

Concerns Management Policy

This policy has been screened for relevance to equality. No potential negative impact has been identified so a full equality impact assessment is not required.

August 2025 - This policy has been updated to reflect changes in management structures in the Health Board

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1. PURPOSE

- 1.1 This is a high-level Policy supported by a number of standard operating procedures and should be read in conjunction with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“Regulations”) and Putting Things Right Guidance on dealing with concerns about the NHS from 1st April 2011. Please note that section 18-21 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, deals with the management of concerns relating to Primary Care Providers, who are not part of the Redress arrangements.
- 1.2 This policy should also be read in conjunction with the Health and Social Care (Quality and Engagement Act) (Wales) 2020 and in particular Part 3 of the Act which covers the Duty of Candour.
- 1.3 The Policy and its accompanying standard operating procedures detail the Health Board’s arrangements for handling concerns and redress notified by persons in respect of services provided by or under arrangements with the Health Board and covers concerns which are made up of:
- Complaints;
 - Patient Safety Incidents;
 - Redress cases made by patients up to the value of £25,000
- 1.4 The purpose of the Regulations is to:
- allow for redress to be provided in circumstances where there is a qualifying liability in tort in relation to the provisions of qualifying services. Redress may encompass apologies, explanations, action plans, remedial treatment and, if appropriate financial compensation.
 - develop a culture of accepting and supporting when dealing with concerns about treatment and care, with staff at all levels being encouraged to apologise for adverse outcomes and to offer explanations why they may have arisen and learn from the events.
 - ensure a patient/user focus rather than process-driven, approach is evident throughout the organisation, which also empowers people to raise concerns and have them dealt with as soon as they arise.
 - emphasise the importance of resolving concerns in a timely fashion, openly and honestly – a philosophy of “investigate once, investigate well”.
 - Ensure staff can be confident that investigations will be fair and impartial and that they will be supported throughout the process.

- Ensure learning from concerns and errors drives quality improvement and reduces adverse events, and avoidable harm to patients/users.

1.3 The purpose of the Health and Social Care Quality and Engagement (Wales) Act 2020, Part 3

□ The duty of candour comes into effect in relation to an NHS body if it appears to the health board that both of the following conditions are met:

- that a person (the “service user”) to whom health care is being or has been provided by the health board has suffered an adverse outcome.

Or

-that the provision of the health care was or **may** have been a factor in the service user suffering that outcome.

2. POLICY AIM

2.1 The aim of this Policy is to outline how the Health Board will comply with the Regulations and the Health and Social Care Quality and Engagement (Wales) Act 2020

2.2 In support of this the Health Board will publish arrangements for dealing with concerns in a variety of media, formats and languages and will include the internet and via posters and leaflets in public areas.

3. POLICY SCOPE

3.1 This policy applies to all staff, permanent and temporary, employed by or working within the Health Board, including independent providers who have responsibility to report, manage and or be involved in concerns raised.

The Policy covers concerns about:

- Services, care & treatment provided by the Health Board;
- Services, care & treatment provided by Health Board employed staff;
- Services, care & treatment provided by independent contractors;
- Services, care & treatment provided by the independent or voluntary sector which are funded by the Health Board.

Independent contractors are required to have a concerns procedure in place for their NHS patients that is in line with the regulations.

3.2 This policy does not apply to clinical services provided privately, even when provided within Health Board premises, but it will apply to concerns about Health Board services or facilities used as part of that private service.

4. POLICY FRAMEWORK AND DEFINITIONS

4.1 This Policy will be the overarching Policy for the management of concerns and redress and sets out the principles for the handling of the investigations. The Policy is supported by a number of standard operating procedures, provided as appendices, and also should be read in conjunction with the following documents:

- National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011;
- Putting Things Right Guidance on Dealing with Concerns about the NHS from 1st April 2011;
- Patient Safety Incident Procedure;
- Serious Incident Procedure;
- Complaints Procedure;
- Claims Management Policy;
- Inquest Policy;
- Being Open Policy;
- Welsh Risk Pool Standard 5 Concerns and Compensation Claims Management Standard.

4.2 Definitions

CONCERN Means any complaint, claim or reported patient safety incident to be handled under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

COMPLAINT Any expression of dissatisfaction made by a patient, carer, relative.

A formal concern is an expression of dissatisfaction either verbally or in writing that is graded as a 3, 4 or 5 and a relevant and proportionate investigation must be undertaken.

An informal concern is a verbal or written concern raised by a member of the public, that could potentially be resolved immediately or within 2 working days through discussion explanation or the provision of information to the satisfaction of the person raising the concern. The informal process would usually be applied to concerns graded 1 or 2. However there may be exceptions where a grade 3 will be managed informally if that is the request of the complainant.

PATIENT SAFETY INCIDENT Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS funded healthcare.

RESPONSIBLE BODY (a) a Welsh NHS body; (b) a primary care provider; or (c) an independent provider.

PATIENT	A person who has received or will receive clinical services from the Health Board.
CHILD	A person who has not attained the age of 18 years
OFFICER MEMBER	A member of the Board who is an employee of the Health Board
NON-OFFICER MEMBER	A member of the Board who is not an employee of the Health Board
QUALIFYING LIABILITY	As a result of a breach of duty of care, harm has been caused to the patient relating to the care/treatment provided by the Health Board.
INDIVIDUAL PATIENT TREATMENT REQUESTS	A request to the Health Board to fund healthcare for an individual patient that falls outside the range of services and treatments that the health board provides, including those specialist services secured through WHSSC

5. GENERAL PRINCIPLES FOR THE HANDLING AND INVESTIGATION OF CONCERNS

5.1 In accordance with the requirements of the Regulations, the Health Board's arrangements for the handling and investigation of concerns are intended to ensure:

- a single point of logging formal concerns for the submission of concerns;
- concerns are dealt with efficiently and openly; demonstrating the Health Board values;
- concerns are properly investigated and responded to in a values based manner;
- action is taken to establish the expectation of the person notifying the concern and to seek to secure their involvement in the process;
- persons raising concerns are treated with respect and courtesy;
- persons who notify concerns are advised of:
 - the availability of assistance to enable them to pursue their concern;
 - where they may obtain such assistance, if it is required;

- the name of the person who will act as the Health Board contact throughout the handling of the concern;
- consideration is given to the making of an offer of redress where the Health Board's investigation into the matters raised in the concern reveals that there is a qualifying liability in to whilst noting that Redress is not applicable to primary care providers;
- persons notifying concerns receive a timely and appropriate response within the bounds of receiving the appropriate consent;
- persons who notify the Health Board of concerns are advised of the outcome of the Health Board's investigation providing the appropriate consent has been received by the Health Board;
- appropriate action is taken in the light of the outcome of the investigation;
- the Health Board's arrangements take account of any guidance issued by Welsh Ministers.

5.2 In accordance with the requirements of the Health and Social Care Quality and Engagement (Wales) Act 2020 the Health Board's arrangements as part of the candour procedure must ensure:

- on first becoming aware that the duty of candour has come into effect the health board must give notification of this to the service user concerned or someone acting on the service user's behalf
- the health board must notify the service user or their representative of:
 - the identity of a person who has been nominated by the health board as a point of contact for the service user in respect of the candour procedure
 - any further enquiries carried out by the health board in respect of the circumstances in which the duty of candour came into effect
 - of the record-keeping arrangements for the investigation
- The health board must also
 - Offer an apology to the service user

5.3 Reporting Requirements – Duty of Candour

- As soon as practicable after the financial year-end the health board must prepare a report stating whether or not the Duty of Candour has come into effect with regards to the provision of health care. If this Duty has come into effect the report must;
 - Specify how many times this has happened during the reporting period;
 - Give a brief description of the circumstances in which the duty came into effect; and
 - Describe any steps taken by the health board to prevent similar circumstances from arising in the future.
- Note – where primary care services are provided on behalf of the health board, the service provider should prepare a report as described above for the health board to include in its report.

6. ROLES and RESPONSIBILITIES

6.1 The Regulations specifically require every NHS organisation to make it clear who is responsible, in their organisation, for the undertaking of three distinct roles each of which has clear and distinct regulatory responsibilities as set out below:

Strategic oversight of the arrangements

A nominated Non-Officer Member must assume responsibility for maintaining a strategic overview of the operation of the Health Board's arrangements (under the Regulations), particularly as regards ensuring that:

- the Health Board complies with these arrangements;
- the Health Board has arrangements in place to review the outcome of the investigation of any concern, in order to ensure that any deficiencies in actions or service provision that have been identified by the investigation, are acted upon and monitored;
- lessons learned are identified and promulgated throughout the Health Board in order to improve the services that it provides and to seek to reduce future risk.

In the case of SBU Health Board this role has been designated to the Chairman of the Quality and Safety Committee.

Responsible Officer

The Regulations specify that the Responsible Officer is responsible for the effective day to day operation of the Health Board's arrangements for dealing with concerns in an integrated manner. The Executive Director of Nursing is the Responsible Officer for SBU Health Board. [In relation to these regulations 'integrated manner' means that the process for dealing with concerns and claims management (where there is a duty under the Regulations to consider qualifying liabilities) are dealt with under a single governance arrangement.]

The Regulations allow for the functions of the Responsible Officer to be performed by the Director of Governance or any person authorised by the Health Board to act on behalf of the Director.

Senior Investigations Manager

Under the Regulations, the Senior Investigations Manager is responsible for:

- (a) the handling and consideration of concerns in accordance with this Policy;
- (b) performing such other functions relating to the handling and consideration of concerns as the Health Board may specify;
- (c) ensuring co-operation with such other persons or bodies as may be necessary to facilitate the handling and consideration of concerns.

The Head of Patient Experience, Risk & Legal Services is the Senior Investigations Manager for SBU Health Board.

