have been based on the principle of utilising other registrants. The Committee was informed that prior to calculating the professional to patient ratio requirements for field hospitals, discussions with other Health Boards had taken place and that on analysis, Hywel Dda's modelling is on a par with these. The Committee received assurance on the detailed modelling work that had been undertaken to assist with the workforce calculations underpinning the professional to patient ratios. In July 2020, QSEAC received a further Nurse Staffing Levels report, highlighting HDdUHB's approach in establishing revised processes to ensure that nurse staffing levels are systematically calculated and agreed in line with the requirements of the Act during COVID-19. QSEAC noted the weekly meetings in place with all Heads of Nursing (HoNs) to agree ward configurations which are continually under review, with further ward configurations now required as the Health Board restarts its routine procedures. QSEAC received an assurance that on occasions, where gaps have been identified, professional judgement has been exercised with appropriate mitigations established, including the transfer of staff and temporary bed closures when the number/skill mix of nursing staff on duty is not as per the planned roster and does not meet the clinical needs of patients, in order to comply with the Act. In August 2020, the Committee received a further Nurse Staffing Levels (Wales) Act update in order to provide further assurance regarding compliance with the Act and the processes undertaken in order to maintain day to day staffing levels on wards in line with the principles of the Act. QSEAC received assurance that during COVID-19, the Act had not been stood down and that Heads of Nursing (HONs) hold weekly meetings to discuss nurse staffing in light of the increased demand due to the restart of services. Recognising that capacity may be a concern if all the additional identified 501 Field Hospital beds were to be required, QSEAC was assured that meetings are taking place to identify options to ensure an appropriate nursing team would be available, if necessary.

Critical Care Medicines - in May 2020, the Committee received the Critical Care Medicines report, confirming that during normal business, medicines shortages are routinely managed effectively within pharmacy procurement teams, however for the treatment of COVID-19, there are limited medicines available to treat the virus. Members were informed of the process which has been established to ensure all Health Boards have adequate supplies, including a centralised dashboard of critical medicines which is updated daily, with medicines moved in a timely manner to where they are required. Members were informed that the current risk score of 20 had been calculated on a worst case scenario, which may now be lower than previously predicted given the lower peak in demand anticipated. Members recognised that in light of the recently amended modelling scenarios issued, a re-calculation of the risk score would now be required and captured on the COVID-19 Risk Register. In August 2020, the Committee received the Critical Care Medicines - Update Position (Risk 848) report, noting that given that the expected COVID-19 demand had not materialised, supplies of critical medicines are in a more robust position. However, recognising that the restarting of more routine care will have a further impact on medical supplies, a system has been established which provides an alert when stock

is low which can then be brought to the attention of the service in order to mitigate this. This is in addition to a national system that has also been established where stock levels for all Health Boards across Wales are visible, including a process to ensure that medicines are transferred rapidly to wherever they are required. QSEAC received assurance that when establishing the all Wales process to ensure timely access to end of life (EOL) medicines, access in rural areas had been considered. Whilst concerns still remain regarding the supply of medicines due to Brexit, QSEAC received further assurance that regular discussions take place regarding the supply and distribution of medicines in light of COVID-19 and Brexit. QSEAC noted that the risk score for Risk 848 had been reduced from 16 to 8 as a result of the established safeguards.

Clinical Audit – in June 2020, the Committee received the Clinical Audit Position Statement noting that the majority of clinical audit activity had been suspended by WG due to COVID-19. However, since preparing the report, notification had been received that a national COVID-19 Audit would be introduced, alongside a number of national audits which the Health Board has maintained during COVID-19. QSEAC noted that the Clinical Audit Scrutiny Panel has continued to hold meetings in an attempt to continue some of the core work around assurance for the national programme, and that for the remainder of 2020/21, the clinical audit programme would consist of a smaller number of projects. In February 2021, the Committee received the Clinical Audit Outcomes report, demonstrating the positive amount of audit activity, despite the mandatory audit programme being suspended by WG to allow Health Boards to allocate resources to the COVID-19pandemic response. In relation to the National Hip Fracture Database (NHFD), QSEAC noted that HDdUHB hospital sites have achieved 100% in a number of standards in several categories for patients admitted to hospital with hip and femoral fractures and recognised the excellent work attributed to Bronglais General Hospital (BGH) achieving 5th best in the UK for its National Hip Fracture Database audit outcomes. In relation to the monitoring of improvements from audit outcomes, assurance was provided that audit trackers are used internally to monitor improvement and that an assurance report is submitted to WG and national clinical policy leads. QSEAC noted that feedback from national audits are discussed with cluster leads and, in relation to the National Asthma & Chronic Obstructive Pulmonary Disease Audit Programme (NACAP), outcomes would be considered as cluster plans progress.

External Monitoring Activity Report - with regard to external inspections, whilst Hywel Dda CHC and HIW inspections had ceased at the start of the COVID-19 pandemic, Members received an assurance that any identified actions from previous inspections would still be progressed.

Winter Planning – in October 2020, the Committee received an Assurance Report Winter Planning on Risk 129 & 810, noting that given the number of overlapping risks which relate to winter preparedness, it had been proposed to review these risks in light of the Quarter 3 and 4 2020/21 returns to WG, with a suggestion that the risks are merged into one overarching risk. In relation to Risk 129 - Ability to Deliver an Urgent Primary Care Out of Hours (OOH) Service for Hywel Dda Patients, QSEAC noted that due to COVID-19, performance indicators relating to service performance had been suspended by WG in March 2020, although these have now resumed. QSEAC was advised that given the current shortfalls in capacity and increase in demand, the risk score could not be reduced. In addition, whilst the Advanced Paramedic Practitioner (APP) model has benefited the service, additional GPs had been available at the beginning of the pandemic; as this has now reduced to pre COVID-19 capacity, additional GPs would now be required. QSEAC received assurance that one of the planning objectives for the Health Board includes a 24 hour care model, which will incorporate this service. QSEAC noted that a first point of contact service has been piloted in Cardiff & Value University Health Board (C&VUHB) with early indications that this may be expanded to support part of the response to winter pressures. Following discussions on the tolerance level of Risk 129 which is consistently

above the agreed level, the Committee agreed to accept this and to review the risk later in the year. In relation to Risk 810 Poor quality of care within the unscheduled care pathway, QSEAC received a verbal update confirming that this risk would be included within the review of the Quarter 3 and 4 2020/21 returns to WG. Following evidence that demand within the unscheduled care pathway is increasing and presenting additional pressures on the system, QSEAC noted that a report relating to the quality and safety of services which are identified within the winter plan would be presented to QSEAC in December 2020. It was confirmed that a whole system approach, including delayed transfers of care (DTOC), the impact for patients and any identified harm associated with reduced performance would be included within the report.

In December 2020, the Committee received the Health Board's Winter Plan 2020/21(Including DTOC) - Incorporating Risk 810 report. QSEAC noted the number of previous risks related to care within the Unscheduled Care pathway, however these have been closed and superseded by a new integrated whole system unscheduled care corporate risk. Members were assured that the preparation of the Winter Plan for 2020/21 is the result of a cross-sector approach for the West Wales region. This has included an integrated approach, working in partnership with representatives from the Health Board, Carmarthenshire, Ceredigion and Pembrokeshire County Councils and the third sector and covering all population groups. The plan includes a number of actions which will be closely monitored on a fortnightly basis, and whilst noting that not all will be completed, it was recognised that the impact on key metrics, including quality and safety risks, will be important factors in establishing whether the plan is successful. Whilst acknowledging that this is not a 'normal' winter, Members were advised that the Winter Plan 2020/21 had been modelled on a worst case scenario, with increased flu and COVID-19 admissions. QSEAC welcomed the focus of the report, and whilst acknowledging the current challenges, was assured that the impact of delivery on the quality and safety of care, from a Health Board wide perspective, would be monitored via OQSESC and reported to QSEAC.

Accessing Emergency Specialist Spinal Services – in February 2021, the Committee received the Accessing Emergency Spinal Services report, highlighting the improvement in access to spinal services since the implementation of pathways in September 2020, including the establishment of, and Hywel Dda University Health Board (HDdUHB) representation on, a network of working groups by SBUHB and CVUHB. Further assurance was provided that patient feedback would be reviewed in September 2021 to capture outcomes and that a 120 day follow up via phone call for feedback would be implemented to review how well the pathway and system is working.

Commissioned Services: Long Term Agreement (LTA) and Quality Assurance Update - in February 2021, the Committee received the Commissioned Services: Long Term Agreement (LTA) and Quality Assurance Update report, noting the progress made to date in the strengthening of quality discussions to ensure that the quality agenda is addressed through LTA contracts and the contract management process. Assurance was provided that quality is now embedded within all LTAs and that SBUHB and Powys Teaching Health Board have agreed to align quality metrics into 2021/22 contracts. Further assurance was provided that quality is now a standing agenda item at contract management meetings with Quality and Service Leads in attendance, and that patient experience will be incorporated into contracts as a key metric going forward.

Putting Things Right (PTR) Policy - in June 2020, the Committee received the Putting Things Right: Management and Resolution of Concerns Policy, noting that whilst the principles of the policy are not new and reiterate the process already in place, this represents the first time these two elements have been brought together within a single policy of the Health Board. The need for a seamless Health Board process was acknowledged, recognising it can be overwhelming for a complainant where they are referred to a number of individuals following concerns raised. It

was agreed that the Assistant Director (Legal Services/Patient Experience) would arrange a meeting with Hywel Dda CHC to discuss any further concerns they may have following on from discussions already held with CHC advocates. QSEAC approved the Putting Things Right: Management and Resolution of Concerns policy following assurance that due process had been followed.

Management and Distribution of Safety Alerts and Notices Policy - in June 2020, the Committee received the Management and Distribution of Safety Alerts and Notices Policy, noting this represents an updated policy which reiterates the process already in place. It was suggested that the document should be referred to as a 'Procedure' rather than a 'Policy' and that it should include additional narrative in relation to WG guidance. It was also suggested that Section 5 should include all types of alerts that could be relevant to the Health Board. It was proposed that once the suggested amendments had been included, the policy should be presented for approval to a future QSEAC meeting. In August 2020, the Committee received the Management and Distribution of Safety Alerts and Notices Policy for approval, with confirmation received that comments made at QSEAC on 9th June 2020 had been addressed. Following assurance received that the Health Board's Written Control Documentation Policy had been adhered to in the development of the policy, and with no further comments from Members, the Management and Distribution of Safety Alerts and Notices Policy was approved.

Claims Management Report – High Value/Novel Claims – in August 2020, the Committee received the Claims Management Report – High Value/Novel Claims, noting that one case had been settled by the Health Board since the previous report to QSEAC. QSEAC received confirmation that any themes and learning following this case would be presented to the L&LSC.

