Patient Experience, Quality & Safety Committee

Tue 25 April 2023, 09:30 - 12:15

Agenda

09:30 - 09:30
0 min

1. PRELIMINARY MATTERS

PEQS_ Agenda_25April2023 Final.pdf (2 pages)

1.1. Welcome and Apologies

1.2. Declarations of Interest

1.3. Minutes from the previous meeting held on the 23 February 2023 for approval

PEQS_Item_1.3_unconfirmed Minutes 2023-02-23.pdf (11 pages)

1.4. Committee Action Log

PEQS_Item_1.4_Action Log April 2023.pdf (2 pages)

09:30 - 09:30
0 min

2. ITEMS FOR ASSURANCE

2.1. Integrated Quality Report

PEQS_Item_2.1_Integrated Quality Paper April23.pdf (12 pages)
PEQS_Item_2.1b_Duty of Candour Statutory Guidance 2023.pdf (41 pages)
PEQS_Item_2.1c_Duty of Candour Statutory Guidance 2023.pdf (43 pages)
PEQS_Item_2.1d_Duty of Quality Statutory Guidance 2023.pdf (44 pages)
PEQS_Item_2.1e_Canllawiau Statudol y Ddyletswydd Ansawdd 2023.pdf (44 pages)
PEQS_Item_2.1f_Communications Toolkit - Interim Learning Report.pdf (11 pages)
PEQS_Item_2.1g_HIW Inspection Claerwen Ward.pdf (34 pages)
PEQS_Item_2.1h_HIW Inspection Tawe Ward.pdf (24 pages)
PEQS_Item_2.1i_WRP National Review - Consent to Examination & Treatment.pdf (17 pages)
PEQS_Item_2.1k_PTHB-2223-06 Incident Management Final IA Report.pdf (18 pages)

2.1.1. Duties of Quality and Candour implementation

2.2. WHSSC Quality and Safety Committee Report January 2023

PEQS_Item_2.2_QPSC Chairs report Jan 2023.pdf (10 pages)

09:30 - 09:30
0 min

3. ITEMS FOR DISCUSSION

There are no items for discussion.

09:30 - 09:30
0 min

4. ESCALATED ITEMS

4.1. Maternity Services de-escalation to business as usual

PEQS_Item_4.1_Maternity De-escalation March 2023.pdf (6 pages)

09:30 - 09:30
0 min

5. ITEMS FOR INFORMATION

There are no items for information.

09:30 - 09:30
0 min

6. OTHER MATTERS

6.1. Committee Risk Register - risks overseen by this Committee

PEQS_Item_6.1_Committee Risk Report_Apr23.pdf (3 pages)
PEQS_Item_6.1a_Appendix A_Committee Risk Register_May23.pdf (6 pages)

6.2. Work Programme

6.3. Items to be brought to the attention of the Board and/or other Committees

6.4.

6.5. Any other urgent business

6.6. Date of the next meeting:

4 July 2023

POWYS TEACHING HEALTH BOARD
PATIENT EXPERIENCE, QUALITY AND SAFETY COMMITTEE

TUESDAY 25 APRIL 2023
09:30 – 12:15
VIA MICROSOFT TEAMS

Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

AGENDA

Time	Item	Title	Attached/Oral	Presenter
	1	**PRELIMINARY MATTERS**		
09:30	1.1	Welcome and Apologies	Oral	Chair
	1.2	Declarations of Interest	Oral	All
09.35	1.3	Minutes from the previous Meeting 23 February 2023	Attached	Chair
09.40	1.4	Committee Action Log	Attached	Chair
	2	**ITEMS FOR ASSURANCE**		
09.45	2.1	Integrated Quality Report • Duties of Quality and Candour Implementation	Attached Presentation	Director of Nursing and Midwifery
11.00		COMFORT BREAK		
11.15	2.2	WHSSC Quality and Safety Committee Report – January 2023	Attached	Director of Nursing and Midwifery
	3	**ITEMS FOR DISCUSSION**		
		There are no items for discussion.		
	4	**ESCALATED ITEMS**		
11.25	4.1	Maternity Services de-escalation to business as usual	Attached	Director of Nursing and Midwifery
	5	**ITEMS FOR INFORMATION**		
		There are no items for information.		
	6	**OTHER MATTERS**		
11:45	6.1	Committee Risk Register – risks overseen by this Committee	Attached	Director of Corporate Governance/Director of Nursing & Midwifery
11.55	6.2	Work Programme	Oral	Director of Corporate Governance
12:00	6.3	Items to be Brought to the Attention of the Board and/or Other Committees	Oral	Chair
12:05	6.4	Any Other Urgent Business	Oral	Chair
12:15	6.6	Date of the Next Meeting: 4 July 2023		

Powys Teaching Health Board is committed to openness and transparency and conducts as much of its business as possible in a session that members of the public are normally welcome to attend and observe.

Meetings are currently held virtually, should you wish to observe a virtual meeting of a committee, please contact the Director of Corporate Governance at PowysDirectorate.CorporateGovernance@wales.nhs.uk at least 24 hours in advance of the meeting in order that your request can be considered on an individual basis.

Papers for the meeting are made available on the website in advance and a copy of the minutes are uploaded to the website once agreed at the following meeting.

POWYS TEACHING HEALTH BOARD
PATIENT EXPERIENCE, QUALITY & SAFETY COMMITTEE
UNCONFIRMED

MINUTES OF THE MEETING HELD ON THURSDAY 23 FEBRUARY 2023 VIA MICROSOFT TEAMS

Present:

Kirsty Williams	Vice-Chair (Committee Chair)
Jennifer Owen Adams	Independent Member
Simon Wright	Independent Member

In Attendance:

Claire Roche	Director of Nursing and Midwifery
Claire Madsen	Director of Therapies and Health Sciences
Helen Bushell	Director of Corporate Governance (from 11.00)
Jacqui Seaton	Chief Pharmacist
Marie Davies	Deputy Director Nursing
Joy Garfitt	Assistant Director – Mental Health Services
Amanda Edwards	Assistant Director – Innovation and Improvement
Helen McIntyre	Service Manager Adult Mental Health

Observing:

Carl Cooper	PTHB Chair

Apologies for absence:

Mark Taylor	Independent Member
Ian Phillips	Independent Member
Carol Shillabeer	Chief Executive
Hayley Thomas	Director of Primary, Community Care and MH/Deputy CEO
Kate Wright	Medical Director
Mererid Bowley	Interim Director of Public Health
Zoe Ashman	Assistant Director of Quality and Safety

Committee Support:

Liz Patterson	Interim Head of Corporate Governance

PEQS/22/74	**WELCOME AND APOLOGIES FOR ABSENCE** The Committee Chair welcomed Members to the meeting. Apologies for absence were noted as recorded above.
PEQS/22/75	**DECLARATIONS OF INTERESTS** No interests were declared in addition to those already declared in the published register.
PEQS/22/76	**MINUTES OF THE EXPERIENCE, QUALITY AND SAFETY COMMITTEE MEETING HELD ON 24 NOVEMBER 2022 (FOR APPROVAL)** The minutes of the previous meeting held on 24 November 2022 were AGREED as a true and accurate record.
PEQS/22/77	**PATIENT EXPERIENCE, QUALITY AND SAFETY COMMITTEE ACTION LOG** The Action Log recorded updates with the following update was provided during the meeting: PEQS/22/41 - Key Performance Indicators to be developed for inclusion in the Integrated Quality Report – the Director of Nursing and Midwifery advised that key performance indicators were being reviewed ahead of the implementation of the Quality and Engagement Act in April 2023. An Annual Quality Report will be required from May 2024 which will be contain information sourced from the quarterly Integrated Quality Reports. This action was CLOSED. The Committee received the updates on the action log.
	ITEMS FOR ASSURANCE
PEQS/22/78	**INTEGRATED QUALITY REPORT** The Director of Nursing and Midwifery presented the report and drew attention to the following areas: • guidance is awaited for the Quality and Engagement Act which will come into force from April 2023; • the team are on track to complete reviews of nosocomial cases by April 2024; • compliance with the 30 day response time for complaints had improved although small numbers mean these figures can be volatile; • patient experiences are being captured through the Civica system, however, there is additional patient experience work taking place that needs to be captured;

	• maternity services continue to be in local escalation with fortnightly meetings monitoring the core data sets. The Executive Committee will consider in March 2023 whether sufficient progress has been made for the service to be deescalated;
	• key matters for consideration include:
	  ○ timely management of incidents;
	  ○ implementation of a quality data dashboard; and
	  ○ implementation of a robust framework to ensure the requirements of the Quality and Engagement Act are realised.
	
	What is meant by a nosocomial case?
	
	A funded post in place until 2024 to take each case where a patient might have contracted covid-19 in hospital. A review of case notes is undertaken to ascertain if a patient did contract covid-19 in hospital. Complex cases are considered by the Nosocomial Scrutiny Panel and a monthly report provided to the Delivery Unit.
	
	In managing concerns, what is meant by early resolution and enquiries?
	
	Early resolution refers to a complaint that has been logged but was being addressed at source and does not reach the stage of a concern. Enquiries refer to all matters that are not recorded as a complaint or concern.
	
	The first key matter for consideration relates to the timely management of incidents, where is this referenced within the report?
	
	This relates to the summary of incidents per month. Datix reports may initially record a level of harm which, when investigated, may not have resulted in harm. Datix previously showed several cases that had not been investigated which was either due to an administrative issue or a failure to properly investigate incidents. Root Cause Analysis training has been provided which is enabling cases to be confidently investigated more quickly preventing the build-up of a backlog. Tracking of incidents will be a key component of the duty of quality and will be outlined in the next Integrated Quality Report.

	Is there confidence the quality data dashboard is providing the required information? The Delivery Unit are examining the quality indicators which would suggest that further work needs to be undertaken. Quality needs to be embedded throughout the Integrated Performance Report rather than a separate measure. *Where will the Return on the Readiness for Implementation of the Quality and Engagement Act be considered?* The return is provided monthly to the National Implementation Board. The local Implementation Board has met twice, and consideration will be given as to how this is reported to this Committee. **Action: Director of Nursing and Midwifery** The health board is working with the NHS Wales Delivery Unit to trial the implementation of the Duty of Candour. This will be managed within the existing Datix system rather than developing a bespoke reporting system. *How is the service mitigating the inability to appoint to a Head of Midwifery post?* There is a challenge across Wales where midwives appear reluctant to progress to more senior roles. A considerable effort was put into a national campaign to recruit but this was unsuccessful. The Interim role has been strengthened and colleagues will look again to identify what can be done to make the role attractive. The challenges related to competitiveness, and scope and scale. Colleagues from the Corporate Nursing Team have been supporting the Midwifery Team. *The CHC have produced a report on Access to GP services although the response was low. The health board is required to collect the view of 3,500 patients. When will this information be available?* The Director of Nursing and Midwifery undertook to confirm when this information would be available. **Action: Director of Nursing and Midwifery** The considerable number of appendices was noted, and a high level summary requested.

	The inclusion of the Welsh Health Specialised Services Committee (WHSSC) Quality and Patient Safety Committee (QPSC) Chairs Report was noted but the timeliness of this information questioned. The Chair and Director of Nursing and Midwifery undertook to investigate how best to report on the activity of QPSC. **Action: Chair and Director of Nursing and Midwifery** The Integrated Quality Report was DISCUSSED and ASSURANCE was taken from the information provided within the report.
PEQS/22/79	**CLINICAL AUDIT PROGRAMME 2023-24** The Assistant Director – Innovation and Improvement presented the Clinical Audit Programme 2023-24 acknowledging there were a large number of audits with some items likely to be moved allowing for others to be prioritised, within the Clinical Audit Plan to be monitored via service group dashboards. *Is the intention of this audits to drive improvements or identify gaps?* There is a dual purpose for clinical audits both to identify gaps and also as one of a range of improvement tools, none of which are utilised in isolation. *Where are clinical audits cross referenced to risk?* The audit programme is co-produced with service managers who are mindful of the risks in their area. *Are the number of audits proposed proportionate to the service area? How is proportionality assessed?* Proportionality is difficult to assess. A number of audits have to be done for compliance, others are identified as a result of concerns or risks. Many audits will move into the dashboards when they are implemented but there will still be a requirement for certain audits. When health professionals are re-evaluated the ability to demonstrate involvement with an audit is of assistance in the re-evaluation process.

	How will moving to the dashboard improve the process? The dashboards will enable data to be interrogated in real time for those people who need to have easy access to it, to enable decisions to be taken. *The Director of Corporate Governance joined the meeting.* Dashboards are a key tool for managing data in relation to the Duty of Quality. There are expensive digital tools available, but the team are working with digital colleagues to develop dashboards using existing software. The implementation of the Duty of Quality is an opportunity to look at a total quality management system. The Chair suggested the total quality management system could be included within the Board Development session on the Quality and Engagement Act in April 2023. **Action: Director of Nursing and Midwifery**
PEQS/22/80	**ANNUAL REPORT OF THE ACCOUNTABLE OFFICER FOR CONTROLLED DRUGS** The Chief Pharmacist presented the Second Annual Report of the Controlled Drugs Accountable Officer and drew attention to a slight decrease in reporting of incidents (although it was noted that there had been three Controlled Drugs Local Intelligence Network meetings during this period rather than four in the previous reporting period); the increased number of individuals authorised to witness the destruction of controlled drugs, and corresponding improvement in response times to destruction requests; and the need to undertake training with the commission of an e-learning modules 'reducing opioid prescribing in chronic pain' for primary care clinicians. The plans for the next 12 months were outlined including raising awareness of the role and responsibilities of the CDAO across the organisation, ensuring that a full suite of SOPs are in place, ensuring that declarations are received from all primary care clinicians and ensuring that a full self-assessment of CD governance is carried out across the health board. The Chief Pharmacist noted that performance indicators were a starting point for discussion but that other factors such as demographics of practice needed to be considered. The performance indicators showed that the health board is

	performing relatively well compared to some other health boards for some of the indicators, when compared to English organisation, considerable scope for improvement could be seen. The reason for an increase in prescribing needed to be ascertained. The prescribing patterns for opioid patches (for those who are unable to swallow) varies considerably between prescribers. An increase in prescribing of gabapentin and pregabalin, which are difficult to come off, had also been seen. Prescribing at practice level is being monitored and targeted discussions will be held with practices where particular challenges are identified. *If an inappropriate level of prescribing is being observed, what are the alternatives?* The Chief Pharmacist noted self help tool kits are available and are being promoted to support patients suffering from chronic pain. The Paint Toolkit was created by a clinician who suffered from chronic pain. Such toolkits are helpful in managing patient expectation and supporting them to understand that it may not be possible to be pain free. The Director of Therapies and Health Sciences confirmed there was a well-established pain service in the health board. was a well-established pain service in the health board. Although it was noted that the health board does not currently commission a service to support patients who are addicted to prescription medicines. *Why is the difference in prescribing in Cardiff and Vale, and in England so stark?* The Chief Pharmacist confirmed that it was necessary to look at the demographics of each health board. England had recently had a large focus on reducing opioid prescribing which might explain the differences. Prescribing information was provided to surgeries in September and the data within this report dates from November, therefore surgeries have only had a short time to start to address this. The service will continue to draw this to the attention of the surgeries with the intention that prescribing patterns will improve.

	How do prescription opioid dependent patients link with specialist services for addiction, given these prescribed medications and not illegal? The Assistant Director for Mental Health advised the service were running a pilot for a new treatment which had advantages over the methadone approach although was more expensive. There was an additional challenge with the easy availability of opiates online. The Chief Pharmacist advised that services had not been commissioned for prescription addiction as patients did not see themselves as addicted. Co-production of addiction services was known to encourage engagement and there is a complex pathway to work with addicts on their addictions and reasons for addiction. The Committee took ASSURANCE from the update provided and noted the work to be undertaken. The Third Annual Report from the Accountable Officer for Controlled Drugs would be brought to Committee in February 2024.
PEQS/22/81	**NATIONAL COMMISSIONING FUNCTIONS REVIEW** The Director of Corporate Governance presented a letter from the NHS Wales/Welsh Government Director General together with the Terms of Reference for the National Commissioning Functions Review. The review had been delayed by the pandemic but was now expected to report by April 2023. The following comments were made in respect of the Terms of Reference: • the disparity between services provided in Wales and England is stark and of particular issue to Powys Teaching Health Board; • how does the health board gain assurance on commissioned services – the Chair's Report from the WHSSC Quality and Safety Committee is too brief and out of date to be of value; and • how is the balance struck between spending a significant amount of money on a small number of patients. The Director of Corporate Governance advised the outcome of the report would be brought back to the Committee at the appropriate time. **Action: Director of Corporate Governance**

ITEMS FOR DISCUSSION	
PEQS/22/82	**MENTAL HEALTH SERVICES - 111 PRESS 2 PROJECT** The Assistant Director – Mental Health and Service Manager – Adult Mental Health gave a presentation on the new NHS service 111 press 2 for urgent mental health support. Funding from Welsh Government had initially been provided on a population percentage basis; however, this was insufficient to provide the service required and further funding had been made available. The service will initially run until midnight with 2 members of staff, and then with 1 member of staff in the early hours. Out of Hours will be operated from Velindre Ward where there is support to hand. Recruitment and training are ongoing and arrangements for support for cross border patients now agreed. A 12 week peer review will be undertaken. *Could the results of the 12 week review be brought to Committee?* **Action: Director of Primary, Community Care and MH.** The Committee NOTED the update on the 111p2 service.
ESCALATED ITEMS	
PEQS/22/83	There were no escalated items
ITEMS FOR INFORMATION	
PEQS/22/84	**CHILD PRACTICE REVIEW** The Director of Nursing and Midwifery advised the Committee of the sad case of 16 year old Kaylea Titford, who had died unexpectedly in October 2022. Her father had been found guilty of gross negligence manslaughter by causing of allowing the death of a child, her mother had admitted the same offence. The Committee acknowledged Kaylea's life and the sad events that had led to her death.

	Now the criminal proceedings had concluded a Child Practice Review would take place involving colleagues from the police, local authority, health board and other stakeholders. The Chair requested an update from the Safeguarding Group to outline the actions already taken, and that the Child Practice Review be brought to the Committee in due course. **Action: Director of Nursing and Midwifery**
OTHER MATTERS	
PEQS/22/85	**COMMITTEE RISK REGISTER** The Director of Corporate Governance presented the Committee Risk Register noting the risk had changed in relation to the imminent introduction of the Quality and Engagement Act and consequent move from the Health and Care Standards to the Quality Standards. The risk was wide ranging, and work would be undertaken with the Director of Nursing and Midwifery to ascertain the appropriateness of splitting the risk. The Committee: • CONSIDERED the corporate risks within the committee's remit, • DISCUSSED any relevant issues; and • took ASSURANCE that risks were being managed in line with the Risk Management Framework.
PEQS/22/86	**DEVELOPMENT OF COMMITTEE ANNUAL PROGRAMME BUSINESS 23/24** The Director of Corporate Governance presented the development of the Committee Annual Programme report and key points were highlighted to committee which included: • delivery of 2022/23 Annual Programme of Business; • committee terms of reference; • feedback from committees (discussions and performance review); and • feedback from the Board The Director of Nursing and Midwifery welcomed the introduction of a Chair's Group to look across committees, in

	particular in relation to the introduction of the Duty of Quality. The Development of the Committee Annual Programme of Business 2023-24 was NOTED.
PEQS/22/87	**TERMS OF REFERENCE FOR POWER OF DISCHARGE GROUP** The Chair presented the Terms of Reference for the Power of Discharge Group. The Committee AGREED the Terms of Reference for the Power of Discharge Group.
PEQS/22/88	**ITEMS TO BE BROUGHT TO THE ATTENTION OF THE BOARD AND/OR OTHER COMMITTEES** The Chair noted that the matters discussed would be included in the Chair's Report to Board.
PEQS/22/89	**ANY OTHER URGENT BUSINESS** There was no other urgent business.
PEQS/22/90	**DATE OF THE NEXT MEETING** 25 April 2023, via Microsoft Teams.

RAG Status:

At risk	Red - action date passed or revised date needed
On track	Yellow - action on target to be completed by agreed/revised date
Completed	Green - action complete
No longer needed	Blue - action to be removed and/or replaced by new action
Transferred	Grey - Transferred to another group

Meeting Date	Item Reference	Lead	Meeting Item Title	Details of Action	Update on Progress	Original target date	Revised Target Date	RAG status
Patient Experience, Quality and Safety Committee								
OPEN ACTIONS FOR REVIEW								
02-Dec-21	PEQS/21/29	DOCC&MH	Audit Wales Review: PTHB Quality Governance Arrangements	Next Quality Report to include details of actions taken as a result of staff survey	**25.04.23 update** - This is a longstanding action, proposed to agenda a report at the July meeting to provide an update against the actions taken		Jul-23	At risk
24-Nov-22	PEQS/22/63	DNM	Patient Experience Approach	Patient Experience Approach to be reconsidered at Executive Committee and an update be provided to PEQS	**25.04.23 update** - This has been moved from Director of Therapies and Health Sciences to Director of Nursing and Midwifery who is reviewing the new function		Jul-23	At risk
24-Nov-22	PEQS/22/62	Chair	Safeguarding Annual Report	Implementation of Liberty Protection Safeguards to be considered for Committee or Committee Development work programme	**25.04.23 update** - This action is no longer required as the UK Government have confirmed their intention to step away from the Liberty Protection Safeguards (https://www.gov.wales/written-statement-update-implementation-liberty-protection-safeguards)			No longer needed
OPEN ACTIONS - IN PROGRESS BUT NOT YET DUE								
13/09/2022 and 24 Nov 2022	PEQS/22/51 and PEQS IC/22/73	DOCC&MH	Mental Health Services	A further report on Mental Health Services to be brought to the December 2022 Committee meeting	**25.04.23 update** - This item has been rescheduled due to changes in staff structures	Dec-22	Jul-23	On track
24-Nov-22	PEQS/22/59	MD	Clinical Audit Progress and Learning	Revise the Terms and Reference of the Learning Group to reflect changes in reporting of National Audits	**25.04.23 update** - The Terms of Reference have been revised and will be considered for approval at the next Learning Development Meeting	Jul-23		On track
31-Jan-23	ARA/22/109	DNM	LOSSES AND SPECIAL PAYMENTS UPDATE REPORT (transferred from Audit Committee)	Trends and lessons learnt from rebutting negligence claims to be included in the Integrated Quality Report to the Patient Experience, Quality and Safety Committee	**25.04.23 update** - Action has been reviewed and given the low number of claims, data could become individually identifiable. DCN to reconsider how to achieve the action and report back	Oct-23		On track
23-Feb-23	PEQS/22/81	DCG	National Commissioning Functions Review	The Report of the National Commissioning Functions Review be brought back to Committee at the appropriate time	**25.04.23 update** - Added to work programme, date to be confirmed			On track
23-Feb-23	PEQS/22/82	DOCC&MH	Mental Health Services 111 press 2 project	The 12 week review into NHS 111press2 to be brought to Committee	**25.04.23 update** - Added to work programme	Sep-23		On track
23-Feb-23	PEQS/22/84b	DNM	Child Practice Review	Child Practice Review to be brought back to Committee	**25.04.23 update** - Added to work programme, date to be confirmed			On track
ACTIONS RECOMMENDED FOR CLOSURE (MEETING 24 April 2023)								
02-Dec-21	PEQS/21/32	DCG	Mental Health Act Compliance Report, including a report of the Power of Discharge Sub-Group	Requests for training to be considered as part of Board Development Programme	**25.04.23 update -** The request have been added to the draft Board Development programme for 2023/24 and therefore closed on that basis.			Completed

07-Jul-22	PEQS/22/31	DCG	Corporate Risk Register - Risks overseen by this Committee	Discussion on development of risk register at future meeting of PEQS	**25.04.23 update** - The Committee has considered risk at each of its meetings, the CRR will be updated to reflect the 2023/24 delivery plan and as such the Committee will have an opportunity for further review at its next meeting in July.			Completed
23-Feb-23	PEQS/22/78a	DNM	Integrated Quality Report	Confirm how the readiness for implementation of the Quality and Engagement Act will be reported to Committee	**25.04.23 update** - Presentation is scheduled onto the agenda for 25 April 2023			Completed
23-Feb-23	PEQS/22/78b	DNM	Integrated Quality Report	Advise when the health board collect the views of patients on Access to Services	**25.04.23 update** - Themes and trendas from complaints identified Access to Services and from May 2023 we will proactively seeking views of patients using commissioned services as well as specific areas of provider services.			Completed
23-Feb-23	PEQS/22/78c	DNM & Chair	Integrated Quality Report	Chair and Director of Nursing and Midwifery to ascertain how best to report the activity of the QPSC	**25.04.23 updat**e - Agenda item now included on each PEQs agenda			Completed
23-Feb-23	PEQS/22/79	DNM	Clinical Audit Programme 2023-24	The Board Development session in April 2023 to include a session on the Total Quality Management System	**25.04.23 update** - Quality and Engagement Act held with Board in March and information tools subsequently shared with Board members. Future session added to the draft Board Development Programme on Total Quality Management System	Apr-23		Completed

Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Agenda item: 2.1

Patient Experience and Quality Committee	**25 April 2023**
Subject:	**Integrated Quality Report**
Approved and Presented by:	Claire Roche, Executive Director of Nursing & Midwifery
Presented by	Claire Roche, Executive Director of Nursing & Midwifery
Prepared by:	Zoe Ashman, Assistant Director Quality & Safety
Other Committees and meetings considered at:	Executive Committee (via email)

PURPOSE:

The purpose of this report is to provide the Patient Experience and Quality Committee with an overview of the Quality & Safety agenda across the Health Board.

RECOMMENDATION(S):

The Patient Experience and Quality Committee are asked to take assurance that Quality and Safety is appropriately monitored and reported and that continued actions are in place to further develop quality and safety monitoring and reporting.

Approval/Ratification/Decision[i]	**Discussion**	**Information**
✖	✓	✓

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):		
Strategic Objectives:	1. Focus on Wellbeing	×
	2. Provide Early Help and Support	×
	3. Tackle the Big Four	×
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	×
	6. Promote Innovative Environments	×
	7. Put Digital First	×
	8. Transforming in Partnership	×
Health and Care Standards:	1. Staying Healthy	×
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	×
	8. Governance, Leadership & Accountability	✓

ACRONYMS	
PTUHB	Powys Teaching Health Board
NRI	Nationally Reportable Incidents
PTR	Putting Things Right
PSOW	Public Service Ombudsman Wales
PCC	Powys County Council
HM Coroner	Her Majesty's Coroner
PREM's	Patient Reported Experience measures
PROM's	Patient Reported Outcome Measures
GMPI	General Medicine Practice Indemnity
WRP	Welsh Risk Pool

DETAILED BACKGROUND AND ASSESSMENT:

1 Background

The purpose of this report is to provide the Patient Experience and Quality Committee with an update on the quality and safety agenda for Powys Teaching Health Board (PTHB).

2 Specific matters for consideration by this meeting (Assessment)

2.1 Quality & Engagement Act (2023) Implementation

The Health and Social Care (Quality and Engagement) (Wales) Act ('the Act') became law on 1 June 2020 and full implementation commenced on 1 April 2023.

Welsh Government published the response to the Duty of Candour consultation which informed the final guidance and Ministerial approval (Appendix 1).

A supporting presentation to Committee outlining the implementation of the Act along with the health board position (Appendix 2) will be provided and discussed at Committee at the Committee meeting on the 25 April 2023. The Act will:

- strengthen the existing duty of quality on NHS bodies and extend this to the Welsh Ministers in relation to their health service functions.
- establish an organisational duty of candour on providers of NHS services, requiring them to be open and honest with patients and service users when things go wrong.
- strengthen the voice of citizens, by replacing Community Health Councils with a new all-Wales Citizen Voice Body that will represent the interests of people across health and social care.

2.2 Once for Wales Content Management System (RLDatix)

The implementation of the Once for Wales Content Management System (OFWCMS) is complete. However, this excludes the final risk module as this has been delayed for implementation due to the national work required. This has been further delayed to late spring 2023.

Robust reporting with the support of dashboards populated from RLDatix have been realised and shared across services. This not only supports the robust implementation of the Health and Social Care (Quality and Engagement) (Wales) Act, (1 June 2020), but also proactive and timely incident management and organisational learning.

A new incident management Framework is being developed to align with the updated NHS executive guidance for the management of Nationally Reportable Incident (NRI), along with local robust management of incidents from end to end.

2.3 Supporting learning and improvement

The Learning & Development group is supported by all Clinical Directors and their teams. There is collective agreement within the membership that this structure will be supported by the incident management process, facilitating the implementation of a total quality

management system, as described in the Quality and Engagement Act. This forum will be a key enabler to the reporting and monitoring process further supported by the implementation of the Incident Management Framework.

Safe Care Collaborative

The Safe Care Collaborative is part of the Safe Care Partnership, which is a collaboration between NHS Wales health boards and trusts, Improvement Cymru and the Institute for Healthcare Improvement (IHI).

The partnership's aim is to coach and support health boards and trusts to improve the quality and safety of care across their systems. The Safe Care Collaborative creates a learning system where organisations test and measure practice innovations and share their experiences to accelerate learning and widespread implementation of best practices for safe care. It brings together teams, coaches, executives, and senior leaders for safety from across all the health boards and trusts in Wales to focus on a common aim.

At organisational level an aim of this work is to achieve a locally owned and managed safety programme with the infrastructure to support a sustainable learning system that will work towards achieving results at scale.

In partnership, Improvement Cymru and Institute for Healthcare Improvement (IHI) have implemented a program that builds on Improvement Cymru's bold commitment to improve patient safety and achieve the following objectives:

- Support the creation and progress of patient safety improvement projects across all health boards and trusts in Wales.
- Demonstrate improvement in key safety metrics and/or reduction in patient safety harms in health boards or trusts.
- Strengthen improvement capability within the teams being supported by the collaborative.
- Provide a once for Wales approach that seeks to create the culture and conditions for patient safety and to reduce avoidable harm and unnecessary variation across the whole system.
- Share good practice and accelerate knowledge mobilisation to enable improvements in quality and safety at pace and scale across NHS Wales. With the overall aim of achieving and sustaining safer care for patients and populations in a range of care settings across NHS Wales, the Safe Care Collaborative will support health boards and trusts between November 2022 and February 2024. The structure of an Improvement Collaborative.

An Improvement Collaborative is a systematic approach to health care, quality and improvement. Organisations and providers of care will test, measure and practice innovations and share their experiences. This will accelerate learning and achieve widespread implementation of best practice. The Safe Care Collaborative will aim to demonstrate significant improvements and performance by focusing on the following four work stream areas:

1. Leadership for patient safety improvement
2. Safe and effective community care
3. Safe and effective ambulatory care
4. Safe and effective acute care.

This results-focused safety collaborative will be co-designed and co-delivered by Improvement Cymru and IHI, bringing together teams, coaches, executive and senior leaders for safety from across all health boards and trusts. It will align the work of the safety leadership network with teams and coaches engaged in improvement work on identified safety priorities. Demonstrating what is possible through content specific prototyping and delivery of early results, preparation, and planning for spread and scale can be executed beyond the initial phase of the work. This initial phase of collaborative learning is intended to establish learning systems locally and nationally. Building relationships and networks that will ensure an all-Wales approach to improvement and achieve safe reliable and effective health care. Leaders and teams who participate will support the delivery of local leadership plans for the infrastructure to achieve a reliable system for safety and quality. The collaborative offers in-person learning sessions and action period coaching which has proven to be an exceptional foundational tool to creating long-term success. This method can help care settings accelerate work that is already underway and plan for meaningful progress over time. However, it is important to note that the work of genuinely transforming patient experience is a multi-year process.

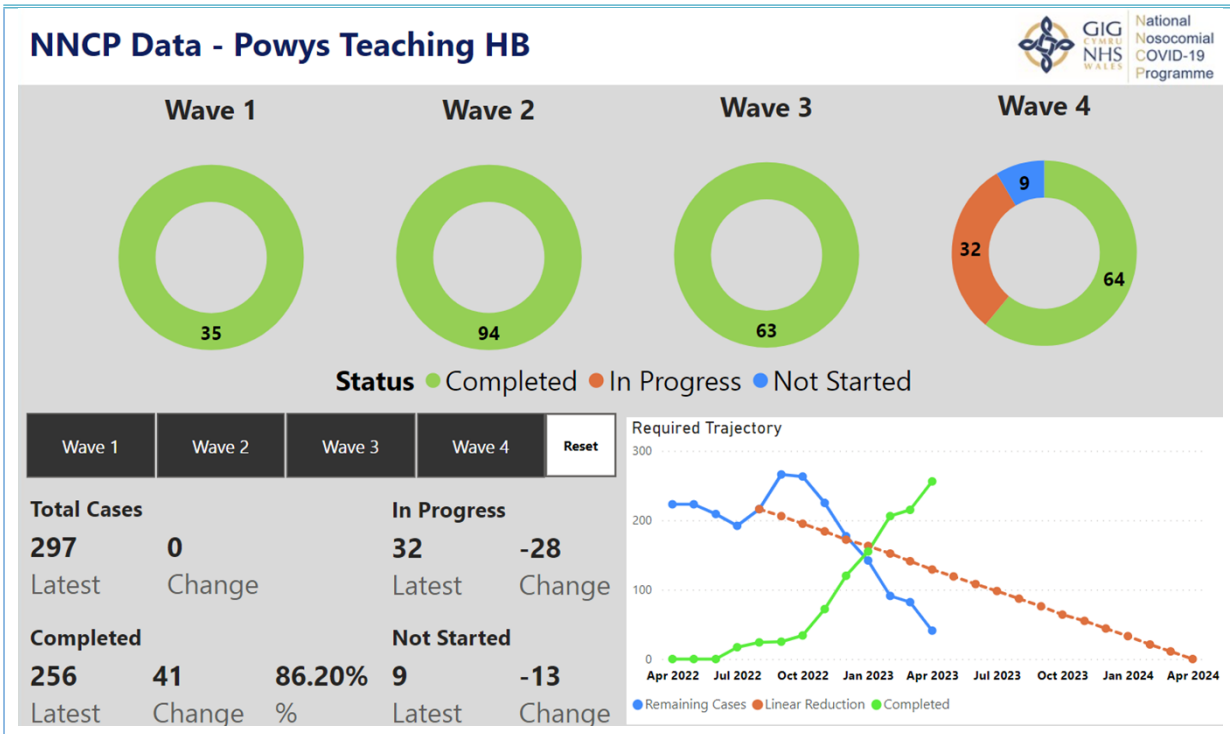
The health board have outlined 4 projects to be aligned to the Safe Care Collaborative:

- Effective discharge planning
- Reduction of people not attending appointments (DNAs)
- Repatriation of Continuous Positive Airway Pressure (CPAP) to Powys
- Introduction of Frailty assessment and scoring

2.4 National Nosocomial Framework

In March 2021, the Framework into the 'Management of patient safety incidents following nosocomial transmission of COVID-19' was published. Any hospital acquired infection, including COVID-19, is considered a patient safety incident and therefore the provisions of the Putting Things Right Regulations (PTR) apply.

Progress is demonstrated in data capture below as monitored by the programme.
Data updated 04/04/23



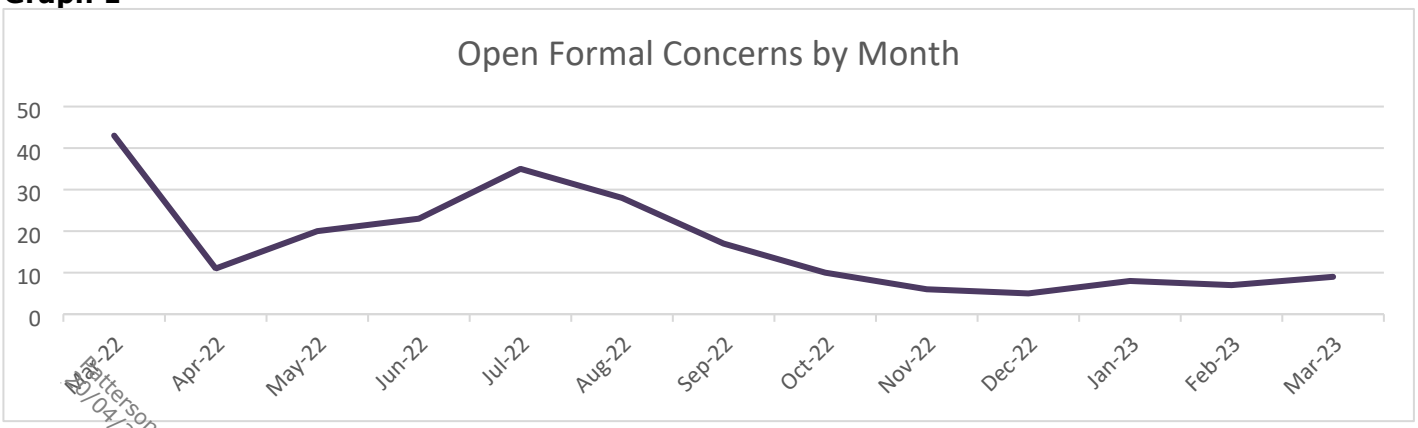
The graph demonstrates that the Health Board has progressed the pace of the programme significantly during Q4 2022/23 with completion anticipated during Q2 2023/24.

National Nosocomial Covid-19 Programme produced an end of year one Interim Learning Report during March 2023 **(Appendix 3)**.

2.5 Putting Things Right – Concerns

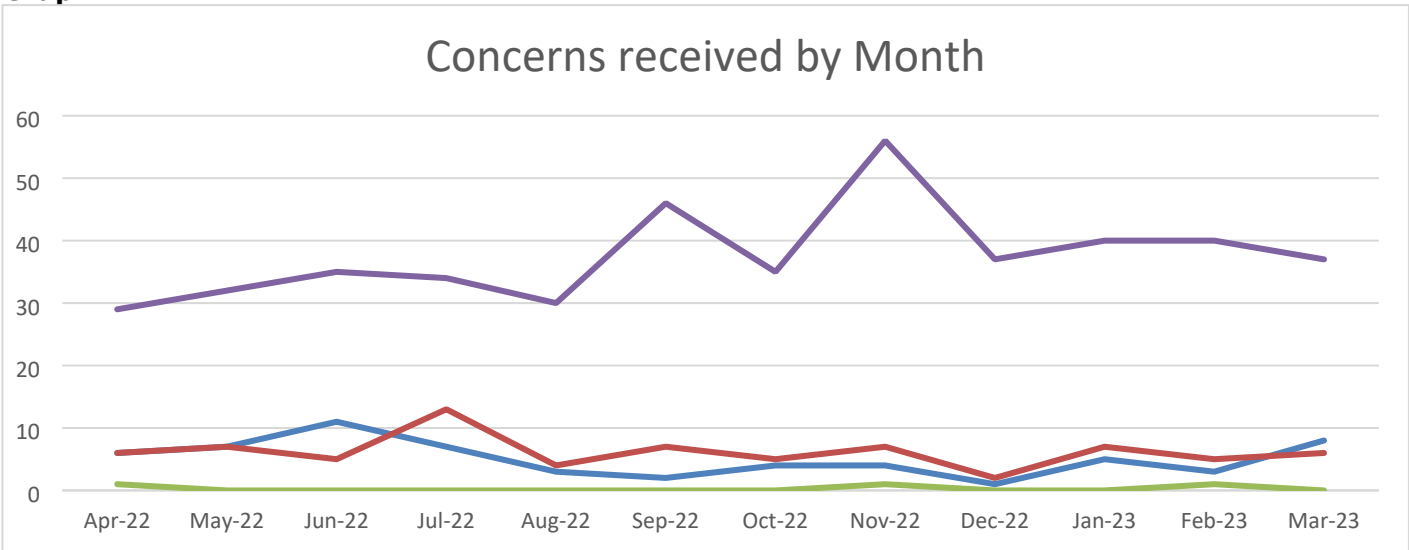
The management of concerns improved significantly during 2022/23 to ensure that concerns that require a formal response are managed appropriately with the required investigation. Those that are best managed proactively as early resolutions/enquiries in line with regulations support a prompt resolution for individuals. The number of open concerns has reduced during 2022/23 due to the improvements made, this improvement has been sustained during Q3 & Q4 as demonstrated in Graph 1 below.

Graph 1



Graph 2 demonstrates the number of new formal concerns along with early resolution and enquiries open by month.

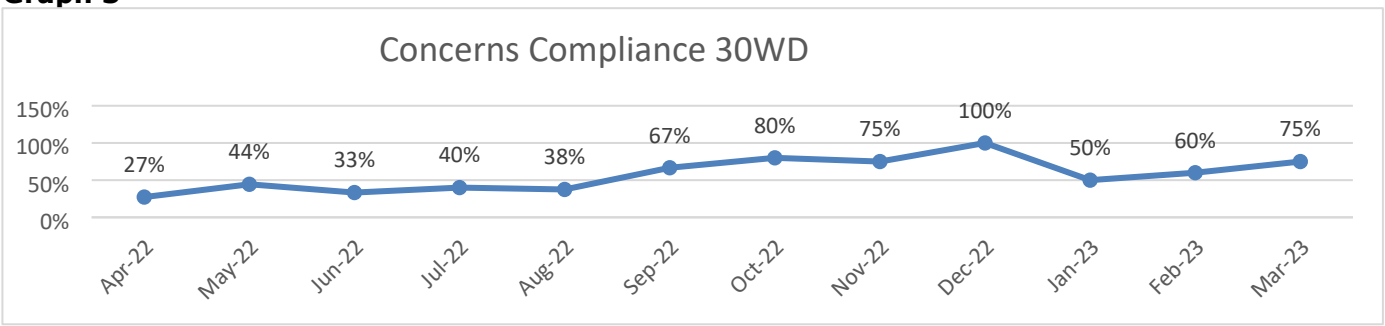
Graph 2



Source: Incidents Module OFWCMS RLDatix system

Significant progress has been made with the management and compliance of formal concerns within 30wd response time (Graph 3).

Graph 3



Source: Incidents Module OFWCMS RLDatix system

The top 3 themes of formal concerns are:

- Access to services, clinical treatment/ assessment
- Complexity of care due to commissioning arrangements and pathways of care
- Delays: Patients waiting longer than expected for appointments, delay in discharge, delay in transfer.

2.6 Public Service Ombudsman for Wales (PSOW)

The Health Board position for 2021/22 with complaints escalated to the PSOW is as below:

Voluntary Settlement	Not Investigated	Upheld	Total
17% (n1)	50% (n3)	33% (n2)	6

Our current position as of 3rd January 2023 is as follows:

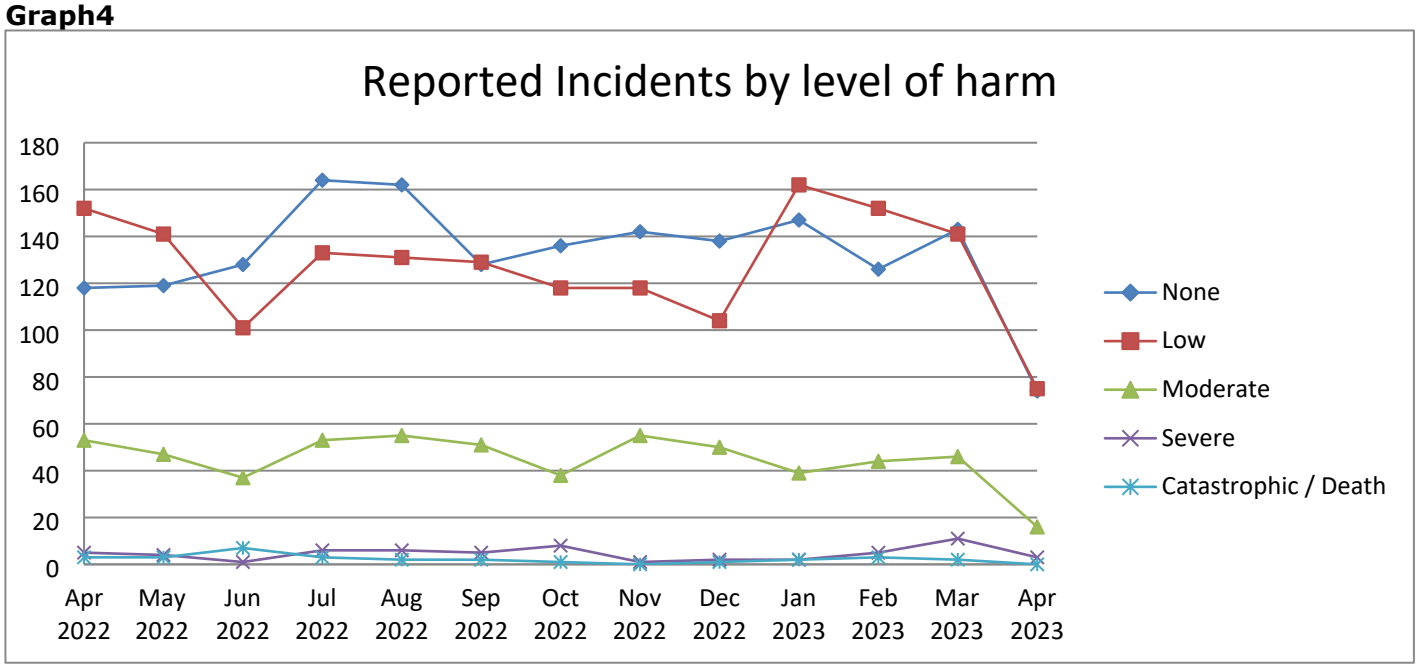
Open Enquiry	Not Upheld	Partially Upheld	Advice Given	Total
3	15	1	2	22

2.7 Incident Management

The number of incidents reported is stable **(Graph 4)** and appropriate with most incidents reported within the Low and No Harm classification.

It must also be recognised that the number of moderate harm incidents has reduced which may be attributed to the increased education and training regarding the classification of harm and incident management.

Graph4



Internal audit has completed their review of the management of incidents (Appendix 7) which has outlined areas for improvement, these actions will be realised with the implementation of the incident Management Framework. The report outcome gave reasonable assurance to the current systems and processes in place.

The highest reported incident themes during Q4:

- Pressure or moisture damage
  Action: All grade 3 pressure ulcers and above are reviewed through the multidisciplinary scrutiny panel process for wider organisational learning and improvement.

- Slip, trip or fall
  Action: Fall's scrutiny panel has commenced during Q3 to assess the themes and trends of falls to inform improvements required within the falls framework. This work will be further supported through the Safe Care Collaborative quality improvement project guided by Improvement Cymru & IHI.

- Behaviour (including violence & aggression) (n91)
  Action: Deep dive to review themes and trends of reporting by the Head of Quality & Safety

2.11 Early Warning Notifications (previously No surprises notifications)

No Early Warning Notifications have been submitted during Q4 2022/23.

2.12 Nationally Reportable Incidents

The current position for open Nationally Reportable Incidents (NRI's) is reported in the table below.

Reported period	Number open in time	Number open overdue	Number awaiting final approval	Closed	Total
Q1	**6**	**0**	**11**	**0**	**16**
Q2	**4**	**2**	**3**	**8**	**17**
Q3	**2**	**5**	**2**	**0**	**9**
Q4	**2**	**4**	**1**	**1**	**8**

The themes for learning and improvement include:
- Standards of record keeping
- Clinical Guidelines not followed or not present.
- Complex pathway of care

3. Patient Experience

Implementation of the Civica patient feedback system has progressed at pace during Q3 & Q4 with engagement from all services across the health board. For noting during this reporting period:

- 35 feedback questionnaires are available within the system, from a range of services inclusive of maternity services, therapies and Your NHS Experience (all Wales).

- The NHS experience questionnaire had a soft launch in December 2022 which was supported by the PTHB social media platforms and health board website in January 2023. 25 responses have been received during Q4, which demonstrated a high level of satisfaction within this small cohort.

Patient stories continue to be obtained which is currently supported by the Welsh language team. Opportunities are being taken to increase the profile of sharing patient stories from across the population.

Due to no additional resource in place to support the implementation of the CIVICA system it must be noted that pace and scale is impacted. The Quality & Safety team members are supporting implementation, but the support is limited and restricting use of the system to its full potential.

Opportunities will be taken during 2023/24 to proactively seek patients feedback by attending the clinical areas and outpatients clinics.

4.1 Inquests

During Q3 there have been <5 HM Coroner enquiries opened, <5 case closed with 16 remaining open.

5. Health and Social Care Inspections Regulatory Recommendations

5.1 Health Inspectorate Wales Inspections

The following unannounced HIW inspections have taken place in January and February 2023:

- Claerwen Ward, Llandrindod Wells Hospital, 17 and 18 January, final report has been received by the health board and action plan submitted for approval (Appendix 4)
- Tawe Ward at Ystradgynlais Hospital, 9-11 January 2023, final report received by the health board and action plan submitted (Appendix 5)
- HIW inspection of Community Mental Health Team (Bryntirion) was undertaken on 14 and 15 February 2023.

5.2 Health and Social Care Regulatory Reports

2 actions remain outstanding 2017-2020. Updates against these are provided below:

HIW Review of Healthcare Services for Young People	Health boards must ensure that children and young people can consistently be treated within designated areas.	Discussion on adult OPD environment with scheduled care managers held, consideration given to move some OPD clinics to children's centres- currently being reviewed re capacity and staffing.

HIW Review of Healthcare Services for Young People	Health boards must ensure there are robust systems to monitor transition policies and pathways across healthcare services to ensure approaches are effective.	Benchmarking against "let me flourish" report 2021 is being undertaken by the Startwell Complex Needs workstream in addition to this being progressed through PTHB transition guidance group

6 KEY MATTERS FOR BOARD/COMMITTEE

6.1 Timely management of incidents is required to ensure appropriate action is taken. **ACTION taken:** Managers and those responsible for managing incidents have been provided with RCA training to manage incidents effectively and in a timely manner. Implementation of the Incident Management Framework will further support the timely and robust management of incidents.

6.2 Limitations to the capability of the CIVICA system due to no additional resource aligned to drive the agenda across the health board. **ACTION taken:** Quality & Safety Team members are being utilised to support the use of the CIVICA system within teams and services, encouraging local service level champions is being considered.

Appendix 1: Duty of Candour: • **Consultation Report** • **Statutory Guidance (x2)**	(NB 2.1a is confidential draft restricted access to Committee Members) **Welsh translation is not yet available for Consultation report**
Appendix 2: Duty of Quality: • **Duty of Quality Statutory Guidance** • **Canllawiau Statudol y Ddyletsw**	
Appendix 3: National Nosocomial Programme; Interim Learning Report: • **Communications Toolkit**	
Appendix 4: HIW Inspection Report, Claerwen Ward	
Appendix 5: HIW Inspection Report, Tawe Ward	
Appendix 6: WRP National Review – Consent to Examination & Treatment	
Appendix 7: WHSSC Quality & Patient Safety Chairs report	Please see item 2.2 of agenda
Appendix 8: Incident Management Final Audit Report	

The following Impact Assessment must be completed for all reports requesting Approval, Ratification or Decision, in-line with the Health Board's Equality Impact Assessment Policy (HR075):

IMPACT ASSESSMENT					
Equality Act 2010, Protected Characteristics:					
	No impact	**Adverse**	**Differential**	**Positive**	**Statement** ***Please provide supporting narrative for any adverse, differential or positive impact that may arise from a decision being taken***
Age	√				
Disability	√				
Gender reassignment	√				
Pregnancy and maternity	√				
Race	√				
Religion/ Belief	√				
Sex	√				
Sexual Orientation	√				
Marriage and civil partnership	√				
Welsh Language	√				
Risk Assessment:					
	Level of risk identified				**Statement** Reputational risk if no improved compliance with Welsh Government performance for management of concerns.
	None	**Low**	**Moderate**	**High**	
Clinical	√				
Financial	√				
Corporate	√				
Operational	√				
Reputational			√		

WG23-09

The Duty of Candour Statutory Guidance 2023

The Health and Social Care (Quality and Engagement) (Wales) Act 2020

Date of issue: 1 April 2023

CONTENTS

GLOSSARY

Interpretation, in this guidance:

- the 2006 Act, means the National Health Service (Wales) Act 2006.
- the 2011 Regulations, means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- the Act means the Health and Social Care (Quality and Engagement) (Wales) Act 2020.
- apology, means an expression of sorrow or regret in respect of the notifiable adverse outcome.
- candour procedure means the procedure set out in the Candour Procedure Regulations that an NHS body must follow in relation to a notifiable adverse outcome.
- Candour Procedure Regulations means The Duty of Candour Procedure (Wales) Regulations 2023.
- Harm includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child.
- health care, means services provided in Wales under or by virtue of the 2006 Act for or in connection with—
    - (a) the prevention, diagnosis or treatment of illness.
    - (b) the promotion and protection of public health.
- illness, has the meaning given in section 206 of the 2006 Act.
- NHS body means—
    - (a) a Local Health Board.
    - (b) an NHS Trust.
    - (c) a Special Health Authority.
    - (d) a primary care provider.

- notifiable adverse outcome occurs when the duty of candour comes into effect in accordance with section 3 of the Act.
- service user, means a person, to whom health care is being or has been provided by an NHS body, who has suffered an adverse outcome.
- Special Health Authority means a body established under section 22 of the 2006 Act; but does not include any cross-border Special Health Authority (within the meaning of section 8A (5) of the 2006 Act) other than NHS Blood and Transplant.
- A person is a primary care provider in so far as (and only in so far as) the person provides health care on behalf of a Local Health Board by virtue of a contract, agreement or arrangement under Part 4, 5, 6 or 7 of the 2006 Act between the person and the Local Health Board.
- A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is more than minimal.

- Review: a review is the clarification of the incident that has been reported and an assessment as to the level of harm that has occurred or could occur to the individual service user by a senior member of staff to assess whether the threshold for triggering the duty of candour has been met. This is sometimes referred to as approving the incident.
- Investigation: the in-depth examination (additional enquiries as listed in the Candour regulations) undertaken to understand what has occurred and any root causes and learning as outlined in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- For the purposes of this guidance and making the links with the Candour Procedure Regulations the term service user/person acting on their behalf is referred to in the Regulations as the 'relevant person.' NHS body is referred to in the Regulations as the 'responsible body.'
- Datix Cymru is a reporting and management digital platform for incidents and concerns and part of the Once for Wales Concerns Management System Programme, which includes Datix Cymru and CIVICA Experience Wales.

FOREWORD

The introduction of the duty of candour through the Health and Social Care (Quality and Engagement) (Wales) Act 2020[1] ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services. The duty is placed on NHS Bodies (Health Boards, NHS Trusts, Welsh Special Health Authorities and NHS Blood and Transplant in relation to their Welsh functions) and on primary care providers in Wales in respect of services they provide under a contract or other arrangements with a Local Health Board.

The focus of the duty in the Act is ultimately to serve service users by ensuring that if the service user experiences, or if the circumstances are such that the service user could experience, any unexpected or unintended harm that is more than minimal, and the provision of health care was or may have been a factor, the service user, (or person acting on their behalf), is informed, provided with an apology and offered details of relevant services or support. The NHS body is also required to provide the service user/or person acting on their behalf with an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate the circumstances of the notifiable adverse outcome, including any actions to be taken under the Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011[2].

[1] Health and Social Care (Quality and Engagement) (Wales) Act 2020 https://www.legislation.gov.uk/asc/2020/1/contents

[2] The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 https://www.legislation.gov.uk/wsi/2011/704/contents/made

Wales is not the only UK jurisdiction to have a duty of candour. In England, the duty is set out at Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014[3]. In Scotland, it is set out in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016[4].

Our overarching policy objective, in line with our aspirations in a Healthier Wales[5] for more integrated care, is to ensure that whether a person receives care from the NHS, or from a regulated provider of health care services, that person can be assured that they will be dealt with in an open and honest way by their care provider.

In social care, a duty of candour already exists for providers and responsible individuals of regulated services under the 2017 Regulations[6].

Separate work is being taken forward to make Regulations to place a duty of candour on providers of independent health care in Wales, using powers under the Care Standards Act 2000[7]. We have enjoyed incredibly positive engagement with representatives of the independent health care sector in Wales and it is intended to collaborate with them to introduce a duty of candour that applies to the independent health care sector in Wales, with a projected coming into force date of April 2024.

We know the overwhelming majority of providers of health care services, want to deliver high quality, safe and compassionate care. However, equally, we know that despite these intentions, inevitably in complex and multi-faceted services, from time to time, people will suffer harm.

When they do, the way in which NHS Bodies, deal with these situations becomes especially important and can make an enormous difference to people's experience and to their ongoing relationship with their care provider. This is particularly important in health care settings where people often have long standing relationships with their care providers. Trust is hard to gain, but easy to lose. Being open and honest should be at the heart of every relationship between those providing, receiving and/or experiencing treatment and care.

[3] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2008/2936). https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20

[4]Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 https://www.legislation.gov.uk/asp/2016/14/contents

[4] Welsh Government 2018 A healthier Wales: long term plan for health and social care **https://gov.wales/healthier-wales-long-term-plan-health-and-social-care**

[6] Welsh Government the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 https://www.legislation.gov.uk/wsi/2017/1264/contents/made

[7] The Care Standards Act 2000 https://www.legislation.gov.uk/ukpga/2000/14/contents

1. Chapter 1 - Introduction and Purpose

Introduction

1.1 The Act will come into force on 1 April 2023. It is a lever for improving and protecting the health, care and well-being of the current and future population of Wales. It aims to ensure a stronger citizen voice and to improve the accountability of services to deliver a better experience and quality of care. Doing so contributes to a healthy and more prosperous country. In totality, the Act is intended to have a cumulative positive benefit for everyone in Wales, supporting a culture and the conditions that focus on driving improvements in health care.

1.2 This statutory guidance is aimed at helping the NHS Bodies to deliver the requirements of the duty of candour.

1.3 The legal basis for the duty is set out in Part 3 of the Act. Section 3 prescribes when the duty of candour applies. Section 4 requires the Welsh Ministers to make Regulations, which set out the procedure that NHS Bodies must follow when the duty of candour is triggered. Sections 5 to 8 prescribe the reporting requirements. These sections of the Act are considered in more detail further in the guidance.

1.4 Compliance with the duty of candour will also facilitate compliance by Local Health Boards, NHS Trusts and Special Health Authorities with:

- the duty of quality contained in section 2 of the Act, requiring Bodies to exercise their functions with a view to securing improvement in the quality of health services.
- the socio-economic duty[8] introduced by the Equality Act 2010[9], requiring Bodies to have due regard to the desirability of exercising their functions in a way that is designed to reduce the inequalities of outcome which result from socio-economic disadvantage; and
- the well-being duty within the Well-being of Future Generations Act (Wales) Act[10] 2015 to conduct sustainable development.

1.5 The duty of candour supports all people in Wales, and information about it is accessible to them. It encourages better decision making and ultimately aims to deliver better outcomes for all people who access health services. It requires NHS Bodies to involve people in decisions that affect them and to facilitate preventative action, thereby improving the quality of services and looking to the long term.

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[8] Statutory Guidance: The Equality Act 2010 (Authorities subject to a duty regarding Socio-economic Inequalities) (Wales) Regulations 2021 https://business.senedd.wales/documents/s113354/CLA5-07-21%20Paper%2023.pdf
[9] 2010 Equality Act https://www.legislation.gov.uk/ukpga/2010/15/contents
[10] Well-being of future generations (Wales) Act 2015 https://www.futuregenerations.wales/about-us/future-generations-act/

1.6 The prevailing intention is therefore to build on the work that has already been achieved through better reporting and proportionate investigation of incidents, in line with the new National Patient Safety Incident Reporting Policy[11] and the introduction of the Putting Things Right[12] process for investigating Concerns and Complaints. The move to implement a more structured organisational duty of candour that is supported by statutory guidance and the Candour Procedure Regulations supports the further development of the culture of openness within the NHS in Wales.

PURPOSE OF THE GUIDANCE

1.7 Being open with service users and their representatives when things go wrong in their care is the right thing to do. The duty of candour is designed to create a safe environment that is supportive and empowering to those providing, receiving and/or experiencing NHS treatment and care.

1.8 In this guidance the word **must** refers to actions that are a legal requirement as set out in the Candour Procedure Regulations or in Part 3 of the Act. The remainder of the guidance is designed to provide a framework of best practice to assist NHS Bodies in the implementation and application of the duty.

1.9 In accordance with section 10 of the Act, NHS Bodies must have regard to the guidance when exercising functions related to the duty of candour. To 'have regard' means that those to whom the Duty applies will have to be familiar with it and demonstrably take its principles into account when making any relevant decisions with regard to incidents or concerns relating to service user health care. Should Bodies to whom the Duty applies decide to depart from the guidance set out here, any such departure should be properly reasoned and rational and balanced against their legal obligations under the Act.

1.10 The guidance contains illustrative examples and case studies to assist NHS Bodies to understand when the duty of candour is triggered and offers step by step procedure flow charts.

1.11 It also includes guidance for NHS Bodies' on compliance with the duties placed upon them with regard to reporting, which is a key element of the duty of candour.

[11] Welsh Government, May 2021 National Patient Safety Incident Reporting Policy https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/

[12] Welsh Government 2011 putting things right Guidance on dealing with concerns about the NHS from 1 April 2011 version 3. https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/

1.12 The guidance provides the foundation for NHS Bodies to develop local policies and procedures, and training and support requirements that are tailored to the body and/or the particular services they provide and will help to achieve consistency of approach and equity of response in effect: an ‘All-Wales model’.

1.13 The guidance will be complemented by an online training package to support NHS Bodies with the implementation of the duty. Building on the work that has already been started as part of the Putting Things Right process to embed candid behaviour, the Welsh Government training programme considers how to encourage the “cultural shift” by making openness and transparency a normal part of the culture across NHS Bodies in Wales.

1.14 The guidance is also intended as a reference for service users and their representatives. Leaflets are available to ensure that everyone in our community can access materials that will empower them to ask questions about the care and services they receive, to help them understand what the duty of candour means, and what they can expect from their care providers when it is triggered.

1.15 It is not intended to be a definitive interpretation of the legislation on duty of candour. The Act, Candour Procedure Regulations and the Duty of Candour guidance should be read together.

1.16 We also recognise the Act, Regulations and the framework around it, whilst important, is only one part of the process. It is also necessary to overcome the known barriers to an open and honest culture for the duty of candour to become truly embedded. The barriers include fear, a culture of secrecy and/or blame, lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture. Disclosure can also be inhibited by fear of blame, professional or institutional repercussions, legal liability, negative reactions and a lack of accountability.

1.17 A system without artificial barriers between NHS Bodies, where care and support are person centred, where staff are supported to improve care rather than just manage or deliver it, and where there is an emphasis on accountability, will help to overcome these barriers.

2 Chapter 2 – The Application of The Duty of Candour

Statutory duty of candour and existing professional duties of candour

2.1 There have been calls to place a duty of candour[13][14][15][16] on NHS Bodies in Wales, separate from, and complementing the non-statutory duties of candour that apply to a range of healthcare professionals as part of their professional regulation. Although, it should be acknowledged that professional Duty of candour guidance applies in more situations than the Welsh organisational Duty of Candour.

2.2 Healthcare professionals who are subject to a professional duty of candour have to be open and honest with service users, colleagues, their employers and relevant organisations, and must take part in reviews and investigations when requested. They must support and encourage each other to be open and honest[17].They must also be open and honest with their regulators, raising concerns where appropriate. The fundamental principles of a duty of candour are therefore already embedded across a wide section of NHS Bodies through those professionals who work within them.

2.3 The statutory duty of candour and the professional duties of candour have the same aims – to be open and transparent with people receiving care and treatment. The strong links between the statutory and professional duties of candour will empower staff to speak openly about concerns, and seamlessly encourage learning to improve the quality-of-care provision.

2.4 The professional duty of candour relates to individual professional practice whereas the statutory organisational duty is placed on an organisation to ensure that when triggered service users have the same openness and transparency about what has occurred with their care applied by the organisation.

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[13] Kennedy, I, and others. The Bristol Royal infirmary inquiry. Learning from Bristol - The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 [Internet]. Crown; 2001. Available from: https://webarchive.nationalarchives.gov.uk/20090811143822/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf

[14] Donaldson, L. Making Amends - A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS [Internet]. Department of Health Publications; 2003. Available from: https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf

[15] Francis, R, and others. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry [Internet]. Staffordshire NHS Foundation Trust; 2013. Available from: https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

[16] Evans, K. "Using the Gift of Complaints" - a review of concerns (complaints) handling in NHS Wales. 2014. https://gweddill.gov.wales/docs/dhss/publications/140702complaintsen.pdf

[17] Nursing and Midwifery Council and General Medical Council 2022 Openness and honesty when things go wrong: the professional duty of candour. https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/read-the-professional-duty-of-candour/#about_guidance

2.5 The statutory duty will promote a system wide culture of openness and honesty. It also places a requirement, at an organisational level for NHS Bodies, to follow a set procedure, underpinned by the Candour Procedure Regulations to evidence that a series of prescribed actions have been undertaken when the duty is triggered. These actions are described in Chapter 3 below, which is supported by a procedure flow chart found in **Annex C**. This infrastructure will help create the conditions for NHS Bodies to discharge the duty of candour with confidence when triggered. There are case studies in annex H which provide some clinical examples.

2.6 Pharmacists and pharmacy technicians
Registered pharmacists, pharmacy technicians and persons working under their supervision in a retail pharmacy should continue to be mindful of the provisions of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 ("the Order")[18]. Pharmacy professionals are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (protection of purchasers of medicinal products) of the Medicines Act 1968[19] in the event that they prepare or dispense medicines erroneously.

2.7 In order to benefit from the defences in section 67B (defence to offence of contravening section 63(a) or (b): product sold or supplied) and section 67C (defence to offence of contravening section 64) of the Medicines Act 1968, the conditions for benefitting from the defences must be satisfied, including the conditions relating to notification of the person to whom the product was intended to be administered.

2.8 Consequently, the requirements of the Order need to be considered alongside and in addition to the statutory duty of candour.

WHO DOES THE DUTY OF CANDOUR APPLY TO?

2.9 The duty of candour within Part 3 of the Act applies to the following NHS Bodies which are listed within section 11(3), and defined by reference to section 11(4) and (7):

- Local Health Boards.
- Primary Care providers in Wales (i.e. General Practitioners, dentists, optometrists and pharmacists) in respect of the services they provide under a contract or arrangement with a Local Health Board (i.e. it applies to the NHS services provided by primary care providers).
- NHS Trusts in Wales.

[18] The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018. https://www.legislation.gov.uk/uksi/2018/181

[19] Medicines Act. https://www.legislation.gov.uk/ukpga/1968/67/contents

- Welsh Special Health Authorities, and NHS Blood and Transplant in relation to the functions it exercises in relation to Wales.

WHEN DOES THE DUTY OF CANDOUR PROCEDURE APPLY?

2.10 The duty comes into effect in relation to an NHS body if **both** of the following conditions are met:

(1) The **first condition** is that a person (the "service user") to whom health care is being or has been provided by the body has suffered an adverse outcome.

2.11 'Health care' means services provided in Wales under or by virtue of the National Health Service (Wales) Act 2006 i.e. as part of any NHS service, for or in connection with:

- the prevention, diagnosis or treatment of illness; or
- the promotion and protection of public health.

2.12 "Illness" includes any disorder or disability of the mind and any injury or disability requiring medical or dental treatment or nursing.

2.13 The meaning of health care is deliberately widely drawn to capture all of the NHS services provided in Wales.

2.14 A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user **could** experience, any unexpected or unintended harm that is more than minimal.

2.15 As set out in the Explanatory Notes to the Act, the duty may be triggered by an action taken by an NHS body during the provision of health care or by an omission to take action.

2.16 For the purpose of the duty of candour, harm includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child (section 11(7) of the Act).

(2) The **second condition** is that the provision of the health care was or may have been a factor in the service user suffering that outcome.

2.17 The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person's illness or underlying condition - see further in chapter 2.

2.18 It need not, however, be certain that the health care caused the harm. It is sufficient that the health care may have been a factor.

2.19 In the Candour Procedure Regulations when both of these conditions are satisfied and the duty is triggered, it is called a “notifiable adverse outcome.” **Annex A** sets out in flow chart form the trigger review process.

