Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

PWYLLGOR ANSAWDD, DIOGELWCH A SICRHAU PROFIOD
QUALITY, SAFETY AND EXPERIENCE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	13 June 2023
TEITL YR ADRODDIAD: TITLE OF REPORT:	Management and Distribution of Safety Alerts and Notices Policy
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Mandy Rayani, Executive Director of Nursing, Quality and Patient Experience
SWYDDOG ADRODD: REPORTING OFFICER:	Cathie Steele, Head of Quality and Governance

Pwrpas yr Adroddiad (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate)
Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

The Quality Safety and Experience Committee (QSEC) is asked to approve the Management and Distribution of Safety Alerts and Notices Policy (Policy 429).

This report provides the required assurance that the Written Control Document (WCD) Policy (Policy number 190) has been adhered to in the development of the above mentioned written control document and that therefore the document is in line with legislation/regulations, available evidence base and can be implemented within the Health Board.

Cefndir / Background

Is this a new or revised document?	Review of existing 429 procedure	
Brief summary of the document	This policy sets out the arrangements for the distribution of Safety Alerts, Notices and Bulletins within Hywel Dda University Health Board.	
Scope of the document	This procedure applies to all managers and employees within the Health Board along with any locum staff and contractors. The procedure does not replace the duty and professional accountability of staff to report any adverse incident involving a medical device, hazardous product or unsafe procedure, in line with Health Board policies and other written control documents.	
Reason(s) for developing/adopting/ reviewing the document	Improve/standardise clinical/organisational procedures	
	Response to complaint, incident or claim	
	Response to alert, safety notifications, WHC	
	Re-organisation of service/department	
	New/amended legislation	
	AW document, national guidance to be adopted	
	Replacement/updating existing documents	Yes
	Other – provide details	

Is the document about invasive procedures?	No
Is the document in support of avoiding a 'Never Event' as defined by WHC/2018/12?	No
Is the Nurse Staffing Levels (Wales) Act 2016 relevant to this document?	No
Owning group	Operational Quality Safety and Experience Sub Committee (OQSESC)
	Willlam Oliver, Chair
	The QSEC is asked to approve OQESC as the new owning group for this policy. (No agreement has previously been made)
Lead author	Cathie Steele

Assurance		
Equality Impact Assessment	A screening Equality Impact Assessment (EqIA) has been undertaken (appendix 2). The procedure has been assessed as having a low relevance to the General Equality Duties.	*Attach a copy of the EqIA*
Evidence base	The reference section lists all the sources of evidence which has informed the content of the document. The Lead Author on behalf of the Owning Group sourced the references themselves?	
Compliance with legislation/regulation/alert	NHS Executive (2023) NHS Executive Policy on Patient Safety Incident Reporting and Management (issued via WHC/2023/017) Welsh Government (2014) Guidance on NHS Wales Patient Safety Solutions This document is in full compliance with the above legislation/regulation/alert.	
Targeted consultation of key stakeholders	The Policy has been shared key stakeholders including Senior Datix Officer, Nominated Health Board Safety Alerts Leads including Head of Clinical Engineering, Clinical Director of Pharmacy and Medicines Management, and Director of Estates, Facilities and Capital Management.	
	No comments have been received from the key stakeholders indicating they are not in agreement with the policy.	
	There has been no feedback on the policy during consultation.	

Collaboration with others (interested parties)	
Global consultation	All Health Board staff via the global email and policy consultation page. No comments were received following global consultation.
Patient Information	No patient information is required to support this policy.
Dissemination	The final WCD will be sent to all triumvirate teams and senior managers for dissemination. A dedicated SharePoint page is in place for all alerts. The news feed on SharePoint is triggered when a new alert is published.
Implementation	The principles of the procedure are not new and reiterate the process already in place.
Monitoring	Compliance will be monitored by the senior members of the Quality Assurance and Safety Team. Issues identified will be addressed as they arise. Where there is ongoing non-compliance, escalation will be to the Assistant Director of Nursing, Quality, Assurance, Safeguarding and Professional Regulation
Proposed review date of the document	The recommended review date is 1st June 2026.

Argymhelliad / Recommendation

QSEC are asked to, prior to approval, receive assurance that the WCD Policy (policy number 190) has been adhered to in the development of the Management and Distribution of Safety Alerts and Notices Policy and that therefore the document is in line with legislation/regulations, available evidence base and can be implemented within the Health Board.