Key Risks and Issues/Matters of Concern
During 2020/21, the following key risks and issues/matters of concern were raised at the Quality, Safety & Experience Assurance Committee and escalated to Board:

- **Quality and Safety Assurance Report presented to April 2020 QSEAC meeting:** given the omission of quality metrics from the WG Delivery Unit to assist Members to interpret the narrative meaning only limited assurance could be gained from the report, it was agreed that a meeting would be arranged to agree these quality metrics as soon as possible.
- **Patient Feedback during COVID-19 presented to May 2020 QSEAC meeting:** concerns relating to the long standing theme of communication within complaints reporting, to be mitigated by a review of this issue by QSEAC.
- **COVID-19 Risk Report presented to June 2020 QSEAC meeting:** given concerns expressed at the significant length of time that a number of the risks have been on the risk register, discussions would take place with operational teams to agree how each risk will be managed appropriately going forward, with the outcome reported to a future QSEAC meeting.
- **Corporate Risk Report (CRR) presented to July 2020 QSEAC meeting:** given the number of queries raised on the clarity of the risks contained within the CRR, together with concerns regarding the priority afforded to this work, QSEAC requested further information regarding the timescales for a review of any new risks to be added to the register, for assurance purposes.
- **Risk 628 Fragility of Therapy Provision across Acute, Community and Primary Care Services presented to October 2020 QSEAC meeting:** recognising it is too early to determine the impact of the actions taken to manage the risks involved, and given that

the Committee requires timescales for the agreed actions, this risk would be monitored by OQSESC, with an update provided to a future QSEAC meeting.

- **Assurance Reports Winter Planning on Risks 129 & 810 presented to October 220 meeting** – given that demand within the unscheduled care pathway is increasing and presenting additional pressures on the system, the Committee agreed that a winter plan report would be presented to QSEAC in December 2020 incorporating a whole system approach, including delayed transfers of care, the impact for patients and any identified harm associated with reduced performance.

- **Mortality Review of the Impact on Patients Waiting for a Procedure During the COVID-19 Pandemic presented to October 2020 meeting** – recognising that triangulated data is required to determine the full impact upon those waiting for treatment from a mortality perspective, and acknowledging this would be a labour intensive process against the backdrop of increasing COVID-19 demand, the Committee agreed that a further update would be presented to QSEAC in February 2021.

- **Update Regarding Field Hospital Utilisation and the Outcome from the Healthcare Inspectorate Wales (HIW) Inspections presented to November 2020 QSEAC meeting:** concerns regarding access and security at Ysbyty Enfys Carreg Las, with confirmation received that areas not being used would be locked to increase security.

- **Specialist Children's and Adolescent Mental Health Services (S-CAMHS) report presented to December 2020 QSEAC meeting:** concerns regarding the potential for a strategic gap in enabling further improvements to be made to reduce the waiting times for S-CAMHS treatment. QSEAC received assurance that as part of the planning objectives for 2020, an overarching 3 year improvement plan for Children's Services is currently in development, which may provide a resolution. For assurance purposes, this plan would be presented to QSEAC once agreed.

- **COVID-19 Impact on Essential Services Report presented to January 2021 QSEAC meeting:** the need to be clear both from a governance and a patient perspective on how communication should be received relating to patient care, with the Command Centre working to develop a more structured point of contact system going forward.

- **Hospital COVID-19 Outbreak Update Report presented to January 2021 QSEAC meeting:** the Committee received assurance that ongoing issues of patient discharge to partner organisations, care packages and domiciliary support, exacerbated by the pandemic, are to be addressed by weekly discussions held with Local Authority colleagues, Directors of Social Care and by the strategic influence of the national Nosocomial Transmission Group and at Regional Partnership Board.

- **Commissioned Services: Long Term Agreement (LTA) and Quality Assurance Update presented to February 2021 QSEAC meeting:** further clarification required regarding the escalation process for quality concerns within LTA contracts.

Escalations:

- **Health Response to the use of the MOD Training Camp at Penally for Men Seeking Asylum in the UK presented to November 2020 QSEAC meeting:** concerns expressed by both Health Board staff and stakeholders regarding quality and safety concerns relating to the Penally site, and the inadequate infrastructure to provide appropriate services for these residents. Whilst the significance of the concerns had been cited within correspondence issued from the Health Board to the Home Office, while the Health Board awaits a response, it was agreed to escalate this concern to the Board.

- **Corporate Risks Assigned to QSEAC presented to February 2021 QSEAC meeting:** Escalation of risk 684: Lack of agreed replacement programme for radiology equipment across UHB; whilst the significance of the concerns had been cited within correspondence to Welsh Government, the Health Board is currently awaiting confirmation of funding.

Matters Requiring Board Approval

- Approval of the Annual Quality Statement
- Approval of the QSEAC revised Terms of Reference
- Approval of the QSEAC Annual Report 2020/21

Update Reports from Sub-Committees

QSEAC received regular update reports from its Sub-Committees during 2020/21. As the full annual reports from each Sub-Committee will be presented to QSEAC separately (Appendices 1-3), only the key risks and issues/matters of concern from each Sub-Committee are reported below:

Operational Quality, Safety & Experience Sub Committee (OQSESC)

During 2020/21, the following key risks and issues/matters of concern were raised to the Quality, Safety & Experience Assurance Committee:

- In August 2020, the Committee received the Operational Quality, Safety and Experience Sub-Committee (OQSESC) exception report noting that in relation to Hospital Acquired Thrombosis (HAT), an organisational wide approach had been agreed which is being supported by the Quality Improvement Team. Furthermore, QSEAC noted that a similar approach is being considered for Falls and Pressure Damage.
- In October 2020, the Committee received the Operational Quality, Safety and Experience Sub-Committee (OQSESC) exception report noting concerns regarding the impact of COVID-19 on the deterioration in waiting times performance in Planned Care; the impact of COVID-19 on the environment and ability to continue all areas of service provision on the PPH site; and a lack of assurance that not all risks aligned to OQSESC are being reviewed regularly and as such, the sub-committee cannot be assured that all risks are being appropriately managed.
- In December 2020, the Committee received the Operational Quality, Safety and Experience Sub-Committee (OQSESC) exception report noting concern regarding Mental Health and Learning Disabilities waiting lists.

Listening and Learning Sub-Committee (LLSC)

During 2020/21, the following key risks and issues/matters of concern were raised to the Quality, Safety & Experience Assurance Committee:

- In June 2020, the Committee received a verbal update from the inaugural meeting of the Listening & Learning Sub-Committee held on 3rd June 2020, where Sub-Committee Members had welcomed the opportunity to review case studies and actions plans to ensure their appropriateness to support improvements across the Health Board. QSEAC also received the Listening & Learning Sub-Committee Terms of Reference (ToRs) for approval and suggested that the Assistant Director of Therapies and Health Science together with direct representation from service users or patient groups be added to the attendance list. With the inclusion of these suggested amendments, the Listening and Learning Sub-Committee ToRs were approved.
- In August 2020, the Committee received the exception report from the Listening and Learning Sub-Committee meetings held on 2nd July and 5th August 2020, noting that the Sub-Committee is currently meeting on a monthly basis to improve the timeliness of action plans, given that the Health Board only has 60 days to respond to learning plans prior to submission to the Welsh Risk Pool (WRP). QSEAC welcomed the

progress made to date, including the escalation of concerns regarding an increase in falls to OQSESC, as noted in the Quality & Safety Assurance Report. Given that falls concerns are being received from a number of different sources, for assurance purposes it was agreed that a deep dive report on Falls Management be presented to a future QSEAC meeting.

Research and Development Sub-Committee (R&DSC)

During 2020/21, the following key risks and issues/matters of concern were raised to the Quality, Safety & Experience Assurance Committee:

- In June 2020, the Committee received the Research & Development (R&D) Activity Report /Annual Reports 2018/19 and 2019/20, and noted the long standing concern regarding the lack of dedicated space for R&D on Health Board sites. Despite these challenges, the team's focus has primarily been on COVID-19 projects, in particular, the Clinical Characterisation Protocol (CCP-UK) study, which has resulted in the Health Board achieving the highest recruitment to a study in Wales, and thanks were expressed for the proactive work undertaken during COVID-19 by the R&D team. Given that the lack of dedicated space for R&D is not a concern that QSEAC can progress, it was suggested this be linked to the social distancing and capital discussions taking place involving the planning team, with an exploration of the offer of accommodation at Swansea University. QSEAC proposed additional narrative be included within the R&D Sub-Committee Annual Report 2019/20, clarifying that during the period, the R&D Sub-Committee had been accountable to the University Partnership Board for its performance. With the inclusion of the suggested amendment, the R&D Sub-Committee Annual Reports for 2081/19 and 2019/20 were approved.
- In August 2020, the Committee received the R&D Restart Activity Report, outlining the approach taken to restarting R&D activity across the Health Board. QSEAC recognised the continuing challenge in regard to the team's access to appropriate accommodation to undertake R&D projects, and that whilst discussions are taking place to identify space in GGH, further challenges in relation to social distancing regulations will require consideration. QSEAC emphasised that without appropriate R&D accommodation, the ability to increase research activity on behalf of the Health Board would be compromised, suggesting that the Board should be providing greater focus in order to resolve this issue as without robust R&D, the consequences include both reputational damage and the omission of evidence based care for the Health Board. For assurance purposes, QSEAC was advised that the social distancing cell has discussed the issues experienced by clinical services and R&D staff going forward, however taking into consideration current infrastructure of the Health Board sites, an early resolution may not be possible. Given that QSEAC is not in a position to resolve this, it was proposed that the concern be escalated to Executive Team to agree priorities, with an update on progress to be included within the R&D Sub-Committee exception report to QSEAC in October 2020. Notwithstanding these challenges, QSEAC credited the R&D team for the excellent research work undertaken during COVID-19.
- In December 2020, the Committee received the Exception Report from the Research & Development Sub-Committee (R&DSC), noting the draft R&D strategy which is as a result of strong leadership within the management of R&D. QSEAC welcomed the focus in terms of R&D across the organisation and the progress relating to the allocation of accommodation for a research facility in GGH.

QSEAC Future Work Plan 2021/22

During 2021/22, there will be a key focus for the Committee on the following:

- Continuous review and evaluation of the QSEAC throughout 2021/22.
- Assurance regarding the Nurse Staffing Levels (Wales) Act 2016, in particular the

Annual Report 2020/21, the 3 Year Report 2018-21, and preparedness for extension of the second duty of the Nurse Staffing Levels (Wales) act 2016 to paediatric inpatient wards.

- Deep dive on Falls Management
- Health Board Winter Plan 2021/22
- Health and Care Standards Fundamentals of Care Audit
- Evaluation of Field Hospitals
- Children's Services 3 Year Plan

Argymhelliad / Recommendation

The Board is requested to endorse the Quality, Safety and Experience Assurance Committee Annual Report 2020/21.

