Concerns

Final Internal Audit Report

January 2022

Cwm Taf Morgannwg University Health Board

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Executive Summary

Purpose

To determine the adequacy of systems and controls in place in relation the management of concerns raised.

Overview

We have issued Limited Assurance in this area. The significant matters which require management attention include:

- Lack of any Standing Operating Procedures to ensure consistent practices across ILG that align to the Health Board's Concerns Policy.
- Limited evidence to support training that has taken place to date and no training needs analysis undertaken to determine who needs to be trained.
- The Concerns policy quality assurance checklist is not used. Whilst there are forms of quality assuring in place, this was not always evidenced or timely.
- The lessons learnt arising from concerns is not happening in a consistent way, with only ad-hoc examples in place and seemingly no cross ILG learning happening.
- Monitoring from a Health Board perspective, especially around trends analysis across ILGs and holding ILGs to account could not be evidenced.

Further matters arising concerning the areas for refinement and further development have also been noted (see Appendix A).

Report Classification

Limited	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved

Assurance summary[1]

	Assurance objectives	Assurance
1	Policy and procedures	Limited
2	Complaints management system	Reasonable
3	Training	Limited
4	Resources	Reasonable
5	Accurate records	Reasonable
6	Quality assurance	Limited
7	Analysis of data for trends and lessons learnt	Limited
8	Monitoring and reporting	Limited

[1]The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

	Key Matters Arising	Assurance Objective	Control Design or Operation	Recommendation Priority
1	Policy and operating procedures	1	Design	High
2	Capturing complaints	2	Operation	Medium
3	Training	3	Operation	High
4	Early resolution classification	2	Operation	Medium
5	Accurate records	5	Operation	Medium
6	Quality assurance	6	Operation	High
7	Re-opened cases	2	Operation	Medium
8	Aged open concerns	5	Operation	Medium
9	Lessons learnt	7	Operation	High
10	Monitoring within ILGs	8	Operation	Medium
11	Monitoring at Health Board level	8	Operation	High

1. Introduction

1.1 Our review of Cwm Taf Morgannwg University Health Board's (the 'Health Board') process for dealing with concerns was completed in line with the 2021/22 Internal Audit Plan. The relevant lead for the review is the Director of Corporate Governance & Board Secretary.

1.2 The Welsh Government NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (the 'all Wales guidance') set out the arrangements that health boards and trusts must have in place for the handling and investigation of concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a Responsible Body in Wales. The Putting Things Right ('PTR') guidance was published in 2013 and is the integrated process for the raising, investigation of, and learning from concerns.

1.3 From April 2020 the Health Board implemented a new operating model. This introduced an Integrated Locality Group (ILG) structure based around the three geographical areas of Merthyr Cynon, Rhondda Taf Ely and Bridgend. Each ILG is responsible for delivering services in their local area, and as such are now responsible for the investigation of the complaints received in relation those services. In addition, there is a corporate team providing oversight and support to the ILGs.

1.4 Records and information of all concerns raised are recorded in the Health Board's module of the 'Once for Wales Concerns Management System – Datix Cymru'. The new system was launched in the Health Board in early July 2021, with concerns raised prior to that date still retained in the previous version of the system.

1.5 The Health Board has a target of responding to 75% of complaints within 30 days. Between April 2020 and March 2021, the Health Board received 1,269 formal complaints. During this time, which includes the first and second wave of the pandemic, on average, 57% of complaints were responded to within 30 days. At the time of our audit fieldwork in August and September 2021, this had risen to 71%.

1.6 The pandemic has had a significant effect on the Health Board's operations, and we have considered this when undertaking our work.

1.7 The risks we considered while doing this review were as follows:

- Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen.
- Complaints are not investigated in timely, open, honest, consistent or impartial fashion, causing distrust in the process.
- Financial implications where there is a failure to meet regulatory requirements for responses.
- Reputational damage.

1.8 At the time of our work, the Welsh Risk Pool were reviewing the PTR redress and claims processes within the Health Board. As such, to avoid duplication, our review focussed on those processes the Health Board has in place to effectively manage complaints and concerns.

1.9 Concerns relating to Primary Care and Medicines Management sit outside the remit of the ILGs and as such were not considered within the scope of this audit.

2. Detailed Audit Findings

Objective 1: A framework for managing complaints is in place including an overarching Health Board policy that sets out roles, responsibilities and accountability and Standard Operating Procedures to promote a consistent approach to investigations and subsequent learning.

2.1 The Health Board's 'Concerns Policy & Procedures' became operational in January 2020. It outlines the roles and responsibilities of specific roles such as the Senior Investigations Manager. In addition to this policy are other supporting corporate documents. These are: a 'Policy for Handling Persistent and Serial Complaints'; a 'Corporate Process for Complaints Handling'; a 'Corporate Complaints Process' flowchart, and a flowchart for dealing with 'Complaints from MPs, MSs, councillors and representatives'.

2.2 The concerns policy predates the Health Board's operating model arrangements, so does not reflect the roles and responsibilities relating to concerns and complaints that are undertaken by the three ILGs, or their interface and liaison with the Corporate Concerns team. **Matter Arising 1**

2.3 The processes and flowcharts referenced in 2.1 vary in their level of detail and most make no reference to the ILGs. Furthermore, the ILGs do not have their own local Standard Operating Procedures (SOPs). As such, there are no documents in place that outline the active management, oversight, investigation, and escalation processes that underpin concerns and complaints. **Matter Arising 1**

Conclusion:

2.4 Whilst the policy and associated documents provide a broad framework, that aligns with the all-Wales guidance and the PTR guidance, these documents are not up to date and do not provide the expected level of detail required to ensure the consistent management of concerns and complaints across the Health Board.We have provided limited assurance against this objective.