The QSEC are also asked to ratify the policy for publication and implementation.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference Cyfeirnod Cylch Gorchwyl y Pwyllgor	To approve related policies and procedures
Cyfeirnod Cofrestr Risg Risk Register Reference:	Not applicable
Safon(au) Gofal ac Iechyd: Health and Care Quality Standard(s):	Safe
Safon(au) Gofal ac Iechyd: Health and Care Quality Standard(s):	Governance, Leadership and Accountability
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Statement	Improve efficiency and quality of services through collaboration with people, communities and partnersImprove efficiency and quality of services through collaboration with people, communities and partners

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Legislation and national policy Similar WCD within other NHS organisations
Rhestr Termau: Glossary of Terms:	Contained within each written control document
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ansawdd, Diogelwch a Sicrhau Profiod: Parties / Committees consulted prior to Quality, Safety and Experience Assurance Committee:	As detailed in the assessment

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	

Ansawdd / Gofal Claf: **Quality / Patient Care:**	Staff accessing written control documentation which is out of date, no longer relevant or contradicts current guidance may have a negative effect on the quality, safety and experience of care. It may also lead to unwarranted variation in care delivery
Gweithlu: **Workforce:**	
Risg: **Risk:**	The presence of written control documentation on the intranet, outside of the Policies, Procedures and other Written Control Documentation intranet webpage, may result in staff accessing documents which are out of date, no longer relevant, or contradicting current guidance
Cyfreithiol: **Legal:**	It is essential that the UHB has up to date policies and procedures in place.
Enw Da: **Reputational:**	Not applicable
Gyfrinachedd: **Privacy:**	Not applicable
Cydraddoldeb: **Equality:**	A summary equality impact assessment has been undertaken for the policy.

1.1

Management and Distribution of Safety Alerts and Notices Policy

DRAFT FOR APPROVAL ONLY

Policy information

1.2 Policy number: *429*

1.3 Classification:
Corporate

1.4 Supersedes:
Previous versions

1.5 Version number:
4

1.6 Date of Equality Impact Assessment:
25/05/2023

Approval information

1.7 Approved by:
Quality, Safety and Experience Committee

1.8 Date of approval:
Enter approval date

1.9 Date made active:
Enter date made active (completion by policy team)

1.10 Review date:

1.11 Enter review date (normally three years from approval date)

1.12

1.13 Summary of document:
This Policy sets out how the HB will fully discharge its accountabilities and obligations in respect of safety alerts by effectively managing the dissemination process and having in place suitable monitoring arrangements for ensuring that actions arising are executed in a timely manner and that in the event of deviation from the recommendations escalation measures are employed

1.14 Scope:
This policy applies to all staff within the Health Board and relates to documents received by the organisation referred to as safety alerts.

For the purpose of this policy the term 'safety alert' will be used as a representative term for all the type of alerts as identified in section 6 of this policy.

The policy does not replace the duty and professional accountability of staff to report any adverse incident involving a medical device, hazardous product or unsafe procedure, in line with Health Board policies and other written control documents

1.15 To be read in conjunction with:
156 - Risk Management Strategy – opens in a new tab
199 - Risk Management Procedure – opens in a new tab
010 - Health & Safety Policy – opens in a new tab
894 – Putting Things Right Policy – opens in a new tab
982 – Incident Near Miss and Hazard Reporting Policy – opens in a new tab
467 – Medical Devices Management Policy – opens in a new tab

1.16 Patient information: No patient information related to this policy

1.17 Owning group:

Date signed off by owning group

1.18 Executive Director job title:
Director of Nursing, Quality and Patient Experience

1.19 Reviews and updates:
1 – new policy 1.6.2015
2 minor changes 2.12.2015
3 full review 13.8.2020
4 full review

1.20 Keywords
Alert, notice, safety notice, patient safety solution

1.21 Glossary of terms

Term	Definition
The Health Board	Hywel Dda University Health Board
Safety Alert	Generic terms which covers a number of different types of alerts and notices.
MHRA	Medicines and Healthcare Products Regulatory Agency

NRLS	National Reporting and Learning System
NWSSP	NHS Wales Shared Services Partnership Facilities Services

Contents

1. Introduction

Safety alerts are issued when there is a specific safety issue that without immediate action being taken could result in a serious or fatal injury. Safety alerts can relate to equipment, processes, procedures or substances. When a safety alert is issued action should be taken although it may not be immediate.