Amcanion: (rhaid cwblhau) **Objectives: (must be completed)**	
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): Hyperlink to NHS Wales Health & Care Standards	Governance, Leadership and Accountability
Amcanion Strategol y BIP: UHB Strategic Objectives: Hyperlink to HDdUHB Strategic Objectives	Not Applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	10. Not Applicable

Gwybodaeth Ychwanegol: **Further Information:**	
Ar sail tystiolaeth: Evidence Base:	Agendas, papers and minutes of QSEAC meetings 2020/21
Rhestr Termau: Glossary of Terms:	Contained within the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	QSEAC Chair, Lead Directors and Committee Members Quality, Safety and Experience Assurance Committee

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: **Financial / Service:**	A sound system of internal control, as evidenced in the Committee's Annual Report, will assist with ensuring financial control, and the safeguard of public funds
Ansawdd / Gofal Claf: **Quality / Patient Care:**	Contained within the report
Gweithlu: **Workforce:**	SBAR template in use for all relevant papers and reports.
Risg: **Risk:**	Contained within the report
Cyfreithiol: **Legal:**	Contained within the report
Enw Da: **Reputational:**	Contained within the report
Gyfrinachedd: **Privacy:**	Not Applicable
Cydraddoldeb: **Equality:**	SBAR template in use for all relevant papers and reports.

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:	Draft Operational Quality, Safety and Experience Sub-Committee (OQSESC) Annual Report 2020/21
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Alison Shakeshaft, Chair, OQSESC, Executive Director of Therapies & Health Science
SWYDDOG ADRODD: REPORTING OFFICER:	Sarah Bevan, Committee Services Officer

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 draft Operational Quality, Safety and Experience Sub-Committee (OQSESC) Annual Report 2020/21. The OQSESC 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 OQSESC require the submission of an Annual Report to the Quality, Safety & Experience Assurance Committee to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Sub-Committee is to focus on the acute services, primary and community services, and mental health and learning disabilities services (MH&LD), quality and safety governance arrangements at an operational level, bringing together accountability and ownership for those quality and safety issues to be resolved operationally, freeing up the Quality, Safety and Experience Assurance Committee to be more strategic in its approach and providing onward assurance to the Board.

The OQSESC Annual Report specifically comments on the key issues considered by the Sub-Committee in terms of quality, safety and experience, and the adequacy of the response, systems and processes in place during 2020/21.

Asesiad / Assessment

OQSESC has been established under Board delegation reporting to the Quality, Safety & Experience Assurance Committee.

The terms of reference clearly detail the Sub-Committee's purpose to provide assurance to the Quality, Safety & Experience Assurance Committee around the organisation's acute, primary and community, and MH&LD services quality and safety governance arrangements at an operational level, bringing together accountability and ownership for those quality and safety issues to be resolved operationally, and providing an upward assurance. The OQSESC terms of reference were most recently revised at the September 2020 Sub-Committee meeting and approved by QSEAC on 6th October 2020.

In discharging this role, the Sub-Committee is also required to oversee and monitor the quality, safety and experience agenda against the following areas of responsibility:

- Resuscitation/RRAILS
- Nutrition and Hydration
- Mental Capacity Act and Consent
- Medical Devices
- Radiation Protection

Other areas of focus include:

- Clinical pathways such as stroke, diabetes, cardiology
- Operational risks from the acute, primary and community, and MH&LD services, where there is an impact on patient quality, safety or experience.

OQSESC Groups
The Groups reporting to OQSESC during 2020/21 were as follows:

Resuscitation/RRAILS Group – established to:
- Provide assurance that robust and reliable mechanisms for the early detection and response to acute illness and management of cardio/respiratory arrest are in place

Nutrition and Hydration Group – established to:
- Set the strategic direction and provide assurance on all matters relating to nutritional care, including aspects of catering services

Mental Capacity Act and Consent Group – established to:
- Provide clear leadership in the promotion of the application of the Mental Capacity Act in every day clinical practice
- Ensure that there is a framework in place to support staff in relation to the Mental Capacity Act and monitor compliance with this legislation through appropriate assurance mechanisms
- Provide assurance that consent processes are being adhered to across the UHB, and where necessary agree corrective action
- Ensure that the Welsh Government Policy for Consent to Examination and Treatment and the associated consent forms are kept up to date and implemented in all relevant areas of the UHB

Medical Devices Group – established to:
- Provide assurance around strategic medical devices management and associated risk matters

Radiation Protection Group – established to:

- Consider radiation protection issues relating to ionising radiations (e.g. X-rays and radioactive materials including radon) and non-ionising radiations (e.g. lasers, MRI, phototherapy, ultrasound) within the Health Board.
- Review implementation of the Health Board's radiation protection arrangements for health and safety, environmental protection (and medical exposures via the Medical Exposure Committee).
- Identify and monitor current activities and developments relating to the use of radiations.
- Review radiation risks and inform the Chief Executive of measures to be taken to secure compliance with relevant legislation and to manage risks.

The OQSESC Annual Report 2020/21 is intended to outline how the Sub-Committee and its Groups have complied with the duties delegated by the Quality, Safety & Experience Assurance Committee 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 in October 2020, the membership of the Sub-Committee was agreed as the following:

- Executive Director of Therapies and Health Science (Chair)
- Assistant Director, Operational Nursing & Quality Acute Services – Vice Chair
- Associate Medical Director, Workforce & Primary Care
- Associate Medical Director, Quality & Safety
- Deputy Director of Operations
- Assistant Director of Nursing Assurance & Safeguarding
- Assistant Director of Therapies and Health Science – Professional Practice, Governance & Safety
- Assistant Director of Workforce & OD
- Assistant Director of Informatics
- County Directors x 3
- Independent Member, HDdUHB
- Head of Medicines Management
- Therapies Lead
- Health Science Lead
- Senior Nurse, Infection Prevention
- Representative from each Triumvirate
- Head of Primary Care
- Head of Nursing, Mental Health and Learning Disabilities

Meetings
Since April 2020, OQSESC meetings have been scheduled on a bi-monthly basis as follows:

- 7th May 2020*
- 2nd July 2020
- 3rd September 2020

- 5th November 2020
- 7th January 2021*
- 28th January 2021 – extraordinary meeting to discuss the on-call system for staffing Bronglais General Hospital (BGH) out of hours (OOH) in theatres.
- 4th March 2021 (narrative to be added to the final Annual Report following the meeting)

* These OQSESC meetings were stood down due to the extraordinary pressures being experienced across all Hywel Dda sites due to COVID-19, in order to free staff up to focus on discharge activity and manage flow.

As OQSESC is directly accountable to the Quality, Safety & Experience Assurance Committee for its performance, following each meeting it provides an assurance to the Committee through a formal written update report, which is received at the subsequent Committee meeting.

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

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

- Monitor the quality, safety and experience of care delivered to patients through, for example, surveys and patient stories, and escalate issues that cannot be resolved operationally to the Quality, Safety and Experience Assurance Committee.
- Ensure that concerns (incidents, complaints and claims) are being managed in a robust and timely manner at service level, agreeing mitigating actions where required.
- Monitor action plans following investigations into serious incidents and concerns and the identification of lessons learned, by ensuring actions are completed in a robust and timely manner, and seek assurance that learning is disseminated and embedded across all of the Health Board's activities as appropriate.
- Ensure and monitor compliance with national guidance, including NICE, NSFs, National Confidential Enquiries, outcome reviews and national clinical audits and Health Board clinical written control documents.
- Inform and monitor progress against agreed performance targets identified in the Quality & Safety Dashboard.
- Consider the themes arising from triangulated information at service specific level and agree and monitor any action plans required to deliver improvements.
- Seek assurance on the management of operational risks that have been aligned to the Sub-Committee, and provide assurance to the Quality, Safety and Experience Assurance Committee that risks are being managed effectively and report any areas of concern, e.g. where risk tolerance is exceeded or lack of timely action.
- Receive assurance from those Groups reporting to the Sub-Committee and consider how escalated issues are addressed:
    - Directorate and County Quality & Governance Groups
    - Resuscitation/RRAILS Group
    - Nutrition and Hydration Group
    - Medical Devices Group (including Point of Care Testing and Ultrasound Governance)

- Mental Capacity Act and Consent Group
- Receive position reports on:
  - Key Risks associated with preventing harm to patients
  - Quality Improvement Pathways:
- Assure itself that clinical written control documentation, which falls within the remit of the Sub-Committee, has been adopted, developed or reviewed in line with HDdUHB Policy 190 – Written Control Documentation prior to approving it, and to provide evidence of that assurance to the Clinical Written Control Documentation Group when recommending a procedure or guideline for uploading or a policy for final approval by the Clinical Written Control Documentation Group.
- Develop an annual work plan, responding to operational service priorities, consistent with the strategic direction for the organisation, for approval by the Quality, Safety and Experience Assurance Committee and oversee delivery to improve the quality, safety and effectiveness of care delivered, and enhance the patient experience.
- Seek assurance reports from relevant partnerships, and consider the actions required in relation to any quality and safety issues identified.
- Inform the work plans for reporting Groups and vice versa.
- Address any other requirements stipulated by the Quality, Safety and Experience Assurance Committee.
- Agree issues to be escalated to the Quality, Safety and Experience Assurance Committee with recommendations for action.

Specific Areas of Responsibility

In discharging its duties during 2020/21, OQSESC received and considered the following during 2020/21:

Health Board wide Assurance Reports:

- **Cancer treatment during COVID-19** - the Sub-Committee received a comprehensive report outlining a summary analysis on the impact of COVID-19 on cancer referral rates, treatment volumes, and referral to diagnostic rates, and also on the current scope of cancer services and treatments during COVID-19, including the Health Board's response to Welsh Government (WG) on the 'Response to the Framework for Recovery of Cancer Services' benchmarked against the eight key actions. Assurance was received on the Health Board's position of a 49% reduction rate on cancer referrals against a 70% reduction across the whole of Wales, and that any suspended treatment pathways had been in line with guidance. Patients on these pathways have since been tracked and treatment recommenced. It was noted that the biggest COVID-19 impact on the diagnostic pathway was colorectal, which was caused by the suspension of Endoscopy Services due to the risk of the aerosol generating procedures and potential COVID-19 transmission. Assurance was also received in terms of surgical cancer treatments with a surgical pathway being maintained for patients that meet the specific criteria through Health Board commissioned services at Werndale Hospital. Despite the lack of Level 2/3 facilities at this hospital, many patients were able to proceed with their treatment. Those patients who were outside of the criteria subsequently received their required surgical interventions within the acute hospitals through the reintroduction of planned care pathways across the acute sites. Through prompt and effective planning,

oncology appointments have continued virtually, and chemotherapy services maintained across the sites. This also applied to diagnostic investigations, radiological imaging, and phlebotomy services. Only one area of concern was highlighted which related to potential delays for patients through capacity issues experienced at the tertiary centres.

