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BEING OPEN PROCEDURE

Introduction and Aim

It is the policy of the UHB to be open with patients and staff following adverse events.

The Being Open framework was introduced to the NHS by the former National Patient Safety Agency (NPSA). It broadly involves:

- acknowledging, apologising and explaining to patients, their families and carers when things go wrong;
- when appropriate, conducting a thorough investigation into adverse incidents and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring;
- providing support for those involved to cope with the physical and psychological consequences of what happened.

The need for openness, transparency and candour was reinforced by Robert Francis QC in the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013 which recommended that a statutory duty of candour be introduced for health and care providers.

The following definitions were referred to the Report and are adopted by the UHB.

- Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

Objectives

This procedure outlines the UHB's responsibilities following a patient safety incident occurring or a concern being raised, in accordance with the principles of Being Open, as established by the NPSA. The 10 principles are as follows:

1. Acknowledgement

2. Truthfulness, timeliness and clarity of communication
3. Apology
4. Recognising patient and carer expectations
5. Professional support
6. Patient safety, risk management and systems improvement
7. Multidisciplinary responsibility
8. Clinical governance
9. Confidentiality
10. Continuity of care

Supporting information behind these principles is defined in the body of this procedure to assist staff to consistently apply these principles.

The procedure assumes the former NPSA's definition of a patient safety incident which is 'any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded care'.

The Putting Things Right guidance for NHS Wales states that where an incident occurs and there has been moderate, severe harm or death, the UHB must advise the patient to whom the concern relates, or his or her representative, of the concern and involve them in the investigation of the matter. This should be managed in accordance with advice set out in the Being Open framework. The exception to this is if informing the patient or their representative could cause a deterioration in their physical or mental health. Such decisions must be taken with careful consideration and the rationale documented fully in the medical records. If a person lacks capacity, any decisions must be taken in accordance with the Mental Capacity Act (2005).

The following severity grading is adopted from the Putting Things Right guidance and applies as indicated to Being Open.

Severity grading / Level of harm	Potential for qualifying liability / Redress	Does Being Open apply?
1 / No harm	Highly unlikely	Not mandated
2 / Low harm	Unlikely	Not mandated
3 / Moderate harm	Possible	Yes
4 / Major harm	Likely	Yes
5 / Catastrophic harm	Very likely	Yes

Scope

This procedure applies to all staff in all locations, including those with honorary or temporary contracts.

The procedure applies when harm to patient/s at moderate, major or catastrophic level has been identified. This is irrespective of whether the harm is identified by patients, their family or carers, for example, through the concerns process or by staff through incident reporting procedures. Any decision to discuss near miss / low harm incidents with patients,

their families and carers will be on an individual patient basis.	
Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be no impact.
Documents to read alongside this Procedure	• Incident, Hazard and Near Miss Reporting Policy and Procedure • Welsh Government Putting Things Right Guidance November 2013 (which includes Serious Incident Reporting) • Never Events, updated April 2018 • UHB Serious Incident process which includes Never Event processes • All Wales Root Cause Analysis (RCA) toolkit • Just Culture guide from NHS Improvement
Approved By	Quality, Safety and Experience Committee
Group with authority to approve procedures	Clinical Board Quality, Safety and Experience Groups
Accountable Executive or Clinical Board Director	Executive Nurse Director
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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
			State if either a new document, revised document (please list main amendments). List title and reference number of any documents that may be superseded
1	18 Dec 2018	15 Jan 2019	New Procedure document devised as Policy and Procedure documents have been separated.

1 Roles and Responsibilities

1.1 **Board members** have a crucial role to play in ensuring the Being Open principles are embedded in the UHB. Being Open should be at the core of the organisation's values and culture of working with patients, the public and staff.

The Being Open procedure is a demonstration of the Board's commitment to publicly endorse the principles of Being Open, setting out the duty of all staff to follow the Being Open principles and reinforcing the organisation's full support of an open, honest and fair culture.

1.2 The **Chief Executive** has overall responsibility for ensuring that there are arrangements in place for the UHB to comply with its obligations for Being Open.

1.3 The **Executive Nurse Director** has delegated responsibility from the Board for the management of patient experience, patient safety and quality. As such, the implementation of the Being Open procedure sits within the remit of the Executive Nurse Director.