2. Policy Statement

Hywel Dda University Health Board (the Health Board) will fully discharge its accountabilities and obligations in respect of safety alerts by effectively managing the dissemination process and having in place suitable monitoring arrangements for ensuring that actions arising are executed in a timely manner and that in the event of deviation from the recommendations, escalation measures are employed.

3. Scope

This policy applies to all staff within the Health Board and relates to documents received by the organisation referred to as safety alerts.

For the purpose of this policy the term 'safety alert' will be used as a representative term for all the type of alerts as identified in section 6 of this policy.

The policy does not replace the duty and professional accountability of staff to report any adverse incident involving a medical device, hazardous product or unsafe procedure, in line with Health Board policies and other written control documents

4. Aim

The aim of this policy is to ensure that the organisation responds in a timely and robust manner to any safety alert received, supported by a management system, which enables Board assurance.

5. Objectives

The aim will be achieved by:

- ensuring safety alerts are promptly and consistently disseminated to relevant directorates / departments / services
- ensuring appropriate corrective actions are taken to address the recommendations made within the alert within the set timeframe
- ensuring that the required governance arrangements are in place to provide the Board with the assurance.

6. Types of Safety Alerts Included in this Policy

A "safety alert" is a generic term which covers a number of different types of alerts and notices. The main types of safety alerts received by the Health Board is listed below:

6.1 Patient Safety Solutions issued by Welsh Government

Through analysis of reports of patient safety incidents submitted to the National Reporting and Learning System (NRLS), and safety information from other sources, advice has been issued to the NHS as and when issues arise. This advice is to help ensure the safety of patients and is issued directly to NHS organisations in Wales. Solutions cover a wide range of topics, from vaccines to patient identification.

As a consequence of the abolition of the NPSA, the Welsh Government has taken over this role and identifies any significant risks and concerns and develops Patient Safety Solutions at a national level for issue to the NHS in Wales.

6.1.1 **Safety alerts**: These require prompt action within a specified implementation date in order to address high risks/significant safety problems.

6.1.2 **Safety notices**: These are issued to ensure that organisations and all relevant healthcare staff are made aware of potential patient safety issues at the earliest opportunity. A Notice allows organisations to assess the potential for similar patient safety risks in their own areas, and take immediate action. This stage „warns" organisations of emerging risk. It can be issued in a timely manner, once a new risk has been identified to allow rapid dissemination of information for action.

Notices may be re-issued as an Alert if increased risk or further action is identified / required.

6.2 Safety Alerts issued by the Medicines and Healthcare Products Regulatory Agency (MHRA)

The MHRA is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA also regulates blood and blood products, working with UK blood services, healthcare providers, and other relevant organisations to improve blood quality and safety.

The MHRA presently use the following forms for the distribution of safety information, these are:

6.2.1 **Medical Device Alerts** usually requires timely action in respect to the safe use and management of medical equipment and can include user information, engineering information of training information.

6.2.2 **Medical Device Bulletins** offers guidance on improved management standards in the field of medical devices. Although promulgated as guidance in the majority of not all of cases bulletins will contain information which supports a safe system of work as would be sought after by HSE in the event of enquiries following serious incident.

6.2.3 **Drug Alerts** require timely action in respect to medicines products and correspond to medical device alerts.

6.2.4 **Safety Warnings for Medicines** safety information which is usually of lesser significance to that contained in Drug Alerts

The MHRA have developed the following protocols in support of their alerts dissemination to NHS staff:

- **Immediate Action:** Used in cases where there is a risk of death or serious injury and where the health Board is expected to take immediate action on the advice.
- **Action:** Used where the Health Board is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or support or follow-up manufacturers' field modifications.
- **Update:** Used to update the Health Board about previously reported incidents or series of incidents, possibly on a topical or device group basis and where further follow-up safety information is judged to be beneficial
- **Information request:** Used to alert the Health Board about a specific issue that may become a problem and where the MHRA are requesting feedback. These alerts will be sent out with additional questions to be completed.

6.3 Safety Alerts issued by the Department of Health (DH) Estates and Facilities

These are aimed at providing a safe environment and reducing risks to patients, staff and visitors in the NHS, by managing the risk relating to non-medical equipment, engineering plant installed services and building fabric in the NHS. There are four categories:

- **Immediate Action:** Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice.
- **Action:** Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to support or follow-up manufacturers' field modifications.
- **Update:** Used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow-up safety information is judged to be beneficial.
- **Information request/notice:** Used to alert users about a specific issue that may become a problem and where NHS Estates are requesting feedback. These alerts will be sent out with additional questions to be completed.