- **Hospital Acquired Thrombosis** - the Sub-Committee received a Health Board position report in relation to Hospital Acquired Thrombosis (HAT) which became a Tier 1 target in 2015/16. WG normally receive reports from the Health Board both monthly and quarterly which include data on the number of positive cases of Venous Thrombo Emboli (VTE) within 90 days of discharge and the number of preventable and unpreventable cases. It was noted that this line of reporting had been suspended during the COVID-19 period, however assurance was received on the following:
    - Health Board internal scrutiny and review processes have been maintained via Root Cause Analysis reports reviewed at local clinical team level and by the Thrombosis Group.
    - Dissemination of Learning from Events through various fora including Directorate / Site Clinical Governance meetings and directly to individual clinicians.
    - In line with the All Wales Thrombo-Prophylaxis Policy, a single risk assessment tool has been developed with the aim of improving compliance, with assessment of patients within a 24 hour period of admission with a planned introduction imminent.
    - All avoidable cases are reviewed by the legal team to ensure patients are kept informed and redress offered if necessary.
    - Development of a HAT Improvement Plan previously endorsed by QSEAC.
    - Establishment of a task & finish group to monitor and implement the plan.

- **Inpatient Falls** - the report on data for inpatient falls during the previous 18 months on each acute hospital site provided a variable illustration on the trends relating to falls and the correlation with quality improvement work initiated in areas deemed as high risk. It was noted that there was a significant downward trend over the 3 month period from the commencement of the initial COVID-19 period, however this was attributed to the reduction of hospital admissions to the non-COVID-19 areas during the pandemic. The Sub-Committee also noted that the quality improvement work had paused due to staff redeployment during COVID-19. Assurance was received that diligence on falls risk assessments is being maintained and post falls protocols followed in clinical areas.

- **Pressure Damage** - the report on pressure damage highlighted a slight increase in pressure damage during 2019/20 particularly in Quarters 3 and 4 which linked to changes made to the reporting and investigating processes as demonstrated by the reclassification of 78 reported incidents not deemed to be actual pressure damage through validation by the Tissue Viability Team. This upward trend was also illustrated in the first quarter report of 2020/21 with a total of 19 incidents in April 2020, 24 in May 2020 and 30 in June 2020. As there is ongoing work to address these, the Sub-Committee received an assurance that these numbers would decrease following the validation process. The impact of pressure damage related to the use of Personal Protective Equipment (PPE) during the COVID-19 period was described in the main as facial indentation caused by the use of face masks with 9 reported incidents. The Sub-Committee received an assurance by the preventative processes put in place such as use of gel strips to reduce pressure and staff awareness training to mitigate risk. The

Sub-Committee acknowledged the additional work being undertaken within acute services to introduce the new All Wales Pressure Damage Assessment Performa, the ongoing works to critically analyse avoidable and unavoidable pressure damage and also introduce improvements to support evidence-based practice.

Pharmacy and Medications Management – Medication Incidents - the Sub-Committee received the Pharmacy and Medicines Management Assurance Report on Primary Care, Community and Acute Services which included reference to the challenges in providing accurate data on medication incidents across the sectors. This largely relies on the DATIX Incident Reporting System which many independent contractors in primary care do not have access to, and pharmacy in the community is only required to report incidents involving controlled drugs, hence the higher number of medication errors reported through the DATIX system across acute services. Assurance was provided that there are a number of mechanisms in place to support learning from reported incidents and to identify opportunities to avoid harm to patients. All improvement plans following the scrutiny of medication errors are subsequently reviewed by the Medicines Event Review Group (MERG) where areas of concern are identified, and shared learning facilitated across the Health Board. The Sub-Committee noted the common themes on medicines management highlighted in Healthcare Inspectorate Wales (HIW) Reports and the repeat offenders in terms of medication errors, which require a change in culture. This particular theme was incorporated into a Health Board workshop on medication errors held in the autumn. The Sub-Committee received an assurance by the systems currently in place and acknowledged the efforts being made to improve processes and to mitigate risk to patients through a zero tolerance approach.

Operational Risk Management

- **Health Board Overview on Top Rated Risks / Actions for Mitigation** – at its meeting on 2nd July 2020, the Sub-Committee noted the content of the Operational Risk Management Report and the mitigation plans put in place. Directorate/Site Services Leads and County Representatives were requested to discuss the risks within their respective Directorate/Site Clinical Governance meetings to ensure that the exception reports and quality issues are aligned.
- **Operational Risk Report** – at its meeting on 3rd September 2020, the Sub-Committee received the Operational Risk Report noting the addition of 7 risks and the removal of 9 risks from the OQSESC Risk Register since the previous meeting, with 2 increasing and 2 decreasing their risk scores. There were 21 red risks, the majority of these relating to staffing, with the remainder relating to ICT issues. It was noted that a small number of risks appeared to have not been reviewed for over a year and the assurance and risk representative at the meeting advised that guidance had been reiterated to all directorates for monthly reviews of all red risks and bi-monthly for amber risks. It was also noted that many of the Therapy Services red risks related to staffing, and that work would be undertaken to amalgamate these into fewer Directorate level risks. In particular, therapies staffing issues relating to stroke, with the Sub-Committee noting that the Health Boards Stroke Re-design Programme had been paused due to COVID-19; once this re-commences, a business case for increased therapies stroke staffing will be developed. Risks 654 and 658 (risk of harm to inpatients at high risk of malnutrition and; risk of poor outcomes for frail and elderly patients in the community with or at risk of malnutrition) were specifically discussed with it noted that these risks are due for review with the anticipation that

the risk scores should reduce. The Sub-Committee sought assurance that risks would be reviewed more frequently, with the Chair requesting all risks to be reviewed by the next OQSESC meeting on 5th November 2020.

- **Operational Risk Report** – at its meeting on 5th November 2020, the Sub-Committee received a composite report describing the operational risks assigned to OQSESC with current scores exceeding the tolerance level. The Sub-Committee noted that two risks (stroke and frail elderly) did not appear to have been reviewed since 2019, however, assurance was provided that these had been reviewed since the report had been prepared. The Sub-Committee also noted that risk 654 (inpatient malnutrition), which had previously been of concern to the Sub-Committee, had now been de-escalated from a Red 20 to a level 10.

Directorate / Site Exception Reports on Risks / Concerns for Escalation

- At its meeting on 2nd July 2020, the Sub-Committee reviewed the recurring themes throughout the exception reports from all Acute and Community Services which outlined the substantial change to services including the introduction of surge capacity as part of the emergency planning associated with COVID-19. Also highlighted were the risks associated with the reintroduction of planned care surgical pathways into some acute sites that had not dealt with major surgical cases for a significant number of years. The plans put in place to ensure patient safety and support staff in these circumstances was acknowledged by OQSESC. The high number of existing nursing vacancies evident across the hospital sites was noted and assurance derived from the efforts made to secure temporary backfill for registered nurse vacancies, with the Sub-Committee commending the development of Healthcare Support Worker (HCSW) Band 4 posts to support the registered nurse workforce.
- At its meeting on 3rd September 2020, the Sub-Committee received 7 Site/Directorate Exception Reports, the majority of which focused on staffing issues, and the impact of COVID-19 on services including staffing availability and facilities/environments. Whilst good progress was noted in a number of areas and the Sub-Committee was assured that directorate teams are managing risks through appropriate mitigations, there were some areas where detailed plans would be required to resolve a number of issues e.g. the impact of COVID-19 on space availability to deliver all services at Prince Philip Hospital (PPH). The Sub-Committee acknowledged the impact COVID-19 has had on planned activity and waiting times and that the Executive Team has requested a recovery plan from the Scheduled Care Directorate, supported by the Transformation Team. It was noted that web-based information would soon be available to patients and their families, providing weekly service updates. It was agreed that the impact on planned care services should be escalated to QSEAC.
- At its meeting on 5th November 2020, Directorate Risk Escalation Reports were received from Mental Health and Learning Disabilities, with the Sub-Committee raising concerns regarding the waiting lists involved and requesting a further report to the next Sub-Committee meeting; Scheduled Care; Women and Children's; and 3 County Community Nursing.

Compliance Status: External Health Regulator Review / Improvement Plan – Healthcare inspectorate Wales: Annual Review - the annual summary of the HIW inspections undertaken within the Health Board during 2019/20 was acknowledged by the Sub-Committee including the themes identified within the recommendations made by HIW for the Health Board. Assurance was provided that learning is evident particularly in paediatrics and medicines management and that HIW recommendations are discussed as part of the Directorate / Site

Clinical Governance Meetings. The Sub-Committee noted that it is anticipated that HIW would be restarting its inspection programme in the near future following a period of suspension during the COVID-19 pandemic.

Report on the Statutory Pre-Planned Maintenance (PPM) (Building and Engineering services) – the Sub-Committee received an assessment of maintenance performance during Quarter 1, 2020/21. While noting a small reduction (91% against a 95% target) for high risk building maintenance, the Sub-Committee was assured that this was not an un-reasonable position given the complexities that COVID-19 restrictions had placed on access, closure of areas, re-purposing of others, demand and a number of other factors. The Sub-Committee was further assured that there has been little impact on the built environment, with regards to maintenance compliance, mitigated by the cancellation of a significant amount of planned building work due to inactive services as a result of COVID-19, for example theatres and endoscopy, and that actions were in place to mitigate the shortfall in target PPM.

Covid-19 Super Bariatric Report - the Sub-Committee received a report outlining the processes to manage super-bariatric patients during the COVID-19 period. The Sub-Committee believed that neither the paper nor the pathway were sufficiently developed at this time. Furthermore, given that no one was available to present to the report, it was agreed to defer the item until a future OQSESC meeting with the Chair agreeing to discuss the necessary amendments with the author.

Defibrillator Replacement Plan – the Sub-Committee received a report outlining issues in relation to the defibrillator replacement plan, noting that whilst securing funding for the replacement defibrillators had now been resolved, the process highlighted a gap in procedures whereby associated patient safety risk had not been reported via the Quality, Safety and Experience reporting structure. The Sub-Committee agreed that, in relation to capital replacement programmes it would be helpful to look at the risks around the challenges brought forward each year, what is funded and the residual unfunded elements. It was agreed that regardless of where the risk sits, OQSESC should be tied into the process to ensure patient safety matters are visible. The Sub-Committee was assured that workshops are being arranged to articulate this process in relation to medical devices and equipment replacement programmes.

Wards 1&3 Orthopaedic Serious Incident Action Plan – the Sub-Committee received an update regarding progress against the four outstanding actions in the Action Plan, with two actions now completed and the remaining two due for completion by the end of September 2020. Whilst it is anticipated that the action plan would be complete by the end of September 2020 and subsequently approved by the Director of Nursing, Quality and Patient Experience, the Sub-Committee expressed concern at the length of time it had taken to resolve many of the issues involved.