In relation to 'performing such other functions relating to the handling and consideration of concerns as the Health Board may specify', the Head of Patient Experience, Risk & Legal Services is responsible for:

- The operation of the Ombudsman and Complaints Team, Legal Services Department, Datix Team, Risk Management Team, Serious Incident Team, Patient Experience Team and its resources;
- the development, integration and embedding of a comprehensive investigation and redress system for concerns,
- acting as the Health Board's Lead Investigation Officer; to lead, facilitate and provide advice on the investigation and analysis of concerns;
- overseeing the investigation of all serious concerns;
- personally investigating and analysing any individual concern when requested to do by the Executive Team;
- Overseeing the effective management and administration of the Datix system; •
Provide assurance to the Board on the Service Delivery Service Groups performance; •
Ensure lessons learned are shared across Service Groups.

6.2 Health Board - General

The Health Board is required by the Regulations to ensure that, at all times, the Senior Investigations Manager has a sufficient number of staff, of the required level of seniority and skills, to assist them in the carrying out of the functions that fall to the Senior Investigations Manager. Further, members of staff must receive adequate training to enable them to fulfill their responsibilities as specified.

The Regulations allow for the functions of the Senior Investigations Manager to be performed personally by them or by a person or persons authorised by the Health Board to act on behalf of the Senior Investigations Manager. If the Health Board should authorise any person to perform the required functions on behalf of the Senior Investigations Manager, the relevant details must be publicised.

The Health Board will ensure that all staff are informed about and receive appropriate training in respect of the operation of this Policy.

6.3 Non-Regulatory Responsibilities

6.3.1 Executive Team

The Medical Director, Director of Nursing and Patient Experience and Chief Operating Officer/Director of Therapies & Health Science have shared responsibility for quality and safety and will provide leadership and support to ensure that the aims of this policy are achieved. Taking into consideration the duty of candour, both of the above mentioned Directors are

responsible for providing authority to admit a breach of duty in respect of their professional accountabilities and consider the Service Group Directors views on admissions.

6.3.2 Service Group Medical Directors, Service Group Nurse Directors, Service Group Directors, are responsible for ensuring:

- that a culture of openness is promoted and encouraged to ensure that staff report all concerns that are patient safety incidents and that concerns are robustly investigated in line with the Regulations and acted upon;
- effective and practical local arrangements are in place across all provided and commissioned services to ensure full implementation of and compliance with this policy and that these are communicated to staff;
- that all staff receive concerns handling, redress, customer care & nipping issues in the bud, and Datix training pertinent to their roles and responsibilities;
- that there is appropriate cross Service Delivery Service Group co-ordination and liaison to achieve compliance with this policy;
- that adequate and appropriate support is made available to staff who are involved in/are the subject of a concern;
- that staff trained in investigations analysis within the Managed Service Delivery Service Groups and are released or have their duties appropriately adjusted to enable them to undertake or support investigations when required;
- that all information pertaining to individual concerns including the outcomes of all investigations are fully and accurately recorded in Datix, that all documents are saved against the Datix record, and all action plans are completed through the Datix system so that compliance can be easily monitored and reviewed;
- that all necessary actions are taken to prevent re-occurrence of issues arising from both individual and aggregated concerns;
- appropriate communication and reporting of relevant information to all appropriate Groups/Committees;
- that lessons are shared across services and the Health Board as relevant;
- create a culture across services where issues are resolved as they arise and informally as far as possible – not allowing unnecessary escalation or protraction of concerns;
- ensure that 80% of concerns are responded to within 30 working days and no concerns receive a response later than 60 working days (Regulatory maximum time period);
- Service Group Datix (patient safety) dashboard is reviewed regularly and core outcomes reported to Groups/Committees/Service Group meetings to assist decision making.

6.3.3 Every manager in the Health Board should:

- ensure all staff, volunteers and contractors are made aware of this policy and the requirements within it;
- create a culture where patient feedback is encouraged and timely action is taken to make any changes required;
- create a culture where all staff are supported and trained to address issues and concerns as they arise as to nip issues in the bud and to ask for help and assistance when required and not allow issues to fester and escalate;
- create and sustain an environment whereby staff feel supported to report concerns that are patient safety incidents and feel that these will be taken seriously and dealt with appropriately;

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- ensure appropriate feedback is given to the reporters of patient safety incidents and all staff involved with or the subject of any concern, including any investigation outcomes and actions taken and to ensure that this feedback is clearly documented;
- ensure appropriate feedback is given to any reporter of a matter that is not considered to be a patient safety incident and information provided on what alternative action(s) will be taken; identify the training needs of individual members of staff, in relation to use of Datix and the handling of concerns, through performance review and PADR and determine a plan to ensure those needs will be met
- ensure their staff are made aware of how to access copies of the Health Board's arrangements for handling concerns, in all the formats, so that they may satisfy any reasonable request made of them for this information.

6.3.4 All Staff employed by the Health Board

All staff must:

- treat persons notifying concerns with respect and courtesy;
- address issues and concerns as they arise and escalate for assistance if unable to manage the matter;
- ensure that patient safety incidents that they are aware of are reported, no matter how minor they might appear. This ensures that the Health Board has the opportunity to take all appropriate actions under this policy including learning from such events and improving matters for the future;
- ensure they report patient safety incidents brought to their attention by patients and other persons. However, patients and other persons are equally entitled to complete and submit an incident report to the Health Board if they wish to do so. Staff should ensure assistance is given in such instances;
- all staff should ensure they are aware of how to access copies of the Health Board's arrangements for handling Concerns, in all the formats, to enable them to satisfy any reasonable request made of them for this information; • be open, honest and transparent at all times; and • adhere to this Policy and supporting procedures.

6.4 Supporting Groups/Committees

All staff supporting Groups/Committees will need to interrogate relevant patient safety data within the Datix System to produce any information on concerns that may be required by those Groups/Committees.

6.4.2 Quality and Safety Governance Group

The Quality and Safety:

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- considers Concerns Management Policy and Health and Social Care Quality & Engagement (Wales) Act 2020 to endorse approval by the Quality and Safety Committee and approves all relevant Standing Operating Procedures;
- oversee compliance with the Concerns Management Policy and affiliated policies, as necessary to ensure compliance with the Strategy and Regulations;
- receive reports at Corporate Directorate Level and Service Group Level in order that key issues can be identified and learning can be shared;
- scrutinise themes and trends for escalation to the Quality & Safety Committee; receive exception reports on patient safety alerts and notices and agree actions required for action and monitoring;
- highlight risk issues that require consideration at a Health Board wide level; and
- highlight risks which require specialist review to the appropriate Corporate Group/Committee for consideration and the Executive Lead.

6.4.2 Quality and Safety Committee

The purpose of the Quality & Safety Committee is to provide:

- evidence based and timely advice to the Board to assist it in discharging its functions and meeting its responsibilities with regard to the quality and safety of healthcare;
- assurance to the Board in relation to the Health Board's arrangements for safeguarding and improving the quality and safety of patient centred healthcare in accordance with its stated objectives and the requirements and standards determined for the NHS in Wales: and
- receive and consider Duty of Candour reporting.

The Quality & Safety Committee will receive and commission reports from the Quality and Safety Governance Group to support achievement of these objectives. A Patient Experience report will be provided as a minimum on a quarterly basis.

7. WHO MAY RAISE A CONCERN / COMPLAINT

7.1 Persons Who May Notify Concerns / Complaints

Almost anyone can raise a concern and the Health Board will be under a duty to consider whether it can be investigated. However, it may not always be possible to share the full details of the investigation with the person raising the concern, for instance if they are not the patient or a person recognised as having authority to access the information.

As set out in Regulation 12 a concern may be notified by:

- (a) people who are receiving or has received services from the Health Board,

- - (b) any person who is affected, or likely to be affected by the action, omission or decision of the Health Board, in relation to the functions of the Health Board;
 - (c) any non-officer member of the Health Board;
 - (d) any member of staff of the Health Board;
 - (d) any person acting on behalf of any person from the above categories (a to d) who has died, is a child, lacks the capacity under the Mental Capacity Act (2005) to notify the concern themselves or has requested the person to act as their representative.

(e) Assembly Members and Members of Parliament

7.2 Concerns Notified by a third party

When a third party acts as a representative on behalf of another e.g. a child or someone who lacks mental capacity if there are reasonable grounds to conclude that they are not suitable to act on their behalf, for example because it does not appear to be in the patients best interests, then they must be advised in writing. However, an investigation into the issues raised may still need to be undertaken. In this instance the Health Board is under no obligation to provide a detailed response to the person who raised the concern, unless it is reasonable to do so.

Concerns raised on behalf of a child / young person

Where a concern is notified by a child, the Health Board must provide the child with any reasonable assistance that the child requires in order to pursue the concern. Specialist advocacy may be required.

In many instances, someone else (parent/ carer/guardian) will raise a concern on behalf of a child / young person. This does not remove the right of the child / young person to take the concern forward themselves with support. The Health Board must satisfy itself whether the child / young person wishes to raise the concern themselves, with support, or if they are happy for the person who raised the concern to represent them. If the child / young person is not willing to proceed with an investigation then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so. The Health Board is under no obligation to provide a response to the person who raised the concern in the first instance.

7.3 Concerns Notified by Staff

Staff wishing to report that something has gone wrong with the care or treatment provided to patients should do so via Datix Web (the Health Board's on-line Incident Reporting mechanism). Where a concern is notified by a member of staff and the initial investigation determines there has been harm, the Health Board is required to:

- (a) notify the patient or his/her representative of the notified concern, and
- (b) involve the patient, or his/her representative in the investigation of the concern

This notification and involvement will be undertaken in accordance with the requirements set out in the Health & Social Care Quality & Engagement (Wales) Act 2020.

Where it is considered that it would not be in the interests of the patient to be informed of the concern or involved in the investigation, the Health Board is required to:

- make a written record of this decision and the reasons for it, and
- keep the decision under review during the investigation of the concern.