3 Chapter 3 – Establishing the level of harm

More Than Minimal Harm

3.1 “More than minimal harm” is not defined in the Act. However, for the purposes of this guidance “more than minimal harm” is considered to constitute moderate harm, severe harm and death. This supports the existing processes for Putting Things Right and Being Open and also aligns with the national patient safety incident reporting policy and the Datix Cymru system, incident reporting module. Therefore, in practice, the duty of candour is triggered if the service user experiences, or the circumstances are such that the user could experience, unexpected or unintended harm that is of moderate degree or above and the provision of health care was (or may have been) a factor in the service user suffering that outcome.

3.2 Moderate Harm: is any significant but not permanent harm or harm that requires a ‘moderate increase in treatment’ relating to the incident. A moderate increase in treatment is defined as an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient or transfer to another treatment area such as intensive care.

3.3 Severe Harm: is the permanent lessening of the bodily, sensory, motor, physiologic or intellectual functions, including the removal of the wrong limb or organ or brain damage, which is related directly to the incident and not related to a natural course of the service user’s illness or underlying condition.

3.4 Death: A death caused or contributed to by a patient safety incident, as opposed to a death which occurs as a direct result of the natural course of the patient’s illness or underlying condition

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3.5 A level of harm framework, providing explanations of harm that are considered moderate and above, is included in **Annex B**.

Harm that is ‘unintended’ or ‘unexpected’

3.6 To be notifiable, the harm must be unintended or unexpected. It can be as a result of either an actual intervention/treatment, or an omission in care, for example, a missed cancer diagnosis.

3.7 Medical or surgical treatment and all care interventions may of course come with inherent risks or may in itself cause a temporary increase in symptoms.

3.8 Harm which is caused by the treatment itself (e.g. impairments in function as a result of surgery,) would not necessarily be notifiable. These may fall into the category of a known risk, which may have been explained to, and accepted by, the patient as part of the consenting process.

Side effects and complications

3.9 It is not the policy intention that all side effects to medication or treatment that have caused harm or yet may cause harm would necessarily trigger the duty of candour Firstly the harm threshold has to be met and the harm must be unintended or unexpected as outlined above. In essence complications associated with care that was not discussed as a risk of the health care provided may meet the trigger threshold for the duty. There are well established mechanisms for reporting and monitoring the side effects and adverse reactions of medication which will still need to be followed and learned from whether the duty is triggered or not.

3.10 It is often unclear in the initial stages whether unintended or unexpected harm has or may occurred and discussion as part of a senior review is recommended where the situation is complex.

Intentional harm

3.11 The majority of patient safety incidents that may lead to the triggering of the duty of candour often involve a conversation between managers and supervisors about whether a staff member involved in a patient safety incident requires specific individual support or intervention to continue to work safely. The implementation of action singling out an individual is rarely appropriate - most patient safety issues have deeper systemic causes and require wider action.

3.12 The Williams Report which reported on gross negligent manslaughter in the NHS highlights this approach[20] and recommended the establishment of a 'Just Culture' providing reassurance to healthcare professionals, patients and their families that gross negligence cases will be dealt with in a fair and compassionate manner and the subsequent just culture algorithm supports these discussions[21].

3.13 However there are rare situations where it becomes clear that individual performance or actions or omissions may have breached professional codes of practice or criminal law and are not part of a wider patient safety

[20] Williams N (2018) Gross negligence manslaughter in healthcare the report of a rapid policy review. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf

[21] NHSE and NHSI (2021) Just culture guide. https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

organisational cause or action. It is imperative that the enactment of the duty of candour doesn't interfere with urgent police investigation or safeguarding multi agency strategy meetings and may be necessary that there is a consideration of a delay for the 'in-person' notification. Discussion with lead investigators prior to any further disclosure is recommended. Regulation 12 of the Candour procedure regulations allows for this.

What does harm the service user 'could experience" mean?

3.14 It is important to note that the duty is triggered not only when harm is known to have occurred, but also in cases **where the circumstances are such that a person could experience harm that is more than minimal in the future from an incident that has already occurred.** For example, where an error in the administration of medication that was administered may cause harm that is more than minimal at a future point.

3.15 NHS Bodies will have to reach a judgment about whether the circumstances are such that the user could experience harm that is more than minimal. In the example of an error in the administration of medication, whether or not such an error may give rise to harm that is more than minimal may be dependent upon the nature of the medication that was given in error or the circumstances of the particular service user

3.16 To put this in context for practitioners, this has been explained by the GMC in their professional duty of candour guidance as, 'in situations where a patient 'may yet suffer harm' as a result of an adverse outcome.

3.17 **Annex H** contains illustrative case studies that set out detailed examples of instances that would trigger the duty of candour and those that would not. It also contains examples of cases that demonstrate the duty being triggered where harm could occur in the future. (Case studies, 9, 10 & 11).

NEAR MISS INCIDENTS

3.18 These are any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care in Wales. Near miss incidents are **not** considered a trigger for the duty of candour procedure. The duty is designed to capture more than minimal harm that is apparent at the time of the incident or may appear later. With a near miss incident, harm (or the potential for future harm) is averted. This is often as the action that would have induced the harm was stopped from occurring or avoided.

3.19 For example, the administration of the wrong medication was averted through an additional step or the intervention of another and so it did not occur.

The difference between a near miss and an incident where harm could yet occur is that in an incident where harm could yet occur the action has occurred however the harm has yet to manifest.

3.20 However, due to their serious nature and the need to learn from such incidents and prevent their recurrence, near miss incidents should be managed following the normal reporting processes[22].

3.21 Even though the statutory duty of candour under the Act is not triggered by a near miss, individual practitioners should familiarise themselves with the guidance on near misses provided by their professional regulatory Bodies. For example, both the Nursing and Midwifery Council[23] and the General Medical Council [24] provide guidance and support to practitioners on when and how to speak to service users about near miss incidents.

Harm that occurs to Service Users whilst waiting for diagnostics or care from the NHS

3.22 Since the Global SARS-CoV-2 Pandemic in 2020 there has been continued significant pressure on resources within the NHS and subsequently many more patients are awaiting diagnostics, procedures and care on NHS waiting lists. Care will need to be taken when considering harm that occurs while a service user is waiting for their treatment. Every step in a clinical pathway will entail a waiting time, which may be longer at times of significant service pressure.

3.23 Where a service user suffers harm whilst on a waiting list, this could **potentially** trigger the duty of candour.

3.24 For a Service User to be on a waiting list for a diagnosis or treatment there must usually be a referral which involves an assessment and clinical decision. In placing the Service user on the waiting list there will have been some consideration of the likely risk of waiting and the best interests of the service user in the prevailing service context. The service user is therefore considered to be

[22] NHS Delivery Unit (2023) Patient Safety incidents. https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/

[23] NMC and GMC (2019) Openness and honesty when things go wrong: the professional duty of candour https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-professional-duty-of-candour.pdf.

[24] GMC (2023) Being open and honest with patients in your care, and those close to them, when things go wrong https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong#paragraph-21

under the care of a consultant or primary care physician and there is often active monitoring of the waiting list which involves an element of clinical input and judgment which also amounts to the provision of health care.

3.25 However, the other key components that must be satisfied before the duty is triggered is that the service user to whom health care is being or has been provided by the body has suffered an "adverse outcome," and that the provision of the health care was or may have been a factor in the service user suffering that outcome. A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any "unexpected or unintended" harm that is more than minimal.

3.26 An example of this in practice is where a service user with angina is placed on a well-managed waiting list for a bypass procedure and suffers a heart attack while waiting. In this scenario the duty may not apply if the harm was as a result of the natural deterioration in their condition. This is because disease progression in itself would not necessarily trigger the duty of candour and the risk of that progression would normally be discussed with the service user. This doesn't mean that the service user shouldn't receive an apology and explanation of what has happened as a matter of best practice. However, if the service user had been mistakenly missed off the list or incorrectly prioritised, therefore creating an undue delay, which gave rise to the adverse outcome then the duty might apply.

3.27 Waiting lists should be actively managed, and new clinical decisions should be taken when the known risk changes to minimise harm to the service user. The materialisation of a risk that is known to the service user and clinician, in itself would not necessarily trigger the duty of candour.

3.28 The initiation of the duty of candour is designed to respond to a service user/ or person acting on their behalf, in an open and transparent way when things have or may have gone wrong in their care. These actions, as previously referenced, are not an admission of liability or breach of statutory duty.

3.29 It is strongly encouraged that, when more than one NHS body engages in the pathway of care, the NHS Bodies involved must work together in partnership to deliver the duty of candour procedure and are fully involved in the process. See chapter 6

4 Chapter 4 – The Candour Procedure

4.1 The Candour Procedure Regulations prescribe the actions that **must** be taken by an NHS body when the duty of candour is triggered.

4.2 This section of the guidance needs to be read in conjunction with those Regulations, and the procedure flow chart included in **Annex C**.

Notification

4.3 The Act and Candour Procedure Regulations require NHS Bodies to notify on **'first becoming aware'** that the duty of candour has come into effect and not to wait for the findings of any initial investigation before notification.

4.4 It is important to note that regulation 4 of the Candour Procedure Regulations requires the NHS body to notify the **service user** who has suffered a notifiable adverse outcome or a **person who is acting on their behalf** (in the Candour Procedure Regulations[25], this person is called the "relevant person").

4.5 Notification may be made to a person who is acting lawfully on the service user's behalf, where the service user:

- has died.
- is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter; or
- is under 16 and not competent to make a decision in relation to their care or treatment. (Also refer to Chapter 7)

4.6 The Candour Procedure Regulations also allow a service user with capacity to nominate a trusted person to act on their behalf in relation to the duty of candour, recognising that not everyone to whom the duty applies will want to engage personally with the process.

4.7 It is important to ensure that at all times the requirements of the UK General Data Protection Regulation (UK GDPR[26]) are adhered to when accessing, processing and disclosing service user information. In cases where a representative is acting on behalf of a service user with capacity, consent for the representative to act should be obtained in writing and be kept under review throughout the process. This is also in line with the 2011 Regulations.

What does on 'first becoming aware' mean?

4.8 The requirement to notify the service user/person acting on their behalf on first becoming aware the duty has been triggered means that the NHS body should reflect and make a considered decision as to whether the conditions as set out in part 4 above have been met. Once determined by the NHS Body that the conditions as set out in part 4 above have been met, this would be considered to be the point at which the NHS body '**first becomes aware**' that the duty has been triggered.

4.9 This is the start date for the duty of candour procedure (referred to in this Guidance and the appendices as "the procedure start date"), which **must** be

[25] National Health Service Wales (2023) The Duty of Candour Procedure (Wales) Regulations 2023.

[26] UK Government (2018) Data Protection Act 2018. https://www.legislation.gov.uk/ukpga/2018/12/contents

followed, starting with the ‘‘‘in-person’’’ notification to the service user/person acting on their behalf.

4.10 Each NHS body should have a robust and consistent process in place for determining whether reported adverse outcomes (incidents) trigger the duty or not. **This does not mean that NHS Bodies investigate the circumstances of the reported incident before making this decision.** There will need to be some reflection and decision making on the part of the NHS body before deciding if the duty has been triggered, but not a detailed investigation. It is important that arrangements are in place for organisations that provide services on behalf of NHS Bodies to ensure that the NHS body is notified of any trigger of the duty of candour (refer to chapter 6).

4.11 The use of the Datix Cymru system is not mandatory. However, its rollout and development has been designed to support the implementation of the duty of candour and it is available, to all NHS Bodies including all primary care providers.

4.12 Consequently, it is anticipated, and encouraged, that NHS Bodies report incidents through the Datix Cymru system. There is a prompt on the system to ask those completing/and or reviewing the incident report whether or not the duty of candour has been triggered and to record the level of harm and the system also facilitates the documentation of reasons that the duty wasn’t triggered.

4.13 NHS Bodies will need to develop a system for locally undertaking the ‘review’ of those incidents that have initially been reported as meeting the criteria for triggering the duty of candour, i.e. where it is thought the conditions as set out in Chapter 2 above have been met. This could, for example, be as simple as recording that on review and after consideration, it was agreed that the threshold for more than minimal harm has been met or that it has not been met or that the harm was not unexpected or the harm that was suffered was not related to the provision of the health care.

4.14 **Therefore, the duty of candour procedure start date is the date on which an NHS body first becomes aware of a notifiable adverse outcome.**

4.15 Where the ‘‘in-person’’ notification is made later than 30 working days after the date the NHS body first becomes aware of a notifiable adverse outcome, which would be the candour procedure start date, an explanation should be provided and the reason for the delayed notification should be recorded on the incident report. This would be a rare occurrence but may happen where the duty of candour is triggered by a case review or a medical examiner review.

4.16 **This does not mean that the NHS body has routinely a 30-day period in which to deliver the ‘in-person’ notification.** The Act is clear that the NHS body must take all reasonable steps to deliver the ‘‘in-person’’ notification as soon as they become aware of the notifiable adverse incident.

4.17 Considering how this would apply in practice, the "sequence of events" would be as follows:

- a service user suffers harm related to (or potentially related to) treatment.
- staff are free to apologise, explain what has happened to the service user/family as they should do to comply with their professional duties of candour.
- they report the "incident" (in the majority of cases using Datix Cymru).
- Datix Cymru prompts consideration of whether the duty of candour is triggered.
- If, in the view of the person reporting the incident, it is felt that the duty is triggered by recording on the Datix Cymru incident module that moderate or above harm has been caused or could be caused, an openness and transparency section will automatically open allowing the reporter to record further information in line with the duty of candour procedure requirement.
- If it is determined that the duty of candour has not been triggered, even though the moderate or above harm has been caused or could be caused, a note of the reasons for reaching such a decision must be recorded on the incident report in Datix Cymru.
- All incidents are reviewed internally by the NHS body (except where health care is provided by a commissioned or hosted partner).
- For those where it is agreed the conditions for meeting the duty of candour (set out at Chapter 2 above) are met, then notification of the service user is initiated.

How to notify

4.18 Notification to the service user or person acting on their behalf should be '"in-person"'[27] which means communication on the telephone, via audio-visual communication (such as a video call) or face to face. It is considered many service users would be surprised to receive a letter in the post advising them the duty had been triggered and may have questions/worries that will need to be answered/alleviated immediately. Leaving voice messages, is also not considered appropriate when making the '"in-person"' contact. Experience from recent stakeholder sessions also demonstrates that an '"in-person"' approach for the first contact is most appropriate.

4.19 However, NHS Bodies have a discretion as to which method of '"in-person"' communication is most appropriate. It may not be achievable in practical terms for there to be a face-to-face meeting with everyone in relation to whom the duty of candour has been triggered. The NHs body should consider each circumstance and identify the preferences of the service user/person acting on their behalf and make every effort to meet these where possible.

4.20 The factors that an NHS body must consider when determining which form of '"in-person"' notification is most appropriate are:

[27] In accordance with regulation 4 of the Candour Procedure Regulations.

a) severity of the harm.
b) nature and complexity of the notifiable adverse outcome.
personal circumstances of the service user (if known)

c) any communication already undertaken with the service user/person acting on their behalf
d) any known preferred method of communication of the service user/person acting on their behalf. This is particularly important where the service user may require support, for example where Welsh is the first language of the service user or their family or BSL or a foreign language interpreter may be needed.

4.21 In some situations, the initial notification via the telephone or video call may suffice; in more complex cases it is likely to be more appropriate for a face-to-face meeting with the service user/person acting on their behalf to be arranged.

4.22 The NHS body must take reasonable steps to establish the preferred method of communication. They must also take reasonable steps to ensure that communication is in a manner that the service user/person acting on their behalf can understand[28]. NHS Bodies are subject to Welsh Language Standards requirements as set out in the Welsh Language Standards (No. 7) Regulations 2018[29]

4.23 It is recognised that in some instances, the preferred method of communication or service user contact preference, may not be known at the outset; establishing contact via the telephone may be necessary in the first instance to begin dialogue on what steps might need to be taken to allow the duty of candour procedure to be followed.

Who notifies and the purpose of the notification

4.24 The NHS body will need to determine the most appropriate person or persons to make the initial '"in-person"' notification to the service user/person acting on their behalf. The NHS body needs to consider whom is the most appropriate person or persons to make the initial '"in-person"' notification to the service user/person acting on their behalf.

4.25 Primarily, the initial contact with the service user/person acting on their behalf, is to acknowledge what has happened and offer a meaningful, personalised apology for the harm they have experienced or may yet experience and provide advice on what will happen next. (Refer to annexe E and other professional resources on communicating an apology).

4.26 The NHS body must nominate a person with sufficient knowledge, experience, training and understanding of the duty of candour procedure to be able to assist

[28] See regulation 7 of the Candour Procedure Regulations.

[29] The Welsh Language Standards (No. 7) Regulations 2018 The Welsh Language Standards (No. 7) Regulations 2018 (legislation.gov.uk)

the service user/their representative with any questions that may arise as they go through the process, this is the “nominated point of contact”.

4.27 Regulation 4 of the Candour Procedure Regulations prescribes what **must** be covered in the initial ‘“in-person”’ notification.

4.28 The person making the initial contact with the service user/person acting on their behalf must:

- clearly explain what information they know so far about what has happened.
- outline why the NHS body is of the view the duty of candour has been triggered.
- provide an apology. Guidance on how to make a meaningful, personalised apology is set out below and in Annex E.
- provide the contact details of whom is the nominated point of contact for the NHS body. The nominated point of contact is the person the service user/person acting on their behalf will contact if they have any questions about the duty of candour process.
- provide an explanation of the actions and further enquiries the NHS body will undertake to investigate the circumstances of the notifiable adverse outcome. This includes any actions the NHS body (or where services have been commissioned from an independent provider in Wales, the provider) will take under the 2011 Regulations. The investigation of the notifiable adverse outcome is considered further at Chapter 5.
- communicate to the service user/person acting on their behalf details of any services or sources of support which the NHS body reasonably thinks may be of assistance to them, taking account of their needs. **Annex D** sets out useful contacts for support options.
- Document this in the service users care record and on datix Cymru.

4.29 Regulation 4 also requires the person making the ‘in-person’ notification to provide an explanation to the service user/person acting on their behalf if the date on which the ‘in-person’ notification is made by the NHS body is more than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome. This is to explain any delay in notification that could arise, for example, following a retrospective case review. The law requires that the NHS body makes the ‘“in-person”’ notification on first becoming aware of the notifiable adverse outcome and therefore it does not mean that NHS Bodies routinely have 30 working days from the date the notifiable adverse outcome occurred to make the ‘“in-person”’ notification.

4.30 It is also good practice to establish what the service user/person acting on their behalf understands about what has happened. The person making the notification on behalf of the NHS body should also demonstrate they understand the circumstances and the impact for the person affected. They should not question the extent of harm suffered by the person affected or the circumstances of the ‘incident’ as the service user has experienced it.

4.31 This may be the starting point for longer conversations with the service user/person acting on their behalf and it will be important for all involved that this

initial contact is carried out in the true spirit of the duty, with openness, empathy and sincerity.

4.32 *Things to consider* – ***Before the '"in-person"' notification takes place:***

- has someone from the NHS body already been in contact with the service user/person acting on their behalf? This may be related to this incident or other aspects of their healthcare.
- what discussions or information exchange have already taken place (if any)?
- what is known about what has happened and the level of harm sustained or could be sustained?
- is the preferred method of notification known? e.g. verbal, written, electronic; it is recommended to check any previous datix, Welsh clinical portal, Welsh PAS or care records.
- who will be the nominated point of contact within the NHS body following the initial notification?
- what support is available to the service user/person acting on their behalf, to assist them during the notification process and afterwards?
- ensure that communication is in a manner that the service user or the person acting on their behalf, can understand including Welsh if that is their first language.
- Consider the location of the conversation if it is to be face to face or via video call to ensure privacy and confidentiality are maintained.
- It should also be recognised that a service user may have a number of questions relating to their care and the presence of a member of the clinical team may be prudent

Follow up in writing

4.33 Following the '"in-person"' notification, regulation 5 of the Candour Procedure Regulations requires the NHS body to take all reasonable steps to write to the service user/person acting on their behalf (unless they have indicated they do not wish to engage in the candour process) within five working days after the day of the 'in-person' notification. Notification in writing includes notification via email.

4.34 The aim of the written notification is to confirm in writing what has been discussed at the '"in-person"' notification. This is to aid the understanding of the service user/person acting on their behalf, and also to provide the NHS body with a record of what has been discussed.

4.35 Therefore the written must include:

- a description that explains clearly what information is known so far about what has happened
- a reiteration of the verbal apology,
- the information provided in the 'in-person' notification, which for completeness is as follows:
    - the reason that the NHS body considers that the duty of candour has been triggered.

- the name and contact details of the person at the NHS body nominated as the point of contact for the service user/person acting on their behalf in respect of the duty of candour procedure,
- an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations
- a reiteration of the offer of details of relevant services or support, and
- where the ‘‘in-person’’ notification is made later than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome, an explanation of the reason for the delay.

- Document this on Datix Cymru

4.36 Consideration should be given to personalising the notification letter with a handwritten signature. It has been suggested during focus sessions with members of the public that a handwritten signature has a positive impact when an apology of this nature is being conveyed.

4.37 The NHS body **must** take all reasonable steps to send the written notification to the service user/person acting on their behalf within **five working days** following the date of the ‘‘‘in-person’’’ notification.

4.38 It is important to acknowledge that delayed or poor communication makes it more likely that the service user/person acting on their behalf, will seek information in a different way, for example, by making a complaint or taking legal action. It may also mean that they will not feel that there has been openness and honesty in the process from the outset.

The Apology

4.39 Making a meaningful, personalised apology is a key part of the ‘‘‘in-person’’’ notification process. **Annex E** provides further information on making an apology as part of the duty of candour procedure.

4.40 A meaningful, personalised apology can be a practical way of maintaining or restoring trust. When conveyed with empathy, sincerity and understanding, an apology can be effective and powerful and it is crucial for everyone involved when the duty of candour is triggered, including the service user/person acting on their behalf, and the staff who care for them. The impact on everyone involved when the duty of candour is triggered cannot be underestimated. For the service user/person acting on their behalf, an apology is usually the most important action that any one individual and organisation can take, and it is important that a timely apology is given in accordance with the regulations.

4.41 People who feel that they have not been listened to or informed openly and honestly from the outset are more likely to feel that the harm they have suffered has been compounded and can lead to the loss of trust in their health care provider. This can result in feelings of anger and cause a break down in the relationship. It may also mean that escalated action is taken.

4.42 It is recognised that there may be misconceptions and misunderstanding that the provision of an apology equates to an acceptance of blame, culpability or even legal liability[30].

4.43 This is not the case, and it should not give rise to any such assumption or hinder or delay the offer of an apology.

4.44 "Apology" is defined within regulation 2 of the Candour Procedure Regulations as:

apology means an expression of sorrow or regret in respect of the notifiable adverse outcome.

4.45 Regulation 13 specifically provides that an apology or any other step taken in accordance with the candour procedure does not amount to an admission of negligence or to a breach of statutory duty.

4.46 The giving of an apology acknowledges what has happened or at this stage what is known to have happened and provides assurance, the matter is being taken seriously and opportunities for learning will be taken to prevent similar circumstances from arising in the future. It is important to ensure the apology covers what is known at that point without speculating or including assumptions on what may have happened or caused the incident to occur. It is helpful to admit at this early stage that a lot may be unknown but that more detail is likely to become clearer during the investigation that follows.

4.47 We recognise that sometimes staff can find it difficult to say sorry when harm has occurred or may occur at some point in the future. They may be unclear if they can say sorry and worry that the timing for doing this will not be right, or that they will make things worse, especially as the service user/person acting on their behalf, may be understandably angry and upset. **Annex E** aims to provide guidance to support staff in this regard.

4.48 It is best practice to document the verbal apology in the patient care record. This means that the entire care team will know when an apology has been given and can avoid duplication.

Notification of results of further enquiries

4.49 Regulation 6 of the Candour Procedure Regulations requires NHS Bodies to notify the service user/person acting on their behalf of the results of any further enquiries (investigations) carried out by the NHS body that may have been referred to in the ''in-person'' notification. These enquiries are understood to be the investigation that is to be undertaken by the NHS body.

[30] Compensation Act 2006 section 2. https://www.legislation.gov.uk/ukpga/2006/29/contents

4.50 In practice, in the vast majority of cases once the service user/person acting on their behalf has been notified, the NHS body will undertake further enquiries and investigate the circumstances in which the duty of candour came into effect in accordance with the provisions of the 2011 Regulations. NHS Bodies will be familiar with this process as it governs the way in which incidents are currently investigated.

4.51 Communication with the service user/person acting on their behalf under the provisions of the 2011 Regulations, which includes a requirement to outline in writing the outcome of investigations, will also satisfy the requirements of regulation 6 of the Candour Procedure Regulations, so avoiding duplication in the event that the 2011 Regulations apply.

4.52 As set out below in Chapter 5, the 2011 Regulations do not apply to all NHS Bodies – for example, they do not apply to NHS Blood and Transplant. Additionally, there may be exceptional circumstances where the 2011 Regulations do not apply. In these circumstances, NHS Bodies should ensure that they have arrangements in place to enable them to comply with the notification requirements in regulations 4, 5 and 6.

Communication with service user/person acting on their behalf

4.53 Regulation 7 prescribes what an NHS body must do if it is unable to make contact with the service user or a person acting on their behalf to:

(i) make the ‘‘in-person’’ notification (regulation 4),
(ii) the written notification (regulation 5),
(iii) to notify of results of further enquiries (regulation 6),

or if the service user or person acting on their behalf declines to participate in communication with the NHS body.

4.54 If the NHS body, having taken reasonable steps, is unable to make contact, the attempts to make contact must be recorded as part of the information that is required to be kept by virtue of regulation 9 (Records), see guidance on record keeping below. Ideally the information should be recorded on the incident record, which in most circumstances will be datix Cymru.

4.55 If the service user/person acting on their behalf, indicates that they do not wish to communicate with, or receive information from the NHS body, this must also be clearly recorded in accordance with regulation 9 and the person’s wishes respected. Again, good practice would be to record this on the incident record (datix Cymru), and also on the service user’s care records.

4.56 In accordance with regulation 7(3)(b) of the Candour Regulations NHS Bodies are not required to provide information to or communicate with the service user/person acting on their behalf in these circumstances where they have indicated that they do not wish to communicate with or receive information from the NHS body. However, the investigation of the incident giving rise to the

triggering of the duty must continue so that lessons can be learned, and quality improvements made.

4.57 The NHS body should inform the service user/person acting on their behalf that they can contact the NHS body should they change their mind about their involvement in the process.

4.58 The NHS body must take reasonable steps to ascertain the service user/person acting on their behalf's preferred method of communication and, where reasonably practicable, communicate with them by this method.

4.59 The NHS body must take all reasonable steps to ensure that any communication with the service user/person acting on their behalf is in a manner they can understand this is especially important where disability is present or where the service user is a vulnerable adult or child or young person.

Support and Training

4.60 it is important to recognise that the service user or person acting on their behalf may be very affected by the information contained within the 'in-person' notification and will need ongoing support as they come to terms with the impact on them of the harm that has occurred or may occur as highlighted in chapter 4.

4.61 NHS staff go to work to provide high quality care to those in need of care and treatment. When a service user suffers an adverse outcome and the duty of candour is triggered, it is important to recognise that staff involved in the care of the service user will also be impacted and may require support.

4.62 Regulation 8 of The Candour Procedure Regulations sets out the requirements in relation to training and support.

4.63 The requirements are for relevant training and guidance to be given to all staff involved in:

- the provision of health care; and
- investigating or managing notifiable adverse outcomes, and
- any other relevant members of staff who engage in performing or exercising functions in connection with the duty of candour procedure.

4.64 As well as all clinical staff, in practice this would include senior staff (including Board level staff) responsible for overseeing the management of adverse outcomes in their organisations, those directly involved with the investigation, management and/or notification of notifiable adverse outcomes and any other staff who deal with complaints and concerns. At primary care level this would for example include practice managers.

4.65 Training modules will be developed nationally in liaison and are available via digital platforms to all NHS staff including primary care providers.This guidance document and annexes provide all the relevant support documents to assist NHS Bodies in discharging their duty in respect of ensuring staff awareness of the duty of candour.

4.66 The Candour Procedure Regulations also set out that the NHS body must provide a member of staff who engages in a notifiable adverse outcome with details of services or support available, taking into account:

- the circumstances relating to the notifiable adverse outcome; and
- the staff member's needs.

4.67 NHS Bodies will have mechanisms in place and local support services available to pro-actively offer the appropriate provision of support and assistance to staff members through their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes.

4.68 In addition there are several national support services available via the Health Education & Improvement Wales (HEIW) website[31], such as Health for Health Professionals (Canopi)[32], SilverCloud[33] and Samaritans[34].

4.69 Local Line Managers, Clinical Supervisors, Workforce and OD professionals (including employee wellbeing and occupational health colleagues) and Trade Union representatives will also be able to signpost staff to appropriate support services.

Record keeping

4.70 Section 4(3)(c) of the Act requires the Candour Procedure Regulations to prescribe the records that NHS Bodies must keep in relation to the discharge of the duty.

4.71 Regulation 9 of the Candour Procedure Regulations requires NHS Bodies to keep an accurate written record for each notifiable adverse outcome in respect of which the candour procedure is followed.

4.72 The written record must include every document and piece of correspondence relating to the notifiable adverse outcome, not limited to:

- the notification of the duty.
- attempts to contact the service user/person acting on their behalf.
- any decision by the service user/person acting on their behalf not to be contacted in relation to the duty of candour; and
- all documentation relating to the review to establish whether the duty has been triggered and the subsequent investigation of the notifiable adverse outcome, that is undertaken by the NHS body, including the response or interim report issued under regulations 24, 26 or 31 of the 2011 Regulations.

[31] HEIW (2023) Workforce support. https://heiw.nhs.wales/support/
[32] Canopi (formally Health for health professionals) https://hhpwales.nhs.wales/about-us/
[33] SilvercloudWales. https://nhswales.silvercloudhealth.com/signup/
[34] The Samaritans 2023 https://www.samaritans.org/

4.73 It is considered good practice to record any decision not to trigger the duty (where triggering was contemplated). It is important that accurate records are kept supporting quality assurance mechanisms needed to identify areas for learning and improvement and also to enable NHS Bodies to comply with their reporting requirements under the Act which are considered in part 11 below.

4.74 It is envisaged that the Datix Cymru system will be used for the purposes of reporting and recording keeping.

5 Chapter 5 - The Investigation

5.1 When notifying the service user or person acting on their behalf that the duty of candour has been triggered, an NHS body must (in accordance with regulations 4(3)(e) and 5(3)(c) of the Candour Procedure Regulations) also give an explanation of the actions and further enquiries it will take to investigate the circumstances of the notifiable adverse outcome.

5.2 In the vast majority of cases, this means following the 2011 Regulations procedure for investigating concerns. “Concerns” as defined in the 2011 Regulations includes all patient safety incidents.

5.3 However, there will be instances where, even though the duty of candour applies, an investigation under the 2011 Regulations will not be required. For instance, the 2011 Regulations do not apply to NHS Blood and Transplant, they will follow their internal procedures for investigating patient safety incidents.

5.4 In relation to an investigation under the 2011 Regulations, as is currently the case, the investigation must be proportionate, conducted openly and efficiently and the focus should be on improving quality, safety and sharing learning.

5.5 The service user/person acting on their behalf should be invited to contribute to the terms of reference of the investigation and contact should be maintained throughout the investigation, if this is what has been agreed. The preference of the service user/person acting on their behalf should be considered as not everyone will want to be involved to this extent.

5.6 The outcome of the investigation will be communicated to the service user or their representative in accordance with regulation 24 of those Regulations or, in the case of care provided by Health Boards, NHS Trusts or Welsh Special Health Authorities, in line with regulations 26 and 31 where the redress arrangements have been applied.

5.7 Consideration should be given to whether the incident should be reported to other Bodies e.g. an employer or professional regulator, the Medical Examiner service or HM Coroner. Additionally the incident may meet the National Reportable Incident threshold and be reported to Welsh Government.

5.8 Staff involved in the treatment or care that resulted in the duty being triggered should, where appropriate, be involved in the investigation process and also be

advised of the final outcome. Further information in relation to the investigation and record keeping can be found in **Annex F**.

5.9 There have been some amendments to the 2011 Regulations to make them compatible with the duty of candour. The principal amendments are set out in regulation 14 of the Duty of Candour Procedure Regulations. Their effect is to ensure that both the duty of candour and the PTR procedures work in harmony and to ensure that there is not any duplication of processes.

6 Chapter 6 - Complex Arrangements and The Duty of Candour

Where more than one NHS body may be involved in the Duty of Candour procedure

6.1 It is often the case that a range of NHS Bodies engage in an episode of care where the duty of candour is triggered. **Annex H** has case study examples for reference.

6.2 Although not all of the Bodies involved in the provision of an episode of care will necessarily be the 'providing body' in terms of the legislation (i.e. their provision of health care did not or does not have the potential to trigger the duty of candour) they may need to become involved in providing information as part of a review or providing support for the service user/person acting on their behalf. All parties must co-operate fully in an open and facilitative manner throughout the duty of candour procedure and share with each NHS body any learning identified as a result of the subsequent investigation/ review, including any actions to be taken with a view to preventing similar circumstances from arising in the future.

6.3 There may also be occasions where several NHS Bodies each are providing health care to a single service user and each trigger the duty of candour procedure for multiple 'notifiable adverse outcomes' in relation to a single course of treatment. **Annex H** has case study examples for reference.

6.4 In such circumstances, it would be best practice for the NHS Bodies to seek to communicate with the service user/person acting on their behalf to gain the appropriate consent, in line with UK GDPR, to undertake a co-ordinated approach to notification. Otherwise, there is a risk the service user or person acting on their behalf will feel overwhelmed or confused by the process if they get multiple notifications. This is particularly important where the harm is Severe, or a death has occurred.

6.5 The aim should be to make the process as easy as possible for those involved and, in particular, for the service user or person acting on their behalf.

6.6 However, each NHS body (providing body) still has its own responsibility under the Candour Procedure Regulations and must ensure and be able to evidence

that, as individual organisations, they have complied with the requirements of those Regulations.

6.7 Where there are multiple NHS Bodies involved in the duty of candour, the subsequent investigation is undertaken as detailed in regulation 17 of the 2011 Regulations. Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible Bodies (subject to obtaining the relevant consents from the service user or person acting on their behalf) to cooperate for the purposes of coordinating the handling and investigation of concerns and the provision of a coordinated response.

6.8 If an NHS body discovers that an incident that would trigger the duty of candour procedure has occurred in a different NHS body, the NHS body that discovers the 'incident' should inform the NHS body where the 'incident' occurred so that the latter can then implement the duty of candour procedure. The NHS body that discovers the 'incident' must also be open and transparent with the service user about what they have discovered. However, they are not required to perform the specific duty of candour procedure; this should be conducted by the responsible NHS body, i.e. the 'providing body' where the duty of candour was triggered.

Mixed Care Delivery Between NHS Bodies and Social Care Organisations

6.9 *Where a service user is receiving care from an NHS body and a provider of social care (whether in a mixed model of delivery or separately), it is possible that multiple providers may have contributed to the harm that has been caused to the service user. In such cases each provider will have its own responsibilities under the duty of candour (or its equivalent for providers of social care).*

6.10 The providers of both health and social care should liaise and work together to notify and investigate the incident in order to minimise any distress and to avoid multiple communications to the service userFor example it would not normally be appropriate for a family to receive two separate 'in-person' notifications about the death of a family member because of a lack of communication between providers.

However, each provider will retain their individual responsibilities under their respective duty of candour and must satisfy themselves that they have been met.

Application of the Duty of Candour procedure to commissioned and hosted services

6.11 Section 11 of the Act clarifies which organisation will be responsible for complying with the duty of candour in situations where services are provided by one body on behalf of another. The position, in relation to different arrangements is set out below:

Services Commissioned by an NHS Body from Another NHS Body in Wales

6.12 An NHS body in Wales is responsible for complying with the duty of candour in relation to all care which it actually provides. Therefore, for example, where a Health Board enters into arrangements with a primary care provider for the provision of NHS services, it is the primary care provider who is subject to the duty.

6.13 Similarly, if a Health Board enters into arrangements with an NHS Trust in Wales for the provision of services, the duty rests with the NHS Trust.

Services Commissioned from Non-NHS Bodies in Wales

6.14 If an NHS body enters into an arrangement for the provision of services with someone other than another NHS body, the duty to comply with the duty of candour rests with the NHS body. Therefore, for example, if a local Health Board enters into an arrangement with an independent provider for the provision of services, the duty will apply to the local Health Board.

6.15 In these circumstances, it would be for the NHS body to notify the service user or person acting on their behalf for both the '"in-person"' notification in accordance with regulation 4, and the written notification in accordance with regulation 5.

6.16 The provisions of the 2011 Regulations apply to persons who provide services under arrangements with an NHS body. Therefore, as is the case currently, it would be for the independent provider to investigate the circumstances of the notifiable adverse outcome and communicate the result of that investigation to the service user/person acting on their behalf.

6.17 NHS Bodies should ensure that their commissioning arrangements with non-NHS independent providers in Wales require the independent provider to notify them when they are of the view that the duty of candour has been triggered, so

that the NHS body can comply with its obligations in relation to notification under the Act. The commissioning arrangements will also need to require the independent provider to provide sufficient information to the NHS body to enable them to comply with their reporting obligations under section 7 of the Act.

Application of the Duty of Candour to Care Commissioned Outside of Wales

6.18 The duty of candour under the Act only applies where health care is delivered in Wales as part of an NHS service. If, for example, a local Health Board enters into arrangements with an English provider, whether that provider is an NHS body or an independent provider, for the provision of health care services in England, it is the English duty of candour, under the Health and Social Care Act 2008 that may apply in relation to that care.

6.19 Part 7 of the National Health Services (Concerns, Complaints and Redress arrangements) (Wales) Regulations 2011 outlines the approach to be taken in terms of services carried out by England, Scotland and Northern Ireland NHS Bodies when patient safety incidents and concerns have been raised.

Annex A1 sets out the procedure flow chart for services that are commissioned.

Hosted Services:

6.20 Where healthcare is delivered by an organisation or service that is hosted by an NHS body (for example a clinical network), the Duty of Candour applies to the NHS body as the legal entity that hosts the service or organisation.

7 Chapter 7 – Special Considerations

Children And Young People

7.1 The duty of candour applies in respect of health care that is provided in Wales to children and young people. The welfare of children and young people, and their rights to be fully involved in decisions about their care and treatment, are essential principles to the approach to be taken when things go wrong with a child's or young person's care[35].

7.2 Under the UNCRC (article 12), children and young people - where they are able and wish to be - should be involved in discussions about adverse outcomes that directly affect them. This is in conjunction with the child's or young person's right to the highest attainable levels of health (article 24) and the right to receive and impart information (article 13).

[35] UN Convention on the Rights of the Child - United Nations. https://www.unicef.org.uk/wp-content/uploads/2019/10/UNCRC_summary-1_1.pdf

7.3 Honesty, transparency and openness are the guiding ethical principles to be adopted and discussions must be conducted in a sensitive manner that take age, the child or young person's experience of health care, their mental capacity and the wishes of the individual child or young person and, where appropriate, those with parental responsibility into consideration.

7.4 In discharging the duty of candour in circumstances involving health care that has been provided to a child or young person, the NHS body must notify the "relevant person" of the notifiable adverse outcome (see regulation 3 of the duty of candour regulations). This might be the child or young person themselves, unless they are: [36]

- 16 or over and lack capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter, or
- under 16 and not competent to make a decision in relation to their care or treatment,

in which case the "relevant person" is a person legally acting on the child or young person's behalf.

7.5 Where the matter concerns a child who is under the age of 16, it is important that consideration is given as to whether the child is "Gillick competent" [37] i.e., whether the child has the requisite legal capacity and sufficient maturity and intelligence to understand the information provided and to make decisions about their own health and medical treatment. The health care professional seeking the child or young person's consent should undertake the Gillick competency assessment if they have been adequately trained to do so.

7.6 However, even where the child is "Gillick competent," or where a young person is considered to have the requisite mental capacity, children and young people should be encouraged to involve their parents or guardians in these discussions where that is advisable and beneficial. Alternatively an advocate may be of use in this circumstance. Parents and Guardians are often best placed to understand and advise the health care team and, in many circumstances, an important source of support for the child and young person coming to terms when harm has occurred with their care.

7.7 The use of appropriate language and explanation needs to be thought through carefully and, where appropriate, conducted in a timely manner and in partnership with parents or guardians. The use of appropriate professionals with experience in communicating with children can be of immense value in these circumstances. This is important in order to mitigate against the risk of causing further harm or distress in notifying the child or young person of the notifiable adverse outcome, whilst also remaining open and honest with the child or young person about what has

[36] Regulation 3 of The Duty of Candour Procedure (Wales) Regulations also provide that the "relevant person" is someone acting on the service user's behalf if the service user has died or has informed the responsible body that they have nominated a person to act on their behalf.

[37] Gillick v West Norfolk and Wisbech AHA [1986] A.C. 112

happened in accordance with the duty of candour, and the broader rights of children and young people to be kept fully informed.

7.8 Where a child is not considered to be “Gillick competent” then notification must be given to a person acting on the child’s behalf (e.g., their parents or legal guardian).

7.9 In this circumstance, it is important to take in to account the parents’ or guardians’ views as to how a child or young person can be informed about what has happened in their care or treatment and consideration should be given as to how the health care team can support that discussion. As part of that discussion, consideration should be given as to the best interests of the child or young person in terms of the manner within which the discussion is undertaken, taking care not to cause further harm or distress.

7.10 Consideration must always be given to safeguarding principles and guidance and the need, at times, to report concerns around a child or young person’s safety discovered through these discussions where this is mandated legally or professionally.

7.11 Good documentation of decision-making and the assessment of competency to understand and participate in decisions about their care is imperative. It is also important that any decisions made not to share information are regularly reviewed.

7.12 It must be recognised that children and young people are often aware of incidents and changes in their care, and it can be extremely helpful to a young person to understand why it has happened.

7.13 Often children and young people may fear unclear outcomes. These fears can be generated when issues and incidents are not discussed, and children and young people are left uncertain about why things have occurred and what the next steps are in their care. This leads to increasing anxiety, worry and mental stress.

7.14 Ensuring children and young people are afforded the opportunity to be partners in the decision-making process about their care, with their parents or guardians and their health care team is imperative, where this is appropriate and possible. It is important to always have the child, young person and their family unit at the centre of good honest and open communication and the decisions about their care and this is especially important when unintended or unexpected harm has occurred.

Retrospective Case Reviews

7.15 Adverse outcomes may become known following retrospective serious case reviews, a large number of patients recalled or following a decision made by the medical examiner service or a coroner’s inquest, where the cause of death attributed was not known at the time of the incident. Additionally, further detail, not known during the initial review, may become known during the investigation of the incident. In these cases, the duty may still apply.

7.16 At the point of such a case review, and if the requisite conditions for the duty of candour have been met, the organisation therefore becomes ‘aware’ of the

notifiable adverse outcome. It is at this point that the DOC procedure should be initiated, if not previously initiated.

7.17 In the event that the 'in-person' notification is made later than 30 working days after the responsible body first became aware of the notifiable adverse outcome, the responsible body must provide an explanation of the reason for the delay.

Adverse Outcome Incidents Which Occur Before the Duty of Candour Came into Force

7.18 The Duty of Candour legislation is not intended to operate in respect of adverse outcomes which occurred before the date that the legislation came into force. In practical terms, this means that the conditions triggering the duty of candour (i.e. the provision of health care and the harm which occurred), must have taken place after 1 April 2023. However, we would still expect you to apologise and to be open and transparent with people about whatever has been discovered **in line with the ethos of putting things right**[38].

8 Chapter 8 - Oversight arrangements.

8.1 Regulation 10 requires NHS Bodies to designate a person to be responsible for maintaining a strategic oversight of the operation of the candour procedure set out in the Candour Procedure Regulations. Where the NHS body is a local Health Board, a Trust, or a Special Health Authority (including NHS Blood and Transplant in relation to its Welsh functions) the person must be one of its non-officer or non-executive directors, as appropriate.

8.2 Primary care providers have discretion in relation to whom to assign such roles.

8.3 Regulation 11 requires NHS Bodies to designate a person who has overall responsibility for the effective day to day operation of the procedure under the Candour Procedure Regulations (the "responsible officer"). Where the NHS body is a local Health Board, a Trust, or a Special Health Authority (including NHS Blood and Transplant in relation to its Welsh functions) the responsible officer must be one of its officer members or executive directors, as appropriate.

8.4 For primary care providers, it must be the person who acts as the Chief Executive of the body. If there is no Chief Executive, it is:

- the person who is the sole proprietor.
- in cases of a partnership, a partner; or
- in any other case a director or person responsible for management.

[38] Putting Things Right – Guidance on dealing with concerns about the NHS from 1 April 2011 Version 3 – November 2013 https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/

8.5 The Candour Procedure Regulations allow for the functions of the responsible officer to be delegated to another person, provided that person is under the direct control and supervision of the responsible officer. However, accountability will rest with the responsible officer themselves.

8.6 It is considered good practice for the persons designated in accordance with regulations 10 and 11 of the Candour Procedure Regulations to be the same persons nominated, respectively, under regulations 6 and 7 of the 2011 Regulations[39] due to the close linkages between the candour procedure and the procedure for investigating concerns in the 2011 Regulations.

REPORTING REQUIRMENTS

8.7 Under the duty, NHS Bodies will be required to report annually on compliance with the duty and publish their reports. Local Health Boards will be required to collate this information from those primary care providers with whom they enter into a contract or arrangements for services and publish a combined report. **Annex G** includes a flow chart setting out the reporting, publication and monitoring requirements.

8.8 When reporting, NHS Bodies will be required to specify if the duty of candour has been triggered in the reporting year (defined as each period of 12 months ending on 31st March, (each financial year), and if it has:

1. state how often the duty of candour has been triggered during the reporting year.
2. give a brief description of the circumstances in which the duty was triggered; and
3. specify any steps taken by the body with a view to preventing similar circumstances from arising in the future.

8.9 The report must be prepared as soon as practicable after the end of each financial year.

8.10 To streamline annual reporting in Wales and reduce duplication of content whilst ensuring all regulatory requirements are met**,** Health Boards, Trusts and SHAs should include their candour reports in the Putting Things Right Report which should be published pursuant to regulation 51 of the 2011 Regulations[40] by **31st October** each year.

[39] Reg 6 of the 2011 Regulations requires a person to be appointed to maintain a strategic oversight of the arrangements for dealing with concerns under those Regulations and regulation 7 requires a person to be appointed to have responsibility for ensuring effective day to day operation of the arrangements for dealing with concerns in an integrated manner.

[40] The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (SI 2011/704). Available from: http://www.legislation.gov.uk/wsi/2011/704/contents/made

8.11 Regulation 51 of the 2011 Regulations requires NHS Bodies to prepare an annual report on information regarding concerns, (where concerns is taken to include complaints, patient safety incidents and claims). For primary care providers, this includes sending their report to the Local Health Board with whom they have entered into arrangements with, allowing for collation and publication within a Local Health Board's Annual Putting Things Right report[41], and considered within each organisation's Annual Quality Statement.

Primary Care providers: duty to report

8.12 Primary Care providers must prepare a report in respect of the health care they provide under a contract or other arrangement with their Health Board. The report must state whether during the reporting year (defined as each period of 12 months ending on 31st March, (each financial year)), the duty of candour has been triggered in respect of the provision of health care by the primary care provider.

8.13 If it has, the report must:

1. specify how often this has happened during the reporting year,
2. give a brief description of the circumstances in which the duty was triggered,
3. describe any steps taken by the provider with a view to preventing similar circumstances from arising in future.

8.14 The prepared report must be supplied to the Local Health Board on completion.

8.15 If the Primary Care provider has provided health care on behalf of two or more Local Health Boards, a separate report is to be prepared and supplied to each Local Health Board on completion.

8.16 Local Health Boards receiving the report must prepare a summary of the reports received from the Primary Care providers in the candour report that they publish.

8.17 Consequently, in order to give Local Health Boards time to compile the summary, such reports must be provided to the relevant Local Health Board by no later than **30th September** each year.

8.18 Although the use of the Datix system is not mandated, functionality on Datix will facilitate the collation of information necessary to satisfy the reporting requirements that need to be submitted to local Health Boards.

[41] Welsh Government. Putting things right - Guidance on dealing with concerns about the NHS from 1 April 2011 [Internet]. Welsh Government; 2013. Available from: http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20%20-%2020140122.pdf

Publication of Reports

8.19 The annual reports on the duty of candour must be published as soon as practicable after the end of the financial year. In the case of Local Health Boards, their report must include the summary of the reports provided by primary care providers providing services on the Local Health Board's behalf.

8.20 The Local Health Board will therefore be responsible for publishing information relevant to the duty of candour in respect of its own services and the services provided by primary care providers in its area. This will mean that all the information about the duty of candour in respect of the Local Health Board area will be published together.

8.21 As set out above, such reports should be published by **31st October** each year.

BOARD ASSURANCE AND MONITORING ARRANGEMENTS

8.22 Breach of the duty of candour is not a criminal offence. The focus of the duty to be on learning and improving, not on punitive sanctions when NHS Bodies fall short in their application of the duty.

8.23 However, NHS Bodies should consider how monitoring of the effective implementation of the actions required by the duty of candour can be integrated into existing corporate governance frameworks, processes and procedures. Assurance should be sought to confirm that all elements of the procedure are being implemented when they should be, and that there are ways of supporting continuous improvements and refinements in the way that the NHS body discharges its legal responsibilities.

8.24 Leaders and managers within the NHS body should ensure that the implementation of the duty of candour forms a key part of the learning systems within their service areas, and that the necessary integration and alignment with processes and procedures has taken place and reinforces the values expected in their service area.

8.25 In respect of Health Boards, Trusts and Special Health Authorities, the expectation is that there will be local ownership and accountability with regular updates being provided via Quality and Safety Committee (or equivalent) meetings, where Independent Members can seek assurance, the duty is being discharged and learning is being taken forward and concerns are escalated to the Board if appropriate.

8.26 Implementation of, and compliance with the duty will also be scheduled for discussion at quality and delivery group meetings between Welsh Government and individual NHS Bodies, the national quality and delivery group and will inform the Joint Executive Team (JET) meetings and the Minister for Health and Social Service's appraisals with the Chairs of Health Boards, Trusts and Special Health Authorities.

8.27 The Welsh Government will monitor the content of the annual reports alongside other sources of information which will help triangulate the application of the duty with, for example, consideration of serious incidents reported in line with the new National Patient Safety Incident Reporting policy.

8.28 Compliance with the duty will also form part of the matters considered by Healthcare Inspectorate Wales (HIW) when inspecting and reviewing the NHS.

8.29 The annual reporting requirements will also provide information to the public and the Welsh Government about the duty, which will help to make the process transparent and accessible to the public and Bodies such as the Citizen Voice Body for Health and Social Care, Wales.

CONFIDENTIALITY

8.30 It is important to ensure that at all times the requirements of GDPR are adhered to when accessing, processing and disclosing service user information. Reports and publications must not identify any person to whom health care is being or has been provided by or on behalf of the NHS body, or any person acting on behalf of a service user.

8.31 Care must also be taken not to unwittingly enable a person to be identified from the information provided within a report. It is not necessary to name a person in order for them to be identifiable if, for example, a case has received media attention or, to cite another example, where a person has a rare medical condition and simply naming the condition could render the person identifiable.

8.32 The sharing of any information needs to also consider whether there is a conflicting need that may delay such sharing of information such as a criminal investigation or safeguarding process as set out in regulation 12 of the candour procedure regulations.

8.33 When completing records under duty of candour staff should remember that any records made in relation to the incident may be disclosable to the individual under UK GDPR (if their personal data) or to the general public under the Freedom of Information Act (if not personal data). Staff should also involve their organisation Data Protection Officer (DPO) when a notifiable adverse outcome appears to involve a personal data breach as there may also be reporting requirements to the Information Commissioners Office under UK GDPR.

LIC 23-09

Canllawiau Statudol y Ddyletswydd Gonestrwydd 2023

Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020,

Dyddiad cyhoeddi: 1 Ebrill 2023

CYNNWYS

GEIRFA

Dehongli; yn y canllawiau hyn:

- Ystyr Deddf 2006 yw Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.
- Ystyr Rheoliadau 2011 yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011.
- Ystyr y Ddeddf yw Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020.
- Ystyr ymddiheuriad yw mynegiant o dristwch neu edifeirwch mewn perthynas â'r canlyniad andwyol hysbysadwy.
- Ystyr gweithdrefn gonestrwydd yw'r weithdrefn a nodir yn Rheoliadau'r Weithdrefn Gonestrwydd y mae'n rhaid i gorff GIG ei dilyn mewn perthynas â chanlyniad andwyol hysbysadwy.
- Ystyr Rheoliadau'r Weithdrefn Gonestrwydd yw Rheoliadau'r Weithdrefn Dyletswydd Gonestrwydd (Cymru) 2023.
- Mae niwed yn cynnwys niwed seicolegol ac, yn achos defnyddiwr gwasanaeth sy'n feichiog, golli neu niweidio'r plentyn heb ei eni.
- Ystyr gofal iechyd yw gwasanaethau a ddarperir yng Nghymru o dan neu yn rhinwedd Deddf 2006 ar gyfer neu mewn perthynas ag—
    - (a) atal salwch, gwneud diagnosis ohono neu ei drin.
    - (b) hybu ac amddiffyn iechyd y cyhoedd.
- Mae i salwch yr ystyr a roddir iddo yn adran 206 o Ddeddf 2006.
- Corff GIG yw—
    - (a) Bwrdd Iechyd Lleol.
    - (b) Ymddiriedolaeth GIG.
    - (c) Awdurdod Iechyd Arbennig.
    - (d) darparwr gofal sylfaenol.

- Mae canlyniad andwyol hysbysadwy yn digwydd pan ddaw dyletswydd gonestrwydd yn effeithiol yn unol ag adran 3 o'r Ddeddf.
- Ystyr defnyddiwr gwasanaeth yw person, y mae corff GIG yn darparu neu wedi darparu gofal iechyd iddo, sydd wedi dioddef canlyniad andwyol;
- Ystyr Awdurdod Iechyd Arbennig yw corff a sefydlwyd o dan adran 22 o Ddeddf 2006; ond nid yw'n cynnwys unrhyw Awdurdod Iechyd Arbennig trawsffiniol (o fewn yr ystyr yn adran 8A(5) o Ddeddf 2006) ac eithrio Gwaed a Thrawsblaniadau'r GIG.
- Mae person yn ddarparwr gofal sylfaenol i'r graddau (a dim ond i'r graddau) y mae'r person yn darparu gofal iechyd ar ran Bwrdd Iechyd Lleol yn rhinwedd contract, cytundeb neu drefniant o dan Ran 4, 5, 6 neu 7 o Ddeddf 2006 rhwng y person a'r Bwrdd Iechyd Lleol.
- Mae defnyddiwr gwasanaeth i'w drin fel pe bai wedi dioddef canlyniad andwyol os yw'r defnyddiwr yn profi mwy nag ychydig o niwed annisgwyl neu anfwriadol neu os yw'r amgylchiadau yn golygu y gallai brofi niwed o'r fath.

- Adolygiad: adolygiad yw'r eglurhad o'r digwyddiad sydd wedi'i adrodd ac asesiad o lefel y niwed sydd wedi digwydd neu a allai ddigwydd i'r defnyddiwr gwasanaeth unigol gan uwch-aelod o staff i asesu a yw'r trothwy ar gyfer sbarduno dyletswydd gonestrwydd wedi'i fodloni. Cyfeirir at hyn weithiau fel cymeradwyo'r digwyddiad.
- Ymchwiliad: yr archwiliad manwl (ymholiadau ychwanegol fel y'u rhestrir yn y rheoliadau Gonestrwydd) a gynhelir i ddeall beth sydd wedi digwydd ac unrhyw achosion sylfaenol a dysgu fel y'u hamlinellir yn Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011.
- At ddibenion y canllawiau hyn ac i wneud y cysylltiadau â Rheoliadau'r Weithdrefn Gonestrwydd, cyfeirir at y term defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran fel 'person perthnasol' yn y Rheoliadau. Cyfeirir at y corff GIG yn y Rheoliadau fel 'corff cyfrifol.'
- Mae Datix Cymru yn blatfform digidol i adrodd am ddigwyddiadau a phryderon a'u rheoli, ac mae'n rhan o Raglen System Rheoli Pryderon Unwaith i Gymru, sy'n cynnwys Datix Cymru a Phrofiad CIVICA Cymru.

RHAGAIR

Mae cyflwyno'r ddyletswydd gonestrwydd drwy Ddeddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020[1] ('y Ddeddf'), yn tanlinellu ymrwymiad Llywodraeth Cymru i wasanaethau iechyd diogel, effeithiol sy'n canolbwyntio ar y person. Gosodir y ddyletswydd ar Gyrff GIG (Byrddau Iechyd, Ymddiriedolaethau GIG, Awdurdodau Iechyd Arbennig Cymru a Gwaed a Thrawsblaniadau'r GIG o ran ei swyddogaethau yng Nghymru) ac ar ddarparwyr gofal sylfaenol yng Nghymru o ran y gwasanaethau y maent yn eu darparu dan gontract neu drefniadau eraill gyda Bwrdd Iechyd Lleol.

Prif nod y ddyletswydd yn y Ddeddf yn y pen draw yw gwasanaethu defnyddwyr gwasanaethau drwy sicrhau, os yw'r defnyddiwr gwasanaeth yn profi unrhyw niwed annisgwyl neu anfwriadol sy'n fwy nag ychydig o niwed, neu os yw'r amgylchiadau yn golygu y gallai brofi niwed o'r fath, a bod y ddarpariaeth gofal iechyd yn ffactor neu y gall fod wedi bod yn ffactor, mae'r defnyddiwr gwasanaeth (neu'r person sy'n gweithredu ar ei ran) yn cael gwybod, yn cael ymddiheuriad ac yn cael cynnig manylion gwasanaethau neu gymorth perthnasol. Mae'n ofynnol hefyd i'r corff GIG roi i'r defnyddiwr gwasanaeth neu i'r person sy'n gweithredu ar ei ran eglurhad o'r camau y bydd y corff cyfrifol neu'r darparwr yn eu cymryd, a'r ymholiadau pellach y bydd y corff cyfrifol neu'r darparwr yn eu cynnal, i ymchwilio i amgylchiadau'r canlyniad andwyol hysbysadwy, gan gynnwys unrhyw gamau sydd i'w cymryd o dan Reoliadau Trefniadau Pryderon, Cwynion ac Iawn (Cymru) 2011[2].

[1] Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020 https://www.legislation.gov.uk/asc/2020/1/contents

[2] Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011 https://www.legislation.gov.uk/wsi/2011/704/contents/made

Nid Cymru yw'r unig awdurdodaeth yn y DU i fod â ddyletswydd gonestrwydd. Yn Lloegr, mae'r ddyletswydd wedi'i nodi yn rheoliad 20 o Reoliadau Deddf Iechyd a Gofal Cymdeithasol 2008 (Gweithgareddau a Reoleiddir) 2014[3]. Yn yr Alban, mae wedi'i nodi yn Rhan 2 o Ddeddf Iechyd (Tybaco, Nicotin etc. a Gofal) (Yr Alban) 2016[4].

Ein hamcan polisi cyffredinol, yn unol â'n dyheadau yn Cymru Iachach[5] am ofal mwy integredig, yw sicrhau os bydd person yn cael gofal gan y GIG, neu gan ddarparwr rheoleiddiedig gwasanaethau gofal cymdeithasol, bod y person hwnnw'n gallu bod yn dawel ei feddwl y bydd y darparwr gofal yn ei drin mewn ffordd agored a gonest.

Ym maes gofal cymdeithasol, mae dyletswydd gonestrwydd yn bodoli eisoes ar gyfer darparwyr ac unigolion cyfrifol gwasanaethau rheoleiddiedig o dan Reoliadau 2017[6].

Mae gwaith yn cael ei wneud ar wahân i wneud Rheoliadau i osod dyletswydd gonestrwydd ar ddarparwyr gofal iechyd annibynnol yng Nghymru, gan ddefnyddio pwerau o dan Ddeddf Safonau Gofal 2000[7]. Rydym wedi gallu trafod yn gadarnhaol iawn â chynrychiolwyr o'r sector gofal iechyd annibynnol yng Nghymru, a'r bwriad yw gweithio gyda nhw i gyflwyno dyletswydd gonestrwydd sy'n gymwys i'r sector gofal iechyd annibynnol yng Nghymru. Rhagwelir mai'r dyddiad dod i rym fydd Ebrill 2024.

Rydym yn gwybod bod y mwyafrif llethol o ddarparwyr gwasanaethau iechyd a gofal cymdeithasol eisiau darparu gofal diogel a thosturiol o ansawdd uchel. Fodd bynnag, yn yr un modd, er gwaethaf y bwriadau hyn, gwyddom ei bod hi'n anochel mewn gwasanaethau cymhleth ac amlochrog y bydd pobl yn dioddef niwed o bryd i'w gilydd.

Pan fyddan nhw, mae'r ffordd y mae Cyrff GIG yn delio â'r sefyllfaoedd hyn yn bwysig iawn, a gall wneud gwahaniaeth enfawr i brofiadau pobl ac i'w perthynas barhaus â'u darparwr gofal. Mae hyn yn arbennig o bwysig mewn lleoliadau gofal iechyd, lle mae gan bobl berthynas hirsefydlog â'u darparwyr gofal yn aml. Mae hi'n anodd ennill ymddiriedaeth, ond mae'n hawdd ei cholli. Dylai bod yn agored ac yn onest fod wrth galon pob perthynas rhwng y rhai sy'n darparu, sy'n derbyn ac/neu sy'n cael triniaeth a gofal.

[3] Rheoliadau Deddf Iechyd a Gofal Cymdeithasol 2008 (Gweithgareddau a Reoleiddir) 2014) (OS 2008/2936). https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20

[4]Deddf Iechyd (Tybaco, Nicotin ac ati a Gofal) (Yr Alban) 2016 https://www.legislation.gov.uk/asp/2016/14/contents

[5] Llywodraeth Cymru 2018 – Cymru iachach: cynllun hirdymor ar gyfer iechyd a gofal cymdeithasol Cymru iachach: cynllun hirdymor ar gyfer iechyd a gofal cymdeithasol | LLYW.CYMRU

[6] Llywodraeth Cymru - Rheoliadau Gwasanaethau Rheoleiddiedig (Darparwyr Gwasanaethau ac Unigolion Cyfrifol) (Cymru) 2017 https://www.legislation.gov.uk/wsi/2017/1264/contents/made

[7] Deddf Safonau Gofal 2000 https://www.legislation.gov.uk/ukpga/2000/14/contents

1. Pennod 1 - Cyflwyniad a Diben

Cyflwyniad

1.1 Bydd y Ddeddf yn dod i rym ar 1 Ebrill 2023. Mae'n gyfrwng i wella a diogelu iechyd, gofal a llesiant poblogaeth Cymru yn awr ac yn y dyfodol. Ei nod yw rhoi llais cryfach i ddinasyddion a gwella atebolrwydd gwasanaethau i ddarparu profiad ac ansawdd gofal gwell. Bydd gwneud hynny'n cyfrannu at wlad iach a mwy ffyniannus. Yn ei chyfanrwydd, bwriedir i'r Ddeddf roi budd cadarnhaol cronnus i bawb yng Nghymru, gan gefnogi diwylliant ac amodau sy'n canolbwyntio ar sicrhau gwelliannau mewn iechyd a gofal cymdeithasol.

1.2 Nod y canllawiau statudol hyn yw helpu cyrff y GIG i gyflawni gofynion y ddyletswydd gonestrwydd.

1.3 Nodir y sail gyfreithiol ar gyfer y ddyletswydd yn Rhan 3 o'r Ddeddf. Mae adran 3 yn rhagnodi pryd y mae'r ddyletswydd gonestrwydd yn gymwys. Mae adran 4 yn ei gwneud yn ofynnol i Weinidogion Cymru wneud Rheoliadau sy'n nodi'r weithdrefn y mae'n rhaid i Gyrff GIG ei dilyn pan sbardunir y ddyletswydd gonestrwydd. Mae adrannau 5 i 8 yn rhagnodi'r gofynion adrodd. Ystyrir yr adrannau hyn o'r Ddeddf yn fanylach yn nes ymlaen yn y canllawiau.

1.4 Bydd cydymffurfio â'r ddyletswydd gonestrwydd hefyd yn ei gwneud yn haws i Fyrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig gydymffurfio â:

- y ddyletswydd ansawdd yn adran 2 o'r Ddeddf, sy'n ei gwneud yn ofynnol i Gyrff gyflawni eu swyddogaethau gyda'r bwriad o sicrhau gwelliant yn ansawdd gwasanaethau iechyd.
- y ddyletswydd economaidd-gymdeithasol[8] a gyflwynwyd gan Ddeddf Cydraddoldeb 2010[9], sy'n ei gwneud yn ofynnol i gyrff roi sylw dyladwy i ddymunoldeb cyflawni eu swyddogaethau mewn modd sydd wedi'i gynllunio i leihau'r anghydraddoldebau canlyniadau sy'n deillio o anfantais economaidd-gymdeithasol;
- y ddyletswydd llesiant yn Neddf Llesiant Cenedlaethau'r Dyfodol (Cymru) 2015[10] i gyflawni datblygu cynaliadwy.

1.5 Mae'r ddyletswydd gonestrwydd yn cynorthwyo pawb yng Nghymru, ac mae gwybodaeth amdani ar gael hygyrch iddynt. Mae'n hybu penderfyniadau gwell ac yn y pen draw mae'n ceisio cyflawni canlyniadau gwell i bawb sy'n defnyddio gwasanaethau iechyd. Mae'n ei gwneud yn ofynnol i Gyrff GIG gynnwys pobl

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[8] Canllawiau Statudol: Deddf Cydraddoldeb 2010 (Rheoliadau Awdurdodau sy'n destun dyletswydd ynghylch anghydraddoldebau cymdeithasol-economaidd) (Cymru) 2021 https://senedd.cymru/media/405ljabt/gen-ld14109-w.pdf

[9] Deddf Cydraddoldeb 2010 https://www.legislation.gov.uk/ukpga/2010/15/contents

[10] Deddf Llesiant Cenedlaethau'r Dyfodol (Cymru) 2015 https://www.futuregenerations.wales/about-us/future-generations-act/

mewn penderfyniadau sy'n effeithio arnynt a hwyluso camau ataliol, a thrwy hynny wella ansawdd gwasanaethau ac edrych tua'r tymor hir.

1.6 Y prif fwriad felly yw adeiladu ar y gwaith sydd eisoes wedi'i gyflawni drwy adrodd yn well ac ymchwilio i ddigwyddiadau'n gymesur, yn unol â'r Polisi Cenedlaethol ar Adrodd am Ddigwyddiadau Diogelwch yn Ymwneud a Chleifion[11] newydd a chyflwyno'r broses Gweithio i Wella[12] ar gyfer ymchwilio i bryderon a chwynion. Mae'r broses o gyflwyno dyletswydd gonestrwydd sefydliadol fwy strwythuredig a ategir gan ganllawiau statudol a Rheoliadau'r Weithdrefn Gonestrwydd yn helpu i ddatblygu ymhellach y diwylliant o fod yn agored yn y GIG yng Nghymru.

DIBEN Y CANLLAWIAU

1.7 Bod yn agored gyda defnyddwyr gwasanaethau a'u cynrychiolwyr pan fydd pethau'n mynd o chwith yn eu gofal yw'r peth iawn i'w wneud. Mae'r ddyletswydd gonestrwydd wedi'i chynllunio i greu amgylchedd diogel sy'n gefnogol ac yn rymusol i'r rhai sy'n darparu, yn derbyn ac/neu sy'n cael triniaeth a gofal yn y GIG.

1.8 Yn y canllawiau hyn, mae'r gair **rhaid** yn cyfeirio at gamau gweithredu sy'n ofyniad cyfreithiol fel y nodir yn Rheoliadau'r Weithdrefn Gonestrwydd neu yn Rhan 3 o'r Ddeddf. Mae gweddill y canllawiau wedi'u cynllunio i ddarparu fframwaith arferion gorau i helpu Cyrff GIG i weithredu a chymhwyso'r ddyletswydd.