Closure Report – Withybush Wards 1 and 3 Orthopaedic Serious Incidents – the Sub-Committee received the Closure Report for the Withybush Wards 1 and 3 Serious Incidents, with the Sub-Committee assured that all actions were complete and had been considered at 2 formal quality panels and could therefore be formally closed. It was noted that there had been learning from the length of time taken to reach completion with Health Board processes now in place to monitor action plans at 6 month intervals.

On-call system for staffing Bronglais General Hospital (BGH) Out of Hours in Theatres – the Sub-Committee received options to resolve the changes to the on-call system for staffing BGH out of hours (OOH) in theatres at its extraordinary meeting on 28th January 2021. It was noted that the main risk of avoidable harm is to maternity patients who may require a category 1 caesarean section during these hours. The Sub-Committee noted that application of option 3, would significantly reduce the risk score from 15 to 5 and that this approach mirrors the current operating theatre provision for the obstetric OOH support at GGH where no concerns had been raised by HIW at its recent inspection of the Health Board. Option 3 consisted of the implementation of Operating Department Practitioner (ODP) overnight cover, a resident overnight Healthcare Support Worker (HCSW), and one on-call scrub overnight shift cover. Assurance was received that option 3's reduced risk score of 5 is within the Health Board's tolerance for safety.

Feedback on Attendance at Local Governance Meetings – the Sub-Committee received a verbal update regarding feedback from local governance meetings with the development of a template for terms of reference and agendas for the directorate and county quality and safety meetings, which will be taken through the Bronze Groups for wider discussion and consultation.

Annual Quality Statement (AQS) and Healthcare Standards (HCS) – the Sub-Committee received the proposal for the development of the AQS for 2020/21, which is based on the methodology used for 2019/20 and is supported by evidence around the HCS. The Sub-Committee received assurance that younger service users would be included on the review panel, with the Sub-Committee supporting the proposal.

Feedback from Groups
In terms of feedback from Groups:

Resuscitation/RAILS Group – written update reports from the Resuscitation/RAILS Group (RRAILS) highlighting the key areas of work scrutinised have been received by OQSESC during 2020/21. The Sub-Committee received assurance through the progress reported by the Resuscitation/RAILS Group, and noted the following, including key risks and issues and matters of concern:

- Confirmation that consistent feedback has been received from the Hospitals RRAILS Group with no concerns escalated.
- The Out of Hospitals RRAILS Group Community National Early Warning Score (NEWS) project has been on hold due to the suspension of the Enabling Quality Improvement in Practice (EQIiP) projects during the COVID-19 pandemic. Despite this situation, assurance was provided that community based training had been maintained for District Nurses/GP Practices/ and Out of Hours GPs.
- Work streams relating to the sub group for Paediatrics / Mental Health / and Trauma have been ongoing with no concerns highlighted.
- Assurance received that the Acute Kidney Injury work is being progressed through a pilot to be established in Withybush General Hospital (WGH).
- A briefing received on the transfer of the All Wales DNRCPR forms into Community and Primary Care. The Policy itself has been revised and now stipulates that following appropriate training, Registered Nurses including District Team Leads can sign the form.
- As part of the revision of the Resuscitation Council Guidelines, COVID-19 Response and Resuscitation Flow Charts have been developed with pathways that have been endorsed by the COVID-19 Gold Command Group. To reduce risk to staff and

others in terms of aerosol generation and potential COVID-19 transmission, all patients are to be treated as if they have COVID-19 in relation to resuscitation response. Assurance was provided that in the event of a sudden collapse, all secondary care areas have access to full PPE. It was noted that provision of the latter in Mental Health and Learning Disability / and General Practices is progressing, whilst recognising that further assurance is required in relation to Community Hospitals.

- Due to ongoing delays with the medical review process following inpatient cardiac arrests, a task and finish group has been established to investigate the cause and determine a way forward to reduce delays.
- A position update provided on the Verification of Death Policy (VOD) in adults which is being updated in relation to Welsh Government (WG) guidance on community and virtual VOD. Confirmation was received that the Health Board will not be including family member involvement in this procedure. Assurance was provided that extensive training of over 200 nurses had been conducted across the Community and Field Hospital settings. It was anticipated that the project would be subject to evaluation in July 2020.
- The use of the Sepsis Bundle in the Emergency Departments was reported as consistent, however ward numbers had dropped considerably due to reduced numbers of patients on the wards during COVID-19. Assurance was provided that there will be robust monitoring of Sepsis Bundles in the ward areas to stabilise compliance. Sepsis work in the community would be restarted as part of the EQIiP programme.
- No significant impact was reported on compliance with the admission recognition and response bundles.

Nutrition and Hydration Group – written update reports from the Nutrition and Hydration Group (NHG) highlighting the key areas of work scrutinised have been received by OQSESC during 2020/21. The Sub-Committee received assurance through the progress reported by the Nutrition and Hydration Group, and noted the following, including key risks and issues and matters of concern:

- A decision is awaited regarding the Health Board's (HB) position as to whether naso-gastric (NG) tube placement is a potential aerosol generating procedure (AGP) or not. A report has been presented to the PPE Cell, which defined the problem as high risk and given that clarity was still required, the Chair agreed to raise the issue with Executive colleagues to reach a resolution.
- The HB's work to comply with the actions set out in the Food Safety in NHS estates and facilities alert (EFA-2020/991) and implementation of procedures for mental health patients fed via NG with restraint, paused due to COVID-19. However, this has now re-commenced with progress closely monitored by NHG.
- The Sub-Committee noted the impact of COVID-19 on the nutritional wellbeing of isolated and vulnerable patients and that the increase in food poverty in some communities has caused concern, and were assured that NHG will review the Malnutrition Call to Action Task and Finish Group ToRs to ensure the wider impact is considered.
- The NHG is developing a cohesive approach to governance and will develop a NHG Dashboard.

- An Estates and Facilities alert had been received in relation to allergy management, and an action plan would be developed following the appointment of the new specialist service manager for catering.
- An evidence review has been undertaken, regarding the potential impact of hydration status on staff when wearing PPE, which will be reviewed by the Group.

Mental Capacity Act and Consent Group – written update reports from the Mental Capacity Act and Consent Group (MCACG) highlighting the key areas of work scrutinised have been received by OQSESC during 2020/21. The Sub-Committee received assurance through the progress reported by the Mental Capacity Act and Consent Group, and noted the following, including key risks and issues and matters of concern:

- A legislative gap regarding the ability to lawfully enforce isolation of patients who are infected with COVID-19. The Sub-Committee was advised that this had been escalated to WG, however there has been no response to date. Agreed actions were to re-issue the correspondence to WG, submit a paper on the issue to the Executive Team and for the Vice Chair to discuss with colleagues across other Health Boards.
- As a consequence of COVID-19, the Liberty Protection Safeguards due to be implemented on 1st October 2020 have been deferred to April 2022.
- The Welsh Risk Pool has issued a risk management alert stating that from 2021, Health Boards are required only to use the EIDO patient information leaflets. It was noted that Medical Directors had raised concerns about this and the Chair agreed to ensure Directors of Nursing and Therapies and Health Science are also aware.
- An agreement has been reached for psychiatrists to undertake the mental health assessment part of Deprivation of Liberty Safeguards (DoLS) for patients within Mental Health Services. It was noted, however, that the service is struggling to complete other section 12 responsibilities in relation to the Mental Health Act. The Director of Operations and the Deputy Medical Director for Acute Hospital Services have arranged for further discussion on the possibility of training physicians to be able to contribute to being assessors.

Medical Devices Group – written update reports from the Medical Devices Group highlighting the key areas of work scrutinised have been received by OQSESC during 2020/21. The Sub-Committee received assurance through the progress reported by the Medical Devices Group, and noted the following, including key risks and issues and matters of concern:

- While the Control Group addressing the incorrect patient ID at Point Of Care Testing (PoCT) has not met during the COVID-19 period, spot audits have demonstrated a significant reduction in this practice, with confirmation received that the Control Group will be re-established once COVID-19 priorities allow the POCT manager to conduct further audits.
- The new system to provide end to end assurance for all medical device alerts received by the Health Board has been purchased and is being issued to all device asset owners.
- The Sub-Committee was informed that the introduction of new Medical Devices Regulations, due to come into effect in May 2020 had been delayed until May 2021, with the Health Board on track to meet these regulatory obligations.
- 100% Planned Preventative Maintenance performance has been maintained for high risk devices during the COVID-19 period despite a significant increase in the Medical Devices Inventory.

- Discussions held regarding the potential re-use of single use medical devices as Health Board policy does not currently allow this, however guidance has been received from the Medicines and Healthcare products Regulatory Agency (MHRA), that this can be undertaken. The Scheduled Care Team is in support of the principle and further discussion is underway. It was agreed that a report with the full details, risks and benefits would be provided to the Executive Team for full consideration prior to requesting approval for any pilot testing to be undertaken.
- Confirmation that 26 occurrences had been recorded of battery failure in T34 palliative care syringe drivers in community settings. The MHRA has issued a field safety notice stating that the Health Board should not implement any further version 3 pumps until the company has resolved the issues regarding the batteries. The Sub-Committee was advised that a risk based approach had been undertaken on clinical impact due to the shortage of syringe drivers and that following discussions with County Leads, the syringe drivers have been put in use with the batteries replaced by the Health Board. The Medical Devices Group has approved this approach and other Health Boards have adopted the same process.

Radiation Protection Group (RPG) – Group Update Reports are scheduled to be presented twice a year to OQSESC, however as the May 2020 and January 2021 Sub-Committee meetings had been stood down due to COVID-19 challenges, the next update report will be presented to the Sub-Committee in May 2021.

Key Risks and Issues/Matters of Concern/Escalation to Quality, Safety & Experience Assurance Committee

During 2020/21, in addition to the Operational Risk Report presented to each meeting, the following key risks and issues/matters of concern were raised to the Quality, Safety & Experience Assurance Committee:

- The impact of COVID-19 on the deterioration in waiting times performance within Planned Care;
- The impact of COVID-19 on the environment and the ability to continue all areas of service provision on the PPH site;
- Lack of assurance that not all risks aligned to OQSESC are being reviewed regularly and as such, the Sub-Committee cannot be assured that all risks are being appropriately managed.

OQSESC Developments for 2021/22

The Sub-Committee continues to evolve and reviews its effectiveness on a regular basis. The Sub-Committee continues to discuss and refresh the mechanism for monitoring and providing assurance to QSEAC in relation to operational risks with a potential quality or safety impact on patient care.

Argymhelliad / Recommendation

To endorse the Operational Quality, Safety and Experience 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:** **Gyfrinachedd / Privacy:** **Cydraddoldeb / Equality:**	Contained within the report.