1.4 The **Assistant Director of Patient Experience and Assistant Director of Patient Safety and Quality** are responsible for ensuring that systems and processes for the operational management of concerns are established and consistently applied with the support of the Concerns Department, Patient Experience Team and Patient Safety Team.

1.5 **Clinical Board Management Teams** are responsible for ensuring the Being Open procedure is communicated to staff and implemented in their clinical/service areas. They must ensure they have sound mechanisms in place for recognition and escalation of untoward incidents that may have caused patient harm.

1.6 **Directorate Management Teams** are responsible for ensuring the Being Open procedure is communicated to staff and implemented in their clinical/ service areas. They must ensure they have sound mechanisms in place for recognition and escalation of untoward incidents that may have caused patient harm.

1.7 The **identified person nominated to be the patient/family contact lead person** is responsible for ensuring that communication with patients, family or carers is timely; open and honest; meets their individual needs, for example, use of translators where necessary and is in accordance with the 10 principles of Being Open which are outlined within this procedure.

The contact lead person must ensure that full written records of communication with patients, family or carers are kept.

Staff are encouraged to use the electronic risk management database (Datix) to store the communication log that they maintain.

1.8 **Individual members of staff** are responsible for ensuring that they comply with the Being Open procedure and their associated Code of Conduct for registered healthcare professionals. It is imperative that staff recognise and escalate untoward incidents to their line manager or person in charge, especially where harm to patients has occurred. Staff must ensure that their communication with patients, families or carers is in accordance with the 10 principles of Being Open. Staff must identify if they require training and support in Being Open.

2 Foundations for Being Open

2.1 Open and effective communication with patients should begin at the start of their care and continue throughout their time within the healthcare system.

2.2 This should be no different when a patient safety incident occurs. Being open when things go wrong is key to the partnership between patients and those who provide their care. Openness about what happened and discussing patient safety incidents/concerns promptly, fully and compassionately can help patients and staff cope with the after-effects.

2.3 Concerns can incur extra costs through litigation and further treatment. Openness and honesty at an early stage can help prevent such events becoming formal concerns and litigation claims. Well managed concerns may allow for legal costs to be minimised.

2.4 Being open involves:

- Acknowledging, apologising and explaining when things go wrong;
- Conducting a thorough investigation into the incident and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring;
- Providing support for those involved to cope with the physical and psychological consequences of what happened.

2.5 Saying sorry is not an admission of liability and is the right thing to do. Patients have a right to expect openness in their healthcare.

2.6 To implement Being Open successfully, healthcare organisations need to have the following foundations in place:

- A culture that is open and fair where patient safety and quality of

care is the key priority;

- A strong focus on clinical leadership and direction for patient safety;
- Integrated risk management systems that are mature, proactive and responsive when necessary;
- Staff are encouraged to report incidents and the organisation complies with external reporting requirements;
- Developed mechanisms to involve and communicate with patients and members of the public about the UHB's business;
- Use of recognised investigation methodology to learn how and why incidents happen;
- Processes to embed lessons learnt through changes to practice and appropriate monitoring mechanisms.

3 10 Principles of Being Open

3.1 Principle 1 - Acknowledgement

All concerns should be reported and acknowledged as soon as they are identified. In cases where the patient, their family or carers inform healthcare staff that something untoward has happened, it must be taken seriously from the outset and escalated promptly to an appropriate senior person. Any concerns should be treated with compassion and understanding by all healthcare professionals.

3.2 Principle 2 - Truthfulness, timeliness and clarity of communication

Information about a concern must be given to patients, their families and carers in a truthful and open manner by an appropriate person. Patients should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly. Communication should also be timely. Patients, their families and carers should be provided with information about what happened as soon as practicable.

It is essential that any information given is based solely on the facts known at the time. Healthcare professionals should explain that new information may emerge as the investigation is undertaken, and that patients, their families and carers will be kept up-to-date with the progress of an investigation.

Patients, their families and carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of medical jargon which they may not understand must be avoided.

3.3 **Principle 3 - Apology**

Patients, their families and carers should receive a meaningful apology. It must be a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident or for the experience which has led them to raise the concern. This should be in the form of an appropriately worded and agreed apology as early as possible.