1.9 Yn unol ag adran 10 o'r Ddeddf, rhaid i Gyrff GIG roi sylw i'r canllawiau wrth arfer swyddogaethau sy'n gysylltiedig â'r dyletswydd gonestrwydd. Mae 'rhoi sylw' yn golygu y bydd rhaid i'r rhai y mae'r ddyletswydd yn gymwys iddynt fod yn gyfarwydd â hi a dangos eu bod yn ystyried ei hegwyddorion wrth wneud unrhyw benderfyniadau perthnasol o ran digwyddiadau neu bryderon yn ymwneud â gofal iechyd defnyddwyr gwasanaethau. Pe bai cyrff y mae'r ddyletswydd yn gymwys iddynt yn penderfynu gwyro oddi wrth y canllawiau a nodir yma, dylai unrhyw wyriad o'r fath gael ei resymu'n briodol ac yn rhesymegol a chael ei gydbwyso yn erbyn eu rhwymedigaethau cyfreithiol o dan y Ddeddf.

1.10 Mae'r canllawiau'n cynnwys enghreifftiau ac astudiaethau achos i helpu cyrff GIG i ddeall pryd y mae'r ddyletswydd gonestrwydd yn cael ei sbarduno, ac mae'n cynnig siartiau llif cam wrth gam ar gyfer y weithdrefn.

[11] Llywodraeth Cymru, Mai 2021 Polisi Cenedlaethol ar Adrodd am Ddigwyddiadau'n Ymwneud â Diogelwch Cleifion https://ug.gig.cymru/diogelwch-cleifion-cymru/digwyddiadau-syn-ymwneud-a-diogelwch-cleifion/

[12] Llywodraeth Cymru 2011 Putting Things Right Guidance on dealing with concerns about the NHS from 1 April 2011 version 3. https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/

1.11 Mae hefyd yn cynnwys canllawiau i Gyrff GIG ar gydymffurfio â'r dyletswyddau sydd arnynt o ran adrodd, sy'n elfen allweddol o'r ddyletswydd gonestrwydd.

1.12 Mae'r canllawiau'n rhoi sylfaen i Gyrff GIG ddatblygu polisïau a gweithdrefnau lleol, a gofynion hyfforddi a chefnogi sydd wedi'u teilwra i'r corff a/neu'r gwasanaethau penodol y maent yn eu darparu, a bydd yn helpu i sicrhau cysondeb o ran dull gweithredu a thegwch o ran ymateb: sef 'model Cymru gyfan:

1.13 Bydd y canllawiau'n cael eu hategu gan becyn hyfforddi ar-lein i helpu Cyrff GIG i weithredu'r ddyletswydd. Gan adeiladu ar y gwaith sydd eisoes wedi'i ddechrau fel rhan o'r broses Gweithio i Wella i wreiddio ymddygiad agored, mae rhaglen hyfforddi Llywodraeth Cymru yn ystyried sut i annog y "newid diwylliannol" drwy wneud bod yn agored ac yn dryloyw yn rhan arferol o'r diwylliant ar draws Cyrff GIG yng Nghymru.

1.14 Bwriedir hefyd i'r canllawiau fod yn ddeunydd cyfeirio i ddefnyddwyr gwasanaethau a'u cynrychiolwyr. Mae taflenni ar gael i sicrhau bod pawb yn ein cymuned yn gallu cael gafael ar ddeunyddiau a fydd yn eu grymuso i ofyn cwestiynau am y gofal a'r gwasanaethau y maent yn eu derbyn, i'w helpu i ddeall beth y mae'r ddyletswydd gonestrwydd yn ei olygu, a beth y gallant ei ddisgwyl gan eu darparwyr gofal pan gaiff ei sbarduno.

1.15 Ni fwriedir iddynt fod yn ddehongliad pendant o'r ddeddfwriaeth ar y ddyletswydd gonestrwydd. Dylid darllen y Ddeddf, Rheoliadau'r Weithdrefn Gonestrwydd a chanllawiau'r Ddyletswydd Gonestrwydd gyda'i gilydd.

1.16 Rydym yn cydnabod hefyd mai dim ond rhan o'r broses yw'r Ddeddf, y Rheoliadau a'r fframwaith cysylltiedig, er eu bod yn bwysig. Er mwyn gwreiddio'r ddyletswydd gonestrwydd go iawn bydd hefyd angen goresgyn y pethau sy'n rhwystro diwylliant agored a gonest. Mae'r rhwystrau hynny'n cynnwys ofn, diwylliant o gyfrinachedd a/neu feio, diffyg hyder mewn sgiliau cyfathrebu, ofn ypsetio pobl ac amheuaeth a yw datgelu yn ffordd dda o wella diwylliant. Mae ofni bai, sgil-effeithiau proffesiynol neu sefydliadol, atebolrwydd cyfreithiol, ymatebion negyddol a diffyg atebolrwydd hefyd yn gallu bod yn rhwystrau rhag datgelu.

1.17 Bydd system heb rwystrau artiffisial rhwng Cyrff GIG, lle mae gofal a chymorth yn canolbwyntio ar yr unigolyn, lle mae staff yn cael cymorth i wella gofal yn hytrach na'i reoli neu ei ddarparu'n unig, a lle mae pwyslais ar atebolrwydd, yn helpu i oresgyn y rhwystrau hyn.

2 Pennod 2 – Cymhwyso'r Ddyletswydd Gonestrwydd

Y ddyletswydd gonestrwydd statudol a'r dyletswyddau gonestrwydd proffesiynol presennol.

2.1 Bu galwadau am osod dyletswydd gonestrwydd[13][14][15][16] ar Gyrff GIG yng Nghymru, ar wahân i, a chan ategu'r dyletswyddau gonestrwydd anstatudol sy'n gymwys i amryw o weithwyr gofal iechyd proffesiynol fel rhan o'u rheoleiddio proffesiynol. Er hynny, dylid cydnabod bod canllawiau Dyletswydd Gonestrwydd proffesiynol yn gymwys mewn mwy o sefyllfaoedd na'r Ddyletswydd Gonestrwydd ar sefydliadau yng Nghymru.

2.2 Mae gweithwyr gofal iechyd proffesiynol sy'n ddarostyngedig i ddyletswyddau gonestrwydd proffesiynol yn gorfod bod yn agored ac yn onest gyda defnyddwyr gwasanaethau, eu cydweithwyr, eu cyflogwyr a sefydliadau perthnasol, a rhaid iddynt gymryd rhan mewn adolygiadau ac ymchwiliadau pan ofynnir iddynt wneud hynny. Rhaid iddynt gefnogi ac annog ei gilydd i fod yn agored ac yn onest[17]. Rhaid iddynt hefyd fod yn agored ac yn onest â'u rheoleiddwyr, gan godi pryderon pan fydd hynny'n briodol. Felly, mae egwyddorion sylfaenol dyletswydd gonestrwydd eisoes wedi'u gwreiddio ar draws cyfres eang o Gyrff GIG drwy'r gweithwyr proffesiynol hynny sy'n gweithio ynddynt.

2.3 Mae gan y ddyletswydd gonestrwydd statudol a'r dyletswyddau gonestrwydd proffesiynol yr un nodau – sef bod yn agored ac yn dryloyw gyda phobl sy'n cael gofal a thriniaeth. Bydd y cysylltiadau cryf rhwng y dyletswyddau gonestrwydd statudol a phroffesiynol yn grymuso staff i siarad yn agored am bryderon, ac yn annog dysgu i wella ansawdd y ddarpariaeth gofal.

2.4 Mae dyletswydd gonestrwydd broffesiynol yn ymwneud ag arferion proffesiynol unigolion tra bod y ddyletswydd sefydliadol statudol yn cael ei rhoi ar sefydliad i sicrhau, pan gaiff ei sbarduno, bod defnyddwyr gwasanaethau yn cael eu trin yr

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[13] Kennedy, I, ac eraill.The Bristol Royal infirmary inquiry. Learning from Bristol - The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 [y Rhyngrwyd]. Y Goron; 2001. Ar gael yn: https://webarchive.nationalarchives.gov.uk/20090811143822/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf

[14] Donaldson, L. Making Amends - A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS [y Rhyngrwyd]. Cyhoeddiadau'r Adran Iechyd; 2003. Ar gael yn: https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf

[15] Francis, R ac eraill. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry [y Rhyngrwyd]. Ymddiriedolaeth Sefydledig GIG Swydd Stafford; 2013. Ar gael yn: https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

[16] Evans, K. "Defnyddio Cwynion yn Rhodd – adolygiad o ymdrin â phryderon (cwynion) yn GIG Cymru. 2014. https://gweddill.gov.wales/docs/dhss/publications/140702complaintsen.pdf

[17] Y Cyngor Nyrsio a Bydwreigiaeth a'r Cyngor Meddygol Cyffredinol 2022. Openness and honesty when things go wrong: the professional duty of candour. https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/read-the-professional-duty-of-candour/#about_guidance

un mor agored a thryloyw gan y sefydliad o ran yr hyn a ddigwyddodd yn eu gofal.

2.5 Bydd y ddyletswydd statudol yn hyrwyddo diwylliant o fod yn agored ac yn onest ar draws y system. Mae hefyd yn gosod gofyniad, ar lefel sefydliadol, i Gyrff GIG ddilyn gweithdrefn benodedig a ategir gan Reoliadau'r Weithdrefn Gonestrwydd, i ddangos bod cyfres o gamau rhagnodedig wedi'u cymryd pan sbardunir y ddyletswydd. Disgrifir y camau hyn ym Mhennod 3 isod, a ategir yn **Atodiad C** gan siart lif o'r weithdrefn. Bydd y seilwaith hwn yn helpu i greu'r amodau i Gyrff GIG gyflawni'r ddyletswydd gonestrwydd yn hyderus pan gaiff ei sbarduno. Mae astudiaethau achos yn atodiad H sy'n rhoi enghreifftiau clinigol.

2.6 Fferyllwyr a thechnegwyr fferyllol
Dylai fferyllwyr cofrestredig, technegwyr fferyllol a phobl sy'n gweithio o dan eu goruchwyliaeth mewn fferyllfeydd manwerthu barhau i fod yn ymwybodol o ddarpariaethau Gorchymyn Fferylliaeth (Gwallau Paratoi a Chyflenwi – Fferyllfeydd Cofrestredig) 2018 ("Y Gorchymyn")[18]. Mae gweithwyr fferyllol proffesiynol yn wynebu risg o gael eu herlyn o dan adran 63 (difwyno cynhyrchion meddyginiaethol) ac adran 64 (amddiffyn prynwyr cynhyrchion meddyginiaethol) o Ddeddf Meddyginiaethau 1968[19] os byddant yn gwneud gwallau wrth baratoi neu gyflenwi meddyginiaethau.

2.7 Er mwyn elwa ar yr amddiffyniadau yn adran 67B (amddiffyniad i drosedd o fynd yn groes i adran 63(a) neu (b): cynnyrch a werthwyd neu a gyflenwyd) ac adran 67C (amddiffyniad i drosedd o fynd yn groes i adran 64) o Ddeddf Meddyginiaethau 1968, rhaid bodloni'r amodau ar gyfer elwa ar yr amddiffyniadau, gan gynnwys yr amodau sy'n ymwneud â hysbysu'r person y bwriadwyd rhoi'r cynnyrch iddo.

2.8 O ganlyniad, mae angen ystyried gofynion y Gorchymyn ochr yn ochr â'r ddyletswydd gonestrwydd statudol, ac yn ogystal â hi.

I BWY Y MAE'R DDYLETSWYDD GONESTRWYDD YN GYMWYS?

2.9 Mae'r ddyletswydd gonestrwydd yn Rhan 3 o'r Ddeddf yn gymwys i'r Cyrff GIG canlynol a restrir yn adran 11(3), ac a ddiffinnir drwy gyfeirio at adran 11(4) a (7):

- Byrddau Iechyd Lleol.
- Darparwyr Gofal Sylfaenol yng Nghymru (h.y. ymarferwyr cyffredinol, deintyddion, optometryddion a fferyllwyr) o ran y gwasanaethau a ddarperir ganddynt o dan gontract neu drefniant â Bwrdd Iechyd Lleol (h.y. mae'n

[18] Gorchymyn Fferylliaeth (Gwallau Paratoi a Chyflenwi - Fferyllfeydd Cofrestredig) 2018. https://www.legislation.gov.uk/uksi/2018/181
[19] Y Ddeddf Meddyginiaethau. https://www.legislation.gov.uk/ukpga/1968/67/contents

gymwys i wasanaethau GIG sy'n cael eu darparu gan ddarparwyr gofal sylfaenol).
- Ymddiriedolaethau GIG yng Nghymru.
- Awdurdodau Iechyd Arbennig Cymru, a Gwaed a Thrawsblaniadau'r GIG o ran y swyddogaethau a arferir ganddo mewn perthynas â Chymru.

PRYD Y MAE'R DDYLETSWYDD GONESTRWYDD YN GYMWYS?

2.10 Daw'r ddyletswydd i rym mewn perthynas â chorff GIG os bodlonir y **ddau** amod canlynol:

(1) Yr **amod cyntaf** yw bod y person (y "defnyddiwr gwasanaeth") y mae'r corff yn darparu neu wedi darparu gofal iechyd iddo wedi dioddef canlyniad andwyol.

2.11 Ystyr 'gofal iechyd' yw gwasanaethau a ddarperir yng Nghymru o dan neu yn rhinwedd Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2.11 h.y. fel rhan o unrhyw wasanaeth GIG, ar gyfer neu mewn perthynas ag:
- atal salwch, gwneud diagnosis ohono neu ei drin; neu
- hybu ac amddiffyn iechyd y cyhoedd.

2.12 Mae "salwch" yn cynnwys unrhyw anhwylder neu anabledd meddwl ac unrhyw anaf neu anabledd sy'n gofyn am driniaeth feddygol neu ddeintyddol neu nyrsio.

2.13 Mae ystyr gofal iechyd wedi'i lunio'n eang yn fwriadol i gynnwys yr holl wasanaethau GIG a ddarperir yng Nghymru.

2.14 Mae defnyddiwr gwasanaeth i'w drin fel pe bai wedi dioddef canlyniad andwyol os yw'r defnyddiwr yn profi mwy nag ychydig o niwed annisgwyl neu anfwriadol neu os yw'r amgylchiadau yn golygu y gallai brofi niwed o'r fath.

2.15 Fel y nodir yn y Nodiadau Esboniadol i'r Ddeddf, gall y ddyletswydd gael ei sbarduno gan gam gweithredu a gymerwyd gan gorff GIG wrth ddarparu gofal iechyd neu drwy fethu â chymryd camau gweithredu.

2.16 At ddibenion y ddyletswydd gonestrwydd, mae niwed yn cynnwys niwed seicolegol ac, yn achos defnyddiwr gwasanaeth sy'n feichiog, colli neu niweidio'r plentyn heb ei eni (adran 11(7) o'r Ddeddf).

(2) Yr **ail amod** yw bod darparu'r gofal iechyd yn ffactor, neu y gall fod wedi bod yn ffactor, a achosodd i'r defnyddiwr gwasanaeth ddioddef y canlyniad hwnnw.

2.17 Felly, rhaid bod y canlyniad yn gysylltiedig â darpariaeth y gofal gan y corff GIG yn hytrach na'i fod yn cael ei briodoli'n unig i salwch neu gyflwr isorweddol y person – gweler rhagor ym Mhennod 2.

2.18 Fodd bynnag, nid oes angen bod yn sicr mai'r gofal iechyd a achosodd y niwed. Mae'n ddigon y gallai'r gofal iechyd fod wedi bod yn ffactor.

2.19 Yn Rheoliadau'r Weithdrefn Gonestrwydd pan fo'r ddau amod hyn wedi'u bodloni a'r ddyletswydd wedi'i sbarduno, gelwir hyn yn "ganlyniad andwyol hysbysadwy". Yn **Atodiad A** ceir siart llif sy'n amlinellu'r broses adolygu sbardunau.

Pennod 3 - Sefydlu lefel y niwed

Mwy nag ychydig o niwed

3.1 Nid yw "mwy nag ychydig o niwed" wedi'i ddiffinio yn y Ddeddf. Fodd bynnag, at ddibenion y canllawiau hyn ystyrir bod "mwy nag ychydig o niwed" yn golygu niwed cymedrol, niwed difrifol a marwolaeth. Mae hyn yn ategu'r prosesau sy'n bodoli eisoes ar gyfer Gweithio i Wella a Bod yn Agored, ac yn cyd-fynd hefyd â'r polisi cenedlaethol ar adrodd am digwyddiadau diogelwch cleifion a'r modiwl adrodd am ddigwyddiadau yn system Datix Cymru. Felly, yn ymarferol, sbardunir y ddyletswydd gonestrwydd os yw'r defnyddiwr gwasanaeth yn profi niwed annisgwyl neu anfwriadol sy'n gymedrol neu'n fwy, neu os yw'r amgylchiadau'n golygu y gallai brofi niwed o'r fath, a bod y ddarpariaeth gofal iechyd yn ffactor (neu y gall fod wedi bod yn ffactor) a achosodd i'r defnyddiwr gwasanaeth ddioddef y canlyniad hwnnw.

3.2 Niwed Cymedrol: yw unrhyw niwed neu niwed parhaol ond nid yw'n golygu bod angen 'cynnydd cymedrol mewn triniaeth' yn gysylltiedig â'r digwyddiad. Diffinnir cynnydd cymedrol mewn triniaeth fel dychweliad heb ei gynllunio at lawdriniaeth, ailddderbyniad heb ei gynllunio i'r ysbyty, episod estynedig o ofal, amser ychwanegol yn yr ysbyty neu fel cleifion allanol neu drosglwyddo i ardal driniaeth arall megis gofal dwys.

3.3 Niwed Difrifol: yw lleihau'r swyddogaethau corfforol, synhwyraidd, echddygol, ffisiolegol neu ddeallusol yn barhaol, gan gynnwys tynnu'r aelod anghywir o'r corff neu'r organ anghywir neu niwed i'r ymennydd, sy'n gysylltiedig yn uniongyrchol â'r digwyddiad ac nad yw'n gysylltiedig â chwrs naturiol salwch neu gyflwr isorweddol y defnyddiwr gwasanaeth.

3.4 Marwolaeth: Marwolaeth a achoswyd neu y cyfrannwyd ati gan ddigwyddiad diogelwch cleifion, yn hytrach na marwolaeth sy'n digwydd o ganlyniad uniongyrchol i gwrs naturiol salwch neu gyflwr isorweddol y claf

.

3.5 Mae fframwaith lefelau niwed, sy'n egluro'r mathau o niwed a ystyrir yn gymedrol ac yn uwch, wedi'i gynnwys yn **Atodiad B**.

Niwed 'anfwriadol' neu 'annisgwyl'

3.6 I fod yn hysbysadwy, rhaid i'r niwed fod yn anfwriadol neu'n annisgwyl. Gall fod o ganlyniad i naill ai ymyrraeth/triniaeth go iawn, neu ddiffyg mewn gofal, er enghraifft colli diagnosis o ganser.

3.7 Wrth gwrs, gall triniaeth feddygol neu lawfeddygol a phob ymyrraeth gofal fod â risgiau cynhenid, neu gall y driniaeth ynddi ei hun achosi cynnydd dros dro mewn symptomau.

3.8 Ni fyddai niwed sy'n cael ei achosi gan y driniaeth ei hun (e.e. amhariadau i swyddogaeth o ganlyniad i lawdriniaeth,) yn hysbysadwy o reidrwydd. Gall y rhain fod yn perthyn i'r categori risg hysbys, a allai fod wedi cael ei hesbonio i'r claf, a'i derbyn ganddo, fel rhan o'r broses gydsynio.

Sgil-effeithiau a chymhlethdodau

3.9 Nid yw'n fwriad polisi y byddai pob sgil-effaith i feddyginiaeth neu driniaeth sydd wedi achosi niwed neu a allai achosi niwed yn sbarduno'r ddyletswydd gonestrwydd. Yn gyntaf, rhaid bodloni'r trothwy niwed a rhaid i'r niwed fod yn anfwriadol neu'n annisgwyl fel yr amlinellir uchod. Yn ei hanfod gall cymhlethdodau sy'n gysylltiedig â gofal, na chafodd eu trafod fel risg i'r gofal iechyd a ddarparwyd, fodloni'r trothwy sbardun ar gyfer y ddyletswydd. Mae mecanweithiau sefydledig ar gael ar gyfer adrodd am a monitro sgil-effeithiau ac adweithiau niweidiol meddyginiaeth, a bydd angen dal i ddilyn y rhain a dysgu oddi wrthynt, waeth a yw'r ddyletswydd yn cael ei sbarduno ai peidio.

3.10 Mae'n aml yn aneglur yn y camau cychwynnol a oes niwed anfwriadol neu annisgwyl wedi digwydd neu y gallai ddigwydd, ac argymhellir cynnal trafodaeth fel rhan o adolygiad uwch os yw'r sefyllfa'n gymhleth.

Niwed bwriadol:

3.11 Mae'r mwyafrif o ddigwyddiadau diogelwch cleifion a allai arwain at sbarduno'r ddyletswydd gonestrwydd yn aml yn cynnwys sgwrs rhwng rheolwyr a goruchwylwyr ynghylch a oes gofyn i aelod o staff sy'n rhan o ddigwyddiad diogelwch cleifion gael cymorth neu ymyrraeth unigol benodol i barhau i weithio'n ddiogel. Anaml iawn y bydd yn briodol rhoi cam gweithredu ar waith

sy'n canolbwyntio ar unigolyn – mae gan y rhan fwyaf o faterion diogelwch cleifion achosion systemig dyfnach sy'n gofyn am weithredu ehangach.

3.12 Mae Adroddiad Williams a adroddodd ar laddiad drwy esgeuluster difrifol yn y GIG yn tynnu sylw at y dull hwn[20] gan argymell sefydlu 'Diwylliant Cyfiawn' sy'n rhoi sicrwydd i weithwyr gofal iechyd proffesiynol, cleifion a'u teuluoedd y bydd achosion o esgeulustod difrifol yn cael eu trin mewn modd teg a thosturiol a bod yr algorithm diwylliant cyfiawn dilynol yn cynorthwyo'r trafodaethau[21] hyn.

3.13 Fodd bynnag, ceir ambell sefyllfa brin lle daw'n amlwg y gallai perfformiad neu weithredoedd neu anweithredoedd unigolion fod wedi mynd yn groes i godau ymarfer proffesiynol neu gyfraith droseddol ac nad ydynt yn rhan o achos neu gam gweithredu ehangach yn y sefydliad sy'n ymwneud â diogelwch cleifion. Mae'n hanfodol nad yw rhoi'r ddyletswydd gonestrwydd ar waith yn ymyrryd ag ymchwiliad brys gan yr heddlu neu gyfarfodydd strategaeth diogelu amlasiantaethol, a gall fod yn angenrheidiol ystyried oedi cyn rhoi'r hysbysiad "uniongyrchol". Argymhellir trafod ag ymchwilwyr arweiniol cyn unrhyw ddatgelu pellach. Mae rheoliad 12 o Reoliadau'r Weithdrefn Gonestrwydd yn caniatáu hyn.

Beth yw ystyr niwed 'y gallai' defnyddiwr gwasanaeth ei brofi?

3.14 Mae'n bwysig nodi bod y ddyletswydd yn cael ei sbarduno nid yn unig pan fo'n hysbys fod niwed wedi digwydd, ond hefyd mewn achosion **lle mae'r amgylchiadau'n golygu y gallai person ddioddef mwy nag ychydig o niwed yn y dyfodol yn sgil rhywbeth sydd eisoes wedi digwydd.** Er enghraifft, pe bai gwall wrth roi meddyginiaeth yn achosi mwy nag ychydig o niwed y dyfodol.

3.15 Bydd rhaid i Gyrff GIG farnu a yw'r amgylchiadau'n golygu y gallai'r defnyddiwr brofi mwy nag ychydig o niwed. Yn achos gwall wrth roi meddyginiaeth, gallai barnu a allai gwall o'r fath arwain at fwy nag ychydig o niwed ddibynnu ar natur y feddyginiaeth a roddwyd mewn camgymeriad, neu amgylchiadau'r defnyddiwr gwasanaeth penodol

3.16 Er mwyn ei roi yn ei gyd-destun ar gyfer ymarferwyr, mae'r Cyngor Meddygol Cyffredinol wedi esbonio hyn yn ei ganllawiau ar ddyletswydd gonestrwydd broffesiynol fel sefyllfaoedd lle y gallai'r claf eto ddioddef niwed oherwydd canlyniad andwyol.

3.17 Mae **Atodiad H** yn cynnwys astudiaethau achos enghreifftiol sy'n rhoi enghreifftiau manwl o achosion a fyddai'n sbarduno'r ddyletswydd gonestrwydd

[20] Williams N (2018) Gross negligence manslaughter in healthcare The report of a rapid policy review. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf

[21] NHSE and NHSI (2021) Just culture guide. https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

a’r rheini na fyddent yn gwneud hynny. Mae hefyd yn cynnwys enghreifftiau o achosion sy’n dangos y ddyletswydd yn cael ei sbarduno lle gallai niwed ddigwydd yn y dyfodol. (Astudiaethau achos 9, 10 ac 11).

ACHOSION Y BU OND Y DIM IDDYNT DDIGWYDD

3.18 Y rhain yw unrhyw ddigwyddiadau diogelwch cleifion a oedd â'r potensial i achosi niwed ond a ataliwyd, gan arwain at ddim niwed i bobl sy'n cael gofal a ariennir gan y GIG yng Nghymru. **Nid** yw achosion y bu ond y dim iddynt ddigwydd yn cael eu hystyried yn sbardun ar gyfer y weithdrefn dyletswydd gonestrwydd. Bwriad y ddyletswydd yw cofnodi mwy nag ychydig o niwed sy’n amlwg adeg y digwyddiad neu a allai ymddangos yn nes ymlaen. Gydag achosion o’r fath, mae’r niwed (neu’r potensial ar gyfer niwed yn y dyfodol) yn cael ei osgoi. Y rheswm, yn aml, yw bod y cam gweithredu a fyddai wedi ysgogi'r niwed wedi’i atal rhag digwydd neu wedi’i osgoi.

3.19 Er enghraifft, cafodd cyflenwi’r feddyginiaeth anghywir ei osgoi drwy gam ychwanegol neu drwy ymyrraeth gan rywun arall, ac felly ni ddigwyddodd.
Y gwahaniaeth rhwng achos y bu ond y dim iddo ddigwydd a digwyddiad lle gallai niwed ddigwydd eto yw bod y camau, mewn digwyddiad lle gallai niwed ddigwydd eto, wedi digwydd ond nad yw’r niwed wedi dod i’r amlwg eto.

3.20 Fodd bynnag, oherwydd eu natur ddifrifol a’r angen i ddysgu o ddigwyddiadau o’r fath a’u hatal rhag digwydd eto, dylid rheoli achosion y bu ond y dim iddynt ddigwydd drwy ddilyn y prosesau adrodd arferol[22].

3.21 Er nad yw’r ddyletswydd gonestrwydd statudol o dan y Ddeddf yn cael ei sbarduno gan achosion y bu ond y dim iddynt ddigwydd, dylai ymarferwyr unigol fod yn gyfarwydd â’r canllawiau ar achosion y bu ond y dim iddynt ddigwydd a ddarperir gan eu cyrff rheoleiddio proffesiynol. Er enghraifft, mae’r Cyngor Nyrsio a Bydwreigiaeth[23] a’r Cyngor Meddygol Cyffredinol[24] yn darparu arweiniad a

[22] NHS Delivery Unit (2023) Patient Safety incidents. https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/

[23] NMC and GMC (2019) Openness and honesty when things go wrong: the professional duty of candour https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-professional-duty-of-candour.pdf

[24] GMC (2023) Being open and honest with patients in your care, and those close to them, when things go wrong https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong#paragraph-21

chymorth i ymarferwyr ynghylch pryd a sut i siarad â defnyddwyr gwasanaethau am achosion y bu ond y dim iddynt ddigwydd.

Niwed sy'n digwydd i Ddefnyddwyr Gwasanaethau wrth aros am ddiagnosis neu ofal gan y GIG

3.22 Ers y pandemig SARS-CoV-2 byd-eang yn 2020 mae pwysau sylweddol wedi bod ar adnoddau yn y GIG ac, o'r herwydd, mae llawer mwy o gleifion yn aros am ddiagnosis, triniaethau a gofal ar restrau aros y GIG. Bydd angen bod yn ofalus wrth ystyried niwed sy'n digwydd tra bod defnyddiwr gwasanaeth yn aros am driniaeth. Bydd pob cam ar lwybr clinigol yn golygu amser aros, a allai fod yn hirach ar adegau o bwysau sylweddol ar wasanaethau.

3.23 Os bydd defnyddiwr gwasanaeth yn dioddef niwed tra'i fod ar restr aros, gallai hyn **o bosibl** sbarduno'r ddyletswydd gonestrwydd.

*3.*24 Er mwyn i ddefnyddiwr gwasanaeth fod ar restr aros am ddiagnosis neu driniaeth rhaid cael atgyfeiriad fel arfer, sy'n cynnwys asesiad a phenderfyniad clinigol. Wrth osod y defnyddiwr gwasanaeth ar y rhestr aros bydd rhywfaint o ystyriaeth wedi bod o'r risg debygol o aros, a lles gorau'r defnyddiwr gwasanaeth yng nghyd-destun y gwasanaeth sy'n bodoli. Felly, ystyrir bod y defnyddiwr gwasanaeth o dan ofal ymgynghorydd neu feddyg gofal sylfaenol ac yn aml mae'r rhestr aros yn cael ei monitro'n weithredol, sy'n cynnwys elfen o fewnbwn a barn glinigol sydd hefyd yn gyfystyr â darparu gofal iechyd.

3.25 Fodd bynnag, yr elfennau allweddol eraill y mae'n rhaid eu bodloni cyn i'r ddyletswydd gael ei sbarduno yw bod y defnyddiwr gwasanaeth y mae gofal iechyd yn cael ei ddarparu neu wedi'i ddarparu iddo gan y corff wedi dioddef "canlyniad andwyol" a bod y ddarpariaeth gofal iechyd yn ffactor a achosodd i'r defnyddiwr gwasanaeth ddioddef y canlyniad hwnnw neu y gall fod wedi bod yn ffactor. Mae defnyddiwr gwasanaeth i'w drin fel pe bai wedi dioddef canlyniad andwyol os yw'n profi unrhyw niwed "annisgwyl neu anfwriadol" sy'n fwy nag ychydig o niwed neu os yw'r amgylchiadau'n golygu y gallai brofi niwed o'r fath.

3.26 Enghraifft o hyn yn ymarferol yw pan fo defnyddiwr gwasanaeth ag angina yn cael ei roi ar restr aros a reolir yn dda i gael llawdriniaeth ddargyfeiriol ar y galon ac yn dioddef trawiad ar y galon wrth aros. Yn y senario hon mae'n bosibl na fydd y ddyletswydd yn gymwys os digwyddodd y niwed o ganlyniad i'r dirywiad naturiol yng nghyflwr y claf. Y rheswm am hyn yw na fyddai datblygiad y clefyd ynddo'i hun o reidrwydd yn sbarduno'r ddyletswydd gonestrwydd a byddai'r risg sy'n deillio o'r datblygiad hwnnw fel arfer yn cael ei drafod gyda'r defnyddiwr gwasanaeth. Nid yw hyn yn golygu na ddylai'r defnyddiwr gwasanaeth gael ymddiheuriad ac esboniad o'r hyn sydd wedi digwydd fel mater o arfer gorau. Fodd bynnag, pe bai defnyddiwr gwasanaeth wedi'i golli oddi ar y rhestr drwy amryfusedd neu wedi cael ei flaenoriaethu'n anghywir, gan greu oedi gormodol a esgorodd ar y canlyniad andwyol, fe allai'r ddyletswydd fod yn gymwys.

3.27 Dylid rheoli rhestrau aros yn weithredol, a dylid gwneud penderfyniadau clinigol newydd pan fydd y risg hysbys yn newid, er mwyn lleihau niwed i'r defnyddiwr gwasanaeth. Ni fyddai ymddangosiad risg sy'n hysbys i'r defnyddiwr gwasanaeth ac i'r clinigydd, ynddo'i hun, yn sbarduno'r ddyletswydd gonestrwydd o reidrwydd.

3.28 Bwriad cychwyn dyletswydd gonestrwydd yw ymateb i ddefnyddiwr gwasanaeth neu berson sy'n gweithredu ar ei ran, mewn ffordd agored a thryloyw pan fydd pethau wedi mynd o chwith, neu efallai wedi mynd o chwith, yn eu gofal. Nid yw'r camau hyn, fel y cyfeiriwyd yn gynharach, yn gyfaddefiad o atebolrwydd nac yn groes i ddyletswydd statudol.

3.29 Pan fydd mwy nag un corff GIG yn cymryd rhan yn y llwybr gofal, anogir yn gryf bod y cyrff GIG sy'n rhan o'r prosiect yn cydweithio mewn partneriaeth i roi'r weithdrefn dyletswydd gonestrwydd ar waith a'u bod yn cymryd rhan lawn yn y broses. Gweler Pennod 6

Pennod 4 – Y Weithdrefn Gonestrwydd

4.1 Mae Rheoliadau'r Weithdrefn Dyletswydd Gonestrwydd yn rhagnodi'r camau y mae'n **rhaid** i gorff GIG eu cymryd pan fydd y ddyletswydd gonestrwydd yn cael ei sbarduno.

4.2 Mae angen darllen yr adran hon o'r canllawiau ar y cyd â'r Rheoliadau hynny, a siart llif y weithdrefn sydd i'w gweld yn **Atodiad C**.

Hysbysu

4.3 Mae'r Ddeddf a Rheoliadau'r Weithdrefn Gonestrwydd yn ei gwneud yn ofynnol i Gyrff GIG roi hysbysiad **"wrth ddod yn ymwybodol gyntaf"** fod y ddyletswydd gonestrwydd wedi dod i rym, ac i beidio ag aros am ganfyddiadau unrhyw ymchwiliad cychwynnol cyn rhoi hysbysiad.

4.4 Mae'n bwysig nodi bod rheoliad 4 o Reoliadau'r Weithdrefn Gonestrwydd yn ei gwneud yn ofynnol i'r corff GIG hysbysu'r **defnyddiwr gwasanaeth** sydd wedi dioddef canlyniad andwyol hysbysadwy neu berson sy'n gweithredu ar ei ran (yn Rheoliadau'r Weithdrefn Gonestrwydd[25] gelwir y person hwn yn "berson perthnasol").

4.5 Gellir rhoi gwybod i'r person sy'n gweithredu'n gyfreithlon ar ran y defnyddiwr gwasanaeth, os yw'r defnyddiwr gwasanaeth:

- wedi marw.
- yn 16 oed neu'n hŷn ac nad oes ganddo'r galluedd (o fewn ystyr Deddf Galluedd Meddyliol 2005) mewn perthynas â'r mater; neu os yw

[25] Gwasanaeth Iechyd Gwladol Cymru (2023) Rheoliadau Gweithdrefn y Ddyletswydd Gonestrwydd (Cymru) 2023.

- o dan 16 oed ac nad yw'n gymwys i wneud penderfyniad mewn perthynas â'i ofal neu ei driniaeth (Cyfeiriwch hefyd at Bennod 7)

4.6 Mae Rheoliadau'r Weithdrefn Gonestrwydd hefyd yn caniatáu i ddefnyddiwr gwasanaeth â galluedd enwebu person y mae'n ymddiried ynddo i weithredu ar ei ran mewn perthynas â'r ddyletswydd gonestrwydd, gan gydnabod na fydd pawb y mae'r ddyletswydd yn gymwys iddynt yn dymuno ymwneud â'r broses yn bersonol.

4.7 Mae'n bwysig sicrhau bod gofynion Rheoliad Cyffredinol y DU ar Ddiogelu Data (GDPR[26] y DU) yn cael eu dilyn bob amser wrth gyrchu, prosesu a datgelu gwybodaeth defnyddwyr gwasanaethau. Mewn achosion lle mae cynrychiolydd yn gweithredu ar ran defnyddiwr gwasanaeth sydd â galluedd, dylid cael caniatâd ysgrifenedig i'r cynrychiolydd weithredu ac adolygu hyn drwy gydol y broses. Mae hyn hefyd yn unol â Rheoliadau 2011.

Beth yw ystyr 'dod yn ymwybodol gyntaf'?

4.8 Mae'r gofyniad i hysbysu'r defnyddiwr gwasanaeth / y person sy'n gweithredu ar ei ran pan ddeuir yn ymwybodol gyntaf fod y ddyletswydd wedi'i sbarduno yn golygu y dylai'r corff GIG fyfyrio a gwneud penderfyniad ystyriol ynghylch a yw'r amodau fel y'u nodir yn rhan 4 uchod wedi'u bodloni. Ar ôl i'r corff GIG farnu bod yr amodau fel y'u nodir yn rhan 4 uchod wedi'u bodloni, byddai hyn yn cael ei ystyried fel y pwynt lle mae y corff GIG yn **'dod yn ymwybodol gyntaf'** bod y ddyletswydd wedi'i sbarduno.

4.9 Dyma'r dyddiad cychwyn ar gyfer gweithdrefn y ddyletswydd gonestrwydd (y cyfeirir ato yn y Canllawiau hyn a'r atodiadau fel "dyddiad cychwyn y weithdrefn"), y mae'n **rhaid** ei ddilyn, gan ddechrau â'r hysbysiad "uniongyrchol" i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran.

4.10 Dylai fod gan bob corff GIG broses gadarn a chyson ar waith i benderfynu a yw canlyniadau andwyol (digwyddiadau) yr adroddir amdanynt yn sbarduno'r ddyletswydd ai peidio. **Nid yw hyn yn golygu bod Cyrff GIG yn ymchwilio i amgylchiadau'r digwyddiad a adroddwyd cyn gwneud y penderfyniad hwn.** Bydd angen rhywfaint o fyfyrio a gwneud penderfyniadau ar ran y corff GIG cyn penderfynu a yw'r ddyletswydd wedi'i sbarduno, ond nid ymchwiliad manwl. Mae'n bwysig bod trefniadau ar waith i sefydliadau sy'n darparu gwasanaethau ar ran Cyrff GIG i sicrhau bod y corff GIG yn cael ei hysbysu am unrhyw achos o sbarduno'r ddyletswydd gonestrwydd (gweler Pennod 6).

4.10 Nid yw defnyddio system Datix Cymru yn orfodol. Fodd bynnag, mae'r gwaith o gyflwyno a datblygu hwn wedi'i gynllunio i gefnogi'r gwaith o weithredu'r ddyletswydd gonestrwydd ac mae ar gael am ddim i bob corff GIG.

26 Llywodraeth y DU. Deddf Diogelu Data 2018 https://www.legislation.gov.uk/ukpga/2018/12/contents

4.11 O ganlyniad, rhagwelir y bydd y rhan fwyaf o Gyrff GIG yn hysbysu am ddigwyddiadau drwy system Datix Cymru, ac mae hynny'n cael ei annog. Mae nodyn atgoffa yn y system i ofyn i'r rhai sy'n llenwi ac/neu'n adolygu'r adroddiad am y digwyddiad a yw dyletswydd gonestrwydd wedi'i sbarduno ai peidio ac i gofnodi lefel y niwed. Mae'r system hefyd yn hwyluso'r broses o ddogfennu'r rhesymau pam na sbardunwyd y ddyletswydd.

4.13 Bydd angen i gyrff GIG ddatblygu system ar gyfer cynnal yr 'adolygiad' yn lleol o'r digwyddiadau hynny yr adroddwyd yn wreiddiol eu bod yn bodloni'r meini prawf ar gyfer sbarduno'r ddyletswydd gonestrwydd, h.y. pan dybir bod yr amodau a nodir ym mhwynt 4.13 uchod wedi'u bodloni. Gallai hyn, er enghraifft, fod mor syml â nodi y cytunwyd, ar ôl adolygu ac ystyried, nad yw'r trothwy ar gyfer mwy nag ychydig o niwed wedi'i fodloni neu nad oedd y niwed a ddioddefodd yr unigolyn yn gysylltiedig â'r ddarpariaeth gofal iechyd.

4.14 **Felly, dyddiad cychwyn y weithdrefn dyletswydd gonestrwydd yw'r dyddiad y daw corff GIG yn ymwybodol gyntaf o ganlyniad andwyol hysbysadwy.**

4.15 Pan wneir yr hysbysiad "uniongyrchol" yn hwyrach na 30 diwrnod gwaith ar ôl y dyddiad y daw'r corff GIG yn ymwybodol gyntaf o ganlyniad andwyol hysbysadwy, sef dyddiad cychwyn y weithdrefn gonestrwydd, dylid darparu esboniad a dylid cofnodi'r rheswm dros yr hysbysiad gohiriedig yn yr adroddiad am y digwyddiad. Byddai hyn yn ddigwyddiad prin ond gallai ddigwydd pan fo dyletswydd gonestrwydd yn cael ei sbarduno gan adolygiad achos neu adolygiad archwilydd meddygol.

4.16 **Nid yw hyn yn golygu bod gan y corff GIG gyfnod o 30 diwrnod fel mater o drefn i ddarparu'r hysbysiad 'uniongyrchol'.** Mae'r Ddeddf yn nodi'n glir bod rhaid i'r corff GIG gymryd pob cam rhesymol i ddarparu'r hysbysiad '"uniongyrchol" cyn gynted ag y byddant yn dod yn ymwybodol o'r digwyddiad andwyol hysbysadwy.

4.17 Gan ystyried sut y byddai hyn yn gweithio'n ymarferol, byddai'r "gyfres digwyddiadau" yn digwydd fel a ganlyn:

- defnyddiwr gwasanaeth yn dioddef niwed sy'n gysylltiedig â thriniaeth (neu a all fod yn gysylltiedig â hynny).
- mae'r staff yn rhydd i ymddiheuro, esbonio i'r defnyddiwr gwasanaeth/y teulu beth sydd wedi digwydd, er mwyn cydymffurfio â'u dyletswyddau gonestrwydd proffesiynol.
- maent yn adrodd am y "digwyddiad" (gan ddefnyddio Datix Cymru yn y rhan fwyaf o achosion).
- Mae Datix Cymru yn eu hatgoffa i ystyried yw'r ddyletswydd gonestrwydd wedi'i sbarduno.
- Os bydd y person sy'n cofnodi'r digwyddiad yn teimlo bod y ddyletswydd wedi'i sbarduno wrth gofnodi ym modiwl digwyddiadau Datix Cymru bod niwed cymedrol neu fwy wedi'i achosi neu o bosibl wedi'i achosi, bydd adran 'bod yn agored ac yn dryloyw' yn agor yn awtomatig gan alluogi'r cofnodydd i gofnodi

rhagor o wybodaeth yn unol â'r gofyniad ar gyfer gweithdrefn y ddyletswydd gonestrwydd.

- Os penderfynir nad yw'r ddyletswydd gonestrwydd wedi'i sbarduno, er bod niwed cymedrol neu fwy wedi'i achosi, neu o bosibl wedi'i achosi, dylid cadw nodyn o'r rhesymau dros ddod i benderfyniad o'r fath yn yr adroddiad am y digwyddiad yn Datix Cymru.
- Caiff pob digwyddiad ei adolygu'n fewnol gan y corff GIG (ac eithrio pan fo gofal iechyd yn cael ei ddarparu gan bartner sy'n cael ei gomisiynu neu ei gynnal).

- Yn achos y rhai y cytunir bod yr amodau ar gyfer bodloni'r ddyletswydd gonestrwydd (a nodir ym Mhennod 2 uchod) wedi'u bodloni, cychwynnir hysbysu'r defnyddiwr gwasanaeth.

Sut i hysbysu

4.18 Dylai'r hysbysiad i'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran fod "yn uniongyrchol"[27] sy'n golygu cyfathrebu ar y ffôn, cyfathrebu clyweledol (fel galwad fideo) neu gyfathrebu wyneb yn wyneb. Ystyrir y byddai llawer o ddefnyddwyr gwasanaeth yn synnu o gael llythyr drwy'r post yn rhoi gwybod iddynt bod y ddyletswydd wedi'i sbarduno ac mae'n bosibl y byddai ganddynt gwestiynau/pryderon y byddai angen eu hateb neu eu lleddfu ar unwaith. Nid yw gadael negeseuon llais, chwaith, yn cael ei ystyried yn briodol wrth wneud y cyswllt "uniongyrchol". Mae profiad o sesiynau rhanddeiliaid diweddar hefyd yn dangos mai dull "uniongyrchol" sydd fwyaf priodol ar gyfer y cyswllt cyntaf.

4.19 Fodd bynnag, mae gan Gyrff GIG ddisgresiwn ynghylch pa ddull o gyfathrebu "uniongyrchol" sydd fwyaf priodol. Mae'n bosibl na fydd yn bosibl yn ymarferol i gynnal cyfarfod wyneb yn wyneb â phawb y sbardunwyd dyletswydd gonestrwydd ar eu cyfer. Dylai'r corff GIG ystyried pob amgylchiad a nodi'r hyn a ffefrir gan y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran a gwneud pob ymdrech i fodloni'r rhain lle bo modd.

4.20 Dyma'r ffactorau y mae'n rhaid i gorff GIG eu hystyried wrth benderfynu pa ddull o hysbysu'n "uniongyrchol" sydd fwyaf priodol:

a) difrifoldeb y niwed.
b) natur a chymhlethdod y canlyniad andwyol hysbysadwy. amgylchiadau personol y defnyddiwr gwasanaeth (os ydynt yn hysbys)
c) unrhyw gyfathrebu a wnaed eisoes â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran
d) unrhyw ddull y gwyddys bod y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn ei ffafrio. Mae hyn yn arbennig o bwysig lle gallai fod angen cymorth ar y defnyddiwr gwasanaeth, er enghraifft os y Gymraeg yw iaith gyntaf y defnyddiwr gwasanaeth neu ei deulu, neu pan fo angen dehonglydd BSL neu gyfieithydd iaith dramor.

[27] Yn unol â rheoliad 4 o Reoliadau'r Weithdrefn Gonestrwydd.

4.21 Mewn rhai sefyllfaoedd, gallai'r hysbysiad cychwynnol dros y ffôn fod yn ddigonol; mewn achosion mwy cymhleth mae'n debygol y byddai'n fwy priodol trefnu cyfarfod wyneb yn wyneb gyda'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran.

4.22 Rhaid i'r corff GIG gymryd camau rhesymol i sefydlu'r dull cyfathrebu a ffefrir. Rhaid iddo hefyd gymryd camau rhesymol i sicrhau ei fod yn cyfathrebu mewn modd sy'n golygu y bydd y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn ei ddeall[28]. Mae Cyrff GIG yn ddarostyngedig i ofynion Safonau'r Gymraeg fel y'u nodir yn Rheoliadau Safonau'r Gymraeg (Rhif 7) 2018.[29]

4.23 Cydnabyddir mewn rhai achosion na fydd hi efallai'n hysbys ar y dechrau pa ddull cyfathrebu sy'n cael ei ffafrio na pha ddull cysylltu y mae'r defnyddiwr gwasanaeth yn ei ffafrio; efallai y bydd angen cysylltu dros y ffôn i ddechrau er mwyn cael sgwrs ynghylch pa gamau y gellid bod angen eu cymryd i sicrhau bod y weithdrefn dyletswydd gonestrwydd yn cael ei dilyn.

Pwy sy'n hysbysu a diben hysbysu

4.24 Bydd angen i'r corff GIG bennu'r person neu'r personau mwyaf priodol i roi hysbysiad "yn uniongyrchol" i ddechrau i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran. Bydd angen i'r corff GIG ystyried pwy yw'r person neu'r personau mwyaf priodol i roi hysbysiad "yn uniongyrchol" i ddechrau i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran.

4.25 Diben pennaf y cyswllt cychwynnol â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yw cydnabod yr hyn sydd wedi digwydd a chynnig ymddiheuriad ystyrlon, personoledig am y niwed y maent wedi'i brofi neu y gallent ei brofi eto a rhoi cyngor ar yr hyn fydd yn digwydd nesaf. (Gweler Atodiad E ac adnoddau proffesiynol eraill ar gyfleu ymddiheuriad.)

4.26 Rhaid i'r corff GIG enwebu rhywun sydd â digon o brofiad a gwybodaeth am y weithdrefn dyletswydd gonestrwydd a dealltwriaeth ohoni er mwyn gallu cynorthwyo'r defnyddiwr gwasanaeth/ei gynrychiolydd ag unrhyw gwestiynau a allai godi wrth iddynt fynd drwy'r broses; dyma'r "pwynt cyswllt enwebedig".

4.27 Mae rheoliad 4 o Reoliadau'r Weithdrefn Gonestrwydd yn rhagnodi'r hyn y mae'n **rhaid** ymdrin ag ef yn yr hysbysiad "uniongyrchol" cychwynnol.

4.28 Rhaid i'r person sy'n gwneud y cyswllt cyntaf â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran wneud y canlynol:

- esbonio'n glir pa wybodaeth sydd ganddynt hyd yma am yr hyn sydd wedi digwydd.

[28] Gweler rheoliad 7 o Reoliadau'r Weithdrefn Gonestrwydd.

[29] Rheoliadau Safonau'r Gymraeg (Rhif 7) 2018 Rheoliadau Safonau'r Gymraeg (Rhif 7) 2018 (legislation.gov.uk)

- amlinellu pam y mae'r corff GIG o'r farn fod y ddyletswydd gonestrwydd wedi'i sbarduno.
- rhoi ymddiheuriad. Ceir canllawiau ar sut mae rhoi ymddiheuriad personoledig ac ystyrlon isod ac yn Atodiad E.
- rhoi'r manylion cyswllt y pwynt cyswllt enwebedig ar gyfer y corff GIG. Y pwynt cyswllt enwebedig yw'r person y bydd y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn cysylltu ag ef/hi os bydd ganddynt unrhyw gwestiynau am y broses dyletswydd gonestrwydd.
- rhoi esboniad o'r camau a'r ymholiadau pellach y bydd y corff GIG yn eu cymryd i ymchwilio i amgylchiadau'r canlyniad andwyol hysbysadwy. Mae hyn yn cynnwys unrhyw gamau gweithredu y bydd y corff GIG (neu lle mae gwasanaethau wedi'u comisiynu gan ddarparwr annibynnol yng Nghymru, y darparwr) yn cymryd o dan Reoliadau 2011. Ystyrir yr ymchwiliad i'r canlyniad andwyol hysbysadwy ymhellach ym Mhennod 5 .
- rhoi i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran fanylion unrhyw wasanaethau neu ffynonellau cymorth y mae'r corff GIG yn credu'n rhesymol y gallent fod o gymorth iddynt, gan ystyried eu hanghenion. Mae **Atodiad D** yn nodi cysylltiadau defnyddiol ar gyfer opsiynau cymorth.
- Dogfennu hyn yng nghofnod gofal y defnyddiwr gwasanaeth ac yn Datix Cymru.

4.29 Mae rheoliad 4 hefyd yn ei gwneud yn ofynnol i'r person sy'n rhoi'r hysbysiad "uniongyrchol" roi esboniad i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran os yw'r dyddiad yr hysbysiad "uniongyrchol" yn hwyrach na 30 diwrnod gwaith ar ôl y dyddiad y daeth y corff GIG yn ymwybodol gyntaf o'r canlyniad andwyol hysbysadwy. Diben hyn yw esbonio unrhyw oedi a allai ddigwydd cyn hysbysu, er enghraifft yn dilyn adolygiad ôl-weithredol o achos. O dan y gyfraith, mae'n ofynnol i'r corff GIG roi'r hysbysiad "uniongyrchol" pan ddaw i wybod gyntaf am y canlyniad andwyol hysbysadwy, ac felly nid yw'n golygu bod gan Gyrff GIG 30 diwrnod gwaith o'r dyddiad y digwyddodd y canlyniad andwyol hysbysadwy i roi'r hysbysiad "uniongyrchol".

4.30 Mae hefyd yn arfer da sefydlu beth mae'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn ei ddeall am yr hyn sydd wedi digwydd. Dylai'r person sy'n rhoi gwybod ar ran y corff GIG hefyd ddangos ei fod yn deall yr amgylchiadau a'r effaith ar y person dan sylw. Ni ddylent gwestiynu maint y niwed a ddioddefodd y person yr effeithiwyd arno nac amgylchiadau'r 'digwyddiad' fel y mae'r defnyddiwr gwasanaeth wedi'i brofi.

4.31 Gallai hyn fod yn fan cychwyn ar gyfer sgyrsiau hirach â'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran, a bydd yn bwysig i bawb dan sylw bod y cyswllt cyntaf hwn yn cael ei gynnal yng ngwir ysbryd y ddyletswydd; yn agored, gydag empathi ac yn ddidwyll.

*Pethau i'w hystyried – **Cyn i'r hysbysiad "uniongyrchol" ddigwydd:***

- a oes rhywun o'r corff GIG wedi bod mewn cysylltiad eisoes â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran? Gall hyn fod yn gysylltiedig â'r digwyddiad hwn neu agweddau eraill ar ei ofal iechyd.

- pa drafodaethau sydd wedi'u cynnal eisoes neu pa wybodaeth sydd wedi'i chyfnewid eisoes (os o gwbl)?
- beth sy'n hysbys am yr hyn sydd wedi digwydd a lefel y niwed a gafwyd neu y gellid ei gael?
- a yw'r dull cyfathrebu a ffefrir yn hysbys? e.e. geiriol, ysgrifenedig, electronig; argymhellir gwirio unrhyw gofnodion blaenorol yn Datix; porth clinigol Cymru, PAS Cymru neu gofnodion gofal.
- pwy fydd y pwynt cyswllt enwebedig yn y corff GIG yn dilyn yr hysbysiad cychwynnol?
- pa gymorth sydd ar gael i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran, i'w cynorthwyo yn ystod y broses hysbysu ac wedyn?
- sicrhau bod y cyfathrebu'n digwydd mewn modd y gall y defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran ei ddeall, gan gynnwys Cymraeg os dyna'u hiaith gyntaf.
- Ystyried lleoliad y sgwrs os yw am fod wyneb yn wyneb neu drwy alwad fideo, i sicrhau bod preifatrwydd a chyfrinachedd yn cael eu cynnal.
- dylid cydnabod hefyd y gallai defnyddiwr gwasanaeth fod â nifer o gwestiynau yn ymwneud â'i ofal ac y gallai fod yn ddoeth i aelod o'r tîm clinigol fod yn bresennol.

Hysbysu'n ysgrifenedig wedyn

4.33 Yn dilyn yr hysbysiad "uniongyrchol", mae rheoliad 5 o Reoliadau'r Weithdrefn Gonestrwydd yn ei gwneud yn ofynnol i'r corff GIG gymryd pob cam rhesymol i ysgrifennu at y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran (oni bai ei fod wedi nodi nad yw'n dymuno cymryd rhan yn y broses gonestrwydd) o fewn pum diwrnod wedi diwrnod yr hysbysiad "uniongyrchol". Mae hysbysu'n ysgrifenedig yn cynnwys hysbysu drwy e-bost.

4.34 Nod yr hysbysiad ysgrifenedig yw cadarnhau'n ysgrifenedig yr hyn a drafodwyd yn yr hysbysiad ''uniongyrchol''. Diben hyn yw cynorthwyo dealltwriaeth y defnyddiwr gwasanaeth/y person sy'n gweithredu ar eu rhan, a hefyd ddarparu cofnod i'r corff GIG o'r hyn sydd wedi'i drafod.

4.35 Felly, rhaid i'r hysbysiad ysgrifenedig gynnwys:

- disgrifiad sy'n esbonio'n glir pa wybodaeth sy'n hysbys hyd yn hyn ynglŷn â'r hyn a ddigwyddodd
- ailadrodd yr ymddiheuriad geiriol
- yr wybodaeth a ddarparwyd yn yr hysbysiad uniongyrchol, sydd fel a ganlyn:
  - y rheswm pam y mae'r corff GIG o'r farn bod y ddyletswydd gonestrwydd wedi'i sbarduno
  - enw a manylion cyswllt y person yn y corff GIG a enwebwyd fel pwynt cyswllt ar gyfer y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran mewn perthynas â'r weithdrefn dyletswydd gonestrwydd
  - esboniad o'r camau gweithredu y bydd y corff cyfrifol neu'r darparwr yn eu cymryd, a'r ymholiadau pellach y bydd y corff cyfrifol neu'r darparwr yn eu cynnal, i ymchwilio i amgylchiadau'r canlyniad andwyol

hysbysadwy, gan gynnwys unrhyw gamau sydd i'w cymryd o dan Reoliadau 2011

- ailadrodd y cynnig o fanylion gwasanaethau neu gymorth perthnasol
- os yw'r hysbysiad "uniongyrchol" wedi'i wneud yn hwyrach na 30 diwrnod gwaith ar ôl y dyddiad y daeth corff GIG yn ymwybodol gyntaf o'r canlyniad andwyol hysbysadwy, esboniad o'r rheswm dros yr oedi

• Dogfennu hyn yn Datix Cymru.

4.36 Dylid ystyried personoli'r llythyr hysbysu drwy roi llofnod mewn llawysgrifen. Awgrymwyd yn ystod sesiynau ffocws gydag aelodau'r cyhoedd bod llofnod wedi'i ysgrifennu â llaw yn cael effaith gadarnhaol pan fydd ymddiheuriad o'r math hwn yn cael ei roi.

4.37 **Rhaid** i'r corff GIG gymryd pob cam rhesymol i anfon yr hysbysiad ysgrifenedig at y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran o fewn **pum niwrnod gwaith** ar ôl dyddiad yr hysbysiad "uniongyrchol"

4.38 Mae'n bwysig cydnabod bod cyfathrebu araf neu wael yn ei gwneud yn fwy tebygol y bydd y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn chwilio am wybodaeth mewn ffordd wahanol, fel cwyno neu gymryd camau cyfreithiol. Gall hefyd olygu na fyddant yn teimlo bod y broses wedi bod yn agored ac yn onest o'r cychwyn cyntaf.

Yr Ymddiheuriad

4.39 Mae ymddiheuro mewn ffordd ystyrlon a phersonoledig yn rhan allweddol o'r broses hysbysu "uniongyrchol". Mae **Atodiad E** yn rhoi rhagor o wybodaeth am ymddiheuro fel rhan o weithdrefn y ddyletswydd gonestrwydd.

4.40 Mae ymddiheuro'n ystyrlon mewn ffordd bersonoledig yn gallu bod yn ffordd ymarferol o adfer ymddiriedaeth. Gall ymddiheuro mewn ffordd ystyrlon, ddidwyll gyda dealltwriaeth fod yn effeithiol ac yn bwerus ac mae'n hanfodol i bawb dan sylw pan fydd y ddyletswydd gonestrwydd yn cael ei sbarduno, gan gynnwys y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran, a'r staff sy'n gofalu amdano. Ni ddylid diystyru'r effaith ar bawb dan sylw pan fydd y ddyletswydd gonestrwydd yn cael ei sbarduno. I'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran, ymddiheuro yw'r cam pwysicaf y gall unrhyw unigolyn neu sefydliad ei gymryd fel arfer, ac mae'n bwysig bod ymddiheuriad amserol yn digwydd yn unol â'r rheoliadau.

4.41 Mae pobl sy'n teimlo nad ydynt wedi cael gwybod mewn ffordd agored ac onest o'r dechrau yn fwy tebygol o deimlo bod y niwed maent wedi'i ddioddef wedi'i wneud yn waeth, a gall hyn arwain at golli ymddiriedaeth yn eu darparwr gofal iechyd. Gall hyn arwain at deimladau o ddicter ac achosi i'r berthynas chwalu. Gall hefyd olygu bod camau pellach yn cael eu cymryd.

4.42 Cydnabyddir y gall fod camargraff a chamddealltwriaeth fod ymddiheuriad yn gyfystyr â derbyn y bai, beiusrwydd neu hyd yn oed atebolrwydd cyfreithiol[30].

4.43 Nid yw hyn yn wir, ac ni ddylai esgor ar unrhyw dybiaeth o'r fath na llesteirio neu oedi'r cynnig o ymddiheuriad.

4.44 Diffinnir “ymddiheuriad” yn rheoliad 2 o Reoliadau'r Weithdrefn Gonestrwydd fel a ganlyn:

ymddiheuriad yw mynegiant o dristwch neu edifeirwch mewn cysylltiad â'r canlyniad andwyol hysbysadwy.

4.45 Mae rheoliad 12 yn nodi'n benodol nad yw ymddiheuriad neu unrhyw gam arall a gymerir yn unol â'r weithdrefn gonestrwydd yn gyfystyr â chyfaddefiad o esgeulustod neu o dorri dyletswydd statudol.

4.46 Mae rhoi ymddiheuriad yn cydnabod yr hyn sydd wedi digwydd, neu ar y cam hwn yr hyn y gwyddys ei fod wedi digwydd, ac yn rhoi sicrwydd bod y mater yn cael ei gymryd o ddifrif ac y manteisir ar gyfleoedd dysgu i atal amgylchiadau tebyg rhag codi yn y dyfodol. Mae'n bwysig sicrhau bod yr ymddiheuriad yn cwmpasu'r hyn sy'n hysbys bryd hynny heb ddyfalu neu gynnwys rhagdybiaethau am yr hyn a allai fod wedi digwydd neu a allai fod wedi achosi'r digwyddiad. Mae'n ddefnyddiol cyfaddef yn y cyfnod cynnar hwn y gallai llawer fod yn anhysbys ond fod rhagor o fanylion yn debygol o ddod yn gliriach yn ystod yr ymchwiliad sy'n dilyn.

4.47 Rydym yn cydnabod y gall staff weithiau ei chael yn anodd ymddiheuro pan fydd niwed wedi digwydd neu pan allai ddigwydd rywbryd yn y dyfodol. Efallai na fyddant yn sicr a ydyn nhw'n cael ymddiheuro ac efallai y byddant yn poeni na fydd amseriad yr ymddiheuriad yn iawn, neu y byddant yn gwneud pethau'n waeth, yn enwedig gan y gallai'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran fod yn flin ac yn ypsét, yn naturiol. Nod **Atodiad E** yw darparu canllawiau i gynorthwyo staff yn hyn o beth.

4.48 Mae'n arfer da cofnodi'r ymddiheuriad llafar yng nghofnod gofal y claf. Mae hyn yn golygu y bydd y tîm clinigol cyfan yn gwybod pan fydd ymddiheuriad wedi'i roi, a gall osgoi dyblygu.

Hysbysu am ganlyniadau ymholiadau pellach

4.49 Mae rheoliad 6 o Reoliadau'r Weithdrefn Gonestrwydd yn ei gwneud yn ofynnol i Gyrff GIG hysbysu'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran am ganlyniadau unrhyw ymholiadau pellach (ymchwiliadau) a gynhaliwyd gan y corff GIG y gellid bod wedi cyfeirio atynt yn yr hysbysiad “uniongyrchol”. Deellir mai'r ymholiadau hyn yw'r ymchwiliad sydd i'w gynnal gan y corff GIG.

[30] Deddf lawndal 2006 adran 2. https://www.legislation.gov.uk/ukpga/2006/29/contents

4.50 Yn ymarferol, yn y rhan fwyaf o achosion, ar ôl i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran gael ei hysbysu, bydd y corff GIG yn ymchwilio i'r amgylchiadau pan ddaeth y ddyletswydd gonestrwydd i rym, yn unol â darpariaethau Rheoliadau 2011. Bydd Cyrff GIG yn gyfarwydd â'r broses hon gan ei bod yn llywio'r ffordd yr ymchwilir i ddigwyddiadau ar hyn o bryd.

4.51 Bydd cyfathrebu â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran o dan ddarpariaethau Rheoliadau 2011, sy'n cynnwys gofyniad i amlinellu canlyniad ymchwiliadau yn ysgrifenedig, hefyd yn bodloni gofynion rheoliad 6 o Reoliadau'r Weithdrefn Gonestrwydd, gan osgoi dyblygu petai Rheoliadau 2011 yn gymwys.

4.52 Fel y nodir isod ym Mhennod 5, nid yw Rheoliadau 2011 yn gymwys i'r holl Gyrff GIG – er enghraifft, nid ydynt yn gymwys i Gwaed a Thrawsblaniadau'r GIG. Ar ben hynny, efallai y bydd amgylchiadau eithriadol pan na fydd Rheoliadau 2011 yn gymwys. Yn yr amgylchiadau hyn, dylai Cyrff GIG sicrhau bod ganddynt drefniadau ar waith i'w galluogi i gydymffurfio â'r gofynion hysbysu yn rheoliadau 4, 5 a 6.

Cyfathrebu â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran

4.53 Mae rheoliad 7 yn rhagnodi'r hyn y mae'n rhaid i gorff GIG ei wneud os na all gysylltu â'r defnyddiwr gwasanaeth neu berson sy'n gweithredu ar ei ran i wneud y canlynol:

(i) rhoi'r hysbysiad "uniongyrchol" (rheoliad 4),
(ii) rhoi'r hysbysiad ysgrifenedig (rheoliad 5),
(iii) hysbysu am ganlyniadau ymholiadau pellach (rheoliad 6),

neu os yw'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran yn gwrthod cymryd rhan mewn cyfathrebu â'r corff GIG.

4.54 Os nad yw'r corff GIG, ar ôl cymryd camau rhesymol, yn gallu cysylltu, rhaid cofnodi'r ymdrechion i gysylltu fel rhan o'r wybodaeth y mae'n ofynnol ei chadw yn rhinwedd rheoliad 9 (Cofnodion), gweler y canllawiau ar gadw cofnodion isod. Yn ddelfrydol, dylid cofnodi'r wybodaeth yn y cofnod digwyddiad, sef Datix Cymru y rhan fwyaf o amgylchiadau.

4.55 Os bydd y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn rhoi gwybod nad yw'n dymuno cyfathrebu â'r corff GIG na derbyn gwybodaeth ganddo, rhaid cofnodi hyn yn glir hefyd yn unol â rheoliad 9 a dylid parchu dymuniadau'r unigolyn. Unwaith eto, byddai'n arfer da cofnodi hyn ar y cofnod digwyddiad (Datix Cymru), a hefyd yn nodiadau gofal y defnyddiwr gwasanaeth.

4.56 Yn unol â rheoliad 7(3)(b) o'r Rheoliadau Gonestrwydd nid yw'n ofynnol i Gyrff GIG ddarparu gwybodaeth i neu gyfathrebu â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn yr amgylchiadau hyn os ydynt wedi nodi nad ydynt am gyfathrebu â neu dderbyn gwybodaeth gan y corff GIG. Fodd bynnag, rhaid

i’r adolygiad o’r digwyddiad a arweiniodd at sbarduno’r ddyletswydd barhau fel y gellir dysgu gwersi a gwneud gwelliannau o ran ansawdd.

4.57 Dylai’r corff GIG roi gwybod i’r defnyddiwr gwasanaeth/y person sy’n gweithredu ar ei ran bod modd iddo gysylltu â’r corff GIG os bydd yn newid ei feddwl am gymryd rhan yn y broses.

4.58 Rhaid i’r corff GIG gymryd camau rhesymol i ganfod pa ddull cyfathrebu sydd orau gan y defnyddiwr gwasanaeth/y person sy’n gweithredu ar ei ran a, phan fo’n rhesymol ymarferol, cyfathrebu â nhw drwy’r dull hwn.

4.59 Rhaid i’r corff GIG gymryd pob cam rhesymol i sicrhau bod unrhyw gyfathrebu â’r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran yn digwydd mewn modd y gallant ei ddeall – mae hyn yn arbennig o bwysig os oes anabledd neu os yw’r defnyddiwr gwasanaeth yn oedolyn neu'n blentyn neu'n berson ifanc agored i niwed.

Cymorth a Hyfforddiant

4.60 Mae'n bwysig cydnabod y gallai'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran gael ei effeithio'n fawr gan yr wybodaeth sydd wedi'i chynnwys yn yr hysbysiad “uniongyrchol” ac y bydd angen cymorth parhaus arnynt wrth iddynt ddod i delerau ag effaith y niwed sydd wedi digwydd neu a allai ddigwydd fel yr amlygwyd ym Mhennod 4.

4.61 Mae staff y GIG yn mynd i’r gwaith i ddarparu gofal o ansawdd uchel i’r rheini y mae angen gofal a thriniaeth arnynt. Pan fydd defnyddiwr gwasanaeth yn dioddef canlyniad andwyol a bod y ddyletswydd gonestrwydd yn cael ei sbarduno, mae’n bwysig cydnabod y bydd effaith hefyd ar staff sy’n ymwneud â gofalu am y defnyddiwr gwasanaeth ac y gallai fod angen cymorth arnynt.

