



Strategic Risk Register – Risk 2

Controls

Existing Control			Sources of Assurance	Level at which the Assurance is provided to					Assessment of each Assurance
No.	Control	Exec Owner		Team / Division / Project	Directorate Team / Exec Lead	Business Exec Team / Sub Groups	Committee / Sub group	Board	
2.1	Corporate Quality Management systems	Executive Director Quality, Nursing and Allied Health	Quality Indicators Performance Monitoring as reported in the Integrated Performance Report	X	X	X		X	Moderate
			Health and Care Standards regular Monitoring at Board - IPR – ongoing monitoring of implementation		X	X		X	Moderate
			Health and Care Standards - Arrangements / system in place.	X	X	X	X		Strong
			Corporate Safeguarding Annual Report			X	X		Weak
			Infection Control Annual Report			X	X		Weak
			PTR Quarterly Report (IPR Monthly)			X	X	X	Strong
			PTR Annual Report			X	X		Moderate
			Quarterly Alert exception Report			X	X	X	Moderate
			Annual Quality Statement		X	X	X	X	Strong
			Quality and Clinic Audit Plan - Annual Report and update reports			X	X		Strong
2.2	Professional Regulation		Annual report to People and OD Committee /QSIC		X	X	X		Strong
2.3	Incident Reporting Management System		Quality Review Visit by medical revalidation support unit	X	X	X	X		Moderate
			Putting Thing Right - Report			X	X		Moderate
			Putting Thing Right - Annual			X	X		Strong
			Organisational Annual Report – (Reported to WG)			X	X		Strong
			SI reporting as occurs			X	X	X	Moderate
			2.4	Directorates Mid & end year review process	Directorates Mid and year end reports		X	X	
2.5	External Reviews		HIW Inspections			X	X	X	Strong
			HSC			X	X		Strong
			JAG accreditation	X	X	X			Weak
			UKAS Accreditation	X	X	X	X		Weak
			Audit Wales Structured Assessment	X	X	X	X	X	Strong
2.6	Health Care Support worker programme		Update reports (PODCOM) (Annual)		X	X	X		Moderate
2.7	Medicines Management System		Medicines Management Policy			X	X		Weak
			Medicines Management Procedure			X	X		Weak
			Pharmaceutical SLA with Cardiff & Vale University Health Board			X			Weak
2.8	Medical Devices Arrangements		Medical Devices Policy			X	X		Weak
		Medical Devices Procedure			X	X		Weak	
		Medical Devices Registers (Microbiology Laboratories)	X					Weak	
		Medical Devices Screening Division Register	X					Weak	
		Medical Devices Register (Corporate)	X					Moderate	
2.9	Public Health Services QMS	Exec Director of Public Health Services/Medical Director	Local Audit	X					Moderate
		Vertical & Horizontal Audits of Microbiology Laboratory Services	X						Strong
2.10	Failsafe systems	Executive Director of Public Health Services/Medical Director	Defined failsafe task and finish groups (papers and notes) to review screening programmes against policy	X					Weak
			SI reporting as occurs to Board and quarterly to QS&I Committee			X	X	X	Moderate
			Screening Division – Standard Operating Procedures (document development, review and approval)	X					Moderate