It is important to identify the most appropriate person to express an apology to the patient, their family and carers. A Serious Incident meeting provides a suitable forum for this discussion to take place. However, there may be an urgent need to disclose to a patient, their family and carers that a patient safety incident has occurred. This may occur out of hours, in which case support from appropriate management staff may be necessary.

Where it is possible to plan and prepare for the disclosure and apology, the decision should consider the seniority of the person to lead the process; their relationship with the patient and their experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are encouraged because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as practicable once staff are aware an incident has occurred. A written apology should follow which clearly states that the UHB is sorry for the suffering and distress resulting from the incident. Written apologies should be issued following advice and input from relevant senior managers.

Corporate departments such as the Concerns Department and Patient Safety Team must also be consulted.

An initial meaningful apology should not be delayed as there is evidence that delays are likely to increase the anxiety, anger or frustration experienced by patients, their families and carers. Focus groups on this matter have reported that patients were more likely to seek legal advice if verbal and written apologies were not delivered promptly.

3.4 **Principle 4 – Recognising patient and carer expectations**

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident and its consequences, in a face-to-face meeting with representatives from the UHB. They should be treated sympathetically, with respect and consideration. They should also be provided with support in a manner appropriate to their needs – e.g. a translator or advocate where necessary.

Where appropriate, information on support available from Community

Health Councils (CHC) and other relevant groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient or their family and carers as soon as possible.

3.5 Principle 5 – Professional support

The UHB must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

To ensure a robust and consistent approach to incident investigation and management of staff involved, managers are encouraged to use the Just Culture guide, published by NHS Improvement which can be accessed here

Where there is reason for the UHB to believe that a member of staff has committed a punitive or criminal act, the UHB must take appropriate steps in conjunction with advice from Workforce and Development. In such circumstances, the staff member(s) should be advised that separate legal advice and/or representation may be appropriate.

The UHB encourages staff to seek support from relevant professional bodies following significant adverse events. Occupational Health referral and use of services available from the Employee Assistance Programme may be beneficial.

Appropriate support mechanisms must also be in place for the Being Open lead.

3.6 Principle 6 – Risk management and systems improvement

Root Cause Analysis (RCA), Significant Event Audit (SEA) or other recognised investigation methodology must be used to uncover the underlying causes of a patient safety incident. The investigation should focus on identifying care and service delivery problems in order to develop solutions that will make improvements to systems and minimise the risk of recurrence.

The Being Open procedure is integrated into the UHB's incident reporting and risk management policies and procedures. It is embedded within the UHB's overarching Quality, Safety and Improvement Framework.

3.7 Principle 7 – Multidisciplinary responsibility

Managers and senior clinical staff are expected to support and guide their teams through investigations and the resulting risk management processes. Most healthcare provision is delivered through multidisciplinary teams and this should be reflected in the way that patients, their families and carers are communicated with following a patient safety incident. This will ensure that the Being Open process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual. Generating solutions following adverse events should be a multidisciplinary process to maximise the chance of successfully embedding change.

3.8 Principle 8 – Clinical governance

The Being Open process requires sound quality and safety improvement procedures, underpinned by a robust clinical governance framework. Within this framework, patient safety incidents and concerns will be investigated and analysed in order to prevent their recurrence. The findings from the investigations will be disseminated to healthcare professionals so that they can learn from patient safety incidents.

This principle requires a system of accountability where all staff take personal responsibility to ensure that necessary changes are implemented with audit programmes in place to monitor effectiveness. Mechanisms to feedback to staff widely across the UHB and more broadly where appropriate must be in place.

It is imperative therefore, that Directorate and Clinical Board quality and safety arrangements are sufficiently mature to ensure that robust clinical governance is in place.

Likewise, various committees of the Board have a crucial role in ensuring that accountable systems are in place, for example, Quality, Safety and Experience Committee.

Other means by which the effectiveness of governance is assessed include Internal Audit; Welsh Risk Pool claims assessments; Welsh Government Serious Incident reporting and monitoring mechanisms.

3.9 Principle 9 – Confidentiality

Patient confidentiality and the right to privacy for the patient, their family and carers must be respected. All staff involved in a patient safety

incident also have the right to confidentiality. Communication with parties outside of the immediate people involved should be on a strictly need-to-know basis.