4.62 Mae rheoliad 8 o Reoliadau’r Weithdrefn Gonestrwydd yn nodi'r gofynion mewn perthynas â hyfforddiant a chymorth.

4.63 Y gofynion yw rhoi hyfforddiant a chanllawiau perthnasol i'r holl staff sy'n ymwneud â:

- darparu gofal iechyd;
- ymchwilio i ganlyniadau andwyol hysbysadwy neu eu rheoli;
- unrhyw aelodau perthnasol eraill o staff sy'n ymwneud â chyflawni neu arfer swyddogaethau mewn perthynas â gweithdrefn y ddyletswydd gonestrwydd.

4.64 Yn ogystal â'r holl staff clinigol, byddai hyn yn ymarferol yn cynnwys uwch staff (gan gynnwys staff ar lefel y Bwrdd) sy'n gyfrifol am oruchwylio’r gwaith o reoli canlyniadau andwyol yn eu sefydliadau, y rhai sy'n ymwneud yn uniongyrchol ag ymchwilio i ganlyniadau andwyol hysbysadwy, eu rheoli a/neu hysbysu amdanynt, ac unrhyw staff eraill sy'n delio â chwynion a phryderon. Ar lefel gofal sylfaenol, byddai hyn er enghraifft yn cynnwys rheolwyr practis.

4.65 Bydd modiwlau hyfforddi yn cael eu datblygu'n genedlaethol drwy gydgysylltu a byddant ar gael ar blatfformau digidol i holl staff y GIG gan gynnwys darparwyr

gofal sylfaenol. Mae'r ddogfen ganllawiau hon a'r atodiadau iddi yn darparu'r holl ddogfennau cymorth perthnasol i helpu cyrff y GIG i gyflawni eu dyletswydd o ran sicrhau bod staff yn ymwybodol o'r ddyletswydd gonestrwydd.

4.66 Mae Rheoliadau'r Ddyletswydd Gonestrwydd hefyd yn nodi bod rhaid i'r corff GIG roi manylion am y gwasanaethau neu'r cymorth sydd ar gael i aelod o staff sy'n ymwneud â chanlyniad andwyol hysbysadwy, gan ystyried:

- yr amgylchiadau sy'n ymwneud â'r canlyniad andwyol hysbysadwy;
- anghenion yr aelod o staff.

4.67 Bydd gan Gyrff GIG fecanweithiau ar waith a gwasanaethau cymorth lleol ar gael i gynnig y ddarpariaeth briodol o gymorth a chynhorthwy priodol i aelodau staff drwy eu Gwasanaeth Llesiant Gweithwyr/Rhaglen Iechyd Galwedigaethol/Rhaglen Cymorth i Weithwyr.

4.68 Yn ogystal mae nifer o wasanaethau cymorth cenedlaethol ar gael drwy wefan Addysg a Gwella Iechyd Cymru (AaGIC)[31], megis Iechyd i Weithwyr Iechyd Proffesiynol (Canopi)[32], SilverCloud[33] a'r Samariaid[34].

4.69 Bydd rheolwyr llinell lleol, goruchwylwyr clinigol gweithwyr proffesiynol sy'n ymwneud â'r gweithlu a datblygu sefydliadol (gan gynnwys cydweithwyr sy'n ymwneud a lles gweithwyr ac iechyd galwedigaethol) a chynrychiolwyr undebau llafur hefyd yn gallu cyfeirio staff at wasanaethau cymorth priodol.

Cadw cofnodion

4.70 Mae adran 4(3)(c) o'r Ddeddf yn ei gwneud yn ofynnol i Reoliadau'r Weithdrefn Gonestrwydd ragnodi'r cofnodion y mae'n rhaid i Gyrff GIG eu cadw mewn perthynas â chyflawni'r ddyletswydd.

4.71 Mae rheoliad 9 o Reoliadau'r Weithdrefn Gonestrwydd yn mynnu bod cyrff y GIG yn gadw cofnod ysgrifenedig cywir ar gyfer pob canlyniad andwyol hysbysadwy lle mae'r weithdrefn gonestrwydd wedi'i dilyn.

4.72 Rhaid i'r cofnod ysgrifenedig gynnwys pob dogfen a darn o ohebiaeth sy'n ymwneud â'r canlyniad andwyol hysbysadwy, heb fod yn gyfyngedig i:

- yr hysbysiad o'r ddyletswydd.
- ymdrechion i gyfathrebu â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran.
- unrhyw benderfyniad gan y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran i beidio â chael gwybod am faterion yn ymwneud â'r ddyletswydd gonestrwydd.

[31] https://aagic.gig.cymru/cefnogaeth/
[32] Canopi (Iechyd i weithwyr iechyd proffesiynol, gynt) https://canopi.nhs.wales/cy/amdanom-ni/
[33] SilvercloudWales. https://nhswales.silvercloudhealth.com/signup/
[34] Y Samariaid 2023 https://www.samaritans.org/

- pob dogfen sy'n ymwneud â'r adolygiad i ganfod a yw'r ddyletswydd wedi'i sbarduno a'r ymchwiliad dilynol i'r canlyniad andwyol hysbysadwy, sy'n cael ei wneud gan y corff GIG, gan gynnwys yr ymateb neu'r adroddiad interim a gyhoeddwyd o dan reoliadau 24, 26 neu 31 o Reoliadau 2011.

4.73 Fe'i hystyrir yn arfer da i gofnodi unrhyw benderfyniad i beidio â sbarduno'r ddyletswydd (os ystyriwyd sbarduno). Mae'n bwysig bod cofnodion cywir yn cael eu cadw i gefnogi mecanweithiau sicrhau ansawdd sydd eu hangen i nodi meysydd ar gyfer dysgu a gwella a hefyd i alluogi Cyrff GIG i gydymffurfio â'u gofynion adrodd o dan y Ddeddf sy'n cael eu hystyried yn rhan 11 isod.

4.74 Rhagwelir y defnyddir system Datix Cymru i adrodd a chadw cofnodion.

Pennod 5 - YR YMCHWILIAD

5.1 Wrth roi gwybod i'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran bod y ddyletswydd gonestrwydd wedi'i sbarduno, rhaid i'r corff GIG (yn unol â rheoliadau 4(3)(e) a 5(3)(c) o Reoliadau'r Weithdrefn Gonestrwydd) hefyd roi esboniad o'r camau y bydd yn eu cymryd i ymchwilio i amgylchiadau'r canlyniad andwyol hysbysadwy.

5.2 Yn y mwyafrif helaeth o achosion, mae hyn yn golygu dilyn gweithdrefn Rheoliadau 2011 ar gyfer ymchwilio i bryderon. Mae "pryderon" fel y'u diffinnir yn Rheoliadau 2011 yn cynnwys pob digwyddiad yn ymwneud â diogelwch cleifion.

5.3 Fodd bynnag, bydd achosion, er bod dyletswydd gonestrwydd yn gymwys, lle na fydd angen ymchwiliad o dan Reoliadau 2011. Er enghraifft, nid yw Rheoliadau 2011 yn gymwys i Gwaed a Thrawsblaniadau'r GIG. Byddant yn dilyn eu gweithdrefnau mewnol eu hunain ar gyfer ymchwilio i ddigwyddiadau diogelwch cleifion.

5.4 Mewn perthynas ag ymchwiliad o dan Reoliadau 2011, fel sy'n wir ar hyn o bryd, rhaid i'r ymchwiliad fod yn gymesur, rhaid iddo gael ei gynnal yn agored ac yn effeithlon a dylai'r pwyslais fod ar wella ansawdd, diogelwch a rhannu'r hyn sy'n cael ei ddysgu.

5.5 Dylid gwahodd y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran i gyfrannu at gylch gorchwyl yr adolygiad, a dylid cadw mewn cysylltiad drwy gydol y broses adolygu, os dyna a gytunwyd. Dylid ystyried beth yw dewis y defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran, gan na fydd pawb yn dymuno cymryd rhan i'r graddau hyn.

5.6 Rhoddir gwybod i'r defnyddiwr gwasanaeth neu ei gynrychiolydd am ganlyniad yr adolygiad yn unol â rheoliad 24 o'r Rheoliadau hynny neu, yn achos gofal a ddarperir gan Fyrddau Iechyd, Ymddiriedolaethau'r GIG neu Awdurdodau Iechyd Arbennig Cymru, yn unol â rheoliadau 26 a 31 pan fo'r trefniadau iawn wedi'u rhoi ar waith.

5.7 Dylid ystyried a ddylid rhoi gwybod i gyrff eraill e.e. cyflogwr neu reoleiddiwr proffesiynol, y gwasanaeth Archwilio Meddygol neu Grwner Ei Fawrhydi. Yn ogystal gallai'r digwyddiad gyrraedd y trothwy o ran Digwyddiadau Adroddadwy Cenedlaethol a chael ei adrodd i Lywodraeth Cymru.

5.8 Dylai'r staff a oedd yn ymwneud â'r driniaeth neu'r gofal a arweiniodd at sbarduno'r ddyletswydd gonestrwydd fod yn rhan o'r broses adolygu lle bo hynny'n briodol, a dylent gael gwybod am y canlyniad terfynol hefyd. Mae rhagor o wybodaeth am yr adolygiad ac am gadw cofnodion ar gael yn **Atodiad F**.

5.8 Gwnaed rhai diwygiadau i Reoliadau 2011 i'w gwneud yn gydnaws â'r ddyletswydd gonestrwydd. Nodir y prif ddiwygiadau yn rheoliad 14 o Reoliadau'r Weithdrefn Dyletswydd Gonestrwydd. Eu heffaith yw sicrhau bod y ddyletswydd gonestrwydd a'r gweithdrefnau Gweithio i Wella yn gweithio'n gydnaws â'i gilydd a sicrhau nad oes dyblygu prosesau.

Pennod 6 Trefniadau Cymhleth a'r Ddyletswydd Gonestrwydd

Pan fydd mwy nag un corff GIG yn rhan o'r weithdrefn Dyletswydd Gonestrwydd

6.1 Yn aml, mae amryw o Gyrff GIG yn ymwneud ag episod o ofal lle mae'r ddyletswydd gonestrwydd yn cael ei sbarduno. Mae **Atodiad H** yn cynnwys enghreifftiau o astudiaethau achos er gwybodaeth.

6.2 Er na fydd yr holl gyrff sy'n ymwneud â darparu episod o ofal o reidrwydd yn 'gorff darparu' o ran y ddeddfwriaeth (h.y. nid oedd neu nid oes gan eu gofal y potensial i sbarduno'r ddyletswydd gonestrwydd) mae'n bosibl y bydd angen iddynt ddarparu gwybodaeth fel rhan o adolygiad neu drwy ddarparu cymorth i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran. Disgwylir i bob parti gydweithredu'n llawn mewn modd agored, gan hwyluso'r weithdrefn dyletswydd gonestrwydd drwyddi draw a rhannu unrhyw wersi a ddysgir o ganlyniad i'r adolygiad/ymchwiliad dilynol, gan gynnwys unrhyw gamau sydd i'w cymryd er mwyn atal amgylchiadau tebyg rhag codi yn y dyfodol.

6.3 Efallai y bydd achlysuron hefyd lle mae sawl corff GIG yr un yn darparu gofal iechyd i un defnyddiwr gwasanaeth a phob un yn sbarduno'r weithdrefn dyletswydd gonestrwydd ar gyfer nifer o 'ganlyniadau andwyol hysbysadwy' mewn perthynas ag un cwrs o driniaeth. Ceir enghreifftiau o astudiaethau achos yn **Atodiad H** i gyfeirio atynt.

6.4 Dan amgylchiadau o'r fath, byddai'n arfer dda i'r Cyrff GIG geisio cyfathrebu â'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran i gael y caniatâd priodol, yn unol â GDPR y DU, i ymgymryd â dull cydgysylltiedig o hysbysu. Fel arall, mae risg y bydd y defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran yn teimlo ei fod yn cael ei lethu neu ei ddrysu gan y broses, os bydd yn

cael sawl hysbysiad. Mae hyn yn arbennig o bwysig os yw'r niwed yn ddifrifol, neu os oes marwolaeth wedi digwydd.

6.5 Y nod ddylai fod gwneud y broses mor hawdd â phosibl i'r rhai dan sylw ac, yn benodol, i'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran.

6.6 Fodd bynnag, mae gan bob corff GIG (corff darparu) ei gyfrifoldeb ei hun o hyd o dan Reoliadau'r Weithdrefn Gonestrwydd a rhaid iddo sicrhau y gall ddangos tystiolaeth ei fod, fel sefydliad unigol, wedi cydymffurfio â gofynion y Rheoliadau hynny.

6.7 Os oes nifer o Gyrff GIG yn ymwneud â'r ddyletswydd gonestrwydd, cynhelir yr ymchwiliad dilynol yn unol â'r manylion yn rheoliad 17 o Reoliadau 2011. Mae rheoliad 17 yn ymdrin â phryderon sy'n ymwneud â mwy nag un corff cyfrifol. Mae'n gosod dyletswydd ar gyrff cyfrifol (yn amodol ar gael y cydsyniadau perthnasol gan y defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran) i gydweithredu at ddibenion cydlynu'r gwaith o drin ac ymchwilio i bryderon a darparu ymateb cydgysylltiedig.

6.8 Os bydd corff GIG yn darganfod bod digwyddiad a fyddai'n sbarduno'r weithdrefn dyletswydd gonestrwydd wedi digwydd mewn corff GIG gwahanol, dylai'r corff GIG sy'n canfod y 'digwyddiad' roi gwybod i'r corff GIG lle digwyddodd y 'digwyddiad' fel y gall hwnnw wedyn weithredu'r weithdrefn dyletswydd gonestrwydd. Rhaid i'r corff GIG sy'n darganfod y 'digwyddiad' hefyd fod yn agored ac yn dryloyw gyda'r defnyddiwr gwasanaeth ynghylch yr hyn y mae wedi'i ddarganfod. Fodd bynnag, nid yw'n ofynnol iddo gyflawni'r weithdrefn dyletswydd gonestrwydd benodol; dylai'r corff GIG sy'n gyfrifol wneud hyn, h.y. y 'corff darparu' lle cafodd y ddyletswydd gonestrwydd ei sbarduno.

Gofal a ddarperir yn gymysg rhwng Cyrff GIG a Sefydliadau Gofal Cymdeithasol

6.9 Pan fo defnyddiwr gwasanaeth yn cael gofal gan gorff GIG a darparwr gofal cymdeithasol (boed mewn model cymysg o gyflenwi neu ar wahân), mae'n bosibl y gallai darparwyr lluosog fod wedi cyfrannu at y niwed sydd wedi'i achosi i'r defnyddiwr gwasanaeth. Mewn achosion o'r fath bydd gan bob darparwr ei gyfrifoldebau ei hun o dan y ddyletswydd gonestrwydd (neu'r ddyletswydd gyfatebol i ddarparwyr gofal cymdeithasol).

6.10 Dylai darparwyr iechyd a gofal cymdeithasol drafod a chydweithio i hysbysu ac ymchwilio i'r digwyddiad er mwyn lleihau unrhyw ofid ac osgoi cyfathrebu lluosog i'r defnyddiwr gwasanaeth. Er enghraifft ni fyddai'n briodol fel arfer i deulu gael dau hysbysiad "uniongyrchol" ar wahân am farwolaeth aelod o'r teulu oherwydd diffyg cyfathrebu rhwng darparwyr.

Fodd bynnag, bydd pob darparwr yn cadw'i gyfrifoldebau unigol o dan ei briod ddyletswydd gonestrwydd a rhaid iddo fodloni ei hun eu bod wedi'u bodloni.

Cymhwyso'r weithdrefn Dyletswydd Gonestrwydd i gomisiynu a chynnal gwasanaethau.

6.11 Mae adran 11 o'r Ddeddf yn egluro pa sefydliadau fydd yn gyfrifol am gydymffurfio â'r ddyletswydd gonestrwydd mewn sefyllfaoedd lle caiff gwasanaethau eu darparu gan un corff ar ran corff arall. Mae'r sefyllfa, mewn perthynas â threfniadau gwahanol, wedi'i nodi isod:

Gwasanaethau a Gomisiynir gan un Corff GIG oddi wrth un arall yng Nghymru

6.12 Mae corff GIG yng Nghymru yn gyfrifol am gydymffurfio â'r ddyletswydd gonestrwydd mewn perthynas â'r holl ofal y mae'n ei ddarparu. Felly, er enghraifft, pan fydd Bwrdd Iechyd yn ymrwymo i drefniadau gyda darparwr gofal sylfaenol i ddarparu gwasanaethau GIG, y darparwr gofal sylfaenol sy'n rhwym wrth y ddyletswydd.

6.13 Yn yr un modd, os bydd Bwrdd Iechyd yn ymrwymo i drefniadau gydag Ymddiriedolaeth GIG yng Nghymru i ddarparu gwasanaethau, yr Ymddiriedolaeth GIG sy'n gyfrifol am y ddyletswydd.

Gwasanaethau a Gomisiynir gan Gyrff nad ydynt yn Gyrff GIG yng Nghymru

6.14 Os bydd corff GIG yn ymrwymo i drefniant i ddarparu gwasanaethau gyda rhywun ar wahân i un o gyrff eraill y GIG, y corff GIG sy'n gyfrifol am gydymffurfio â'r ddyletswydd gonestrwydd. Felly, er enghraifft, pe bai bwrdd iechyd lleol yn ymrwymo i drefniant gyda darparwr annibynnol i ddarparu gwasanaethau, byddai'r ddyletswydd yn gymwys i'r Bwrdd Iechyd lleol.

6.15 Yn yr amgylchiadau hyn, mater i'r corff GIG fyddai hysbysu'r defnyddiwr gwasanaeth neu'r person sy'n gweithredu ar ei ran, yn achos yr hysbysiad "uniongyrchol" yn unol â rheoliad 4 a'r hysbysiad ysgrifenedig yn unol â rheoliad 5.

6.16 Mae darpariaethau Rheoliadau 2011 yn gymwys i bersonau sy'n darparu gwasanaethau o dan drefniadau gyda chorff GIG. Felly, fel sy'n wir ar hyn o bryd, mater i'r darparwr annibynnol fyddai ymchwilio i amgylchiadau'r canlyniad andwyol hysbysadwy a chyfleu canlyniad yr ymchwiliad hwnnw i'r defnyddiwr gwasanaeth/y person sy'n gweithredu ar ei ran.

6.17 Dylai Cyrff GIG sicrhau bod eu trefniadau comisiynu gyda darparwyr annibynnol yng Nghymru nad ydynt yn rhan o'r GIG yn ei gwneud yn ofynnol i'r darparwr annibynnol eu hysbysu pan fyddant o'r farn bod y ddyletswydd gonestrwydd wedi'i sbarduno, fel y gall y corff GIG gydymffurfio â'i rwymedigaethau mewn perthynas â hysbysu o dan y Ddeddf. Bydd angen i'r trefniadau comisiynu hefyd ei gwneud yn ofynnol i'r darparwr annibynnol roi digon o wybodaeth i'r corff GIG i'w alluogi i gydymffurfio â'i rwymedigaethau adrodd o dan adran 7 o'r Ddeddf.

Cymhwyso'r Ddyletswydd Gonestrwydd i Ofal a Gomisiynir y Tu Allan i Gymru

6.18 Dim ond os yw'r gofal iechyd yn cael ei ddarparu yng Nghymru fel rhan o wasanaeth yn y GIG y mae'r ddyletswydd gonestrwydd yn gymwys o dan y Ddeddf. Er enghraifft, os bydd Bwrdd Iechyd lleol yn ymrwymo i drefniadau gyda darparwr yn Lloegr, boed y darparwr hwnnw'n gorff GIG neu'n ddarparwr annibynnol, i ddarparu gwasanaethau gofal iechyd yn Lloegr, dyletswydd gonestrwydd Lloegr o dan Ddeddf Iechyd a Gofal Cymdeithasol 2008 fydd yn gymwys mewn perthynas â'r gofal hwnnw.

6.19 Mae Rhan 7 o Reoliadau'r Gwasanaethau Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011 yn amlinellu'r dull gweithredu i'w ddefnyddio o ran gwasanaethau yr ymgymerir â hwy gan Gyrff GIG Lloegr, yr Alban a Gogledd Iwerddon pan fo digwyddiadau a phryderon yn codi sy'n ymwneud â diogelwch cleifion.

Mae **Atodiad A1** yn nodi siart llif y weithdrefn ar gyfer gwasanaethau a gomisiynir.

Gwasanaethau a Gynhelir:

6.20 Pan fo gofal iechyd yn cael ei ddarparu gan sefydliad neu wasanaeth sy'n cael ei gynnal gan y corff GIG (er enghraifft rhwydwaith clinigol), mae'r ddyletswydd gonestrwydd yn gymwys i'r corff GIG fel yr endid cyfreithiol sy'n cynnal y gwasanaeth neu'r sefydliad.

Pennod 7 – Ystyriaethau Arbennig

Plant a Phobl Ifanc

7.1 Mae'r ddyletswydd gonestrwydd yn gymwys o ran gofal iechyd sy'n cael ei ddarparu yng Nghymru i blant a phobl ifanc. Mae lles plant a phobl ifanc, a'u hawliau i gael eu cynnwys yn llawn mewn penderfyniadau am eu gofal a'u triniaeth, yn egwyddorion hanfodol i'r dull gweithredu pan fydd pethau'n mynd o chwith gyda gofal plentyn neu berson ifanc[35].

7.2 O dan Gonfensiwn y Cenhedloedd Unedig ar Hawliau'r Plentyn (erthygl 12), dylai plant a phobl ifanc fod yn rhan – os ydyn nhw'n gallu bod ac yn dymuno bod – o drafodaethau am ganlyniadau andwyol sy'n effeithio'n uniongyrchol arnyn nhw. Mae hyn ar y cyd â hawl y plentyn neu'r person ifanc i'r safonau

[35] Confensiwn y Cenhedloedd Unedig ar Hawliau'r Plentyn - y Cenhedloedd Unedig. https://www.unicef.org.uk/wp-content/uploads/2019/10/UNCRC_summary-1_1.pdf

iechyd uchaf y gellir eu cyrraedd (erthygl 24) a'r hawl i gael a rhoi gwybodaeth (erthygl 13).

7.3 Gonestrwydd, tryloywder a didwylledd yw'r egwyddorion moesegol arweiniol i'w mabwysiadu a rhaid cynnal trafodaethau mewn modd sensitif sy'n ystyried oedran, profiad y plentyn neu'r person ifanc o ofal iechyd, ei alluedd meddyliol a dymuniadau'r plentyn neu'r person ifanc unigol a, lle bo hynny'n briodol, y rhai sydd â chyfrifoldeb rhieni.

7.4 Wrth gyflawni'r ddyletswydd gonestrwydd mewn amgylchiadau sy'n ymwneud â gofal iechyd a ddarparwyd i blentyn neu berson ifanc, rhaid i gorff GIG hysbysu'r "person perthnasol" o'r canlyniad andwyol hysbysadwy (gweler rheoliad 3 o reoliadau'r ddyletswydd gonestrwydd). Gall hwn fod y plentyn neu'r person ifanc ei hun, oni bai ei fod: [36]

- yn 16 oed neu drosodd a heb y galluedd (o fewn ystyr Deddf Galluedd Meddyliol 2005) mewn perthynas â'r mater, neu
- o dan 16 oed a ddim yn gymwys i wneud penderfyniad mewn perthynas â'i ofal neu ei driniaeth;

os felly, mae'r "person perthnasol" yn berson sy'n gweithredu'n gyfreithiol ar ran y plentyn neu'r person ifanc.

7.5 Os yw'r mae'r mater yn ymwneud â phlentyn sydd o dan 16 oed, mae'n bwysig bod ystyriaeth yn cael ei rhoi ynglŷn ag a yw'r plentyn yn bodloni "cymhwysedd Gillick"[37] h.y. a oes gan y plentyn y galluedd gofynnol yn ôl y gyfraith ac a yw'n ddigon aeddfed a deallus i ddeall yr wybodaeth a ddarperir ac i wneud penderfyniadau am ei iechyd a'i driniaeth feddygol ei hun. Dylai'r gweithiwr gofal iechyd proffesiynol sy'n ceisio cydsyniad y plentyn neu'r person ifanc gynnal yr asesiad cymhwysedd Gillick os yw wedi'i hyfforddi'n ddigonol i wneud hynny.

7.6 Fodd bynnag, hyd yn oed os yw plentyn yn bodloni cymhwysedd Gillick, neu os ystyrir bod gan berson ifanc y galluedd meddyliol gofynnol, dylid annog plant a phobl ifanc i gynnwys eu rhieni neu warcheidwaid yn y trafodaethau hyn lle bo hynny'n ddoeth ac yn fuddiol. Fel arall, gall eiriolwr fod o ddefnydd yn yr amgylchiad hwn. Yn aml, rhieni a gwarcheidwaid sydd yn y sefyllfa orau i ddeall a chynghori'r tîm gofal iechyd ac, yn aml, maent yn ffynhonnell gymorth bwysig i'r plentyn a'r person ifanc sy'n dod i delerau â'r ffaith fod niwed wedi digwydd yn sgil eu gofal.

7.7 Mae angen meddwl yn ofalus am ddefnyddio iaith ag eglurhad priodol a, lle bo'n briodol, dylid gwneud hyn mewn modd amserol ac mewn partneriaeth â rhieni neu warcheidwaid. Gall defnyddio gweithwyr proffesiynol priodol sydd â

[36] Mae rheoliad 3 o Reoliadau Gweithdrefn y Ddyletswydd Gonestrwydd (Cymru) hefyd yn darparu mai'r "person perthnasol" yw rhywun sy'n gweithredu ar ran y defnyddiwr gwasanaeth os yw wedi marw neu os yw wedi rhoi gwybod i'r corff cyfrifol ei fod wedi enwebu person i weithredu ar ei ran.

[37] Gillick v West Norfolk and Wisbech AHA [1986] A.C. 112

phrofiad o gyfathrebu â phlant fod o werth aruthrol yn yr amgylchiadau hyn. Mae hyn yn bwysig er mwyn lliniaru yn erbyn y risg o achosi niwed neu ofid pellach wrth hysbysu'r plentyn neu'r person ifanc o'r canlyniad andwyol hysbysadwy, gan barhau hefyd i fod yn agored ac yn onest gyda'r plentyn neu'r person ifanc am yr hyn sydd wedi digwydd yn unol â dyletswydd gonestrwydd, a hawliau ehangach plant a phobl ifanc i gael eu cadw'n gyfan gwbl yn y darlun.

7.8 Os nad ystyrir bod y plentyn yn bodloni cymhwysedd Gillick rhaid rhoi hysbysiad i berson sy'n gweithredu ar ran y plentyn (e.e. ei rieni neu ei warcheidwad cyfreithiol).

7.9 Yn yr amgylchiad hwn, mae'n bwysig ystyried barn y rhieni neu'r gwarcheidwaid ynghylch sut y gellir hysbysu plentyn neu berson ifanc am yr hyn sydd wedi digwydd yn eu gofal neu eu triniaeth a dylid ystyried sut y gall y tîm gofal iechyd gefnogi'r drafodaeth honno. Fel rhan o'r drafodaeth honno, dylid ystyried buddiannau gorau'r plentyn neu'r person ifanc o ran y modd y cynhelir y drafodaeth, gan ofalu peidio ag achosi niwed neu ofid pellach.

7.10 Rhaid ystyried i'r egwyddorion a'r canllawiau diogelu gael eu hystyried bob amser, ynghyd â'r angen weithiau i roi gwybod am bryderon ynghylch diogelwch plentyn neu berson ifanc a ddarganfuwyd drwy'r trafodaethau hyn lle bo hyn wedi'i fandadu'n gyfreithiol neu'n broffesiynol.

7.11 Mae'n hanfodol bod y broses o wneud penderfyniadau ac o asesu cymhwysedd i ddeall a chymryd rhan mewn penderfyniadau am eu gofal yn cael ei dogfennu'n dda. Mae'n bwysig hefyd fod unrhyw benderfyniadau sy'n cael eu gwneud i beidio â rhannu gwybodaeth yn cael eu hadolygu'n rheolaidd.

7.12 Rhaid cydnabod bod plant a phobl ifanc yn aml yn ymwybodol o ddigwyddiadau a newidiadau yn eu gofal, a gall fod o gymorth mawr i berson ifanc ddeall pam y mae wedi digwydd.

7.13 Yn aml gall plant a phobl ifanc ofni canlyniadau aneglur. Gall ofnau o'r fath gael eu creu pan na thrafodir materion a digwyddiadau gyda nhw, a'r plant a'r bobl ifanc yn cael eu gadael yn ansicr ynghylch pam fod pethau wedi digwydd a beth yw'r camau nesaf yn eu gofal. Mae hyn yn arwain at gynyddu pryder, gofid a straen meddyliol.

7.14 Mae'n hanfodol sicrhau bod plant a phobl ifanc yn cael y cyfle i fod yn bartneriaid yn y broses o wneud penderfyniadau am eu gofal, gyda'u rhieni neu warcheidwaid a'u tîm gofal iechyd, lle bo hyn yn briodol ac yn bosibl. Mae'n bwysig fod y plentyn, y person ifanc a'i uned deuluol bob amser yn rhan ganolog o broses dda o gyfathrebu gonest ac agored, ac o benderfyniadau am eu gofal ac mae hyn yn arbennig o bwysig pan fo niwed anfwriadol neu annisgwyl wedi digwydd.

Adolygu Achosion yn Ôl-weithredol

7.15 Gall canlyniadau andwyol ddod yn hysbys yn dilyn adolygu achosion difrifol yn ôl-weithredol, pan fydd nifer fawr o gleifion yn cael eu hadalw, neu yn dilyn penderfyniad gan y gwasanaeth archwilio meddygol neu gwest crwner, lle nad oedd yr achos a briodolir i'r farwolaeth yn hysbys adeg y digwyddiad. Yn ogystal, gall manylion pellach, nad oeddent yn hysbys yn ystod yr adolygiad cychwynnol, ddod yn hysbys yn ystod yr ymchwiliad i'r digwyddiad. Yn yr achosion hyn, gallai'r ddyletswydd ddal i fod yn gymwys.

7.16 Pan gynhelir adolygiad achos o'r fath, ac os yw'r amodau gofynnol ar gyfer dyletswydd gonestrwydd wedi'u bodloni, mae'r sefydliad felly'n dod yn 'ymwybodol' o'r canlyniad andwyol hysbysadwy. Yr adeg hon y dylid cychwyn y weithdrefn dyletswydd gonestrwydd, os nad oedd wedi'i chychwyn o'r blaen.

7.17 Pe bai'r hysbysiad 'uniongyrchol' yn cael ei wneud yn hwyrach na 30 diwrnod gwaith ar ôl i'r corff cyfrifol ddod yn ymwybodol gyntaf o'r canlyniad andwyol hysbysadwy, rhaid i'r corff cyfrifol roi esboniad o'r rheswm dros yr oedi*.*

Digwyddiadau Canlyniadau Andwyol sy'n Digwydd cyn i'r Ddyletswydd Gonestrwydd Ddod i Rym

7.18 Ni fwriedir i'r ddeddfwriaeth dyletswydd gonestrwydd gael ei defnyddio ar gyfer canlyniadau andwyol a ddigwyddodd cyn y dyddiad y daeth y ddeddfwriaeth i rym. Mewn termau ymarferol, mae hyn yn golygu bod rhaid bod yr amodau sy'n sbarduno dyletswydd gonestrwydd (h.y. darparu gofal iechyd a'r niwed a ddigwyddodd), wedi digwydd ar ôl 1 Ebrill 2023. Fodd bynnag, byddem yn dal i ddisgwyl i chi ymddiheuro a bod yn agored a thryloyw gyda phobl am beth bynnag sydd wedi'i ddarganfod **yn unol ag ethos gweithio i wella**[38].

Pennod 8 Trefniadau goruchwylio

8.1 Mae rheoliad 10 yn ei gwneud yn ofynnol i Gyrff GIG ddynodi person i fod yn gyfrifol am gynnal trosolwg strategol o weithrediad y weithdrefn gonestrwydd a nodir yn Rheoliadau'r Weithdrefn Gonestrwydd. Pan fo'r corff GIG yn Fwrdd Iechyd Lleol, yn Ymddiriedolaeth neu'n Awdurdod Iechyd Arbennig (gan gynnwys Gwaed a Thrawsblaniadau'r GIG o ran ei swyddogaethau yng Nghymru) rhaid i'r person fod yn un o'i aelodau nad ydynt yn swyddogion neu'n un o'i gyfarwyddwyr anweithredol, fel y bo'n briodol.

8.2 Mae gan ddarparwyr gofal sylfaenol ddisgresiwn ynghylch i bwy y maent yn neilltuo rolau o'r fath.

[38] Gweithio i Wella – Canllawiau ar ddelio â phryderon am y GIG o 1 Ebrill 2011 Fersiwn 3 – Tachwedd 2013 https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/

8.3 Mae rheoliad 11 yn ei gwneud yn ofynnol i Gyrff GIG ddynodi person sydd â chyfrifoldeb cyffredinol dros weithredu'r weithdrefn yn effeithiol o ddydd i ddydd o dan Reoliadau'r Weithdrefn Gonestrwydd"). Pan fo'r corff GIG yn Fwrdd Iechyd Lleol, yn Ymddiriedolaeth neu'n Awdurdod Iechyd Arbennig (gan gynnwys Gwaed a Thrawsblaniadau'r GIG o ran ei swyddogaethau yng Nghymru) rhaid i'r swyddog cyfrifol fod yn un o'i aelodau sy'n swyddogion neu'n un o'i gyfarwyddwyr gweithredol, fel y bo'n briodol.

8.4 Ar gyfer darparwyr gofal sylfaenol, rhaid i hwn fod y person sy'n gweithredu fel Prif Weithredwr y corff. Os nad oes Prif Weithredwr, rhaid iddo fod:

- y person sy'n unig berchennog.
- mewn achosion o bartneriaeth, partner; neu
- mewn unrhyw achos arall, cyfarwyddwr neu berson sy'n gyfrifol am reolaeth.

8.5 Mae Rheoliadau'r Weithdrefn Gonestrwydd yn caniatáu i swyddogaethau'r swyddog cyfrifol gael eu dirprwyo i berson arall, ar yr amod bod y person hwnnw o dan reolaeth a goruchwyliaeth uniongyrchol y swyddog cyfrifol. Fodd bynnag, bydd yr atebolrwydd yn nwylo'r swyddog cyfrifol ei hun.

8.6 Ystyrir ei bod yn arfer da i'r unigolion sy'n cael eu dynodi yn unol â rheoliadau 10 ac 11 o Reoliadau'r Weithdrefn Gonestrwydd fod yr un unigolion a enwebir, yn y drefn honno. o dan reoliadau 6 a 7 o Reoliadau 2011[39], oherwydd bod cysylltiadau agos rhwng y weithdrefn gonestrwydd a'r weithdrefn ar gyfer ymchwilio i bryderon yn Rheoliadau 2011.

GOFYNION ADRODD

8.7 O dan y ddyletswydd, bydd yn ofynnol i Gyrff GIG gyflwyno adroddiad blynyddol ar gydymffurfio â'r ddyletswydd a chyhoeddi eu hadroddiadau. Bydd gofyn i Fyrddau Iechyd Lleol gasglu'r wybodaeth hon gan y darparwyr gofal sylfaenol hynny y byddant yn ymrwymo i gontract neu i drefniadau am wasanaethau gyda nhw a chyhoeddi adroddiad cyfun. Mae **Atodiad G** yn cynnwys siart llif sy'n nodi'r gofynion adrodd, cyhoeddi a monitro.

8.8 Wrth adrodd, bydd rhaid i Gyrff GIG nodi a yw'r ddyletswydd gonestrwydd wedi cael ei sbarduno yn ystod y flwyddyn adrodd (a ddiffinnir fel pob cyfnod o 12 mis a ddaw i ben ar 31 Mawrth (pob blwyddyn ariannol)), ac os ydyw:

1. nodi pa mor aml mae'r ddyletswydd gonestrwydd wedi cael ei sbarduno yn ystod y flwyddyn adrodd;
2. rhoi disgrifiad byr o'r amgylchiadau a arweiniodd at sbarduno'r ddyletswydd;

[39] Mae rheoliad 6 o Reoliadau 2011 yn ei gwneud yn ofynnol i berson gael ei benodi i gynnal trosolwg strategol o'r trefniadau ar gyfer ymdrin â phryderon o dan y Rheoliadau hynny ac mae rheoliad 7 yn ei gwneud yn ofynnol i berson gael ei benodi i fod yn gyfrifol am sicrhau bod y trefniadau ar gyfer ymdrin â phryderon yn cael eu gweithredu'n effeithiol o ddydd i ddydd mewn modd integredig.

3. nodi unrhyw gamau sydd wedi cael eu cymryd gan y corff gyda golwg ar atal amgylchiadau tebyg rhag codi yn y dyfodol.

8.9 Rhaid paratoi'r adroddiad cyn gynted ag y bo'n ymarferol ar ôl diwedd pob blwyddyn ariannol.

8.10 I symleiddio'r drefn adrodd yn flynyddol yng Nghymru ac i leihau dyblygu cynnwys, ond gan sicrhau bod yr holl ofynion rheoleiddiol yn cael eu bodloni**,** dylai Byrddau Iechyd**,** Ymddiriedolaethau ac Awdurdodau Iechyd Arbennig gynnwys eu hadroddiadau gonestrwydd yn yr Adroddiad Gweithio i Wella y dylid ei gyhoeddi yn unol â rheoliad 51 o Reoliadau 2011[40] erbyn 31 Hydref bob blwyddyn.

8.11 Mae rheoliad 51 o Reoliadau 2011 yn ei gwneud yn ofynnol i Fyrddau Iechyd Lleol, Ymddiriedolaethau a darparwyr gofal sylfaenol baratoi adroddiad blynyddol yn rhoi gwybodaeth ynglŷn a phryderon, (gan gymryd bod pryderon yn cynnwys cwynion, digwyddiadau diogelwch cleifion a hawliadau). Ar gyfer darparwyr gofal sylfaenol, mae hyn yn cynnwys anfon eu hadroddiad at y Bwrdd Iechyd Lleol y maent wedi ymrwymo i drefniadau ag ef, gan ganiatáu ar gyfer ei gasglu a'i gyhoeddi yn adroddiad Blynyddol Gweithio i Wella y Bwrdd Iechyd Lleol[41], a'i ystyried yn Natganiad Ansawdd Blynyddol pob sefydliad.

Darparwyr Gofal Sylfaenol: dyletswydd i adrodd

8.12 Rhaid i ddarparwyr gofal sylfaenol baratoi adroddiad mewn perthynas â'r gofal iechyd y maent yn ei ddarparu dan gontract neu drefniant arall gyda'u Bwrdd Iechyd. Rhaid i'r adroddiad ddatgan, yn ystod y flwyddyn adrodd (a ddiffinnir fel pob cyfnod o 12 mis a ddaw i ben ar 31 Mawrth, (pob blwyddyn ariannol)), a yw'r ddyletswydd gonestrwydd wedi'i sbarduno mewn perthynas â darparu gofal iechyd gan y darparwr gofal sylfaenol.

8.13 Os ydyw, rhaid i'r adroddiad wneud y canlynol:

1. pennu pa mor aml y mae hyn wedi digwydd yn ystod y flwyddyn adrodd;
2. rhoi disgrifiad byr o'r amgylchiadau a arweiniodd at sbarduno'r ddyletswydd;
3. disgrifio unrhyw gamau sydd wedi'u cymryd gan y darparwr gyda golwg ar atal amgylchiadau tebyg rhag codi yn y dyfodol.

8.14 Rhaid cyflwyno'r adroddiad a baratowyd i'r Bwrdd Iechyd Lleol ar ôl ei gwblhau.

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[40] Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011) (OS 2011/704). Ar gael yn: http://www.legislation.gov.uk/cy/wsi/2011/704/contents/made

[41] Llywodraeth Cymru. Gweithio i wella - Canllawiau ar ymdrin â phryderon am y GIG o 1 Ebrill 2011 [y Rhyngrwyd]. Llywodraeth Cymru; 2013. Ar gael yn: http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20%20-%2020140122.pdf

8.15 Os yw'r darparwr Gofal Sylfaenol wedi darparu gofal iechyd ar ran dau neu ragor o Fyrddau Iechyd Lleol, bydd adroddiad ar wahân yn cael ei baratoi a'i roi i bob Bwrdd Iechyd Lleol ar ôl ei gwblhau.

8.16 Rhaid i Fyrddau Iechyd Lleol sy'n derbyn yr adroddiad baratoi crynodeb o'r adroddiadau a dderbyniwyd gan y darparwyr Gofal Sylfaenol yn yr adroddiad gonestrwydd y byddant yn ei gyhoeddi.

8.17 O ganlyniad, er mwyn rhoi amser i Fyrddau Iechyd Lleol lunio'r crynodeb, rhaid rhoi adroddiadau o'r fath i'r Bwrdd Iechyd Lleol perthnasol heb fod yn hwyrach na **30 Medi** bob blwyddyn.

8.18 Er nad yw defnyddio system Datix yn orfodol, bydd swyddogaethau yn Datix yn hwyluso casglu gwybodaeth sy'n angenrheidiol i fodloni'r gofynion adrodd y mae angen eu cyflwyno i Fyrddau Iechyd lleol.

Cyhoeddi Adroddiadau

8.19 Rhaid cyhoeddi'r adroddiadau blynyddol ar y ddyletswydd gonestrwydd cyn gynted ag y bo'n ymarferol ar ôl diwedd pob blwyddyn ariannol. Yn achos Byrddau Iechyd Lleol, rhaid i'w hadroddiad gynnwys crynodeb o'r adroddiadau sydd wedi'u darparu gan ddarparwyr gofal sylfaenol sy'n darparu gwasanaethau ar ran y Bwrdd Iechyd Lleol.

8.20 Felly, bydd y Bwrdd Iechyd Lleol yn gyfrifol am gyhoeddi gwybodaeth sy'n berthnasol i'r ddyletswydd gonestrwydd mewn perthynas â'i wasanaethau ei hun a'r gwasanaethau a ddarperir gan ddarparwyr gofal sylfaenol yn ei ardal. Bydd hyn yn golygu bod yr holl wybodaeth am y ddyletswydd gonestrwydd mewn perthynas ag ardal y Bwrdd Iechyd Lleol yn cael ei chyhoeddi gyda'i gilydd.

8.21 Fel y nodir uchod, dylai adroddiadau o'r fath gael eu cyhoeddi erbyn **31 Hydref** bob blwyddyn.

TREFNIADAU SICRWYDD A MONITRO'R BWRDD

8.22 Nid yw mynd yn groes i'r ddyletswydd gonestrwydd yn drosedd. Prif nod y ddyletswydd yw canolbwyntio ar ddysgu a gwella, yn hytrach nag ar gosbi pan nad yw cyrff y GIG yn cyflawni'r ddyletswydd.

8.23 Fodd bynnag, dylai Cyrff GIG ystyried sut gellir integreiddio'r gwaith o fonitro gweithrediad effeithiol y camau gweithredu sy'n ofynnol o dan y ddyletswydd gonestrwydd i'r fframweithiau, y prosesau a'r gweithdrefnau llywodraethu corfforaethol presennol. Dylid ceisio sicrwydd i gadarnhau bod holl elfennau'r weithdrefn yn cael eu rhoi ar waith pan ddylent fod, a bod ffyrdd o gynorthwyo gwaith gwella a mireinio parhaus yn y ffordd y mae'r corff GIG yn cyflawni ei gyfrifoldebau cyfreithiol.

8.24 Dylai arweinwyr a rheolwyr yn y corff GIG sicrhau bod gweithredu'r ddyletswydd gonestrwydd yn rhan allweddol o'r systemau dysgu yn eu meysydd gwasanaeth, a bod yr integreiddio a'r cysoni angenrheidiol â phrosesau a gweithdrefnau wedi digwydd ac yn atgyfnerthu'r gwerthoedd a ddisgwylir yn eu maes gwasanaeth.

8.25 O ran Byrddau Iechyd, Ymddiriedolaethau ac Awdurdodau Iechyd Arbennig, disgwylir y bydd perchnogaeth ac atebolrwydd lleol, gyda diweddariadau rheolaidd yn cael eu darparu drwy gyfarfodydd y Pwyllgor Ansawdd a Diogelwch, lle y gall Aelodau Annibynnol ofyn am sicrwydd bod y ddyletswydd yn cael ei chyflawni, bod y dysgu'n cael ei ddatblygu a bod pryderon yn cael eu huwchgyfeirio i'r Bwrdd os yw hynny'n briodol.

8.26 Bydd y gwaith o weithredu a chydymffurfio â'r ddyletswydd hefyd yn cael ei drefnu i'w drafod mewn cyfarfodydd grŵp ansawdd a chyflawni rhwng Llywodraeth Cymru a Chyrff GIG unigol, y grŵp ansawdd a chyflawni cenedlaethol a bydd yn sail i gyfarfodydd y Cyd-dîm Gweithredol a gwerthusiadau'r Gweinidog Iechyd a Gwasanaethau Cymdeithasol gyda Chadeiryddion Byrddau Iechyd, Ymddiriedolaethau ac Awdurdodau Iechyd Arbennig.

8.27 Bydd Llywodraeth Cymru yn monitro cynnwys yr adroddiadau blynyddol ochr yn ochr â ffynonellau eraill o wybodaeth a fydd yn helpu i driongli'r defnydd o'r ddyletswydd gan ystyried, er enghraifft, ddigwyddiadau difrifol sy'n cael eu hadrodd yn unol â'r polisi cenedlaethol newydd ar Gofnodi Digwyddiadau sy'n ymwneud â Diogelwch Cleifion.

8.28 Bydd cydymffurfiaeth â'r ddyletswydd yn rhan o'r materion y bydd Arolygiaeth Gofal Iechyd Cymru yn eu hystyried wrth arolygu ac adolygu'r GIG.

8.29 Bydd y gofynion adrodd blynyddol hefyd yn darparu gwybodaeth i'r cyhoedd ac i Lywodraeth Cymru am y ddyletswydd, a fydd yn helpu i wneud y broses yn dryloyw ac yn hygyrch i'r cyhoedd ac i gyrff fel Corff Llais y Dinesydd ar gyfer Iechyd a Gofal Cymdeithasol.

CYFRINACHEDD

8.30 Mae'n bwysig sicrhau y glynir wrth ofynion GDPR bob amser wrth gyrchu gwybodaeth am ddefnyddwyr gwasanaethau, ei phrosesu a'i datgelu. Rhaid i adroddiadau a chyhoeddiadau beidio â datgelu pwy yw unrhyw un y mae gofal iechyd yn cael ei ddarparu iddo neu wedi cael ei ddarparu iddo gan neu ar ran y corff GIG, nac unrhyw un sy'n gweithredu ar ran defnyddiwr gwasanaeth.

8.31 Rhaid gofalu hefyd na fydd modd adnabod rhywun yn ddiarwybod drwy'r wybodaeth sy'n cael ei rhoi mewn adroddiad. Nid oes angen enwi rhywun er mwyn gallu ei adnabod os yw'r achos wedi cael sylw yn y wasg, er enghraifft . Neu, i roi enghraifft arall, pan fydd gan rywun gyflwr meddygol prin iawn ac y gallai enwi'r cyflwr olygu bod modd adnabod yr unigolyn.

8.32 Wrth rannu unrhyw wybodaeth hefyd, mae angen ystyried a oes gwrthdaro rhwng anghenion, a allai achosi oedi cyn rhannu gwybodaeth o'r fath; er enghraifft ymchwiliad troseddol neu broses ddiogelu, fel y nodir yn rheoliad 12 o reoliadau'r weithdrefn gonestrwydd.

8.34 Wrth gwblhau cofnodion o dan ddyletswydd gonestrwydd, dylai staff gofio y gallai unrhyw gofnodion a wneir mewn perthynas â'r digwyddiad gael eu datgelu i'r unigolyn o dan GDPR y DU (os eu data personol ydynt) neu i'r cyhoedd o dan y Ddeddf Rhyddid Gwybodaeth (os nad eu data personol ydynt). Dylai staff hefyd gynnwys Swyddog Diogelu Data eu sefydliad pan ymddengys od canlyniad andwyol hysbysadwy yn golygu tor diogelwch data personol, gan y gallai hefyd fod gofynion adrodd i Swyddfa'r Comisiynydd Gwybodaeth o dan GDPR y DU.

Llywodraeth Cymru
Welsh Government

WG23-12

The Duty of Quality Statutory Guidance 2023

and Health and Care Quality Standards 2023

The Health and Social Care (Quality and Engagement) (Wales) Act 2020

The Health and Social Care (Community Health and Standards) Act 2003

Date of issue: 1 April 2023

CONTENTS

Glossary

Interpretation, in this guidance:

- The 2003 Act means the Health and Social Care (Community Health and Standards) Act 2003.
- "Health care" for the purposes of the 2003 Act means (a) services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness; and (b) the promotion and protection of public health.
- The 2006 Act means the National Health Service (Wales) Act 2006;
- The Act means the Health and Social Care (Quality and Engagement) (Wales) Act 2020.
- NHS body, in the context of the duty of quality in Wales, means -
  (a) a Local Health Board.
  (b) an NHS Trust.
  (c) Wales-only Special Health Authority.
- Where the word **must** is used, it refers to actions that are a legal requirement, as set out in Part 2 of the Act;
- Part 2 of the Act amends the National Health Service (Wales) Act 2006 to insert new provisions 1A, 12A, 20A and 24A into the 2006 Act. For the purposes of those new provisions:
  - "Health services" means any services provided or secured in accordance with the 2006 Act: and
  - "Quality" includes, but is not limited to, quality in terms of –
    (a) The effectiveness of health services,
    (b) The safety of health services, and
    (c) The experience of individuals to whom health services are provided.

FOREWORD

Introducing a duty of quality through the Health and Social Care (Quality and Engagement) (Wales) Act 2020 [1] ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services. The Act places an overarching duty of quality on the Welsh Ministers regarding their health-related functions. It broadens the existing duty on NHS bodies (Local Health Boards, NHS Trusts and Welsh Special Health Authorities).

Ultimately, the purpose of the duty of quality is to ensure that Welsh Ministers and NHS bodies secure improvements in the quality of services they provide. The duty represents our ambition of achieving ever-higher standards of person-centred health services in Wales.

Quality is more than just meeting service standards. It needs to be a system-wide way of working to continuously, reliably and sustainably meet the needs of the population that we serve. A culture of continuous learning and improvement is crucial.

In discharging the duty of quality, NHS bodies are required to take into account the Health and Care Quality Standards when making decisions about health services so that improved outcomes are secured. This supports the five ways of working (long term, integration, involvement, collaboration and prevention) within the Well-being of Future Generations (Wales) Act 2015 [2] as well as promoting the well-being goal of A Healthier Wales[3]. The Welsh Ministers must also take into account the Health and Care Quality Standards when conducting reviews of, and investigation into the provision of health care by and for NHS bodies under section 70 of the Health and Social Care (Community Health and Standards) Act 2003. In practice, the role of conducting such reviews and investigations is undertaken by Healthcare Inspectorate Wales (HIW) on behalf of the Welsh Ministers.

The Welsh Government published the Quality and Safety Framework[4] in September 2021. This was intended to serve as a steppingstone to the new duties of quality and candour under the Act whilst we emerged from the coronavirus pandemic.

In order to build clear connections between the duty of quality and standards, this guidance now incorporates the new Health and Care Quality Standards that will

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[1] Welsh Government (2020) Health and Social Care (Quality and Engagement) (Wales) 2020 Act https://www.legislation.gov.uk/asc/2020/1/contents

[2] Welsh Government (2015) Well-being of Future Generations (Wales) Act https://www.futuregenerations.wales/about-us/future-generations-act/

[3] Welsh Government (2019) A Healthier Wales: our Plan for Health and Social Care A healthier Wales: long term plan for health and social care | GOV.WALES

[4] Welsh Government (2021) Quality and Safety Framework: Learning and Improving https://gov.wales/sites/default/files/publications/2021-09/quality-and-safety-framework-learning-and-improving_0.pdf

replace the Health and Care Standards[5] that were issued in 2015. This new approach sets out a clear and simple framework for quality management that will strengthen the connection between the duty, standards and the wider quality management process in Welsh health services.

I am proud that 'Putting quality and safety above all else' is the first core value described in "A Healthier Wales", our long-term strategy for integrated health and care in Wales. As Dr Tedros Adhanom Ghebreyesus, World Health Organisation Director General recently reminded us, "Quality is not a given. It takes vision, planning, investment, compassion, meticulous execution, and rigorous monitoring, from the national level to the smallest, remotest clinic."[6]

We have a significant opportunity to refresh and strengthen our commitment to "A Healthier Wales" through the new duty of quality. We have a collective responsibility to achieve improved quality of services and outcomes for our population.

Eluned Morgan, Minister for Health and Social Services

[5] Welsh Government (2015) Health and Care Standards https://www.gov.wales/sites/default/files/publications/2019-05/health-and-care-standards-april-2015.pdf

[6] World Health Organisation (2022) Fundamentals of Quality https://qualityhealthservices.who.int/quality-toolkit/new-to-health-system-quality-thinking/fundamentals-of-quality

1. Introduction

1.1 The duty of quality, as part of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 ("the Act"), will come into force on 1 April 2023. It is a lever for improving and protecting the health, care and well-being of the current and future population of Wales. The Act aims to ensure a stronger citizen voice and to improve the accountability of services to deliver a better experience and quality of care. Doing so contributes to a healthy and more prosperous country. The Act is intended to have positive benefits for everyone in Wales, supporting a culture and the conditions needed to drive improvements in health care.

1.2 This document serves a dual purpose of providing statutory guidance which aims to help NHS bodies in Wales deliver the requirements of the duty of quality, and also sets out the new Health and Care Quality Standards issued under section 47(1) of the Health and Social Care (Community Health and Standards) Act 2003. NHS Bodies are under a duty to take into account these standards when discharging the duty of quality.

1.3 The legal basis for the duty of quality is set out in Part 2 of the Act.

1.4 The duty of quality supports all people in Wales. The new duty of quality requires the Welsh Ministers and NHS bodies to think and act differently by applying the concept of "quality" across all functions within the context of the health service and health needs of their populations. It requires quality-driven decision-making and planning, to ultimately deliver better outcomes for all people who require health services. It requires involving people in decisions that affect them, balancing short-term needs with planning for the longer-term, with action to prevent problems occurring or getting worse.

1.5 The duty also supports the application of prudent and value-based healthcare principles, referred to in the National Clinical Framework[7] as 'prudent in practice'. This increasingly shifts the focus to person centred care that can support people to stay well, self-manage their condition and, when necessary, provide seamless and appropriate specialist support. The focus is on the person rather than the setting in which the service is delivered.

1.6 Value-based health care[8] encourages us to focus on meeting the goals of our patients and to help manage expectations throughout their care or treatment. Value in health encourages us to improve how patients are involved in decision

[7] Welsh Government (2021) National Clinical Framework: A Learning Health and Care System at https://www.gov.wales/sites/default/files/publications/2021-05/national-clinical-framework-a-learning-health-and-care-system_0.pdf

[8] Welsh Value in Health Care (2022) Value-based Healthcare for Wales at https://vbhc.nhs.wales/value-based-healthcare-for-wales/policy-and-culture/

making using the best evidence available, avoiding any unnecessary variation in care, and becoming more creative to determine where our resources are best spent to improve patient outcomes. By working with patients and teams from across the healthcare system in Wales, and collaborating with industry and third sector, we can deliver the outcomes that matter to people with the resources available to us in a way that is sustainable.

1.7 The prevailing intention is to build on the positive culture of quality at the heart of the Welsh health system[9], enacting a broader system-wide duty of quality which strengthens decision-making, action, improvement and ultimately, improved outcomes for the population.

[9] Organisation for Economic Co-operations and Development (OECD) Reviews of Health Care Quality: United Kingdom 2016: Raising Standards https://www.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-care-quality-united-kingdom-2016_9789264239487-en

2. Purpose of the guidance

2.1 Improving the quality of our services to achieve better outcomes for people is the right thing to do.

2.2 The guidance sets out best practice to assist NHS bodies in the implementation and application of the duty of quality. NHS bodies must have regard to the guidance issued by the Welsh Ministers.

2.3 The guidance provides a foundation on which quality management systems, relevant policies and procedures, training and support requirements will be built. It facilitates clarity about the duty of quality, consistency of approach and equity of response to improve the quality of health services and outcomes for people.

2.4 The guidance sets out a definition of quality and describes the overarching requirements to strengthen our quality management systems with quality-driven decision-making and planning. In turn, this strengthens our responsibilities to learn and create opportunities to share learning. The purpose of the duty overall is to improve outcomes for our population.

2.5 It is intended as a reference for our workforce as well as our population and partner organisations, so we develop a common understanding about the duty of quality.

2.6 It is not intended to be a prescriptive document, nor is it intended to be a quality manual or 'how to' guide. It is ultimately for NHS bodies to satisfy themselves that they are complying with the new duty to secure improvement in the quality of health services that is imposed on them in the 2006 Act, though it is envisaged that this guidance will provide a helpful framework to assist such bodies accordingly. Furthermore, this guidance document also sets out new Health and Care Quality Standards which will replace the Health and Care Standards (April 2015) issued under section 47(1) of the Health and Social Care (Community Health and Standards) Act 2003(which is a power that permits the Welsh Ministers to publish statements of standards in relation to the provision of health care). NHS bodies will be required to take these new standards into account for the purpose of discharging the duty of quality. In addition, the Welsh Ministers are also required to take into account these new standards in conducting reviews of, and investigations into, the provision of health care by and for NHS bodies under section 70 of the Health and Social Care (Community Health and Standards) Act 2003. In practice, the role of conducting such reviews and investigations is undertaken by Healthcare Inspectorate Wales (HIW) on behalf of the Welsh Ministers.

2.7 It is acknowledged that implementation of the duty of quality will need to be monitored over the course of several years to determine its success. Welsh Ministers and NHS bodies will need to be able to demonstrate the steps they

have taken to improve the quality of services aligned to the duty for implementation to be assessed and monitored.

2.8 To that end, Welsh Ministers and NHS bodies must publish an annual quality report on the steps they have taken to comply with the duty of quality.

3. Legislative background

3.1 The key purpose of Part 2 of the Act is to reframe and broaden the duty of quality which was first set out in section 45(1) of the Health and Social Care (Community Health and Standards) Act 2003[10] ("the 2003 Act"). Section 45(1) of the 2003 Act imposes a duty on Welsh NHS bodies to ensure that appropriate arrangements are in place to monitor and improve the quality of health care[11] provided by or for those bodies.

3.2 Section 45(1) of the 2003 Act is repealed and replaced with a revised duty to secure quality in health services in sections 1A (Welsh Ministers' duty), 12A (Local Health Board's duty), 20A (NHS Trust's duty) and 24A (Special Health Authority's duty) of the National Health Service (Wales) Act 2006[12] ("the 2006 Act"). The 2006 Act (as amended by Part 2 of the Act) also requires those bodies to publish an annual report on the steps it has taken to comply with the duty of quality.

3.3 The 2006 Act (as amended by Part 2 of the Act) requires that the Welsh Ministers issue guidance to the Welsh NHS bodies in relation to the duty of quality and the requirement to publish an annual report. Therefore, this guidance document is issued by the Welsh Ministers under Sections 12A (5), 20A (5) and 24A (5) of the 2006 Act in pursuance of that requirement. The new Health and Care Standards, which are also contained in this document, are issued under the powers in section 47 of the 2003 Act (see further on that in paragraph 3.9 below).

3.4 The revised duty of quality (which also applies to the Welsh Ministers, as well as NHS bodies) reframes the concept of "quality" by ensuring that it is used in its broader definition. Quality includes the effectiveness and safety of health services and the quality of the experience of users of health services. However, it is not limited to the quality of services provided to an individual nor to service

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[10] UK Government (2003) Health and Social Care (Community Health and Standards) Act https://www.legislation.gov.uk/ukpga/2003/43/contents

[11] For the purposes of the 2003 Act, "health care" means (a) services provided to individuals for or in connection with the prevention, diagnosis or treatment or illness; and (b) the promotion and protection of public health.

[12] UK Government (2006) National Health Service (Wales) Act. https://www.who.int/publications/i/item/9789240011632

standards. It relates to securing improvement in the quality of "health services" which means any services provided or secured in accordance with the 2006 Act. Accordingly, the revised duty intends quality to be a system-wide way of working with on the intention of improving outcomes. Inserting the new duty into the 2006 Act reflects the importance that the Welsh Ministers place on the new, broader duty, and the Welsh Ministers' intention to further strengthen and embed quality at the heart of decision making for health services.

3.5 Welsh Ministers have a duty to exercise any of their functions that relate to the health service with a view to securing improvement in the quality of health services.[13]

3.6 Local Health Boards[14], NHS Trusts[15] and Welsh Special Health Authorities[16] have a duty to exercise **all** of their functions with a view to securing improvement in the quality of health services. The duty of quality therefore applies to all clinical and non-clinical functions.

3.7 Reframing and strengthening the duty of quality represents a further step on the journey towards ever-higher standards of person-centred health services in Wales.

3.8 Part 2 of the Act also makes consequential amendments to section 47 and section 70 of the 2003 Act.

3.9 Section 47(1) of the 2003 Act permits the Welsh Ministers to prepare and publish statements of standards in relation to the provision of health care by and for Welsh NHS bodies. The Welsh Ministers are required to keep the standards under review and may publish amended statements whenever it considers appropriate. The last standards were published under this provision in April 2015.[17] Section 47(4) of the 2003 Act required that the standards set out in statements are to be taken into account by every Welsh NHS body in discharging its duty under section 45 of the 2003 Act. Given that section 45(1) is repealed, section 47(4) is amended such that the standards set out in statements are to be taken into account by a Welsh NHS body in discharging the revised duty of quality in the 2006 Act.

3.10 In accordance with the Welsh Ministers' duty to review and the power in section 47 of the 2003 to publish amended statements of standards, the Health and Care Standards (April 2015) are withdrawn and replaced with the Health and Care Quality Standards as set out in this guidance and which align with the new

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[13] Section 1A of the 2006 Act
[14] Section 12A of the 2006 Act
[15] Section 20A of the 2006 Act
[16] Section 24A of the 2006 Act
[17] Welsh Government (2015) Health and Care Standards https://www.gov.wales/sites/default/files/publications/2019-05/health-and-care-standards-april-2015.pdf

duty of quality. This is to reflect the inextricable relationship that exists between the duty of quality and the standards.

3.11 Furthermore, section 70(1) of the 2003 Act provides that the Welsh Ministers have the function of conducting reviews of, and investigations into, the provision of health care by and for Welsh NHS bodies. In practice this function is carried out by Healthcare Inspectorate Wales (HIW) on behalf of the Welsh Ministers. Section 70(3) of the 2003 Act also imposes a specific function of conducting reviews into the arrangements made by Welsh NHS bodies for the purpose of discharging the duty of quality. Section 70(3) is amended such that this relates to the revised duty of quality under the 2006 Act. Section 70(4) of the 2003 Act requires the Welsh Ministers to take into account the standards published under section 47 in exercising its functions under section 70.

Key messages

- The key purpose of the Act is to reframe and broaden the duty of quality which was first set out in the 2003 Act
- The duty of quality set out in section 45(1) of the 2003 Act is repealed and replaced with a revised duty to secure quality in health services in the 2006 Act
- The revised duty requires that the Welsh Ministers must exercise their health-related functions with a view to secure improvement in the quality of health services
- The revised duty also requires that NHS bodies must exercise all of their functions with a view to securing improvement in the quality of health services
- The Act makes consequential amendments to section 47 and section 70 of the 2003 Act such that any standards that are issued under the 2003 Act are taken into account by an NHS body in discharging the revised duty of quality in the 2006 Act, and that the Welsh Ministers has the function of conducting reviews of the steps taken by an NHS body for the purpose of discharging the revised duty of quality. The latter function is delegated to Healthcare Inspectorate Wales (HIW).
- The Health and Care Standards (2015) that were issued under section 47 of the 2003 Act are withdrawn and replaced with the Health and Care Quality Standards to reflect the inextricable relationship between the duty of quality and the standards

4. Strategic and policy context

4.1 A Healthier Wales: our Plan for Health and Social Care (" A Healthier Wales") sets out the vision for a whole system approach to health and social care in Wales.

4.2 It lays out the Welsh Government's ambitions for progress and improvement and describes the core values that underpin the NHS in Wales. These are:

- Putting quality and safety above all else
- Integrating improvement into everyday working
- Focusing on prevention, health improvement and inequality
- Working in true partnerships
- Investing in our staff

4.3 The Act supports the ambitions in A Healthier Wales by setting out the requirements for the improvement in the quality of health services.

4.4 The Act describes that quality includes, but is not limited to, the safety and effectiveness of health services and the experience of individuals who receive health services.

4.5 The Welsh Government published the Quality and Safety Framework in September 2021[18].

4.6 It provides an overview of quality principles and arrangements that need to be in place to ensure high quality services are being delivered.

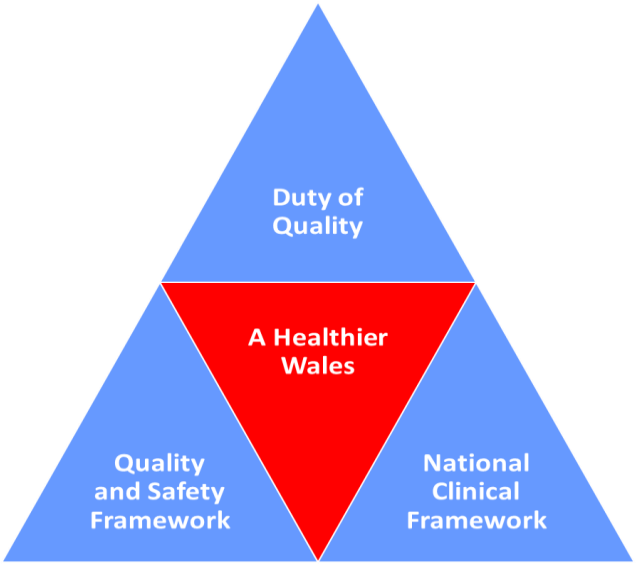
4.7 It requires the NHS to establish effective quality management systems that focus on learning and driven by their boards. It explains how Quality Control, Quality Planning, Quality Improvement and Quality Assurance must work together to form the quality management system that is required.

4.8 The intention was for the Framework to provide a steppingstone to the new duty of quality.

[18] Welsh Government 2021 Quality and Safety Framework learning and improving. https://gov.wales/nhs-quality-and-safety-framework

Figure 1
Diagram to demonstrate the quality management cycle as referred to in the Welsh Government's Quality and Safety Framework (2021).

Figure 2
Diagram to demonstrate the central strategic context of A Healthier Wales alongside the duty of quality, National Clinical Framework and Quality and Safety Framework



Key messages

- We must put the quality and safety of our health services above everything else
- The duty of quality influences many health-related policies and frameworks
- In turn, these also affect how we approach delivering quality in healthcare services
- Strengthening our quality management system helps us make sure our decision-making focuses on improving the quality of health services

5. Who does the duty of quality apply to?

5.1 The Act lists the following individuals and NHS bodies in Wales as being subject to the duty in Part 2 of the Act:

- Welsh Ministers (in relation to their health functions).
- Local Health Boards.
- NHS Trusts.
- Special Health Authorities that operate on a Wales-only basis.

5.2 The duty of quality and Welsh Ministers

The Welsh Ministers, with regards to their health-related functions, have responsibility for oversight of the NHS in Wales. They must ensure that health services are organised and delivered in such a way that system-wide, continuous improvement in the quality of health services is achieved.

5.3 Welsh Ministers will have to actively consider whether their decisions in relation to the health service are taken with a view to securing improvement in the quality of health services.

5.4 Welsh Ministers must ensure that national bodies with regulatory, performance management or support responsibilities have a cohesive and collaborative approach to system-wide improvement.

5.5 Welsh Ministers must issue guidance to NHS bodies in relation to the requirement to exercise their functions with a view to securing improvement in the quality of health services, and the requirement to publish an annual report on the steps they have taken to comply with this duty. The latter is described in section 9 Reporting requirements.