6.4 Safety Alerts issued by the NHS Wales Shared Services Partnership Facilities Services (previously Welsh Health Estates)

NHS Wales Shared Services Partnership Facilities Services (NWSSP) is committed to promoting and facilitating the delivery of high standards in patient care in Wales through the built environment.

6.5 Others types of safety alerts include the following;

- Pharmaceutical Alerts
- Product recalls
- Field Safety Notices

6.5.1 **Pharmaceutical Alerts** allow practitioners to keep up to date with changes affecting their practice, including drug news, safety updates, drug alerts, legislative changes and new guidance or standards.

6.5.2 **Field Safety Notices** are the principal means by which manufacturers of medical devices communicate safety information to consumers of their products. These notices provide an early warning to consumers that a product may not be fit for purpose and hence sound distribution of these notices by the health board is imperative.

The list is not exhaustive and from time-to-time other safety alerts may be received which require an equivalent response by the Health Board.

7. Safety Alerts Principles: external information

This refers to safety information coming into the organisation, for example from Welsh Government.

7.1 Safety Alerts Process

The Health Board has a duty to disseminate safety alerts throughout the organisation and to ensure that appropriate action is taken in order to minimise risk to staff and patients. This is shown in the flowchart of process in Appendix 1.

7.2 Receipt of Alerts

All safety alerts will be received via the Quality Assurance and Safety Team (formerly the Assurance, Safety and Improvement Team), using by e-mail HDD.Alerts@wales.nhs.uk and will be recorded on a central database.

As an additional safeguard the Quality Assurance and Safety Team will periodically check the Public Health Alerts/Contacts web site for all safety alerts issued within NHS Wales to ensure that none have been missed.

Safety alerts are occasionally received independently by individual members of staff e.g. the Medical Director. Any member of staff receiving a safety alert **must** inform the Quality Assurance and Safety Team, through the email address HDD.Alerts@wales.nhs.uk address, to ensure that the team are aware of the safety alert and that appropriate action can be taken.

7.3 Initial Distribution

The Quality Assurance and Safety Team will monitor the alerts email box for newly issued safety alerts. The Quality Assurance and Safety Team will email the safety alert to the agreed Nominated Health Board Safety Alerts Lead for action.

The safety alert will also shared on the SharePoint Safety Alerts and Notices page (unless advised otherwise by the Nominated Health Board Safety Alerts Lead).

7.4 Nominated Health Board Safety Alerts Leads

The Nominated Health Board Safety Leads (Safety Alert Leads) will support the procedure by providing guidance and instruction. The Safety Alerts Leads are detailed below:

Issuing Authority	Safety Alert	Nominated Health Board Safety Alerts Leads
Welsh Government	Patient Safety Alert	Head of Quality and Governance
	Patient Safety Notice	Head of Quality and Governance
MHRA	Medical Device Alerts	Head of Clinical Engineering
	Medical Device Bulletins	Head of Clinical Engineering
	Drug Alerts	Clinical Director of Pharmacy and Medicines Management
	Safety Warnings for Medicines	Clinical Director of Pharmacy and Medicines Management
Department of Health	Estates and Facilities	Director of Estates, Facilities and Capital Management
NWSSP Facilities Services	Estates and Facilities	Director of Estates, Facilities and Capital Management
Royal Pharmaceutical Society or drug companies	Pharmaceutical Alerts	Head of Medicines Management
Medical Device companies	Product recalls / Manufacturer Field Safety Notices	Head of Clinical Engineering,

8. Safety Alerts Principles: internal information

This refers to information which has become known within the organisation as a result of local incidents and near misses.

8.1 Reporting of incidents and near misses

All staff must follow the Health Board Policy 514 - Management and Investigation of Incident Policy, when reporting incidents or near misses involving:

- Medical equipment and supplies. This includes medical devices, laboratory equipment and medical supplies
- Estates equipment, including engineering plant, installed services, piped medical gas and gas scavenging system, buildings, building fabrics and vehicles.

The member of staff reporting an incident or near miss relating to a medical device much ensure that the equipment is secured. The equipment should not be returned to the manufacturer without consent

to do so from the Head of Clinical Engineering. Please refer to the relevant section of Policy 467 – Medical Devices Management Policy.

The Health Board has a duty to review incidents or near misses as described above.