In the majority of cases, the investigation of a concern will require access to medical records and so the issue of consent will need to be considered. Further information is contained with the Welsh Government's *'Guidance on dealing with concerns about the NHS from 1 April 2011'* which can be accessed here

3.10 **Principle 10 – Continuity of care**

Patients are entitled to expect that they will continue to receive their usual treatment and continue to be treated with dignity, respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, this should be arranged where possible.

4 The Being Open Process

4.1 Stage 1: Incident detection or recognition

The Being Open process begins with the recognition that a patient has suffered harm or has died as a result of a patient safety incident. It may be identified by:-

- a member of staff at the time of the incident;
- a member of staff retrospectively when an unexpected outcome is detected;
- a patient, their family or carers express concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively;
- incident detection systems such as incident reporting, medical records reviews or mortality reviews;
- external processes such as via Her Majesty's Coroner.

As soon as a patient safety incident is identified, the key priority is prompt and appropriate clinical care and prevention of further harm. Where additional treatment is required, this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent.

The UHB's processes for incident reporting must be followed in order to ensure compliance with clinical governance procedures and other onward reporting requirements.

4.1.1 Patient safety incidents occurring elsewhere

A patient safety incident may have occurred in an organisation other

than where it is detected or it may involve care provided across multiple providers. In these situations, the UHB will need to liaise with the other organisation(s) involved and agree roles and responsibilities, including the Being Open arrangements.

4.1.2 **Criminal or intentional unsafe acts**

Patient safety incidents are almost always unintentional. However, if at any stage it is determined that harm may have been the result of a criminal or intentional unsafe act, the matter must be escalated to a line manager immediately. The Executive Nurse Director or designated deputy must be informed as soon as practically possible. Out of hours, the on call Executive must be informed. The Just Culture guide from NHS Improvement should be referred to.

Additional notification

4.1.3 In addition, the following notifications should be considered where appropriate:

- Contacting the patient's GP where there are implications for care;
- All cases of untimely, unexpected or unexplained deaths and suspected unnatural deaths must be reported to Her Majesty's Coroner. Any restrictions or requests from the Coroner to the UHB must be heeded whilst his/her investigations take place. This should not preclude a verbal and written, meaningful apology or expression of regret being given to the family or carers of the patient. It should be made clear to the family how internal investigation arrangements will correlate with the Coroner's procedures. The Coroner often finds internal investigation reports to be useful as part of the inquest process. To that end, it is not uncommon for the UHB to provide the Coroner, family/carers and staff with an interim investigation report, pending any additional information that may come to light during the inquest process. Coroner's investigations and inquests can often be stressful for families/carers and healthcare professionals. Individuals should be signposted to appropriate support mechanisms from the outset, for example, bereavement support; Employee Assistance Programme.
- The UHB must ensure it complies with national incident notification requirements for reporting adverse incidents - for example, Serious Incident reporting to Welsh Government, Health and Safety Executive, Medicines and Healthcare Products Regulatory Agency.

4.2 **Stage 2: Preliminary team discussion**

4.2.1 The UHB has flowcharts in place to guide senior clinical staff and managers following a significant patient safety incident. They can be accessed here

4.2.2 Directorate and Clinical Board management teams should host an initial Serious Incident meeting. In the case of a Never Event, the Executive Nurse Director will usually chair the meeting but may delegate this to another person for example, the Assistant Director of Patient Safety and Quality.

4.2.3 The staff involved in the care of the patient at the time of the patient safety incident will not usually be present at the initial meeting. The purpose of the meeting is to establish an appropriate response to the incident. For example, investigation arrangements; liaison with the patient and their family; staff support. The consultant responsible for the care of the patient may be required to attend the initial meeting to provide information and background. Due consideration will be needed if the consultant was personally involved in the patient safety incident.

Timing of the initial discussion with the patient, family and carers

4.2.4 The initial Being Open discussion with the patient, their family and carers should occur as soon as possible after recognition of the patient safety incident. Factors to consider when timing this discussion include:

- clinical condition of the patient;
- patient preference (in terms of when and where the meeting takes place, whether they wish family/friends to be present and which healthcare professional leads the discussion);
- privacy and comfort of the patient;
- availability of the patient, their family and/or carers;
- availability of key staff involved in the incident and in the Being Open process;
- availability of support staff, for example - a translator or independent advocate, if required;
- arranging the meeting in an appropriate location – for example, at the patient's home;
- some patients, families/carers may require more than one meeting to ensure that all the information has been communicated and understood by them.