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2.11	Microbiology Stabilisation Programme	Executive Director of Public Health Services/Medical Director	Microbiology Division – Standard Operating Procedures (document development, review and approval)	X					Strong
			Stabilisation Action Plan process Update on hold due to Covid	X	X	X			No Assurance
			Stabilisation Action Plan: Progress Update Reports to QSIC on hold due to Covid			X	X		No Assurance
			Reports to Board (AD HOC) on hold due to Covid			X		X	No Assurance
			Microbiology Programme Board Reports on hold due to Covid			X			No Assurance
2.12	Recruitment Procedures and Checks policy	Acting Director of People & Organisational Development	Appropriate job descriptions	X					Weak
2.13	Statutory & Mandatory training Competency and role based training and Regulatory standards		Included in Integrated Performance Report			X		X	Strong
2.14	People & OD Performance Information and Reports (Including Detailed recruitment MI)		Included in Integrated Performance Report			X		X	Strong
2.15	Personal Development Reviews ‘My Contribution’		Included in Integrated Performance Report			X		X	Strong
2.16	Workforce Plan		Reports to People & OD Committee (as part of the IMPT process)				X		Moderate
			Directorate workforce plans		X	X			Weak
2.17	Staff Survey		Staff Survey results			X	X	X	Moderate
			Engagement Reporting			X	X		Weak
2.18	Leadership and Management development Programme		Performance Data Report		X	X		X	Strong
2.19	Occupational Health provision		Reports to QS&I Committee and POD Committee				X		Weak
2.20	Policies	Board Secretary & Head of Board Business Unit	Policy, Procedures and other written control documents Policy			X	X	X	Moderate
			Policy, procedures and other written control documents Procedure		X	X			Moderate
			Policy register report to Audit and Corporate Governance Committee on compliance with Policies		X	X	X	X	Moderate
			Policy register report of relevant policies to each Board Committee			X	X		Moderate
2.21	Internal Audit Programme		Internal audit plan			X	X		Moderate
			Audit reports as a result of the annual programme		X	X	X		Moderate
			Annual head of internal audit report			X	X	X	Moderate
			Internal audit action log (and follow up of actions)		X		X		Moderate
2.22	Department Standard Operating Procedures	Exec Team (report via Board Secretary)							
2.23	Health & Safety plan	Deputy Chief Exec/ Exec Director of Operations & Finance	Health and safety action plan and associated reports	X	X		X		Moderate

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Action Plan

Control Number	Gaps in controls	Gaps in assurance		Action Plan	Exec Lead	Due Date	Progress
			1	Develop a Quality assurance dashboard		May 2021	<p>March 21: Working with the Planning Team to develop the quality section of the Performance Assurance Dashboard is ongoing.</p> <p>January update – The first iteration of the Quality section of the Performance and Assurance Dashboard will be presented to Board on 28th January</p> <p>October Update: The standard quality indicators reported to BET/Board (eg. Complaints, incidents etc), will be developed into interactive dashboards by December 2020. The quality assurance dashboard model is currently in development and requires further engagement with the planning team. This will be completed by May 2021. QSIC approved change of target date to May 2021. (approved by QSIC 17.11.20)</p> <p>Previous Update: The draft Quality assurance dashboard in conjunction with a revised format for the PTR report, has been developed and will be presented to the Quality, Safety and Improvement Committee on 11 February 2020 for consideration. The management dashboard component of this action was completed and further work is ongoing to further improve the dashboard and PTR report. This work has been superseded by the development of the Performance and Assurance Dashboard.</p>
			3	Ensure the Quality Assurance Dashboard includes measures / indicators to include the IPC and safeguarding indicators		March 2021	<p>March 21: As below</p> <p>February 21 Update: Data (Quality) for the Performance and Assurance dash Board is drawn from the datix system, work is ongoing to improve data quality. Measures for IP&C and Safeguarding are in the process of being finalised and should be ready for reporting by the end of March 2021</p> <p>October Update: On track Safeguarding KPIs in place and reported against in the annual report. IP+C being developed and will form part of our annual reporting arrangements</p>
			4	Develop an Integrated Governance Model		April 2021	<p>March update: Integrated Governance Model was approved by the Board on 25 February 2021.</p> <p>Request to approve removal of this action as it has been completed.</p> <p>December update: A proposed Integrated Governance Model has been developed and input is currently being sought from members of the Board and Executive Team. The model is expected to be discussed at Audit and Corporate Governance Committee on 19 January and Board on 25 March.</p>