8.2 Sharing of Learning (external)

Where appropriate, such incidents or near misses will be reported to the relevant agency e.g. Welsh Government, MHRA etc. The relevant technical and/or specialist managers will be responsible for making the appropriate report to the relevant agency, and will make a record of the report on the relevant Datix record.

8.3 Sharing of Learning (internal)

Local Safety Notices (LSNs) are created and distributed within the Health Board for the purpose of disseminating important safety information to users without delay. These may be followed up by formal issue of a safety alert to an external government authority or agency such as the MHRA. The principal distribution mechanism for LSNs is the Health Board's intranet site although this is usually supported by the use of targeted email distribution of the notice to staff known to have an interest. LSNs should be given the same priority as externally issued notices as they might contain the earliest safety information to be available on a particular issue.

9. Roles and Responsibilities

9.1 Chief Executive

The Chief Executive has overall responsibility for the management of safety alerts and for ensuring that information relating to patient and staff safety is acted upon. For the practical operation of the system, and due to the wide range of alerts received by HDUHB, the Chief Executive has allocated oversight of this process to the Director of Nursing, Quality and Patient Experience.

9.2 Director of Nursing, Quality and Patient Experience

Executive responsibility for risk matters, including robustly distributing and monitoring safety alerts, is delegated by the Chief Executive to the Director of Nursing, Quality and Patient Experience.

9.3 Quality Assurance and Safety Team

The Quality Assurance and Safety Team will, upon receipt of a safety alert:

1. Log the Safety Alert on the central risk management system (Datix)
2. Email all the relevant Nominated Health Board Safety Alerts Lead(s)
3. The email will advise Nominated Health Board Safety Alerts Lead of the deadline date for return, and will carry a reminder flag on the deadline date. The email will also have attached a link to the safety alert record on the central risk management system (Datix) where the required action will be recorded.

4. Email the Health Board Communication Team for the safety alert to be included in the internal communication, *Hywel Dda Heddiw/Today* and on the intranet page under *Staff/Clinical Alerts* (unless advised otherwise by the Nominated Health Board Safety Alerts Lead).
5. Monitor the central risk management system (Datix) for updates provided by the Nominated Health Board Safety Alerts Lead. Where details of actions undertaken have not been captured on the central risk management system (Datix) a reminder will be sent by the Quality Assurance and Safety Team to the Nominated Health Board Safety Alerts Lead. Escalation for continued non-action will be to the relevant Director.

Thereafter, the Quality Assurance and Safety Team will ensure the following actions will be undertaken:

6. Attach any email or other evidence to the appropriate safety alerts record within the central risk management system (Datix).
7. Compile a final compliance report which will be posted on the alerts intranet page.
8. Prepare a compliance report for presentation to the Operational Quality Safety and Experience Sub Committee.
9. Work with Safety Alerts Leads and subject experts to develop LSNs

9.4 Nominated Health Board Safety Alerts Leads

The Nominated Health Board Safety Alerts Lead(s) will receive all relevant safety alerts (see section 7) and will have a responsibility to:

1. Provide appropriate guidance or instruction, such as reports or position statements in relation to the content of each individual safety alert received within seven working days
2. Assess if action is required in accordance with the alert
3. Distribute, where appropriate, relevant safety alerts to the relevant General Manager(s) for action within their area of responsibility, requesting that confirmation is received that there is compliance with the safety alert.
4. Where a safety alert requires a written control document review or development of a new written control document, ensure that the relevant organisational lead is aware of this requirement and takes appropriate action. The Chair of the Clinical Written Control Document Group should be copied into the correspondence.
5. Ensure that the required actions are completed by the due date and that a record of actions is recorded on the central risk management system (Datix), along with any evidence of compliance
6. If the Health Board is unable to comply with the safety alert by the required date, ensure that a non-compliance form is completed and returned to the Quality Assurance and Safety Team. The non-compliance form must indicate:
    a. The reason(s) why the Health Board is unable to comply with the alert
    b. The actions being taken to achieve compliance
    c. The date that non-compliance was entered onto the Health Board risk register
    d. The estimated date that the Health Board will be compliant with the alert.
7. Report areas of non-compliance to safety alerts to the appropriate sub-committee or group
8. Support the Quality Assurance and Safety Team with preparation of the report on compliance to Operational Quality Safety and Experience Sub Committee
9. Ensure that relevant incidents are reported to the relevant agency e.g. Welsh Government, MHRA etc. and that a record of the report is captured on the relevant Datix record
10. Work with the Quality Assurance and Safety Team to develop LSNs.