Choosing the individual to communicate with patients, their families and carers

4.2.5 The most suitable person to be the main contact with the patient/family will depend on the facts of each case. It may be that the most senior person responsible for the patient's care is the most suitable person or it could be someone with experience and expertise in the type of incident that has occurred. Ideally, the person should have received training in communication after patient safety incidents or have experience in managing patient safety incidents.

Other factors to consider when choosing the main contact person are that the

person should :

- be known to, and trusted by, the patient, their family and carers or have an ability to develop a professional relationship in difficult circumstances;
- have a good grasp of the facts relevant to the incident;
- be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients, their families and carers, and colleagues;
- have excellent interpersonal skills, including being able to communicate with patients, their families and carers in a way they can understand, and avoiding use of medical jargon;
- be willing and able to offer a meaningful apology, reassurance and feedback to patients, their families and carers;
- be able to maintain a medium to long-term relationship with the patient, their family and carers, where possible, and to provide continued support and information;
- be culturally aware and informed about the specific needs of the patient, their family and carers.

4.2.6 In exceptional circumstances, if the allocated lead cannot attend the initial meeting with the patient/family, the responsibility may be delegated to another appropriately trained clinician.

4.2.7 If it becomes clear during the Being Open process that the patient, family or carers would prefer to speak to a different healthcare professional, this should be respected and alternative arrangements should be made.

4.2.8 Junior staff or those in training would not generally lead the Being Open process except when all of the following criteria have been considered:

- the incident resulted in low harm;
- they have expressed a wish to be involved in the discussion with the patient, their family and carers;
- the senior healthcare professional responsible for the care is present for support;
- the patient, their family and carers agree.

4.2.9 Where a junior healthcare professional asks to be involved in the Being Open discussion, it is important that they are accompanied and supported by a senior team member.

4.2.10 In situations where a healthcare professional wishes to contribute to Being Open discussions to personally apologise to the patient, family or carers, they should be provided with support from senior colleagues unless a preference from the patient, family or carers is expressed for that person not to be present. In such circumstances, a personal written apology can be offered as an alternative.

4.3 Stage 3 – Initial Being Open discussion

4.3.1 The patient, their family and carers should be advised of the identity and role of all people attending the Being Open discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff they want to be present.

4.3.2 If for any reason it becomes clear that the patient, family or carers would prefer to speak to a different healthcare professional, their wishes should be respected. A substitute with whom they are satisfied should be provided.

4.3.3 It must be acknowledged that patients, their families and carers may be anxious, angry and frustrated, even when the discussion is conducted appropriately. The discussion must not speculate, attribute blame, deny responsibility or provide conflicting information.

4.3.4 The initial discussion should cover:

- An expression of genuine sympathy, regret and a meaningful apology for the harm that has occurred.
- The facts that are known as agreed by the multidisciplinary team. Where there is disagreement or lack of clarity about the facts, communication about them must be deferred until such time as they are confirmed through the investigation process.
- The patient, family and carers are informed that an investigation is to be completed and more information will become available as it progresses.
- The patient, family and carers' understanding of what happened is taken into consideration, as well as any questions they may have.
- Formal noting of the patient, family and carers' views and concerns demonstrates that these are being heard and taken seriously.
- Appropriate language and terminology are used when speaking to the patient, family and carers. If their first language is not English, arrangements must be made to communicate in their language of choice.
- An explanation about what will happen in terms of the short through to long-term treatment plan, sharing of incident investigation findings and improvement plan arrangements.
- Information on likely short and long-term effects of the incident (if known). The long-term effects may have to be presented at a subsequent meeting when more is known.
- An offer of practical and emotional support for the patient, family and carers. This may involve support from third parties such as voluntary organisations or the Community Health Council. Information about the patient and the incident must not be disclosed without consent.
- It should be explained to the patient that they are entitled to

continue to receive all their usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made where possible.

- The patient, their family or carers should be given information about Putting Things Right.

4.4 Stage 4 – Follow-up discussions

4.4.1 Follow-up discussions with the patient, family or carers are an important step in the Being Open process. Depending on the incident and the timeline for the investigation, there may be more than one follow-up discussion.