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:	Listening and Learning Sub-Committee Annual Report 2020/21
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Mandy Rayani, Director of Nursing, Quality and Patient Experience
SWYDDOG ADRODD: REPORTING OFFICER:	Louise O'Connor, Assistant Director (Legal Services/Patient Experience)

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 Listening and Learning Sub-Committee Annual Report 2020/21 to the Quality, Safety & Experience Assurance Committee. The Sub-Committee Annual Report provides assurances in respect of the work that has been undertaken 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 Listening and Learning Sub-Committee require the submission of an Annual Report to the Quality, Safety & Experience Assurance Committee to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Sub-Committee is to provide clinical teams across the Health Board with a forum to share and scrutinise learning from concerns and to share innovation and good practice. The Sub-Committee will also provide a forum to promote changes and innovations to service delivery and ensure that best practice is shared and areas of concern are highlighted and communicated to the responsible officer or Board Committee/Working Group. Through identifying learning points and changes to practice evolving from investigation and review of concerns and patient experiences, the Sub-Committee will identify themes and trends, providing assurance that robust management plans are in place for current and emerging clinical risks.

The Listening and Learning Sub-Committee Annual Report specifically comments on the key issues considered by the Sub-Committee in terms of assurance around lessons learnt.

Asesiad / Assessment

The Listening and Learning Sub-Committee has been established under Board delegation with the Health Board approving terms of reference for the Quality, Safety & Experience Assurance Committee most recently at its Board meeting on 28th May 2020. The terms of reference of the

Listening and Learning Sub-Committee were approved at its inaugural meeting on 3rd June 2020.

These terms of reference clearly detail the Sub-Committee's purpose to provide assurance to the Quality, Safety & Experience Assurance Committee around the organisation's management of learning from events from significant events, and identification and escalation of risk.

In discharging this role, the Sub-Committee is required to oversee and monitor the Concerns Management and Learning from Events agenda for the Quality, Safety & Experience Assurance Committee in respect of its provision of advice to the Board, and ensure implementation of the agenda against the following areas of responsibility:

- Learning from the investigation of concerns (incidents, complaints and claims, health and safety incidents) is shared with, and communicated with, clinical teams across the Health Board.
- Patient experience informs the evaluation of known or emerging concerns or challenges with clinical services, and solutions to improve the quality and safety of the services provided by the Health Board.
- Provide a safe and open forum for peer review and support for the investigation processes, and recommendations or learning arising from this work.
- Identify themes and trends from feedback, external reviews, and through other patient experience mechanisms such as surveys and patient stories.
- Request 'deep dive' reviews into any areas of concern highlighted by the review of emerging themes/trends. Escalate any immediate areas of concern to the relevant Group/Committee or senior staff, as appropriate.
- Consider actions that have been, or are proposed to be, implemented following investigations into concerns and consider where actions can be shared with other services to ensure that best practice and improvements to the quality and safety of patients and learning is disseminated across the Health Board.

The Listening and Learning Sub-Committee Annual Report 2020/21 is intended to outline how the Sub-Committee has complied with the duties delegated by the Quality, Safety & Experience Assurance Committee through the terms of reference set, and to identify key actions that have been taken to address issues within the Sub-Committee's remit.

Constitution
From the terms of reference approved in June 2020, the membership of the Sub-Committee was agreed as the following:

- Health Board Chair (Chair)
- Independent Member (Vice Chair)
- Independent Member
- Deputy Medical Director (Acute Services)
- Associate Medical Director (Primary Care and Community)
- Associate Medical Director (Quality and Safety)
- Assistant Director (Legal Services/Patient Experience) (Lead Officer)
- Assistant Director of Nursing (Quality Improvement/Service Transformation)
- Assistant Director of Nursing (Operational Nursing and Quality Acute Services)

- Clinical Director, Therapies
- Assistant Director of Therapies and Health Science
- Senior Member Triumvirate Team – Mental Health and Learning Disabilities
- Head of Quality and Governance
- Concerns Manager
- Head of Legal Services/Solicitor
- Patient Experience Manager
- Head of Health, Safety and Security
- Ombudsman Liaison Manager
- Risk and Assurance representative
- Service representatives – invited according to agenda

Meetings
Since its inception in June 2020, with the exception of September 2020 and January 2021 meetings which were cancelled due to pressures associated with the pandemic, Sub-Committee meetings have been held on a monthly basis and all were quorate as follows: ,

- 3rd June 2020
- 1st July 2020
- 5th August 2020
- 7th October 2020
- 4th November 2020
- 2nd December 2020
- 3rd February 2021
- 3rd March 2021

As the Listening and Learning Sub-Committee is directly accountable to the Quality, Safety & Experience Assurance Committee for its performance, assurance has been provided to the Committee through a formal written update report following each meeting, which is received at the subsequent Committee meeting.

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

- **Forum to scrutinise and share learning across the Health Board**
  During 2020/21, the Sub-Committee has reviewed over 40 cases across the spectrum of complaints, redress, patient experience, claims, serious incidents and external reports including Healthcare Inspectorate Wales (HIW) and Public Services Ombudsman reports. Ombudsman report reviews include public interest reports against other Health Boards for consideration of the learning from other public bodies.

- **Promote changes, innovations and share best practice**
  The Sub-Committee has identified a number of common themes following review of the cases, which have resulted in deep dives/quality improvement initiatives being initiated to address the learning in these areas. Themes include:

    - Avoidable Inpatient Falls
    - Delays/Missed Diagnosis due to failure to act on test results

- Missed Fractures
- Review and audit of the World Health Organisation (WHO) surgical checklist
- Referral process and management of patients requiring specialist services
- Process for the management of patients presenting with Head and Neck Pain to the Emergency Department

Findings from external reviews on patient experience have been shared to inform best practice and national publications on themes and trends across Wales, including those from the Welsh Risk Pool and Legal and Risk Services.

Any issues requiring escalation have also been referred to the appropriate Lead Officer, Sub-Committee, or Committee. However, this is an area that will require further strengthening as the Sub-Committee develops during the next financial year to ensure that the relevant Group or Committee is engaged in the review and assurance process.

Key Risks and Issues/Matters of Concern

During 2020/21, the following key risks and issues/matters of concern were raised at the Quality, Safety & Experience Assurance Committee:

- Record keeping and records management – concerns were raised in relation to the quality of the clinical entries and standard of documentation; security of the record (part or whole of the record was missing); and standard of the filing and maintenance of the record.
- Avoidable inpatient falls was a consistent theme across the concerns agenda, with the standard of risk assessment documentation, and lack of preventative measures being taken, identified as the main contributory factors.
- Follow up and action of test results, which had been noted as one of the root causes in concerns resulting in delayed or missed diagnosis. A quality improvement initiative was established to identify solutions.
- Diagnosis and management of fractures had also been identified as a common theme in concerns, which is being taken forward as a quality improvement initiative.

Sub-Committee Developments for 2021/22

The Sub-Committee is currently undertaking a review of the terms of reference and outcomes/successes during its inaugural year.

The Sub-Committee will seek to strengthen the use of patient stories, invite service user/carer attendance at meetings, and further develop the links between staff and patient experience.

The Improving Experience Charter will be implemented during 2021/22. Reporting on the key performance indicators will be incorporated into the patient experience feedback.

The Sub-Committee will consider establishing a working group, which would oversee the triangulation and use of feedback from various sources including engagement, staff experience, carers, and equality and diversity.

Argymhelliad / Recommendation

To endorse the Listening and Learning 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:** **Gyfrinachedd / Privacy:** **Cydraddoldeb / Equality:**	Included within the report, where appropriate.

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:	08 June 2021
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research and Development Sub-Committee Annual Report 2020/21 (FINAL Version 1, 10/05/2021)
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Philip Kloer, Medical Director / Deputy CEO
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Leighton Phillips, Director for 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. 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 the Quality, Safety & Experience Assurance Committee to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Sub-Committee is to assure the Board, via the Quality, Safety and Experience Assurance Committee, 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.

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 the Quality, Safety & Experience Assurance Committee 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 the Quality, Safety & Experience Assurance Committee 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 the Quality, Safety & Experience Assurance Committee 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

- Research and Development Strategy.
- R&D Strategic Objectives.
- R&D Annual Plan.
- R&D Policies.
- R&D Standard Operating Procedures.
- R&D Guidelines for Researchers.

The Research & Development 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 Research & Development 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 Groups

The Groups reporting to the R&D Sub-Committee during 2020/21 were as follows:

- **Research Quality Management Group** – established to:
- Oversee the quality and safety of research activity carried out within the organisation.
- Monitor the production of research standard operating procedures 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 Groups have complied with the duties delegated by the Quality, Safety & Experience Assurance Committee 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 the Quality, Safety & Experience Assurance Committee meetings in June and August 2020.

From the R&D activity report (June 2020) to the Quality, Safety & Experience Assurance Committee, 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 (August 2020) to the Quality, Safety & Experience Assurance Committee, Members were asked to note that Health and Care Research Wales, Welsh Government, had asked 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 Research Quality Management Group 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 the Quality, Safety & Experience Assurance Committee for its performance, following each meeting it provides an assurance to the Committee through a formal written update report which is received at the subsequent Committee 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 Groups
In terms of feedback from Groups:

- **Research Quality Management Group** – written update reports from the Research Quality Management Sub-Group (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 for the Research Quality Management Sub-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: Standard Operating Procedure, 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 had noted in November 2020 that 60% of the core R&D Standard Operating Procedures (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 would end in March 2021, work has been progressed to develop a new 3-5 year R&D strategy to cover innovation as well as 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 the Quality, Safety & Experience Assurance Committee 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 Strategy and University Status would be presented to the Quality, Safety & Experience Assurance Committee.
- The Good Clinical Practice Training Policy (822) approved by the Research Quality Management Group 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 the Quality, Safety & Experience Assurance Committee:

- 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, but the project was over budget and there are limits 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 Quality, Safety & Experience Assurance Committee 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: The lack of dedicated research space on the acute hospital sites (Risk 148) which was also related to Risk 556 (Failure to increase the number of research studies – a 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) and 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 into this Sub-Committee.

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:	Included within the report

Gweithlu / Workforce: **Risg / Risk:** **Cyfreithiol / Legal:** **Enw Da / Reputational:** **Gyfrinachedd / Privacy:** **Cydraddoldeb / Equality:**	

Appendix 1

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

IS-BWYLLGOR YMCHWIL A DATBLYGI
RESEARCH AND DEVELOPMENT SUB-COMMITTEE

DYDDIAD Y CYFARFOD: **DATE OF MEETING:**	10 May 2021
TEITL YR ADRODDIAD: **TITLE OF REPORT:**	Research Quality Management Sub-Group (RQMG) Annual Report 2020/21 (FINAL Version 1, 10/05/2021)
CYFARWYDDWR ARWEINIOL: **LEAD DIRECTOR:**	Dr Sam Rice, Clinical Director of Research and Development and RQMG Chair
SWYDDOG ADRODD: **REPORTING OFFICER:**	Dr Lisa Seale, Senior Research and Development Manager, Research Quality Assurance Lead and RQMG Vice-Chair.