Objective 2: An effective complaints management system is in place to i) enable timely responses to complaints, ii) enable effective quality assurance of complaint responses and iii) minimise the occurrence of 're-opened' complaints.

2.5 The Health Board's webpages relating to concerns and complaints provides public facing guidance and contact details for each of the ILGs as well as the Corporate Concerns team. However, numerous email addresses and phone numbers are listed which may cause confusion to the public if they are unaware of which ILG

their concern relates to and may result in the inconsistent handling of concerns as they enter the system. **Matter Arising 2**

2.6 Where possible, an effort should be made to resolve concerns within two working days of when the concern was raised. Where this is not achievable the concern status should be classed as 'formal', and a full investigation undertaken. Our review of data in relation to cases that were closed and classified as 'early resolution' found a number of errors, mostly within one ILG. As a consequence, the ILG appears to have over reported the number of cases closed at the 'early resolution' stage. It appears that there was no monitoring either within the ILG or corporately to identify and prevent such errors occurring. **Matter Arising 4**

2.7 Our detailed testing of 'early resolution' concerns in each of the ILGs confirmed that the initial grading and classification of the concern was correct, there was suitable narrative in Datix to support the closure, and in most cases the concern was resolved to the satisfaction of the complainant with a written record retained.

2.8 Occasionally closed concerns end up being re-opened. For our sample of re-opened concerns all had valid reasons for reopening, mostly due to the complainant contacting the Health Board for clarity, or to express dissatisfaction, with their PTR response. However, the concerns policy states that cases should only be re-opened when there are new issues to investigate, and not if the complainant is dissatisfied. **Matter Arising 7**

Conclusion:

2.9 We have provided reasonable assurance against this objective. While the current systems that are in place to underpin timely access and response to complaints and avoid re-opening are working, more work needs to be done to refine the processes in place, ensure alignment to policies, and undertake monitoring of activity to identify outliers and allow sharing of best practice across ILGs. Findings in relation to quality assurance processes have been captured under objective 6.

Objective 3: Training is provided to staff to support effective raising and reporting of complaints, recording on Datix and the subsequent investigation and response process.

2.10 In July 2021 the new version of Datix 'Once for Wales' became operational in relation to concerns. All concerns should be logged on the system and categorised. The system is then used to track the progress of the investigation with notes and evidence saved to the concern file to record the work done and lessons learnt. There are three levels of system training depending on a person's role: work is ongoing to provide the necessary training to relevant staff. However, at the time of our review there were no records of who had been trained and at what level. **Matter Arising 3**

2.11 The Health Board has a Patient Experience training plan which focusses on the approach to Putting Things Right (PRT) concerns and complaints training. Three levels of training have been identified, from general awareness through to performing quality assurance functions. The plan includes a framework to identify which staff groups need to undertake which training, but a training needs analysis

to identify individuals falling into the various groups as not been carried out. **Matter Arising 3**

2.12 Whilst some training has been delivered, we have not been able to determine how this links to the training plan, nor have we seen detailed records of who attended the training. Different approaches were adopted by the ILGs in relation to who they nominated to attend the training. **Matter Arising 3**

Conclusion:

2.13 Whilst it is encouraging that the Health Board has devised a training plan in relation to concerns and has started rolling out training on the new Datix system, improvements are required to ensure the right people are attending the required level of training for their role (both concerns and Datix training), and that records are retained of those that have been trained. We have provided limited assurance in this area.

Objective 4: Suitable resources are in place to allow the i) effective investigation of complaints and ii) oversight of them.

2.14 The Concerns policy requires staff trained in concerns investigations to be released or have their duties appropriately adjusted to enable them to undertake or support investigations when required. Our testing indicated that suitable levels of resource were in place to allow the investigation of concerns. However, our testing findings outlined under objective 3 identified that not all staff carrying out investigations have had recent training.

2.15 Within each ILG the Heads of Quality and Safety and the ILG senior managers (the Triumvirate) have oversight of the concerns cases in their ILG through the weekly summary reports provided to them. As described under objective 8, improvements are needed around the monitoring process.

Conclusion:

2.16 Whilst we have not raised any specific Matters Arising under this objective in relation to resources, we have identified some related issues that have been reported under other objectives. As such we have provided reasonable assurance in this area.

Objective 5: Accurate records are retained of all complaints, their investigation (if not resolved informally) and outcome.

2.17 Whilst there are no standard operating procedures in place, the Concerns policy provides an overview of the steps to be followed when concerns are raised. The details of all actions undertaken in relation to each concerns investigation, and any associated correspondence and paperwork, should be saved in Datix by the investigating officer.

2.18 We tested a sample of cases across the ILGs to determine their compliance with the policy. There was no evidence in any of the cases sampled of an offer to meet the complainant in the first two days to discuss their concern. **Matter Arising 5**

2.19 Other instances of non-compliance included for example: acknowledgement letters issued outside the two-day timeframe; lack of evidence of multi-disciplinary involvement in investigations; quality assurance checks not being carried out in a timely manner; 'Putting Things Right' (PTR) letters containing errors and not always signed off by a member of the ILG Triumvirate in a timely manner. **Matter Arising 5**

2.20 We looked at 'aged' open concerns data and identified that some ILGs have a high number of cases breaching the 30-day target, with many cases still open after three and six months. Our review of a sample of case notes identified that a number did not include the expected documentation including sufficient information to establish the reasons or justification for the case being open that length of time. **Matter Arising 8**

Conclusion:

2.21 Across the ILGs, while there were some gaps in the information, for the cases that we sampled, most of the information was complete, and as such we have provided reasonable assurance in this area.

Objective 6: Complaint investigations and corrective actions are quality assured and approved by appropriate officers.