4.4.2 The following guidance is offered in order to make the communication effective:

- The discussion occurs at the earliest practical opportunity when there is additional information to report.
- Consideration is given to the timing of the meeting, based on both health and wellbeing and personal circumstances of the patient, family or carers.
- Consideration is given to the location of the meeting – it may be appropriate to be held at the family's home, for example.
- Appropriate attendees need to be invited, for example, Community Health Council representative where appropriate, in addition to UHB staff and the patient, family and carers.
- Feedback is given on progress to date and information provided on the investigation process.
- There should be no speculation or attribution of blame. The healthcare professional communicating the incident must not criticise or comment on matters outside of their expertise.
- A written record of the discussion is kept and shared with the patient, their family and carers.
- All queries are responded to appropriately.
- If completing the process at this point, the patient, their family and carers should be asked if they are satisfied with the investigation and a note made of this in the record of the discussion. The patient should be provided with contact details of an appropriate person so that there is a defined route for them to return to the UHB at a later date, should the need arise.

4.5 Stage 5 – Process completion

4.5.1 Communication with the patient, family and carers

On completion of the investigation, feedback to the patient, family and carers should take the form most appropriate and acceptable to them. It must include the following information:

- The chronology of clinical and other relevant facts;
- Details of the patient, family and carer concerns;
- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident;
- A summary of the factors that contributed to the incident;
- Information on what has and will be done to avoid recurrence of the incident and how these improvements will be monitored.

4.5.2 It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases, information may be withheld or restricted if there are legal requirements that preclude disclosure for specific purposes. In these circumstances, the patient, family and carer must be informed of the reasons for the restrictions.

4.5.3 Sometimes patients, family and carers may request investigation reports be shared with them in order that they can digest the content before meeting with UHB representatives. Care must be taken to avoid untimely arrival of the report, for example, over a weekend. Follow up arrangements may be required to make contact with the patient, family and carers following their receipt of the report in case immediate additional support is required.

Continuity of care

4.5.4 When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, the clinical management plan must be discussed and agreed with them. Patients, family and carers must be reassured that they will continue to be treated according to their clinical needs, even in circumstances where there is a dispute between them and the healthcare team. They should be advised that they have the right to continue their treatment elsewhere if they prefer and the UHB will assist them with this request wherever possible. If the patient, family or carer request that care be transferred, advice should be sought from Directorate and Clinical Board management teams in the first instance.

Communication with the GP and other community care service

providers when patient safety incidents did not occur in primary care

4.5.5 Wherever possible, it is advisable to send a brief communication to the patient's GP, prior to discharge from secondary care, describing what happened. It may be necessary to share information with appropriate community care services who will have ongoing contact with the patient. Consideration will be needed as to whether consent to share information will be required from the patient.

4.5.6 Such communication should contain summary details of:

- The nature of the patient safety incident and the continuing care and treatment;
- The current condition of the patient;
- Key investigations that have been carried out to establish the patient's clinical condition;
- Recent results;
- Prognosis.

4.5.7 It may be valuable to consider including the GP in a follow-up Being Open discussion if deemed appropriate and if the patient agrees.

Monitoring

4.5.8 Any recommendations for systems improvements and changes should be monitored for effectiveness in preventing a recurrence. Directorates and Clinical Boards must ensure they have processes in place to monitor compliance with improvement action plans.

Communicating changes to staff

4.5.9 Effective communication with staff is a vital step in ensuring that the recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of Being Open.

5 Documentation

5.1 Throughout the Being Open process it is important to record discussions with the patient, family and carers. Written notes should be made and shared with the relevant parties. Alternatively, voice recordings can be made and downloaded for electronic storage if all parties are in agreement that the meeting be recorded. The Concerns Department and Patient Safety and Quality Department have access to voice recording equipment.

5.2 The incident report, record of the investigation and Being Open process should be filed separately to the patient's medical records. Information can be uploaded to the relevant record on the UHB's risk management database (Datix).