Depending on the nature and content of the safety alert, a co-ordinated approach may be required to provide advice and appropriate documentation, such as risk assessments, throughout the Health Board. In this situation, the safety alerts lead will inform the responsible General Managers and will arrange a meeting of the parties, in order to provide a co-ordinated and integrated response to the safety alert.

9.5 General Managers

General Managers (directorate and site) will receive, from the Safety Alerts Lead, a copy of relevant safety alerts. The General Manager will play a key role in ensuring appropriate dissemination of the safety alert and the action to be taken. Dissemination will include to Heads of Department and Ward Managers

The General Manager may identify, from within their area of responsibility, a nominated person to action the safety alert; however, the General Manager will retain the responsibility for action within their area of responsibility. Where the General Manager is unable, or believes it would be inappropriate, to implement certain actions, this should be recorded in the safety alerts return. These returns will be captured on the central database (Datix) for reporting to the Operational Quality, Safety and Experience Sub Committee. Non-compliance with an alerts should also be discussed and recorded at the Directorate Quality and Safety Group

9.6 Heads of Department and Ward Managers

Heads of Department and Ward Managers will:

- Read carefully each safety alert they receive
- Respond to safety alert emails without delay, particularly when responses are required within a specific timescale.
- Note that response times notified will vary according to the urgency of the action required and read receipts will be requested when emails are sent
- Ensure that safety alerts relating to their area are easily accessible to all staff and that staff are made aware of the safety alert.
- Where bank staff, agency staff or staff from other areas are working in a particular location, safety alerts directly relating to patient safety and/or relevant equipment, must be highlighted.

9.7 All Staff

All staff have a duty to read the safety alerts they receive and implement measures introduced in response to safety alert.

Any member of staff independently receiving any type of ‘safety alert’, such as a manufacturer’s safety sheet issued directly to the member of staff, should forward the safety alert to the Quality Assurance and Safety Team, through the email address HDD.Alerts@wales.nhs.uk address, and seek appropriate advice before the formal distribution procedure is initiated.

10 Governance Framework: Scrutiny and Assurance on behalf of the Board

The Health Board must ensure that areas of non-compliance with safety alerts are monitored and reported to the appropriate Committee of the Board and / or Sub-Committee including any mitigation to manage the risk. The Health Board must have a robust system in place to assure themselves that progress is being achieved against compliance with solutions.

10.1 Operational Quality, Safety and Experience Sub-Committee

The Operational Quality, Safety and Experience Sub-Committee will receive regular reports detailing compliance against safety alerts and exception reports where necessary. The Sub-Committee will be accountable for advising the Quality, Safety and Experience Assurance Committee of any clinical, financial or other risk to the organisation related to safety alerts.

The Operational Quality, Safety and Experience Sub Committee will be supported by formally groups who carry out on its behalf specific aspects of Sub-Committee business, for example the Medical Devices Group.

10.2 Directorate Quality, Safety and Experience Groups

Directorates and departments must ensure compliance against safety alerts. Relevant safety alerts should be received at the directorate quality, safety and experience group.

When a directorate or department is unable to attain compliance with a safety alert, the safety alert should be formally discussed at the directorate quality, safety and experience group and any areas of concern discussed. A risk assessment must be undertaken and entered onto the Directorate risk register by the General Manager or the departmental risk register by the Departmental Manager.

The Directorate must report non-compliance and mitigations to the Operational Quality, Safety and Experience Sub Committee.

10.3 Directorate Written Control Documentation Groups

Directorate written control documentation groups will be responsible for ensuring written control documents consider relevant safety alerts in the development of new written control documents and also ensure that existing written control documents are reviewed when a new safety alert is published.

10.4 Clinical Written Control Documentation Group

The clinical written control documentation group will assure itself that relevant safety alerts have been considered when new written control documents are developed or when existing written control documents are reviewed.