8. MATTERS & CONCERNS EXCLUDED FROM CONSIDERATION UNDER THIS POLICY

Not all concerns can be dealt with under the regulations. Matters excluded are set out in regulation 14 and include:

- (a) A concern notified by a Primary Care Provider relating to the contract under which it provides Primary Care services - these are to be managed through the contractual arrangements;
- (b) A concern notified by any member of staff relating to that person's contract of employment - these are to be managed through the Health Boards HR procedures;
- (c) A concern that is being or has been investigated by the Public Services Ombudsman for Wales;
- (d) A concern arising out of an alleged failure of the Health Board to comply with a request for information under the Freedom of Information Act 2000 – these would be dealt with by the Information Commissioners Office;
- (e) Disciplinary proceedings that the Health Board is taking or proposing to take, arising from the investigation of a concern notified and dealt with in accordance with this Policy- these would be via the Health Boards HR procedures;
- (f) A concern that is notified verbally and is resolved to the satisfaction of the person who notified the concern within 48 hours of the concern being notified;
- (g) A concern with the same subject matter as a concern that was previously notified verbally and was resolved to the satisfaction of the person who notified the concern within 2 working day, unless the Health Board considers that it is reasonable to re-open the concern and undertake an investigation under this Policy;
- (h) A concern previously considered under this Policy or the Health Board's previous Complaints Policy and Procedure;
- (i) A concern that is/becomes the subject matter of Civil Proceedings. If court proceedings are issued when a concern is already under investigation in accordance with the regulations, all further investigation of the concern must stop;
- (j) A concern that is/becomes the subject of a concern related to an Individual Patient Treatment Request.
- (k) Police criminal investigation

(I) Safeguarding Concerns

The Health Board will advise the person who notified the concern, as soon as reasonably practicable, in writing, of the reason(s) for any decision that the concern is excluded from the scope of the Regulations and, thereby, this Policy. However, this written notification/justification is not required in relation to a concern that was notified verbally and resolved to the satisfaction of the person who notified the concern within 48 hours of the concern being notified.

9. TIME LIMITS FOR THE NOTIFICATION OF CONCERNS

A concern must be notified:

- (a) within 12 months of the date on which the subject matter of the concern occurred, or
- (b) within 12 months of the date on which the subject matter of the concern came to the notice of the patient. (Where a patient has opted to have a representative act on his/her behalf, this date is the patient's date of knowledge, NOT the date that the representative was informed of the concern by the patient).

To investigate a concern after this 12 month deadline the Health Board must consider whether the person raising the concern had good reason not to notify the Health Board of the concern earlier and whether, given the time lapse, is it still possible to investigate the concern thoroughly and fairly.

However, a concern under these regulations **may not be notified 3 or more years after the date on which the subject matter occurred or after the date that the subject matter came to the notice of the patient**. The Health Board will, therefore, refuse to consider any such concern. (Where a patient has opted to have a representative act on his/her behalf, this date is the patient's date of knowledge, NOT the date that the representative was informed of the concern by the patient). If the person who raised the concern is a child at the time of injury the three year period does not begin to run until the individual reaches the age of 18 years and runs out on their 21st birthday.

If the Health Board makes an exception to this it must make it clear to the person who raised the concern that the investigation may be limited in some aspects based on the information available as key staff may have left the Health Board and memory in relation to the circumstances will be poor.

10. WITHDRAWAL OF A CONCERN

A concern may be withdrawn at any time by the person who notified it. The withdrawal can be communicated to the Health Board by written, electronic or verbal means.

Where a withdrawal is communicated verbally, the Health Board is required to write to the person to confirm the withdrawal.

The Health Board can continue to investigate any concern that has been withdrawn, should it be considered reasonable and necessary to do so.

11. CONCERNS THAT INVOLVE OTHER ORGANISATIONS

Where the Health Board is notified of a concern that also involves the functions of another organisations, (whether this is known by the person notifying the concern or not), the Health Board is required to seek the consent of the person to contact any other relevant organisations and notify it of the concern. This consent must be sought within 2 working days of the receipt of the concern and done at the same time as acknowledging the concern. However there may be occasions when it is not immediately evident that GP records need to be reviewed and comments sought

Once consent is received, the Health Board is required to contact all other relevant organisations involved in the concern within 2 working days of the consent being received.

All NHS Bodies involved in a concern are under a duty to co-operate to:

- (a) co-ordinate the handling and investigation of the concern, and
- (b) ensure that a co-ordinated response is provided to the person who notified the concern.

The Health Board must agree with the other organizations and person raising the concern which organization will take the lead, co-ordinate the investigation and provide the response. All relevant organizations should be included in any meetings arranged to discuss the concern.

12. CONCERNS NOTIFIED TO THE HEALTH BOARD INVOLVING PRIMARY CARE PROVIDERS

Regulations 18-21 deal with concerns notified about services provided by a primary care provider under a contract or arrangements with the Health Board.

When the Health Board receives a concern, notified by or on behalf of a person who is receiving or has received services from a Primary Care provider, it is necessary to determine whether it is appropriate for the Health Board to consider the concern or whether it is more appropriate for the concern to be considered by the Primary Care provider that is the subject of the concern. Before making this decision, and within 2 working days the Health Board must determine, from the person who notified the concern, whether:

- (a) the concern has already been considered by the Primary Care provider, and if so, whether a response has been issued by the Primary Care provider that is in accordance with the requirements in the Regulations

(b)the person who notified the concern consents to details of the concern being sent to the Primary Care provider who is the subject of the concern.

If the concern has been investigated by the Primary Care provider and a response issued then the Health Board must not re-investigate it. The person must be advised of this and reminded of their right to take the matter to the Public Services Ombudsman for Wales.

If the concern has not been investigated by the Primary Care Provider and the Health Board considers this is a concern that it should investigate consent is required to allow the Health Board to send details of the concern to the relevant Primary Care provider who is subject of the concern. If consent is not provided the Health Board must not investigate the concern as it would not be possible to investigate without the co-operation of the Primary Care Practitioner, and the Practitioner should, in the interest of fairness know when a concern about them is being investigated.

If the Health Board decides that it is appropriate for it to deal with a concern, it is required to advise the person who notified the concern and the Primary Care provider of this decision within 5 working days, giving the reasons for this decision. Primary Care Providers are under an obligation to co-operate with investigations undertaken by the Health Board. However, the Health Board **may not** make any determination about the liability in tort of a Primary Care Provider. If such matters are alleged by the person raising the concern or arise during the investigation, the Primary Care Provider should be advised to involve their Medical Defence Organisation. The person raising the concern will need to be notified that the Health Board cannot become involved in those aspects of any concern about a Primary Care Provider.

If the Health Board decides that it is more appropriate for the concern to be dealt with by the Primary Care provider, the Health Board is required to advise the person who notified the concern and the Primary Care provider of this decision and why the decision has been made. The person raising this concern may be unhappy with this decision and should be informed as part of this decision letter of their right to take their concern to the Public Services Ombudsman for Wales.

When the Primary Care provider receives the notification of the Health Board's decision, the Primary Care provider must deal with the Concern in accordance with the Regulations.

13. HANDLING OF CONCERNS

13.1 Verbal Concerns / Complaints

Where a concern is notified verbally, the member of staff to whom the concern has been notified must make every effort to respond to that complaint there and then with due consideration to the Duty of candour. If unable to do so to the satisfaction of the complainant they must escalate to someone more senior e.g. Ward Manager, On-call Manager, Departmental manager etc. All attempts should be made to deal with these issues as soon after they arise (taking no longer than 48 hours). These should be documented as informal concerns in the PALs module of Datix. Exceptions are

Primary Care and Mental Health Learning Disabilities Service Service Groups who do not have PALS teams.

If the complaint cannot be resolved to the satisfaction of the complainant then the person dealing with the complaint must make a WRITTEN record of the concern and PROVIDE A COPY of the written record to the person who notified the concern.

13.2 Acknowledgement of concerns

The Health Board must acknowledge receipt of the concern within **2 working days** of the day on which the concern is received.

The acknowledgement may be made in writing or electronically, depending upon how the concern was notified to the Health Board.

Where the concern was notified verbally, the Health Board is required to acknowledge the concern in writing, outlining what the issues were and what has been agreed in relation to matters for investigation.

For care & treatment concerns attempts should 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 in person 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. The written acknowledgement must confirm this and also include details in relation to who to contact in relation to the investigation being undertaken :

- (a) the manner in which the Health Board will handle the investigation, including consent to the use of medical records;
- (b) the availability of advocacy and support services that may be of assistance to the person in their pursuit of the concern;
- (c) the period within which the Health Board is likely to complete the investigation of the concern and send a response to the person.

Further details on investigating and responding to concerns is provided in the Health Boards Concerns Procedure.

13.3 Consent

Where the patient has raised the concern then in doing so, they can be deemed to have given implied consent to an investigation. This will also apply if a concern is raised by a representative who has shown proof that they are legally entitled to act for the patient/data subject (e.g. the representative has a Power of Attorney and the terms of the Power of Attorney have been met). However, in order for individuals to be clear in the knowledge that their medical records may need

to be accessed, this should be explained in the acknowledgement letter so that they have the opportunity to indicate if they do not want their health records accessed.

Where a third party has raised a concern on behalf of someone else, then the patient or their representative will have to be asked to give written consent to access to medical records and the conduct of an investigation.

13.4 Timescales for Response:

Regulation 24 requires the Health Board to take all reasonable steps to send the response to the person who notified the Concern **within 30 working days, beginning on the day that the notification of the Concern was first received.** It is essential that from the outset that the investigating officer advises the person who raised the concern of the predicted timescale for a response. If the Health Board is unable to provide a response within 30 working days, the following actions are required:

- (a) a written explanation setting out the reasons for the delay must be provided to the person who raised the concern, with estimation or anticipated date for completion of response and personalised to the complainant
- (b) the response must be sent as soon as reasonably practicable, within 60 working days if possible. Responses should not be sent later than 6 months, from the day that the notification of the concern was first received.