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			5	Implement Integrated Governance Model		April 2022	<p>March21: Implementation of the model will take a phased approach, with the following aspects of governance piloted applying the model, once subject area focused (Information Governance) and one service focused, (an agreed Screening Programme) and the COVID-19 response. A base line assessment will be undertaken and the learning will be used to inform wider organisational learning and application and to develop an implementation plan.</p> <p>December update: Implementation will take a phased approach, with continuous improvement applied after each phase. Gap analysis and Stakeholder map will be completed during implementation of the model.</p>
2.1		Gaps in consistently applied, monitored and reported quality and improvement measures aligned to strategic priority outcomes and integrated performance report	6	Develop and approve Quality and Improvement Strategy		April 2021	<p>June update: the Strategy was approved by the Board in May 2021. Action to be closed.</p> <p>March 21. The Quality and Improvement Strategy is due to be received at the April 2021 meetings of BET and the Quality, Safety and Improvement Committee.</p> <p>December Update: The quality and Improvement strategy is in draft, a logic model session with key Directorate representatives was held in January 21 to consider 'creating the conditions' for quality and improvement. The final document will be tabled at the April 21 QSIC.</p> <p>October Update: Progress has been made on the development of the Quality and Improvement Strategy, submission to QSIC has now been moved back to January due to COVID-19 pressures. QSIC Committee approved change of date to January 2021. (approved by QSIC 17.11.20)</p> <p>Previous Update: Work is ongoing to engage key stakeholders on the Quality and Improvement Strategy and Executive Directors have been asked to identify Quality and Improvement champions and the role profile has been developed. This work has been paused due to the Quality Improvement team having been redeployed to other duties to support the Covid-19 emergency response. A meeting was held in August to agree the content of the strategy, and the first draft will be shared and engage with directorates. This will be reported to BET in October, and QSIC in November 2020.</p>
			7	QNHAPS working in conjunction with planning team, to develop quality indicators with the Stage 2 workstreams in order to be able to measure and monitor outcomes and improvements.		To be determined	<p>March 21: Meeting pending with the Planning Team to progress this work.</p> <p>January 21: This work is ongoing but has been significantly impacted by the Health Protection response as key leads are deployed almost full time on to the response.</p>

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							October Update: This work is ongoing and will be progressed through the implementation of the new Operational plan. Previous update: Draft indicators presented to Gold. Further work to be undertaken to refine the quality indicators by working with Stage 2 workstreams, in order that they can be incorporated into the performance and assurance dashboard.
		Gaps in ownership of improvement actions at Directorate for the Health Care Standards Self-Assessment.	8	Support ownership in Directorates and Divisions in identifying improvements and enacting action plans		February 2021	March 21: Workshop has been held to establish the current self-assessment position and improvement actions for 2021/22. In light of organisational mobilisation the self-assessment and identifications of improvements are being looked at via the operational plan January 21: A Health and Care standard tool has been developed to support Directorates with updating their improvement actions. Session with Directorates being arranged in February. October Update: In progress. Previous update: Self-assessment template has been amended to ensure a responsible owner for each improvement action is identified. This was further explained during a workshop in October 2019, and again at the Peer Review session in January 2020. Improvement actions will continue to be monitored on a quarterly basis via the Integrated Performance Report. A report to close the 2019/20 Health and Care Standards report was received by the Quality, Safety and Improvement Committee on 7 September 2020. A revised process for 2020/21 will be re-issued and adapted to reflect the current COVID context. This will be reported to BET in February 2021, and QSIC thereafter.
		Gaps in consistently applied KPIs for IPC and Safeguarding	9	Develop Quality Management Dashboard to include assurance for IPC and Safeguarding to provide regular reporting to QSIC		March 2021	March 21: IPC and Safeguarding KPIs will be completed by the end of March 2021. December Update: As per October update. October Update: The IP+C and Safeguarding indicators will be reported against within annual report. QSIC approved change of date to March 21. (approved by QSIC 17.11.20) Previous update: Work is progressing to identify KPIs in both safeguarding and IPC and these will be included in the Quality Management and Assurance Dashboard when finalised. This work has been paused as the safeguarding lead has been redeployed to support the Covid-19 emergency response.