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 Quality Management Sub-Group Annual Report 2020/21 to the Research and Development Sub-Committee for approval, to be included as Appendix 1 of the Research and Development Sub-Committee's Annual Report 2020/21 to the Quality, Safety & Experience Assurance Committee. The Research Quality Management Sub-Group Annual Report provides assurances in respect of the work that has been undertaken by the Sub-Group during 2020/21 and outlines the main achievements which have contributed to robust integrated governance across the University Health Board (UHB). The Research Quality Management Sub-Group Annual Report 2020/21 was approved by the Research Quality Management Sub-Group by Chair's Action (14th April 2021) and at the last meeting (15th April 2021) and was presented for information to the R&D Strategic Management Team on 21st April 2021 (no comments received).

Cefndir / Background

The UHB's Standing Orders and the terms of reference for the Research Quality Management Sub-Group require the submission of an Annual Report to the Research and Development Sub-Committee to summarise the work of the Sub-Group and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Research Quality Management Sub-Group is to assure the Research and Development Sub-Committee and the Board, via the Quality, Safety and Experience Assurance Committee, that it is discharging its functions and meeting its responsibilities with regards to the quality and safety of research activity carried out within the Health Board.

The Annual Report specifically comments on the key issues considered by the Sub-Group in terms of the Health Board's Research Quality Management System which is underpinned by

Research and Development Written Controlled Documentation (Policies and Procedures), and the adequacy of the research governance and quality assurance in place.

Asesiad / Assessment

The Research Quality Management Sub-Group was established in November 2018 and meets bi-monthly to provide assurance to the Research and Development Sub-Committee of the Board that all research and development (R&D) activities in the Health Board comply with the UK Policy Framework for Health and Social Care Research and other applicable research legislation, and that International Conference for Harmonisation of Good Clinical Practice (ICH-GCP) standards for research are met.

The Sub-Group oversees the Research Governance Audit Programme, approves and authorises the completion of Corrective And Preventative Action (CAPA) plans arising from Statutory Inspections, ensures compliance with the Health Board's Human Tissue Authority License for Research (including oversight of the Health Board's Biobank), oversees CAPAs from Routine/Triggered Audits and Monitoring Visits, and approves R&D Written Controlled Documentation (Policies, Standard Operating Procedures, Guidelines, etc).

The terms of reference of the Research Quality Management Sub-Group (Version 0.2) were approved by the Research and Development Sub-Committee on 27th January 2020. These terms of reference clearly detail the Sub-Group's purpose to provide assurance to the Research and Development Sub-Committee around the organisation's Research Quality Management System, ensuring that there is an accurate reflection of oversight, safety and incident reporting and risk management of research studies, including clinical trials of investigational medicinal products, to deliver against gaps in assurance.

In discharging this role, the Sub-Group is required to oversee and monitor the research governance agenda for the Research and Development Sub-Committee in respect of its provision of advice to the Quality, Safety & Experience Assurance Committee of the Board, and ensure the implementation of the research quality assurance agenda against the following areas of responsibility:

Assuring the Research and Development Sub-Committee and the Quality, Safety and Experience Assurance Committee in relation to arrangements for ensuring compliance with all relevant frameworks, UK Clinical Trials and other Regulations (transposed into UK law from European Union Directives) and ensuring reporting requirements are met.

- Routine risk-based Research Governance Audit programme was put on hold from March 2020 as a result of the Covid-19 pandemic.
- Face-to-face Good Clinical Practice training was also suspended by Health and Care Research Wales, Welsh Government.
- Bespoke training was provided by the Advanced Biomedical Scientist (Research) and the Quality Assurance Officer (Research)/GCP Facilitator to research teams as required (e.g. to ensure novice researchers received appropriate research training prior to joining a research team, and in response to Protocol Deviations or breaches of GCP in active research studies). Training was delivered via Microsoft Teams and/or training webinars.

Considering the implications for the Health Board of the outcomes arising from relevant review, audit or inspection carried out by external regulatory authorities, review progress with resulting Corrective And Preventative Action plans (CAPAs) and authorising their completion.

- No statutory inspections were carried out by either the Medicines and Healthcare products Regulatory Agency or the Human Tissue Authority during 2020/21.
- The Research Quality Assurance Team continued to provide ad hoc 'Inspection Ready' training to the Health Board's Research Delivery and Researcher Development Teams.
- Ad hoc advice and training continued to be provided remotely by the Research Quality Assurance Team during the Covid-19 pandemic.

Overseeing the development of the Research and Development Quality Management System, seeking endorsement from the Research and Development Sub-Committee, for sign off by the Board following scrutiny from the Quality, Safety and Experience Assurance Committee.

- Review and approval of Research and Development Written Controlled Documents (Policies, Standard Operating Procedures, Guidelines, Templates, Forms, Checklists and Flow Charts).
- Advising on the Human Tissue Authority's requirements including the establishment of an independent Biobank Access Committee to consider applications for accessing the Health Board's BioBank samples by assessing the scientific merit and potential benefits to patients, staff or the organisation.

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

Constitution

From the terms of reference approved in January 2020, the membership of the Sub-Group was agreed as the following:

- Deputy Research and Development Director (Chair).
- Senior Research and Development Manager (Vice Chair).
- Quality Assurance Officer (Research).
- Research Governance Officer.
- Research and Development Manager.
- Lead Research Nurse(s).
- Advanced Biomedical Scientist (Research) – co-opted member as required.
- Clinical Trials Pharmacist – co-opted member as required.
- Independent Member.

Meetings

Since 12th March 2020, the Research Quality Management Sub-Group meetings have been held on a bi-monthly basis as follows:

- 20th August 2020.
- 15th October 2020.
- 17th December 2020.
- 18th February 2021.

The first two meetings scheduled to take place in 2020/21, on 21st May 2020 and 30th July 2020, were stood down as a result of the Covid-19 pandemic.

As the Research Quality Management Sub-Group is directly accountable to the Research and Development Sub-Committee for its performance, following each meeting it provides an assurance to the Sub-Committee through a formal written update report which is received at the subsequent Sub-Committee meeting. Four formal reports highlighting the key areas of work scrutinised and identifying key risks and issues and matters of concern, have been received by the Research and Development (R&D) Sub-Committee during 2020/21, including the following:

- R&D Governance Report from the Research Quality Management Sub-Group meeting on 20th August 2020 to the R&D Sub-Committee at its meeting on 14th September 2020.
- R&D Governance Report from the Research Quality Management Sub-Group meeting on 15th October 2020 to the R&D Sub-Committee at its meeting on 9th November 2020.
- R&D Governance Report from the Research Quality Management Sub-Group meeting on 17th December 2020 to the R&D Sub-Committee at its meeting on 11th January 2021 (meeting subsequently cancelled).
- R&D Governance Report from the Research Quality Management Sub-Group meeting on 18th February 2021 to the R&D Sub-Committee at its meeting on 08th March 2021.

During 2020/21, the Sub-Group met on 4 occasions and was quorate at all meetings.

Sub-Group Terms of Reference and Principal Duties
In discharging its duties, the Research Quality Management Sub-Group has undertaken work during 2020/21 against the following areas of responsibility in relation to its terms of reference:

Ensure that the Health Board research community, including research partners, conduct health care research in compliance with applicable research legislation, policies and procedures, and in line with Health Board Policies.

- Good Clinical Practice Policy (822)
- BioBank Policy (466).

Endeavour to ensure the delivery of high quality research across the Health Board, including via effective communication with the Health Board's research partners.

- Acknowledgement of an Information Governance breach within the Health Board which was identified when an academic research partner received human tissue samples for a collaborative research project.
- Agreed actions following multiple breaches of the Data Protection Act/General Data Protection Regulation as a result of unencrypted Personal Identifiable Information being sent to email addresses outside the Digital All Wales Network, DAWN (@wales.nhs.uk).

Agree issues to be escalated to the Research and Development Sub-Committee with recommendations for action.

- No issues required escalation during the period of the Annual Report.

Other Areas of Responsibility
During 2020/21, the Research Quality Management Sub-Group (RQMG) also received, and considered the following:

- Oncotype Dx trial handover facilitated by Quality Assurance Officer (Research) before the current Study Coordinator left his post (21/08/2020).
- FTIR Triggered Audit Report approved by RQMG Chair's Action and sent to Wales REC 7 on 17/07/2020.

- Approved the FTIR study human tissue sample destruction in compliance with the Biobank Policy (466) and HDdUHB's Human Tissue Authority License for Research.
- Forthcoming Good Clinical Practice (GCP) training webinars via Health and Care Research Wales (HaCRW) involving HDdUHB's GCP Training Facilitator.
- Research QA Team involvement in investigating research-related incidents and events, and authorising research-related DATIX reports.
- Progress update for HDdUHB's Biobank Database project.
- Discussion relating to establishing an independent Biobank Access Committee to consider requests for, and oversee the release of, human tissue samples from HDdUHB's Biobank.
- Developing Guidance for R&D staff and the research community on Statutory Inspections by the Medicines and Healthcare products Regulatory Agency (MHRA) /Human Tissue Authority (HTA).
- Written Controlled Documents approved at the meeting: Standard Operating Procedure (SOP)(RDSOP-01): Production, Review and Approval of Research Standard Operating Procedures; Form (RDF-04): Request for New or Change to Existing R&D SOP; Template (RDT-16): R&D SOP Template; Flow Chart (RDFC-02): Flow Chart for production, review and approval of R&D SOPs; Guidance (RDG-01): Guidance for Requesting Good Clinical Practice and other Research Training; and Checklist (RDC-02): Checklist for External Staff/Students Joining a Research Study Team via an Honorary Research Contract or Letter of Access.
- Documents approved by Chair's Action: Templates (RDT-03): Research Participant Enrolment Log, (RDT-04): Research Subject ID Code List, (RDT-05): File Note for Research Files, (RDT-06): Research Study Delegation Log, (RDT-07): Site Initiation Visit Report, (RDT-08): Site Initiation Visit Attendance Log, and (RDT-13): Template for recording Research Training Records; and Form (RDF-05): Protocol Deviation Form.
- Corrective Actions for the Oncotype Dx study (Breast Care Unit, Prince Philip Hospital) to be addressed by the new Trial Manager (from 01/10/2020) after the previous Trial Manager left.
- Final FTIR study Triggered Audit Report, related to the MedLUNG study Triggered Audit, accepted by Wales Research Ethics Committee (REC) 7, and the proposed formal close down of both studies approved (21/10/2020).
- New Template Freezer Logs (for depositing, exporting and importing research samples) to be expedited to prevent further human tissue sample chain of custody issues pending rewrite of previous R&D SOP: Accessing Research Fridges and Freezers in the Clinical Research Centre (RDSOP-22, V1.0, 2014) which is not fit for purpose.
- Good Clinical Practice Training Policy (Policy 822) updated for RQMG approval prior to ratification at R&D Sub-Committee (pending).
- DATIX reports following research-related safety incidents/protocol deviations.
- Review of model Materials Transfer Agreement (MTA) to control and document human tissue sample transfer between HDdUHB and external partners (Preventative Action arising from multiple Triggered Audits due to poor research record keeping).
- Confirmation of FTIR study human tissue sample destruction in compliance with the Biobank Policy (Policy 466) and HDdUHB's Human Tissue Authority License for Research.
- Progress update for HDdUHB's Biobank Database project with Aberystwyth University.