5.6 Welsh Ministers are required to publish an annual report on the steps they have taken to comply with the duty to exercise their functions in relation to the health service with a view to securing improvement in the quality of health service and within that report to include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.

5.7 The duty of quality and NHS bodies

The NHS in Wales delivers health services through 7 Local Health Boards and 3 NHS Trusts.

5.8 The Health Boards and Trusts work in partnership with 2 Special Health Authorities – Health Education and Improvement Wales (HEIW) and Digital Health and Care Wales (DHCW).

5.9 Several Local Health Boards and NHS Trusts host national organisations that support the delivery of health services. In hosting the national organisations, the Local Health Boards and NHS Trusts are exercising functions in relation to

the health service and therefore must do so with a view to securing improvement in the quality of health services. The hosted organisations must comply with the duty of quality in line with the governance of their hosting arrangements.

5.10 The duty of quality applies to Local Health Boards who are responsible for planning and delivering NHS services in their areas with the aims of:

- Improving physical and mental health outcomes.
- Promoting well-being.
- Reducing health inequalities across their population.
- Commissioning services from other organisations to meet the needs of their residents.

5.11 The 3 NHS Trusts and 2 SHAs have their own specific service delivery responsibilities to which the duty of quality will apply.

5.12 Accountability for compliance with the duty of quality ultimately rests with the Chief Executive of an NHS body.

5.13 Similar in approach to other legislation, it is recommended that NHS bodies designate appropriate senior leads to hold responsibility for the strategic implementation and oversight of the duty of quality. An officer member of the board should be delegated the responsibility to ensure the necessary strategic implementation and oversight. It should be noted however, that the responsibility to ensure due consideration is given to the duty of quality applies to all officer and non-officer board members whilst exercising the functions within their roles.

5.14 A designated operational lead to support the implementation of the duty of quality is also recommended.

5.15 There is a collective responsibility of all Board members to support the Chief Executive to: -

5.15.i) comply with the duty of quality by internal governance and assurance arrangements that are structured within a robust quality management system;

5.15.ii) ensure that health services are organised and delivered in such a way that system-wide, continuous improvement in the quality of health services is achieved;

5.15.iii) actively consider whether the Board's decisions will improve service quality and secure improvement in outcomes for the population;

5.15.iv) demonstrate how they have exercised their functions and improved the quality of services in accordance with the duty of quality. This is described in section 9 Quality reporting requirements.

5.16 The duty of quality applies to all health service functions in both clinical and non-clinical settings. Therefore, all staff have responsibility for complying with the duty within their role and service function. It is a collective responsibility to comply with the duty of quality.

5.17 The duty of quality in commissioned services

It is recognised that health services may be provided across geographical boundaries through commissioning arrangements with NHS and non-NHS service providers. Local Health Boards, NHS Trusts and SHAs must exercise their functions with a view to securing improvement in the quality of health services. The NHS body that is commissioning the health service is exercising its functions and must therefore ensure it is doing so with a view to securing improvement in the quality of the health service. Regardless of who is delivering health services when they are commissioned, the duty is the responsibility of the commissioning body.

5.17.i) Services commissioned by an NHS body from another NHS body in Wales:

The NHS body that is commissioning the health service is exercising its functions and must ensure it is doing so with a view to securing improvement in the quality of the health service. The duty of quality is the responsibility of the commissioning body. The commissioning body will wish to ensure that health services delivered by the alternative provider will secure improvement in the quality of health services. The Welsh NHS body providing services on behalf of the commissioner must also ensure that they are compliant with the duty that will also apply directly to them for the services they are providing.

5.17.ii) Services provided by primary medical, dental, optical and pharmaceutical services in Wales: In accordance with the 2006 Act, each Local Health Board must, to the extent that it considers necessary to meet all reasonable requirements, provide primary medical, dental, optical and pharmaceutical services within its area. Local Health Boards enter into arrangements with primary care providers for the delivery of primary care services in pursuit of those duties. The duty of quality does not directly apply to primary care providers. The duty of quality rests with the Local Health Boards to secure improvement in the quality of health services, and this extends to the services that are delivered by primary care providers on behalf of the Local Health Board. Local Health Boards must therefore exercise their duties in relation to primary care, with a view to securing quality in the provision of services.

5.17.iii) Services commissioned from non-NHS bodies:

The NHS body that is commissioning the health service from an independent provider is exercising its functions and must ensure it is doing so with a view to securing improvement in the quality of the health service. The duty of quality is the responsibility of the commissioning NHS body. The commissioning body will

wish to ensure that health services delivered by the alternative or independent provider will secure improvement in the quality of health services. This may be a consideration in contracting arrangements.

5.17.iv) Services commissioned outside of Wales:

The Welsh NHS body that is commissioning the health service is exercising its functions and must ensure it is doing so with a view to securing improvement in the quality of the health service. The commissioning body will wish to ensure that health services delivered by the alternative provider will secure improvement in the quality of health services. The service provider will be responsible for the quality of health services they directly provide under the relevant jurisdiction within which the services are provided.

5.18 Welsh Ministers and NHS bodies have a responsibility to encourage shared learning and expertise as they progress along their quality improvement journey. Much can also be learnt from high performing care systems globally.

5.19 There is a need at all levels to ensure that the health system has the resources, capacity, time and autonomy needed to develop their approaches to improving quality. This is supported by the World Health Organisation's Quality health services: a planning guide in the foundational requirements for quality initiatives[19].

[19] World Health Organisation (2020) Quality Health Services: a planning guide https://www.who.int/publications/i/item/9789240011632

Key messages

- The duty of quality applies to Welsh Ministers (in relation to their health functions)
- The duty of quality also applies to Local Health Boards, NHS Trusts and Special Health Authorities that operate on a Wales-only basis
- Accountability for the duty of quality ultimately rests with the Chief Executive of an NHS body who may designate a lead officer and senior operational lead to oversee the implementation of the duty in the organisation
- All Board members are collectively responsible for the implementation of the duty of quality
- Several Local Health Boards and NHS Trusts host national organisations that support the delivery of health services. The hosted organisations must comply with the duty of quality in line with the governance of their hosting arrangements. The duty does not apply directly to primary care providers, non-NHS providers of health services or to NHS providers outside of Wales
- The NHS bodies are responsible for exercising their functions with a view to securing improvement in the quality of health services. This includes services that they commission from other providers
- The duty of quality will ensure that health services are organised and delivered in a way that seeks to secure continuous improvement in quality and improves outcomes for the population
- Welsh Ministers and NHS bodies will have to actively consider whether their decisions will improve service quality and improve outcomes
- Welsh Ministers and NHS bodies will need to be able to demonstrate, supported by evidence, how they have complied with the duty of quality
- All staff have a role in achieving improved service quality; the duty of quality applies to all health service functions in both clinical and non-clinical settings
- System-wide learning and sharing is actively encouraged

6. Defining quality

6.1 Numerous definitions of quality relating to health and care services have been described by various global organisations, including the Institute for Healthcare Improvement[20] and World Health Organisation[21].

6.2 For the purposes of this guidance, quality is considered to be defined as continuously, reliably, and sustainably meeting the needs of the population that we serve. In achieving this, Welsh Ministers and NHS bodies will need to ensure that health services are **safe, timely, effective, efficient, equitable and person-centred**[22].

6.3 NHS bodies and Welsh Ministers will need to continually seek to understand the needs of their population to inform their decision-making and secure improvement in outcomes. The population too, will have their own part to play to inform the process.

6.4 **Domains of quality**

Welsh Ministers and NHS bodies should ensure the decisions they make deliver care that is **safe, timely, effective, efficient, equitable and person-centred.** These quality dimensions provide a framework to assess quality and guide improvement. Therefore, it is important to explain what the quality dimensions aspire to achieve and what we intend them to mean in Wales as part of the duty of quality.

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[20] Sampath B, Rakover J, Baldoza K, Mate K, Lenoci-Edwards J, Barker P. Whole System Quality: A Unified Approach to Building Responsive, Resilient Health Care Systems. IHI White Paper. Boston: Institute for Healthcare Improvement; 2021. https://www.ihi.org/resources/Pages/IHIWhitePapers/whole-system-quality.aspx.

[21] WHO (2020) Quality health services: a planning guide https://www.who.int/publications/i/item/9789240011632

[22] Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C: National Academy Press; 2001.

6.4.1 **Safe**

Safe
Our healthcare system is a high quality, highly reliable and safe system that avoids preventable harm, maximising the things that go right and learning from when things go wrong to prevent them occurring again. People's health, safety and welfare are actively promoted and protected; risks are identified and monitored and where possible, risks to safety are reduced or prevented. We promote and protect the wellbeing, and safety of children and adults who become vulnerable or at risk at any time. Where children or adults may be experiencing or are at risk of abuse or neglect, we take appropriate, timely action and report concerns.

6.4.2 **Timely**

Timely
Our healthcare system ensures people have access to the high-quality advice, guidance and care they need quickly and easily, in the right place, first time. We care for those with the greatest health need first, and where treatment is identified as necessary, we treat people based on their identified and agreed clinical priority.

6.4.3 **Effective**

Effective

Our healthcare system ensures decision-making, care and treatment reflects evidence-based best practice, to ensure that people receive the right care to achieve the optimal and possible outcomes that matter to them. We design transformative, evidenced-based, whole-of-life pathways that cover prevention, care and treatment, rehabilitation and embed these into local service delivery.

6.4.4 Efficient

Efficient

Our health care system takes a value-based approach to improve outcomes that matter most to people in a way that is as sustainable as possible and avoids waste. We make the most effective use of resources to achieve best value in an efficient way. We only do what is needed and undertake treatments that ensure any interventions represent the best value that will improve outcomes for people.

6.4.5 Equitable

Equitable

Our health care system provides everyone with an equal opportunity to attain their full potential for a healthy life which does not vary in quality because of personal characteristics (such as age, gender, sexual orientation, race, language preference, disability, religion or beliefs, socio-economic status or political affiliation). We embed equality and human rights in our health care system and promote.

6.4.6 Person-centred

Person-centred

Our health care system meets people's needs and ensures that their preferences, needs and values guide decision-making that is made in partnership between individuals and the workforce. We care about the well-being of individuals, their families, carers and our staff. We ensure that everyone is always treated with kindness, empathy and compassion and we respect their privacy, dignity and human rights. We are committed to working better together to put people and their families at the centre of decisions, seeing them as experts working alongside professionals to get the best outcome and experience.

6.5 **Quality enablers**

A system-wide approach to quality requires a culture that embeds continuous learning and improvement at its heart. This should be underpinned by a clear definition and understanding of what good quality looks like utilising national and benchmarked standards, peer review and audit.

6.6 Learning from internationally recognised organisations that have well-established and effective approaches to quality provides a blueprint for what good quality should look like. The quality enablers underpin and influence this blueprint to ensure a system-wide approach to improving quality.

6.7 Experience has shown that maturing and embedding these concepts can take a number of years. It is recognised that there has been a positive culture with quality being "at the heart of the Welsh health system"[23].

6.8 The quality enablers that underpin this blueprint to ensure a system-wide approach to improving quality are:

[23] Organisation for Economic Co-operations and Development (OECD) Reviews of Health Care Quality: United Kingdom 2016: Raising Standards at https://www.who.int/publications/i/item/9789240011632

6.8.1 **Leadership**

Leadership

Our health care system has visible and focused leadership at all levels, with its activities driven by the organisations' vision and values for quality. Our leaders and managers take a long-term, stakeholder-centric view to develop a clear organisational vision. They have the appropriate skills and capacity to create the conditions for a functioning quality management system. We ensure our governance, leadership and accountability is effective in sustainably delivering care.

6.8.2 **Workforce**

Workforce

Our healthcare system recruits, retains, develops and extends roles to ensure we have enough, confident people with the right knowledge and skills available at the right time to deliver safe care. We value our people and the commitment and resilience they demonstrate in the care they provide. We care about their wellbeing, protect their rights and support them to feel well and happy at work; and provide them with the tools, systems and environment to work safely and effectively. Our workforce planning focuses on investing in our people and nurturing, growing and transforming our workforce to create a sustainable workforce for the future.

6.8.3 **Culture**

Culture

Our healthcare system creates the right climate and culture to nurture and encourage quality and system safety, valuing people in a supportive, collaborative and inclusive workplace so that our people feel psychologically safe to raise concerns and try out new ideas and approaches. Relationships within teams and with the people we serve are effective and based on transparency, accountability, ethical behaviour, trust and just culture, where people can thrive.

6.8.4 **Information**

Information

Our healthcare system ensures information is available and shared appropriately for all who need it. We turn data to knowledge by triangulating quantitative and qualitative performance, experience and outcome measures to understand the quality of services, efficacy of improvement work and impact of decisions made. We monitor, report and escalate indicators through our governance structures to ensure that appropriate action is taken at every level in terms of learning, improvement and accountability.

6.8.5 **Learning, improvement and research**

Learning, improvement and research

Our healthcare system creates the conditions and capacity for an organisation and system-wide approach to continuous learning, quality improvement and innovation, which it actively promotes. We use new knowledge to influence improvements in practice and to inform our decision-making. We ensure our learning and improvement activity is linked to our strategic vision to deliver transformational, organisation-wide change. We commit to participating in research because research-active organisations provide improved quality of care and outcomes for people.

6.8.6 **Whole systems approach**

Whole systems approach

Our healthcare system ensures safety in healthcare goes beyond individual patient safety. We will look within and beyond our organisational boundaries to learn how we can continually, reliably and sustainably meet the evolving needs of people. We will strengthen relationships and work with all of our partners to achieve good outcomes. Our policies incorporate the broader ambitions within the seven well-being goals and five ways of working in the Well-being of Future Generations Act.

6.8.7 The six quality enablers complement the implementation of a methodology and approach to managing quality, as set out in the Quality and Safety Framework (2021).

6.8.8 Together, the domains of quality and quality enablers create our new Health and Care Quality Standards. See also section 7.

6.8.9 Welsh language needs and choice of people must be considered through the quality lens. See also section 11.

6.8.10 The insights, learning and expertise created within NHS organisations across primary, community and secondary care will drive improvements in quality within Regional Partnership Board footprints and accelerate efforts to improve

Key messages

- Quality is defined as continuously, reliably, and sustainably meeting the needs of the population that we serve
- Welsh Ministers and NHS bodies will need to ensure that health services are **Safe, Timely, Effective, Efficient, Equitable and Person-centred**
- These quality dimensions provide a framework to assess quality and guide improvement
- Quality enablers have been identified which underpin and influence a blueprint to ensure a system-wide approach to improving quality
- The quality enablers are **Leadership; Workforce; Culture; Information; Learning, improvement and research and Whole-systems approach**

- Together, the quality domains and enablers comprise the **Health and Care Quality Standards**
- Maturing and embedding a quality management system takes time, vision, ambition, and an active commitment to learning and improving

quality across the whole health and care system in NHS Wales.

7. Health and Care Quality Standards

7.1 Section 47(1) of the 2003 Act permits the Welsh Ministers to prepare and publish statements of standards in relation to the provision of health care by and for Welsh NHS bodies. The Welsh Ministers are required to keep the standards under review and may publish amended statements whenever it considers appropriate. The last standards were published under this provision in April 2015.[24]

7.2 Section 47(4) of the 2003 Act (as amended by Part 2 of the 2006 Act) requires that the standards set out in statements are to be taken into account by a Welsh NHS body in discharging its duty of quality in the 2006 Act. Accordingly, there is an inextricable relationship that exists between the duty of quality and the standards issued under section 47(1) and such standards should therefore align with and support the duty of quality. In developing the duty of quality guidance and reviewing the April 2015 Standards the Welsh Ministers have withdrawn the Health and Care Standards (April 2015) and replaced them with the Health and Care Quality Standards, as set out in section 6 of this guidance. This change is being made as the introduction of the duty of quality provides an opportunity to directly align the standards not only with the duty but with wider quality management practice in health. The domains as described in this guidance are widely used in health care and are being implemented in the wider Welsh health system. The revised Health and Care Quality Standards are designed to simplify the requirements and be flexible with the wide remit of the duty of quality.

7.3 Healthcare Inspectorate Wales (who exercise functions on behalf of the Welsh Ministers) will also have to take these standards into account for the purpose of undertaking reviews and investigations relating to the provision of health care in Wales under section 70 of the 2003 Act. The Health and Care Quality Standards provide a high-level framework for describing, implementing and monitoring the duty of quality. The Health and Care Quality Standards set out what people in Wales can expect when they access health services.

7.4 The Health and Care Quality Standards provide a structure on which to implement the duty of quality, whether at a national policy level or by service providers and are relevant in all clinical and non-clinical services and settings. The Health and Care Quality Standards integrate with the wider health system.

7.5 It should be noted that A Healthier Wales introduced 'quality statements' to describe the outcomes and standards expected in high quality, person-

[24] Welsh Government (2015) Health and Care Standards
https://www.gov.wales/sites/default/files/publications/2019-05/health-and-care-standards-april-2015.pdf

focussed services, setting out the ambitions to be delivered consistently across Wales.

7.6 This was further described in the National Clinical Framework. It explained that quality statements will set out the policy expectations for the future planning and accountability arrangements for the NHS in Wales.

7.7 The Health and Care Quality Standards are high level organisational standards. Detailed service standards are usually produced by professional and advisory bodies.

Figure 3

Visual to illustrate the six domains of quality supported by six quality enablers. Together, these comprise the Health and Care Quality Standards.

Key messages

- **Welsh Ministers have a duty to review standards issued under section 47 of the 2003 Act and may publish amended statements of standards whenever it considers appropriate**
- **The Health and Care Standards (2015) are withdrawn and replaced by the Health and Care Quality Standards, comprised of six domains of quality and six quality enablers, to reflect the inextricable relationship between the duty of quality and standards**
- **The revised Health and Care Quality Standards ensures direct alignment between the duty of quality and standards, ensuring the simplified framework can be widely and flexibly applied**
- **The Health and Care Quality Standards set out the high-level standards that people in Wales can expect when they access health services**
- **The wide remit of the Health and Care Quality Standards is intended to provide a structure on which to implement the duty of quality, whether at national policy level or by service providers and they are intended to apply to all clinical and non-clinical services and settings. They integrate with the wider health system.**
- **It is anticipated that the duty of quality will ensure an aligned approach to improving the quality of our services to achieve better outcomes for the population, applied through the Health and Care Quality Standards**

8. Meeting the duty of quality

8.1 The duty of quality requires:

8.1.1) Welsh Ministers to exercise their functions in relation to the health service with a view to securing improvement in quality of health services.

8.1.2) Each Local Health Board, NHS Trust and Wales-only Special Health Authority to exercise their functions with a view to securing improvement in the quality of health services.

8.2 This means that the duty of quality requires the Welsh Ministers (in respect of its functions in relation to the health service) and NHS bodies (in respect of all its functions) to:

8.2.1) Ensure that all strategic decisions are made through the lens of improving the quality of health services and outcomes for the population.

8.2.2) Exercise their functions in a way that considers how they will improve quality and outcomes on an ongoing basis.

8.2.3) Actively monitor progress on the improvement of quality services and outcomes and routinely share this information with their population.

8.2.4) Strengthen governance arrangements by reporting annually on the steps taken to comply with the duty of quality and assess the extent of improvements in outcomes.

8.2.5) Ensure that NHS organisations develop their quality management system with appropriate focus on quality control, quality planning, quality improvement and quality assurance with the aim of achieving a learning and improving environment; and create a culture of quality within organisations.

8.3 In accordance with section 47(4) of the 2003 Act, NHS bodies must take into account the Health and Care Quality Standards described in this guidance and issued under section 47(1) of the 2003 Act in discharging the duty of quality.

8.4 Furthermore, there are six steps that an NHS body should take to plan, deliver and sustain the necessary focus on improving quality, which should be

underpinned by a clear understanding of what good quality looks like for the organisation[25]:

8.4.1) Securing Board support

The Board has collective responsibility for ensuring the duty of quality is delivered and they must demonstrate this in their actions and behaviours. They must demonstrate their long-term commitment to improving quality when setting the strategic direction and seeking assurance of delivery. This should be underpinned by a willingness and financial support to develop the skills and infrastructure for implementation. The Board should prioritise national and regional initiatives along with recommendations that fit the organisation's way of working. The Board needs to ensure they adhere to the duty of quality in their decision-making and seek assurance with regard to decisions made by others.

8.4.2) Assessing readiness

There needs to be system-wide understanding of what good quality looks like for the broad range of services. NHS bodies should understand their 'readiness for change' to be clear about where the capability gaps are and have a plan to address them. They should use regular assessments, investigations and measurement over time to identify areas to improve quality. The NHS body should consider psychological readiness in addition to having the infrastructure, governance, system understanding and leadership in place for change.

8.4.3) Securing wider organisational buy-in and co-creating a vision

NHS bodies should create a compelling vision for improved quality that is recognised and intrinsically motivates staff at each level of the organisation. A culture of distributed leadership gives staff at all levels the permission, opportunity and confidence to test new ideas to improve quality that are aligned to the organisation's vision. Leaders should champion improvements in quality that are strategically aligned, driven and owned by the teams responsible for delivering health services.

8.4.4) Developing improvement skills and infrastructure

25 The Health Foundation (2019) The improvement journey: Why organisation-wide improvement in health care matters, and how to get started https://www.health.org.uk/publications/reports/the-improvement-journey

NHS bodies need a systematic approach to managing quality that includes building improvement capability to ensure teams at each level of the organisation have the general and specialist improvement skills needed. This should be accompanied by a suite of measures and a system that collects, analyses and feeds back on the impact of the improvements. Standard operating models to standardise core processes and activities should also be developed to address variations in quality.

8.4.5) Aligning and coordinating activity

NHS bodies need to ensure that initiatives to improve quality are consistent with their overall strategy and mission and barriers are identified and unlocked. A leader with oversight of all the organisation's activity should ensure that all strands of activity align over time. They should ensure that learning from success and weaker areas continue to shape the improvements in quality that are required.

8.4.6) Sustaining an organisation-wide approach

NHS bodies must invest in maintaining the momentum for improvements in quality and recognise that this is a longer-term journey. A focus on early wins shifts to the challenge of maintaining success and continuing to engage staff and stakeholders, with the Board managing expectations and supporting staff to maintain a focus on improvements aligned to the organisation's purpose. The Board should seek assurance that quality improvement activities are sustainable with appropriate assurance mechanisms to maintain the improvements.

Key messages

- **Welsh Ministers must exercise their functions in relation to the health service with a view to secure improved quality of health services**
- **NHS bodies must exercise its functions with a view to securing improvement in the quality of health services**
- **Welsh Ministers and NHS bodies will need to ensure that strategic decisions are made through a quality lens**
- **Welsh Ministers and NHS bodies must exercise their functions in a way that considers improvement in quality and outcomes on an ongoing basis**
- **The focus must be on improving the quality of services and outcomes for the population**
- **NHS bodies should develop their quality management system and create a culture of quality within their organisations**
- **There are six steps an NHS body should take to plan and sustain the focus on improving quality, underpinned by a clear understanding of what good quality looks like for the organisation. These are:**
    1. **Securing Board support**
    2. **Assessing readiness**
    3. **Securing wider organisational buy-in and co-creating a vision**
    4. **Developing improvement skills and infrastructure**
    5. **Aligning and coordinating activity**
    6. **Sustaining an organisation-wide approach**

9 Quality reporting requirements

9.1 The Welsh Ministers are required to publish an annual quality report on the steps they have taken to comply with the duty to exercise their functions in relation to the health service with a view to securing improvement in the quality of health services. The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps, and the Welsh Ministers must lay a copy of the report before the Senedd.

9.2 Each Local Health Board, NHS Trust and Wales-only Special Health Authority is required to publish an annual quality report on the steps it has taken to comply with the duty to exercise its functions with a view to securing improvement in the quality of health services. The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.

9.3 This section of the guidance provides guidance about the requirement to publish an annual quality report, the evidence to be used in support of an assessment and the conduct of an assessment.

9.3.1 The annual quality report allows actions taken by Welsh Ministers and NHS bodies and quality improvements to be monitored transparently. The report should describe the progress and challenges on the quality journey to their respective population and stakeholders. Quality reporting needs to be meaningful for NHS bodies, their stakeholders and our population if it is to optimise real time learning, improvement and sharing opportunities. Quality reporting should reflect the breadth of the Health and Care Quality Standards and quality management system within its structure and content.

9.4 In addition to the annual quality reporting requirement, it is proposed that NHS bodies develop a so-called ‘always on’ reporting mechanism. ‘Always on’ means that organisations collate, monitor and make information about the quality of their services readily available to their population and stakeholders, both within the organisation and externally.

9.4.1 ‘Always on’ reporting requires organisations to have a whole system approach to the routine use of information across their quality management system. ‘Always on’ encourages recognition and sharing of good practice and early escalation and intervention when signals suggest that action is necessary.

9.5 NHS bodies may choose to use various qualitative and quantitative data and information to support their quality reporting duty. They should focus on information that will demonstrate the duty of quality in decision-making, action taken following learning, quality improvement and ultimately, improved outcomes

for the population. The Health and Care Quality Standards and quality management system components provide a quality report structure.

9.5 It is recognised that there is already significant work underway across the health system relating to indicators and measures. The intention is that NHS bodies will make use of information and reporting mechanisms already in place wherever possible. They will need to adopt an agile approach to mature their quality report as outcome measures develop, aligned to the Health and Care Quality Standards.

9.6 The annual quality report is intended to summarise and reflect an NHS body's progress to improve the quality of their services and population outcomes. It is anticipated that NHS bodies will sign-post readers to the information provided through the 'Always on' reports that outline learning and improvements that have been made at regular intervals through the year.

9.7 The annual quality report should include a look back at what has been achieved, including where things may not have gone well, together with a forward look about the organisation's quality priorities and ambitions for the upcoming year, alongside how progress will be monitored. There should be continuity between annual reports across subsequent years.

9.8 The annual quality report will describe what key strategic decisions have been taken by the NHS body, and how the duty of quality has informed these decisions.

9.9 The annual quality report should be prepared as soon as practicable after the end of each financial year. To streamline reporting requirements and reduce duplication, it is suggested that NHS bodies align the annual quality report to their Annual Report and Accounts process.

9.10 Additional information will be available in a supplementary reporting framework, as a supporting resource.

9.11 Examples of evidence to be used to assess the duty of quality and the extent of any improvement in outcomes includes:

9.11.1) Existing performance, outcome and delivery indicators and measures from the quality management system

9.11.2) Patient Reported Outcome Measures and Patient Reported Experience Measures (PROMS and PREMS)

9.11.3) Mortality data

9.11.4) Information contained within the Once for Wales Concerns Management System such as incidents and concerns

9.11.5) Patient and staff stories

9.11.6) Strategic decision-making that has been driven by the Health and Care Quality Standards

9.11.7) Reports following external reviews or inspections by inspectorate and licensing bodies

9.11.8) Consideration of the recommendations and implications of significant national reports, for example, following national inquiries

9.11.9) It should be noted that this list provides illustrative examples and is not exhaustive

9.12 NHS bodies will conduct the assessment of the extent of any improvement in outcomes achieved through:

9.12.1) Self-assessment

9.12.2) Peer review and feedback

9.12.3) National clinical audit

9.12.4) Internal audit

9.12.5) External review, for example, Wales Audit Office

9.12.6) Inspections, for example, Healthcare Inspectorate Wales

9.12.7) It should be noted that this list provides illustrative examples and is not exhaustive.

9.12.8) It is recognised that there are strengths and weaknesses to the various forms of assessment outlined. Thus, NHS bodies should seek to ensure a range of assessments are considered.

9.13 It is of crucial importance that NHS bodies actively engage with their population to ensure their voice is heard and to promote working in partnership to achieve the aims of the duty of quality.

9.14 Information about the provision of services through the Welsh language should be included in quality reports. Uptake of the Active Offer[26] and capturing people's experience through patient and staff stories provide monitoring opportunities through quality reporting requirements.

[26] The Active Offer is described in the Welsh Government (2022) More than just words: Five Year Plan 2022 – 2027 as providing a service in Welsh without someone having to ask for it. It means creating a culture that places the responsibility on health and social care providers to provide a proactive language offer so that people can access care, as equal partners, through the medium of Welsh. https://www.gov.wales/sites/default/files/publications/2022-07/more-than-just-words-action-plan-2022-2027.pdf

9.15 It is important to ensure that UK General Data Protection Regulation (UK GDPR) is adhered to when accessing and processing information to prepare for the duty of quality reports.

Key messages

- **Welsh Ministers and NHS bodies must exercise their functions with a view to secure improved quality of health services**
- **Welsh Ministers and NHS bodies must publish an annual quality report that sets out the steps they have taken to secure improved quality of health services**
- **The annual quality report must include an assessment of the extent of any improvement in outcomes achieved**
- **This guidance sets out guidance about the conduct of this assessment and evidence to support it, as well as the requirement to submit an annual quality report**
- **Annual quality reports must be a transparent reflection of progress and challenges on the quality journey. Forthcoming quality priorities and how they will be monitored should be set out**
- **The annual quality report must assess any improvement in outcomes**
- **It should demonstrate how the duty of quality has informed strategic decision-making**
- **It should outline action taken as a result of learning and describe how that has been shared**
- **The annual quality report should be prepared as soon as practicable after the end of the financial year to coincide with the Annual Report and Accounts process**
- **It is recognised that data to support the quality reporting process is a developing area and it will take time for a suite of outcome measures to be in place. Therefore, an agile approach to use of indicators and measures will be required**
- **In addition to annual quality reporting, NHS bodies are encouraged to develop an 'always on' reporting process where they collate, monitor and share quality information with their population at regular intervals during the year**
- **'Always on' reporting promotes routine use of information to inform decision-making and quality improvement. It supports recognition and sharing of good practice as well as allowing early escalation and intervention when action is necessary**
- **It is of crucial importance that NHS bodies actively engage with their population to ensure their voice is heard and to promote working in partnership to achieve the aims of the duty of quality**

10. Decision-making, monitoring and assurance

10.1 The duty of quality requires the Welsh Ministers and NHS bodies to think and act differently by applying the concept of quality across all functions within the context of the health services and health needs of their populations.

10.2 The duty requires quality-driven decision-making and planning to ultimately deliver better outcomes for all people who require health services. It means involving people in decisions that affect them and balancing short-term needs with planning for the longer-term; it requires action to prevent problems occurring or getting worse.

10.3 It needs a system-wide approach with acknowledgement that the duty of quality is a collective responsibility.

10.4 The focus of the duty of quality is on learning and improving, not on punitive sanctions when those to whom the duty applies fall short in their implementation of it.

10.5 However, NHS bodies must consider how effective implementation and monitoring of the duty of quality can be integrated into existing corporate governance frameworks, processes and procedures. This includes existing performance and quality reports.

10.6 When designing or introducing new structures and processes it will be necessary to embed the duty of quality within them.

10.7 When considering review processes and assurance mechanisms they must also take account of the duty of quality. This includes, for example, planning of the annual internal audit and clinical audit programmes.

10.8 In respect of NHS bodies, the Board will be required to seek assurance that the duty of quality is being appropriately discharged as a system-wide and collective responsibility. As such, it is for all committees to report to the Board regarding the duty of quality; it is not only for the quality and safety committee.

10.9 In seeking assurance in NHS bodies, the committees will look to ensure that sustainable quality improvement is being made and quality improvements are maintained.

10.10 When the Board considers and agrees the Board Assurance Framework and strategic risk register, it should also comply with the duty of quality.

10.11 Welsh Ministers and NHS bodies must ensure the effective implementation and monitoring of the duty of quality. It must be integrated into existing governance frameworks, processes and procedures with regular updates to the relevant committees and board meetings for assurance purposes.

10.12 Compliance with the duty will also form part of the matters considered by Healthcare Inspectorate Wales (HIW) when inspecting and reviewing the provision of health care.

10.13 The annual quality report and 'always on' approach provides information to the public, the NHS body itself, the Welsh Government and other key partners to ensure transparency and accessibility to information about the implementation of the duty of quality.

Key messages

- **The duty of quality requires Welsh Ministers and NHS bodies to ensure quality-driven decision-making and planning is in place to ultimately deliver better outcomes for all people who require health services**
- **Quality needs to be system-wide; applied across all clinical and non-clinical services within the context of the well-being and health needs of the population**
- **The focus is on learning and improvement rather than punitive sanctions when the duty of quality has been compromised**
- **The duty must be integrated into existing corporate procedures, including but not limited to, planning, performance, quality, Internal Audit reviews**
- **It must be embedded within all structures and processes that are established**
- **The Board will be required to seek assurance that the duty of quality is being appropriately discharged as a system-wide and collective responsibility**
- **The Board will need to seek assurance that sustainable quality improvement is being made, with appropriate assurance mechanisms in place to ensure that quality improvements are maintained**
- **When the Board considers and agrees the Board Assurance Framework and strategic risk register, it should also comply with the duty of quality**
- **Compliance with the duty of quality will be monitored. It will be integrated into existing monitoring mechanisms. The various monitoring mechanisms across the health system must embed the duty of quality within their processes**
- **The annual quality report and 'always on' approach will be integral to the monitoring process to ensure the duty of quality is being delivered**

11. Welsh Language

11.1 It is recognised that health services in Wales are delivered within a bilingual nation.

11.2 **More than just words** (2022) is the Welsh Government's plan to strengthen Welsh language provision in health and social care. Its aim is to support Welsh-speakers to receive services in their first language, because receiving services in Welsh should be an integral part of person-centred care.

11.3 The ambition is to Actively Offer people their care in Welsh. It is the responsibility on health and social providers to offer services in Welsh rather than people having to request it.

11.4 Being able to access services in the Welsh language makes a significant positive difference to the quality of the overall experience and health and well-being outcomes for many Welsh-speakers.

11.5 People have reported that it can be difficult to access services they need in the Welsh language and can feel reluctant to ask if Welsh-language services are not offered.

11.6 The Welsh Government's plan to strengthen the provision of Welsh language in health and social care aligns to the duty of quality. It is important for Welsh language considerations to be embedded in culture and leadership, quality planning, supporting and developing the skills of the workforce and sharing best practice through an enabling approach.

11.7 Welsh language requirements must also be considered through the lens of the Health and Care Quality Standards and as an integral component of the quality management system.

11.8 Welsh language must also be included in quality reports. Uptake of the Active Offer and capturing people's experience through patient and staff stories provide monitoring opportunities through quality reporting requirements.

Key messages

- **Being able to access services in the Welsh language makes a significant positive difference to the overall experience for many Welsh-speakers**
- **Being able to access services in the Welsh language can improve the quality, safety and outcomes for Welsh-speakers**
- **Welsh language considerations must be embedded in the culture of quality**
- **Welsh language responsibilities must be embedded in quality reports**

12. Conclusion

12.1 The fundamental intention of the duty of quality is to build on the positive culture of quality at the heart of the Welsh health system.

12.2 The duty of quality strengthens system-wide decision-making, action, improvement with the intention of ultimately improving outcomes for the population.

12.3 The duty of quality applies to Welsh Ministers with regards to their functions in relation to the health service and NHS bodies (Local Health Boards, NHS Trusts and Special Health Authorities that operate on a Wales-only basis) in relation to all their functions.

12.4 The duty of quality does not directly apply to primary care services or non-NHS providers of health services. The NHS body that directly provides or commissions the service holds the duty of quality responsibility.

12.5 Whilst accountability for implementing the duty of quality ultimately rests with the Welsh Ministers and Chief Executive of an NHS body, responsibility for operational implementation and oversight may be delegated to appropriate leaders.

12.6 Implementation of the duty of quality is a collective responsibility. It applies to everyone in clinical and non-clinical services, including Welsh Government policy makers.

12.7 The guidance provides a definition for quality for guidance purposes. It outlines a framework through which quality can be assessed and improved using the Health and Care Quality Standards. These, in turn, support the maturing of our quality management systems.

12.8 The Health and Care Quality Standards set out in the guidance are high level aspirations that describe what people in Wales can expect when they access health services. In order to ensure alignment between standards and the duty of quality, the Health and Care Standards (April 2015) are withdrawn and replaced with the Health and Care Quality Standards. NHS bodies are required to take into account the Health and Care Quality Standards in discharging the duty of quality, and HIW (on behalf of the Welsh Ministers) are required to take into account the Health and Care Quality Standards in conducting reviews and investigations of the provision of health care by and for those NHS bodies.

12.9 There are several steps an organisation should take to prepare to meet the duty of quality[27].

[27] The Health Foundation (2019) The improvement journey: Why organisation-wide improvement in health care matters, and how to get started

12.10 NHS bodies are placed under a duty to report on the steps they have taken to comply with the duty of quality on an annual basis.

12.11 NHS bodies should develop a so-called 'always on' reporting mechanism to provide timely information about the quality of their services to their population and stakeholders.

12.12 NHS bodies must ensure the effective implementation and monitoring of the duty of quality. It must be integrated into existing governance frameworks, processes and procedures with regular updates to the relevant committees and board meetings for assurance purposes.

12.13 Welsh language considerations must be embedded in the culture of quality.

12.14 It is acknowledged that culture change takes time. The duty is in force from the 1 April 2023 at which point NHS bodies will need to be able to demonstrate how they are complying with the duty. Developing the infrastructure to progress 'always on' quality reporting with appropriate outcome-focused measures will need to be an agile and iterative process.

12.15 Essentially however, principles of quality improvement methodology will need to be robustly in place for Welsh Ministers and NHS bodies to build quality as a broad system-wide way of working that is embedded in a culture of continuous learning and improvement.

12.16 Our active and heightened efforts to ensure a relentless focus on quality and safety, as a priority above all else, are needed more than ever in the history of the NHS.

https://www.health.org.uk/publications/reports/the-improvement-journey

LIC23-12

Canllawiau Statudol y Ddyletswydd Ansawdd 2023 a Safonau Ansawdd 2023

Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020

Deddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2023

Dyddiad cyhoeddi: 1 Ebrill 2023

CYNNWYS

Dehongli - yn y canllawiau hyn:

- Ystyr" Deddf 2003" yw Deddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003.
- Ystyr "gofal iechyd" at ddibenion Deddf 2003 yw (a) gwasanaethau a ddarperir i unigolion ar gyfer neu mewn cysylltiad ag atal, canfod neu drin salwch; a (b) hybu a diogelu iechyd y cyhoedd.
- Ystyr "Deddf 2006" yw Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.
- Ystyr "y Ddeddf" yw Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020.
- Ystyr "corff GIG", yng nghyd-destun y ddyletswydd ansawdd yng Nghymru, yw:
  (a) Bwrdd Iechyd Lleol.
  (b) Ymddiriedolaeth GIG.
  (c) Awdurdod Iechyd Arbennig Cymru-yn-unig.
- Pan ddefnyddir y gair **rhaid**, mae'n cyfeirio at gamau gweithredu sy'n ofyniad cyfreithiol, fel y nodir yn Rhan 2 o'r Ddeddf;
- Mae Rhan 2 o'r Ddeddf yn diwygio Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006 i fewnosod darpariaethau newydd 1A, 12A, 20A a 24A yn Neddf 2006. At ddibenion y darpariaethau newydd hynny:
  - Ystyr "gwasanaethau iechyd" yw unrhyw wasanaethau a ddarperir neu a sicrheir yn unol â Deddf 2006;
  - Mae "ansawdd" yn cynnwys, ond heb fod yn gyfyngedig i, ansawdd o ran –
    (a) Effeithiolrwydd gwasanaethau iechyd,
    (b) Diogelwch gwasanaethau iechyd,
    (c) Profiad unigolion y darperir gwasanaethau iechyd iddynt.

RHAGAIR

Mae cyflwyno dyletswydd ansawdd drwy Ddeddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020[1] ('y Ddeddf'), yn dangos ymrwymiad Llywodraeth Cymru i wasanaethau iechyd diogel, effeithiol sy'n canolbwyntio ar yr unigolyn. Mae'r Ddeddf yn gosod dyletswydd ansawdd drosfwaol ar Weinidogion Cymru o ran eu swyddogaethau sy'n ymwneud ag iechyd. Mae'n ehangu'r ddyletswydd bresennol ar gyrff GIG (Byrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig Cymru).

Yn y pen draw, pwrpas y ddyletswydd ansawdd yw sicrhau bod Gweinidogion Cymru a chyrff GIG yn sicrhau gwelliannau yn ansawdd y gwasanaethau a ddarperir ganddynt. Mae'r ddyletswydd yn cynrychioli ein huchelgais o sicrhau safonau uwch fyth o wasanaethau iechyd sy'n canolbwyntio ar yr unigolyn yng Nghymru.

Mae ansawdd yn golygu mwy na dim ond bodloni safonau gwasanaeth. Mae angen iddo fod yn ffordd o weithio ar draws y system i ddiwallu anghenion y boblogaeth m mewn modd parhaus, ddibynadwy a chynaliadwy. Mae diwylliant o ddysgu a gwella parhaus yn hollbwysig.

Wrth gyflawni'r ddyletswydd ansawdd, mae'n ofynnol i gyrff GIG ystyried y Safonau Ansawdd Iechyd a Gofal wrth wneud penderfyniadau am wasanaethau iechyd fel bod gwell canlyniadau'n cael eu sicrhau. Mae hyn yn cefnogi'r pum ffordd o weithio (hirdymor, integreiddio, cynnwys, cydweithio ac atal) yn Neddf Llesiant Cenedlaethau'r Dyfodol (Cymru) 2015[2] yn ogystal â hyrwyddo nod llesiant Cymru Iachach[3]. Rhaid i Weinidogion Cymru hefyd ystyried y Safonau Ansawdd Iechyd a Gofal wrth gynnal adolygiadau o ddarpariaeth gofal iechyd gan gyrff GIG ac ar eu cyfer, o dan adran 70 o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd a Safonau Cymunedol) 2003. Yn ymarferol, mae'r rôl o gynnal adolygiadau ac ymchwiliadau o'r fath yn cael ei gwneud gan Arolygiaeth Gofal Iechyd Cymru ar ran Gweinidogion Cymru.

Cyhoeddodd Llywodraeth Cymru y Fframwaith Ansawdd a Diogelwch[4] ym mis Medi 2021. Y bwriad oedd i hyn fod yn gam tuag at y dyletswyddau newydd o ran ansawdd a gonestrwydd o dan y Ddeddf wrth i ni ddod allan o bandemig y coronafeirws.

Er mwyn meithrin cysylltiadau clir rhwng y ddyletswydd ansawdd a'r safonau, mae'r canllawiau hyn bellach yn ymgorffori'r Safonau Ansawdd Iechyd a Gofal newydd a

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[1] Llywodraeth Cymru (2020) Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020 https://www.legislation.gov.uk/cy/asc/2020/1/contents
[2] Llywodraeth Cymru (2015) Deddf Llesiant Cenedlaethau'r Dyfodol https://www.futuregenerations.wales/cy/about-us/future-generations-act/
[3] Llywodraeth Cymru (2019) Cymru Iachach: Ein Cynllun ar gyfer Iechyd a Gofal Cymdeithasol https://www.llyw.cymru/cymru-iachach-cynllun-hirdymor-ar-gyfer-iechyd-gofal-cymdeithasol
[4] Llywodraeth Cymru (2021) Fframwaith Ansawdd a Diogelwch: Dysgu a Gwella https://llyw.cymru/sites/default/files/publications/2021-09/fframwaith-ansawdd-a-diogelwch-dysgu-a-gwella.pdf

fydd yn disodli'r Safonau Iechyd a Gofal a gyhoeddwyd yn 2015[5]. Mae'r dull newydd hwn yn gosod fframwaith clir a syml ar gyfer rheoli ansawdd a fydd yn cryfhau'r cysylltiad rhwng y ddyletswydd, y safonau a'r broses rheoli ansawdd ehangach yng ngwasanaethau iechyd Cymru.

Rwy'n falch mai 'Rhoi ansawdd a diogelwch uwchlaw popeth arall' yw'r gwerth craidd cyntaf a ddisgrifir yn "Cymru Iachach", sef ein strategaeth hirdymor ar gyfer iechyd a gofal integredig yng Nghymru. Fel y dywedodd Dr Tedros Adhanom Ghebreyesus, Cyfarwyddwr Cyffredinol Sefydliad Iechyd y Byd, yn ddiweddar "Nid yw ansawdd yn digwydd heb ymdrech. Mae'n gofyn am weledigaeth, cynllunio, buddsoddi, tosturi, gweithredu'n fanwl a monitro trylwyr, o'r lefel genedlaethol i'r clinigau lleiaf, mwyaf anghysbell."[6]

Mae gennym gyfle arwyddocaol i adnewyddu a chryfhau ein hymrwymiad i "Cymru Iachach" drwy'r ddyletswydd ansawdd newydd. Mae gennym gyfrifoldeb ar y cyd i sicrhau gwell ansawdd gwasanaethau a chanlyniadau i'n poblogaeth.

Eluned Morgan, y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

[5] Llywodraeth Cymru (2015) Safonau Iechyd a Gofal https://www.llyw.cymru/sites/default/files/publications/2019-05/safonau-iechyd-a-gofal-ebrill-2015.pdf

[6] Sefydliad Iechyd y Byd (2022) Fundamentals of Quality https://qualityhealthservices.who.int/quality-toolkit/new-to-health-system-quality-thinking/fundamentals-of-quality

1. Cyflwyniad

1.1 Bydd y ddyletswydd ansawdd, fel rhan o Ddeddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020 ("y Ddeddf") yn dod i rym ar 1 Ebrill 2023. Mae'n gyfrwng ar gyfer gwella a diogelu iechyd, gofal a llesiant poblogaeth Cymru nawr ac yn y dyfodol. Nod y Ddeddf yw rhoi llais cryfach i ddinasyddion a gwella atebolrwydd gwasanaethau i ddarparu profiad ac ansawdd gofal gwell. Bydd gwneud hynny'n cyfrannu at wlad iach a mwy ffyniannus. Bwriedir i'r Ddeddf fod o fudd cadarnhaol i bawb yng Nghymru, gan gefnogi diwylliant a'r amodau sydd eu hangen i ysgogi gwelliannau mewn gofal iechyd.

1.2 Mae dau ddiben i'r ddogfen hon, sef darparu canllawiau statudol sydd â'r nod o helpu cyrff GIG yng Nghymru i gyflawni gofynion y ddyletswydd ansawdd, a nodi'r Safonau Ansawdd Iechyd a Gofal a ddyroddir o dan adran 47(1) o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003. Mae dyletswydd ar gyrff GIG i ystyried y safonau hyn wrth gyflawni'r ddyletswydd ansawdd.

1.3 Mae'r sail gyfreithiol ar gyfer y ddyletswydd ansawdd wedi'i nodi yn Rhan 2 o'r Ddeddf.

1.4 Mae'r ddyletswydd ansawdd yn cefnogi pawb yng Nghymru. Mae'r ddyletswydd ansawdd newydd yn ei gwneud yn ofynnol i Weinidogion Cymru a chyrff GIG feddwl a gweithredu'n wahanol drwy gymhwyso'r cysyniad o "ansawdd" ar draws pob swyddogaeth yng nghyd-destun y gwasanaeth iechyd ac anghenion iechyd eu poblogaethau. Mae'n gofyn am wneud penderfyniadau a chynllunio ar sail ansawdd, er mwyn sicrhau canlyniadau gwell yn y pen draw i bawb y mae angen gwasanaethau iechyd arnynt. Mae'n gofyn am gynnwys pobl mewn penderfyniadau sy'n effeithio arnynt, gan gydbwyso anghenion tymor byr â chynllunio ar gyfer y tymor hwy, gyda chamau gweithredu i atal problemau rhag digwydd neu waethygu.

1.5 Mae'r ddyletswydd hefyd yn cefnogi defnyddio egwyddorion gofal iechyd darbodus sy'n seiliedig ar werth, y cyfeirir atynt yn y Fframwaith Clinigol Cenedlaethol[7] fel 'arferion darbodus'. Mae hyn yn newid y ffocws yn gynyddol at ofal sy'n canolbwyntio ar yr unigolyn, sy'n gallu helpu pobl i gadw'n iach ac i reoli eu cyflyrau eu hunain a, phan fo angen, yn gallu darparu cymorth arbenigol priodol a di-dor. Mae'r ffocws ar y person yn hytrach na'r lleoliad lle caiff y gwasanaeth ei ddarparu.

[7] Llywodraeth Cymru (2021) Fframwaith Clinigol Cenedlaethol: System Iechyd a Gofal sy'n Dysgu https://www.llyw.cymru/sites/default/files/publications/2021-05/fframwaith-clinigol-cenedlaethol-system-iechyd-a-gofal-syn-dysgu-update_0.pdf

1.6 Mae gofal iechyd seiliedig ar werth[8] yn ein hannog i ganolbwyntio ar gyflawni nodau ein cleifion a helpu i reoli disgwyliadau drwy gydol eu gofal neu eu triniaeth. Mae gwerth mewn iechyd yn ein hannog i wella'r ffordd y mae cleifion yn cael eu cynnwys yn y broses o wneud penderfyniadau gan ddefnyddio'r dystiolaeth orau sydd ar gael, gan osgoi unrhyw amrywiad diangen mewn gofal, a dod yn fwy creadigol i benderfynu ar y ffordd orau o ddefnyddio ein hadnoddau i wella canlyniadau cleifion. Drwy weithio gyda chleifion a thimau ym mhob rhan o'r system gofal iechyd yng Nghymru, a chydweithio â diwydiant a'r trydydd sector, gallwn sicrhau'r canlyniadau sy'n bwysig i bobl gyda'r adnoddau sydd ar gael i ni mewn ffordd gynaliadwy.

1.7 Y bwriad yw adeiladu ar y diwylliant cadarnhaol o ansawdd sydd wrth wraidd system iechyd Cymru[9], gan weithredu dyletswydd ansawdd ehangach ar draws y system sy'n cryfhau'r broses o wneud penderfyniadau, gweithredu, gwella ac, yn y pen draw, gwell canlyniadau i'r boblogaeth.

[8] Gofal Iechyd sy'n Seiliedig ar Werth (2022) Gofal Iechyd sy'n Seiliedig ar Werth i Gymru https://gisw.gig.cymru/gofal-iechyd-syn-seiliedig-ar-werth-i-gymru/polisi-a-diwylliant/

[9] Y Sefydliad ar gyfer Cydweithrediad a Datblygiad Economaidd (OECD) Reviews of Health Care Quality: United Kingdom 2016: Raising Standards https://www.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-care-quality-united-kingdom-2016_9789264239487-en

2. Diben y canllawiau

2.1 Gwella ansawdd ein gwasanaethau er mwyn sicrhau gwell canlyniadau i bobl yw'r peth iawn i'w wneud.

2.2 Mae'r canllawiau yn nodi'r arferion gorau i helpu cyrff GIG i weithredu a chymhwyso'r ddyletswydd ansawdd. Rhaid i gyrff GIG roi sylw i'r canllawiau a ddyroddir gan Weinidogion Cymru.

2.3 Mae'r canllawiau'n darparu sylfaen ar gyfer adeiladu systemau rheoli ansawdd, polisïau a gweithdrefnau perthnasol, gofynion hyfforddi a chefnogi. Mae'n hwyluso eglurder ynghylch dyletswydd ansawdd, cysondeb dull gweithredu a thegwch yr ymateb i wella ansawdd gwasanaethau iechyd a gwella canlyniadau i bobl.

2.4 Mae'r canllawiau yn nodi diffiniad o ansawdd ac yn disgrifio'r gofynion trosfwaol i gryfhau ein systemau rheoli ansawdd drwy wneud penderfyniadau a chynllunio ar sail ansawdd. Yn ei dro, mae hyn yn cryfhau dyletswyddau i ddysgu ac yn creu cyfleoedd i rannu'r hyn a ddysgir. Diben y ddyletswydd yn gyffredinol yw gwella canlyniadau i'n poblogaeth.

2.5 Bwriedir iddynt fod yn gyfeirbwynt i'n gweithlu yn ogystal â'n poblogaeth a'n sefydliadau partner er mwyn i ni allu meithrin dealltwriaeth gyffredin o'r ddyletswydd ansawdd.

2.6 Ni fwriedir i'r ddogfen fod yn un gyfarwyddol nac yn llawlyfr ansawdd neu ganllaw cam wrth gam. Yn y pen draw, mater i gyrff GIG yw eu bodloni eu hunain eu bod yn cydymffurfio â'r ddyletswydd newydd i sicrhau gwelliant yn ansawdd gwasanaethau iechyd a orfodir arnynt yn Neddf 2006, er y rhagwelir y bydd y canllawiau hyn yn darparu fframwaith defnyddiol i gynorthwyo cyrff o'r fath yn unol â hynny. Ar ben hynny, mae'r ddogfen ganllaw hon hefyd yn nodi Safonau Iechyd a Gofal newydd a fydd yn disodli'r Safonau Iechyd a Gofal (Ebrill 2015) a ddyroddwyd o dan adran 47(1) o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003 (sy'n bŵer sy'n caniatáu i Weinidogion Cymru gyhoeddi datganiadau safonau mewn perthynas â darparu gofal iechyd). Bydd yn ofynnol i gyrff GIG ystyried y safonau newydd hyn er mwyn cyflawni'r ddyletswydd ansawdd. Yn ogystal, mae'n ofynnol hefyd i Weinidogion Cymru ystyried y safonau newydd hyn wrth gynnal adolygiadau o, ac ymchwiliadau i, ddarparu gofal iechyd gan gyrff GIG ac ar eu cyfer o dan adran 70 o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003. Yn ymarferol, mae'r gwaith o gynnal adolygiadau ac ymchwiliadau o'r fath yn cael ei wneud gan Arolygiaeth Gofal Iechyd Cymru ar ran Gweinidogion Cymru.

2.7 Cydnabyddir y bydd angen monitro gweithrediad y ddyletswydd ansawdd dros nifer o flynyddoedd er mwyn penderfynu ar ei llwyddiant. Bydd angen i Weinidogion Cymru a chyrff GIG allu dangos y camau y maent wedi'u cymryd i wella ansawdd gwasanaethau, ar y cyd â'r ddyletswydd i asesu a monitro'r gweithredu.

2.8 I'r perwyl hwnnw, rhaid i Weinidogion Cymru a chyrff GIG gyhoeddi adroddiad ansawdd blynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd ansawdd.

3. Y cefndir deddfwriaethol

3.1 Prif ddiben Rhan 2 o'r Ddeddf yw ailfframio ac ehangu'r ddyletswydd ansawdd a nodwyd gyntaf yn adran 45(1) o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003[10] ("Deddf 2003"). Mae adran 45(1) o Ddeddf 2003 yn gosod dyletswydd ar gyrff GIG yng Nghymru i sicrhau bod trefniadau priodol ar waith i fonitro a gwella ansawdd y gofal iechyd[11] a ddarperir gan y cyrff hynny neu ar eu cyfer.

3.2 Mae adran 45(1) o Ddeddf 2003 yn cael ei diddymu a'i disodli gan ddyletswydd ddiwygiedig i sicrhau ansawdd mewn gwasanaethau iechyd yn adrannau 1A (dyletswydd Gweinidogion Cymru), 12A (dyletswydd Bwrdd Iechyd Lleol), 20A (dyletswydd Ymddiriedolaeth GIG) a 24A (dyletswydd Awdurdod Iechyd Arbennig) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006[12] ("Deddf 2006"). Bydd Deddf 2006 (fel y'i diwygiwyd gan Ran 2 o'r Ddeddf) hefyd yn ei gwneud yn ofynnol i'r cyrff hynny gyhoeddi adroddiad blynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd ansawdd.

3.3 Mae Deddf 2006 (fel y'i diwygiwyd gan Ran 2 o'r Ddeddf) yn ei gwneud yn ofynnol i Weinidogion Cymru ddyroddi canllawiau i gyrff GIG yng Nghymru mewn perthynas â'r ddyletswydd ansawdd a'r gofyniad i gyhoeddi adroddiad blynyddol. Felly, dyroddir y ddogfen ganllawiau hon gan Weinidogion Cymru o dan Adrannau 12A (5), 20A (5) a 24A (5) o Ddeddf 2006 yn unol â'r gofyniad hwnnw. Mae'r Safonau Iechyd a Gofal newydd, sydd hefyd wedi'u cynnwys yn y ddogfen hon, yn cael eu dyroddi o dan y pwerau yn adran 47 o Ddeddf 2003 (gweler rhagor am hynny ym mharagraff 3.9 isod).

3.4 Mae'r ddyletswydd ansawdd ddiwygiedig (sydd hefyd yn gymwys i Weinidogion Cymru, yn ogystal â chyrff GIG) yn ailfframio'r cysyniad o "ansawdd" drwy sicrhau ei fod yn cael ei ddefnyddio yn ei ddiffiniad ehangach. Mae ansawdd yn cynnwys effeithiolrwydd a diogelwch gwasanaethau iechyd ac ansawdd profiad defnyddwyr gwasanaethau iechyd. Fodd bynnag, nid yw wedi'i gyfyngu i ansawdd y gwasanaethau a ddarperir i unigolyn nac i safonau gwasanaeth. Mae'n ymwneud â sicrhau gwelliant yn ansawdd "gwasanaethau iechyd" sy'n golygu unrhyw wasanaethau a ddarperir neu a sicrheir yn unol â Deddf 2006.

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[10] Llywodraeth y DU (2003) Deddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) https://www.legislation.gov.uk/ukpga/2003/43/contents

[11] At ddibenion Deddf 2003, ystyr "gofal iechyd" yw (a) gwasanaethau a ddarperir i unigolion ar gyfer neu mewn cysylltiad ag atal, canfod neu driniaeth neu salwch; a (b) hybu a diogelu iechyd y cyhoedd.

[12] Llywodraeth y DU (2006) Deddf y Gwasanaeth Iechyd Gwladol (Cymru). https://www.who.int/publications/i/item/9789240011632

Yn unol â hynny, mae'r ddyletswydd ddiwygiedig yn bwriadu i ansawdd fod yn ffordd o weithio ar draws y system, gan ganolbwyntio ar y bwriad o wella canlyniadau. Mae gosod y ddyletswydd newydd yn Neddf 2006 yn adlewyrchu'r pwysigrwydd y mae Gweinidogion Cymru yn ei roi ar y ddyletswydd ehangach newydd, a bwriad Gweinidogion Cymru i gryfhau a gwreiddio ansawdd ymhellach yn y broses o wneud penderfyniadau ar gyfer gwasanaethau iechyd.

3.5 Mae gan Weinidogion Cymru ddyletswydd i gyflawni eu swyddogaethau sy'n gysylltiedig â'r gwasanaeth iechyd gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd[13].

3.6 Mae gan Fyrddau Iechyd Lleol[14], Ymddiriedolaethau GIG[15] ac Awdurdodau Iechyd Arbennig Cymru[16] ddyletswydd i gyflawni **pob un** o'u swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Mae'r ddyletswydd ansawdd, felly, yn gymwys i'r holl swyddogaethau clinigol ac anghlinigol.

3.7 Mae ailfframio a chryfhau'r ddyletswydd ansawdd yn gam pellach ar y daith tuag at safonau cyson uwch o wasanaethau iechyd sy'n canolbwyntio ar yr unigolyn yng Nghymru.

3.8 Mae Rhan 2 o'r Ddeddf hefyd yn gwneud diwygiadau canlyniadol i adran 47 ac adran 70 o Ddeddf 2003.

3.9 Mae adran 47(1) o Ddeddf 2003 yn caniatáu i Weinidogion Cymru lunio a chyhoeddi datganiadau safonau mewn perthynas â darparu gofal iechyd gan gyrff GIG Cymru ac ar eu cyfer. Mae'n ofynnol i Weinidogion Cymru barhau i gadw golwg ar y safonau a chânt gyhoeddi datganiadau diwygiedig pryd bynnag y maent o'r farn fod hynny'n briodol. Cyhoeddwyd y safonau diwethaf o dan y ddarpariaeth hon ym mis Ebrill 2015[17]. Roedd adran 47(4) o Ddeddf 2003 yn ei gwneud yn ofynnol i bob corff GIG yng Nghymru ystyried y safonau a nodir mewn datganiadau wrth gyflawni ei ddyletswydd o dan adran 45 o Ddeddf 2003. Gan fod adran 45(1) wedi'i diddymu, mae adran 47(4) wedi'i diwygio fel bod y safonau a nodir mewn datganiadau i gael eu hystyried gan gorff GIG Cymru wrth gyflawni'r ddyletswydd ansawdd ddiwygiedig yn Neddf 2006.

3.10 Yn unol â dyletswydd Gweinidogion Cymru i adolygu a'r pŵer yn adran 47 o Ddeddf 2003 i gyhoeddi datganiadau diwygiedig o safonau, mae'r Safonau Iechyd a Gofal (Ebrill 2015) yn cael eu tynnu'n ôl a'u disodli gan y Safonau Ansawdd Iechyd a Gofal a nodir yn y canllawiau hyn ac sy'n cyd-fynd â'r

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[13] Adran 1A o Ddeddf 2006
[14] Adran 12A o Ddeddf 2006
[15] Adran 20A o Ddeddf 2006
[16] Adran 24A o Ddeddf 2006
[17] Llywodraeth Cymru (2015) Safonau Iechyd a Gofal https://www.llyw.cymru/safonau-iechyd-gofal

ddyletswydd ansawdd newydd. Mae hyn er mwyn adlewyrchu'r berthynas annatod sy'n bodoli rhwng y ddyletswydd ansawdd a'r safonau.

3.11 Ar ben hynny, mae adran 70(1) o Ddeddf 2003 yn nodi bod gan Weinidogion Cymru y swyddogaeth o gynnal adolygiadau ac ymchwiliadau i ddarpariaeth gofal iechyd gan gyrff GIG Cymru ac ar eu cyfer. Yn ymarferol, cyflawnir y swyddogaeth hon gan Arolygiaeth Gofal Iechyd Cymru ar ran Gweinidogion Cymru. Mae adran 70(3) o Ddeddf 2003 hefyd yn gosod swyddogaeth benodol o gynnal adolygiadau o'r trefniadau a wneir gan gyrff GIG Cymru at ddibenion cyflawni'r ddyletswydd ansawdd. Mae adran 70(3) wedi'i diwygio fel bod hyn yn ymwneud â'r ddyletswydd ansawdd ddiwygiedig o dan Ddeddf 2006. Mae adran 70(4) o Ddeddf 2003 yn ei gwneud yn ofynnol i Weinidogion Cymru ystyried y safonau a gyhoeddwyd o dan adran 47 wrth arfer eu swyddogaethau o dan adran 70.

Negeseuon allweddol

- Prif bwrpas y Ddeddf yw ailfframio ac ehangu'r ddyletswydd ansawdd a nodwyd gyntaf yn Neddf 2003
- Diddymir y ddyletswydd ansawdd a nodir yn adran 45(1) o Ddeddf 2003 a'i disodli gan ddyletswydd ddiwygiedig i sicrhau ansawdd mewn gwasanaethau iechyd yn Neddf 2006
- Mae'r ddyletswydd ddiwygiedig yn ei gwneud yn ofynnol i Weinidogion Cymru gyflawni eu swyddogaethau sy'n ymwneud ag iechyd gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd
- Mae'r ddyletswydd ddiwygiedig hefyd yn ei gwneud yn ofynnol i gyrff GIG gyflawni eu holl swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd
- Mae'r Ddeddf yn gwneud diwygiadau canlyniadol i adran 47 ac adran 70 o Ddeddf 2003 fel bod unrhyw safonau a ddyroddir o dan Ddeddf 2003 yn cael eu hystyried gan gyrff GIG wrth gyflawni'r ddyletswydd ansawdd ddiwygiedig yn Neddf 2006, a bod gan Weinidogion Cymru y swyddogaeth o gynnal adolygiadau o'r camau a gymerwyd gan gorff GIG at ddibenion cyflawni'r ddyletswydd ansawdd ddiwygiedig. Mae'r swyddogaeth olaf wedi'i dirprwyo i Arolygiaeth Gofal Iechyd Cymru.
- Mae'r Safonau Iechyd a Gofal (2015) a ddyroddwyd o dan adran 47 o Ddeddf 2003 yn cael eu tynnu'n ôl a'u disodli gan y Safonau Ansawdd Iechyd a Gofal i adlewyrchu'r berthynas anorfod rhwng y ddyletswydd ansawdd a'r safonau.

4. Y cyd-destun polisi a strategol

4.1 Mae Cymru Iachach: ein Cynllun ar gyfer Iechyd a Gofal Cymdeithasol ("Cymru Iachach") yn nodi'r weledigaeth ar gyfer dull system gyfan o ymdrin ag iechyd a gofal cymdeithasol yng Nghymru.

4.2 Mae'n nodi uchelgeisiau Llywodraeth Cymru ar gyfer cynnydd a gwelliant ac yn disgrifio'r gwerthoedd craidd sy'n sail i'r GIG yng Nghymru, sef:

- Rhoi ansawdd a diogelwch uwchlaw popeth arall
- Integreiddio gwelliannau i waith bob dydd
- Canolbwyntio ar atal, gwella iechyd ac anghydraddoldeb
- Gweithio mewn partneriaethau go iawn
- Buddsoddi yn ein staff

4.3 Mae'r Ddeddf yn cefnogi uchelgeisiau Cymru Iachach drwy nodi'r gofynion ar gyfer gwella ansawdd gwasanaethau iechyd.

4.4 Mae'r Ddeddf yn disgrifio bod ansawdd yn cynnwys, ond nad yw'n gyfyngedig i, ddiogelwch ac effeithiolrwydd gwasanaethau iechyd a phrofiad unigolion sy'n derbyn gwasanaethau iechyd.

4.5 Cyhoeddodd Llywodraeth Cymru y Fframwaith Ansawdd a Diogelwch ym mis Medi 2021[18].

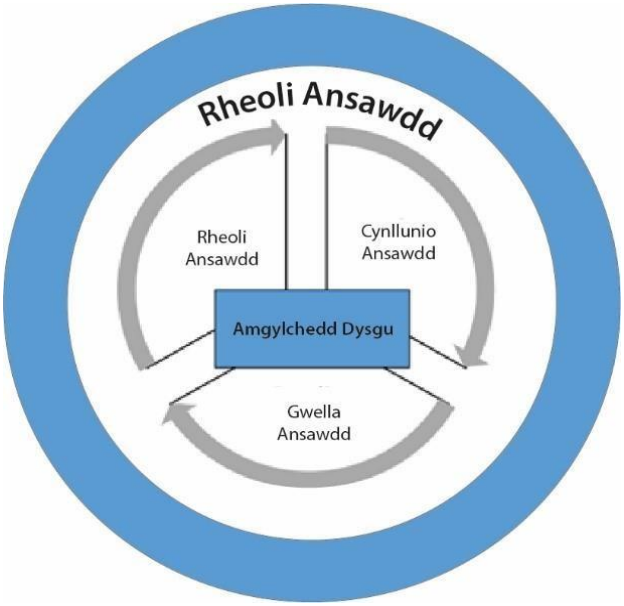
4.6 Mae'n rhoi trosolwg o'r trefniadau a'r egwyddorion ansawdd y mae angen eu sefydlu er mwyn sicrhau bod gwasanaethau o ansawdd uchel yn cael eu darparu.

4.7 Mae'n ei gwneud yn ofynnol i'r GIG sefydlu systemau rheoli ansawdd effeithiol sy'n canolbwyntio ar ddysgu ac sy'n cael eu gyrru gan eu byrddau. Mae'n egluro sut mae'n rhaid i Reoli Ansawdd, Cynllunio Ansawdd, Gwella Ansawdd a Sicrhau Ansawdd gydweithio i ffurfio'r system rheoli ansawdd sy'n ofynnol.

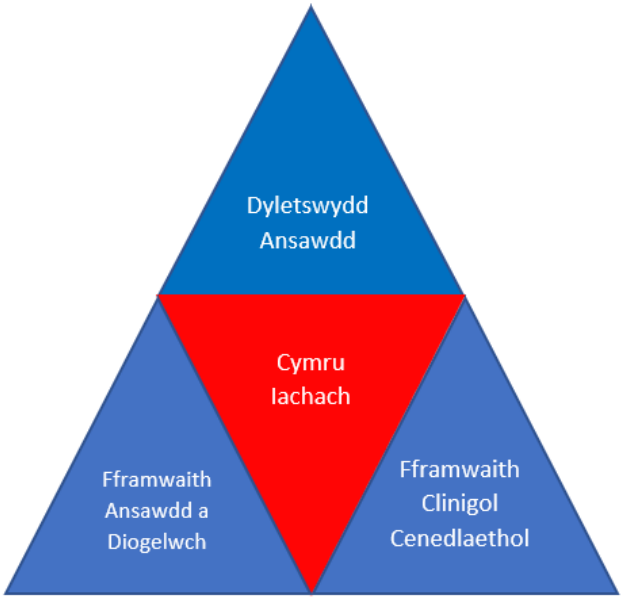
4.8 Y bwriad oedd i'r Fframwaith fod yn gam tuag at y ddyletswydd ansawdd newydd.