If there are exceptional circumstances that prevent the Health Board adhering to the 6 month extended period for provision of the response, the Health Board must contact the person who notified the concern of the reasons for the delay and when the response may be expected.

13.5 Response The Regulations require that the Health Board's written response to the concern are below in addition the Health Board expects responses to be values based

- (a) summarise the nature and substance of the matter or matters raised in the concern;
- (b) describe the investigation undertaken by the Health Board; specifically providing details under each aspect of the Regulatory requirements;
- (c) contain copies of any expert opinions that the investigator(s) received during the investigation;
- (d) contain a copy of any relevant medical records, where this is appropriate;
- (e) where appropriate, contain an apology;
- (f) identify what action, if any, the Health Board will take in light of the outcome of the investigation;

- (g) contain information about the Health Board's consideration of any allegation that has or may have been caused. Specifically, if the Health Board decides that there is no qualifying liability in tort, the reasons for this decision will be detailed
- (h) contain details of the right to notify the concern to the Public Services Ombudsman for Wales with the relevant paragraph indicating 12 months' timescale for contacting Ombudsman, and Advocacy support details.
- (i) offer the person notifying the concern the opportunity to discuss the contents of the response further;
- (j) be signed by the Responsible Officer or a person to whom delegated responsibility has been given by the Responsible Officer.

Where the Concern includes an allegation that harm has or may have been caused, but the Health Board is of the view that there is no qualifying liability, the Health Board must detail the reasons for this view in the response. In essence the response must say: what went wrong, why it went wrong and what action will be taken to prevent it occurring in the future.

Where the investigation determines that a qualifying liability does or may exist then the redress requirements outlined below must be included.

13.6 Where a Qualifying Liability does or may exist (redress)

Regulation 26 requires that where the Health Board's investigation of a concern determines that a qualifying liability exists or may exist, it is required to determine whether or not an offer of Redress should be made.

To establish liability, the following elements must be met:

- That the Health Board had / has a duty of care to the person. A legal duty of care arises when the health care system accepts the patient.
- The duty of care has been breached i.e. the standard of care / treatment provided fell below the expected standard.
- Causation of damage. Did the healthcare provider's acts or omissions cause harm to the patient as a result of the breach of duty of care.

An offer of Redress may be made by the Health Board, in accordance with the Regulations, where it is established that a qualifying liability exists

When the Health Board's investigation determines that there is or there may be a qualifying liability, the Health Board is required to produce an interim report (if unable to provide a full final report that contains a redress offer) that:

- (a) summarises the nature and substance of the matter or matters notified in the concern;

- (b) describes the investigation undertaken by the Health Board;
- (c) describes why the Health Board believes that there is, or there may be, a qualifying liability;
- (d) offer/provide a copy of any relevant medical records;
- (e) explains the availability of access to legal advice, without charge, Legal Advice and Instruction of Medical Experts.
- (f) explains the availability of advocacy and support services which may be of assistance;
- (g) explains the procedure that the Health Board will follow to determine whether or not a qualifying liability exists and the procedure for making an offer of Redress, if such a qualifying liability is found to exist;
- (h) confirms that, when prepared, a copy of the investigation report will be made available to the person who is seeking Redress;
- (i) contains details of the right to notify the concern to the Public Services Ombudsman for Wales;
- (j) offers the person who is seeking Redress the opportunity to discuss the contents of the Interim Report with a member of the Health Board
- (k) is signed by the Responsible Officer or a person with delegated responsibility;

13.7 Form of Redress

Redress takes many forms and can consist of one or more of the following:

- (a) the provision of a written apology;
- (b) the provision of an explanation of events;
- (c) the provision of a report on the action that has been, or will be, taken to prevent similar cases arising.
- (d) the making of an offer of compensation in that the Health Board offers can take the form of entry into a contract to provide care/treatment or an offer of financial compensation, or both in respect of a qualifying liability up to £25,000.

If the Health Board considers that the qualifying liability justifies financial compensation exceeding £25,000, the Health Board must not offer Redress in the form of financial compensation under the Regulations. The Health Board may, however, make an offer of settlement outside of the provision of the Regulations.

The Health Board must assess and calculate damages for Pain, Suffering and Loss of Amenity on the Common Law basis and in conjunction with Judicial College Guidelines. Welsh Ministers have

issued a Compensation Tariff, which, the Health Board's legal team will apply when calculating financial compensation.

A patient, or his or her representative, has 6 months from the date the offer is made to respond to an offer of financial compensation made by the Health Board, however there may be situations that this can be extended to 9 months (this is discretionary). After 6 months, the liability will no longer be considered as being the subject of an application for Redress.

In cases where the Health Board has decided that it considers there is no qualifying liability, and has decided not to make an offer of Redress, that liability will not be considered to be the subject of an application for Redress after 6 months from the date on which the Health Board communicated its decision.

Redress is not available, and must not be offered, in relation to a liability that is, or has been, the subject of Civil Proceedings. If such Civil Proceedings are issued during the course of the Health Board considering Redress, the Health Board must cease all consideration of Redress and must advise the person who notified the Concern accordingly.

Legal advice and the Instruction of Medical Experts

When the Health Board determines that a qualifying liability exists, or may exist, it is necessary to ensure:

(a) that legal advice, free of charge, is available to the person seeking Redress

and

(b) if a medical expert or experts need to be instructed, that such instruction is carried out jointly by the Health Board and the person who has notified the Concern.

Legal advice must only be sought from firms of accredited solicitors who have an expertise in the field of clinical negligence. Firms will be recognised as having the necessary expertise if they have at least one partner or employee who is a member of the Law Society Clinical Negligence Panel or the Action Against Medical Accidents Clinical Negligence Panel.

The free-of-charge legal advice, is to be made available in relation to:

(a) the joint instruction of medical experts, including seeking clarification from such experts on issues arising from their reports;

(b) any offer of financial compensation that the Health Board has made;

(c) any refusal by the Health Board to make such an offer; and

(d) any settlement agreement that is proposed.

The Health Board must bear the full cost of this legal advice and the costs arising from the instruction of the medical experts.

Reopened Complaints

In the event that a complainant is dissatisfied with their response and there are no new issues to investigate then the complaint will be reopened and reconsidered. A meeting with the complainant will be offered or further response issued. Where the complainant is happy with the response but raises new issues then a new complaint will be opened.

14. ENSURING A LEARNING AND SUPPORTIVE CULTURE

14.1 Learning from Concerns

The Health Board will ensure that it has arrangements in place to review the outcome of any Concern that has been subject to an investigation under the Regulations, in order to ensure that any deficiencies in its actions or its provision of services, identified during the investigation, are:

- (a) Acted upon - where immediate action cannot be taken an action plan will be developed using the template action plan in Datix. All action plans will be recorded in Datix Action Plan module; and
- (b) Monitored - by the Service Delivery Service Group to ensure the actions are implemented timely and the action(s) taken are minimizing the risk of reoccurrence.

Learning lessons throughout the Health Board and taking action to ensure any necessary improvements are made is critical to avoid such deficiencies recurring. Where a matter progresses under Part 6 of the Regulations, i.e. a Qualifying Liability exists, then the Health Board has a duty to provide learning in the form of a 'Learning from Events Report to the Welsh Risk Pool within 60 days of confirming a Qualifying Liability exists.

14.2 Supporting Staff

The Health Board promotes an open and fair culture where staff are supported and the emphasis will be on learning and taking action to avoid a reoccurrence. Where allegations are made that members of staff's behaviour included one of the following:

- involved a deliberate intent to harm
- was a flagrant disregard for the safety of patients or others (e.g. treating patients whilst under the influence of alcohol)
- foreseeably placed the safety of patients at risk
- was a deliberately repeated breach of policy or procedures

- was a criminal act (e.g. assault)
- was a malicious act
- evidences repeated non-reporting of errors or violations
- evidences repeated failure to engage in learning lessons

The Health Board will utilise the 'Incident Decision Tree' tool, developed by the National Patient Safety Agency, to ensure appropriate and consistent decisions are made in this respect.

14.3 Confidentiality

Information contained within a reported/notified concern falls within the definition of personal data contained within the Data Protection Act 1998. The Health Board also has duties under the requirements of Caldicott and the Human Rights Act 1998 in respect of the right to privacy and also the Freedom of Information Act 2000 in respect of openness.

Information on individual reported/notified concerns should not be disclosed/copied/shown to any external agency without the permission of the Responsible Officer or nominated deputies. All requests for access to such information should, therefore, be directed to the appropriate Manager, or nominated deputy, for the service area that is the subject of the concern, in the first instance.

15. MANAGING MEDIA INTEREST/MEDIA COMMUNICATIONS

The management of any media interests/communications in relation to incidents, either individually or generally, will be undertaken by the Health Board Communications Department based at Health Board Headquarters, Baglan.

16. TRAINING

All staff responsible for the management of complaints and concerns at all levels of the Health Board must have appropriate training. This will vary from customer care and nipping issues in the bud awareness on induction, to formal customer care & nipping issues in the bud training to full complaints and redress training days for managers.

Datix Web e – learning training should be undertaken by all staff who are required to use the Datix system.

Managers will identify training needs of individual members of staff through the performance review and PADR and make staff available to attend such training programmes.

Where an investigation of a concern reveals a training issue, the line manager will consider not only what actions should be taken to support the individual but also whether there is a need for training. Where this need is considered to extend beyond the local remit or there are implications for Health Board-wide training, Service Group should highlight this to the Quality and Safety

Governance Group.

