Management and Distribution of Safety Alerts and Notices Policy

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Summary of document:
This Policy sets out how 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

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 ‘types of safety alerts’ 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

To be read in conjunction with:
156 - Risk Management Strategy – opens in a new tab
674 - Risk Assessment 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

Owning group: Quality Assurance and Safety team

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

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1 – new policy 1.6.2015
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3 - full review 13.8.2020
4 - full review 13.6.2023
5 - full review 12.02.2026

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Glossary of terms

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
DH	Department of Health
AMAT	Audit Management and Tracking (software package)
LSN	Local Safety Notice

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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.

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.

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 ‘types of safety alerts’ of this policy.

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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.

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.

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 are listed below:

Patient Safety Solutions issued by Welsh Government

Through analysis of reports of patient safety incidents submitted to Patient Safety Incident Management System (PSIMS) (in England), 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.

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

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.

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:

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.

Medical Device Bulletins offers guidance on improved management standards in the field of medical devices. Although presented as guidance, in most cases these bulletins contain information that supports a safe system of work, of the type the HSE (in England would expect to see if enquiries were made following a serious incident.

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

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.

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.

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

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

Other types of safety alerts include the following;

- Pharmaceutical Alerts
- Product recalls
- Field Safety Notices

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.

Safety Alerts Principles: external information

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

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.

Receipt of Alerts

All safety alerts will be received via the Quality Assurance and Safety 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.

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 an agreed Nominated Health Board Safety Alerts Lead for action.

The safety alert will also shared on the SharePoint Safety Alerts and Notices page – opens in a new tab - (unless advised otherwise by the Nominated Health Board Safety Alerts Lead).

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	Clinical Director of Pharmacy and Medicines Management
Medical Device companies	Product recalls / Manufacturer Field Safety Notices	Head of Clinical Engineering,

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.

Reporting of incidents and near misses

All staff must follow the Health Board 982 Incident, Near Miss and Hazard Reporting Policy (opens in a new tab) 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 must 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. Refer to the relevant section of Policy 467 – Medical Devices Management Policy. (opens in a new tab).

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

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.

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.

Roles and Responsibilities

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 the Health Board, the Chief Executive has allocated oversight of this process to the Director of Nursing, Quality and Patient Experience.

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.

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 management system (Database and AMaT system)

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 management system (AMaT) where the required action will be recorded.
4. Email the Health Board Communication Team / load to the Sharepoint page for the safety alert to be included in the internal communication, *Hywel Dda Heddiw/Today/ Viva Engage* and on the intranet page under *Report Somethingf/Safety Alerts and Notices* (unless advised otherwise by the Nominated Health Board Safety Alerts Lead).
5. Monitor the management system (AMaT) for updates provided by the Nominated Health Board Safety Alerts Lead. Where details of actions undertaken have not been captured on the central management system (AMaT) 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 management system (AMaT) if required.
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

Nominated Health Board Safety Alerts Leads

The Nominated Health Board Safety Alerts Lead(s) will receive all relevant safety alerts (see Safety alerts and notices) 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 management system (AMaT), 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 AMaT 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.

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 (AMaT) for reporting to Quality, Safety and Experience Committee. Non-compliance with an alerts should also be discussed and recorded at the Directorate Quality and Safety Group

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.

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.

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.

Quality, Safety and Experience Committee

The Quality, Safety and Experience Committee will receive regular reports detailing compliance against safety alerts and exception reports where necessary. The 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 Quality, Safety and Experience Committee will be supported by formally groups who carry out on its behalf specific aspects of Committee business, for example the Medical Devices Group.

Clinical Care Group Quality, Safety and Experience Groups

Directorates and departments must ensure compliance against safety alerts. Relevant safety alerts should be received at the Clinical Care Group's 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 Quality, Safety and Experience Committee.

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.

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.

Storage and Retention of Safety Alerts

All safety alerts and supporting technical guidance and instruction will be available on the intranet Safety alerts and notices (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

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