2.22 The Concerns Policy contains a quality assurance checklist for management to use. The checklist covers the investigation process through to the PTR response letter and the plans to share learning. In addition, one of the corporate process flowcharts refers to PTR letters needing to be sent to the corporate team for quality checking ahead of sending to the complainant. Our testing identified that neither of these processes are followed. **Matter Arising 6**

2.23 For the majority of the cases that we tested we saw evidence of the ILG Triumvirate undertaking quality checks and signing off the PTR letters. However, this was not always done in a timely manner. **Matter Arising 6**

2.24 However, we could not evidence quality checking taking place within the Clinical Service Groups (CSGs) where the investigations were being carried out. This is something we were informed should be happening, but in the absence of any Standard Operating Procedures, there is nothing documented to confirm this. **Matter Arising 6**

2.25 Finally, there does not appear to be any reviews or monitoring of quality at a corporate level to ensure there is consistency across the ILGs and for the sharing of learning. **Matter Arising 6**

Conclusion:

2.26 Whilst our testing has identified that there are some quality assurance processes in operation across the ILGs, these are not in line with what is recorded in the policy, corporate flowchart or what we were informed should be taking place within CSGs. As such we have provided limited assurance in this area.

Objective 7: Analysis of complaints data takes place allowing trends or themes to be identified, follow up actions monitored, and the regular sharing of learning across ILGs.

2.27 The Concerns policy states the importance of learning from the outcomes of concerns raised. While we saw examples of CSGs and ILGs sharing learning within their areas, we did not see any documentation on how the Health Board is approaching the sharing of learning, though we are aware they are in the process of developing a 'learning framework'. **Matter Arising 9**

2.28 Fortnightly meetings are held between the ILG Heads of Quality & Safety and the Interim Head of Concerns, Redress & Legal. We were informed these meetings incorporate the sharing of learning and the following up on actions. As the meetings are not documented we could not establish what is being discussed. We were also made aware of the 'Shared Listening and Learning Forum'. However, at the time of our audit field work the Heads of Quality & Safety informed us that these meetings were stood down due to the pandemic. We understand that they have re-convened, and the three Heads of Quality & Safety should be attending. **Matter Arising 9**

Conclusion:

2.29 Whilst there was some evidence of reviewing concerns information to identify trends and the subsequent sharing of lessons learnt, this was not taking place in a consistent way either within ILGs or across ILGs. The Health Board wide meetings where learning should be shared were either happening informally (not documented), or not happening regularly. We have provided limited assurance in this area.

Objective 8: Effective arrangements are in place to monitor and report the progress and outcomes of complaints and their investigation at appropriate levels within the Health Board.

2.30 The ILG Triumvirates are provided with weekly concerns and complaints activity tracker reports from the Health Board's Datix team. We saw some evidence of the CSGs, the ILG Heads of Quality & Safety and ILG Quality & Safety groups reviewing data. However, the detail presented and associated meeting notes varied so we could not see if there were consistent levels of scrutiny.

2.31 Whilst each ILG receives its own data, and some Health Board Executives receive data for all three ILGs there does not appear to be an analysis of data across the ILGs. Our testing of early resolution cases and re-opened cases identified a need for more detailed analysis to be undertaken to allow trends and themes to be identified and shared learning on processes followed to take place. **Matter Arising 11**

Furthermore, there does not appear to be clear oversight and monitoring of concerns data at a Health Board level. The link between those who are responsible corporately for concerns management and the ILGs is not clear. We have not been able to determine where the ILGs are being held to account for their performance, or where the monitoring of concerns in relation to corporate teams or those

concerns received directly by the CEX office from MPs, MSs or Councillors takes place. The lack of any Standard Operating Procedures means the escalation of when concerns should be referred from ILGs up to the Health Board Executive is ambiguous. **Matter Arising 11**

Conclusion:

2.32 Whilst we could see some evidence of monitoring taking place, there does not appear to be sufficient monitoring across the different areas and at varying levels within the Health Board. We have provided limited assurance in this area.

Appendix A: Management Action Plan

Matter Arising 1: Policy and Standard Operating Procedures not up to date (Control Design)	**Impact**
The Health Board's 'Concerns Policy & Procedures' document pre-dates the implementation of the current operating model in the Health Board. As such, it reflects concerns and complaints management undertaken from a corporate centralised perspective and makes no reference to the ILG structure that exists under the operating model. A number of supporting documents exist, for example a 'Corporate Complaints Process' flowchart, but none of these are referenced or appended to the overarching policy. Detailed Standard Operating Procedures (SOPs) are not in place. Such documents would outline the responsibility and detail the processes at a corporate and ILG level. SOPs may include management, investigation, quality checking, oversight and monitoring of concerns and complaints and the escalation of serious complaints. The Corporate Concerns Team felt the ILGs should be applying the corporate process documents. When we discussed with the Heads of Quality & Safety in the ILGs, each made reference to the concerns policy (referenced above) and supporting documents. However, our review of these supporting documents identified that some are not very detailed, and all relate to the Corporate Concerns Team, with minimal reference to ILGs and the processes they should follow. As such, it appears that responsibilities are not clearly articulated within the guidance. Furthermore, we identified that some aspects of the concerns process are not being followed. For example, draft response letters are quality checked within the ILG but not sent to the Corporate Concerns Team for quality checking, which is a requirement of the corporate complaints process flowchart.	Complaints are not investigated in timely, open, honest, consistent or impartial fashion, causing distrust in the process.