17. Disability and Special Requirements of a Complainant

At the outset when a complaint is made and a complainant identifies a disability or special requirements in relation to communication every effort must be made to make reasonable adjustments to accommodate the special request/requirement. Once agreed this should be documented in Datix and shared with all staff who will communicate with the individual.

18. DEALING WITH UNREASONABLE DEMANDS

People raising concerns have the right to be heard, understood and respected. On occasions there may be times when persons raising the concern out of character and become determined, forceful, and angry and make unreasonable demands of staff. The Health Board recognises that persons who complain despite being advised on other avenues available to them may also show aggression towards staff or continue to persistently pursue their concern by telephone, in writing, or in person

Behaviours that escalate into actual or potential aggression towards staff are not acceptable.

What is unreasonable, unacceptable aggressive or abusive, violent behaviour?

Definitions

- Violence – behaviour that produces damaging or harmful effects, physically or emotionally on other people.
- Persistent unacceptable behaviour – behaviour that is deemed unacceptable within one event or on a number of occasions within a period of time.

Examples of unacceptable aggressive or abusive behaviour –

- Verbal threats unsubstantiated allegations or offensive statements can also be termed as abusive violent behaviour.
- Threatening remarks e.g. both written and oral.
- Unreasonable demands e.g. Demands for responses within unrealistic timescales, repeatedly phoning, writing or insisting on speaking to particular members of staff.

19. DEALING WITH UNACCEPTABLE ACTIONS OR BEHAVIOUR

If staff encounter situations where a person behaves in an unacceptable manner towards staff, appropriate action should be taken in line with The Health Board policies and procedures. If the person raising the concern becomes aggressive or abusive consideration should be given to the following actions:

- a. Threats or physical violence to staff should be reported to the police. An Anti Social Behaviour Referrals completed (An anti social behaviour is summarised under the Crime and Disorder Act as “where a person has acted in a manner that caused or was likely to cause harassment, alarm, or distress.
- b. An incident form should also be completed and recorded on the Datix Incident system
- c. Correspondence if received is deemed to be abusive and contains threats to staff or the organisation this must be reported to a Senior Manager /police. If unsubstantiated allegations are received then the person should be told that the language used is unnecessary and unhelpful. It should be made clear that if the behaviour and use of language continues all forms of communication will stop.
- d. If a person is aggressive, abusive or offensive whilst on the telephone the person should be informed that their behaviour is unacceptable and if it continues the telephone call will be terminated (please refer to telephone aggression training provided).

20. DEALING WITH ABUSIVE BEHAVIOUR BY TELEPHONE

Abusive behaviour by telephone is no more acceptable than it is in person and should not be tolerated. Sometimes a caller may be expressing frustration at their own situation and it is not meant to be directed personally at the staff member receiving the call. Although the tone of the conversation may initially be unacceptable, staff may feel that they can overcome this by reasoning with the caller. There may be occasions when the caller is beyond reason and no amount of understanding and concern will have any effect on their conduct, The staff member should interrupt the conversation at an opportune moment and state clearly that the tone and content is unacceptable and request the caller modify it accordingly. If this is not heeded the caller must then be told if they continue the call will be terminated. If the caller does not comply with the request the member of staff should inform the person that the call is to be terminated and do so immediately. An incident form should be completed. The incident should be reported to a senior staff member.

Support

Following the incident the staff member involved should have a de-briefing session with a senior staff member to ascertain if further input is required to support the staff member.

Capacity

The Mental Capacity Act 2005 states that the starting assumption must always be that a person has the capacity to make a decision, unless it can be established that they lack capacity. A person is unable to make a decision if they cannot:

- Understand information about the decision to be made (relevant information);
- Retain that information in their mind;
- Use or weigh that information as part of the decision making process or communicate their decision (by talking, using sign language or any other means).

21. MANAGING PERSISTENT BEHAVIOUR

If a person repeatedly telephones, visits, or writes raising a concern which has already been investigated and a response sent then consideration should be made for:

- a. Putting arrangements in place whereby calls can only be received from them at set times on set days;
- b. One staff member is allocated as a point of contact for written or verbal communication;
- c. Restrict contact to written correspondence only;
- d. If it is necessary to meet with the complainant as all other options have been explored , the **meeting should never be undertaken alone**;
- e. Communication that no further correspondence or telephone call will be responded to unless new issues are raised , and any correspondence will only be acknowledged;
- f. In extreme cases legal advice should be sought.

Importantly each stage it should be made clear to the person what actions are being taken, why and when they will be reviewed.

1. General

Not everything that happens is a reportable patient safety incident. For example, patients are admitted to hospital and despite care, they may suffer a natural event, with no failing apparent. In these circumstances. Such an occurrence is not a reportable patient safety incident unless it is considered that there may have been or there was some untoward contributory factor - for example, it might have been possible to resuscitate the patient following the arrest, but staff were unable to do so because the defibrillator was defective.

If staff are uncertain, they should discuss the issue with their Line Manager or the Service Groups Quality and Safety Team for advice

An incident report should not be completed where staff wish to register a point of view or highlight that a situation is less than ideal. There are other, more appropriate, means of raising and dealing

with such situations, which would include risk assessment. The Health Board also has other policies that may be the more appropriate avenue for raising a Concern e.g. the Whistle Blowing

Policy, the Grievance Policy and Procedure. In the event that a member of staff is unsure whether

an occurrence meets the definition of a reportable patient safety incident, this should be discussed with the line manager, with escalation through the Service Group, Professional Leads etc., as necessary. Alternatively, staff can contact the Patient Experience, Risk & Legal Services

Department at HQ for initial advice.

2. Definitions

Patient Safety Incident

Any unexpected or unintended incident, which did lead to harm for a patient or could have led

to harm for a patient.

This definition includes any unexpected or unintended incident, which could have led to harm but when that harm was prevented by way of some intervention.

Harm

Harm is considered to be any injury (physical or psychological), disease, suffering, disability, impairment of normal function or death.

Harm should be viewed from the patient's perspective.

The definitions of the various grades of Harm are detailed in the Grading of Concern section .

2. THE IMMEDIATE MANAGEMENT OF INCIDENTS

Notifications/Initial Contacts

Each Service Delivery Service Group should define its specific arrangements for ensuring compliance with the following requirements and communicate these to all staff.

Incidents occurring within normal working hours (Monday-Friday, 09.00 – 17.00) The senior person on duty should be informed of the any patient safety incident.

In the event of a serious (Red) incident, the senior person at the scene should inform the relevant/nominated member of the Service Group, by telephone, of the situation and the actions taken so far and follow the Management of Serious Incidents Procedure

Incidents occurring outside normal working hours

The senior person taking responsibility at the scene must notify the On-Call Manager of the Incident and the action being taken.

Responding To The Immediate Needs Of The Persons Involved

Ensure the immediate safety and care of the patient involved. Where the patient has sustained an injury, an appropriate level of examination and treatment must be offered. If the patient is not an inpatient, this might include referral to A&E. Refusal of that offer should be noted in the incident report.

If the Incident in any way relates to the use of medical equipment, disconnect the equipment from the patient and refer to section on medical devices.

The consultant or lead professional in charge of the patient's care must be informed, who should consider the communications with the patient/relatives/carers at this time.

If the Incident occurs in a community setting, and it is considered that the GP should be made aware, the patient should be advised to contact the GP, or the member of staff should personally notify the GP as soon as practicable after the incident. If the incident is sufficiently serious, the GP should be notified immediately and/or an ambulance should be called.

Re-Establishing A Safe Environment

Appropriate action must be taken to contain the situation, as agreed with the contact person/senior person on duty. There should be notification to or advice sought from specialist advisors/departments, as necessary (e.g. Infection Control, Pharmacy etc).

Preservation of Evidence

It is important that there is a common sense approach and that there is discussion within the Service Group or with relevant specialists in any given situation.

Where it is suspected that drugs may be defective/contaminated/out of date etc, they **must** be taken out of use and contact made with Pharmacy for advice.

If the incident is serious (Red), all the relevant evidence must be preserved and kept secure. There may be a police investigation as well as a Health Board investigation. If necessary, secure the area, to ensure that everything is left untouched. Lock doors and put up signs clearly stating that no-one is permitted to enter the area. Explain the reason for the closure to patients, relatives, visitors and staff in the vicinity, ensuring that confidentiality is not breached.

If the Incident involves the use of **medical equipment**, the item(s) of equipment must be removed from use, appropriately labelled and retained for inspection by the Medical Equipment Management Service (EBME/Medical Electronics) or other specialist departments. All accessories and disposables/consumables must be retained intact. Settings must not be adjusted. The equipment must be clearly labelled as 'Evidence - Not To Be Used' and it must be stored in a place and manner such that it cannot be accidentally or intentionally brought back into use until all investigations are complete and formal approval has been given for the reintroduction of the item. The supplier or manufacturer of an item should **not** be contacted at this particular time.

If the Incident involves the use of **non-medical equipment**, it must be removed from use, appropriately labelled and retained for inspection by Estates or IT. All accessories and disposables/consumables must be retained intact. Settings must not be adjusted. The equipment must be clearly labelled as 'Evidence - Not To Be Used' and it must be stored in a place and manner such that it cannot be accidentally or intentionally brought back into use in the intervening period until all investigations are complete and formal approval has been given for the reintroduction of the item. The supplier or manufacturer of an item should **not** be contacted at this particular time.

Equipment must be decontaminated/cleaned in accordance with relevant Health Board

procedures, to ensure that it does not present a biological hazard to staff inspecting or repairing it. Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled, and placed in a secure location

There must be very good reason if any equipment involved in the incident is not to be removed from use. A discussion with the senior manager in charge, relevant specialist department will be necessary before such a decision is taken. Where an item is not removed from use, a full and accurate description of the state of the device at the time must be recorded and photographs taken (by using staff camera/phone).