Written records of the Being Open discussions

5.3 There should be documentation of the following:

- the time, place (note: these may be telephone calls as well as face to face meetings), date; the name and role/relationships of all attendees;
- plans for providing further information to the patient, their family and/or their carers;
- offers of assistance, and the patient's, their family and/or their carers' response;
- questions raised by the patient, family, carers or their representatives, and the answers given;
- plans for follow-up as discussed;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient, their family and/or their carers;
- copies of letters sent to the patient, their family and/or their carers and the GP for patient safety incidents involving the GP but originating in secondary care;
- copies of any documents gathered in the investigation process will be shared at an appropriate time, for example, when the investigation report is shared. Documents may include statements taken in relation to the patient safety incident, the incident form, policies and procedures referred to in the report etc.

5.4 The records of the Being Open discussions should be shared with the patient, their family and/or carers.

6 Patient issues to consider

Advocacy and support

6.1 Patients, their families and carers may need considerable practical and emotional help and support after experiencing a patient safety incident. It is important to discuss their needs with the relevant individuals. Support may be provided by patients' families, social workers, religious representatives, advocates and the Community Health Council.

Where the patient, their family and/or their carers require long-term support, advice can be sought from charitable organisations such as Cruse Bereavement Care or via the GP.

Particular patient circumstances

6.2 When a patient dies

6.2.1 When a patient safety incident has resulted in a patient's death, it is even more

crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's family and carers may need information on the processes that will be followed to identify the cause(s) of death in addition to needing emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Usually the Being Open discussion and any investigation occurs before the Coroner's inquest. In some circumstances it may be appropriate to wait for the Coroner's inquest before holding the Being Open discussion with the patient's family and carers. The Coroner's post mortem report may be a key source of information that will help to complete the picture of events leading up to the patient's death and help the UHB determine if Being Open disclosure is required. In any event, an apology should be issued as soon as possible after the patient's death, together with an explanation that the Coroner's process has been initiated and a realistic timeframe of when the family and carers will be provided with more information.

Children

6.2.2 Where a child under the age of 16 is judged to have the intelligence and maturity to understand the information provided, he/she should be involved directly in the Being Open process after a patient safety incident, unless they decide that they don't want to be involved. The opportunity for parents to be involved should be provided unless the child expresses a wish for them not to be. Where children are assessed not to have sufficient intelligence or maturity, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. In general though, children should be as involved in the process as they wish to be.

Patients with mental health or learning disability issues

6.2.3 Being Open for patients with mental health or learning disability issues should follow normal procedures unless the patient also lacks mental capacity to decide whether or how to participate in the process (see section 6.2.4). The circumstances in which it is appropriate to withhold patient safety incident information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who considers it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient.

Patients with cognitive impairment

6.2.4 Some patients have conditions that limit their ability to understand what is happening to them. However, they may have authorised a person to act on their behalf by executing a Lasting Power of Attorney (LPA). In these cases, steps must be taken to ensure that the LPA covers the relevant medical care and treatment of the patient and (where relevant) making complaints on their behalf. Patients may also have had a deputy appointed for them by the court, although deputies covering health and welfare decisions are rarely appointed. The Being Open discussion would be conducted with the attorney of the Lasting power of attorney (if the patient is assessed to lack mental capacity to make decisions about their participation in the process) or deputy. Where there is no such person and the patient is unable to determine who they would like to be involved, the clinicians may act in the patient's best interests, in accordance with the Mental Capacity Act 2005 in deciding who (if anyone) the appropriate person is to discuss incident information with. Care must be taken not to breach the patient's confidentiality, unless it is in the patient's best interests to do so. However, patients with cognitive impairment should, wherever possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

<u>Patients with different language or cultural considerations</u>

6.2.5 If a patient and/or family/carers' first language is not English, or there are other communication barriers, their needs should be addressed using available services and aids. The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety incident information. It is advisable to obtain guidance from an advocate or translator before the meeting on the most sensitive way to discuss the information. The use of 'unofficial translators' such as the patient's family or friends must be avoided wherever possible so as to reduce the risk that they may distort information by editing what is communicated and also to avoid breaching the patient's confidentiality.

<u>Patients with different communication needs</u>

6.2.6 Patients may have particular communication difficulties, such as a hearing impairment. Plans for any meetings must take these sensory needs fully into account.