Recommendations	Priority
1.1 The concerns policy should be reviewed and updated to accurately reflect the structure, roles, responsibilities and active involvement of the corporate function and the ILGs in respect of the management, investigation and reporting arrangements relating to concerns and complaints.	**Medium**
1.2 A comprehensive set of Standard Operating Procedures should be developed setting out the process to follow from the point a concern or complaint is received though to the provision of a response. The SOP should include concerns from all sources such as those received via the dedicated email accounts, those made in person or issues raised via local MPs or MSs. The responsibilities of the Corporate Concerns Team and the ILGs should be clearly set out.	**High**

Agreed Management Action	Target Date	Responsible Officer
1.1 Changes will be made to the Concerns Policy and management process in line with the Concerns Improvement project. This will be undertaken via a collaborative process between Corporate and the ILGs and in light of any changes to the Operating Model following the current review.	June 2022	Interim Head of Concerns, Redress & Legal
1.2 Review the PTR Guidance alongside the CTM structures to identify what Standard Operating Procedures are required and develop and implement to support the new process.	June 2022	Interim Head of Concerns, Redress & Legal

Matter Arising 2: Methods for raising a concern (Operation)		**Impact**
The correct phone and email contact details for the Corporate Concerns team and the three ILG Governance teams are available on the concerns and complaints page of the Health Board's internet site. Complainants are also referred to the Patient Advice and Liaison Service (PALS) for support in raising a concern, but at the time of our fieldwork PALS teams were only operating in the Bridgend ILG area. The Chief Executive's contact details are also listed on the website as a route to raising a concern. We also note that public concerns are also received by the Health Board via MPs, MSs, and Councillors. While having a number of different ways to raise concerns is good, there is a risk that inconsistencies in recording classifying them may occur. Furthermore, it is not clear within the three ILGs what other forms of public information is available to raise awareness of the Health Board's concerns and complaints process, for those patients that do not have access to the internet.		Reputational damage if issues are not brought to the Health Board's attention.
Recommendations		**Priority**
To ensure consistency, a more simplified approach to receiving concerns and complaints into the Health Board should be developed. The Health Board should ensure that relevant and up to date information is available across their respective areas to ensure that it is clear who and how patients, carers and families contact, should they have a concern or complaint to report.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
Review the Health Board website and any other documentation i.e. (posters, leaflets) in respect of how to raise a concern, to ensure there is a single point of	June 2022	Interim Head of Concerns, Redress & Legal

access. This will reflect a new process for the management of concerns as per 1.1 above.		

Matter Arising 3: Training plans and activity(Operation)	**Impact**
Concerns training falls into two categories, each has three levels of training that is determined by role and responsibility. These are set out below: <u>Once for Wales Datix training</u> The new system became operational in July 2021. We understand that complaint handlers have received the required training (level 1), and training has commenced for complaint reviewers (level 2) and responsible managers (level 3). However, we have not seen a record of who has been trained on the new system, or to what level each individual has been trained. <u>Putting Things Right (PTR)/Concerns training</u> Our findings relating to PTR training are: • Whilst a detailed training plan exists, a training needs analysis has not been carried out to identify the staff who require training. From our meetings with the Corporate Concerns Team and the ILG Heads of Quality & Safety, it is not clear who is responsible for identifying training needs and delivery. • We understand that general PTR awareness training (level 1) forms part of the staff induction programme, but there are no records to confirm who has received the training. • Training around aspects of the concerns process was delivered in early 2021 to the ILG Concerns Teams by NWSSP Legal and Risk Services, though it is unclear what level within the Concerns Training Plan this relates to. • In February 2021, the ILG Concerns teams received 'investigation skills' training provided by the Public Service's Ombudsman for Wales (PSOW) office. This appears to equate to level 2 training (root cause analysis and process for managing concerns) outlined in the training plan, but it is not clear. Whilst we have been provided with some names, no formal records have been kept corporately or within ILGs of who attended the PSOW training.	Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen. Complaints are not investigated in timely, open, honest, consistent or impartial fashion, causing distrust in the process.

• There have been different approaches across the ILGs as to who was invited to attend the training. Within RTE ILG the PSOW training was arranged for the ILG Concerns Team plus some of the senior medical and nursing staff who undertake investigations. Within MC ILG only the Concerns Team were offered the training. We understand that training for those who undertake investigations was due to take place imminently. No response was received from Bridgend ILG in relation to PSOW training participants. • Our testing of a sample of ten concerns investigations in each ILG, identified that more people undertake investigations than those recorded as trained. However, we acknowledge that investigators may have received training in the past. • There was no evidence to confirm who has participated in level three training (quality assurance), though we understand that the Head of Quality & Safety in the three ILGs have been trained.	
Recommendations	**Priority**
3.1a A training programme should be developed and rolled out across the Health Board to ensure that staff are suitably trained for the roles they are performing in relation to the Concerns process. 3.1b A training needs analysis should be undertaken in each ILG and for corporate teams to identify the staff that fall into the three levels of training outlined in the Concerns Training Plan. The PADR process could be used in the future to help identify training needs.	**High**
3.2 Those staff who may have received training previously or are experienced in the role of investigator or quality assurance, should receive 'refresher' training to ensure awareness of current processes and the application of consistent practices across the Health Board.	**Medium**
3.3 Records of all training attended in relation to both PTR/Concerns training and Datix Once for Wales Training should be retained.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
3.1a CTM Concerns Management training programme to be developed encompassing Putting Things Right, the Once for Wales Concerns Management System and Welsh Risk Pool procedures, more specifically Learning from Events Reports. 3.1b Training Needs Analysis Template to be developed following development of Concerns Management training programme. To be shared with the ILGs for completion and identification of all staff who should receive the training.	April 2022 June 2022	Interim Head of Concerns, Redress & Legal Interim Head of Concerns, Redress & Legal/ILG Heads of Quality & Safety
3.2 This will be picked up as part of the Training Needs Analysis in 3.1b and where relevant, training will be provided as part of the training programme.	June 2022	Interim Head of Concerns, Redress & Legal
3.3 Undertake scope on training record management and how this is captured within CTM if it is not retained within ESR Discussion with ESR team to ascertain whether training records can be included on ESR for Concerns Management training. Discussion with Organisational Development regarding retention of training records and how this links to PADRs.	Feb 2022	Interim Head of Concerns, Redress & Legal