Once investigations are complete, should any equipment be identified as requiring service or repair, a works requisition must be submitted as a matter of urgency or any other necessary action taken but it is vitally important that a photograph of the equipment be taken prior to repair taking place.

Advice can be sought from specialist departments or the Patient Experience, Risk & Legal Services Department if it is considered that photographs of the environment/facility are necessary or would be helpful.

3. REPORTING PATIENT SAFETY INCIDENTS (WITHIN THE HEALTH BOARD)

Reporting serious (Red) patient safety incidents

If the incident concerns more than one Service Group, the nominated senior person notified of the incident should make contact with each and a lead Service Group should be agreed.

The nominated Service Group senior person should inform the Chief Operating Officer of the incident.

The Chief Operating Officer will inform the remaining members of the Executive Team and the Chief Executive. A decision will be made on whether the incident requires instigation of the Major Incident Procedure. If this is considered necessary, suitable arrangements will be made to inform the Chairman.

Additionally, an automated email trigger has been established within the on-line incident reporting system that will inform the Clinical Executive Directors and their deputies, Head of Patient Experience, Risk & Legal Services and the Serious Incident Team of any serious (Red) patient safety incidents at the time of reporting. If this is the first notification of the matter within the Health Board, all appropriate notifications to the Executive Team will be instigated at this time.

Completing the on-line incident report

Incidents are to be reported using the on-line incident reporting facility. This is accessible from the Health Board intranet.

A guide for all staff, on how to use the online incident report form, is accessible from the same location.

Where/if there are exceptional operational circumstances that present difficulties in accessing the intranet and, therefore, the online reporting facility, the Service Group must specify the arrangements for its staff for the initial capture of the incident information. It must also specify its arrangements for how it will ensure that information is then reported using the on-line incident reporting facility.

The on-line incident report must be completed within **3 working days** of the occurrence of the incident.

If the matter is serious (Red), the on-line incident report must be completed **within 24 hours** of the occurrence.

As far as possible, the person most directly involved in the patient safety incident should complete the incident report.

Witnesses to a patient safety incident

The Witness Account Form (IR2) is available from the Intranet.

Any witnesses to a patient safety incident should complete a Witness Report (IR2), on which they should record the facts of what they witnessed.

Any Witness Report(s) (IR2) can be attached as a 'Document' to the on-line incident report, by the incident reporter. If a Witness Report is not yet available at the time of completing the online incident report, it should be attached to the incident record in the Datix system, when it is available, in accordance with the arrangements defined by the Service Group.

Witnesses should be reminded that no allegations are being made against them and that the purpose of providing a report is simply to obtain factual information that could be of assistance in establishing the facts leading up to the incident.

A Witness Report or a formal statement may also be requested later, as part of an investigation of a patient safety incident.

4. GRADING CONCERNS THAT ARE PATIENT SAFETY INCIDENTS

There are common features in the Grading process and matrix for all types of Concerns. Specifically, the Table of Consequences is common. However, as far as patient safety incidents are concerned, there are two Grades to be determined, as follows, and it is the HIGHER of these that determines the nature and scale of investigation required and the reporting requirements.

1. the actual outcome/consequences of the patient safety incident (SEVERITY)
2. assessment of future risk potential (FUTURE RISK GRADE)

The reporter of a patient safety incident will make a judgement on both Severity and Future Risk Grade at the time of reporting, using the Grading Matrix and Tables in the Risk Management Framework.

The assessment of either Severity or Future Risk Grade should not delay completion/submission of the incident report. The reporter should make the most reasonable assessment possible based on the information available at the time. There is always scope for re-grading the incident, if necessary, as facts and issues emerge. An incident Grading can also be re-

examined at the time when the risk reduction options are determined. This will also assist in prioritising the actions planned.

Grading Actual Outcome (Severity)

Actual Outcome (Severity) = the actual or apparent outcome/harm/impact of the incident. Harm includes psychological harm as well as physical harm.

The actual or apparent outcome has to be mapped against the Outcome (Consequences) Table in order to determine the relevant descriptor. Once chosen in the On-line incident form, the relevant colour code for the Grade will automatically be allocated.

Grading Future Risk Potential

There are three steps involved in determining the Future Risk Potential.

Step 1:

- Assess the likelihood of the incident happening again in the Health Board and map against the descriptors in the Likelihood Table.

Step 2:

- Assess what the **most likely** outcome would be if the incident were to re-occur and map against the Outcome (Consequences) Table.

Step 3:

- The answers obtained in Steps 1 and 2 are plotted on the Future Risk Matrix in the Online incident form, which determines the overall risk score and Grade for a potential future

incident.

Reporters and Reviewers involved in grading Future Risk Potential need to think about the patient safety incident that has just occurred and the circumstances surrounding it. Was the outcome a 'lucky outcome' today? Could the outcome realistically have been much worse? If the Incident should happen again, how might people realistically be affected? What potential implications would there be in terms of resources, cost, relations with the public etc? The Outcome (Consequences) Table helps to map the answers to these questions. Each of the columns must be considered and a decision made on the **most realistic scenario** if the Incident should re-occur.

Additionally, when incidents are assessed for Future Risk Potential, the *status quo* must be maintained in terms of circumstances, i.e. the same type of patient, in the same place, at the same time, in the same circumstances. Also, the assessment cannot take account of any additional risk control actions over and above those that are already in place.

Risk Matrix

Step 1 – Measure of Consequence

The envisaged or actual consequences and likelihood are analysed in the context of any risk controls that have already been put into place using Table 1. It is acknowledged that in practice, both Steps 1 and 2 are subjective and will depend on the knowledge and expertise of the person(s) involved in the risk assessment process. To mitigate this, risk assessment is most appropriately conducted as a group/multidisciplinary activity.

Descriptor	Actual or potential unintended impact on individual(s) - Patient, family member, visitor, contractor, staff	Actual or potential impact on the Health Board
1 NEGLIGIBLE Green	No harm, harm prevented or very minor harm. Example(s): Cut or bruise. First-aid treatment only required. Some extra observation required. Unsatisfactory patient experience not related to patient care.	No damage or very minor damage. No direct financial loss or financial loss up to 1k Very minimal impact. No service disruption. Example(s): Wastepaper basket fire
2 MINOR Yellow	Avoidable short-term, non-permanent harm or impairment of health – full recovery in up to 1 month. Example(s): Minor healthcare associated infection. Temporary avoidable increase in pain experience. Unsatisfactory patient experience – readily resolvable	Short-term damage, remedial within 1 month. Increased length of hospital stay/level of care – between 1 and 7 days. Single failure to meet internal quality standards. Damage or direct financial loss up to £10,000. Staff sickness < 3 days. Low risk of complaint.
3 MODERATE Amber	Avoidable semi-permanent injury or impairment of health or damage - recovery in up to 1 year. Additional interventions required or treatment needed to be cancelled. Necessary to transfer to another centre for treatment/care. Example(s): Temporary loss of mobility Temporary loss of vision Healthcare associated infection taking up to 1 year to resolve e.g. MRSA Further/new surgical intervention required Mismanagement of patient care	Damage remedial in up to 1 year. Direct financial loss/cost up to £100,000. Increased length of hospital stay/increased level of care – 8 to 15 days. Temporary restrictions on service(s) / service disruption. Repeated failures to meet internal quality standards. Staff sickness > 3 days. Local adverse publicity / moderate loss of confidence in organisation. Risk of litigation with cost up to £500,000. MHRA Reportable. Mental Health Act Commission Assessment. HSE Improvement Notice issued.

4 SEVERE Red	Irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental well being. Example(s)/including: Procedures involving wrong patient/ body part. Loss of major body part(s). Retained instrument/material after surgery. Healthcare associated infection, which may result in major permanent harm e.g. Hepatitis C. Haemolytic transfusion reaction. Radiation dose much greater/less than intended, whilst undergoing a medical exposure. Mis-diagnosis with poor prognosis of return to health Infant abduction or discharge to the wrong family. Serious concerns re patient experience or clinical service requiring escalation to executive level for investigation/action.	Adverse national publicity. Loss of confidence in the Health Board. Ability of Health Board to provide a service adversely affected / temporary service closure/resources needed to remedy situation – up to £1M. Increased length of stay or care over 15 days. Risk of litigation with cost up to £1M. Prohibition Notice / Executive Officer fined. Failure to meet national and professional standards of quality. Example(s): Trust-wide PAS/PIMs failure.
5 MAJOR Red	Avoidable loss of life or unnecessary shortening of life expectancy. Example(s)/including: Unexpected death of a patient whilst under the direct care of a healthcare professional. Healthcare associated infection resulting in or with potential to result in death, e.g. hospital acquired legionellosis. Suicide or homicide committed by a patient being treated for a mental health condition. Unacceptable patient experience which would lead to an investigation by external bodies eg Mid Staffordshire	Significant adverse national / international publicity. Severe loss of confidence in the Health Board. Extended service closure. Risk of litigation with cost over £1M. Criminal prosecution. Direct financial cost over £1M. Example(s): Major loss of healthcare facilities due to fire. Loss/destruction of medical records department and all patient records Screening errors and failure to recall.