[18] Llywodraeth Cymru 2021 Fframwaith Ansawdd a Diogelwch - dysgu a gwella. https://llyw.cymru/fframwaith-ansawdd-diogelwch-y-gig

Ffigur 1
Diagram sy'n dangos y cylch rheoli ansawdd fel y cyfeirir ato yn Fframwaith Ansawdd a Diogelwch Llywodraeth Cymru (2021).



Ffigur 2
Diagram sy'n dangos cyd-destun strategol canolog Cymru lachach ochr yn ochr â'r ddyletswydd ansawdd, y Fframwaith Clinigol Cenedlaethol a'r Fframwaith Ansawdd a Diogelwch



Negeseuon allweddol

- Rhaid inni roi ansawdd a diogelwch ein gwasanaethau iechyd uwchlaw popeth arall
- Mae'r ddyletswydd ansawdd yn dylanwadu ar lawer o bolisïau a fframweithiau sy'n gysylltiedig ag iechyd
- Yn eu tro, mae'r rhain hefyd yn effeithio ar sut rydym yn mynd ati i ddarparu ansawdd mewn gwasanaethau gofal iechyd
- Mae cryfhau ein system rheoli ansawdd yn ein helpu i wneud yn siŵr bod ein penderfyniadau'n canolbwyntio ar wella ansawdd gwasanaethau iechyd

5. I bwy mae'r ddyletswydd ansawdd yn gymwys?

5.1 Mae'r Ddeddf yn rhestru'r canlynol (unigolion a chyrff GIG yng Nghymru) fel rhai sy'n ddarostyngedig i'r ddyletswydd yn rhan 2 o'r Ddeddf:

- Gweinidogion Cymru (mewn perthynas â'u swyddogaethau iechyd).
- Byrddau Iechyd Lleol.
- Ymddiriedolaethau GIG.
- Awdurdodau Iechyd Arbennig sy'n gweithredu yng Nghymru yn unig.

5.2 **Y ddyletswydd ansawdd a Gweinidogion Cymru**

Mae gan Weinidogion Cymru, o ran eu swyddogaethau sy'n ymwneud ag iechyd, gyfrifoldeb dros oruchwylio'r GIG yng Nghymru. Rhaid iddynt sicrhau bod gwasanaethau iechyd yn cael eu trefnu a'u darparu mewn modd sy'n sicrhau gwelliant parhaus ar draws y system yn ansawdd gwasanaethau iechyd.

5.3 Bydd rhaid i Weinidogion Cymru fynd ati i ystyried a yw eu penderfyniadau mewn perthynas â'r gwasanaeth iechyd yn cael eu gwneud gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd.

5.4 Rhaid i Weinidogion Cymru sicrhau bod gan gyrff cenedlaethol sydd â chyfrifoldebau rheoleiddio, rheoli perfformiad neu gefnogi ddull cydlynol a chydweithredol ar gyfer gwella ar draws y system gyfan.

5.5 Rhaid i Weinidogion Cymru ddyroddi canllawiau i gyrff GIG mewn perthynas â'r gofyniad i gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd, a'r gofyniad i gyhoeddi adroddiad blynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd hon. Mae'r olaf yn cael ei ddisgrifio yn adran 9 Gofynion adrodd.

5.6 Mae'n ofynnol hefyd i Weinidogion Cymru gyhoeddi adroddiad blynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd i gyflawni eu swyddogaethau mewn perthynas â'r gwasanaeth iechyd gyda'r bwriad o sicrhau gwelliant yn ansawdd y gwasanaeth iechyd ac, o fewn yr adroddiad hwnnw, i gynnwys asesiad o hyd a lled unrhyw welliant mewn canlyniadau a gyflawnir yn rhinwedd y camau hynny.

5.7 Y ddyletswydd ansawdd a chyrff GIG

Mae'r GIG yng Nghymru yn darparu gwasanaethau gofal drwy 7 Bwrdd Iechyd Lleol a 3 Ymddiriedolaeth GIG.

5.8 Mae'r Ymddiriedolaethau a'r Byrddau Iechyd yn gweithio mewn partneriaeth â 2 Awdurdod Iechyd Arbennig – Addysg a Gwella Iechyd Cymru ac Iechyd a Gofal Digidol Cymru.

5.9 Mae nifer o Fyrddau Iechyd Lleol ac Ymddiriedolaethau GIG yn cynnal sefydliadau cenedlaethol sy'n cefnogi'r gwaith o ddarparu gwasanaethau iechyd. Wrth gynnal y sefydliadau cenedlaethol, mae'r Byrddau Iechyd Lleol ac

Ymddiriedolaethau GIG yn cyflawni swyddogaethau mewn perthynas â'r gwasanaeth iechyd ac felly rhaid iddynt wneud hynny gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Rhaid i'r sefydliadau a gynhelir gydymffurfio â'r ddyletswydd ansawdd yn unol â threfn lywodraethiant eu trefniadau cynnal.

5.10 Mae'r ddyletswydd ansawdd yn gymwys i Fyrddau Iechyd Lleol sy'n gyfrifol am gynllunio a darparu gwasanaethau'r GIG yn eu hardaloedd gyda'r nod o wneud y canlynol:

- Gwella canlyniadau iechyd corfforol a meddyliol.
- Hybu lles.
- Lleihau anghydraddoldebau iechyd ar draws eu poblogaeth.
- Comisiynu gwasanaethau oddi wrth sefydliadau eraill i ddiwallu anghenion eu preswylwyr.

5.11 Mae gan y ddwy Ymddiriedolaeth GIG a'r ddau Awdurdod Iechyd Arbennig eu cyfrifoldebau penodol eu hunain o ran darparu gwasanaethau y bydd y ddyletswydd ansawdd yn gymwys iddynt.

5.12 Prif Weithredwyr cyrff GIG sy'n atebol yn y pen draw am gydymffurfio â'r ddyletswydd ansawdd.

5.13 Yn yr un modd â deddfwriaeth arall, argymhellir bod cyrff GIG yn dynodi uwch-arweinwyr priodol i fod yn gyfrifol am weithredu a goruchwylio'r ddyletswydd ansawdd yn strategol. Dylid dirprwyo'r cyfrifoldeb i swyddog-aelod o'r bwrdd i sicrhau'r gweithredu a'r goruchwylio strategol angenrheidiol. Fodd bynnag, dylid nodi bod y cyfrifoldeb i sicrhau bod ystyriaeth briodol i'r ddyletswydd ansawdd yn gymwys i holl aelodau'r bwrdd sy'n swyddogion a'r rhai nad ydynt yn swyddogion wrth gyflawni swyddogaethau o fewn eu rolau.

5.14 Argymhellir hefyd cael arweinydd gweithredol dynodedig i gefnogi'r gwaith o weithredu'r ddyletswydd ansawdd.

5.15 Mae gan holl aelodau'r Bwrdd gyfrifoldeb ar y cyd i gefnogi'r Prif Weithredwr i wneud y canlynol:

5.15.i) cydymffurfio â'r ddyletswydd ansawdd drwy drefniadau llywodraethiant a sicrwydd mewnol sydd wedi'u strwythuro o fewn system rheoli ansawdd gadarn;

5.15.ii) sicrhau bod gwasanaethau iechyd yn cael eu trefnu a'u darparu mewn modd sy'n sicrhau gwelliannau parhaus ar draws y system yn ansawdd gwasanaethau iechyd;

5.15.iii) mynd ati i ystyried a fydd penderfyniadau'r Bwrdd yn gwella ansawdd y gwasanaeth ac yn sicrhau gwelliant mewn canlyniadau i'r boblogaeth;

5.15.iv) dangos sut y maent wedi cyflawni eu swyddogaethau ac wedi gwella ansawdd gwasanaethau yn unol â'r ddyletswydd ansawdd. Disgrifir hyn yn adran 9 Gofynion adrodd ar ansawdd.

5.16 Mae'r ddyletswydd ansawdd yn gymwys i holl swyddogaethau'r gwasanaeth iechyd mewn lleoliadau clinigol ac anghlinigol. Felly, mae'r holl staff yn gyfrifol am gydymffurfio â'r ddyletswydd yn eu rôl a'u swyddogaeth gwasanaeth. Mae'n gyfrifoldeb ar y cyd i gydymffurfio â'r ddyletswydd ansawdd.

5.17 Y ddyletswydd ansawdd mewn gwasanaethau a gomisiynir

Cydnabyddir y gall gwasanaethau iechyd gael eu darparu ar draws ffiniau daearyddol drwy drefniadau comisiynu gyda darparwyr gwasanaethau sy'n rhan o'r GIG a rhai nad ydynt yn rhan o'r GIG. Rhaid i Fyrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Mae'r corff GIG sy'n comisiynu'r gwasanaeth iechyd yn cyflawni ei swyddogaethau ac felly rhaid iddo sicrhau ei fod yn gwneud hynny gyda golwg ar sicrhau gwelliant yn ansawdd y gwasanaeth iechyd. Ni waeth pwy sy'n darparu gwasanaethau iechyd pan gânt eu comisiynu, cyfrifoldeb y corff comisiynu yw'r ddyletswydd.

5.17.i) Gwasanaethau a gomisiynir gan gorff GIG oddi wrth gorff GIG arall yng Nghymru:

Mae'r corff GIG sy'n comisiynu'r gwasanaeth iechyd yn cyflawni ei swyddogaethau a rhaid iddo sicrhau ei fod yn gwneud hynny gyda golwg ar sicrhau gwelliant yn ansawdd y gwasanaeth iechyd. Cyfrifoldeb y corff comisiynu yw'r ddyletswydd ansawdd. Bydd y corff comisiynu'n dymuno sicrhau y bydd gwasanaethau iechyd a ddarperir gan y darparwr amgen yn sicrhau gwelliant yn ansawdd y gwasanaethau iechyd. Rhaid i'r corff GIG yng Nghymru sy'n darparu gwasanaethau ar ran y comisiynydd hefyd sicrhau ei fod yn cydymffurfio â'r ddyletswydd a fydd hefyd yn gymwys iddo yn uniongyrchol ar gyfer y gwasanaethau y mae'n eu darparu.

5.17.ii) Gwasanaethau a ddarperir gan wasanaethau meddygol deintyddol, optegol a fferyllol sylfaenol yng Nghymru:

Yn unol â Deddf 2006, rhaid i bob Bwrdd Iechyd Lleol fodloni pob gofyniad rhesymol i ddarparu gwasanaethau meddygol, deintyddol, optegol a fferyllol sylfaenol yn ei ardal. Mae'r Byrddau Iechyd Lleol yn ymrwymo i drefniadau gyda darparwyr gofal sylfaenol ar gyfer darparu gwasanaethau gofal sylfaenol i roi'r dyletswyddau hynny ar waith. Nid yw'r ddyletswydd ansawdd yn gymwys yn uniongyrchol i ddarparwyr gofal sylfaenol. Y Byrddau Iechyd Lleol sy'n gyfrifol am y ddyletswydd ansawdd i sicrhau gwelliant yn ansawdd gwasanaethau iechyd, ac mae hyn yn estyn i'r gwasanaethau a ddarperir gan ddarparwyr gofal sylfaenol ar ran y Bwrdd Iechyd Lleol. Felly, rhaid i Fyrddau Iechyd Lleol arfer eu dyletswyddau mewn perthynas â gofal sylfaenol, gyda'r nod o sicrhau ansawdd wrth ddarparu gwasanaethau.

5.17.iii) Gwasanaethau a gomisiynir oddi wrth gyrff nad ydynt yn rhan o'r GIG:

Mae'r corff GIG sy'n comisiynu'r gwasanaeth iechyd oddi wrth ddarparwr annibynnol yn cyflawni ei swyddogaethau a rhaid iddo sicrhau ei fod yn gwneud hynny gyda golwg ar sicrhau gwelliant yn ansawdd y gwasanaeth iechyd. Cyfrifoldeb y corff GIG sy'n comisiynu yw'r ddyletswydd ansawdd. Bydd y corff comisiynu'n dymuno sicrhau y bydd gwasanaethau iechyd a ddarperir gan y darparwr amgen neu annibynnol yn sicrhau gwelliant yn ansawdd y gwasanaethau iechyd. Gallai hyn fod yn ystyriaeth mewn trefniadau contractio.

5.17.iv) Gwasanaethau a gomisiynir y tu allan i Gymru:

Mae'r corff GIG yng Nghymru sy'n comisiynu'r gwasanaeth iechyd yn cyflawni ei swyddogaethau a rhaid iddo sicrhau ei fod yn gwneud hynny gyda golwg ar sicrhau gwelliant yn ansawdd y gwasanaeth iechyd. Bydd y corff comisiynu'n dymuno sicrhau y bydd gwasanaethau iechyd a ddarperir gan y darparwr amgen yn sicrhau gwelliant yn ansawdd y gwasanaethau iechyd. Bydd y darparwr gwasanaeth yn gyfrifol am ansawdd y gwasanaethau iechyd y mae'n eu darparu'n uniongyrchol o dan yr awdurdodaeth berthnasol y darperir y gwasanaethau ynddi.

5.18 Mae cyfrifoldeb ar Weinidogion Cymru a chyrff GIG i annog dysgu ac arbenigedd ar y cyd wrth iddynt symud ymlaen ar eu taith i wella ansawdd. Gellir dysgu llawer hefyd o systemau gofal sy'n perfformio'n dda yn fyd-eang.

5.19 Mae angen sicrhau ar bob lefel fod gan y systemau iechyd yr adnoddau, y capasiti, yr amser a'r ymreolaeth sydd eu hangen arnynt i ddatblygu eu dulliau o wella ansawdd. Cefnogir hyn gan Sefydliad Iechyd y Byd yn canllaw *Quality health services: a planning guide in the foundational requirements for quality initiatives*[19].

[19] Sefydliad Iechyd y Byd (2020) Quality Health Service: a planning guide https://www.who.int/publications/i/item/9789240011632

Negeseuon allweddol

- Mae'r ddyletswydd ansawdd yn gymwys i Weinidogion Cymru (o ran eu swyddogaethau sy'n ymwneud ag iechyd)
- Mae'r ddyletswydd ansawdd hefyd yn gymwys i Fyrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig sy'n gweithredu yng Nghymru yn unig
- Mae atebolrwydd am y ddyletswydd ansawdd yn y pen draw yn nwylo Prif Weithredwr corff GIG a all ddynodi swyddog arweiniol ac uwch-arweinydd gweithredol i oruchwylio'r gwaith o weithredu'r ddyletswydd yn y sefydliad
- Mae holl aelodau'r Bwrdd yn gyfrifol ar y cyd am weithredu'r ddyletswydd ansawdd
- Mae nifer o Fyrddau Iechyd Lleol ac Ymddiriedolaethau GIG yn cynnal sefydliadau cenedlaethol sy'n cefnogi'r gwaith o ddarparu gwasanaethau iechyd. Rhaid i'r sefydliadau a gynhelir gydymffurfio â'r ddyletswydd ansawdd yn unol â threfn lywodraethiant eu trefniadau cynnal. Nid yw'r ddyletswydd yn gymwys yn uniongyrchol i ddarparwyr gofal sylfaenol, darparwyr gwasanaethau iechyd y tu allan i'r GIG nac i ddarparwyr y GIG y tu allan i Gymru
- Mae cyrff GIG yn gyfrifol am gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Mae hyn yn cynnwys gwasanaethau y maent yn eu comisiynu oddi wrth ddarparwyr eraill
- Bydd y ddyletswydd ansawdd yn sicrhau bod gwasanaethau iechyd yn cael eu trefnu a'u darparu mewn ffordd sy'n ceisio sicrhau gwelliant parhaus mewn ansawdd ac yn gwella canlyniadau i'r boblogaeth
- Bydd rhaid i Weinidogion Cymru a chyrff GIG fynd ati i ystyried a yw eu penderfyniadau yn gwella ansawdd gwasanaethau ac yn gwella canlyniadau
- Bydd angen i Weinidogion Cymru a chyrff GIG allu dangos, gyda thystiolaeth, sut y maent wedi cydymffurfio â'r ddyletswydd ansawdd
- Mae gan yr holl staff rôl yn y gwaith o sicrhau gwell ansawdd gwasanaeth; mae'r ddyletswydd ansawdd yn gymwys i holl swyddogaethau'r gwasanaeth iechyd mewn lleoliadau clinigol ac anghlinigol
- Eir ati i annog dysgu a rhannu ar draws y system

6. Diffinio ansawdd

6.1 Mae nifer o ddiffiniadau o ansawdd sy'n ymwneud â gwasanaethau iechyd a gofal wedi cael eu disgrifio gan wahanol sefydliadau byd-eang, gan gynnwys y Sefydliad Gwella Gofal Iechyd[20] a Sefydliad Iechyd y Byd[21].

6.2 At ddibenion y canllawiau hyn, ystyrir bod ansawdd yn cael ei ddiffinio fel bodloni anghenion y boblogaeth rydym yn ei gwasanaethu mewn modd bprhaus, dibynadwy a chynaliadwy. Wrth gyflawni hyn, bydd angen i Weinidogion Cymru a chyrff GIG sicrhau bod gwasanaethau iechyd **yn ddiogel, yn amserol, yn effeithiol, yn effeithlon, yn deg ac yn canolbwyntio ar yr unigolyn**[22].

6.3 Bydd angen i gyrff GIG a Gweinidogion Cymru geisio deall anghenion eu poblogaeth yn barhaus er mwyn llywio'r broses o wneud penderfyniadau a sicrhau gwelliant mewn canlyniadau. Bydd gan y boblogaeth hefyd ei rhan ei hun i'w chwarae o bwydo i'r broses.

6.4 Meysydd ansawdd

Dylai Gweinidogion Cymru a chyrff GIG sicrhau bod y penderfyniadau a wnânt yn darparu gofal sydd **yn ddiogel, yn amserol, yn effeithiol, yn effeithlon, yn deg ac yn canolbwyntio ar yr unigolyn**. Mae'r dimensiynau ansawdd hyn yn darparu fframwaith i asesu ansawdd ac arwain gwelliannau. Felly, mae'n bwysig egluro beth mae'r dimensiynau ansawdd yn anelu at ei gyflawni a beth yr ydym yn bwriadu iddynt ei olygu yng Nghymru fel rhan o'r ddyletswydd ansawdd.

[20] Sampath B, Rakover J, Baldoza K, Mate K, Lenoci-Edwards J, Barker P. Whole System Quality: A Unified Approach to Building Responsive, Resilient Health Care Systems. IHI White Paper. Boston: Institute for Healthcare Improvement; 2021. https://www.ihi.org/resources/Pages/IHIWhitePapers/whole-system-quality.aspx.

[21] Sefydliad Iechyd y Byd (2020) Quality health services: a planning guide https://www.who.int/publications/i/item/9789240011632

[22] Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C: National Academy Press; 2001.

6.4.1 **Diogel**

Diogel
Mae ein system gofal iechyd yn un o ansawdd uchel sy'n ddibynadwy ac yn ddiogel iawn. Mae'n osgoi niwed y gellir ei atal, yn gwneud y gorau o'r pethau sy'n gweithio'n iawn ac yn dysgu pan fydd pethau'n mynd o chwith er mwyn eu hatal rhag digwydd eto. Eir ati i hybu ac amddiffyn iechyd, diogelwch a lles pobl; mae risgiau'n cael eu nodi a'u monitro, a lle bo modd caiff risgiau diogelwch eu lleihau neu eu hatal. Rydym yn hybu ac yn amddiffyn llesiant a diogelwch plant ac oedolion sy'n agored i niwed neu sy'n wynebu risg ar unrhyw adeg. Pan allai plant neu oedolion fod yn profi neu'n wynebu risg o gam-drin neu esgeulustod, rydym yn cymryd camau priodol ac amserol ac rhoi gwybod am bryderon.

6.4.2 **Amserol**

Amserol
Mae ein system gofal iechyd yn sicrhau bod pobl yn gallu cael y cyngor, yr arweiniad a'r gofal o ansawdd uchel sydd eu hangen arnynt yn gyflym ac yn rhwydd, yn y lle iawn y tro cyntaf. Rydym yn gofalu am y rheini sydd â'r angen iechyd mwyaf yn gyntaf, a phan nodir fod triniaeth yn angenrheidiol, rydym yn trin pobl ar sail eu blaenoriaeth glinigol benodol a chytunedig.

6.4.3 **Effeithiol**

Effeithiol

Mae ein system gofal iechyd yn sicrhau bod y broses o wneud penderfyniadau, y gofal a'r driniaeth yn adlewyrchu arferion gorau sy'n seiliedig ar dystiolaeth, i sicrhau bod pobl yn cael y gofal cywir er mwyn cyflawni'r canlyniadau gorau posibl a'r canlyniadau sy'n bwysig iddynt. Rydym yn dylunio llwybrau trawsnewidiol, oes gyfan, wedi'u seilio ar dystiolaeth, sy'n ymdrin ag atal, gofal a thriniaeth ac adsefydlu, ac yn ymgorffori'r rhain yn narpariaeth gwasanaethau lleol.

6.4.4 **Effeithlon**

Effeithlon

Mae ein system gofal iechyd yn defnyddio dull sy'n seiliedig ar werth i wella'r canlyniadau sydd bwysicaf i bobl mewn ffordd sydd mor gynaliadwy â phosibl ac sy'n osgoi gwastraff. Rydym yn gwneud y defnydd mwyaf effeithiol o adnoddau i sicrhau'r gwerth gorau mewn ffordd effeithlon. Dim ond yr hyn sydd ei angen rydym yn ei wneud, ac wrth roi triniaethau rydym yn sicrhau bod unrhyw ymyriadau yn cynrychioli'r gwerth gorau a fydd yn gwella canlyniadau i bobl.

6.4.5 **Teg**

Teg

Mae ein system gofal iechyd yn rhoi cyfle cyfartal i bawb gyflawni eu potensial llawn ar gyfer bywyd iach nad yw'n amrywio o ran ansawdd oherwydd nodweddion personol (megis oedran, rhyw, cyfeiriadedd rhywiol, hil, dewis iaith, anabledd, crefydd neu gredoau, statws economaidd-gymdeithasol neu ymlyniad gwleidyddol). Rydym yn gwreiddio cydraddoldeb a hawliau dynol yn ein system gofal iechyd.

6.4.6 **Person-ganolog**

Person-ganolog

Mae ein system gofal iechyd yn diwallu anghenion pobl ac yn sicrhau bod eu dewisiadau, eu hanghenion a'u gwerthoedd yn llywio'r broses o wneud penderfyniadau a wneir mewn partneriaeth rhwng unigolion a'r gweithlu. Mae llesiant unigolion, eu teuluoedd, gofalwyr a'n staff yn bwysig i ni. Rydym yn sicrhau bod pawb yn cael eu trin â charedigrwydd, empathi a thosturi bob amser ac rydym yn parchu eu preifatrwydd, eu hurddas a'u hawliau dynol. Rydym wedi ymrwymo i weithio'n well gyda'n gilydd i sicrhau bod pobl a'u teuluoedd yn ganolog i benderfyniadau, gan eu gweld fel arbenigwyr sy'n gweithio ochr yn ochr â gweithwyr proffesiynol i gael y canlyniad a'r profiad gorau.

6.5 Galluogwyr ansawdd

Mae dull system gyfan o ymdrin ag ansawdd yn gofyn am ddiwylliant y mae dysgu a gwelliant parhaus yn ganolog iddo. Dylai hyn fod yn seiliedig ar ddiffiniad a dealltwriaeth glir o'r hyn y mae ansawdd da yn ei olygu, gan ddefnyddio safonau cenedlaethol a safonau wedi'u meincodi, adolygu gan gymheiriaid ac archwilio.

6.6 Mae dysgu gan sefydliadau sy'n cael eu cydnabod yn rhyngwladol ac sydd â dulliau sefydledig ac effeithiol o sicrhau ansawdd yn darparu glasbrint ar gyfer yr hyn y dylai ansawdd da fod. Mae'r galluogwyr ansawdd yn sail i'r glasbrint hwn ac yn dylanwadu arno er mwyn sicrhau dull gweithredu ar draws y system i wella ansawdd.

6.7 Mae profiad wedi dangos bod datblygu a gwreiddio'r cysyniadau hyn yn gallu cymryd nifer o flynyddoedd. Cydnabyddir bod y diwylliant wedi bod yn gadarnhaol, a bod ansawdd yn ganolog i system iechyd Cymru[23].

6.8 Y galluogwyr ansawdd sy'n sail i'r glasbrint hwn er mwyn sicrhau dull gweithredu ar draws y system i wella ansawdd yw:

6.8.1 **Arweinyddiaeth**

[23] Y Sefydliad ar gyfer Cydweithrediad a Datblygiad Economaidd - Reviews of Health Care Quality: United Kingdom 2016: Raising Standards at https://www.who.int/publications/i/item/9789240011632

Arweinyddiaeth

Mae gan ein system gofal iechyd arweinyddiaeth weladwy ac iddi ffocws, ar bob lefel, a chaiff ei gweithgareddau eu llywio gan weledigaeth a gwerthoedd y sefydliadau ar gyfer ansawdd. Mae ein harweinwyr a'n rheolwyr yn arddel agwedd hirdymor, a rhanddeiliaid yn ganolog iddi, i ddatblygu gweledigaeth sefydliadol glir. Mae ganddynt y sgiliau a'r gallu priodol i greu'r amodau ar gyfer system rheoli ansawdd weithredol. Rydym yn sicrhau bod ein llywodraethiant, ein harweinyddiaeth a'n hatebolrwydd yn effeithiol wrth ddarparu gofal mewn ffordd gynaliadwy.

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6.8.2 **Gweithlu**

Gweithlu

Mae ein system gofal iechyd yn recriwtio, yn cadw, yn datblygu ac ymestyn rolau i sicrhau bod gennym ddigon o bobl hyderus â'r wybodaeth a'r sgiliau cywir ar gael ar yr adeg gywir i ddarparu gofal diogel. Rydym yn gwerthfawrogi ein pobl a'r ymrwymiad a'r gwydnwch a ddangosir ganddynt wrth ddarparu gofal. Mae eu llesiant yn bwysig inni, rydym yn diogelu eu hawliau ac yn eu helpu i deimlo'n dda ac yn hapus yn eu gwaith; ac yn rhoi'r offer, y systemau a'r amgylchedd iddynt allu gweithio'n ddiogel ac effeithiol. Mae ein gwaith o gynllunio'r gweithlu yn canolbwyntio ar fuddsoddi yn ein pobl a meithrin, tyfu a thrawsnewid ein gweithlu i greu gweithlu cynaliadwy ar gyfer y dyfodol.

6.8.3 **Diwylliant**

Diwylliant

Mae ein system gofal iechyd yn creu'r hinsawdd a'r diwylliant cywir i feithrin ac annog ansawdd a diogelwch systemau, gan werthfawrogi pobl mewn gweithle cefnogol, cydweithredol a chynhwysol fel bod ein pobl yn teimlo'n ddiogel yn seicolegol i allu mynegi pryderon a rhoi cynnig ar syniadau a dulliau newydd. Mae perthnasoedd mewn timau a chyda'r bobl rydym yn eu gwasanaethu yn effeithiol ac yn seiliedig ar dryloywder, atebolrwydd, ymddygiad moesegol, ymddiriedaeth a diwylliant cyfiawn, lle gall pobl ffynnu.

6.8.4 **Gwybodaeth**

Gwybodaeth

Mae ein system gofal iechyd yn sicrhau bod gwybodaeth ar gael a'i bod yn cael ei rhannu'n briodol ar gyfer pawb sydd ei hangen. Rydym yn troi data'n wybodaeth drwy driongli perfformiad meintiol ac ansoddol, profiad a dulliau mesur canlyniadau i ddeall ansawdd gwasanaethau, effeithiolrwydd gwaith gwella ac effaith penderfyniadau a wneir. Rydym yn monitro, yn adrodd ac yn uwchgyfeirio dangosyddion drwy ein strwythurau llywodraethiant i sicrhau bod camau priodol yn cael eu cymryd ar bob lefel o ran dysgu, gwella ac atebolrwydd.

6.8.5 **Dysgu, gwella ac ymchwil**

Dysgu, gwella ac ymchwil

Mae ein system gofal iechyd yn creu'r amodau a'r gallu i gael dull gweithredu ar draws sefydliadau a systemau ar gyfer dysgu parhaus, gwella ansawdd ac arloesi, ac mae'n mynd ati i'w hyrwyddo. Rydym yn defnyddio gwybodaeth newydd i ddylanwadu ar welliannau mewn ymarfer ac i lywio ein penderfyniadau. Rydym yn sicrhau bod ein gweithgarwch dysgu a gwella yn gysylltiedig â'n gweledigaeth strategol i ddarparu newid trawsnewidiol, ledled y sefydliad. Rydym yn ymrwymo i gymryd rhan mewn ymchwil oherwydd bod sefydliadau sy'n weithgar o ran ymchwil yn darparu ansawdd gofal a chanlyniadau gwell i bobl.

6.8.6 **Ymagwedd systemau cyfan**

Ymagwedd systemau cyfan

Mae ein system gofal iechyd yn sicrhau bod diogelwch mewn gofal iechyd yn mynd y tu hwnt i ddiogelwch cleifion unigol. Byddwn yn edrych o fewn ein ffiniau sefydliadol a'r tu hwnt iddynt i ddysgu sut y gallwn ddiwallu anghenion esblygol pobl mewn modd parhaus, dibynadwy a chynaliadwy. Byddwn yn cryfhau perthnasoedd ac yn gweithio gyda'n holl bartneriaid i sicrhau canlyniadau da. Mae ein polisïau yn ymgorffori'r uchelgeisiau ehangach o fewn y saith nod llesiant a'r pum ffordd o weithio yn Neddf Llesiant Cenedlaethau'r Dyfodol

6.8.7 Mae'r chwe galluogwr ansawdd yn ategu'r gwaith o weithredu methodoleg a dull o reoli ansawdd, fel y nodir yn y Fframwaith Ansawdd a Diogelwch (2021).

6.8.8 Gyda'i gilydd, mae meysydd ansawdd a galluogwyr ansawdd yn creu ein Safonau Ansawdd Iechyd a Gofal newydd. Gweler hefyd adran 7.

6.8.7 Rhaid rhoi sylw dyladwy i anghenion a dewis pobl o ran y Gymraeg drwy'r lens ansawdd. Gweler adran 11 hefyd.

6.8.8 Bydd y ddealltwriaeth, yr hyn a ddysgir a'r arbenigedd sy'n digwydd yn sefydliadau'r GIG ar draws gofal sylfaenol, cymunedol ac eilaidd yn arwain at welliannau mewn ansawdd yn ardaloedd daearyddol y Byrddau Partneriaeth Rhanbarthol ac yn cyflymu'r ymdrechion i wella ansawdd ar draws y system iechyd a gofal gyfan yn GIG Cymru.

Negeseuon allweddol

- Diffinnir ansawdd fel diwallu anghenion y boblogaeth rydym yn ei gwasanaethu mewn modd parhaus, dibynadwy a chynaliadwy
- Bydd angen i Weinidogion Cymru a chyrff GIG sicrhau bod gwasanaethau iechyd yn **Ddiogel,** yn **Amserol,** yn **Effeithiol,** yn **Effeithlon,** yn **Deg** ac yn **Berson-ganolog**
- Mae'r dimensiynau ansawdd hyn yn darparu fframwaith i asesu ansawdd ac i lywio gwelliannau
- Nodwyd galluogwyr ansawdd sy'n sail i'r glasbrint hwn ac sy'n dylanwadu arno er mwyn sicrhau dull gweithredu ar draws y system i wella ansawdd
- Y galluogwyr ansawdd yw **Arweinyddiaeth; Gweithlu; Diwylliant; Gwybodaeth; Dysgu, gwella ac ymchwil ac Ymagwedd systemau cyfan**
- Gyda'i gilydd, mae'r meysydd a'r galluogwyr ansawdd yn ffurfio'r Safonau Ansawdd Iechyd a Gofal
- Mae datblygu a gwreiddio system rheoli ansawdd yn cymryd amser, gweledigaeth, uchelgais ac ymrwymiad gweithredol i ddysgu a gwella

7. Safonau Ansawdd Iechyd a Gofal

7.1 Mae adran 47(1) o Ddeddf 2003 yn caniatáu i Weinidogion Cymru lunio a chyhoeddi datganiadau safonau mewn perthynas â darparu gofal iechyd gan gyrff GIG Cymru ac ar eu cyfer. Mae'n ofynnol i Weinidogion Cymru barhau i gadw golwg ar y safonau a chânt gyhoeddi datganiadau diwygiedig pryd bynnag yr ystyrir bod hynny'n briodol. Cyhoeddwyd y safonau diwethaf o dan y ddarpariaeth hon ym mis Ebrill 2015[24].

7.2 Mae adran 47(4) o Ddeddf 2003 (fel y'i diwygiwd gan Ran 2 o Ddeddf 2006) yn ei gwneud yn ofynnol i'r safonau a nodir mewn datganiadau gael eu cymryd i ystyriaeth gan gyrff GIG Cymru wrth gyflawni'r ddyletswydd ansawdd

[24] Fframwaith Safonau Iechyd a Gofal (llyw.cymru)

yn Neddf 2006. Yn unol â hynny, mae perthynas anorfod yn bodoli rhwng y ddyletswydd ansawdd a'r safonau a ddyroddir o dan adran 47(1) ac felly dylai safonau o'r fath gyd-fynd â'r ddyletswydd ansawdd a'i hategu. Wrth ddatblygu canllawiau'r ddyletswydd ansawdd ac adolygu Safonau Ebrill 2015, mae Gweinidogion Cymru wedi tynnu Safonau Iechyd a Gofal Ebrill 2015 yn ôl ac wedi rhoi Safonau Ansawdd 2023 yn eu lle fel y nodir yn adran 6 o'r canllawiau hyn. Gwneir y newid hwn gan fod cyflwyno'r ddyletswydd Ansawdd yn gyfle i gysoni'r safonau'n uniongyrchol nid yn unig â'r ddyletswydd ond ag arferion rheoli ansawdd ehangach ym maes iechyd hefyd. Mae'r meysydd fel y'u disgrifir yn y canllawiau hyn yn cael eu defnyddio'n helaeth mewn gofal iechyd ac maent yn cael eu gweithredu yn system iechyd ehangach Cymru. Mae'r Safonau Ansawdd newydd wedi'u cynllunio i symleiddio'r gofynion ac i fod yn hyblyg o ran cylch gwaith eang y ddyletswydd ansawdd.

7.3 Bydd rhaid hefyd i Arolygiaeth Gofal Iechyd Cymru (sy'n arfer swyddogaethau ar ran Gweinidogion Cymru) ystyried y safonau hyn at ddibenion cynnal adolygiadau ac ymchwiliadau yn ymwneud â darparu gofal iechyd yng Nghymru o dan adran 70 o Ddeddf 2003. Mae'r Safonau Ansawdd Iechyd a Gofal yn darparu fframwaith lefel uchel ar gyfer disgrifio, gweithredu a monitro'r ddyletswydd ansawdd. Mae'r Safonau Ansawdd Iechyd a Gofal yn nodi'r hyn y gall pobl yng Nghymru ei ddisgwyl pan fyddant yn defnyddio gwasanaethau iechyd.

7.4 Mae'r Safonau Ansawdd Iechyd a Gofal yn darparu strwythur i weithredu'r ddyletswydd ansawdd, boed ar lefel polisi cenedlaethol neu gan ddarparwyr gwasanaethau ac maent yn gymwys ym mhob gwasanaeth a lleoliad clinigol ac anghlinigol. Mae'r Safonau Ansawdd Iechyd a Gofal yn integreiddio â'r system iechyd ehangach.

7.5 Dylid nodi bod Cymru Iachach wedi cyflwyno 'datganiadau ansawdd' i ddisgrifio'r canlyniadau a'r safonau a ddisgwylir mewn gwasanaethau o ansawdd uchel sy'n canolbwyntio ar yr unigolyn, gan nodi'r uchelgeisiau i'w cyflawni'n gyson ledled Cymru.

7.6 Disgrifiwyd hyn ymhellach yn y Fframwaith Clinigol Cenedlaethol. Roedd hwn yn egluro y bydd datganiadau ansawdd yn nodi'r disgwyliadau polisi ar gyfer trefniadau cynllunio ac atebolrwydd y GIG yng Nghymru yn y dyfodol.

7.7 Mae'r Safonau Ansawdd Iechyd a Gofal yn rhai sefydliadol lefel uchel. Caiff safonau gwasanaeth manwl eu llunio gan gyrff proffesiynol a chynghorol fel arfer.

Ffigur 3
Diagram sy'n dangos y chwe maes ansawdd a ategir gan chwe galluogwr ansawdd. Gyda'i gilydd, maent yn ffurfio'r Safonau Ansawdd Iechyd a Gofal.

Negeseuon allweddol

- **Mae gan Weinidogion Cymru ddyletswydd i adolygu'r safonau a ddyroddwyd o dan adran 47 o Ddeddf 2003 a chânt gyhoeddi datganiadau diwygiedig pryd bynnag y maent yn ystyried bod hynny'n briodol**
- **Mae Safonau Iechyd a Gofal (2015) yn cael eu tynnu'n ôl a'u disodli gan y Safonau Ansawdd Iechyd a Gofal, sy'n cynnwys chwech o feysydd ansawdd a chwech o alluogwyr ansawdd i adlewyrchu'r berthynas annatod rhwng y ddyletswydd ansawdd a'r safonau**
- **Mae'r Safonau Ansawdd Iechyd a Gofal diwygiedig yn sicrhau cyfatebiaeth uniongyrchol rhwng y ddyletswydd ansawdd a'r safonau, gan sicrhau y gall y fframwaith symlach gael ei gymhwyso'n eang ac yn hyblyg**
- **Mae'r Safonau Ansawdd Iechyd a Gofal yn nodi'r safonau lefel uchel y gall pobl yng Nghymru eu disgwyl pan fyddant yn defnyddio gwasanaethau iechyd**
- **Bwriad cylch gwaith eang y Safonau Ansawdd Iechyd a Gofal yw darparu strwythur ar gyfer gweithredu'r ddyletswydd ansawdd, boed hynny ar lefel polisi cenedlaethol neu gan ddarparwyr gwasanaethau a bwriedir iddynt fod yn gymwys i bob gwasanaeth a lleoliad clinigol ac anghlinigol. Maent yn integreiddio â'r system iechyd ehangach.**
- **Rhagwelir y bydd y ddyletswydd ansawdd yn sicrhau dull cyson o o wella ansawdd ein gwasanaethau er mwyn sicrhau canlyniadau gwell i'r boblogaeth, drwy gyfrwng y Safonau Ansawdd Iechyd a Gofal**

8. Bodloni'r ddyletswydd ansawdd

8.1 Mae'r ddyletswydd ansawdd yn ei gwneud y canlynol yn ofynnol:

8.1.1) Gweinidogion Cymru i gyflawni eu swyddogaethau mewn perthynas â'r gwasanaeth iechyd gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd.

8.1.2) Byrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig Cymru-yn-unig i gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd.

8.2 Mae hyn yn golygu bod y ddyletswydd ansawdd yn ei gwneud yn ofynnol i Weinidogion Cymru (mewn perthynas â'u swyddogaethau'n ymwneud â'r gwasanaeth iechyd) a chyrff GIG (mewn perthynas â'u holl swyddogaethau) wneud y canlynol:

8.2.1) Sicrhau bod yr holl benderfyniadau strategol yn cael eu gwneud o safbwynt gwella ansawdd gwasanaethau iechyd a chanlyniadau iechyd i'r boblogaeth.

8.2.2) Cyflawni eu swyddogaethau mewn ffordd sy'n ystyried sut byddant yn gwella ansawdd a chanlyniadau'n barhaus.

8.2.3) Mynd ati i fonitro cynnydd o ran gwella ansawdd gwasanaethau a chanlyniadau a rhannu'r wybodaeth hon â'u poblogaeth fel mater o drefn.

8.2.4) Cryfhau trefniadau llywodraethiant drwy adrodd yn flynyddol ar y camau a gymerwyd i gydymffurfio â'r ddyletswydd ansawdd ac asesu i ba raddau y mae'r canlyniadau wedi gwella.

8.2.5) Sicrhau bod sefydliadau GIG yn datblygu eu system rheoli ansawdd gan roi sylw priodol i reoli ansawdd, cynllunio ansawdd, gwella ansawdd a sicrhau ansawdd gyda'r nod o sicrhau amgylchedd dysgu a gwella; a chreu diwylliant o ansawdd mewn sefydliadau.

8.3 Yn unol ag adran 47(4) o Ddeddf 2003, rhaid i gyrff GIG ystyried y Safonau Ansawdd Iechyd a Gofal a ddisgrifir yn y canllawiau hyn ac a ddyroddir o dan adran 47(1) o Ddeddf 2003 wrth gyflawni'r ddyletswydd ansawdd.

8.4 Ar ben hynny, mae chwe cham y dylai cyrff GIG eu cymryd i gynllunio, darparu a chynnal y ffocws angenrheidiol ar wella ansawdd, a dylai hyn fod yn seiliedig ar ddealltwriaeth glir o beth yw ansawdd da i'r sefydliad[25]:

8.3.1) Sicrhau cefnogaeth y Bwrdd

Mae gan y Bwrdd gyfrifoldeb ar y cyd dros sicrhau bod y ddyletswydd ansawdd yn cael ei chyflawni a rhaid iddo ddangos hyn yn ei weithredoedd a'i ymddygiad. Rhaid iddo ddangos ei ymrwymiad hirdymor i wella ansawdd wrth bennu'r cyfeiriad strategol a cheisio sicrwydd o ran cyflawni. Dylai hyn fod yn seiliedig ar barodrwydd a chefnogaeth ariannol i ddatblygu'r sgiliau a'r seilwaith ar gyfer gweithredu. Dylai'r Bwrdd roi blaenoriaeth i fentrau cenedlaethol a rhanbarthol ynghyd ag argymhellion sy'n cyd-fynd â ffordd y sefydliad o weithio. Mae angen i'r Bwrdd sicrhau ei fod yn glynu wrth y ddyletswydd ansawdd wrth wneud penderfyniadau, ac yn ceisio sicrwydd o ran penderfyniadau a wneir gan eraill.

8.3.2) Asesu parodrwydd

25 The Health Foundation (2019) The improvement journey: Why organisation-wide improvement in health care matters, and how to get started https://www.health.org.uk/publications/reports/the-improvement-journey

Mae angen dealltwriaeth ar draws y system o'r hyn y mae ansawdd da yn ei olygu ar gyfer yr ystod eang o wasanaethau. Dylai cyrff GIG ddeall eu 'parodrwydd ar gyfer newid' er mwyn bod yn glir ynghylch ble mae'r bylchau o ran gallu, a chreu cynllun i fynd i'r afael â nhw. Dylent ddefnyddio asesiadau, ymchwiliadau a mesuriadau rheolaidd dros amser i nodi meysydd i wella ansawdd. Dylai'r corff GIG ystyried parodrwydd seicolegol yn ogystal â rhoi'r seilwaith, y system lywodraethiant, y ddealltwriaeth o'r system, a'r arweinyddiaeth ar waith i sicrhau newid.

8.3.3) Sicrhau cefnogaeth ehangach gan y sefydliad a chreu gweledigaeth ar y cyd

Dylai cyrff GIG greu gweledigaeth gref ar gyfer gwella ansawdd sy'n cael ei chydnabod ac sy'n ysgogi staff ar bob lefel yn y sefydliad. Mae diwylliant o arweinyddiaeth wasgaredig yn rhoi'r hawl, y cyfle a'r hyder i staff ar bob lefel roi cynnig ar syniadau newydd i wella ansawdd sy'n cyd-fynd â gweledigaeth y sefydliad. Dylai arweinwyr hyrwyddo gwelliannau ansawdd sydd wedi'u halinio'n strategol ac sy'n cael eu perchnogi a'u gyrru gan y timau sy'n gyfrifol am ddarparu gwasanaethau iechyd.

8.3.4) Datblygu seilwaith a sgiliau gwella

Mae ar gyrff GIG angen dull systematig o reoli ansawdd sy'n cynnwys meithrin gallu i wella er mwyn sicrhau bod gan dimau ar bob lefel o'r sefydliad y sgiliau gwella cyffredinol ac arbenigol sydd eu hangen. Dylai hyn gynnwys cyfres o fesurau a system sy'n casglu, yn dadansoddi ac yn rhoi adborth am effaith y gwelliannau. Dylid hefyd ddatblygu modelau gweithredu safonol i safoni prosesau a gweithgareddau craidd, i fynd i'r afael ag amrywiadau mewn ansawdd.

8.3.5) Cysoni a chydlynu gweithgarwch

Mae angen i gyrff GIG sicrhau bod cynlluniau i wella ansawdd yn gyson â'u strategaeth a'u cenhadaeth gyffredinol a bod rhwystrau'n cael eu nodi a'u goresgyn. Dylai arweinydd sydd a throsolwg o holl weithgareddau'r sefydliad sicrhau bod pob elfen o weithgarwch yn cyd-fynd dros amser. Dylai sicrhau bod dysgu o lwyddiannau a meysydd gwannach yn parhau i lywio'r gwelliannau mewn ansawdd sydd eu hangen.

8.3.6) Cynnal dull gweithredu ar draws y sefydliad

Rhaid i gyrff GIG fuddsoddi i gynnal y momentwm ar gyfer gwelliannau mewn ansawdd a chydnabod bod hon yn daith hir. Mae canolbwyntio ar lwyddiant cynnar yn arwain at yr her o gynnal llwyddiant a pharhau i ymgysylltu â staff a rhanddeiliaid, gyda'r Bwrdd yn rheoli disgwyliadau ac yn cefnogi staff i gynnal ffocws ar welliannau sy'n cyd-fynd â phwrpas y sefydliad. Dylai'r Bwrdd geisio

sicrwydd bod gweithgareddau gwella ansawdd yn gynaliadwy a bod mecanweithiau sicrwydd priodol ar waith i gynnal y gwelliannau.

Negeseuon allweddol

- **Rhaid i Weinidogion Cymru gyflawni eu swyddogaethau mewn perthynas â'r gwasanaeth iechyd gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd**
- **Rhaid i gyrff GIG gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd**
- **Bydd angen i Weinidogion Cymru a chyrff GIG sicrhau bod penderfyniadau strategol yn cael eu gwneud drwy lens ansawdd**
- **Rhaid i Weinidogion Cymru a chyrff GIG gyflawni eu swyddogaethau mewn ffordd sy'n ystyried yn barhaus welliannau mewn ansawdd a chanlyniadau**
- **Rhaid i'r ffocws fod ar wella ansawdd gwasanaethau a chanlyniadau i'r boblogaeth**
- **Dylai cyrff GIG ddatblygu eu system rheoli ansawdd a chreu diwylliant o ansawdd yn eu sefydliadau**
- **Mae chwe cham y dylai cyrff GIG eu cymryd i gynllunio a chynnal y ffocws ar wella ansawdd yn seiliedig ar ddealltwriaeth glir o beth mae ansawdd da yn ei olygu ar gyfer y sefydliad. Dyma nhw:**
    1. **Sicrhau cefnogaeth y Bwrdd**
    2. **Asesu parodrwydd**
    3. **Sicrhau cefnogaeth ehangach gan y sefydliad a chreu gweledigaeth ar y cyd**
    4. **Datblygu seilwaith a sgiliau gwella**
    5. **Cysoni a chydlynu gweithgarwch**
    6. **Cynnal dull gweithredu ar draws y sefydliad**

9. Gofynion adrodd ar ansawdd

9.1 Mae'n ofynnol i Weinidogion Cymru gyhoeddi adroddiad ansawdd blynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd i gyflawni eu swyddogaethau mewn perthynas â'r gwasanaeth iechyd gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Rhaid i'r adroddiad gynnwys asesiad o hyd a lled unrhyw welliant mewn canlyniadau a gyflawnwyd yn rhinwedd y camau hynny, a rhaid i Weinidogion Cymru osod copi o'r adroddiad gerbron y Senedd.

9.2 Mae'n ofynnol i bob Bwrdd Iechyd Lleol, Ymddiriedolaeth GIG ac Awdurdod Iechyd Arbennig Cymru-yn-unig gyhoeddi adroddiad ansawdd blynyddol ar y camau y mae wedi'u cymryd i gydymffurfio â'r ddyletswydd i gyflawni ei swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd. Rhaid i'r adroddiad gynnwys asesiad o hyd a lled unrhyw welliant mewn canlyniadau a gyflawnwyd yn rhinwedd y camau hynny.

9.3 Mae'r adran hon o'r canllawiau yn rhoi arweiniad ar y gofyniad i gyhoeddi adroddiad ansawdd blynyddol, y dystiolaeth sydd i'w defnyddio i gefnogi asesiad, a chynnal asesiad.

9.3.1 Mae'r adroddiad ansawdd blynyddol yn caniatáu i gamau a gymerir gan Weinidogion Cymru a chyrff GIG a gwelliannau ansawdd gael eu monitro mewn modd tryloyw. Dylai'r adroddiad ddisgrifio'r cynnydd a'r heriau ar eu taith ansawdd i'w poblogaeth a'u rhanddeiliaid perthnasol. Mae angen i adroddiadau ansawdd fod yn ystyrlon i gyrff GIG, eu rhanddeiliaid ac i'n poblogaeth er mwyn manteisio i'r eithaf ar gyfleoedd i ddysgu, gwella a rhannu mewn amser real. Dylai strwythur a chynnwys yr adroddiadau ansawdd adlewyrchu ehangder y Safonau Ansawdd Iechyd a Gofal a'r system rheoli ansawdd.

9.4 Yn ogystal â'r gofyniad i adrodd ar ansawdd yn flynyddol, cynigir bod cyrff GIG yn datblygu mecanwaith adrodd 'ar waith bob amser', fel y'i gelwir. Mae 'ar waith bob amser' yn golygu bod sefydliadau'n casglu, yn monitro ac yn sicrhau bod gwybodaeth am ansawdd eu gwasanaethau ar gael yn rhwydd i'w poblogaeth a'u rhanddeiliaid, o fewn y sefydliad a'r tu allan iddo.

9.4.1 Mae adrodd 'ar waith bob amser' yn gofyn i sefydliadau fod â dull system gyfan ar gyfer defnyddio gwybodaeth yn rheolaidd ar draws eu system rheoli ansawdd. Mae 'ar waith bob amser' yn annog cydnabod a rhannu arferion da ac uwchgyfeirio ac ymyrryd yn gynnar pan fydd arwyddion yn awgrymu bod angen gweithredu.

9.5 Cydnabyddir bod gwaith sylweddol yn cael ei wneud eisoes ar draws y gyfundrefn iechyd mewn perthynas â dangosyddion a mesurau. Y bwriad yw y bydd cyrff GIG yn defnyddio mecanweithiau gwybodaeth ac adrodd sydd eisoes

ar waith lle bynnag y bo modd. Bydd angen iddynt fabwysiadu dull ystwyth o aeddfedu eu hadroddiad ansawdd wrth i fesurau canlyniadau ddatblygu, wedi'u halinio â'r Safonau Ansawdd Iechyd a Gofal.

9.6 Bwriad yr adroddiad ansawdd blynyddol yw crynhoi ac adlewyrchu cynnydd corff GIG o ran gwella ansawdd ei wasanaethau a'r canlyniadau i'r boblogaeth. Rhagwelir y bydd cyrff GIG yn cyfeirio darllenwyr at yr wybodaeth a ddarperir yn yr adroddiadau 'ar waith bob amser' sy'n amlinellu'r hyn a ddysgwyd a'r gwelliannau a wnaed yn rheolaidd drwy gydol y flwyddyn.

9.7 Dylai'r adroddiad ansawdd blynyddol edrych yn ôl ar yr hyn sydd wedi'i gyflawni, gan gynnwys adegau pan nad aeth pethau'n dda o bosibl, a hefyd edrych ymlaen ar flaenoriaethau ac uchelgeisiau ansawdd y sefydliad ar gyfer y flwyddyn sydd i ddod, ynghyd â sut y bydd cynnydd yn cael ei fonitro. Dylid cael cysondeb rhwng adroddiadau blynyddol yn ystod y blynyddoedd dilynol.

9.8 Bydd yr adroddiad ansawdd blynyddol yn disgrifio pa benderfyniadau strategol allweddol y mae'r corff GIG wedi'u gwneud, a sut mae'r ddyletswydd ansawdd wedi cyfrannu at y penderfyniadau hyn.

9.9 Dylid paratoi'r adroddiad ansawdd blynyddol cyn gynted ag y bo'n ymarferol ar ôl diwedd pob blwyddyn ariannol. Er mwyn symleiddio'r gofynion adrodd a lleihau dyblygu, awgrymir bod cyrff GIG yn trefnu bod yr adroddiad ansawdd blynyddol yn cyd-fynd â'u proses Adroddiadau a Chyfrifon Blynyddol.

9.10 Bydd gwybodaeth ychwanegol ar gael mewn fframwaith adrodd atodol, fel adnodd ategol.

9.11 **Rhai enghreifftiau o'r dystiolaeth i'w defnyddio i asesu'r ddyletswydd ansawdd ac i ba raddau y gwelwyd gwelliant mewn canlyniadau:**

9.11.1) Dangosyddion perfformiad, canlyniadau a chyflawni presennol a mesurau o'r System Rheoli Ansawdd

9.11.2) Mesurau Canlyniadau a Adroddir gan Gleifion a Mesurau Profiadau a Adroddir gan Gleifion

9.11.3) Data am farwolaethau

9.11.4) Gwybodaeth sydd wedi'i chynnwys yn y System Rheoli Pryderon Unwaith i Gymru, megis digwyddiadau a phryderon

9.11.5) Straeon cleifion a staff

9.11.6) Prosesau penderfynu strategol sydd wedi'u llywio gan y Safonau Ansawdd Iechyd a Gofal

9.11.7) Adroddiadau yn dilyn adolygiadau neu arolygiadau allanol gan arolygiaethau a chyrff trwyddedu

9.11.8) Ystyried argymhellion a goblygiadau adroddiadau cenedlaethol arwyddocaol, er enghraifft yn dilyn ymchwiliadau cenedlaethol

9.11.9) Dylid nodi mai enghreifftiau sydd yn y rhestr hon ac nad yw'n gynhwysfawr

9.12 Bydd cyrff GIG yn cynnal asesiad o hyd a lled unrhyw welliant mewn canlyniadau a gyflawnir drwy:

9.12.1) Hunanasesiad

9.12.2) Adolygu ac adborth gan gymheiriaid

9.12.3) Archwiliad clinigol cenedlaethol

9.12.4) Archwiliad mewnol

9.12.5) Adolygiad allanol, er enghraifft gan Swyddfa Archwilio Cymru

9.12.6) Arolygiadau, er enghraifft gan Arolygiaeth Gofal Iechyd Cymru

9.12.7) Dylid nodi mai enghreifftiau sydd yn y rhestr hon ac nad yw'n gynhwysfawr

9.12.8) Cydnabyddir bod cryfderau a gwendidau i'r gwahanol fathau o asesu a amlinellir. Felly, dylai cyrff GIG geisio sicrhau bod amrywiaeth o asesiadau'n cael eu hystyried.

9.13 Mae'n hanfodol bwysig bod cyrff GIG yn mynd ati i ymgysylltu â'u poblogaeth i sicrhau bod eu llais yn cael ei glywed ac i hyrwyddo gweithio mewn partneriaeth er mwyn cyflawni nodau'r ddyletswydd ansawdd.

9.14 Dylid cynnwys gwybodaeth am ddarparu gwasanaethau drwy gyfrwng y Gymraeg mewn adroddiadau ansawdd. Mae manteisio ar y Cynnig Rhagweithiol[26] a chasglu profiadau pobl drwy wrando ar straeon cleifion a staff yn darparu cyfleoedd monitro drwy ofynion adrodd ar ansawdd.

9.15 Mae'n bwysig sicrhau y glynir wrth Reoliad Cyffredinol y DU ar Ddiogelu Data (GDPR y DU) wrth gael gafael ar wybodaeth a'i phrosesu er mwyn paratoi ar gyfer y ddyletswydd o ran adroddiadau ansawdd.

[26] Disgrifir y Cynnig Rhagweithiol yn nogfen Llywodraeth Cymru (2022) Mwy na geiriau: Cynllun Pum Mlynedd 2022 - 2027 fel darparu gwasanaeth yn Gymraeg heb i rywun orfod gofyn amdano. Mae'n golygu creu diwylliant sy'n rhoi'r cyfrifoldeb ar ddarparwyr iechyd a gofal cymdeithasol i ddarparu cynnig iaith rhagweithiol fel bod pobl yn gallu cael mynediad at ofal, fel partneriaid cyfartal, trwy gyfrwng y Gymraeg. https://www.llyw.cymru/sites/default/files/publications/2022-07/mwy-na-geiriau-cynllun-gweithredu-2022-2027.pdf

Negeseuon allweddol

- **Rhaid i Weinidogion Cymru a chyrff GIG gyflawni eu swyddogaethau gyda golwg ar sicrhau gwelliant yn ansawdd gwasanaethau iechyd**
- **Rhaid i Weinidogion Cymru a chyrff GIG gyhoeddi adroddiad ansawdd blynyddol sy'n nodi'r camau y maent wedi'u cymryd i sicrhau gwasanaethau iechyd o ansawdd gwell**
- **Rhaid i'r adroddiad ansawdd blynyddol gynnwys asesiad o hyd a lled unrhyw welliant mewn canlyniadau a gyflawnwyd**
- **Mae'r canllawiau hyn yn nodi canllawiau ar gynnal yr asesiad hwn a thystiolaeth i'w gefnogi, yn ogystal â'r gofyniad i gyflwyno adroddiad ansawdd blynyddol**
- **Rhaid i adroddiadau ansawdd blynyddol fod yn adlewyrchiad tryloyw o'r cynnydd a'r heriau ar y daith ansawdd. Dylid nodi'r blaenoriaethau ansawdd arfaethedig a sut y cânt eu monitro**
- **Rhaid i'r adroddiad ansawdd blynyddol asesu unrhyw welliant mewn canlyniadau**
- **Dylai ddangos sut mae'r ddyletswydd ansawdd wedi llywio'r broses o wneud penderfyniadau strategol**
- **Dylai amlinellu'r camau a gymerwyd o ganlyniad i'r hyn a ddysgwyd a disgrifio sut y mae hynny wedi cael ei rannu**
- **Dylid paratoi'r adroddiad ansawdd blynyddol cyn gynted ag y bo'n ymarferol ar ôl diwedd y flwyddyn ariannol i gyd-fynd â'r broses Cyfrifon ac Adroddiad Blynyddol**
- **Cydnabyddir bod data i gefnogi'r broses adrodd ansawdd yn faes sy'n datblygu ac y bydd yn cymryd amser i gyfres o fesurau canlyniadau fod ar waith. Felly, bydd angen dull ystwyth o ddefnyddio dangosyddion a mesurau**
- **Yn ogystal ag adroddiadau ansawdd blynyddol, anogir cyrff GIG i ddatblygu proses adrodd 'ar waith bob amser' lle maent yn casglu, yn monitro ac yn rhannu gwybodaeth o ansawdd gyda'u poblogaeth yn rheolaidd yn ystod y flwyddyn**
- **Mae adrodd 'ar waith bob amser' yn hyrwyddo defnyddio gwybodaeth yn rheolaidd fel sail ar gyfer gwneud penderfyniadau a gwella ansawdd. Mae'n cynorthwyo i gydnabod a rhannu arferion da yn ogystal â chaniatáu uwchgyfeirio ac ymyrryd yn gynnar pan fydd angen gweithredu**
- **Mae'n hollbwysig fod cyrff GIG yn mynd ati i ymgysylltu â'u poblogaeth i sicrhau bod eu llais yn cael ei glywed ac i hyrwyddo gweithio mewn partneriaeth er mwyn cyflawni nodau'r ddyletswydd ansawdd**

10. Gwneud penderfyniadau, monitro a sicrwydd

10.1 Mae'r ddyletswydd ansawdd yn ei gwneud yn ofynnol i Weinidogion Cymru a chyrff GIG feddwl a gweithredu'n wahanol drwy gymhwyso'r cysyniad o ansawdd ar draws pob swyddogaeth yng nghyd-destun y gwasanaethau iechyd ac anghenion iechyd eu poblogaethau.

10.2 Mae'n gofyn am wneud penderfyniadau a chynllunio sy'n seiliedig ar ansawdd, er mwyn sicrhau canlyniadau gwell yn y pen draw i bawb sydd angen gwasanaethau iechyd. Mae'n golygu cynnwys pobl mewn penderfyniadau sy'n effeithio arnynt a chydbwyso anghenion tymor byr â chynllunio ar gyfer y tymor hwy; mae'n gofyn am gamau i atal problemau rhag digwydd neu waethygu.

10.3 Mae angen dull gweithredu ar draws y system gan gydnabod bod y ddyletswydd ansawdd yn gyfrifoldeb ar y cyd.

10.4 Mae ffocws y ddyletswydd ansawdd ar ddysgu a gwella, nid ar sancsiynau cosbi pan fydd y rhai y mae'r ddyletswydd yn gymwys iddynt yn methu â'i rhoi ar waith.

10.5 Fodd bynnag, rhaid i gyrff GIG ystyried sut y gellir integreiddio'r gwaith o weithredu a monitro'r ddyletswydd ansawdd yn effeithiol i fframweithiau, prosesau a gweithdrefnau llywodraethiant corfforaethol sy'n bodoli'n barod. Mae hyn yn cynnwys adroddiadau perfformiad ac ansawdd presennol.

10.6 Wrth gynllunio neu gyflwyno strwythurau a phrosesau newydd, bydd angen ymgorffori'r ddyletswydd ansawdd ynddynt.

10.7 Wrth ystyried prosesau adolygu a mecanweithiau sicrwydd, rhaid iddynt hefyd ystyried y ddyletswydd ansawdd. Mae hyn yn cynnwys, er enghraifft, cynllunio'r archwiliadau mewnol a'r rhaglenni archwilio clinigol blynyddol.

10.8 Yng nghyswllt cyrff GIG, bydd yn ofynnol i'r Bwrdd geisio sicrwydd bod y ddyletswydd ansawdd yn cael ei chyflawni'n briodol fel cyfrifoldeb ar y cyd ac ar draws y system. O'r herwydd, mae adrodd ar y ddyletswydd ansawdd i'r Bwrdd yn fater i'r holl bwyllgorau; nid dim ond i'r pwyllgor ansawdd a diogelwch.

10.9 Wrth geisio sicrwydd gan gyrff GIG, bydd y pwyllgorau'n ceisio sicrhau bod gwelliannau cynaliadwy i ansawdd yn cael eu gwneud a bod gwelliannau i ansawdd yn cael eu cynnal.

10.10 Pan fydd y Bwrdd yn ystyried ac yn cytuno ar Fframwaith Sicrwydd y Bwrdd a'r gofrestr risg strategol, dylai hefyd gydymffurfio â'r ddyletswydd ansawdd.

10.11 Rhaid i Weinidogion Cymru a chyrff GIG sicrhau bod y ddyletswydd ansawdd yn cael ei gweithredu a'i monitro'n effeithiol. Rhaid ei hintegreiddio â fframweithiau, prosesau a gweithdrefnau llywodraethiant presennol, gyda diweddariadau rheolaidd i'r pwyllgorau perthnasol a chyfarfodydd bwrdd at ddibenion sicrwydd.

10.12 Bydd cydymffurfio â'r ddyletswydd hefyd yn rhan o'r materion a ystyrir gan Arolygiaeth Gofal Iechyd Cymru wrth iddi arolygu ac adolygu'r ddarpariaeth gofal iechyd.

10.13 Mae'r adroddiad ansawdd blynyddol a'r dull 'ar waith bob amser' yn rhoi gwybodaeth i'r cyhoedd, i'r corff GIG ei hun, i Lywodraeth Cymru ac i bartneriaid allweddol eraill am y ddyletswydd i sicrhau tryloywder a hygyrchedd gwybodaeth am weithredu'r ddyletswydd ansawdd.

Negeseuon allweddol

- **Mae'r ddyletswydd ansawdd yn ei gwneud yn ofynnol i Weinidogion Cymru a chyrff GIG sicrhau bod prosesau gwneud penderfyniadau a chynllunio sy'n seiliedig ar ansawdd ar waith i sicrhau canlyniadau gwell yn y pen draw i bawb sydd angen gwasanaethau iechyd**
- **Mae angen i ansawdd fod ar waith ar draws y system gyfan; yn cael ei gymhwyso ar draws yr holl wasanaethau clinigol ac anghlinigol yng nghyd-destun anghenion iechyd a llesiant y boblogaeth**
- **Mae'r ffocws ar ddysgu a gwella, yn hytrach nag ar sancsiynau cosbi mewn achosion o fethu â chyflawni'r ddyletswydd ansawdd**
- **Rhaid integreiddio'r ddyletswydd i weithdrefnau corfforaethol presennol, gan gynnwys ond heb fod yn gyfyngedig i, gynllunio, perfformiad, ansawdd, adolygiadau archwilio mewnol**
- **Rhaid ei ymgorffori ym mhob strwythur a phroses a sefydlir**
- **Bydd yn ofynnol i'r Bwrdd geisio sicrwydd bod y ddyletswydd ansawdd yn cael ei chyflawni'n briodol fel cyfrifoldeb ar y cyd ac ar draws y system**
- **Bydd angen i'r Bwrdd geisio sicrwydd bod gwelliannau ansawdd cynaliadwy yn cael eu gwneud, gyda mecanweithiau sicrwydd priodol ar waith i sicrhau bod gwelliannau ansawdd yn cael eu cynnal**
- **Pan fydd y Bwrdd yn ystyried ac yn cytuno ar Fframwaith Sicrwydd y Bwrdd a'r gofrestr risg strategol, dylai hefyd gydymffurfio â'r dyletswydd ansawdd**
- **Bydd cydymffurfiaeth â'r ddyletswydd ansawdd yn cael ei fonitro. Bydd yn cael ei integreiddio â'r mecanweithiau monitro presennol. Rhaid i'r gwahanol fecanweithiau monitro ar draws y gyfundrefn iechyd ymgorffori'r ddyletswydd ansawdd yn eu prosesau**
- **Bydd yr adroddiad ansawdd blynyddol a'r dull 'ar waith bob amser' yn rhan annatod o'r broses fonitro i sicrhau bod y ddyletswydd ansawdd yn cael ei chyflawni**

11. Y Gymraeg

11.1 Cydnabyddir bod gwasanaethau iechyd yng Nghymru yn cael eu darparu mewn gwlad ddwyieithog.

11.2 **Mwy na geiriau** (2022) yw cynllun Llywodraeth Cymru i gryfhau'r ddarpariaeth Gymraeg ym maes iechyd a gofal cymdeithasol. Ei nod yw cefnogi siaradwyr Cymraeg i dderbyn gwasanaethau yn eu hiaith gyntaf, oherwydd dylai derbyn gwasanaethau yn Gymraeg fod yn rhan annatod o ofal sy'n canolbwyntio ar yr unigolyn.

11.3 Yr uchelgais yw rhoi Cynnig Rhagweithiol i bobl gael eu gofal yn Gymraeg. Cyfrifoldeb darparwyr iechyd a gofal cymdeithasol yw cynnig gwasanaethau yn Gymraeg, yn hytrach na chyfrifoldeb ar y claf i orfod gofyn amdanynt.

11.4 Mae gallu cael gafael ar wasanaethau yn y Gymraeg yn gwneud gwahaniaeth cadarnhaol sylweddol i ansawdd y profiad cyffredinol a chanlyniadau iechyd a llesiant llawer o siaradwyr Cymraeg.

11.5 Mae pobl wedi dweud y gall fod yn anodd cael gafael ar wasanaethau sydd eu hangen arnynt yn Gymraeg, a gallant deimlo'n gyndyn o ofyn os nad yw gwasanaethau Cymraeg yn cael eu cynnig.