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		Development of Quality and Clinical Audit Plan was not fully aligned with adherence to SOPs and improvement activity.	10	Further develop Quality and Clinical Audit Plan to ensure alignment with adherence to SOPs and improvement activity for next audit planning cycle	Executive Director Quality, Nursing and Allied Health Professionals	May 2021	<p>March 21: The appointment of Quality and Clinical Audit Facilitator has been made to take this work forward.</p> <p>December Update: Ongoing.</p> <p>October Update: Discussions ongoing with directorates to ensure their audit cycles also include reviews of their SOPs</p> <p>Previous update: The Quality and Clinical Audit Plan for 2020/21 was approved by the Quality, Safety and Improvement Committee at its meeting in September 2020. The plan will be updated and reviewed during 2020/21, and a 6 monthly report will be provided to QSIC. The 2021/22 Quality and Clinical Audit Plan will be received at QSIC in May 2021.</p>
2.3	Lack of systematic and embedded approach to reflecting and learning from raising concerns (Whistleblowing)	Lack of assurance mechanism for 'raising concerns' (Whistleblowing)	11	Implement an organisational approach to disseminating and raising awareness of the 'Raising Concerns' (whistleblowing) policy	Board Secretary and Head of Board Business Unit	March 2021 March 2022	<p>May 2021 update: Actions remain ongoing, website remains active and up to date. Propose to extend timescale to allow for review of the effectiveness of the work during 21/22.</p> <p>December Update (and relevant for February 2021): An All Wales policy review has been instigated, in the meantime the dedicated webpage will be reviewed and promoted through existing staff communication channels.</p> <p>October Update: Update: Work will recommence on this in December 2020.</p> <p>Previous update: This work has been temporarily paused due to the Covid-19 response but will be resumed in the coming weeks. The All Wales policy, dedicated intranet page and advice remains in place.</p>
2.7	Absence of up to date and accurate medical devices register		12	See action plan for 2.8 (Actions 14,15,16)			
2.8	Lack of systematic assurance mechanism in relation to management of medical devices		13	Strengthen organisational governance of medical devices (including registers)	Executive Director of Public Health Services/Medical Director Executive Director Quality, Nursing and Allied Health Professionals	March 2021 June 2021	<p>March 21: The position update paper in relation to Medical Devices was received at BET who requested a baseline assessment gap analysis be undertaken and a Corporate Medical Devices Assets register established by June 2021.</p> <p>February update: Work is progressing to identify and record any medical devices being used throughout Public Health Wales, including any software which may be considered to be a medical device.</p> <p>* NB. Microbiology services are in the process of implementing a new electronic Quality Management System which includes a medical devices register. The QMS is currently being piloted in the 'hot' labs and Cryptosporidium Reference Unit before it is rolled out to other areas of microbiology, in order to ensure that the system runs</p>