Step 2 – Measure of Likelihood

Table 2

Level and Descriptor	Description	Example
1 RARE	Would only occur/reoccur in very exceptional circumstances; considered a very remote probability that it could happen / happen again.	10 Yearly
2 UNLIKELY	Not expected to occur/reoccur but there is some possibility.	Yearly
3 POSSIBLE	May occur/reoccur at some time / occasionally.	Monthly
4 PROBABLE	Will probably occur/reoccur but will not be a persistent issue.	Weekly
5 EXPECTED	Will occur/reoccur and likely to be frequent.	Daily

Step 3 Risk Rating

Multiply the consequence and likelihood together to provide the Risk Rating which determines the overall risk ranking and priority of the risk for action (risk treatments), in accordance with the Risk Matrix:

Risk Matrix	LIKELIHOOD				
CONSEQUENCES	1 Rare	2 Unlikely	3 Possible	4 Probable	5 Expected
1 Negligible	1	2	3	4	5
2 Minor	2	4	6	8	10
3 Moderate	3	6	9	12	15
4 Major	4	8	12	16	20
5 Critical	5	10	15	20	25

1 - 4 LOW	This level of risk is considered acceptable and no additional action is required over and above existing management measures.
5 - 8 Manageable	This level of risk is marginally acceptable and efforts should be made to reduce the risk although the costs of reduction must be carefully considered. Risk reduction actions should be completed within 12 months.
9 - 15 Moderate	This level of risk should be discussed and actions agreed by the Service Delivery Service Group. Action to reduce the risk should be completed in 6 months.

**16 - 25
HIGH**

Board level notification/attention of this level of risk is required, via the Quality and Safety Forum. Urgent attention to the risk is required by the Service Group with actions to reduce the risk commencing within 1 month. Close monitoring required. Immediate action may be required, including halting the process although before doing so the risk must be assessed to ensure it is safe to do so..

4. ACKNOWLEDGEMENT OF A PATIENT SAFETY INCIDENT REPORT

On clicking the 'Submit' button, the reporter of the incident will receive an instant, on screen, acknowledgement of the incident report having been received.

The reporter will receive feedback following conclusion of the investigation and closure of the incident which will be sent to the e-mail address provided.

5. REVIEWING THE INCIDENT REPORT

The purpose of the review is to:

- Ensure that the matter reported constitutes a reportable patient safety incident.
- Ensure that all the information is accurate and comprehensive.
- Ensure that all appropriate actions in response to the incident have been taken or are underway. This includes commissioning an appropriate investigation.
- Ensure that all appropriate communications are undertaken.
- Ensure that appropriate and timely feedback is provided to the incident reporter.

The full details of the actions required of Reviewers are provided on the intranet.

The review and approval/rejection of the patient safety incident must occur within **3 working days** of the date that the incident is reported.

The reviewer should ensure that any person who is directly involved in the incident is informed of the report, either directly or through his/her manager, as is deemed most appropriate. If the reviewer believes that this action should not be taken, the reasons for this decision must be fully documented in the Datix record. Advice can be sought from the Patient Feedback Team, if necessary.

Staff involved in patient safety incidents may require assistance and support. What is appropriate is likely to depend on the nature of what has happened and the outcome. Some areas may be covered by particular policies, such as the Inoculation Injury Policy. The Reviewer of the incident report will need to consider the involvement of and advice from appropriate persons and departments including the Service Group Management Team, Professional Leads, Executive Directors, Personnel, and Occupational Health Department etc.

Reviewing serious (Red) incident reports

The Serious Incident Team will review the incident report and make contact with the relevant Service Group to discuss and agree all necessary actions.

6. BEING OPEN

Where a patient safety incident is notified by a member of staff and the Reviewer of the incident is satisfied that the patient has suffered or is likely to have suffered **Moderate or Severe harm or death as a consequence of that incident**, the Health Board is required to:

- (a) notify the patient or his/her representative of the patient safety incident, and
- (b) involve the patient, or his/her representative, in the investigation of the patient safety incident.

The Being Open process must be formally commenced and followed by the Service Group.

This process will govern all communications with the patient/representative.

Where the Reviewer of the patient safety incident has cause to believe that it would not be in the interests of the patient to be informed of the patient safety incident or involved in the investigation, the Reviewer must

- make a written record of this decision and the reasons for it against the Datix record, and
- keep the decision under review during the investigation of the patient safety incident and act in accordance with the Being Open process if the decision should change.

7. EXTERNAL REPORTING

Specific requirements for serious (Red) Incidents Welsh Government – Improving Patient Safety Team

All such incidents must be reported to the NHS Delivery Unit Patient Safety Team in accordance with the requirements specified by that team. The Serious Incident Team will ensure these incidents are reported and updates provided. This is covered in more detail in the Management of Serious Incidents procedure.

Health Commission Wales

Serious patient safety incidents involving Forensic Psychiatry should be reported to Health Commission Wales at the same time as they are reported to WG. This should be done by a nominated person within the Mental Health Directorate.

Health & Safety Executive

The Head of Health & Safety will consider any necessity to make contact with the Health and Safety Executive and will inform the Executive Team accordingly.

Police

The Chief Executive and Executive Team will decide whether the Police should be notified of the incident and instigate the necessary actions.

Requirements for specific types of incidents

A number of external organisations/agencies must be contacted when a particular type of Incident has occurred. The following section lists these organisations and gives brief information on the mechanisms for reporting.

NHS Partners, Tertiary and Specialist Providers/Contractors, Social Services, Local Authority Departments

Except where other specific arrangements or requirements may exist, the Executive Team will consider and agree the level and nature of communications in respect of any individual, patient safety incident and the extent of any involvement of such partners/stakeholders in the overall Incident management and learning process.

Incidents involving ionising radiation

The Ionising Radiation Regulations 1999 specify reporting requirements for a range of incidents including loss of radioactive sources and equipment faults resulting in a patient exposure 'much greater than intended'. The reporting arrangements for incidents involving medical exposures are included in the Health Board Ionising Radiation Safety Policy, Corporate Procedure C and Appendix 16. Incidents involving exposure of patients to ionising radiation to an extent which is 'much greater than intended' will be reported to HIW via the Medical Director on the advice of the Radiation Protection Adviser.

Drug Reactions and Medicine Defects

These incidents need to be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).

The reporting of any suspected drug reaction can be made by any professional member of staff using the Yellow Card system for reporting, which can be found on the back page of the BNF. The person making the report should also advise the Chief Pharmacist, who will consider whether a Health Board incident report needs to be completed and submitted.

Medicine defects, such as cloudiness of liquid or discoloration of medicines, should be reported to the Chief Pharmacist who will advise the all Wales Medicines Quality Controller and complete an Incident Report if appropriate.

Medical Devices and Equipment

These incidents need to be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).

Where any Incident relates to/involves the use of medical equipment, there should be contact with the Nominated Device Specialist who will advise on or assist with the investigation of the incident, as appropriate and make a report to the MHRA, if required.

Communicable Diseases and Inoculation Injuries

The Infection Control team will report notifiable Incidents to the Centre for Communicable Disease Control and will undertake EPINET reporting for inoculation injuries.

Serious Hazards of Transfusion (SHOT)

This is a voluntary reporting scheme to which the Health Board submits reports of relevant incidents. Automated email triggers from the on-line reporting system will alert the Blood Transfusion Practitioners of any such reported incidents.

Incidents involving the death of a patient detained under the Mental Health Act or the discovery of unlawful detention

The Mental Health Directorate will report Incidents involving the death of a patient detained under the Mental Health Act or the discovery of unlawful detention to the Mental Health Act Commission, by telephone, during office hours on the same day or first thing the following day.

Safeguarding

Swansea Bay University Health Board recognises every staff member has a duty to Safeguard and promote the welfare of children, young people and adults at risk. The Health Board has statutory duties to comply with legislation in relation to Safeguarding and Public Protection. It discharges these duties by working within regional partnership arrangements and complying with both UK and Welsh Government Codes of Practice and national safeguarding procedures.

Statutory Duty to Report

From April 2016 the Social Services & Well-being (Wales) Act 2014 introduced the statutory duty for all who work for the Health Board to report to the Local Authority any concerns that a child or an adult is at risk as identified in the Health Board Safeguarding and Public Protection Policy (2020) and the Wales Safeguarding Procedures, 2019.

All employees must take positive and decisive action when witnessing incidents, experiencing concerns or receiving information alleging abuse or inappropriate care of a child or adult at risk. Employees can obtain advice and support about concerns they may have from their line manager, Safeguarding Lead or the Corporate Safeguarding Team.

All patient safety incidents - National Reporting and Learning System (NRLS)

All NHS organisations are required to report patient safety (with certain exceptions) to the NRLS via an electronic export of data from the Datix System. This task will be undertaken by the Datix Team on a weekly basis.

ADDITIONAL RECORD-KEEPING REQUIREMENTS

A record of a patient safety incident should be written in the patient's clinical notes in addition to completion of an incident report. The incident report itself does not form any part of the patient's record and it should not be printed and filed in the patient's clinical notes.

When an inpatient has been the subject of a patient safety incident, the discharge letter sent to the patient's GP should contain summary details of:

- the nature of the incident and the continuing care and treatment
- the current condition of the patient
- key investigations
- recent results
- prognosis

Where a patient safety incident has occurred in the primary care setting that has resulted in an admission/referral to hospital, it may be expected that letter sent from the GP should contain summary details of:

- the nature of the incident
- the current condition of the patient
- any medical tests/investigations
- any immediate treatment given



STANDARD OPERATING PROCEDURE: SERIOUS INCIDENT INVESTIGATION TEAM

1. Introduction

SBU Health Board's Serious Incident Team will investigate Serious Incidents where death or severe harm (i.e. life changing injury) has occurred during secondary NHS funded care across SBU Health Board, and where on the balance of probability, the death¹ or serious injury was avoidable. In addition, regardless of any harm caused, the Serious Incident Team will investigate all Department of Health defined Never Event Incidents².

The Serious Incident Team forms part of the Patient Experience, Risk & Legal Services Department who are line managed by the Deputy Head of the Department.

The Serious Incident Team will work directly with Hospital Managed Service Groups during the investigation process, liaising directly with Service Group Senior Teams and/or nominated deputies. The Serious Incident Team's hours of operation are between 09:00hrs to 17:00hrs Monday to Friday, excluding Bank Holidays.

This procedure sets out how all Serious Incidents³ will be reported, managed and investigated universally across SBU Health Board.