<u>Patients who do not agree with the information provided</u>

6.2.7 Sometimes, the relationship between the patient, their family and carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Being Open process. In this case, following strategies may assist:

- deal with the issue as soon as it emerges;

- where the patient agrees, ensure their family and carers are involved in discussions from the beginning;
- ensure the patient has access to support services including advocacy – e.g. Community Health Council;
- where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team;
- offer the patient, their family and carers another contact person with whom they may feel more comfortable; this could be another member of the team or senior manager;
- use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution;
- ensure the patient, their family and carers are fully aware of the formal complaints procedures;
- write a comprehensive list of the points that the patient, their family and carers disagree with, reassure them you will follow up these issues and report the outcomes back to them.

7 Strengthening Being Open by supporting staff

7.1 When a patient safety incident occurs, healthcare professionals involved in the patient's clinical care may also require emotional support and advice. Professionals who have been involved directly in the incident, those with the responsibility for Being Open discussions and those who support the Being Open process (people who can provide mentoring and support to their colleagues, e.g. staff within the Concerns department and Patient Safety Team) should be given access to assistance, support and any information they need to fulfil their roles.

7.1.1 To support healthcare staff involved in patient safety incidents, the UHB will:

- Actively promote an open and fair culture that fosters peer support and discourages the attribution of blame. The UHB will continue to work towards a just culture where human error is understood to be a consequence of flaws in the healthcare system, not necessarily the individual.
- Opportunities to educate staff about Being Open will be taken, ensuring that staff understand that apologising to patients, their families and carers is not an admission of liability and is the right thing to do;
- Will promote the value of debriefing of the clinical team involved in the patient safety incident. This will be separate from the requirement of staff to contribute to the investigation process which may require additional support for staff, such as statement writing. Feedback to staff regarding the outcome of the investigation process is essential. Involving staff in generating solutions is also encouraged.
- Offer specific systems of support for staff via line management routes,

Occupational Health and the Employee Assistance Programme.

- Provide advice and training on the management of patient safety incidents via the Patient Safety Team.

7.2 The UHB actively encourages staff to raise concerns about safety. If for any reason they feel unable to report an incident in line with this procedure, there are other routes for them to raise their concerns. These would include Freedom to Speak Up, Safety Valve and Whistleblowing Policy. Click here for more information about raising a concern.

7.3 The UHB recognises that being involved in an adverse incident can have devastating effects on staff. It is vital that the appropriate supporting mechanisms are put in place.

7.4 The Just Culture Guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Further information can be found here.

8 Training

8.1 Being Open is embedded and promoted as part of all existing training on incident reporting and concerns management offered by the Concerns Department and Patient Safety Team.

8.1.1 E-learning opportunities are available on the following websites:

Royal College of Surgeons – Duty of Candour e-learning:
http://vle.rcseng.ac.uk/course/view.php?id=321

NHS e-learning repository – Being Open e-learning: (create an account with a valid NHS email address)
https://www.elearningrepository.nhs.uk//

9 IMPLEMENTATION

9.1 This procedure reflects existing practice across the UHB and will therefore be implemented with immediate effect. The requirements of this procedure will be re-enforced within Clinical/Service Boards and Directorates/Departments by local risk management and quality and safety arrangements.

10 EQUALITY

10.1 We have undertaken an Equality Impact Assessment and received feedback on this policy and procedure and the way it operates. We wanted to know of any possible or actual impact that this policy may have on any groups in respect of gender, maternity and pregnancy, carer status, marriage or civil

partnership issues, race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no adverse impact to the equality groups mentioned. Where appropriate we have taken the necessary actions required to minimise any stated impact to ensure that we meet our responsibilities under the equalities and human rights legislation.

11 MONITORING

11.1 It will be necessary to ensure that Clinical/Service Boards are adhering to the requirements of this procedure. This will be monitored via a number of performance indicators such as local audit of compliance by Directorates and Clinical Boards; corporate arrangements such as by the Concerns Department and Patient Safety Team; formal assessments including Health and Care Standards, Internal Audits.

The Quality, Safety and Experience Committee will monitor implementation of this policy.

12 DISTRIBUTION

12.1 This procedure will be available on the UHB Clinical Portal, Intranet and Internet Site.

12.1.1 Line Managers/Departmental Managers/Lead Nurses/Directorate Managers/Clinical Directors are responsible for ensuring that all staff have access to this document.

13 REVIEW

13.1 This procedure will be reviewed every three years or sooner if required.