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							smoothly. Each laboratory will then update the medical devices module in due course, but the timeframe for this is likely to go beyond May.
			14	Review the Medical Devices Policy and Procedure (due to Medical Devices and IVD Regulations)		March 2021 November 2021	<p>March 21: Medical Devices Policy is still in date and not due to be reviewed until November 2021.</p> <p>February Update: The current policy was due to be reviewed following the introduction of the Medical Devices (MDR) and in Vitro Diagnostic (IVDR) Regulations 2017. As a result of the coronavirus pandemic, the European Commission agreed to postpone the transition period for implementation until May 2021. As the UK will have left the European Union before this date, the EU Regulations will no longer be automatically applicable to the UK.</p> <p>The 2002 Medical Devices Regulations referred to in the current policy are still applicable. The current policy is not due to be reviewed until November 2021.</p> <p>A new Medicines and Medical Devices Act has recently been introduced and it is likely that further legislation will be introduced in due course. It is recommended that the introduction of new legislation be monitored and the policy and procedure be updated accordingly.</p>
			15	Scope non-clinical areas to ensure that no devices remain unaccounted for in the governance arrangements		April 2021	<p>March 21: The position update paper in relation to Medical Devices was received at BET who requested a baseline assessment gap analysis be undertaken and a Corporate Medical Devices Assets register established by May 2021.</p> <p>December Update: Work has commenced to scope what medical devices are held in non-clinical areas of the organisation. Report to QSIC scheduled for April.</p>
2.10	Delivery of the National Health Protection Service Transformation Programme		16	See Action in Risk 3			
2.20	Process inconsistently applied for updating and disseminating new/ updated policies		17	Development of existing procedure to ensure a consistent approach to policy development, approval and communication that is timely and effective.	Board Secretary and Head of Board Business Unit	May 2021	<p>May Update Action can be closed, work completed.</p> <p>December Update: Procedure in process of consultation with staff and will be provided to BET, requesting approval at the end of February. The new</p>

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							<p>procedure will then be applied with changes communicated to improve consistency of approach.</p> <p>Significant work has been undertaken to ensure the existing database of policies is accurate and assurance reports continue to be provided to Board Committees.</p> <p>October Update: On track. Previous update: This is in progress. The Policy for policies, and procedures and other written control documents has been revised and approved by the Board. The procedure will be consulted on during the Autumn. Work will then commence on improving communication and compliance.</p>
2.21	Clear picture of all audit related activity across the organisation (corporate & clinical)		18	Develop a comprehensive overview that collates and summarises all audit activity planned for April 2021 onwards – repeat on an annual basis	Board Secretary and Head of Board Business Unit / Executive Director Quality, Nursing and Allied Health Professionals	May 2022	<p>December Update: Due to current pressures, it is proposed that this recommendation be implemented for the 2022/23 year. May – nothing to add.</p> <p>October Update: Work is scheduled to commence and target remains on track. Mapping exercise from PHW Quality and Clinical Audit Plan to domains of the NHS Wales Delivery Framework completed. Further discussions planned with BDU to ensure, as an organisation, we have clear oversight regarding clinical audits.</p>
2.22	Confirmation of appropriate processes being in place within each directorate for updating and disseminating new/updated standard operating procedures	Gap in assessment of adherence with SOPs and testing using Quality and Clinical Audit.	19	Conduct Audit of what Standard Operating Procedures (SOPs) processes are in place in each directorate that meets a required standard.	Executive team members (reported via Board Secretary and Head of Board Business Unit)	June 2021	<p>March 21: This work will form part of the Quality and Clinical Audit Planning.</p> <p>January Update: Audit of SOPs not yet commenced corporately, some work is underway in some areas of the organisation. Delay is largely due to lack of capacity due to COVID.</p> <p>October Update: This work commenced prior to COVID within Public Health Services, and will now be resumed.</p>
			21	Test compliance and adherence with SOPs		September 2021	
new			22	Once for Wales Datix system to be implemented by March 2021	Executive Director Quality, Nursing and Allied Health Professionals	March 2021 October 2021	<p>March 21: The implementation of the OFWCMS has been put back to October 21 as some of the modules are still being developed and the difficulties in staff being released to undertake training due to the continuing support to the COVID 19 response.</p> <p>January update: A paper was submitted to BET in December 2020 where the decision was made that the OFWCMS would be implemented and adopted as the Public Health Wales system in line with all other NHS organisation. Work continues at Public Health Wales to be ready for the implementation of the new system in April 2021 although concerns remain as to whether or not the system will be fit for purpose on that date.</p> <p>October Update: Paper to BET in November 2020</p>

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							Previous update: The implementation of the entire system has been brought forward to March 2021 subject to Public Health Wales agreed the WG timeline. Public Health Wales are considering the resource implications.