Matter Arising 4: Classification of early resolution concerns (Operation)	Impact
Where suitable, efforts should be made to achieve an early resolution (within two working days) to concerns raised. It is our understanding that the 'early resolution' category is attributed to a concern by a concerns handler based on the information contained in the initial concern. A record of the concern resolution should be recorded on Datix. If the concern cannot be resolved early, then it should be recategorised as a 'formal concern' and the normal investigation process begins. We analysed concerns that were closed between the period January to July 2021. This is set out in the table below:	Reputational damage and loss of public trust in processes where concerns and complaints are not resolved promptly. Or in contrast, where they are closed promptly but not investigated to the satisfaction of the complainant.

	Total concerns closed (Early & Formal)	% of total	Number resolved at 'Early resolution'	% resolved early	% of early resolution cases closed within two days	Number escalated to 'Formal'	% escalated to formal
Bridgend	292	25%	53	18%	98%	239	82%
MC	386	32%	138	36%	95%	248	64%
RTE	339	28%	130	39%	78%	209	61%
Corporate	183	15%	78	43%	92%	105	57%
Total	**1,200**	**-**	**399**	**-**	**-**	**801**	**-**

The table shows that Bridgend close far less of their concerns at early resolution stage than the other areas in the Health Board. We have not been able to determine the reason for this.

We also note that within RTE, concerns that were initially identified as 'early resolution', but not closed within two days, are not being re-categorised with the same rigour as shown by other areas of the Health Board. 29 of the 130 (22%) concerns closed as 'early resolution' appear to be erroneous. For example, one case took 191 days to close, yet it was still classified as 'early resolution'. The lack of SOPs and training may be contributory factors to these errors.

We have been unable to determine what monitoring or oversight there is of early resolution cases at either an ILG level or collectively, and therefore where outlying information as identified in the table and testing above would be reviewed and challenged.

Recommendations	Priority
4.1 A review should be carried out to establish why Bridgend ILG is closing fewer concerns at an early resolution stage in comparison to the other ILGs. The review should include identifying if there is a link between concerns closed at early resolution stage and concerns re-opened. Any learning identified from the review should be shared across the ILGs and where necessary processes followed should be captured in a Standard Operating Procedure.	**Medium**
4.2a Management should understand why RTE has not been re-categorising early resolution concerns that were not resolved in the timeframe and take appropriate action to resolve and accurately record in Datix. 4.2b To ensure consistency, a Standard Operating Procedure (SOP) should be in place outlining the process for re-categorising concerns, including who is responsible for performing this task. Training should be provided where necessary.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
4.1 Audit of Complaints Management to be reintroduced looking at all aspects of complaints management. Audit will commence with BILG to address this risk	April 2022	Complaints Manager

and will then be conducted across the other sites. A programme of on-going audit will be re-introduced.		
4.2a As 4.1 above 4.2b Standard Operating procedure to be developed as part of a suite of SOPs outlined in 1.2 above.	April 2022 April 2022	Complaints Manager Interim Head of Concerns, Redress & Legal

Matter Arising 5: Accurate concerns records (Operation)	**Impact**
We tested a sample of ten concerns from each ILG to ensure compliance with the 'Concerns Policy & Procedures' document. The table below summarises where we identified instances of non-compliance.	Complaints are not investigated in timely, open, honest, consistent or impartial fashion, causing distrust in the process.

Area of policy non-compliance	**Bridgend ILG**	**MC ILG**	**RTE ILG**
Incorrect initial classification of concern	1	0	1
Offer of a meeting to discuss concern in first 2 days not evident	10	10	10
Acknowledgement letter issues (e.g. including timeliness of letter and evidence retained on Datix)	2	1	0
Investigation process issues (e.g. including prompt commencement, evidence of multi-disciplinary involvement, Datix fully completed, delays in clinician responses)	2	9	1
Quality assurance checks not done in a timely manner	0	1	3
Letters not provided to complainant to explain delays	0	0	1
PTR letter quality issues (e.g including not empathetic, containing jargon and errors, not signed by member of ILG Triumvirate, not signed in a timely manner and lack of offer to meet)	7	1	2

Our testing identified that there appears to be some aspects of the process that are referenced in the Concerns policy that the ILGs are not doing. The policy states '*Attempts should always be made to contact the person who raised the concern to have a discussion with them prior to the acknowledgement going out to thank them for raising the concern, offer an apology that they have needed to do so, and offer a meeting with the manager of the area or clinicians responsible for services concerned'*. If contact is being

made with the complainants and offers of meetings made, then none of the ILGs are documenting this in Datix. Given that none of our sample of 30 had this information, which would suggest that the ILGs were not aware of this requirement in the process.

We also note from our testing that MC ILG appears to have a higher frequency of non-compliance in relation to the investigation process, with the main issues being around information not being fully documented in Datix and delays in investigators receiving responses from clinicians.

Bridgend ILG had a higher frequency of non-compliance in relation to the production and content of the PTR letter. Information about these issues and the other quality assurance aspects identified can be found in Matter Arising 6 below.

For most of the cases that we reviewed across the ILGs a limited level of detail was recorded in Datix to document the investigation work carried out and the subsequent learning shared.

Our testing also identified one potential data breach incident in MC ILG that warranted the need to complete a Datix incident form and for the Information Governance Manager to be contacted. This process did not take place for over three weeks after the concern was raised.