2. Definition of a Serious Incident

A serious incident is defined¹ as an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following:

- Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- A never event – all never events are defined as serious incidents although not all never events necessarily result in severe harm or death (see Never Events Framework)
- A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- Allegations, or incidents, of physical abuse and sexual assault or abuse; and/or;
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

3. Accountability & Responsibility of the Serious Incident Investigation Team The Executive Director of Nursing holds executive accountability and responsibility for the Serious Incident Team. The day-to-day management of the Team will be through the Lead Serious Incident Investigator reporting to the Head and Deputy Head of Patient Experience, Risk & Legal Services Department.

The Serious Incident Investigation Team will:

- Be responsible for overseeing the appropriate grading of all Serious Incidents graded major or critical and/or Never Event reported via the Datix Risk Management System. In the event that a Serious Incident is reported by other means, the Serious Incident Team will ensure the matter is reported on Datix at the earliest opportunity by the reporting area.

¹ National Framework for Reporting and Learning from Serious Incidents Requiring Investigation NPSA2010

-
- Be responsible, in consultation with Service Group Senior Team, for agreeing the appropriate grade, Welsh Government reporting criteria and appropriate level of investigation i.e. local investigation or Serious Incident Team investigation, in line with Serious Incident Toolkit.
 - Be responsible for processing Serious Incident Notification to the NHS Delivery Unit once submitted by the relevant reporting area.
 - Where the Serious Incident Team investigate, be responsible for setting the Terms of Reference and Scope of the investigation.
 - Where the Serious Incident Team investigate, be responsible for undertaking the investigation in line with the investigation timeframes.
 - Be responsible for informing the Communications Department SBU Health Board of the Incident at the point of notification to the NHS Delivery Unit or before where considered necessary, to enable suitable preparation for any potential calls from the public/media;
 - Consider the need for any immediate legal advice through the Legal Services Department;
 - Ensure the Serious Incident notification is sent to NHS Delivery Unit;
 - Maintain robust and accurate documentation and evidence logs and ensure Datix is kept up to date throughout the investigation;
 - Report and escalate any immediate patient safety concerns to the relevant Clinical Director;
 - Be the Health Board's point of contact for all external stakeholders in respect of Never Events and Serious Incidents e.g. Welsh Government, Police, HSE with the exception of HM Coroner whose direct contact point will be the Legal Services Manager within the Health Board.
 - Update the NHS Delivery Unit on progress of the investigation and liaising with the Service Group to complete the closure form at the appropriate time and include lessons learned.
 - Share learning from Serious Incidents investigated by the Serious Incident Team and Never Events with Service Groups via the Alerts System in RL Datix.

4. Accountability and Responsibility of the Serious Incident

Accountability and responsibility of the Serious Incident remains with the relevant Service Group Senior Team or nominated deputy. Service Group will:

- Identify and facilitate relevant clinical support to the Serious Incident Team. More than one clinical / technical advisers may be required and would be dependent on the complexity of the incident;
- Ensure there is a point of contact for the patient /family with a full initial explanation of what has happened, and to keep up to date on progress and provide a single point of contact for the patient and family, ensuring appropriate communication and inclusion throughout the investigation process.
- Provide support to all staff involved in incident;
- Take immediate remedial / preventative action as required – escalate matters beyond their direct control;
- Ensure the investigation report is disseminated to all relevant staff and taken to their governance forum as well as Board / Cabinet;
- Be responsible for ensuring that actions are taken in a timely manner to prevent a reoccurrence, for developing, implementing and monitoring its action plan and sharing its learning;
- Sign off and take ownership of the final investigation report.

5.1 Serious Incidents Occurring During Monday To Friday, 09.00hrs to 17.00hrs

Step 1 - Immediate Action

The immediate handling of the Incident will be the responsibility of the most senior person at the scene of the Incident. That person needs to:

- Ensure the immediate safety and care of people involved i.e. patients, visitors, staff.
- If warranted, make contact with the emergency services.
- Preserve all evidence for the subsequent investigation; ensuring it is kept secure (this may be a police investigation as well as an internal investigation).
- If necessary, secure the area, to ensure everything is untouched. Lock doors and put up signs clearly stating that no-one is permitted to enter the area.
- Explain the reason for the closure to patients, relatives, visitors and staff in the vicinity, without breaching confidentiality.
- Inform appropriate Hospital Managed Service Group Senior Team and the Serious Incident Team of the situation (see Step 2 - Reporting).

- Commence completion of the Incident Report (IR1), documenting the sequence of events. (The IR1 must be received by the Serious Incident Team within 24 hours of the incident occurring). If there are witnesses, ensure they complete a Witness Report (IR2) and that these are stored securely.

Step 2 - Internal Reporting and Further Actions

The senior person at the scene should inform the relevant member of the Service Group Senior Team by telephone of the situation and actions taken so far. The Serious Incident Team must also be notified by e-mail

SBU.SeriousIncidentsTeam@wales.nhs.uk to review the incident.

The relevant member of the Service Group to complete the Serious Incident Form and e-mail to: SBU.SeriousIncidentsTeam@wales.nhs.uk.

Medical Director, Director of Nursing and Patient Experience (or, in their absence, nominated deputies) to be notified of the incident at the time of informing the NHS Delivery Unit and thereafter kept up to date of developments by the Serious Incident Team. The Executives will brief the Chief Executive and a decision will be made on whether the incident requires instigation of the Health Board's Major Incident Procedure. Suitable arrangements will be made to inform the Chairman/Deputy Chairman and brief the Board members, if this is considered necessary.

If the incident involves a patient - ensure the responsible consultant or the most senior member of the care team is informed and that he/she speaks with the relevant parties, which may include the patient, next of kin, their carer, their GP etc. as soon as possible. Formal actions required under the Being Open Policy must then be planned.

If a member/members of staff are involved - make arrangements to ensure the relevant next of kin is kept fully apprised of the situation.

5.2 Serious Incidents Occurring Outside the hours of Monday To Friday, 09:00hrs – 17:00hrs

Step 1 - Immediate Action

The immediate handling of the Incident will be the responsibility of the most senior person at the scene. That person needs to:

- Ensure the immediate safety and care of people involved i.e. patients, visitors, staff.
- If warranted, make contact with the emergency services.
- Preserve all evidence for the subsequent investigation, ensuring it is kept secure (this may be a police investigation as well as an internal investigation).
- If necessary, secure the area, to ensure everything is untouched. Lock doors and put up signs clearly stating that no-one is permitted to enter the area.
- Explain the reason for the closure to patients, relatives, visitors and staff in the vicinity, without breaching confidentiality.
- Inform the appropriate person of the situation (see Step 2 - Reporting), including the relevant on-call Senior Manager.
- Commence completion of the Incident Report (IR1), documenting the sequence of events. (This must be received by the Serious Incident Team within 24 hours of normal working hours commencing.) If there are witnesses, ensure they complete a Witness Report (IR2).
- Separate procedures exist for reporting any incidents to the Health Board occurring during the provision of primary care Out of Hours services.

Step 2 - Immediate Internal and External Reporting

- The senior person taking responsibility at the scene must notify the On-Call Manager of the Incident and the action being taken.
- The On-Call Manager must notify the Executive Director On-Call of the Incident and discuss the action already being taken and to be taken.
- The On-Call Manager and Executive Director On-Call will organise contact with the senior staff on the scene to ensure that all appropriate action is taken prior to commencement of the next working day

- If the Incident is sufficiently serious, the Executive Director On-Call should contact the Chief Executive and a decision will be made on whether contact with the designated On-call Professional at the Welsh Government (such contact being through the main switchboard at Cathays Parc – 02920 823650).
- The Executive Director On-Call will contact the Medical Director, Executive Director of Nursing and Patient Experience relevant Clinical Director(s) and Serious Incident Team the next working day, following which, the steps outlined under the 'Normal Working Hours' procedure should be followed.

Further guidance and assistance regarding management of Serious Incidents or whether a matter is considered a Serious Incident can be sought from the Serious Incident Investigation Team within working hours.

From: SBU Inquiries

Sent: 22 March 2021 13:10

To: Adel Davies (Swansea Bay UHB - Trauma, Orthopaedics and Spinal)

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Cc: Catrin Evans (Swansea Bay UHB - Strategy) <Catrin.A.Evans@wales.nhs.uk>; Clare Dauncey (Swansea Bay UHB - Human Resources) <Clare.Dauncey@wales.nhs.uk>; Ebony Smith (Swansea Bay UHB - Corporate Services) <Ebony.Smith@wales.nhs.uk>; Francesca Proietti (Swansea Bay UHB - Informatics Directorate) <Francesca.Proietti@wales.nhs.uk>; Jillian Rix (Swansea Bay UHB - Chair Chief Execs Office) <Jillian.Rix@wales.nhs.uk>; Kirsty Joseph (Swansea Bay UHB - Corporate Services) <Kirsty.Joseph@wales.nhs.uk>; Linda Smith (Swansea Bay UHB - Nursing Division) <Linda.Smith@wales.nhs.uk>; Paula Picton (Swansea Bay UHB - Strategy) <Paula.Picton@wales.nhs.uk>; Sally Anne Jones (Swansea Bay UHB - Executive Medical Directors Dept) <Sallyanne.Jones@wales.nhs.uk>; Sonja Anderson (Swansea Bay UHB - Finance) <Sonja.Anderson@wales.nhs.uk> **Subject:** Policy email

I write to advise that the following policy has been updated and added to the Corporate Policies database:

□ Concerns Management Policy (previously called 'Putting Things Right')

The policy is available to view via the [corporate policy database](#)

Gwasanaethau Corfforaethol / Corporate Services

Bwrdd Iechyd Prifysgol Bae Abertawe/ Swansea Bay University Health Board

Pencadlys / Headquarters

Un Porthfa Talbot/ One Talbot Gateway, Baglan, Port Talbot, SA12 7BR