11.6 Mae cynllun Llywodraeth Cymru i gryfhau'r ddarpariaeth Gymraeg ym maes iechyd a gofal cymdeithasol yn cyd-fynd â'r ddyletswydd ansawdd. Mae'n bwysig bod ystyriaethau sy'n ymwneud â'r Gymraeg yn cael eu hymgorffori mewn diwylliant ac arweinyddiaeth, cynllunio ansawdd, cefnogi a datblygu sgiliau'r gweithlu a rhannu arferion gorau drwy ddull galluogi.

11.7 Rhaid ystyried gofynion o ran y Gymraeg hefyd drwy lens y Safonau Ansawdd Iechyd a Gofal ac fel rhan annatod o'r system rheoli ansawdd.

11.8 Rhaid cynnwys y Gymraeg mewn adroddiadau ansawdd hefyd. Mae manylion ynghylch manteisio ar y Cynnig Rhagweithiol a chasglu profiadau pobl drwy glywed straeon cleifion a staff yn darparu cyfleoedd monitro drwy ofynion adrodd ar ansawdd.

Negeseuon allweddol

- **Mae gallu cael gafael ar wasanaethau yn y Gymraeg yn gwneud gwahaniaeth cadarnhaol sylweddol i brofiad cyffredinol llawer o siaradwyr Cymraeg**
- **Mae gallu cael gafael ar wasanaethau yn y Gymraeg yn gallu gwella ansawdd, diogelwch a chanlyniadau siaradwyr Cymraeg**
- **Rhaid ymgorffori ystyriaethau sy'n ymwneud â'r Gymraeg yn y diwylliant ansawdd**
- **Rhaid ymgorffori cyfrifoldebau sy'n ymwneud â'r Gymraeg mewn adroddiadau ansawdd**

12. Casgliad

12.1 Bwriad sylfaenol y ddyletswydd ansawdd yw adeiladu ar y diwylliant cadarnhaol o ansawdd sy'n ganolog i system iechyd Cymru.

12.2 Mae'r ddyletswydd ansawdd yn cryfhau'r broses o wneud penderfyniadau, gweithredu a gwella ar draws y system, gyda'r bwriad yn y pen draw o wella canlyniadau'r boblogaeth.

12.3 Mae'r ddyletswydd ansawdd yn gymwys i Weinidogion Cymru o ran eu swyddogaethau sy'n ymwneud â'r gwasanaeth iechyd ac i gyrff GIG (Byrddau Iechyd Lleol, Ymddiriedolaethau GIG ac Awdurdodau Iechyd Arbennig sy'n gweithredu yng Nghymru yn unig) mewn perthynas â'u holl swyddogaethau.

12.4 Nid yw'r ddyletswydd ansawdd yn gymwys yn uniongyrchol i wasanaethau gofal sylfaenol na darparwyr gwasanaethau iechyd y tu allan i'r GIG. Y corff GIG sy'n darparu neu'n comisiynu'r gwasanaeth yn uniongyrchol sy'n gyfrifol am y ddyletswydd ansawdd.

12.5 Er mai Gweinidogion Cymru a Phrif Weithredwr cyrff GIG sy'n gyfrifol am weithredu'r ddyletswydd ansawdd yn y pen draw, gellir dirprwyo'r cyfrifoldeb dros weithredu a goruchwylio gweithredol i arweinwyr priodol.

12.6 Mae gweithredu'r ddyletswydd ansawdd yn gyfrifoldeb ar y cyd. Mae'n gymwys i bawb mewn gwasanaethau clinigol ac anghlinigol, gan gynnwys llunwyr polisïau Llywodraeth Cymru.

12.7 Mae'r canllawiau'n darparu diffiniad o ansawdd at ddibenion rhoi arweiniad. Mae'n amlinellu fframwaith y gellir ei ddefnyddio i asesu a gwella ansawdd drwy ddefnyddio'r Safonau Ansawdd Iechyd a Gofal. Mae'r rhain, yn eu tro, yn helpu'r broses o aeddfedu ein systemau rheoli ansawdd.

12.8 Mae'r Safonau Ansawdd Iechyd a Gofal a nodir yn y canllawiau yn ddyheadau lefel uchel sy'n disgrifio'r hyn y gall pobl yng Nghymru ei ddisgwyl pan fyddant yn defnyddio gwasanaethau iechyd. Er mwyn sicrhau cyfatebiaeth rhwng y safonau a'r ddyletswydd ansawdd, mae'r Safonau Iechyd a Gofal (Ebrill 2015) yn cael eu tynnu'n ôl a'u disodli gan y Safonau Ansawdd Iechyd a Gofal. Mae'n ofynnol i gyrff GIG ystyried y Safonau Ansawdd Iechyd a Gofal wrth gyflawni'r ddyletswydd ansawdd, ac mae'n ofynnol i Arolygiaeth Gofal Iechyd Cymru (ar ran Gweinidogion Cymru) ystyried y Safonau Ansawdd Iechyd a Gofal wrth gynnal adolygiadau ac ymchwiliadau i ddarpariaeth gofal iechyd gan y cyrff GIG hynny ac ar eu cyfer.

12.9 Mae nifer o gamau y dylai sefydliad eu cymryd i baratoi i fodloni'r ddyletswydd ansawdd[27].

12.10 Rhoddir ddyletswydd ar gyrff GIG i adrodd yn flynyddol ar y camau y maent wedi'u cymryd i gydymffurfio â'r ddyletswydd ansawdd.

12.11 Dylai cyrff GIG ddatblygu mecanwaith adrodd 'ar waith bob amser' er mwyn darparu gwybodaeth amserol am ansawdd eu gwasanaethau i'w poblogaeth a'u rhanddeiliaid.

12.12 Rhaid i gyrff GIG sicrhau bod y ddyletswydd ansawdd yn cael ei gweithredu a'i monitro'n effeithiol. Rhaid integreiddio'r ddyletswydd â'r fframweithiau, prosesau a gweithdrefnau llywodraethiant presennol, gyda diweddariadau rheolaidd i gyfarfodydd perthnasol y bwrdd a'r pwyllgorau at ddibenion sicrwydd.

12.13 Rhaid ymgorffori ystyriaethau sy'n ymwneud â'r Gymraeg yn y diwylliant ansawdd.

12.14 Cydnabyddir bod newid diwylliant yn cymryd amser. Mae'r ddyletswydd yn dod i rym ar 1 Ebrill 2023, ac o hynny ymlaen bydd angen i gyrff GIG allu dangos sut maent yn cydymffurfio â'r ddyletswydd. Bydd angen cael proses ystwyth ac iteraidd i ddatblygu'r seilwaith ar gyfer proses o adrodd ar ansawdd sydd 'ar waith bob amser' gyda mesurau priodol sy'n canolbwyntio ar ganlyniadau.

12.15 Fodd bynnag, yn ei hanfod bydd angen i egwyddorion methodoleg gwella ansawdd fod yn gadarn yn eu lle er mwyn i Weinidogion Cymru a chyrff GIG adeiladu ansawdd fel ffordd eang o weithio ar draws y system sy'n rhan annatod o ddiwylliant o ddysgu a gwella parhaus.

12.16 Mae angen ein hymdrechion gweithredol cynyddol i sicrhau ffocws diflino ar ansawdd a diogelwch, fel blaenoriaeth uwchlaw popeth arall, yn fwy nag erioed yn hanes y GIG.

[27] The Health Foundation (2019) The improvement journey: Why organisation-wide improvement in health care matters, and how to get started https://www.health.org.uk/publications/reports/the-improvement-journey

Communication and Engagement Toolkit

National Nosocomial COVID-19 Programme

GIG CYMRU NHS WALES

Contents

Background

The National Nosocomial COVID-19 Programme (NNCP) was established in April 2022 to support NHS Wales organisations conduct proportionate investigations into Patient Safety Incidents of nosocomial COVID-19, which occurred between March 2020 and April 2022. The programme has established a collaborative approach with Health Boards/Trusts which ensures consistency across investigations and maximises opportunities for learning and improvement.

At the end of the first year of the programme, an Interim Learning Report has been produced to outline the work undertaken before and during the first year of the programme, and to summarise the early learning that has emerged. Please use this Communication and Engagement Toolkit for the Interim Learning Report to share information about the programme and subsequent learning.

Nosocomial COVID-19 is an extremely sensitive issue for service users, families, carers and NHS staff – especially those directly involved in the programme. However, it is imperative that this programme offers transparent insights that will lead to meaningful change. In addition to being a personally sensitive issue for many, there are also political sensitives around the programme. Politicians, media and other groups frequently discuss whether a Wales-specific COVID-19 Inquiry is needed. These wider conversations are likely to influence the commentary around the NNCP.

The communication and engagement approach has been designed to mitigate risk of deviation from the core messages, but Health Boards/Trusts should expect some challenging messages. Please exercise your professional judgement in choosing whether to engage with individuals and how to respond. Your Health Board/Trust NNCP communications lead has an open line of communication with the NNCP Head of Programme Communications and is encouraged to discuss points of particular interest so any arising issues can be addressed.

Interim Learning Report

The National Nosocomial COVID-19 Programme Interim Learning Report has been hosted on the NHS Wales website. On the web page (which is linked in toolkit content) there is a summary of the programme and learning, as well as links to a PDF of the Interim Learning Report and an Easy Read Summary.

NHS Wales website

GIG CYMRU NHS WALES

Interim Learning Report

Easy Read Summary - Interim Learning Report

Scheduling guidance

Please schedule/publish toolkit content from no earlier than midnight on Tuesday 28 March 2023. Health Boards/Trusts are encouraged to promote the NNCP using the materials provided on the morning of Wednesday 29th March and thereafter to maximise impact.

Wednesday 29th March

- Staff SharePoint/intranet article
- News item for Health Board/Trust website
- First social media post

Additional Materials

- Staff update
- Stakeholder letter template

All assets are hosted on Padlet

:Padlet

Media relations overview

A press release will be issued to Wales media on 27th March 2023 from the National Nosocomial COVID-19 Programme, under embargo until midnight on Tuesday 28th March 2023. Media requests will be managed centrally by the Welsh Government press office and communicated with the programme and Health Boards/Trusts. Health Boards/Trusts are also likely to receive media requests directly to their press offices.

Please make Welsh Government and the NNCP aware of all media requests relating to the NNCP at the earliest opportunity to ensure oversight. The Head of Programme Communications for the NNCP is also available to provide advice and guidance from a programme perspective.

The below criteria has been set out to support the review of media requests:

- National Nosocomial COVID-19 Programme (NHS Wales Delivery Unit/ NHS Wales Executive) – responsible for responding to media requests about the detail of the programme, including its design, progress and findings.
- Health Boards/Trusts – responsible for responding to requests that have an organisational/operational focus or cover a specific patient case study.
- Welsh Government – responsible for responding to media requests about national policy/guidance and broader issues around COVID-19, guidance and the pandemic response.

Staff communications

Please use the content below to add a news item to your organisation's staff SharePoint site. The 'Staff Update' is also available to be used in newsletters or via other staff communication methods such as email or apps.

View SharePoint News Item

View Staff Update

Download Visual Assets

(via main Padlet page)



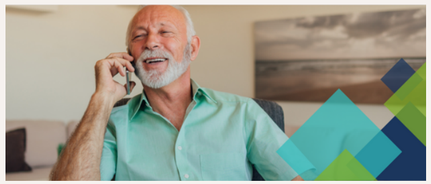

In the coming months we'll be in touch about further staff engagement.

Health Board/Trust websites

Please use the content below to add a news item to your Health Board/Trust website.

View News Item

Download Visual Assets
(via main Padlet page)



Social media

Please use the content below to share the Interim Learning Report across your social media channels.

View Social Media Content

Download Visual Assets

Remember you can contact us at the programme if you need advice on responding to any comments or queries.

Stakeholder communications

Please use the letter template below to share the Interim Learning Report with key stakeholders. Your organisation may want to tailor this for specific stakeholders with additional or different information.

View Stakeholder Letter Template

Contacts

NHS Wales Delivery Unit/ NHS Wales Executive
David Williams, Head of Programme Communications
National Nosocomial COVID-19 Programme
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Welsh Government Press Office
Vicky Ferris, Vicky.Ferris@gov.wales
Matthew Pritchard, Matthew.Pritchard@gov.wales

Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Hospital Inspection Report (Unannounced)

Claerwen Ward, Llandrindod Wells Memorial Hospital, Powys Teaching Health Board

Inspection date: 17 and 18 January 2023

Publication date: XX XXX 20XX

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

Communications Manager

Healthcare Inspectorate Wales
Welsh Government

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Merthyr Tydfil

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Or via

Phone: 0300 062 8163

Email: hiw@gov.wales
Website: www.hiw.org.uk

Digital ISBN

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Contents

1. What we did

Full details on how we inspect the NHS and regulate independent healthcare providers in Wales can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an unannounced inspection at Llandrindod Wells War Memorial Hospital, Powys Teaching Health Board on 17 and 18 January 2023. We inspected Claerwen Ward, which provides rehabilitation of the elderly and palliative care services. At the time of the inspection the ward was operating at a maximum capacity of 21 beds.

Our team for the inspection comprised of two HIW Healthcare Inspectors, two clinical peer reviewers and one patient experience reviewer. The inspection was led by a HIW Senior Healthcare Inspector.

Note the inspection findings relate to the point in time that the inspection was undertaken.

This (full) report is designed for the setting, and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our website.

2. Summary of inspection

Quality of Patient Experience

Overall summary:
We saw evidence that staff provided respectful and dignified care. Patients were encouraged to be active and were given equipment to help them walk and move. We saw occupational therapists and assistants working well with patients throughout the inspection. We saw evidence of some initiatives that had been introduced to help care for patients living with dementia. The patients we spoke with during the inspection provided positive feedback about the care they had received while on the ward.

This is what we recommend the service can improve:

- Welsh speaking staff could be made more easily identifiable to patients, for example by wearing a 'iaith gwaith' badge
- Further work could be done to fully utilise all the initiatives available on the ward to provide dementia care in line with best practice guidelines
- A regular formal process of collecting patient and family and carer feedback should be implemented.

This is what the service did well:

- Staff attended to the needs of patients in a discreet and professional manner. This was particularly evident in relation to the care provided to patients requiring palliative care
- A defibrillator deactivation magnet was available to help provide better dignity for patients with implantable cardioverter defibrillators requiring end of life care.

Delivery of Safe and Effective Care

Overall summary:
We found that staff were committed to providing patients with safe and effective care. Suitable equipment was available and being used to help prevent patients developing pressure sores and to prevent patient falls. We were assured that the management and storage of medicines was being undertaken in a safe and effective manner. A pharmacy technician provided good support to staff on the ward. We found that the standards set out in the All Wales Hospital Nutrition Care Pathway were generally being met.

Immediate assurances:

Throughout the inspection we had concerns over the arrangements in place to safely manage a patient emergency:

- We could not be assured whether the emergency equipment items were in date as no daily or weekly checks were being undertaken and recorded
- One staff member we spoke with did not know how to use the defibrillator
- Some staff members we spoke with did not know how to open the resuscitation trolley.

Details of the concerns for patient safety and the immediate improvements that were required are provided in Appendix A.

This is what we recommend the service can improve:

- Staff must be reminded about their responsibilities in relation to effective hand hygiene and audits must be effective at highlighting poor compliance
- Deprivation of Liberty Safeguards assessments must take place when required and recorded appropriately within the patient records to ensure patients are not illegally deprived of their liberty
- The individual needs of each patient must be documented, particularly around specifying what assistance is required during mealtimes
- The security of patient records must be improved; we saw multiple instances where patient records had been left unattended.

This is what the service did well:

- Yellow warning stickers were being used to warn staff of patients with similar names to avoid medication errors
- Incidents of pressure and tissue damage and falls were low, and falls prevention was being managed particularly well.

Quality of Management and Leadership

Overall summary:

The staff we spoke with told us that senior managers were visible and engaged with staff on a regular basis, and told us they felt able to report concerns. The ward was operating at a high acuity with many patients requiring enhanced patient support. Staff members that we spoke with during the inspection felt that it was often a challenge to spend enough time with patients and ensure care was being provided safely to these patients. There was a feeling that staff wellbeing was potentially at risk if patient acuity remained high. The health board must involve and communicate with staff when evaluating the evidence as part of the next staffing establishment review. We have recommended a large number of

improvements following the inspection which indicates there is work to be done to ensure senior managers have better oversight of the day-to-day running of the ward.

This is what we recommend the service can improve:

- A better system of enabling staff to monitor training compliance should be implemented
- Staff compliance with Intermediate Life Support should be taken into account when creating rosters to ensure staff working each shift have the appropriate skills in the event of an emergency
- Senior managers must ensure staff are kept informed of any improvements identified from audits, incidents or national patient safety notices.

3. What we found

Quality of Patient Experience

Patient Feedback

During the inspection we distributed HIW questionnaires to patients to obtain their views on the services provided. A total of two questionnaires were completed. We also spoke with patients on the ward when appropriate to do so.

Patients provided positive feedback about their experiences. Both patients who completed a questionnaire rated the service they had received as very good. All patients we spoke with were very complimentary about the care provided and about their interactions with staff.

Patients were asked in the questionnaires how the setting could improve the service it provides. The only comment we received was:

> *"More staff in the morning when bed making."*

Staying Healthy

Health Protection and Improvement
We saw information displayed throughout the ward about how patients could improve their health and wellbeing as well as details of local support services and groups. Patients we spoke with told us that staff have also provided them with information on how to look after themselves and their health.

The ward promoted protected mealtimes. This ensured that patients were not disturbed during breakfast, lunch and tea time. We observed patients receiving their meals at lunch time and saw staff assisting patients in a calm, unhurried and dignified way, allowing patients sufficient time to chew and swallow their food. Both patients who completed a questionnaire agreed that staff helped them to eat or drink when they needed assistance.

Dignified care

Dignified care
Both patients who completed a questionnaire said that they had been treated with dignity and respect by the staff at the hospital. The patients we spoke with also confirmed that staff had treated them with kindness.

We saw good interactions between staff and patients, with staff attending to patients' needs in a discreet and professional manner. This was particularly evident in relation to the care provided to patients requiring palliative care. Patients were able to wear their own clothes and bed bound patients appeared clean and well cared for.

Patients told us that they were offered either a daily wash or a shower. Both patients who completed a questionnaire agreed that staff gave them a choice about which method they wished to use when they needed the toilet, and provided assistance in a sensitive way. We observed staff closing curtains when administering care to patients to help protect their privacy and dignity.

The bathroom facilities on the ward were communal. During the inspection we found the bathrooms to be clean at all times. The furnishings and fittings though appeared tired and were in need of modernisation. Curtains were available in the communal washing area, but we did not feel this fully protected the privacy and dignity of patients using the facilities. Further information on the improvements required to the environment of the ward can be found in the 'Managing risk and promoting health and safety' section of this report.

It was positive to see that a defibrillator deactivation magnet was available to help provide better dignity for patients with implantable cardioverter defibrillators requiring end of life care.

Communicating effectively

Both patients who completed a questionnaire agreed that staff have talked to the about their medical conditions and helped them to understand them. Patients also agreed that staff have listened to them.

It was positive that the language requirement of patients was assessed on admission. We saw that some patient information was available to patients in Welsh and English. We were told that only a small number of nursing staff could speak Welsh. During our time on the ward, we could not easily distinguish whether any of the nurses spoke Welsh. **The health board should ensure Welsh speaking staff are easily identifiable to indicate to patients that they speak Welsh, for example by wearing a 'iaith gwaith' badge.** We were informed that translation services would be sought should patients wish to speak Welsh and no Welsh speaking staff were available.

We saw evidence of some initiatives that had been introduced to help care for patients living with dementia. For example, large clocks had been installed on the walls, and red trays and beakers were used to help staff identify which patients

needed extra attention when eating and drinking. However, we found other schemes were available but weren't being used. For example, although the ward had butterfly stickers, they were not being displayed to make staff aware which patients were living with dementia. In addition, we noted that although 'This is me' forms were available in patient records, they were not being completed by staff. **The health board must ensure they fully utilise all the initiatives available on the ward to provide dementia care in line with the guidelines described in the Dementia Friendly Hospital Charter for Wales.**

Patient information

Claerwen Ward was clearly signposted from outside and within the hospital. There was a board behind the nursing station that displayed the names of the staff on duty by day and night. However, there was limited information on display for patients and carers to help them during their time on the ward. For example, we could not see any information displayed in relation to mealtimes, language services, or how patients could make a complaint or raise a concern through the Putting Things Right process. We raised this with the ward manager who informed us that new folders were in the process of being created which will contain useful information for patients and carers to help them understand their care and provide an overview of the ward. **The health board must ensure these are produced in a timely manner.**

Timely care

Timely Access

Both patients who completed a questionnaire agreed that they had access to a call bell and that when they used it, staff came to them. The patients we spoke with did not raise any concerns about having to wait a long time when asking for help.

Individual care

Planning care to promote independence

Patients were encouraged to be active and were given equipment to help them walk and move. The ward had access to occupational therapists (OTs) and occupational therapy assistants and we witnessed these working well with patients throughout the inspection.

We saw staff spending time with patients and supporting them to be independent. We noted that one patient on the ward during the inspection had registered as visually impaired, and staff had put positive arrangements in place to ensure the patient could eat meals without assistance.

Some patients on the ward had a ‘do not attempt cardiopulmonary resuscitation (DNACPR)’ form in place. We saw evidence that showed discussions and decision making around DNACPRs had been undertaken and documented appropriately.

It was clear that discussions about patient discharges were happening between appropriate agencies and services. We saw evidence of packages of care that had been arranged for patients. Some patients we spoke with also confirmed that packages of care had been put in place. However, we could not always find clear evidence of this documented in the patient records. In addition, we noted that the discharge form on the Welsh Nursing Care Record (WCNR) digital system had not been completed for a patient that was discharged during the inspection. **The health board must ensure decisions around all aspects of discharge planning are fully documented in patient records and on WNCR.**

People’s rights

Both patients who completed a questionnaire said they felt they could access the right healthcare at the right time regardless of any protected characteristics. We were told that patients can access advocacy services when required.

Visits to the ward by family and friends were bookable via one hour slots between the hours of 1pm and 6:30pm. Some patients reported that this was not always convenient for family or friends due to work commitments. However, the ward manager told us that the visiting hours can be flexible if necessary and that staff would make sure any requests are accommodated wherever possible.

Listening and learning from feedback

Throughout the ward we saw numerous thank you cards being displayed from past patients. While it is good practice to share positive feedback with staff, we noted that no structure was in place to capture the views of patients or their family and carers. **The health board must implement a regular formal process of collecting patient and family and carer feedback to help identify any necessary improvements and enable the hospital to demonstrate listening and learning from patient feedback.**

Delivery of Safe and Effective Care

Safe Care

Managing risk and promoting health and safety
We saw that the entrance to the ward was kept secure at all times during the inspection. However, visitors to the ward had to knock the door because there was no buzzer or call bell to the nursing station. This meant that some visitors were kept waiting outside until a staff member was able to let them in. We were also told by patients near the door that the regular knocking can be a disturbance. **The health board must review the access arrangements on to the ward to ensure patients are not disturbed.**

The ward environment was generally accessible for people with mobility difficulties. We did note there was a lack of space in the communal bathrooms by the wash basin areas, and that there was only one walk in shower available.

The corridors were generally clean and clear from clutter. It was clear that the ward environment was looking tired and in need of attention. We were informed that some estates work was in the process of being undertaken, which included replacing metal bins with plastic bins and the installation of lockable information boards for the corridor walls. We were also told that the ward would be shortly undergoing a refurbishment, which we welcomed as a positive move to modernise the environment for patients. However, we noted a number of issues related to the environment that needed to be fixed in the meantime. This included:

- Paint had peeled away in places on the corridor walls, particularly outside bays 2 to 7
- The communal bathroom facilities and furnishings were well worn and in need of modernisation, including providing patients with more accessible options to shower and with more privacy
- Tape was being used on the flooring to cover gaps between floor panels which presented as a trip hazard to vulnerable patients
- The roof in the female staff changing room had a visible leak and was in need of repair
- No changing facilities were available for male staff.

The health board must ensure the environment remains suitable for patients until the refurbishment, which would include, but not limited to, rectifying the issues listed above.

During the tour of the ward, we noted that some areas were not being kept tidy. We raised this with staff and it was positive to note that these areas had been tidied by the end of the inspection.

While we were informed that visual checks were being regularly made on the environment by staff, this was not evidenced. We were provided with a health and safety folder, but noted that relevant information was either missing, or was out of date. For example:

- Only one Control of Substances Hazardous to Health (COSHH) risk assessment was contained in the folder
- The health and safety policy was not the most recent version
- Risk assessments appeared to be at least two years out of date.

Senior staff assured us that a new health and safety risk assessment was due to be undertaken and that documented ward walk arounds were to be re-introduced shortly to monitor the safety of the environment. **The health board must provide evidence of progress and the actions taken since the inspection in relation to these issues.** We did note appropriate documentation was available in respect of fire safety throughout the ward.

Preventing pressure and tissue damage

We saw evidence that patients were being assessed for whether they were at risk of developing pressure and tissue damage on admission. Patients also received appropriate skin assessments. Senior managers had good oversight of incidents of pressure and tissue damage through monthly scrutiny meetings to review incidents and identify any lessons learned. However, during our review of patient records, we identified the following issues:

- We saw two instances where care plans had not been developed for patients as required by their skin assessment score
- We could not see evidence of frequent repositioning throughout the day and night for three out of the five patient records
- In all five patient records we saw instances where patients had not been monitored as often as required by their care plans. For example, one patient was required to be checked every eight hours, but we saw that checks had not occurred for 11 hours and 12 hours on two separate occasions within a three day period.

Although instances of pressure and tissue damage acquired on the ward appeared to be low, **the health board must rectify the issues identified above to help prevent instances of pressure and tissue damage in patients going forward.**

Falls prevention

We were assured that suitable processes were in place to help prevent falls from patients throughout the ward. Falls prevention equipment and mats were being used. The number of incidents of patient falls was relatively low, which was positive considering the layout of the ward made it difficult to always monitor patient movements. Senior managers again had good oversight of incidents, with scrutiny meetings taking place every two weeks to review incidents and identify any lessons learned. Improvements were required in some areas:

- Fall care plans had not been developed for two of the four patients that required them
- One patient had not received their falls risk assessment in a timely manner; the patient was assessed the day after their admission
- The reducing falls policy was last reviewed in 2019 and needed updating.

The health board must action the improvements listed above. However, in general, we felt that falls prevention was being managed well.

Infection prevention and control

During our inspection the floors and surfaces of the ward appeared clean. We saw cleaning schedules displayed on the wall which were being maintained appropriately. Both patients that completed a questionnaire, and all patients we spoke with, felt that the ward environment was kept clean throughout their stay.

We saw that Personal Protective Equipment was available and excess stock was being stored appropriately. However, during the inspection we observed clean PPE (e.g. face masks) for staff and visitors placed on top of a clinical waste bin at the entrance to the ward. We raised this with senior staff who immediately moved the PPE and set up a new station for clean PPE.

We saw hand washing facilities and hand sanitiser dispensers available throughout the ward. Hand hygiene audits were being regularly undertaken, and we noted that compliance with the December 2022 hand hygiene audit was 100%. However, we visually observed very poor compliance with best practice hand hygiene techniques from staff during our inspection. For example, we observed a doctor shake hands with a patient and then move on to the next patient without decontaminating his hands in between. We also witnessed staff moving from one patient bay to another without washing their hands after patient contact. **The health board must remind staff about their responsibilities in relation to effective hand hygiene and ensure audits are effective at highlighting poor compliance.**

We reviewed the minutes of previous staff team meetings and saw that there had been multiple reminders provided to staff about adhering to the uniform policy. However, despite these reminders, throughout the inspection we saw instances of staff contravening the uniform policy. For example, some staff members were not bare below the elbow, and some staff members were wearing clothing over their uniform. **The health board must take action to ensure staff adhere to the uniform policy at all times.**

Equipment generally appeared to be well maintained, apart from one air pressure cushion which was torn. We raised this with staff who immediately arranged for the cushion to be replaced. While the equipment appeared to be clean, we saw that stickers were not being used to indicate to staff that reusable medical equipment was clean and safe to use. We did not raise this with staff at the time, but we did note that on the second day of the inspection the stickers had started to be used.

We spoke with housekeeping staff who were aware of their roles and responsibilities in relation to effective infection prevention and control measures. However, we noted that on one occasion the cleaning cupboard had been left unlocked. **The cleaning cupboard must be locked at all times when not in use to prevent unauthorised access to hazardous cleaning materials.**

Nutrition and hydration

We were assured that the standards set out in the All Wales Hospital Nutrition Care pathway were generally being met. We saw that nutritional risk assessments had been completed within 24 hours of admission in the patient records we reviewed. A system was in place to identify patients who needed assistance to eat. Patients had access to softer options and alternative textures if required. We saw that where necessary, food and fluid intake was being monitored and recorded.

However, it appeared from our review of patient records that care plans in relation to the nutrition and hydration needs of patients were generic. **The health board must ensure that the individual needs of each patient are documented, particularly around specifying what assistance was required.**

We noted that patients always had access to water throughout the inspection. The patients we spoke with told us that they were happy with the quality and choice of food on offer. However, we were made aware that on occasions patients have to wait until staff have delivered food to all patients before they are able to return and assist patients who may need help. **The health board must ensure that enough staff are available to help patients eat once food has been served to ensure the food remains hot and edible.**

Medicines management

Overall, we were assured that the management and storage of medicines was being undertaken in a safe and effective manner. We saw that patients were wearing identification bands and observed staff checking names and date of birth with each patient before administering medication. We saw good practice in the use of yellow warning stickers that were being used to warn staff of patients with similar names.

Medicines were stored securely in the clinic room and fridge. Lockable medicine cupboards were also available on the wall by each bed to allow quick access to patient medication.

Fridge and room temperatures were being checked. However, we did note some gaps in the recording of both temperatures. **The health board must ensure both fridge and room temperatures are consistently logged.** We also noted that the checking sheets did not contain any guidance on what the accepted temperature range should be, or what to do if the temperate recorded fell outside the range. **We recommend the health board adds this guidance to the checking sheets to help ensure staff can quickly identify any temperatures that fall outside of the recommended range and can escalate accordingly.**

A pharmacy technician visited the ward three times a week and provided good support to staff on the ward. This included undertaking regular stock checks and arranging the medication for patients to take home once discharged. We saw that controlled drugs were being recorded and signed for correctly.

We viewed a sample of the All Wales Drug Charts (the chart) and noted that they had been mainly completed correctly. However, we saw some instances where there was incorrect instructions recorded regarding the prescribed dose which could have led to confusion or a medication error. We asked staff to amend the documentation during the inspection to provide better clarity to staff. **The health board must ensure that the charts are written clearly and contain the correct prescribed dose for staff to administer.**

We checked the stock of medical equipment on the ward and found that only two safer sharp needles were available for staff to use. **The health board must increase the availability of needles with safety mechanisms to better protect staff from the risk of needle stick injuries and the risk of exposure to blood borne viruses.**

Safeguarding children and safeguarding adults at risk

All of the patients we spoke with said that they felt safe while on the ward. Staff we spoke with were able to describe the relevant safeguarding issues and how to raise concerns.

There were numerous patients on the ward that required constant enhanced care and were subject to one-to-one observations. We saw evidence that mental capacity assessments were being undertaken on admission. However, we found one instance where a doctor had determined that a patient lacked capacity, but there was no evidence within the patient records that a deprivation of liberty safeguards (DOLS) assessment had been undertaken. **The health board must ensure that DOLS assessments take place as required and recorded appropriately within the patient records to ensure patients are not illegally deprived of their liberty.**

Blood management

Llandrindod Wells War Memorial Hospital is a community hospital and staff do not administer blood components to patients. We were told that any patients requiring a blood transfusion would be transferred to an acute hospital to receive the treatment.

Medical devices, equipment and diagnostic systems

There was appropriate and sufficient equipment in place on the ward to support the needs of the patients. This included hoists, walking frames and monitoring equipment. Staff were able to describe the arrangements for reporting faults with equipment. We saw that the majority of equipment had been serviced or checked within the last 12 months. However, we did not see servicing labels on the chair weighing scale or the patient transfer scale. We also found some out-of-date blood medical equipment (blood bottle, needles and cannulas) which needed to be replaced. **The health board must ensure the scales, and other similar equipment on the ward, are calibrated regularly to ensure they give accurate measurements. In addition, a system must be implemented to monitor when the servicing or replacement of equipment is due.**

Effective care

Safe and clinically effective care

The staff we spoke with knew how to access relevant clinical policies and procedures to help provide safe and effective care to patients.

Staff discussed the procedures that were in place to help identify and manage cases of sepsis. A sepsis screening tool was being used for all patients. Due to the number of patients requiring palliative care on the ward, the health board may wish to consider whether using a sepsis screening tool designed specifically for

palliative care patients may be more appropriate in some instances. We were told that a National Early Warning Score (NEWS) score of three or above requires immediate escalation for a potential sepsis diagnosis. However, we saw one instance of a NEWS score of four which had been noted by the doctor, but it was not clear from the documentation what escalation procedures, for example increased observations, had been determined. **The health board must ensure that decisions around escalation procedures in suspected cases of sepsis are clearly documented for staff to follow.**

We saw resuscitation equipment was available that was conveniently placed towards the centre of the ward. However, throughout the inspection we had concerns over the arrangements in place to safely manage a patient emergency:

- We could not be assured whether the emergency equipment items were in date as no daily or weekly checks were being undertaken and recorded
- One staff member we spoke with did not know how to use the defibrillator
- Some staff members we spoke with did not know how to open the resuscitation trolley.

We raised these issues with staff and it was positive that immediate actions were taken to address our concerns. Further information on the actions taken by the health board are referred to in Appendix A of this report.

We saw that a Patient Status at a Glance (PSAG) Board was located in the staff room which helped to protect the privacy and confidentiality of patient information. The information contained on the board was also included as part of daily staff handover notes. However, we noted a disparity between the information on the board and in the handover notes, and staff confirmed that the board was not up-do-date. We were informed that plans were in place to use an electronic PSAG board, but that issues with the internet were delaying this from happening. In the meantime, the disparity between the board and the handover notes presented a potential risk of staff making decisions using incorrect information. **The health board must improve the process of recording and displaying contemporaneous information about patients to staff so that it can be understood and used effectively by all relevant disciplines.**

Quality improvement, research and innovation

During our tour we saw that a 'How we are doing' board was displayed in the corridor that provided safety performance metrics for the ward such as the monthly number of falls and pressure sores. However, we noted that the board was out of date, and displayed the data for September 2022. **The health board must ensure that the 'How we are doing' board is kept up to date to provide real time information and raise awareness of any improvements needed.**

Record keeping

During the inspection we reviewed five patient records. We found evidence of good and clear documentation recorded of the day-to-day activities of patients. Patient care was planned in a way that promoted independence. Nursing documentation was being recorded via a mix of paper and electronically. We saw the digital nursing records were being used effectively. Some improvements were needed in the maintenance of the paper nursing records:

- We saw that care plans were not always being fully completed during the initial patient assessment and were not always being updated on a weekly basis thereafter
- Three out of the five care plans were not individualised to specific patient needs
- We saw one instance of a nutritional risk assessment, and two instances of pain risk assessments, that had not been undertaken when required
- In all five patient records we saw that SSKIN care bundles were not always being completed as required. For example, one patient was required to have 4 hourly checks, but we saw multiple occasions with gaps between checks of at least 5 hours.

The health board must ensure all nursing documentation is maintained in accordance with clinical standards guidance to ensure patients receive safe and effective care.

Patient records were being stored in two trolleys in a room behind the nursing station. However, we noted that both trolleys were not secure. One trolley was unlocked, and while the other trolley was locked, the code to the electronic keypad was visible next to the keypad. We also observed the doctor leaving the trolleys in the main corridor while undertaking ward rounds. This meant patient records were unattended and easily accessible on multiple occasions. In addition, we noted on one occasion the handover sheet containing confidential patent information was left unattended on top of one of the trolleys. We raised this with senior managers who assured us that the doctor would be reminded of their responsibility to protect patient confidentiality and privacy. **The health board must provide further assurance on the processes put in place since the inspection to improve the security of patient records in the room behind the nursing station and during ward rounds.**

Quality of Management and Leadership

We asked staff at the hospital to complete an online HIW questionnaire to find out what working conditions were like and to obtain their views on the standard of care. Unfortunately, we did not receive enough responses to include in this report. However, throughout the inspection we spoke with several members of staff of a variety of roles and grades, and their views are included where relevant.

Governance, Leadership and Accountability

The staff we spoke with told us that senior managers were visible and engaged with staff on a regular basis, and told us they felt able to report concerns. Staff also told us that they have been able to receive clinical supervision and receive annual performance appraisal development reviews (PADRs). However, we saw that only 58% of staff had received their PADR as of December 2022. **The health board must ensure all staff receive their annual PADR in a timely manner.**

We saw that overall compliance with mandatory training for staff was 72%. The ward manager informed us about the plans in place to increase this rate in the near future. The Electronic Staff Record (ESR) system was being used to determine overall staff compliance. However, it did not appear to be easy for senior staff to identify the compliance of each member of staff, or compliance by training course. For example, it took senior staff some time to determine which staff members were compliant with Basic and Intermediate Life Support training. **The health board must implement a better system of monitoring training compliance which allows quicker identification of which staff members are in date, and who requires training to be completed.**

When looking at the training compliance for Basic and Intermediate Life Support, it was apparent that some staff members were out of date with their training. We raised this with the ward manager who immediately booked those staff members on to future courses. **The health board must ensure staff compliance with Intermediate Life Support is taken into account when creating rosters to ensure staff working each shift have the appropriate skills in the event of an emergency.**

We saw that a range of quality improvement audits were being undertaken to monitor compliance with best practice guidance. Regular scrutiny meetings were also being held to review and discuss recent incidents. However, we could not find evidence of actions resulting from audits or incident reviews being shared with staff. In addition, some members of staff we spoke with told us that they were not aware of any patient safety notices that had been shared with them. **The health**

board must ensure staff are kept informed of any improvements identified from audits, incidents or national patient safety notices.

Workforce

We reviewed staffing rosters and saw that the agreed staffing establishments for the ward were being met. We were told that there were currently 9.85 whole time equivalent registered nurse vacancies, and it was clear from our discussions with staff that there are often staffing deficits on the ward. While these deficits are typically filled by bank staff, or agency staff, staff we soke with felt this was challenging for them. For example:

- We asked staff whether they had enough time to provide care safely and answers were mixed. The ward was currently operating at a high acuity with many patients requiring enhanced patient support. Staff felt that it was often a challenge to spend enough time with patients and ensure care was being provided safely to these patients
- One staff member raised concerns to us that on some occasions they have been unable to meet the required frequency of intentional rounding due to staffing deficits
- More than one member of staff told us that they felt the staffing establishment of two healthcare support workers at night was insufficient due to the needs of the patients. This was echoed in the minutes of previous staff team meetings, where we noted that staff had said that staff morale was low, and that staff raised concerns about being unable to provide patient care, particularly at night.

Furthermore, during our review of the documentation provided to us during the inspection we saw two incidents of staff shortages potentially affecting patient care. In the first instance, a patient required enhanced care but could not receive it due to there only being one healthcare assistant available due to a shortage of staff. In the second instance, we saw an example where one shift operated with only one registered nurse instead of the required two registered nurses.

We were told that the last review of the staffing establishments for the ward was undertaken in September 2022, and that another review would be taking place shortly. We were left with a sense that staff are feeling tired and that staff wellbeing is at risk if things continued as they have been. **The health board must involve and communicate with staff when evaluating the evidence as part of the next staffing establishment review.**

4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
During the tour of the ward, and from discussions we had with staff, we identified the following issues in relation to resuscitation arrangements: • Staff did not know whether emergency items were in date due to the trolley being open, but no documented daily checks being recorded • One staff member informed us that they	This meant we could not be assured that appropriate arrangements were in place to safely manage a patient emergency.	We immediately spoke with senior managers on the ward about our concerns.	Senior managers took the following immediate actions during the inspection: • The resuscitation trolley was checked and appropriately sealed to indicate to staff all items were safe to use • All staff members on shift were shown how to open the resuscitation trolley and arrangements were made to show staff on subsequent shifts • A checking sheet was created for staff to undertake documented checks of the emergency equipment and medication going forward.

did not know how to use the defibrillator • Some staff members did not know how to open the resuscitation trolley.			
During the inspection we observed clean PPE (e.g., face masks) for staff and visitors placed on top of a clinical waste bin at the entrance to the ward.	This meant we could not be assured that PPE being used by staff and visitors on the ward had not been contaminated by the dirty clinical waste bin.	We immediately spoke to the ward manager about our concerns.	We raised this with senior staff who immediately moved the PPE and set up a new station for clean PPE.

Appendix B - Immediate improvement plan

Service: Claerwen Ward

Date of inspection: 17 and 18 January 2023

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues were identified on this inspection.				

Appendix C - Improvement plan

Service: Claerwen Ward

Date of inspection: 17 and 18 January 2023

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The health board should ensure Welsh speaking staff are easily identifiable to indicate to patients that they speak Welsh.	Communicating effectively			
The health board must ensure they fully utilise all the dementia care initiatives available on the ward.	Communicating effectively			
The health board must ensure the new patient information folders are produced and made available as soon as possible.	Patient information			

The health board must ensure decisions around all aspects of discharge planning are fully documented in patient records and on WNCR.	Planning care to promote independence			
The health board must implement a regular formal process of collecting patient and family and carer feedback.	Listening and learning from feedback			
The health board must review the access arrangements on to the ward to ensure patients are not disturbed.	Managing risk and promoting health and safety			
The health board must ensure the environment remains suitable for patients until the refurbishment, which would include, but not limited to, rectifying the issues listed in this report.	Managing risk and promoting health and safety			
The health board must provide evidence of progress and the actions taken since the inspection in relation to improving the health	Managing risk and promoting health and safety			

and safety evidence and documentation.				
The health board must ensure skin care plans are developed as required following skin assessments.	Preventing pressure and tissue damage			
The health board must ensure patients are repositioned throughout the day and night where relevant.	Preventing pressure and tissue damage			
The health board must ensure patients are being checked in line with the required frequency stated in their care plans.	Preventing pressure and tissue damage			
The health board must ensure falls care plans are created for patients that require them.	Falls prevention			
The health board must ensure that patients receive their falls risk assessment in a timely manner.	Falls prevention			
The health board must review the reducing falls policy.	Falls prevention			

The health board must remind staff about their responsibilities in relation to effective hand hygiene and ensure audits are effective at highlighting poor compliance	Infection prevention and control			
The health board must take action to ensure staff adhere to the uniform policy at all times.	Infection prevention and control			
The health board must ensure the cleaning cupboard is locked at all times when not in use to prevent unauthorised access to hazardous cleaning materials.	Infection prevention and control			
The health board must ensure that the individual needs of each patient are documented, particularly around specifying what assistance was required.	Nutrition and hydration			
The health board must ensure that enough staff are available to help patients eat once food has been served to ensure the food remains hot and edible.	Nutrition and hydration			

The health board must ensure both fridge and room temperatures are consistently logged in the clinic room.	Medicines management			
The health board must add guidance to the temperature checking sheets.	Medicines management			
The health board must ensure that All Wales Drug Charts are written clearly and contain the correct prescribed dose for staff to administer.	Medicines management			
The health board must increase the availability of needles with safety mechanisms.	Medicines management			
The health board must ensure that DOLS assessments take place as required and recorded appropriately within the patient records to ensure patients are not illegally deprived of their liberty.	Safeguarding children and safeguarding adults at risk			
The health board must ensure weighing scales, and other similar	Medical devices, equipment and			

equipment on the ward, are calibrated regularly to ensure they give accurate measurements	diagnostic systems			
The health board must ensure a system is implemented to monitor when the servicing or replacement of equipment is due.	Medical devices, equipment and diagnostic systems			
The health board must ensure that decisions around escalation procedures in suspected cases of sepsis are clearly documented for staff to follow.	Safe and clinically effective care			
The health board must improve the process of recording and displaying contemporaneous information about patients to staff.	Safe and clinically effective care			
The health board must ensure that the 'How we are doing' board is kept up to date to provide real time information and raise awareness of any improvements needed.	Quality improvement, research and innovation			

The health board must ensure all nursing documentation is maintained in accordance with clinical standards guidance.	Record keeping			
The health board must provide further assurance on the processes put in place since the inspection to improve the security of patient records in the room behind the nursing station and during ward rounds.	Record keeping			
The health board must ensure all staff receive their annual PADR in a timely manner.	Governance, Leadership and Accountability			
The health board must implement a better system of monitoring training compliance.	Governance, Leadership and Accountability			
The health board must ensure staff compliance with Intermediate Life Support is taken into account when creating rosters to ensure staff working each shift have the appropriate skills in the event of an emergency.	Governance, Leadership and Accountability			

The health board must ensure staff are kept informed of any improvements identified from audits, incidents or national patient safety notices.	Governance, Leadership and Accountability			
The health board must involve and communicate with staff when evaluating the evidence as part of the next staffing establishment review.	Workforce			

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print):

Job role:

Date:

Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Hospital Inspection Report (Unannounced)

Tawe Ward, Ystradgynlais Community Hospital, Powys University Health Board

Inspection date: 9 - 11 January 2023

Publication date: XX XXX 20XX

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Digital ISBN

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Contents

1. What we did

Full details on how we inspect the NHS and regulate independent healthcare providers in Wales can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an unannounced inspection at Tawe Ward, Ystradgynlais Community Hospital, Powys University Health Board on the evening of 9 January 2023 and the following days of 10 and 11 January 2023. Tawe Ward provides mental health services for older adults of both genders, experiencing organic or functional disorders.

Our team for the inspection comprised of one HIW Healthcare Inspector, three clinical peer reviewers and one patient experience reviewer. The inspection was led by a HIW Senior Healthcare Inspector.

Note the inspection findings relate to the point in time that the inspection was undertaken.

This (full) report is designed for the setting and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our website.

2. Summary of inspection

Quality of Patient Experience

Overall summary:
We found a dedicated staff team that were committed to providing a high standard of care to patients. We saw staff interacting with patients respectfully throughout the inspection.

This is what we recommend the service can improve:

- Provide health information on the ward for patients and visitors
- Upgrade the appearance of the garden and to make it safe for patients to use.

This is what the service did well:

- Staff interacted and engaged with patients respectfully
- Good team working and motivated staff.

Delivery of Safe and Effective Care

Overall summary:
The hospital environment was equipped with suitable furniture, fixtures, and fittings for the patient group, however, there were outstanding environmental issues that needed to be resolved.

There were established processes and audits in place to manage risk, health and safety and infection control. This enabled staff to continue to provide safe and clinically effective care. However, some improvements are required in relation to updating policies and compliance with mandatory training.

This is what we recommend the service can improve:

- Maintenance of the hospital facilities
- Organisation and completion of patient records
- Care plan documentation

This is what the service did well:

- Safe and effective medicine management.

Quality of Management and Leadership

Overall summary:
We observed a committed staff team who had a good understanding of the needs of the patients at the hospital. There was dedicated and passionate leadership displayed by the ward manager.

This is what we recommend the service can improve:

- Completion of mandatory training
- Completion of supervision and appraisals
- Regular staff meetings should take place and be minuted.

This is what the service did well:

- Staff were positive about the support and leadership they received
- Motivated and patient focused staff team.

Details of the concerns for patient's safety and the immediate improvements and remedial action required are provided in Appendix B.

3. What we found

Quality of Patient Experience

Staying Healthy

Health Protection and Improvement

We handed out HIW questionnaires during the inspection to obtain views on the service provided at the hospital. We received no responses to the questionnaires. However, family members spoken to during the inspection spoke highly of staff and the care provided to their relatives. We also reviewed internal patient feedback logs to help us form a view on the overall patient experience.

We noted positive compliments through thank you letters and cards.

We looked at a sample of patient records and saw evidence that patients received appropriate physical assessments upon their admission in addition to their mental healthcare. Patients also received ongoing physical health checks during their stay such as weight management and monitoring.

We checked if patients had access to outdoor spaces. The ward had a garden area, however, this area was overgrown and had a notable number of weeds, broken furniture and was not safe for patients to use. This was disappointing as the garden area could be a useful therapeutic area for patients to spend time in. We recommend that work is undertaken to improve the appearance and safety of the garden for patients to use.

It was also disappointing to see that the conservatory room leading out onto the garden area was not safe for patients to use. The conservatory was cluttered with occupational therapy equipment, and it appeared to be used as a storage room. The health board must ensure that this area is decluttered as this could be used as an additional room for patients to meet with friends and family and enjoy the view of the garden.

Tawe Ward had a large dining area and lounge for patients to socialise, watch TV and participate in activities. There was one bathroom, which was well equipped and contained a supported bath. The ward also had a shower room for patients. Male and female toilet facilities were also available.

Clocks were available on the ward; however, these were small and possibly difficult for the patient group to read. The health board should consider using dementia friendly clocks to assist the patient group.

The main patient areas on the ward did not appear very welcoming or interesting for the patient group. There were no pictures on the walls, and they were sparsely decorated. The health board should review this and make some improvements to make the patient areas more interesting for the patient group.

There were appropriate aids available to provide additional support for patients if required.

Dignified care

Dignified care

We noted that all employees, ward staff, senior management, and administration staff, interacted and engaged with patients appropriately and treated patients with dignity and respect.

The staff we spoke with were enthusiastic about their roles and how they supported and cared for the patients. We saw most staff taking time to speak with patients and address any needs or concerns the patients raised, this showed that staff had responsive and caring attitudes towards the patients.

Staff we spoke to demonstrated a good level of understanding of the patients they were caring for.

Patients were able to personalise their rooms and store their own possessions. A telephone was available at the hospital for patients to use to contact friends and family if needed.

Communicating effectively

During the inspection we observed staff engaging and communicating in a positive way with patients.

We saw that staff engaged with patients in a sensitive way and took time to help them understand their care using appropriate language.

Patient information

We noted there was limited information displayed in the hospital to help patients and their families understand their care. There were no details on display about

organisations that can provide help and support to patients and families affected by mental health conditions.

There was no information available on display on the role of HIW and how patients can contact the organisation. This is required by the Mental Health Act 1983 Code of Practice for Wales.

Staff told us that information on advocacy, and other support networks was available, however this was not displayed for patients or family members to see.

The health board must review the notice boards on the ward and ensure that information is up to date and relevant. The health board must make sure that particular attention is paid to what information is displayed. Information displayed must be relevant to patients and visitors.

Timely care

Timely Access

The ward held bed status management meetings to establish the bed occupancy levels, and to discuss patients who had been placed in other wards within the health board or independent providers.

Access to the hospital out of hours was difficult, the call bell was not working, and the outside wall mounted phone was in a poor condition. The health board must ensure that these are fixed or replaced.

Individual care

Planning care to promote independence

There were limited facilities for patients to see their families in private. We were told that space would be made available in the dining room or in the patient's own bedroom.

We looked at the records for patients who were detained under the Mental Health Act (the Act) and saw that documentation required by legislation was in place within the sample of patient records we saw. This showed that patients' rights had been promoted and protected as required by the Act. The quality of these documents is discussed later in the report.

People's rights

We found that arrangements were in place to promote and protect patient rights.

Legal documentation we saw to detain patients under the Mental Health Act was compliant with the legislation. However, while reviewing one record, we noted that there were no capacity assessments being recorded. Therefore, there was no record to determine if the patient had capacity to make informed decision around:

- Administration of medication within the ward environment
- Understanding the salient points of having been admitted onto a locked ward with all its inherent restrictions.

There was also no information displayed on the ward to inform patients, who were not restricted by the Act, about their rights to leave the ward.

Listening and learning from feedback

There was the opportunity for patients, relatives, and carers to provide feedback on the care provided via the NHS Putting Things Right process. Senior ward staff confirmed that wherever possible they would try to resolve complaints immediately.

There was no evidence of regular patient meetings taking place, where patients would have the opportunity to discuss any improvements or patient initiatives.

It was positive to note that the hospital kept a record of thank you cards, and compliments received from patients' family members and friends.

Delivery of Safe and Effective Care

Safe Care

Managing risk and promoting health and safety
Access to the ward was secure to prevent unauthorised access. Staff could enter the ward with an identification code and visitors rang the buzzer at the ward entrance.

We noted that staff were not wearing alarms and there was no policy or risk assessment in place to indicate why staff were not given alarms. Given that there is no psychiatric emergency response available other than on the ward, this presents a risk to staff and patient safety.

There were nurse call points around the hospital and within patient bedrooms and bathrooms so that patients could summon aid if needed. However, nurse calling point control panels were flashing faults. The health board need to fix this fault to ensure that the alarm system is working correctly.

We saw evidence of various risk assessments that had been conducted including ligature point risk assessments and fire risk assessments. However, the current ligature risk assessment needs to include one specific area. This was not included in the current one presented to the inspection team. The health board should document how they will mitigate this risk. In addition, the health board should review the location of the ligature cutters so that all staff can have access in an emergency.

Strategies were described for managing challenging behaviour to promote the safety and wellbeing of patients. We were told that preventative techniques were used and where necessary staff would observe patients more frequently if their behaviour was a cause for concern. Senior staff confirmed that the safe physical restraint of patients was used, but this was rare and only used as a last resort. Any use of restraint was documented. Information produced to the inspection team confirmed that restraint data was low.

There was an established electronic system in place for recording, reviewing, and monitoring incidents. Incidents were entered on to the health board's incident reporting system (DATIX).

The inspection team considered the hospital environment during a tour of the hospital on the first night of the inspection and the remaining days of the inspection. Overall, the ward appeared clean and tidy, however we identified several decorative and environmental issues that required attention:

- Flooring in corridor outside Ward Managers office needs replacing
- Ceiling tile outside the ward entrance door needs replacing
- Some patients' bedrooms don't have magnetic curtains on doors or windows which could interrupt sleep and is a dignity issue
- Dripping tap in the sluice and one of the bedroom areas needs fixing
- Overloaded extension leads in the staff room.

Most of the above issues had been raised within the environmental spot checks undertaken by the Ward Manager but had not been resolved by the health board. It is important that the health board resolve these issues to ensure staff and patient safety on the ward.

Preventing pressure and tissue damage

We found that appropriate checklists were completed, and any ongoing risks would be monitored. Pressure relieving mattresses and cushions were available and being used.

Falls prevention

There were risk assessments in place for patients on the ward. We found that ward staff assessed patients for their risk of falling and made efforts to prevent falls.

Patient falls would be reported via the health board electronic incident recording system. Staff explained that the incident reporting system would be followed to ensure lessons were learnt and acted on appropriately.

Infection prevention and control

We found suitable IPC arrangements in place at the hospital. A range of up-to-date policies were available that detailed the various infection control procedures to keep staff and patients safe. Regular audits had been completed to check the cleanliness of the environment and check compliance with hospital procedures.

Cleaning equipment was stored and organised appropriately. There were suitable arrangements in place for the disposal of clinical waste.

We also saw that staff had access to, and were using, personal protective equipment (PPE) where appropriate. Staff we spoke to confirmed that PPE was

always readily available. Sufficient hand washing and drying facilities were available.

On the first night of the inspection, we noted an overflowing clinical waste bag in the rear of Adelina Patti Ward which is an adjoining ward to Tawe Ward. This was brought to the attention of staff and immediately removed.

The wall mounted PPE stations need to be reviewed, PPE aprons were hanging out of the stations and pose a risk of infection and other safety risks.

Nutrition and hydration

The hospital provided patients with meals on the ward, making their choices from the hospital menu. We were told that specific dietary requirements were accommodated and if patients missed mealtimes, they would be provided with sandwiches. Staff said patients make their food choices in advance and stated if a patient changes their mind they can usually be accommodated with another option.

The dining room was clean and tidy and provided a suitable environment for patients to eat their meals.

Medicines management

Overall, we noted that medication was securely stored. Staff locked the clinic room and medication cupboards to prevent unauthorised access.

Staff locked medication fridges when not being accessed. There was evidence of regular temperature checks of the medication fridge to monitor that medication was stored at the manufacturer's advised temperature.

There was regular pharmacy input and audit undertaken that helped the management, prescribing and administration of medication on the ward. It was also positive to see that in patient records, discussions between the consultant psychiatrist and pharmacist on suitability of medication for patients had been documented, discussed and reviewed.

The Medication Administration Records reviewed were fully completed by staff. We saw several medication rounds, and saw that staff undertook these appropriately and professionally, interacting with patients respectfully and considerately.

Safeguarding children and safeguarding adults at risk

There were established health board policies and processes in place to ensure that staff safeguarded vulnerable adults and children, with referrals to external agencies as and when required.

Ward staff had access to the health board's safeguarding procedures via its intranet. Senior ward staff confirmed they were confident that staff were aware of the correct procedure to follow should they have a safeguarding concern. During discussions with staff, they were able to show knowledge of the process of making a safeguarding referral.

Medical devices, equipment and diagnostic systems

There were regular clinical audits undertaken at the hospital and we saw evidence of regular auditing of resuscitation equipment. Staff had documented when these had occurred to ensure that the equipment was present and in date.

During staff discussions, it was evident that staff were aware of the locations of ligature cutters in case of an emergency. Ligature cutters were currently kept in the clinical room. The health board should consider having additional ligature cutters placed elsewhere on the ward to ensure that all staff can have easy access in an emergency.

Staff told us that there was no defibrillator on the ward, however they could access one if needed from another area of the hospital. It would be beneficial for staff if they had a defibrillator specifically for Tawe Ward.

Effective care

Safe and clinically effective care

Overall, we found that systems and governance arrangements were in place, which helped ensure that staff provided safe and clinically effective care for patients. There was an established electronic system in place for recording, reviewing, and monitoring patient safety incidents. Staff confirmed that de-briefs take place following incidents. Meetings we attended and evidence obtained during the inspection confirmed that incidents and use of physical interventions are reviewed in governance meetings.

Information governance and communications technology

We found that patient records and identifiable patient data was not always kept securely to ensure that confidentiality was maintained. The Patient Status at a Glance board was in the nursing office. However, the board was visible to patients and visitors. The health board must make every effort to consistently protect patient confidentiality.

Record keeping

Patient records were mainly paper files that were stored and maintained within the locked nursing office, with some electronic documentation, which was password protected.

Further information on our findings in relation to patient records and care plans is detailed in the Monitoring the Mental Health (Wales) Measure 2010 Care planning and provision section of this report.

Mental Health Act Monitoring

We reviewed the statutory detention documents for three patient on Tawe Ward.

Whilst it was evidenced that patients were being informed of their rights under the Act on detention, there was no record of ongoing provision of rights as directed by the Mental Health Act Code of Practice for Wales. This means that patients may not be fully aware of their rights under the Act.

Copies of detention papers were not available in records we reviewed. The health board must ensure that copies of detention papers are held with patients record.

A review of patient records also highlighted that there was limited involvement from advocacy services. The health board needs to consider how it fulfils individuals right to advocacy and how the hospital can support and ensure that independent patient representation is provided at the hospital.

Errors were also noted on some forms, were crossing outs were initialled and not signed in full.

There were also incomplete pages of the joint medical recommendation for admission for treatment (HO7) and record of detention (HO14) forms, which seem to have been separated from copies of the original legal forms, so it appears that two sets of documents were on file. The health board must ensure that the Mental Health Act office undertake regular audit activity of the records to ensure that records are well maintained, fully completed and easy to navigate.

Monitoring the Mental Health (Wales) Measure 2010: Care planning and provision

We reviewed the Care and Treatment Plans of four patient records and highlighted areas where improvements are required.

Patient care plan records were not being regularly assessed and monitored by the health board to ensure quality of the service and to identify, assess and manage risk relating to safe patient care. Risk assessments were not up to date or comprehensive enough to enable a member of staff who does not know a patient to be confidently aware of the risks.

This would be of particular concern for an agency member of staff attending the ward for the first time where it would be very difficult for them to understand patient behaviours and the appropriate actions to take to manage them.

Of the care plans reviewed; we identified several areas that required improvement.

- No evidence of pain assessment being completed
- Risk assessments not completed when change in patient presentation
- Some Section 17 leave forms incomplete (no date of review)
- Unmet needs not completed
- Dols care plan only partially completed
- Nursing assessment not completed six days post admission
- Lack of reference to discharge planning in notes
- Lack of structure around admissions and treatment goals during the admission.

In addition, we would recommend that the current patient records need to be reviewed and any information that is no longer relevant is removed. The files used by staff were extremely bulky and challenging to navigate. The health board should review the patients records to make them more user friendly.

Quality of Management and Leadership

Governance, Leadership and Accountability

We observed a committed staff team who had a good understanding of the needs of the patients at the hospital.

We found that staff were committed to providing patient care to high standards. Throughout the inspection, staff were receptive to our views, findings and recommendations.

Staff were positive about the support they received from their colleagues and management teams.

We were told that staff meetings did take place, however these were not structured. The health board must ensure that regular team meetings can take place, these should be planned to make this a more meaningful, supportive, and valuable process for staff. The meetings should also be documented, and records kept.

Workforce

Staff showed strong team working and appeared motivated to provide dedicated care for patients. Staff we spoke with were positive about the support they received from colleagues, and leadership by their managers.

Staff also told us that they were supported by the doctors working on Adelina Patti Ward who were always available to support Tawe Ward patients with any physical health needs.

During our time on the ward, we observed good relationships between staff who we observed working well together as a team. It was clear to see that staff were striving to provide high levels of care to the patient groups.

The inspection team considered staff training compliance and was provided with a list of staff mandatory training compliance. Training figures indicated that improvements are required with 60% overall compliance with mandatory training. We were told that these figures would be immediately improved as staff sickness and maternity leave had affected compliance. In addition, the health board advised us that the impact of the Covid -19 pandemic had impacted on training figures. The health board must ensure that mandatory training compliance figures are improved.

The inspection team were provided with a range of policies, however, upon review most of the versions we received had passed their review date. The following policies were found to be out of date:

- Physical health and Monitoring procedure due for review August 2021
- Therapeutic engagement and observation policy due for review November 2022
- Putting things right Policy due for review May 2021
- Rapid Tranquilisation policy due for review November 2022.

The health board must make sure that all policies are updated and reviewed.

Newly appointed staff undertook a period of induction under the supervision of the experienced ward staff. Staff showed us documentary evidence and talked us through the systems of induction in place at the hospital.

There were vacancies on the ward. We were told that positions had been advertised and the management team told us they were trying to fill vacancies and recruit permanent staff to reduce the requirement to use agency staff.

The staffing levels appeared appropriate to support the safety of patients within the hospital at the time of our inspection.

4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
Clinical waste disposal found outside adjoining ward	Hazard and safety issue	Immediately brought to the attention of Ward Manager	Clinical waste disposed of

Appendix B - Immediate improvement plan

Service: Tawe Ward - Ystradgynlais Community Hospital

Date of inspection: 9 - 11 January 2023

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No Immediate Assurances identified				

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative:

Name (print):

Job role:

Date:

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Cronfa Risg Cymru
Shared Services Partnership
Welsh Risk Pool Services

A National Review of Consent to Examination & Treatment Standards in NHS Wales

A Report by the Welsh Risk Pool Safety and Learning Team

Powys Teaching Health Board

Report March 2023

Cydsynio i Archwiliad a Thriniaeth
Consent To Examination & Treatment

Gwella Diogelwch Cleifion Trwy Ddysgu
Improving Patient Safety Through Learning

A National Review of Consent to Examination & Treatment Standards in NHS Wales

A Report by the Welsh Risk Pool Safety and Learning Team

March 2023

About this Report

This report is intended for health bodies within NHS Wales, with the aim to improve patient safety and compliance in relation to the process for sharing information and obtaining informed consent to examination and treatment.

The report follows an evidence-gathering exercise against the published Welsh Risk Pool Standard. Each health body was invited to provide evidence and populate a structured template against each Area of Assessment.

This report provides draft findings for each health body and is circulated for comments and factual accuracy considerations.

The report identifies a number of proposed recommendations. These are shared to enable each organisation to develop an action plan which addresses the findings and supports the prioritisation of improvement activity in this topic area.

This final copy of the report has taken account of comments and points of factual accuracy submitted by the organisation. Additionally, the action plan submitted by the organisation to address the recommendations has been included.

Evidence Gathering	May 2021 – Sep 2021
Pause due to pandemic	Oct 2021 – Sep 2022
Evidence Gathering Update	Oct 2022 – Dec 2022
Draft Findings shared	January 2023
Action Plan Received	March 2023
Final Report Published	March 2023

Version
PTHB Report VFinal1

CONTENTS

1 Purpose of Review

1.1 A number of significant clinical negligence claims submitted to the Welsh Risk Pool Committee (WRP) relate to failures to provide patients with information and failures to document what information was provided.

1.2 In particular, the discussions that took place regarding the benefits and risks (including material risks) of the proposed treatment and the benefits and risks of any available alternative treatments (including no treatment).

1.3 The WRP committee has requested that the Welsh Risk Pool Safety & Learning Team undertake a review of the organisations policies and their clinical application, for obtaining informed consent to examination or treatment with a particular focus on the areas identified above.

1.4 Outputs from the assessment will be an All-Wales summary report and individual reports for each of the organisations assessed. The reports will provide recommendations to enable organisations to develop an improvement plan to address areas for development.

2 Scope of Review

2.1 The aim is to assess the policies and their clinical application in Health Body against the All-Wales Consent to Examination or Treatment Model policy. The WRP has produced an assessment tool that outlines the areas for assessment. This was circulated to the organisation's executive and operational leads for consent to assist organisations in identifying the evidence required to be submitted as part of the assessment.

2.2 The assessments commenced in May 2021 starting with the collection by the organisations of the evidence outlined in the assessment tool. The terms of reference included the opportunity for site visits and staff interviews to consolidate evidence.

2.3 By completing the assessments, organisations were required to scrutinise and interrogate their consent processes. This enabled local teams to familiarise with the WRP Standard and identify source evidence which demonstrated compliance or achievement against each area for assessment.

2.4 The evidence submitted by all organisations was comprehensive and covered the topics required in the standard. Audits on consent provided an honest reflection of each organisations' own current position. This meant that further site visits were not required.

2.5 The clinical areas selected for the focus of the assessment in acute organisations were:

- Unscheduled Orthopaedics
- Elective Endoscopy
- Elective Gynaecology

2.6 The review was disrupted due to the impact of the pandemic and the WRP Committee agreed to recommence the work in this area on 21st September 2022. The Welsh Risk Pool Consent Assessment Team subsequently reviewed the information supplied by each organisation and provided the assessment material back to designated contacts for their further analysis, augmentation where required and final submission. The team did not apply an overall outcome for each standard at that time, as the process was intended to be formative. Several comments were made from the team making suggestions for change or alternative sources of evidence.

2.7 A number of organisations have managed to improve their compliance with the areas of assessment since the original evidence was submitted in 2021 and it is clear that all organisations have been working on improving consent to examination and treatment processes.

3 Assessment Team

3.1 The Welsh Risk Pool assembled a team of specialist practitioners with experience in the topic area:

Sponsor:	Jonathan Webb, Head of Safety & Learning
Field Work:	Susan Derbyshire, Clinical Assessor
	Isobel Smith, Clinical Assessor
Clinical Lead:	Ben Thomas
	National Lead - Consent to Examination & Treatment
Legal Advice:	Sarah Watt, Solicitor
	Gavin Knox, Solicitor
Oversight:	Manon Gwilym, Principal Safety & Learning Advisor
	Eleri Wright, Safety & Learning Advisor

4 Review Findings

4.1 Policy Content

The organisation has adopted the All-Wales Model Policy for consent to examination or treatment and adapted it into organisational policy format. The organisation's policy was approved in February 2021.

There is no review date noted on the Policy, however the organisation states that 'as it is a Welsh Government policy, Powys THB has declared that the review date is at the discretion of Welsh Government and will be updated by Powys THB if and when an update to the policy is issued by Welsh Government'. The organisation is asked to note that the All-Wales Model Policy has been developed by and is the responsibility of the All-Wales Consent to Treatment Group supported by the Welsh Risk Pool, rather than the government. Whilst it is understood by the Assessment Team that the policy will be changed when there are national changes effected, it is recommended that the organisation's Policy is reviewed at least every 3 years (or to follow any local organisational cycles of review) to ensure that references to local information is relevant and all hyperlinks work.

The policy includes detail of the Welsh Language requirements.

The organisation states that its policy is displayed on the Powys THB intranet site, however evidence by way of a link to the policy has not been shared.