Recommendations	Priority
5.1 For each concerns investigation undertaken, in the absence of detailed Standing Operating Procedures, the process outlined in the Concerns Policy and Procedure documents should be followed. Comprehensive notes and evidence should be added to Datix in a timely manner to support the process followed, the investigation carried out and the lessons learnt. Where aspects of the policy are not being undertaken at all, it should be established if this is due to staff not being aware of this aspect of the process or if the policy is in fact out of date and in relation to current practices.	**Medium**
5.2 Where there is a potential data breach, the necessary Datix Incident Forms should be completed and the Information Governance Manager notified promptly.	**Low**

Agreed Management Action	Target Date	Responsible Officer
5.1 To be included in training programme as per 3.1a and 3.1b above	April 2022	Interim Head of Concerns, Redress & Legal
5.2 To be included in training programme as per 3.1a and 3.1b above	April 2022	Interim Head of Concerns, Redress & Legal

Matter Arising 6: Quality assurance processes (Operation)	**Impact**
The Concerns policy contains a quality assurance checklist, but it is not used. While not in the Concerns Policy, we understand that CSG management should carry out some form of quality checking ahead of the PTR letter being forwarded to the ILG Triumvirate for sign off. We saw no evidence in Datix of these checks taking place. In addition, the 'Corporate Process for Complaints Handling' document states that draft PTR letters should be 'sent to Ynysmeurig House for quality checking'. The document does not specify who is to receive the draft letter. Our testing confirmed that this process is not happening. Furthermore, we saw no evidence of corporate level oversight or retrospective quality assurance checks to facilitate learning and improvement. We looked at PTR response letters to confirm that they were clear and addressed the concern raised, the content was empathetic and showed concern, and there was evidence of quality checks by management. A small number of issues were identified in all ILGs as outlined in the table in Matter Arising 5. Points to draw attention to are: • Two instances in Bridgend in relation to the letter content and tone. One letter was extremely lengthy and contained a lot of technical content in relation to medication (though we acknowledged these terms may be known to the patient). The second letter was found to contain grammatical and typographic errors. • Three instances in RTE and one in MC where the time taken to quality check and sign off the PTR letter by the ILG Triumvirate was lengthy, up to eleven weeks. • One instance in Bridgend where the final PTR letter had been signed by the Head of Midwifery, however the individual had also been involved in the investigation as part of a previous role held. • One instance in RTE where the Head of Nursing had signed off the PTR letter. • One instance in MC where the copy of the letter retained in Datix was unsigned.	Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm, does not happen.

Recommendations		Priority
6.1a A SOP should be developed that documents the quality assurance processes underpinning the end stages of the investigation that lead to the issue of the PTR Concerns Response Letters. The SOP should include who is responsible for quality checking and how quality checks should be documented, including, if deemed necessary, the use of the checklist contained in the policy. Training on the required quality assurance process documented in the SOP should be carried out with relevant staff. 6.1b The Quality Assurance Checklist contained in Appendix 4 of the Concerns Policy should be reviewed and a decision made regarding the expectation for it to be used.		**High**
6.2 Evidence should be retained of CSG management's contribution to the quality checking process of review and oversight of the investigation's outcomes and the draft PTR Concerns Response letters prior to their submission to an ILG Director for sign-off.		**Medium**
6.3 A process of retrospectively reviewing the quality assurance processes applied in ILG should be introduced at a corporate level to ensure oversight, challenge and facilitate learning.		**Medium**
6.4 All ILGs should ensure that the content of their PTR Concerns Response Letters are empathetic, showing concern and explaining with clarity the outcomes and lessons learned arising from the reported complaint. Letters should be independently reviewed and signed by an ILG Director in a timely manner.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
6.1a Standard Operating procedure to be developed as part of a suite of SOPs outlined in 1.2 above 6.1b QA checklist to be reviewed at the same time as the SOP is developed	April 2022 April 2022	Interim Head of Concerns, Redress & Legal

6.2 Standard Operating procedure to be developed as part of a suite of SOPs outlined in 1.2 above	June 2022	Interim Head of Concerns, Redress & Legal
6.3 To form part of the rolling corporate concerns management audit programme	April 2022	Interim Head of Concerns, Redress & Legal
6.4 This recommendation should be achieved following development of SOPs, Training and the QA process.	End of June 2022	Interim Head of Concerns, Redress & Legal

Matter Arising 7: Re-opened concerns (Operation)	**Impact**
The Concerns Policy and Procedures document states that '*if the complainant is dissatisfied with the response they receive in their PTR letter, then a meeting will be offered, however the case will not be re-opened if there are no new issues to investigate'*. The PTR Concerns response letter issued to complainants provides a clear offer of a meeting to discuss the content of the investigation outcome with senior Health Board staff. However, each ILG Head of Quality & Safety informed us that if there is further contact from the complainant stating dissatisfaction of the letter's content, the case is reopened, which appears to contradict the policy. In the absence of a SOP to provide any clarity, it appears that cases are closed on Datix when the PTR letter is sent to the complainant. As such, there is no 'grace period' to allow complainants to contact the Health Board and take up the offer of a meeting. Without re-opening a case in Datix it is unclear how further narrative or documentation as a result of a meeting could be captured. During the period January to June 2021 Datix shows that there were 31 re-opened cases (1 in Bridgend, 3 in MC, 24 in RTE, and 3 Corporate). By comparison there were 1200 new complaints received during the same period. We tested all re-opened cases in Bridgend and MC and a sample of 5 in RTE, (therefore 9 in total) to establish the reason for re-opening and to ensure Datix records were updated. We identified that: • 8/9 cases the re-opening was to record evidence of subsequent meetings with the complainant, and not as a result of new issues to investigate, as set out in the policy. • 8/9 cases did not include narrative on Datix to confirm if CSG management and the ILG Head of Quality & Safety were updated as to why the concern was re-opened. From our sample, 3/9 re-opened cases (33%) originated from cases that were originally closed as early resolution (two from MC and one from RTE). In each case the concern was re-opened as the complainant felt that all aspects of their original concern had not been fully addressed. As we have identified in Matter Arsing 11, there does not appear to be any analysis undertaken of re-opened and early resolution cases to establish if there are any trends.	Additional resources are required to revisit cases previously closed. Reputational damage and perceived lack of trust and transparency in processes where concerns are not resolved satisfactorily first time.