11 Storage and Retention of Safety Alerts

All safety alerts and supporting technical guidance and instruction will be available on the intranet http://howis.wales.nhs.uk/sitesplus/862/page/62753 (opens in a new tab)

A list of all Patient Safety Solutions can be found at http://www.patientsafety.wales.nhs.uk/safety-solutions (opens in a new tab)

All MHRA safety alerts can be found at https://www.gov.uk/drug-device-alerts (opens in a new tab)

All Royal Pharmaceutical Society alerts can be found https://www.rpharms.com/publications/pharmacy-alerts/ (opens in a new tab)

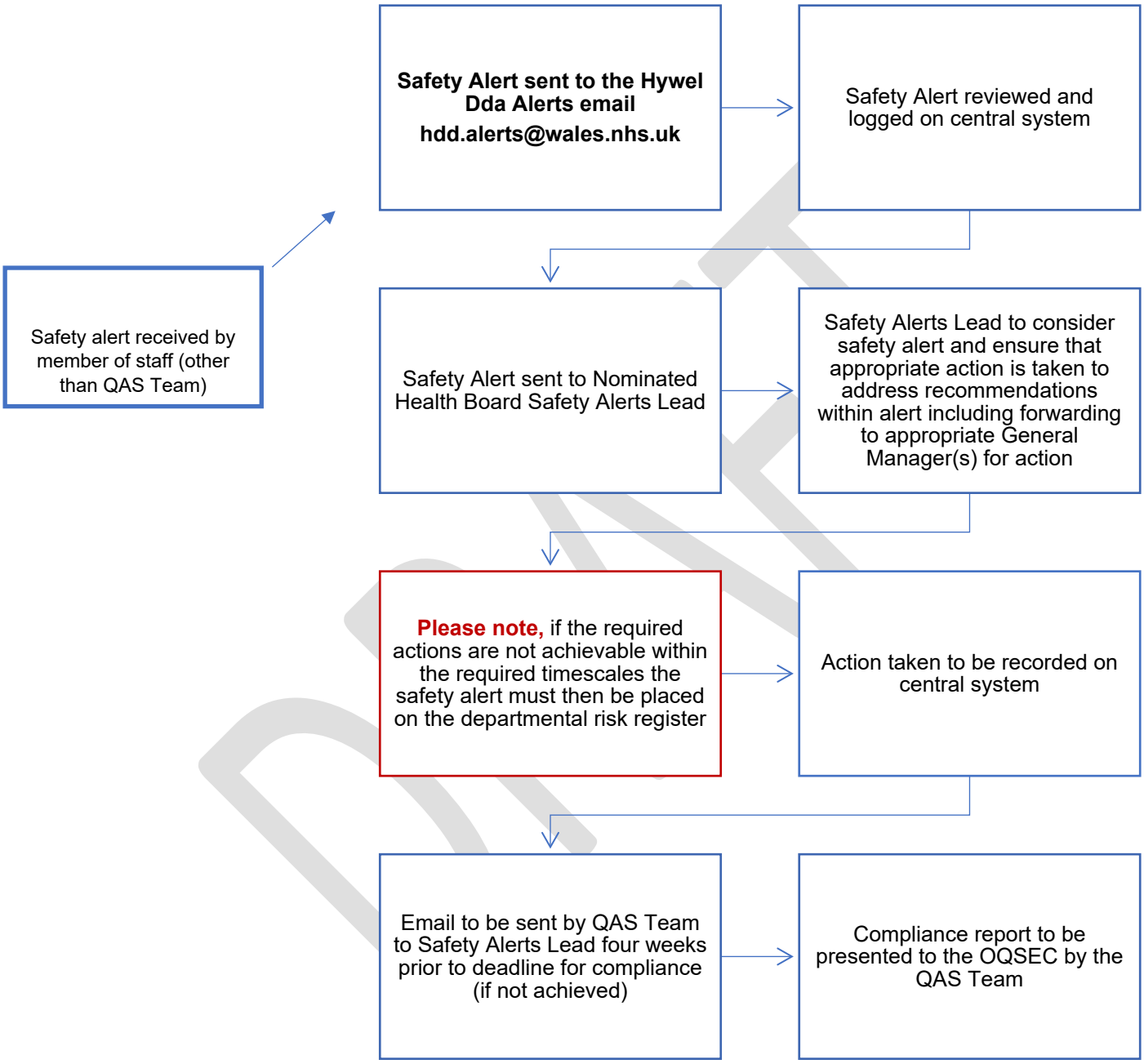
The Quality Assurance and Safety Team will store the original safety alert and all responses received from the Nominated Health Board Safety Alerts Leads

12 References

NHS Executive (2023) NHS Executive Policy on Patient Safety Incident Reporting and Management (issued via WHC/2023/017)