Compliance with Standard: COMPLIANT

4.2 Consent Forms

The organisation states that relevant specialties use All Wales Consent Forms 1 and 4 and that Form 2 is not used as its surgery and endoscopy services do not treat children and young people.

The All-Wales forms are in line with the All-Wales policy and are compliant with Welsh Language Standards

The organisation's position is that Procedure Specific Consent Forms should not be used as a replacement for the standard All Wales Consent Form 1. The Assessment Team therefore presume that the organisation is not using locally-developed procedure specific consent forms (PSCF's). However, the Assessment Team consider that it is likely that local PSCF's will be required as work continues to address the backlog of delays to procedures arising from the pandemic and therefore it is important to have a formal documented governance process for the development and approval of such PSCF's.

The organisation has provided audit evidence of the use and completion of Consent Form 1 within its surgery and endoscopy services. Documentation of confirmation that the patient had been given a copy of the consent form has been identified as an area that requires improvement.

Compliance with Standard: PARTIAL

4.3 Training in Consent

The organisation advises that it does not have junior medical staff and that its practitioners are either substantive or appointed on a sessional basis.

For all other staff who take consent, staff are encouraged to undertake training on consent via ESR. In the calendar year 2022, 2 people had completed the old Informed Consent to Examination or Treatment Module and 69 had completed the new Decision Making and Consent in Wales e-learning package.

There is no other single training event for consent. Instead, staff undertake training according to their role / specialty e.g.,

- There is a Theatre/Endoscopy Day Surgery Ward Training Package. This package has a competency section relating to consent which includes the theory and practice of consent
- Staff attend JETS workforce training and work through competencies in the JETS workforce portfolio
- All Health Care Support workers complete the All-Wales HCSW Competency Framework
- There are also competencies specific to some specialities, e.g., ophthalmology.

Work is ongoing to integrate the training record of surgery and endoscopy staff onto ESR.

Compliance with Standard: COMPLIANT

4.4 Consent Process for Adults

The organisation has adopted the All-Wales Model Policy for consent to examination or treatment and adapted it into organisational format. The specific guidance for obtaining consent involving adult patients noted in Area for assessment 2 is included the organisation's policy.

Compliance with Standard: COMPLIANT

4.5 Consent Process for Children & Young People

The organisation has adopted the All-Wales Model Policy for consent to examination or treatment and adapted it into organisational format. The specific guidance for obtaining consent involving children and young people adult patients noted in Area for assessment 3 is included in the organisation's policy.

Compliance with Standard: COMPLIANT

4.6 Patient Information

The organisation uses EIDO patient information leaflets for all procedures undertaken by its surgery and endoscopy services. Its dentistry service uses some leaflets that have been developed by its professional body. EIDO leaflets are compliant with Welsh Language Standards.

The organisation does not state that it uses locally developed patient information leaflets and it is therefore presumed that the organisation is not using such leaflets. However, the Assessment Team consider that it is likely that local patient information leaflets are required in the future and it would be beneficial to have a formal documented and approved governance process for development and approval of such local leaflets.

Although the organisation's policy states that any written information that is given to the patient is recorded in the patient notes, the organisation does not currently consistently record that this has been done.

There is limited evidence (surgical 2019 audit) that patient leaflets have been provided to patients to enable an informed choice on consent. The organisation states that this will be included in future training packages, and it is recommended that awareness of the need to provide this confirmation within the patient's healthcare record / on the consent form is emphasised.

The organisation also intends to undertake an audit addressing the issue of the information given to the patient within its 2023/34 audit cycle. A Task and Finish group has also commenced a review into the use of patient information leaflets within the consent process across the organisation. This work will inform future development of the use of a digital system to share patient information leaflets.

Compliance with Standard: PARTIAL

4.7 Monitoring of the Consent Process

The organisation provided evidence of audits of the completed consent form 1 in surgical services in 2019, 2021 and 2022. An audit was also undertaken in endoscopy services in March 2021. Dentistry have not completed any recent audits. This is something that should be addressed during the 2023/24 audit cycle.

The organisation has not provided evidence of formal reports of the data collected.

The organisation provided evidence of a draft report by the Medical Director to the Patient Experience, Quality and Safety (PEQS) committee giving an update on the 2022-2023 clinical audit plan which includes a Tier 2 audit within surgery and endoscopy of record keeping & consent.

No evidence was provided of reports been reported at Board level. The organisation states that this will now be reported through the Quality Governance Group to the Board.

Minutes from Team Leader meetings were presented as evidence to show how audit findings are fed back via audit presentations to the Group. The results are discussed and the need for any corrective actions and/or re-audits agreed.

There was no evidence of action plans having been developed to address the identified shortfalls and any progress made to address those shortfalls save for re audit.

Compliance with Standard: PARTIAL

5 Assurance Rating

5.1 Having considered the evidence submitted against each Area for Assessment, the Review Team have determined an overall assurance rating. This utilises the NHS Wales Internal Audit Framework outlined in Appendix 1.

REASONABLE ASSURANCE		The organisation can take **reasonable assurance** that arrangements to secure governance, risk management and internal control in relation to Consent to Treatment are suitably planned and applied effectively. Some matters require management attention in control design or compliance with low to moderate impact on residual risk exposure until resolved.

6 Main Themes

6.1 The organisation has a consent policy in place which addresses specific guidance in relation to consenting adults, children, and young people.

6.2 All Wales Consent Forms 1 and 4 and EIDO patient information leaflets are used within the organisation, however documentation of these having been handed to patients needs to be addressed.

6.3 All appropriate staff groups can access training on consent via ESR.

6.4 Evidence of audit reports to include reporting at Board level was lacking. This has been identified as an area which requires addressing and this will be actioned in 2023. An action plan is in development to address all identified shortfalls.

7 Recommendations

It is recommended that the organisation:

7.1 Reviews it Policy on Consent at least every 3 years (or Health Board cycle of review) to ensure that reference to local information is relevant and all hyperlinks work.

7.2 Develops a formally approved procedure setting out the organisation's governance process in relation to the development and approval of local PSCF's

7.3 Implements a requirement for all clinicians who take consent from patients to complete a recognised training programme. It is recommended that the frequency of this training should be at least once per revalidation cycle for the relevant professional group, it being accepted that such training is more relevant to some groups than others. This could be either via the national e-learning consent training package or an approved in-house face to face training session.

7.4 Develops a database of patient information leaflets used within the consent process.

7.5 Concludes its review into the use of patient information leaflets within the consent process in order to develop a digital system to share patient information leaflets.

7.6 Develops a formally approved document setting out the governance process for the development and approval of local patient information leaflets

7.7 Puts a process in place to comply with the 'Criteria for use of Procedure-specific Patient Information Leaflets following publication of RMA2020-01' namely - Where an organisation wishes to deviate from the use of an EIDO patient information leaflet, or where no EIDO leaflet or compliant alternative is available, this will need to be notified via email to consenttreatment@wales.nhs.uk.

7.8 Undertakes a peer review of the organisation's consent process using the peer review tool developed on an All-Wales basis. In addition to monitoring the organisation's consent process it will enable the organisation to comply with requirement number 6 of the WRP RMA 2020-01 Consent to Treatment - monitoring of compliance with the requirements of consent to treatment documentation (which may be in patient records or on a consent form) of the provision of procedure specific patient information leaflets.

7.9 Continues to monitor and address any shortfalls in the use, provision of and documentation of patient information leaflets and addresses any shortfalls through e.g., training materials on consent.

7.10 Develops audit reports which are presented through the Quality Governance Group to the Board.

7.11 Continues to feedback on the audit results to both individuals and more generically in order to initiate improvements.

8 Conclusion

8.1 Powys Teaching Health Board can take reasonable assurance in respect of the processes relating to Consent to Examination & Treatment.

8.2 The organisation is aware of the shortfalls identified in the consent and governance processes and has demonstrated a commitment to improvement in this area.

8.3 The Welsh Risk Pool wish to thank the NHS organisations and the staff who were involved in this assessment. The effort involved for those who participated is much appreciated.

9 Appendices

Appendix 1 NHS Wales Assurance Framework

Appendix 2 Organisational Action Plan

Appendix 1

NHS Wales Assurance Framework

SUBSTANTIAL ASSURANCE		The organisation can take **substantial assurance** that arrangements to secure governance, risk management and internal control in relation to Consent to Treatment are suitably planned and applied effectively. Few matters require attention and are compliance or advisory in nature with low impact on residual risk exposure.
REASONABLE ASSURANCE		The organisation can take **reasonable assurance** that arrangements to secure governance, risk management and internal control in relation to Consent to Treatment are suitably planned and applied effectively. Some matters require management attention in control design or compliance with low to moderate impact on residual risk exposure until resolved.
LIMITED ASSURANCE		The organisation can take **limited assurance** that arrangements to secure governance, risk management and internal control in relation to Consent to Treatment are suitably planned and applied effectively. More significant matters require management attention with moderate impact on residual risk exposure until resolved.
NO ASSURANCE		The organisation has **no assurance** that arrangements to secure governance, risk management and internal control in relation to Consent to Treatment are suitably planned and applied effectively. Action is required to address the whole control framework in this area with high impact on residual risk exposure until resolved.

Appendix 2

Organisational Action Plan

A copy of the action plan received from the organisation in response to the draft recommendations has been included here.

ACTION PLAN FOR IMPROVEMENT	
Reference	**A National Review of Consent to Examination & Treatment Standards in NHS Wales A Report by the Welsh Risk Pool Safety and Learning Team January 2023**
Directorate	**Organisational wide**
Lead Officer for Action Plan	**Assistant Director Quality & Safety**
Date action plan commenced	**January 2023**

Recommendation	Action needed	Progress & Evidence	Monitoring Arrangements	By who	Deadline date for completion & insert date of completion
1. Ensure Policy on Consent is reviewed at least every 3 years (or Health Board cycle of review) to ensure that reference to local information is relevant and all hyperlinks work.	Update review cycle of policies to ensure a monitoring process is in place to review every 3yrs at a minimum	Updated process in place	Learning Group	HC	February 2023
2. Develop a formally approved procedure setting out the organisation's governance process in relation to the development and approval of local Procedure Specific Consent Forms (PSCF)	Review the governance arrangements in place Agree a HB wide process for approval of PSCF	Scoping exercise in place to understand the current processes in place.	Community CSG Governance Group	NC	May 2023
3. Implement a requirement for all clinicians who take consent from patients to complete a recognised	Review current training programme in place.	Await the national training package and when available include within the	Training and Education	Practice Educators/WOD	April 2023

Recommendation	Action needed	Progress & Evidence	Monitoring Arrangements	By who	Deadline date for completion & insert date of completion
training programme. It is recommended that the frequency of this training should be at least once per revalidation cycle for the relevant professional group, it being accepted that such training is more relevant to some groups than others.	Ensure that ESR training requirements are updated for all professionals to include the national e-learning consent training package.	mandatory training metrix within ESR			
4. Develop a database of patient information leaflets used within the consent process.	Complete a scoping exercise to ensure all patient information leaflets in use across the HB are realised. Following completion of a database ensure all leaflets meet the HB standard and are managed within a robust review process.	Services have been asked to share the leaflets in place by the end of February 2023.	Learning Group	HC	June 2023
5. Conclude review into the use of patient information leaflets within the consent process in order to develop a digital system to share patient information leaflets.	Task and finish group in place to ensure MDT approach to digital solutions	Review of a clinical area and OPD process for consent and use of information leaflets has commenced	Learning Group	AD Q&S	June 2023
6. Develops a formally approved document setting out the governance process for the development and approval of local patient information leaflets	Task and finish group in place. SOP being developed to ensure a HB wide approach is in place	Currently within draft awaiting comments	Learning Group	AD Q&S	May 2023

Recommendation	Action needed	Progress & Evidence	Monitoring Arrangements	By who	Deadline date for completion & insert date of completion
7. Ensure a process is in place to comply with the 'Criteria for use of Procedure-specific Patient Information Leaflets following publication of RMA2020-01' namely - Where an organisation wishes to deviate from the use of an EIDO patient information leaflet, or where no EIDO leaflet or compliant alternative is available, this will need to be notified via email to consenttreatment@wales.nhs.uk .	Task and finish group in place. SOP being developed to ensure a HB wide approach is in place	Currently within draft awaiting comments	Learning Group	AD Q&S	May 2023
8. Undertake a peer review of the organisation's consent process using the peer review tool developed on an All-Wales basis.	Peer review to be included in the 2023/24 audit cycle	Action complete	Learning Group	AD Q&S	February 2023
9. Continue to monitor and address any shortfalls in the use, provision of and documentation of patient information leaflets and addresses any shortfalls through e.g., training materials on consent.	Monitoring through audit and governance reporting structures will ensure learning is proactively addressed	Audit programme in place	Learning Group	AD Q&S	February 2023
10. Develop audit reports which are presented through the Quality Governance Group to the Board.	Audit reporting is in place, which reports to PEQS, executive committee and Board	Reporting structure in place	PEQS	MD	June 2022

Recommendation	Action needed	Progress & Evidence	Monitoring Arrangements	By who	Deadline date for completion & insert date of completion
11. Continue to feedback on the audit results to both individuals and more generically in order to initiate improvements.	Audit reporting is in place, which reports to PEQS, executive committee and Board Ensure learning and improvement is monitored within the learning group and service level governance groups	Reporting structure in place to PEQS Review of learning specifically regarding consent is included within structures in place	Learning Group	MD	March 2023

Status of action:

GREEN	Complete
AMBER	In progress
RED	Missed deadline for completion - escalate

Incident Management

Final Internal Audit Report

March 2023

Powys Teaching Health Board

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Archwilio a Sicrwydd
Shared Services Partnership
Audit and Assurance Services

GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

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Auditors:	Olubanke Ajayi- Olaoye, Principal Auditor Ian Virgill, Head of Internal Audit
Executive sign-off:	Claire Roche, Executive Director of Nursing and Midwifery
Distribution:	Zoe Ashman, Assistant Director of Quality & Safety Elaine Scott, Lead Clinician - Quality & Safety
Committee:	Audit Risk & Assurance Committee

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

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

Executive Summary

Purpose

The overall objective of the audit was to review the arrangements in place within the Health Board for the identification, recording, investigation and management of incidents.

Overview

We have issued reasonable assurance on this area.

The matters requiring management attention include:

- Publishing a Health Board wide Incident Reporting procedural guidance and a navigable incident reporting page on SharePoint.
- Key stages / processes within the incident reporting cycle falling behind expected timelines.
- Lack of evidence of periodic reporting / monitoring of incidents within the Community Services Group.
- Lessons learnt from incidents not being monitored to ensure they are actioned.

A further recommendation / advisory point is within the detail of the report.

Report Opinion

Reasonable

Some matters require management attention in control design or compliance.

Low to moderate impact on residual risk exposure until resolved.

Assurance summary[1]

	Objectives	Assurance
1	Incident management policies and procedures.	Reasonable
2	Identification, recording and investigation of Incidents.	Limited
3	Reporting, monitoring and review of Incidents.	Reasonable
4	Actions taken and lessons learned.	Reasonable
5	Nationally Reportable Incidents.	Substantial

[1]The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Key Matters Arising

		Objective	Control Design or Operation	Recommendation Priority
1	Outcome from CSG's Incident Reporting Review	*2*	Operation	High
2	Requirement of a Health Board Local Guide Procedure	*1*	Design	Medium
3	Accessibility of Incident Management Resources on SharePoint	*1*	Operation	Medium
4	Incidence Reporting and Governance Arrangement	*3&4*	Operation	Medium

1. Introduction

1.1 The review of 'Incident Management' was completed in line with the Powys Teaching Health Board's (the 'Health Board') 2022/23 Internal Audit Plan.

1.2 This review was originally highlighted in the plan as 'Directorate Quality & Safety Governance Arrangements'. However, it was agreed, in discussion with the Executive Director of Nursing and Midwifery, that a focused review be undertaken on a specific element of Quality and Safety each year, beginning with Incident Management.

1.3 All NHS organisations are accountable for the quality and safety of care provided to their respective populations. They must report all incidents of patient harm and near misses locally through their local risk management systems. This includes incidents across the whole patient pathway. They should be investigated appropriately and proportionately with actions taken accordingly, in line with Putting Things Right (PTR) requirements.

1.4 The Health Board is subject to the Duties within the Health and Social Care (Quality and Engagement) (Wales) Act 2020. The Duty of Candour focusses on the need to be open with patients, families and carers when things go wrong, building on the requirements already set out in PTR.

1.5 The Health Board's Serious Incident Policy Reporting, Investigating and Assurance Processes (PEP 004) underlines the procedures essential for the management of serious incidents in line with the Regulations as it applies to staff who have a responsibility to report and manage these serious incidents. "This policy sets out clear guidance on the management of serious incidents from the point of notification to closure of the related investigation, ensuring lessons have been learnt and shared, and assurance provided".[1]

1.6 The Executive Director of Nursing and Midwifery is the Executive lead for this review.

1.7 The potential risks are:

- Non-compliance with relevant legislation;
- Patient harm or poor patient experience;
- Financial loss; and
- Reputational damage with decreased public confidence.

[1] Policies & Written Control Documents - PEP 004 Serious Incident Policy Reporting, Investigating and Assurance Processes.pdf - All Documents (sharepoint.com)

2. Detailed Audit Findings

Objective 1: The Health Board has incident management policies and procedures in place that are up to date and have been communicated to all staff and are readily available

2.1 National incident reporting in NHS Wales changed from 14 June 2021 with the publishing of Phase 1 of the National Patient Safety Incident Reporting Policy by the Welsh Government.

2.2 The NHS Wales National Incident Reporting Policy Implementation Guidance Document (Phase 1) was coordinated and produced by the NHS Wales Delivery Unit for use by all NHS Wales Organisations, supporting how NHS Wales responsible bodies will implement the Welsh Government's National Incident Reporting Policy. Phase 2 which is yet to be published, will focus on new ways of national reporting, including thematic reporting of healthcare incidents.

2.3 The Health Board's SharePoint site has a Quality and safety section which includes Health Board, Welsh Government and the Delivery Unit's policy, guidance documents, training updates, forms and templates. This however requires a review and update to ensure that all the documents and information are current and are easily accessible for viewing by users. ***(Matter Arising 2 – Medium Priority)***

2.4 The Health Board's SharePoint page includes key documents such as:

- National Patient Safety Incident Reporting Policy (Welsh Government, May 2021);
- NHS Wales National Incident Reporting Policy Implementation Guidance Document (Phase 1);
- National Incident reporting flow chart; and
- Powys Health Board Easy guide patient safety Incident reporting at the national level.

2.5 The Health Board has several incident management guides available, however, there is currently no document in place that details the actual incident reporting processes operating within the Health Board. ***(Matter Arising 3 – Medium Priority)***

Conclusion:

2.6 Following the Welsh Government changes in incident reporting that took place in June 2021, the Health Board published a number of guidance documents, most of which are available on the SharePoint page. In order for staff to have ease of reference, a procedure or framework which provides a holistic view of the Health Board's incident reporting processes is required. Also, the SharePoint page requires updating to ensure easy navigation and accessibility of resources to staff. ***(Reasonable Assurance)***

Objective 2: Incidents are identified and responded to in a timely manner and to the required standard in accordance with the relevant legislation

2.7 Incidents occurring within the Health Board are reported on the Once for Wales Incident Management system which has a standard functionality. The Health Board went live with the datix functionality on June 14, 2021. There is an approval system in place within the Health Board when changes are identified as being required within datix, prior to their presentation at the Once for Wales Incident Functionality Group. Changes relating to the core data or data set can only be made via this group.

2.8 It is the responsibility of the staff in the service where the incident occurred to notify of its occurrence via datix and adequately complete the incident form with the relevant information. Incidents are managed at the service level and key staff have been identified within service groups to handle incident reporting. The Quality and Safety team provide continued support in order to embed robust assurance processes and learning from incidents.

2.9 Managers assign the investigators who are notified via a link within the email sent to them. The form is then changed to 'make safe'. Focused reviews via scrutiny panels are undertaken. It is also stated how long the management actions will take in days. Recommendations, lessons learnt, and date completed are also entered on the form.

2.10 Depending on the incident type entered (e.g. violence & aggression, information governance, infection prevention and control) an email is sent to the key responsible staff in the specific area. The Assistant Director of Quality and Safety-Nursing and the Safety Systems and Information Co-ordinator also receive notifications on all reported incidents via email.

2.11 A number of training sessions are available for relevant staff, these include:

- How staff can complete and submit an incident form on datix;
- Manager's training on the completion of the datix form, timeliness of completion, accuracy checks and resources available to access relevant information;
- Investigation trainings on root and causes;
- Ombudsman sessions which can be booked through the ESR system; and
- Other training courses available on ESR.

2.12 The Community Service Group (CSG) was the service area reviewed for Incident reporting management. The Number of reported incidents within CSG from January 2022 to December 2022 was approximately 1952. A number of tests were undertaken on a sample of reported incidents, including timelines in the incident reporting and management process. A number of observations following this testing have been highlighted in Appendix A. ***(Matter Arising 1 – High Priority)***

2.13 The Powys and Hywel Dda Health Board will be trialling a system commencing January 2023 to ensure the duty of candour is followed, that is providers are open and transparent with people who use services and their family members. There will

be added scrutiny to ensure the appropriate level of harm is allocated to the reported incident. These include:

- Is it accurate?
- Has the rating been changed?
- Reason for the change?

Conclusion:

2.14 Training takes place where staff are updated and advised on the requirement and expectations of the incident reporting processes. The sample tests undertaken indicated some stages within the incident reporting process fell behind expected and established timelines. ***(Limited Assurance)***

Objective 3: Incidents are reported, monitored and discussed at appropriate forums within the Health Board and are escalated where required to provide the required assurance

2.15 The Safety Systems and Information Co-ordinator produces incident reports that are presented at various groups and committees, along with a dashboard report from the business intelligence section of datix. Dashboards are developed manipulating data to meet the needs of specific service areas.

2.16 The Health Board's Integrated Quality Report (IQR) includes a serious incidents and concerns section. The reports for July, September and November were reviewed, the relevant areas of the report pertaining to the audit included:

- Reports on the current position of open NRI.
- Report on patient and non-patient safety per non, low, moderate, severe, Catastrophic & death level of harm.
- Highest reported incident themes: Pressure or moisture damage being the highest followed by trip, slip or fall.
- Tabular presentation of new incidents, make safes, incident under investigation and those awaiting closure.

2.17 The IQR is presented at the Executive Committee meeting and the Health Board's Patient Experience Quality and Safety Committee. The report is expected to go to the Executive Committee bimonthly for executive review, however September's report was not presented. ***(Matter Arising 4 – Medium Priority)***

2.18 The two highest reported incident themes are Pressure or moisture damage followed by slip, trip or fall. The following specific panels are held based on these types of reported Incident:

- There is a Pressure Ulcer Scrutiny panel that meets every month and reviews pressure related incidents and investigations;
- All trip, slip or fall incidents reported go to a weekly scrutiny panel; and
- Trip, slip or Fall incidents where there is a reported level of harm also go to a Fall Huddle group for review.

Conclusion:

2.19 The Health Board structure provides a mechanism which offers assurance on incident management through the Executive Committee and the Patient Experience Quality and Safety Committee. However, we were unable to establish a consistent/ organised route of periodic reporting and monitoring of incidents at the Community Service Group Level. ***(Reasonable Assurance)***

Objective 4: There is clear evidence of action being taken and lessons being learned and shared across the Health Board to minimise future occurrence where deficits are identified

2.20 The Incident reporting form on datix has a section where lessons learnt are to be documented. Depending on the level of harm and type of incident, the completion of the lessons learnt section might not be applicable. There is currently no mechanism in place to ensure lessons learnt as stated on datix are actually implemented at an operational level. ***(Matter Arising 5– Low Priority)***

2.21 The Integrated Quality Report (IQR) for July, September and November 2022 were reviewed. In July, there was a write up on the learning from an incident in the Quality Assurance Overview report while September and October highlighted the NRI themes for learning and improvement.

2.22 There is also a learning Newsletter produced quarterly to share learning from Incidents, concerns, Investigations, Inquests, Medicines management, Patient stories, Quality Improvements and Claims. The first issue was published in October 2022.

2.23 As noted previously, we have been unable to ascertain (within the Community Service Group) a system in place or established medium used for the communication of lessons learnt to the operational staff and group as a whole. ***(Matter Arising 4 – Medium Priority)***

Conclusion:

2.24 Lessons learnt are documented on datix and shared via a number of means at the Health Board level from reports presented at the PEQS to the learning newsletters and 7-minute briefs. Methodical Sharing has not been evidenced (via meeting agendas for instance) at the operational level within the Community Services Group. Lessons learnt are currently not monitored for actioning. ***(Reasonable Assurance)***

Objective 5: Relevant incidents, including nationally reportable incidents, are reported in a timely manner in accordance with national reporting requirement

2.25 Nationally Reportable Incidents (NRI) are required to have a rapid meeting. This is held by those 'not' directly involved in the incident. All NRI's have an executive lead allocated to the incident who chairs the rapid meeting.

2.26 Once an incident is recognised as a NRI, a NRI notification is completed and sent to the Concerns Team, the concerns team subsequently cascades this to the right person. The NRI is then submitted to the Delivery Unit by either the Lead Clinician-Quality & Safety or the Ward sister. This is proof checked by the Executive Director of Nursing and Midwifery.

2.27 The Delivery Unit generates a dashboard of how many NRI the Health Board has reported, analysed across months, severity and location. The purpose of this reporting is to ensure good governance both on the part of the Delivery Unit, responsible for the national reporting process, and individual organisational governance responsibilities in complying with the published policies and guidance.

Conclusion:

2.28 The Health Board has processes in place for the reporting of NRIs and the dashboards produced by the Delivery Unit confirm that reporting is taking place. ***(Substantial Assurance)***

Appendix A: Management Action Plan

Matter Arising 1: Outcome from CSG's Incident Reporting Review (Operation)	**Impact**
A sample of eighteen incidents was selected from the total incidents reported and closed between July 2022 and November 2022 for the Community Service Group (CSG). This period was selected for the relevant applicability of the change in policy following the publication of the Welsh Government policy in June 2021 and the migration to the new datix system which took place in April 2022. Safeguarding reported incidents were excluded because they are outside the jurisdiction of the CSG and handled differently from other CSG reported incident. The expectation of timelines stated within the WG Policy and Delivery Unit Guidance are outlined below: The Patient Safety Incidents Policy states: *'When incidents such as these (Patient safety incidents) occur, a comprehensive response is required to ensure immediate make safe actions are taken. 'Page 3* *'…..an initial 'make safe'/ 72 hour review has identified issues to trigger a patient safety incident investigation.' Page 5* NHS Wales National Incident Reporting Policy Implementation Guidance Document (Phase 1) states: *'All incidents should be subject to timely review to ensure immediate make safes are identified and actioned, to reduce future risk of patient harm where applicable, and to determine necessity for national reporting to the DU in keeping with policy timeframes.' Page 5* *'The national Incident reporting flow chart states (in regard to initial review) that management review should be undertaken at the earliest opportunity from the notification to establish appropriate categorisation, immediate actions and make safes.' Page 12* *'The national Incident reporting flow chart also states that report on datix on the earliest opportunity following occurrence or at point of knowledge.' Page 12*	Potential risk of: • Patient harm or poor patient experience • Financial loss

The table below highlights the outcome from the review of the key timelines for the reporting and investigation of the sampled incidents:

Timeline review	Number of exceptions from the sample of 18 incidents	Working days	*Days assumed as 'timely'*
Incident date to Incident reported date	1	21	*1 to 3*
Incident reported date to 'make safe' / review start date	17	8 to 102	*1 to 3*
Days Incident is closed after Investigation end date	4	7 to 35	*1 to 6*

It was observed that the incident reported date to date closed were largely influenced by, and linear to, the date reported to the review start date. This saw the three highest number of working days (incident reported date to date closed) at 103, 87 and 59.

Our review of the sampled incidents also highlighted the following issues:

- Thirteen of the eighteen incidents had lessons learnt highlighted, stating they will be communicated to their local teams and Nurses meeting. There was however no evidence provided to confirm that this had taken place;
- One of the statements under the lessons learnt was just further explaining the incident;
- For twelve of the eighteen incidents, the level of harm was moderate and one of the eighteen was catastrophic/ death. This is an indication that the Health Board has caused a level of harm in these thirteen cases. However, we have been unable to confirm from the CSG key lead if the level of harm allocated is appropriate in regard to the description of the reported incident; and
- Investigators undertake the review of reported incidents; however, we could not evidence any requirement for investigators to undertake the root course Analysis Training prior to carrying out different types and levels of investigation.

Recommendations		Priority
1.1	Management should ensure that: • All incidents are managed in accordance with the required timescales; • Staff are clear on how to assess the level of harm caused as a result of the incident • Lessons learnt only state the learning from the incident reported, communicating it to the relevant teams and groups; • Evidence of meetings held should be adequately stored for ease of future use or reference; and • Staff are Root Cause Analysis trained prior to undertaking incident investigations (where required). The formal documentation of the requirement and processes within a Health Board specific procedure (as per recommendation 2.1 below) will provide a platform where the due process can be referred to minimising the findings noted from the review.	**High**

Agreed Management Action		Target Date	Responsible Officer
1.1	Processes to ensure monitoring of timely incident management are established to escalate delays when incidents are not managed and closed within an appropriate timescale.	May 2023	Assistant Director Quality & Safety
	Additional 'Duty of Candour' training sessions have been established during February and March 2023 to ensure classification of harm is addressed appropriately by those reporting (a recording of this session is available to staff unable to attend).	Completed	Assistant Director Quality & Safety
	Clinical Service Groups to implement a structured process to share learning from incidents.	April 2023	Head of Nursing
	Complete a TNA for all staff investigating incidents to ensure appropriate training has been received.	May 2023	Assistant Director Quality & Safety

Matter Arising 2: Requirement of a Health Board Local Guide Procedure (Design)	**Impact**
The Health Board needs a procedure to provide a structured overview of the incident management process within the Health Board and support the interpretation and implementation of the National Patient Safety Incident Reporting Policy (Welsh Government, May 2021) and NHS Wales National Incident Reporting Policy Implementation Guidance Document. There is currently no Health Board specific guide outlining in one place, the Health Board specific processes or expectation relating to (and not limited to): • Other relevant policies and procedures; • Key responsibilities of staff; • Current governance arrangements as they relates to the internal oversight, scrutiny and quality assurance of all incident reporting and investigation processes within the Health Board; and • required mechanism for demonstrating shared learning.	Potential risk of: • Non-compliance with relevant legislation

Recommendations		**Priority**
2.1	Management should work towards producing an Incident reporting Standard Operating Procedure which will bring together (in one place) a standardised and clear system.	**Medium**

Agreed Management Action		**Target Date**	**Responsible Officer**
2.1	Production of an incident management framework.	June 2023	Assistant Director Quality & Safety

Matter Arising 3: Accessibility of Incident Management Resources on SharePoint (Design)	**Impact**
The incident reporting section of the Health Board's SharePoint site requires re organisation. At the time of review, documents within the site were not categorised or organised in a user-friendly manner. More work is required to determine the best way to display the relevant information and documents under this section. At the time of the audit review, the following findings were made: • The easy guide Patient Safety Incident Reporting at the National Level was uploaded twice on SharePoint; • The HB's Serious Incident Policy is on SharePoint. Although it is still in date, it does not reflect major changes that have taken place following the issue of the WG and the Delivery Unit Incident Reporting Policy and guidance with a name change from 'serious incident' to 'Nationally Reportable Incident'; • There is a Once for Wales Concerns Management (system) guide which is updated quarterly by the Once for Wales Group. The SharePoint site has various copies of the user guide, including the current and previous version and duplicate copies of same version; and • The 'How to report a fall or pressure damage on Datix Cymru' document, though shared via email in April 2022 is not available on SharePoint.	Potential risk of: • Difficulty in staff locating available Incident management resources

Recommendations		**Priority**
3.1	Acknowledging that developing the datix and incident reporting section of the SharePoint site is a work in progress, management should ensure datix and Incident reporting related pages are reviewed to ensure relevance and ease of use.	**Medium**

Agreed Management Action		**Target Date**	**Responsible Officer**
3.1	Review the reporting section of Sharepoint to ensure appropriate and up to date information is contained within it.	April 2023	Assistant Director Quality & Safety

Matter Arising 4: Incidence Reporting and Governance Arrangements (Operation)	**Impact**
The June and November's Integrated Quality Report (IQR) that went to the Patient Experience Quality and Safety Committee (PEQS) was also presented at the Executive Committee. However, the September 2022 IQR, though taken to PEQS was not presented at the Executive Committee. The CSG Quality and Safety Group meet every two months. The August and December meetings took place while October's meeting was stood down. On review of its minutes and ToR, it was observed that: • Information or data relating to incident reporting provided in the CSG monthly Quality and safety report was presented only at the August CSG Q&S meeting. We have been unable to evidence any pattern of periodic review of incident reports or sharing of lessons learnt from incidents within the CSG. • Its ToR is not dated, and it does not state within, the expected frequency of review of incident reporting.	Potential risk of: • Inadequate monitoring and reporting can lead to further patient harm or poor patient experience.

Recommendations		**Priority**
4.1	Management should ensure there is periodic monitoring and reporting of incidents in place at the required forums. Groups should also review and update their ToR as required.	**Medium**

Agreed Management Action		**Target Date**	**Responsible Officer**
4.1	Review reporting structures to ensure consistency and robust reporting processes.	April 2023	Assistant Director Quality & Safety

Matter Arising 5: Monitoring of Actions from Lessons Learnt (Operation)			Impact
The lessons learnt section on the incident reporting form on datix is usually completed and is documented based on the uniqueness in learning of the reported event. Depending on the type of incident, the completion of the lessons learnt section might not be applicable. Evidence from reviewing the Directorate of Nursing and Midwifery and Health Board fora shows synopsis in the identification of lessons learnt. However, there is no form of monitoring (on one system/ database) of the lessons learnt over time and actions which have been undertaken operationally to minimise future occurrence where these deficits are identified.			Potential risk of: • Reputational damage with decreased public confidence.
Recommendations			**Priority**
5.1	As a form of good practise, management is advised to have a system where lessons learnt (and mitigating actions) are collated, especially those that have been seen as a recurring theme across the Health Board and monitored to help mitigate/avoid/minimise further occurrence. Through other audits undertaken, we have seen this as an area of good practise.		**Low**
Agreed Management Action		**Target Date**	**Responsible Officer**
5.1	Review the structures in place within the service groups	May 2023	Head of Nursing & Midwifery

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	**Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**No assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Assurance not applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

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Reporting Committee	**Quality Patient Safety Committee (QPSC)**
Chaired by	**Ceri Phillips**
Lead Executive Director	**Director of Nursing & Quality**
Date of Meeting	**24 January 2023**

Summary of key matters considered by the Committee and any related decisions made

Presentation – Mental Health Deep Dive

The committee received an informative Mental Health (MH) presentation which covered the following key areas:

- Mental Health Strategy – Consultation Feedback
- Secure Services Review
- Single Commissioner
- CAMHS
- Eating Disorders
- Mother and Baby Unit
- Governance and Incident Reporting

Dai Roberts (DR) explained that the majority of HBs had submitted consultation feedback and from the initial review of responses there was no firm opposition to the key elements of the MH strategy. The consultation responses would be used to inform the development of the final strategy and an implementation plan for the strategy was also under development.

Shane Mills (SM) provided a detailed overview of the Secure Mental Health review which he conducted and highlighted the general differences between High, Medium and Low Secure Services, the average lengths of stay as well as other classifications by gender, sexual orientation etc. for patients in each sector.

DR explained that the Single Commissioner Model had been to the WHSSC Joint Committee on 10 January 2023 and that Secure Mental Health Services in Wales should be commissioned by WHSSC. More detailed work needed be done to define the appropriate timescales, but the programme of work is unlikely to be completed before April 2024 at the earliest.

DR provided an update on the positive progress in relation to CAMHS and the de-escalation of Ty Llidiard to Escalation Level 3. The service had been in Escalation Level 4 for a considerable length of time. There will be a piece of work undertaken on referral management, which will be undertaken by NCCU.

In relation to Eating Disorders, interim arrangements are currently in place with

the Priory to ensure access to Eating Disorder beds for adults. A tender process is underway to secure a medium-term solution for the next 2-3 years. The long-term solution will be considered as part of the Specialised Services Strategy for Mental Health.

Several recommendations were made following the review of Tonna Mother and Baby Unit (MB) and an analysis of a permanent option is being conducted in line with the Mental Health Strategy Work.

Welsh Kidney Network (WKN)
QPS members were provided with an update around the two risks documented as they scored above 15, the first being around the financial element and possible inability to meet demands through the current budget. The second high level risk was around the limited outpatient capacity in Morriston Hospital, where there is a plan to establish two new satellite units around the Swansea area which should be running early 2024. The funding for these dialysis units had been approved by the Joint Committee during January 2023.

Ashraf Mikhail (AM) provided an update on the peer review process and gave details on the Quality Statement that was released by WG in 2022, which summarised the aims and objectives for the WKN.

Commissioning Team and Network Updates
Reports from each of the Commissioning Teams were received and taken by exception. Members noted the information presented in the reports and a summary of the services in escalation is attached to this report. The key points for each service are summarised below:

Cancer & Blood
Within the Cancer & portfolio and in relation to the Burns service, WHSSC were notified this week that the Mutual Aid arrangements through the Burns Network had been triggered due to a nurse staffing issue and all the arrangements with the Burns network worked appropriately.

The Corporate Directors Group Board (CDGB) had also agreed to de-escalate the PETIC service.

Neurosciences
There was a performance issue that had been a pre-COVID issue within the Neurosurgery Service, but that had now been de-escalated. Nicola Johnson (NJ) highlighted the good progress that had taken place in terms of access.

The single-handed Consultant within the Neuroendocrine Tumour service (NETS) has taken a leave of absence, but WHSSC have received assurance that contingency arrangements are in place. A Consultant from another accredited Centre is providing support and cover for these clinics.

Within the Neurosciences Commissioning Team, the Cochlear and Baha engagement was launched in December 2022 and this will close on 14 February 2023.

Cardiac
Within the Cardiac surgery services, unfortunately the escalation status has remained at the same level in both C&VUHB and SBUHB.

Following receipt of the Royal College of Surgeons (RCS) Report, it was not considered appropriate to de-escalate the service in SBUHB. WHSSC will be meeting again with the HB at an escalation meeting in February to consider the Action Plan that they have put in place to address the issues highlighted in the report. The position will then be considered again under the Escalation Framework processes.

C&VUHB has reported that hood discussion had taken place around their strategic issues and cultural changes. The provider had expressed the view that the escalation process has helped to maintain the focus of the Health Board on these issues. There will be a further meeting in April 2023.

NJ commented that the RCS Report had been written on the basis of a visit to the HB in March 2022 and the HB had undertaken significant action as a result. WHSSC had written to the HB outlining the areas of concern and the evidence required to provide WHSSC with the necessary assurance. NJ explained that she and Sian Lewis had also met with the Medical Director and Chief Executive of the Health Board and explained the progress that was expected by the next Escalation meeting.

Women & Children
During the winter there had been increased pressure within the paediatric intensive care service. This was anticipated post Covid with a return to children mixing on top of the usual respiratory pressures during the winter months.

AR reminded the Committee that WHSSC continued to attend the Paediatric Intensive Care SitRep meetings. There continues to be high demand for PICU beds.

In response to a query around Paediatric activity levels in C&VUHB, NJ explained that WHSSC had received assurance from the HB that they would be able to deliver the contract for 2022/23, but throughout the year due to pressures of theatre and staffing allocation across other Paediatric surgical disciplines the HB has not been able to deliver the level of planned contract activity. This has remained a focus of the performance meetings with the HB. NJ highlighted that, in conjunction with the JC, WHSSC would be reviewing the contract for next year and the provision for Paediatric Surgery. Outsourcing options remain on the table.

Mental Health & Vulnerable Groups
NJ explained that details around the NWAS and Ty Llidiard Services had been covered within the Mental Health presentation.

Adele Roberts (AR) felt it was important to add to the Mental Health update that WHSSC received a report on 7 November 2022, jointly undertaken by NHS Wales and NHS England, relating to a serious incident, which had led to the death of a patient on 20th April 2022. There were 12 recommendations, which will be considered by the Mental Health and Vulnerable Groups Commissioning Team. The

date of the Inquest has not yet been confirmed. The final report and findings of the inquest will be reported to the Quality and Patient Safety Committee once concluded. An update will be provided to the Joint Committee through the Chair's report.

Intestinal Failure (IF) – Home Parenteral Nutrition
The action on the Intestinal Failure (IF) invoices had been closed and an update has been provided within the report. Some new IF risks will be added onto the CRAF in January 2023 mainly around the financial and contractual arrangements.

4.0 Other Reports Received
Members received reports on the following:

- **Services in Escalation Summary**
  WHSSC currently has 6 services in escalation to report, although this will be reduced to 4 as 2 services are scheduled to come out of escalation. One service has also reduced its level of escalation and there are no new services in escalation. The table at the end of this paper provides a summary of each of those services.
- **CRAF Risk Assurance Framework**
  Members were provided with an updated position regarding the WHSSC CRAF. Members noted the updated Risk Appetite Statement that had recently been approved by the JC.
- **Care Quality Commission (CQC)/ Health Inspectorate Wales (HIW) Summary Update**
  AR provided a briefing on Healthcare Inspectorate Wales (HIW) and Care Quality Commission (CQC) reports published during the period October to December 2022.

It was acknowledged that the structure of the CQC had recently changed and may have had an impact on the structure for producing the reports. However, going forward WHSSC will continue to work closely with the CQC on their action plans and meet with them regularly.

Incident and Concerns report
An update report was noted and received by the Committee for assurance. The Chair asked for the content of the report to be considered with perhaps some additional information added to the next report.

5.0 Items for information:
Members received a number of documents for information only:

- Chair's Report and Escalation Summary to Joint Committee 8 November 2022,
- QPSC Distribution List; and
- QPSC Forward Work Plan.

Key risks and issues/matters of concern and any mitigating actions Key risks are highlighted in the narrative above.	
Summary of services in Escalation (Appendix 1 attached)	
Matters requiring Committee level consideration and/or approval None	
Matters referred to other Committees As above	
Confirmed minutes for the meeting are available upon request	
Date of next scheduled meeting:	21 March 2023 at 13.00hrs

SERVICES IN ESCALATION

Date of Escalation	Service	Provider	Level of Escalation	Reason for Escalation	Current Position 17.01.23	Movement from last month
September 2020	FACTS	CTUHB	2	• Workforce issue	• Last escalation meeting was held on 14/12/22 • Assurance was provided for the remaining key requirements • The service was formally de-escalated to level two on 16/12/22 Service will continue to be monitored through an improvement plan for further de-escalation (confirmation of clinical leadership and recruitment of remaining psychology posts)	**To be removed from escalation** 

Date of Escalation	Service	Provider	Level of Escalation	Reason for Escalation	Current Position 17.01.23	Movement from last month
March 2018 Sept 2020 Aug 2021	Ty Llidiard	CTMUHB	3	• Unexpected Patient death and frequent SUIs revealed patient safety concerns due to environmental shortfalls and poor governance • SUI 11 September	• Escalation meetings held monthly, Exec Lead identified from Health Board. Last escalation meeting 5th December 2022 • Improvement Board established to oversee delivery of an integrated improvement plan • Emergency SOP has been fully implemented • Majority of posts recruited to or start dates agreed. • Improved leadership evident via escalation meetings • Progress against de-escalation action plans, and a favorable report following the latest quality visit provided assurance to support de-escalation of service to Level 3 • Further audit being conducted around the referral processes to enable consideration of further de-escalation.	
July 2021	Cardiac Surgery	SBUHB	3	• Lack of assurance regarding current performance, processes and quality and patient safety based on the findings from the Getting It Right First Time review	• Continued six weekly meetings in place to receive and monitor against the improvement plan. • The service was de- escalated on delivery of the immediate actions required by the GIRFT recommendations (per March update), but remained in level 3 whilst the impact of these actions is ascertained. • The escalation level was discussed at the most recent	

Date of Escalation	Service	Provider	Level of Escalation	Reason for Escalation	Current Position 17.01.23	Movement from last month
					meeting in October 2022 and, although significant progress towards the GIRFT benchmarks was noted, it was agreed that WHSSC would need to review the final report of the Royal College of Surgeons of England (RCS England) Invited Service Review to be prior to any potential further de-escalation. • This report was received in November 2022 and was subsequently reviewed by the Cardiac Commissioning Team. As a result of the report's urgent recommendations to address patient safety risks, and in view of a small number of new concerns identified by the RCS, WHSSC concluded that further assurance was required further assurance before de-escalation could be taken forward, and the service remains in Level 3 escalation.	
July 2021 (original escalation) April 2022 (escalated from 2-3)	Cardiac Surgery	C&VUHB	3	• Lack of assurance regarding processes and patient flow which impact on patient experience	• C&VUHB had previously agreed a programme of improvement work to address the recommendations set out in the GIRFT report. • In view of a failure to provide the requested GIRFT improvement plan and HEIW report, the service was re-	⟷

Date of Escalation	Service	Provider	Level of Escalation	Reason for Escalation	Current Position 17.01.23	Movement from last month
					escalated in April 2022. • The service has since provided both a GIRFT improvement plan and HEIW report (and action plan), and WHSSC has developed de-escalation criteria based on the GIRFT recommendations and action plans. • The de-escalation criteria were discussed at the November 2022 escalation meeting. It was agreed that there was no expectation that the criteria would need to be delivered in full to facilitate de-escalation, but that the service would need to evidence demonstrable progress as a result of targeted actions • A further escalation meeting has been scheduled for April 2023.	
November 2021	Adult burns	SBUHB	3	• At the time of initial escalation, the burns service at SBUHB was unable to provide major burns level care due to staffing issues in burns ITU. An interim model was put in place allowing the service to reopen in February 2022. The current escalation	• Escalation monitoring meetings held on 12th August, 27th September and 1st December 2022. • The current timeline for completion of the capital works to enable relocation of burns ITU to general ITU at Morriston Hospital is the end of 2023. • The capital case remains on target with the planned timeline. • The next escalation monitoring	

Date of Escalation	Service	Provider	Level of Escalation	Reason for Escalation	Current Position 17.01.23	Movement from last month
				concerns the progress of the capital case for the long term solution and sustainability of the interim model.	meeting is arranged for 3rd March 2023.	
February 2022	PETIC	Cardiff University	1	Concern over management capacity within the service to ensure a safe, high quality timely service is maintained for patients. These concerns include: • Recent suspension of production of PSMA due to critical quality control issue identified during MHRA inspection. Service slow top address impact on service for patients. • Failure to undertake a timely recruitment exercise leading to isotope production failures. • Failure to provide a business case of sufficient quality in a timely manner for replacement of the scanner	PETIC has taken forward the agreed actions with regard to increasing management capacity within the service and clarifying the governance arrangements for the service. PETIC has been de-escalated and therefore removed from the table of services in escalation. WHSSC corporate directors agreed to de-escalate PETIC following confirmation on 5th December 2022 that the actions in the escalation action plan had been completed. The service has returned to routine monitoring.	**To be removed from escalation**

Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Agenda Item: 4.1

Patient Experience and Quality Committee (PEQS)	**24 April 2023**
Subject:	**Maternity Assurance Paper (Escalation)**
Approved by:	Claire Roche, Executive Director of Nursing and Midwifery
Prepared and presented by:	Prepared by: Shelly Higgins, Interim Head of Midwifery Presented by: Marie Davies, Deputy Director of Nursing
Other Committees and meetings considered at:	Executive Committee 22 March 2023

PURPOSE:

The purpose of this paper is to provide the Patient Experience and Quality Committee (PEQS) with an update on the escalation arrangements in Powys Teaching Health Board Midwifery Service.

RECOMMENDATION:

The Committee is asked to take **assurance** that local escalation measures in Maternity Services has taken place to realise significant improvements resulting in the decision, by the Executive Committee, to de-escalate to business as usual.

Approval/Ratification/Decision	**Discussion**	**Information**
	✓	✓

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVES AND HEALTH AND CARE STANDARDS:

Strategic Objectives:	Focus on Wellbeing	✓
	Provide Early Help and Support	✓
	Tackle the Big Four	✓
	Enable Joined up Care	
	Develop Workforce Futures	
	Promote Innovative Environments	
	Put Digital First	
	Transforming in Partnership	
Health and Care Standards:	Staying Healthy	✓
	Safe Care	✓

	Effective Care	✓
	Dignified Care	✓
	Timely Care	✓
	Individual Care	✓
	Staff and Resources	✓
	Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

The purpose of this paper is to provide the Patient Experience and Quality Committee with an update on escalation arrangements in Midwifery Services in Powys.

The paper focuses on the Powys provider Midwifery Service de-escalation plan and the progress made against escalated areas. This informed the Executive Committee on the 22 March 2023 and the Executive team approved de-escalation to business as usual.

DETAILED BACKGROUND AND ASSESSMENT:

Local escalation arrangements were enacted within the Midwifery Service in Powys on the 29th June 2022. The decision to enact local escalation was in response to the following:

- Identification of three Nationally Reportable Incidents (NRIs) between February and May 2022

- Findings from a local review of governance in the Midwifery Service that highlighted improvements were required in the review of maternity transfers (particularly intra-partum), review of incidents and the undertaking of root cause analysis (RCA) investigations.

- Concerns around the use of the Perinatal Institute's Gap/Grow programme.

Local escalation resulted in increased monitoring for quality/ safety and assurance purposes.

A weekly escalation meeting was put in place chaired by the Deputy Director of Nursing, which was reduced to fortnightly following improvements and assurance across the service.

De-escalation criteria and indicative timelines were drafted and presented to the November committee covering four key areas and an improvement plan metrics/timeframe and accountable leads confirmed. A further update was presented in January 2023 with an update on the work which is being undertaken.

The core data set continues to be monitored through the local escalation meeting until this is stepped down into business-as-usual governance mechanisms.

The areas of focus:

- Governance - Oversight and scrutiny of Incidents/Concerns and the subsequent learning and actions.
- Perinatal Institute GAP/GROW programme.

1) Governance - Oversight and scrutiny of Incidents/Concerns and associated action and learning

Maternity National Reportable Incidents (NRI's)

There is one new NRI reported in the period since the last report. This is currently being investigated. Progress is being monitored through NRI meetings with the Director of Nursing and Midwifery. There is one NRI that remains outstanding, with the report currently being in the assurance processes.

Weekly Safety Meetings

The senior management team have implemented a weekly safety meeting which is now part of routine business. A Terms of Reference has been drafted for the meeting. The purpose of the meetinng is to:

- Monitor key data for maternity services including escalation, births, and Clinical Information Sharing (CIS) cases.
- Review the weekly incident tracker and to confirm all Datix submissions from the previous week.
- Confirm the method of investigation/review for cases including SBAR, Timeline, RCA/NRI.
- Review progress of incident reviews through review of data obtained from Datix that day.
- Manage the progress of RCA reports for NRI's and escalate any issues.
- Ensure concerns are dealt with in a timely manner.
- Discuss themes and trends related to incidents and concerns.
- Monitor peripartum transfer data
- Considers any items for escalation (for example, threshold for an NRI as described below)
- Discuss any family feedback received related to incidents.

In addition to the weekly safety meeting, patient safety incident huddles are convened for cases where there is consideration that it may meet criteria for NRI. The patient safety huddle ensures swift review of the case, timely reporting and involvement of the Corporate Nursing team including Quality and Safety The maternity service aims for a joint review approach with commissioned services for cases where care has been provided outside of Powys and ensure this ask is made of the commissioned services where necessary as per the Maternity Assurance Framework.

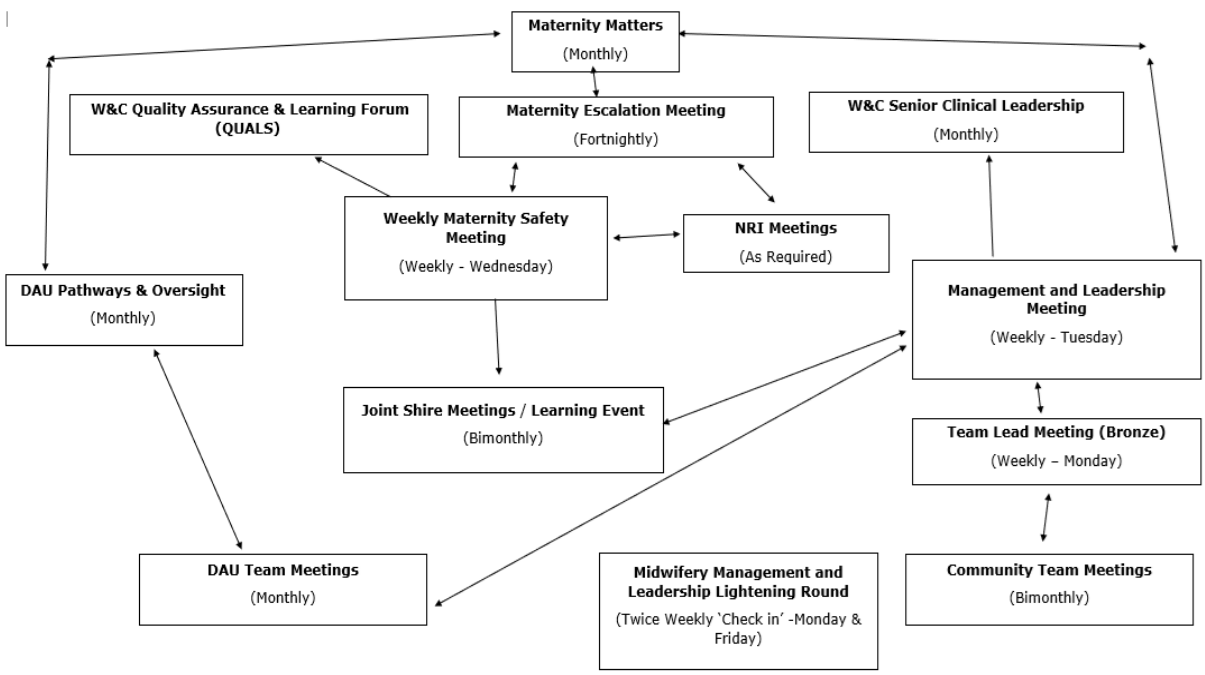
Currently, fortnightly escalation meetings remain in place with the Deputy Director of Nursing where feedback is provided from the weekly safety meetings and monitoring of progress is reviewed.

Maternity service oversight

There is additional monitoring of the service in addition to the weekly safety meeting and current fortnightly escalation meetings achieved through the following:

- Leadership and management team 'check-in' meetings on a Monday and Friday which enable responsiveness to any issues around operational escalation and incidents.
- Weekly Team Leader meeting (bronze) for escalation to the leadership and management team and dissemination to clinical staff of significant information.
- Review of the maternity improvement plan as a standard agenda item for week 1 of the monthly leadership and management meetings.
- Review of the outcome/action plan tracker as a standard agenda item for week 2 of the monthly leadership and management meetings.
- Monthly Quality Assurance and Learning forum where the Quality & Safety paper is shared. This offers the opportunity to review themes and trends within W&CH for incidents, concerns, patient experience and audit.
- A summary update on progress of the improvement plan provided to the monthly maternity matters meeting.
- Day Assessment Unit (DAU) Pathway/Oversight Meeting to support monitoring of the ultrasound provision through maternity services.

Maternity Governance Framework



Closing the loop and feedback to staff

A mechanism of feedback for the wider maternity team is achieved through quarterly learning events and through 'weekly brief', newsletters and email. The first learning event took place in January 2023 with an external expert speaker focusing on a range of topics

including 'thriving not surviving' and psychological safety. This event focused on 2 of the NRI cases in addition to other themes and trends from reviews. A presentation on resilience and staff well-being which is being supported by WoD is planned as part of the next learning event in May, which will incorporate another two of the NRI cases to share the learning. It is intended that the lead reviewer of each case will present the learning moving forwards.

2) Perinatal Institute (PI) GAP/GROW Compliance

One of the key drivers for the implementation of local escalation arrangements was the identification of incidents that highlighted specific actions for Growth Assessment Protocol (GAP) and Gestation Related Optimum Weight (GROW) compliance for the detection of Small for Gestational Age (SGA) babies.

Corrective completed actions included:

- Identification of previously unreported cases of undiagnosed SGA babies from 2020 to July 2022.
- Training of staff to report undiagnosed SGA babies into the GAP/GROW reporting system to the Perinatal Institute (PI). This has been attended by 94% of available staff.
- Working with the PI to enable a GAP-Score report to be generated from the PI around themes and taxonomies relating to SGA. These reports can only be generated following the submission of 30 cases. The GAP-Score is an integral part of the GAP programme & is an electronic audit tool which aims to assist the reviewing of clinical care in the 'missed case' of fetal growth restriction. The care is reviewed in a standardised way, examining potential factors which may have improved the referral rate for suspicion & detection of fetal growth restriction.
- Presentation by the PI to Maternity Matters following generation of the GAP-Score report, this enabled corrective actions to be taken including the skills training sessions and review of capacity in the day assessment unit to fulfil the requirement for growth scans within 72-hours.
- Development of an appropriate agreed process for review of clinical records for undetected small for gestational age babies. This involved developing a flow chart of the process from birth to reporting.
- Development of a system of recording all the historical and new cases of undiagnosed SGA, enabling a pathway to be visible and completed.
- Use of the PI reporting mechanism to support knowledge of the margin of error and identification of cases needing an image review.
- Development of a robust system of image reviews and closure of datix cases.
- Training in recognition of concerns related to fetal growth for all staff involved in clinical care.
- Liaison with obstetric units, with ongoing standard agenda item for quarterly DGH meetings to ensure antenatal care provider remains as PTHB for GAP/GROW reporting to reduce issues with data quality.

- An annual plan for mandatory midwifery updates/PROMPT days to include a session on GAP/GROW including practice of plotting fetal growth and assessment of where a scan or further assessment may be required. Real-life anonymised cases will be used to support this session. All midwives attend this session over a 12-month cycle.

The recent GAP Score report provided by the PI and presented through maternity matters recommended introduction of a digital system GAP 2.0 to support the electronic development of growth charts and automatic plotting of growth to strengthen the identification of concerns around fetal growth. This will also result in automated growth surveillance audit. An SBAR is being drafted to progress this work.

The Perinatal Institute have attended Maternity Matters and have been requested to do so on a quarterly basis to enable further monitoring of themes and trends. The Governance Lead Sonographer for DAU will also present image audit findings at future meetings for completeness.

There is therefore now a robust programme in place for identifying, reporting and reviewing cases where it has been identified a baby was born under the 10th growth centile.

Maternity Improvement Plan

The Maternity Improvement Plan was developed and previously presented to Exec Committee. This includes work required to support de-escalation as well as longer term pieces of work to strengthen the maternity service. The intention will be to have a Continuous Maternity Improvement Plan, informed by the Quality Management System as part of the Integrated Performance Framework. A progress report against the improvement plan will be monitored via maternity matters.

De-Escalation to Business as Usual

On receipt of the information in this paper, the Executive Committee agreed that the service could now return to business as usual governance arrangements.

The business-as-usual mechanisms include the Monthly Maternity Matters meeting, chaired by the Executive Director of Nursing and Midwifery. The Terms of reference for this oversight group will be reviewed and strengthened to support effective quality and safety assurance.

Next Steps

- The Patient Experience and Quality Committee will now receive a Maternity Assurance Report 6 monthly.

Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Agenda item: 6.1

Patient Experience, Quality and Safety Committee	**Date of Meeting: 25 April 2023**
Subject:	**Corporate Risk Register** (Relevant to the committee)
Approved and Presented by:	Director of Corporate Governance and Board Secretary
Prepared by:	Director of Corporate Governance and Board Secretary Interim Corporate Governance Manager
Other Committees and meetings considered at:	Executive Committee – 8 March 2023 PTHB Board – 29 March 2023

PURPOSE:

The purpose of the Committee Risk Register (CRR) is to draw together relevant risks for the Committee from the CRR) to provide a summary of the significant risks to delivery of the health board's strategic objectives.

RECOMMENDATION(S):

It is recommended that the Committee CONSIDERS the April 2022 version of the Committee Risk Register, which reflects the risks identified as requiring oversight by this Committee. This copy of the Committee Risk Register is based upon the Corporate Risk Register (CRR) considered by the Board on 29 March 2023.

The Committee is asked to **consider** the corporate risks within the committee's remit, **discuss** any relevant issues and take **assurance** that risks are being managed in line with the Risk Management Framework.

Approval/Ratification/Decision	Discussion	Information
✘	✓	✓

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):		
Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

The purpose of the Committee Risk Register is to draw together relevant risks for the Committee from the Corporate Risk Register (CRR), to provide a summary of the significant risks to delivery of the health board's strategic objectives.

BACKGROUND AND ASSESSMENT:

The CRR provides a summary of the significant risks to the delivery of the health board's strategic objectives. Corporate risks also include risks that are widespread beyond the local area, and risks for which the cost of control is significantly beyond the scope of the local budget holder. The CRR is reviewed by the Executive Committee on a bi-monthly basis and is noted by the Board.

The Committee is asked to DISCUSS the risks relating to Patient Experience, Quality and Safety Committee and the risk targets within the Committee Based Risk Register, and to CONSIDER whether the targets identified are achievable and realistic.

The full Committee Risk Register is attached at **Appendix A.**

NEXT STEPS:
The group will lead the ongoing development of patient experience, quality and safety risks as set out above. An updated version of the Corporate Risk Register is due to be presented to the Board on 24th May 2023.

Patient Experience, Quality and Safety Committee (28th April 2023) Committee Based Risk Register

CORPORATE RISK HEAT MAP:

There is a risk that…

Impact							
	Catastrophic	5					
	Major	4				• Citizens of Powys receive poor quality care (quality defined as safety, effectiveness and experience) from one or more of a range of providers	
	Moderate	3					
	Minor	2					
	Negligible	1					
			1	2	3	4	5
			Rare	Unlikely	Possible	Likely	Almost Certain
			Likelihood				

Patterson,Liz
20/04/2023 18:12:05

CORPORATE RISK DASHBOARD

Risk Lead	Risk ID	Main Risk Category	Risk Description There is a risk that:	SCORE (Likelihood x Impact)	Board Risk Appetite	Risk Target	At Target ✓/×	Lead Board Committee	Risk Impacts on
DoNM/ MD	CRR 003	**Quality**	Citizens of Powys receive poor quality care (quality defined as safety, effectiveness and experience) from one or more of a range of providers	**4 x 4 = 16**	Minimal	6	×	Patient Experience, Quality and Safety	Organisational Priorities Underpinning WBO 1 to 4

Key

Risk Appetite Descriptors and Categories

Risk Appetite	Description
Averse	Avoidance of risk and uncertainty in achievement of key deliverables or initiatives is key objective. Activities undertaken will only be those considered to carry virtually no inherent risk.
Minimal	Preference for very safe business delivery options that have a low degree of inherent risk with the potential for benefit/return not a key driver. Activities will only be undertaken where they have a low degree of inherent risk.
Cautious	Preference for safe options that have low degree of inherent risk and only limited potential for benefit. Willing to tolerate a degree of risk in selecting which activities to undertake to achieve key deliverables or initiatives, where we have identified scope to achieve significant benefit and/or realise an opportunity. Activities undertaken may carry a high degree of inherent risk that is deemed controllable to a large extent.
Open	Willing to consider all options and choose one most likely to result in successful delivery while providing an acceptable level of benefit. Seek to achieve a balance between a high likelihood of successful delivery and a high degree of benefit and value for money. Activities themselves may potentially carry, or contribute to, a high degree of residual risk.
Eager	Eager to be innovative and to choose options based on maximising opportunities and potential higher benefit even if those activities carry a very high residual risk.

Executive Lead:	
CEO	Chief Executive
DPCCMH	Director of Primary, Community Care and Mental Health
DoNM	Director of Nursing and Midwifery
DFIIT	Director of Finance, Information and IT
MD	Medical Director
DPH	Director Public Health
DWOD	Director of Workforce and OD
DoTHS	Director of Therapies and Health Sciences
DPP	Director of Planning and Performance
BS	Board Secretary
DoE	Director of Environment

Risk Scoring

LIKELIHOOD	IMPACT				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Almost Certain 5	5	10	15	20	25
Likely 4	4	8	12	16	20
Possible 3	3	6	9	12	15
Unlikely 2	2	4	6	8	10
Rare 1	1	2	3	4	5

Very Low	1-3	Low	4-8	Moderate	9-12	High	15-25

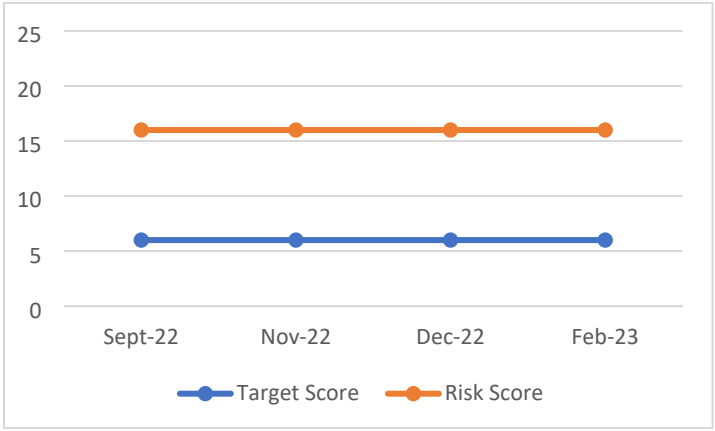
RISK APPETITE	
Category	**Appetite for Risk**
Safety	Averse
Quality	Minimal
Regulation and Compliance	Cautious
Reputation and Public Confidence	Cautious
Performance and Service Sustainability	Cautious
Financial Sustainability	Cautious
Workforce	Cautious
Partnerships	Open
Innovation and Strategic Change	Open

CRR 003 **Risk that:** citizens of Powys receive poor quality care (quality defined as safety, effectiveness and experience) from one or more of a range of providers	**Executive Lead:** Director of Nursing and Midwifery, Medical Director **Assuring Committee:** Patient Experience, Quality and Safety
Risk Impacts on: Organisational Priorities underpinning WBO 1 to 4	**Date last reviewed:** February 2023

Risk Rating

(likelihood x impact):
Inherent: 4 x 5 = 20
Current: 4 x 4 = 16
Target: 2 x 3 = 6

Date added to the risk register
Risk Updated
September 2022



Rationale for current score:

- Intelligence from incidents, concerns and complaints
- Intelligence from patient engagement
- Intelligence and communication from all stakeholders and partners
- Increased pressure on the NHS as a result of multiple factors (aging population, winter pressures, post Covid-19 pandemic)

Controls (What are we currently doing about the risk?)

- Integrated Performance Framework
- Powys Clinical Audit plan
- Internal Audit annual plan of audits
- NHS Wales collaborative management groups and associated peer groups
- Collaboration with the Delivery Unit (NHS Wales)
- Review of CQC and HIW reports for all providers where Powys residents receive care
- Triangulation of concerns, complaints (PTR) and incidents
- Operational arrangements for operational delivery (e.g DCG)
- Partnership with PCC
- Communication and engagement with the public and stakeholders

Mitigating actions (What more will we do?)

Action	Lead	Deadline
Improve and refine the Integrated Performance Framework	DoPP	Sept 2022
Monitor fundamentals of care (provider services)	DoNM	Ongoing
Mortality Reviews	MD	Ongoing
Address inequalities of access	DoPP/ DOMHP	Ongoing
Implement Patient experience system (Civica)	PC DoTH	Dec 2022

Current Risk Rating	Update including impact of actions to date on current risk score
4 x 4 = 16	This risk will continue to be reviewed at PEQs. The integrated Quality Report informs the Committee of triangulated data. Key matters at February meeting include an update of Maternity Services (Powys Provider), preparation for the implementation of the Duty of Quality and Duty of Candour and progress with the National Nosocomial Framework. Focus on concerns/ complaints will now focus on themes and trends identifying priorities for learning, now that process matters have been addressed. Integrated Performance framework - Approved by the Board in September 2022, implementation to be reported through Delivery and Performance Committee. A project group has been established, chaired by the AD Performance and Commissioning, with representatives from commissioning, performance, finance, nursing, workforce and service group colleagues. Duty of Quality and the implementation of a Total Quality Management System as part of the IPF will be Powys THB vehicle for quality control and quality planning.