Recommendations		Priority
7.1 Clarity should be sought, and information documented with a SOP as to when a case should be closed on Datix and the circumstances for when it can be re-opened. To avoid any confusion, information contained in a SOP and the Concerns Policy should align.		**Medium**
7.2 Prior to closing concerns at early resolution stage, some form of quality assurance process should be followed that ensures all aspects of the concern raised by the complainant have been adequately addressed, thus preventing the case being potentially re-opened at a later date. This process should be documented.		**Medium**
7.3 Where cases are re-opened the relevant CSG management team and ILG Head of Quality & Safety should be made aware of the re-opening and the reasons why.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
7.1 To be included in the development of SOPs as per 1.2 above	April 2022	Interim Head of Concerns, Redress & Legal
7.2 To be included in the development of SOPs and training as per 1.2, 3.1a and 3.1b above	June 2022	Interim Head of Concerns, Redress & Legal
7.3 Weekly report to be provided to the CSG teams and ILG Heads of Quality and Safety for review and monitoring on a routine basis.	February 2022	Datix Manager

Matter Arising 8: Review and monitoring of aged open concerns (Operation)	**Impact**
In July 2021 the Health Board had 219 open concerns cases, of which 117 (53%) had breached the 30-day response time target, and 27 (12%) had been open for more than six months. The breakdown is as follows:	Complaints are not investigated in timely, open, honest, consistent or impartial fashion, causing distrust in the process.

	Number open between 30 days and 3 months	Number open between 3 – 6 months	Number open over 6 months	Oldest opened
Bridgend	17	0	0	March 2021
Merthyr Cynon	21	10	16	February 2019
Rhonda Taf Ely	23	7	6	October 2019
Corporate	11	1	5	December 2019

We also tested a sample of 15 older cases to confirm: if the reason for the concern being open for a long time was recorded in Datix; there was evidence that appropriate management had been informed; and there was ongoing contact with the complainant since breaching the 30-day threshold. We note the following:

- 0/15 cases had recorded information to confirm that CSG management and the Head of Quality & Safety been updated on the reasons why the complaint remained open.
- 6/15 did not state reasons and justifications for the concern being open for the lengthy duration. (1 in Bridgend, 2 in MC, 3 in RTE)
- 4/15 of the cases had no evidence of ongoing contact with the complainant since breaching the 30-day threshold. (1 in MC, 3 in RTE)

Recommendations	Priority
8.1 In relation to aged open concerns, it should be ensured comprehensive Datix records are maintained including recording the reason / justification for why the case has remained open and that relevant management are aware of it remaining open.	**Medium**
8.2 Where cases remain open beyond 30 days, ongoing progress contact should be maintained with the complainant and evidence of this retained within Datix.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
8.1 Process already in place which includes dashboards, and is monitored via Patient Safety Executive Meeting. The importance of recording regular updates on Datix will be included as part of 3.1a training programme.	April 2022	Interim Head of Concerns, Redress & Legal
8.2 Will be addressed in the development of the SOPs as per 1.2 and included as part of the training programme as per 3.1a.	April 2022	Interim Head of Concerns, Redress & Legal

Matter Arising 9: Lessons learnt (Operation)	**Impact**
The Concerns Policy & Procedures refers to the need for arrangements to be in place to learn from the outcome of concerns. However, we did not see any guidance that sets out the arrangements or processes, referenced in the policy, that should be in place for ensuring Health Board wide learning arising from concerns and complaints. We have seen some examples of learning arising from concerns, complaints and serious incidents being shared. For example, in RTE a monthly newsletter is produced, and in MC some CSGs have specific governance and learning meetings. However, sharing only appears to happen within ILGs, and in some cases only within CSGs within an ILG. There are fortnightly meetings between the three ILG Heads of Quality & Safety and the Interim Head of Concerns, where we understand shared learning from across the ILGs is discussed. However, these meetings are not formally recorded and as such the extent to which the sharing of learning from concerns is discussed is not clear, nor have we seen evidence that learning is disseminated across the ILGs. We understand that there have been 'Shared listening and learning forums' for wider discussions relating to the sharing of lessons learnt. When we were undertaking our August 2021 fieldwork, we were informed only two meetings had taken place due to the pandemic. We understand that these have re-convened. Furthermore, we have not seen evidence of sharing of best practice in relation to how concerns are being dealt with. For example, if one ILG has less re-opened cases than others, is this due to better investigation processes in that ILG that others could learn from.	Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen.
Recommendations	**Priority**
9.1a A formalised process should be put in place to ensure there is shared learning from the outcome of concerns, complaints and incidents and also the processes followed when dealing with concerns and complaints. This should include how data will be collected and analysed in order	**High**

to identify trends and patterns for example across CSGs, ILGs, specialities or by type of concern. Lessons learnt information should then be shared in a consistent way across the Health Board. 9.1b Subsequently, ILGs should ensure they have suitable processes and methods in place for the dissemination of lessons learnt across all of their CSGs.	
9.2 The 'Shared Listening and Learning Forum' meetings should be held on a regular basis and be appropriately attended by ILG and Corporate staff if they are to be an effective platform for learning to take place.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
9.1a Regular reports are provided from Datix and monitored via various groups and committees. The quality of information provided will be strengthened with engagement with the RL Datix team.	January 2022	Datix Manager
Development of a Learning Framework underway to ensure learning is captured from various avenues and shared across the organisation.	January 2022	AD Nursing & Patient Safety and Interim Head of Concerns, Redress & Legal
9.1b This will form part of the Learning Framework as per 9.1a and included in the SOPs as per 1.2.	January 2022	AD Nursing & Patient Safety and Interim Head of Concerns, Redress & Legal
9.2 The Listening and Learning forum Terms of Reference have been reviewed and the membership will be expanded to include more clinical and multi-disciplinary representation. The forum will also be held as an 'open forum' from Feb 2022 rather than by invitation only as previously.	February 2022	Joint Chairs of Listening & Learning Forum