- Annual update of the RQMG Terms of Reference.
- Written Controlled Documents approved at the meeting: Standard Operating Procedure (RDSOP-10): Application for Sponsorship and Authorisation of a Research Study (approved subject to no further comments received by 29/10/2020); and Pharmacy Standard Operating Procedure and Form for Managing the Return of Clinical Trial Medication (approved subject to no further comments received by 22/10/2020).
- For information, amended documents for Research and Development Sub-Committee approval by Chair's Action: Standard Operating Procedure (RDSOP-05): Research-Related Adverse Event/Serious Adverse Event Reporting (V1.1); Form (RDF-01): Research-Related Adverse Event/Serious Adverse Event Reporting Form (V1.2); and Flow Chart (RDFC-01): Flow Chart for Reporting Research-Related Adverse Events/Serious Adverse Events (V1.1).
- Following discussion at the Research and Development Strategic Management Team (SMT) on 21st October 2020, the Research Quality Management Sub-Group and Research Quality Assurance Team would develop a new system of dashboard metrics for reporting to both SMT and the Research and Development Sub-Committee. The metrics would be reviewed at bi-monthly Research Quality Management Sub-Group and Research Quality Assurance Team meetings and revised accordingly.
- Formal Close-Down Monitoring Visits for the FTIR and MedLUNG studies (following Triggered Audits) pending by the Research QA Team.
- New Research QA Team E-filing system for managing R&D Written Controlled Documents now in use and under continuous development.
- R&D Department Quality Improvement Plan being promoted and supported by the Research QA Team in line with the new R&D Strategy.
- New 'Lessons Learned' standing Agenda item at monthly Operational Leadership Group meetings will ensure that Research QA principles are embedded in each R&D Team, applied across the entire department and promoted to the UHB research community.
- The Draft Research Self-Audit Checklist was piloted in use by the Research Delivery Team at Withybush General Hospital and feedback incorporated into a generic checklist (RDC-04) for monitoring and auditing research studies.
- DATIX reports following research-related safety incidents/protocol deviations discussed.
- Progress update for HDdUHB's Biobank Database project with Aberystwyth University, where continued delays in providing a version for the Biobank Lead to test have been escalated via the Biobank Database Project Group and Strategic Management Team.
- Annual update of the RQMG Terms of Reference (Version 0.3 dated 15/12/2020 reviewed and APPROVED).
- Written Controlled Documents approved at the meeting: (Policy 822): Good Clinical Practice Training Policy; Standard Operating Procedures: (RDSOP-06): Research Participant Recruitment and Intention to Enrol; (RDSOP-12): Research Training Records; (RDSOP-07): Delegation of Responsibilities in Research Studies; (RDSOP-08): Monitoring of Research Studies; (RDSOP-09): Research Audit and Inspections; (RDSOP-10): Application for Sponsorship and Authorisation of a Research Study; (RDSOP-11): Application for Authorisation of a Hosted Research Study; (RDSOP-16): Case Report Form Design and Use; Templates: (RDT-15): Research Participant Screening Log; (RDT-12): Trial Monitoring Plan Template; (RDT-22): Freezer Log for Depositing Research Samples; (RDT-23): Freezer Log for Exporting Research Samples; (RDT-24): Freezer Log for Importing Research Samples; (RDT-25): Signature

Log for Freezer Logs; (RDT-17): Pathway to Portfolio Scoring Matrix, SRP Summary and Recommendation for SMT (V2, 01/07/2020); Forms: (RDF-02): Case Report Form for Research(example) – *Appendix 2 of RDSOP-16*; and (RDF-06): Application Form for Pathway to Portfolio Funding; Checklist: (RDC-04): Research Audit and Monitoring Visit Checklist; and Guidance: (RDG-02): Guidance for Researchers being Audited or Inspected;(RDG-05): Guidance on Applying for Pathway to Portfolio Funding; and (RDG-07): Guidance for Completing a Case Report Form (example) – *Appendix 1 of RDSOP-16*.

- Formal Close-Down Monitoring Visits for the FTIR and MedLUNG studies (following Triggered Audits) are now able to proceed as the Research Audit and Monitoring Visit Checklist (RDC-04), Draft 0.3 (03/02/2021), is now available for Pilot in Use.
- DATIX reports discussed following three separate Data Protection Act/General Data Protection Regulation breaches in the RATE (Commercial) study, affecting 3 patients (30/12/2020), the Novel Technologies/Obstructive Sleep Apnoea (HDdUHB-Sponsored) study, affecting 2 patients (20/01/2021) and the COPE (non-research) study, affecting 98 patients in 2 primary care practices (26/01/2021) - Information Governance Team currently investigating.
- A fourth DATIX report was discussed following a Protocol breach in the Immune Response in COVID (HDdUHB-Sponsored) study, where a participant was recruited despite meeting an exclusion criterion; this represented a repeat occurrence involving the same researcher, and failure to demonstrate lessons learned, so Dr Sam Rice contacted the researcher to advise they are not permitted to recruit any further research participants until they have undertaken Valid Informed Consent for Research training.
- Progress update for HDdUHB's Biobank Database project with Aberystwyth University, advised that a test version of the LiMBuS database had been received on 29/01/2021 (following extensive delays), and was currently being tested by the Biobank Lead.
- The following R&D Policy was pending approval at the Strategic Management Team meeting on 22nd February 2021 and formal ratification by the Research and Development Sub-Committee at the meeting on 8th March 2021: R&D Policy 822: Good Clinical Practice (GCP) Training Policy (Version 1.3, 08/02/2021). The Research and Development Form (RDF-07): The 13 Principles of Good Clinical Practice (GCP) Form (Version 1.1, 04/02/2021) – *Appendix 3 of GCP Training Policy 822* - was approved at the Research Quality Management Sub-Group meeting on 18th February 2021.

Key Risks and Issues/Matters of Concern

During 2020/21, the following key risks and issues/matters of concern were raised to the Research and Development Sub-Committee:

- None reported.

Matters Escalated to Research and Development Sub-Committee

During 2020/21, the following matters requiring Research and Development Sub-Committee level consideration or approval were raised:

- The following three Research and Development Written Controlled Documents were submitted for approval to the Research and Development Sub-Committee on 14th September 2020: Standard Operating Procedure (RDSOP-05) Research-Related Adverse Event/Serious Adverse Event Reporting (V1.0); Form (RDF-01) Research-Related Adverse Event/Serious Adverse Event Reporting Form (V1.1); and Flow

Chart (RDFC-01): Flow Chart for Reporting Research-Related Adverse Events/Serious Adverse Events (V1.0). Minor changes were requested, amended documents to be submitted for approval via Chair's Action.

- Amended documents for Research and Development Sub-Committee approval by Chair's Action: Standard Operating Procedure (RDSOP-05): Research-Related Adverse Event/Serious Adverse Event Reporting (V1.1); Form (RDF-01): Research-Related Adverse Event/Serious Adverse Event Reporting Form (V1.2); and Flow Chart (RDFC-01): Flow Chart for Reporting Research-Related Adverse Events/Serious Adverse Events (V1.1).
- Updated and amended Research Quality Management Sub-Group ToRs were approved as follows: Version 0.3 (15/12/2020) by Research Quality Management Sub-Group 17th December 2020; Version 0.3 (22/12/2020) by Strategic Management Team on 22nd December 2020 via Chair's Action; Version 0.3 (22/12/2020) by Research and Development Sub-Committee on 11th January 2021 via Chair's Action.
- The R&D Policy 822: Good Clinical Practice (GCP) Training Policy (Version 1.3, 08/02/2021) was approved at the Strategic Management Team meeting on 22nd February 2021 and an amended version was formally ratified by the Research and Development Sub-Committee at the meeting on 8th March 2021 (Version 1.4, 22/02/2021). The R&D Form (RDF-07): The 13 Principles of Good Clinical Practice (GCP) Form (Version 1.1, 04/02/2021), approved at the Research Quality Management Sub-Group meeting on 18th February 2021, was included as Appendix 3 of the GCP Training Policy 822.

Research Quality Management Sub-Group Developments for 2021/22

The following developments are planned for the Research Quality Management Sub-Group during 2021/22:

- The Research Quality Management Sub-Group and Research Quality Assurance Team will continue to develop a new system of dashboard metrics for reporting to both the Research and Development Strategic Management Team and the Research and Development Sub-Committee. The proposed new Performance Indicators will initially be based on a reduction of the numbers of Triggered Audits, Protocol Deviations, Serious Breaches of Good Clinical Practice/Protocol and DATIX research-related incident reports over time.
- By sharing lessons learned from research-related adverse event reports and examples of good research practice observed at routine/triggered audits and monitoring visits, the Research Quality Management Sub-Group will continue to progress the Research Governance Quality Improvement Plan through the work of the Research Quality Assurance Team.
- In response to issues arising across the Health Board, two new R&D Standard Operating Procedures (RDSOP-20: *Management and Escalation of Monitoring and Audit Findings, Errors and Near Misses* and RDSOP-19: *Detection and Management of Research Fraud and Misconduct*) and two new R&D Guidance documents (RDG-14: *Information Governance for Research* and RDG-15: *Research Publication*) have been identified for development.

Argymhelliad / Recommendation

To endorse the Research Quality Management Sub-Group Annual Report 2020/21.

Amcanion: (rhaid cwblhau) **Objectives: (must be completed)**	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	9.3 The Sub-Committee may establish groups or task and finish groups to carry out specific aspects of Sub-Committee business on its behalf. The Sub-Committee will receive updates from each Group detailing the business undertaken on its behalf. The following management groups have been or will be established: Research Quality Management Group. (From the Research and Development Sub-Committee ToRs, Section 9: Reporting, Version 0.9, approved 14/09/2020).
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):	3.3 Quality Improvement, Research and Innovation

Effaith/Impact:	
Ariannol / Financial: **Ansawdd / Patient Care:** **Gweithlu / Workforce:** **Risg / Risk:** **Cyfreithiol / Legal:** **Enw Da / Reputational:** **Gyfrinachedd / Privacy:** **Cydraddoldeb / Equality:**	If yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906