Welsh Government (2014) Guidance on NHS Wales Patient Safety Solutions

Appendix 1: Safety Alerts Flowchart



SUMMARY EQUALITY IMPACT ASSESSMENT –

Organisation:	Hywel Dda University Health Board

Proposal Sponsored by:	**Name:**	David James - Quality Improvement Manager Reviewed March 2020 Cathie Steele – Head of Quality and Governance **Reviewed May 2023** **Cathie Steele – Head of Quality and Governance**
	Title:	Head of Quality and Governance
	Department:	Nursing and Quality Directorate

Policy Title:	**Policy for the management and distribution of safety alerts** Reviewed May 2015 Reviewed March 2020 **Reviewed May 2023**

Brief Aims and Objectives of Policy:	The aim of this policy is to ensure safety alerts are disseminated effectively across the organisation, appropriate action taken to address the recommendations made within the alert and that assurance is received that actions have been taken. This will be achieved by • Ensuring there is a consistent approach to the dissemination of Safety Alerts.

	• Ensuring all alerts are disseminated promptly to the relevant members of staff. • Monitoring the implementation and completion of the necessary actions within the required timescales. • Ensuring that there is a robust audit trail providing evidence of compliance and action taken. • Ensuring the compliance against the alerts will be presented at the Operational Quality, Safety and Experience Sub Committee, who will be accountable for advising the Board of any clinical or financial risks to the organisation.

Was the decision reached to proceed to full Equality Impact Assessment?		**No**
If no, are there any issues to be addressed?	Hywel Dda University Health Board is committed to ensuring the health and safety of patients, staff and others; action on safety alerts helps to achieve this. Those most vulnerable are likely to have at least one and probably multiple protected characteristics and this is likely to have particular relevance for the very young, old and people with disabilities. This protocol will assist in protecting the safety and welfare of patients and so has a positive impact on the Human Rights of Patients. A trawl of similar written control documents in NHS Wales and Trusts in NHS England did not identify any potential negative impacts against any protected characteristic. No complaints have been received in relation to equality, diversity or human rights in relation to predecessor policies within the HB. The policy has been derived from a number of “best practice” examples and advice received from the Delivery Unit of the Welsh Government	

	These amendments were assessed as having a positive or neutral impact on protected groups. The procedure is currently out for formal consultation, relevant feedback will be added to update this EqIA when available and any issues of concern raised will be addressed at that point. **Feedback from consultation** – No comments were received during the formal consultation period.

Is the Policy Lawful?	**Yes** √	This procedure is informed by the Medicines and Healthcare Products Regulatory Agency (MHRA), National Patient Safety Agency (NPSA) and NHS Estates

Will the Policy be adopted?	**Yes** √	This is an update of an existing written control document
	If no, please record the reason and any further action required:	

Are monitoring arrangements in place?	**Yes** ☐	
	The Quality Assurance and Safety Team will routinely monitor compliance and progress and will escalate concerns or issues as appropriate.	

	The Health Board Operational Quality, Safety and Experience Sub Committee will monitor compliance every six months. Where matters need escalation, the Sub Committee will receive these by exception. The Health Board is required to report to the Delivery Unit the compliance with patient safety solutions alerts. Any complaints received in relation to equality, diversity or human rights following implementation of the procedure will be addressed on an individual basis and appropriate action taken.

Who is the Lead Officer?	**Name:**	Mandy Rayani (review March 2020) (previous versions: Caroline Oakley - Director of Nursing and Midwifery)
	Title:	Director of Nursing, Quality and Patient Experience
	Department:	Nursing and Quality Directorate
Review Date of Policy:	The written control document will be reviewed every 3 years or sooner if required	

Signature of all parties:	**Name**	**Title**	**Signature**
	David James	Quality Improvement	11/12/13 - Reviewed 01/2015 Reviewed 01/06/2015

		Manager	
	Stuart Moncur	Assistant Director Assurance Safety and Improvement	Reviewed 01/06/2015
	Jackie Hooper	Equality and Diversity Advisor	11/12/13 – Reviewed 01/2015 Reviewed 01/06/2015
	Review March 2020		
	Cathie Steele	Head of Quality and Governance	20/05/2020
	Jackie Hooper	Senior Diversity and Inclusion Officer	Partial update 26/03/2020
	Review May 2023		
	Cathie Steele	**Head of Quality and Governance**	**22/05/2023**

Please Note: An Action Plan should be attached to this Outcome Report prior to signature

n/a at this stage 25/05/2023