Matter Arising 10: Monitoring within ILGs (Operation)	Impact
All three ILGs have CSG Quality and Safety meetings where concerns data is discussed. However, the detail presented and associated meeting notes varied. As such, the level of scrutiny and active monitoring and management of concerns is not clear. Again, within the three ILG Quality and Safety meetings there was evidence of concerns being discussed, but the frequency and depth of discussion varied across the ILGs. On a weekly basis ILG Directors are provided with a Datix Concerns Summary Report and a 'At a Glance Patient Care and Safety' briefing. The summary report provides a breakdown of the data by ILG. While we understand that these reports are reviewed at ILG Triumvirate meetings, we have been unable to confirm this as meetings are not documented. Serious concerns should be escalated to the ILG Triumvirate to ensure that they are aware of these matters and can monitor them appropriately. However, the policy does not provide guidance on this matter.	Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen.

Recommendations	Priority
CSGs and ILGs should be able to demonstrate through meeting minutes or action notes the level of scrutiny that takes place in relation to concerns data to ensure inactivity is challenged, progress is made, and management are fully sighted on the issues in their area of responsibility.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
Monthly performance meetings with the ILGs and CGS to continue.	Immediately	ILG Heads of Quality & Safety
CSG scrutiny panel to continue.	Immediately	ILG Heads of Quality & Safety
Weekly assurance meetings with the CSGs to continue.	Immediately	ILG Heads of Quality & Safety

Development of a standard agenda template and standard concerns management template with KPI to ensure consistent scrutiny across all ILGs Director of Corporate Governance to attend ILG Performance Meetings for the purpose of seeking assurance on concerns data.	February 2022 Jan 2022	Interim Head of Concerns, Redress & Legal Director of Corporate Governance

Matter Arising 11: Monitoring at Health Board level (Operation)	**Impact**
There does not appear to be clear oversight and monitoring of concerns data at a Health Board level. The link between those who are responsible corporately for concerns management and the ILGs is not clear. Whilst we have seen evidence of weekly reports provided to ILG Directors and some members of the Executive team, but we are unclear in which forum these reports are reviewed and discussed. We have not been able to determine where the ILGs are held to account for their performance, or where the monitoring of concerns in relation to corporate teams or those concerns received directly by the CEX office from MPs / AMs, takes place. Furthermore, we have not seen evidence of the ILG Triumvirates providing updates to the corporate team in relation to concerns that may warrant their attention and have Health Board wide implications. This may be linked to the lack of documented procedures setting out the circumstances when cases should be escalated. There does not appear to be monitoring of trends or themes cutting across all three ILGs to allow comparisons to happen. For example, we identified one ILG that had not been recoding early resolution cases and had fewer of these cases than the Datix reports were showing. However, this does not appear to have been identified by either the ILG or the Health Board. Some ILGs appear to be performing better than others, for example if they have less aged concerns open than others, or less re-opened cases. However, we cannot see that work is being done to establish the reasons why some ILGs are better performing and for lessons to then be shared. Similarly, we do not believe any form of analysis takes place to look for patterns, for example between early resolution cases and re-opened cases and again for lessons and good practice to be shared.	Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen.

Recommendations		Priority
Monitoring and scrutiny of concerns data at a Health Board level should take place to allow the Health Board to have a better oversight of concerns performance, make comparisons between ILGs, identify trends, identify areas for improvement, and facilitate the sharing lessons, best practice and better ways of working.		High
Agreed Management Action	**Target Date**	**Responsible Officer**
Weekly meeting are held with ILG Heads of Quality & Safety where concerns data is monitored and scrutinised. This will be strengthened by the establishment of a Senior Leadership Group to oversee the assurance and scrutiny of incidents, concerns and redress data to support the work of the Q&S Committee.	February 2022	Director of Corporate Governance

Matter Arising 12: Analysis of Datix (Design)		**Impact**
Our discussions with the ILG Heads of Quality & Safety identified that it is currently not possible to undertake any analysis or monitoring of near misses or low / no harm complaints due to difficulties Concerns were also raised around the functionality for ILG Heads of Quality & Safety to interrogate Datix at an ILG level to allow more meaningful monitoring, for example being able to identify the stage in the investigation process that the 30-day target is breached.		Learning from complaints does not take place meaning improvements in quality, reduction in adverse events and avoidable harm does not happen.
Recommendations		**Priority**
Consideration should be given to establishing if Datix will allow reports to be run that can identify near miss concerns or low/no harm complaints, so as to allow ILG Heads of Quality & Safety the ability to undertake analysis and learn from such events and hopefully prevent them becoming bigger issues. ILG Heads of Quality & Safety should be provided with the functionality and if necessary, training that allows them to interrogate Datix to a more granular level.		**Low**
Agreed Management Action	**Target Date**	**Responsible Officer**
Engagement with OFWCMS team to ascertain reporting functionality.	January 2022	Datix Manager
Review of current reporting functionality and devise a suite of reports to drive learning and improvement.	January 2022	Datix Manager/Interim Head of Concerns, Redress & Legal

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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