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ALERTS, SAFETY NOTICES AND OTHER GUIDANCE PROCEDURE

Introduction and Aim

This procedure underpins the Alerts, Safety Notices and other Guidance Policy.

This document is designed to ensure a structured and systematic approach to the dissemination and actioning of alerts throughout Public Health Wales, and the reporting of actions taken or not taken against alerts issued.

It should be noted that the term Alerts is used throughout this document to refer to alerts, safety notices and other guidance.

Linked Policies, Procedures and Written Control Documents

[All corporate policies and procedures are available on the Public Health Wales website](#)

Alerts, Safety Notices and other Guidance Policy

Scope

This procedure is relevant to all staff working within Public Health Wales. In the interests of brevity, the term staff is used throughout this document to refer to staff, contractors, agency staff, volunteers, and secondees.

Equality and Health Impact Assessment

This Procedure is covered by the Equality and Health Inequalities Assessment (EHIA) for the Alerts, Safety Notices and other Guidance Policy, available on the PHW Corporate Policies and Procedure website

Approved by

Quality, Safety and Improvement Committee

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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 [Corporate Governance](#).

Summary of reviews/amendments				
Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1.0		15/01/2019	06/02/2019	New document
2.0	15/09/2022	16/02/23	23/02/26	Refresh & change of personnel in key roles relating to this policy and procedure.

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1. Introduction

As part of managing the health, safety and welfare of service users and Staff, Public Health Wales is required to control risks and take action to prevent harm. This includes reducing the risk of incidents happening, improving best practices in clinical areas and ensuring the safety of service users, staff and third parties.

A centrally managed system is used to fulfil this function and the aim of this procedure is to provide guidance so that there is an effective and auditable management system for the distribution, monitoring and record keeping of all alerts in Public Health Wales.

Alerts are received into the organisation via multiple routes as follows:

- Some alerts are distributed via the Patient Safety Solutions (PSS) Module on Datix cloud which is a web-based cascading system operated by the Delivery Unit in Welsh Government. This includes Patient Safety Alerts and Patient Safety Notices (known collectively as Patient Safety Solutions)
- Other alerts (E.g. Chief Medical Officer (CMO) letters, medical device alerts, medication & health & safety alerts) are received via national distribution which are received by the Quality & Nursing Team in the Quality Nursing and Allied Health Professionals Directorate (QNAHPS)

The procedure outlines the process from the point an alert is received into PHW via the PSS module via the Datix Cloud System or via national distribution

It should be noted that Welsh Health Circulars (WHCs) are not managed under this procedure these are handled by the Board Secretary and Board Business Unit under a separate process. Please refer to the Board Secretary or PHW.CorporateGovernance@wales.nhs.uk for further information.

2. Purpose and Scope of this Procedure

The purpose of this procedure is to set out Public Health Wales process for cascading and implementing and reporting progress in relation to identified alerts, thus ensuring continual improvement in the quality of services provided against organisational guidelines, policies and Statutory

requirements. It should be noted that the term Alerts is used throughout this document to refer to alerts, safety notices and other guidance.

This procedure is an organisational wide document and it applies equally to all members of staff, either permanent or temporary and to those working within, or for, PHW under contracted services.

3. Roles and Responsibilities

Chief Executive

Has overall responsibility for ensuring effective arrangements for dissemination, action and review of Alerts

Quality Safety and Improvement Committee

- Is responsible for receiving assurance and monitoring the effectiveness of the implementation of the Alert procedure and adherence to national guidelines.
- The Committee will provide organisational assurance that all actions where appropriate have been mobilised are on track or completed within timeframes

Executive Directors and Directorate Leads

Are responsible for:

- Ensuring that all Directorate and Divisional staff are aware of this procedure and monitoring compliance with Alert management and reporting
- Ensuring that any actions put in place are monitored until compliance with the Alert is achieved
- Through existing governance structures within each Directorate ensure there are designated leads and local processes in place to disseminate and action Alerts

Alert Corporate Facilitator (CF)

The Alert Corporate Facilitator is responsible for:

- Receiving alerts on behalf of Public Health Wales.
- Maintaining a central record of alerts.
- Distributing alerts to the Quality Nursing and Allied Health Professionals (QNAHPS) Alert Directorate Lead and other key staff as appropriate.
- Alerting the Directorate/Divisional leads/ with the Alert notification and actions once instructed to do so by the QNPAS Alert lead where necessary.
- Maintaining records confirming actions.
- Providing a summary of alerts, opened and closed, to the Quality Safety and Improvement Committee.

- Updating the status of alerts within PHW Alert system.
- Providing support and guidance to staff regarding alerts.
- Notifying the Welsh Government Delivery Unit of changes to the Alert corporate facilitators
- Providing training regarding alert processes for relevant members of staff

Quality Nursing and Allied Health Professional Directorate Alert Lead

The Alert lead within QNAHPS has a responsibility to:

- review all initial Alerts on receipt from the Alert corporate facilitator
- Receive and respond to requests for more information an Alert
- Agree which Directorate and leads within the organisation should receive the Alert liaising with appropriate senior staff as necessary
- Agree with the Alert Corporate facilitator a course of action and support them to fulfil their responsibilities

Health & Safety Leads (HSL)

The Health and Safety lead is responsible for:

- Screening all Health & Safety Alerts including High Voltage Hazard Alerts and confirms if requirement to disseminate alerts to nominated DL
- Informing CF whether action is required or not
- Completing and returning the Alerts response form
- Where action is required, monitors progress and confirms with Corporate Facilitator when actions are completed
- Notify the CF of any changes required to nominated HSL (for example annual leave etc)

Divisional Managers/Managers

Are responsible for:

- Responding to alerts in a timely manner.
- Maintaining a robust system for distribution of alerts to appropriate teams.
- Maintaining records confirming distribution.
- Maintaining records of actions taken within teams.
- Providing confirmation of actions taken to the Alert corporate facilitator

- Providing the Alert corporate facilitator with confirmation of completed actions on the system

Service managers / Service leads

Are responsible for:

- Responding to alerts in a timely manner.
- Ensuring actions are taken within area of responsibility to enable compliance with the alert.
- Ensure that they have systems for deputisation or cover when they are on leave.
- Providing documented evidence of actions taken, if requested, to senior managers.
- Ensuring dissemination of information within alerts to relevant personnel within their department using appropriate methods of communication.
- Providing a timely response for each alert received in the department.
- Maintaining a "library" of alerts, allowing staff easy reference.
- Support any review process performed to assess compliance with the Alert process

All staff and contractors (including Locums, Temporary Staff and Bank Staff)

Are responsible for:

- Being familiar with this procedure and take responsibility for adhering to the Alert actions and guidance

4. Abbreviations

Abbreviation	Definition
ARF	Alerts Response Form
ASSH	Alerts Summary Spreadsheet
CF	Corporate Facilitator
CL	Corporate Lead
CMO	Chief Medical Officer
DL	Divisional Lead
DU	Delivery Unit (Welsh Government)
HSL	Health & Safety Lead
PSS	Patient Safety Solutions- Patient Safety Alerts and Patient Safety Notices (known collectively as Patient Safety Solutions)

QNAHPS	Quality Nursing and Allied Health Professional Directorate within PHW
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5. Alert Types & Sources

All Alerts received by PHW are either via the PSS module on Datix Cloud or via the national distribution channels sent to (phw.DatixChanges@wales.nhs.uk) by various regulatory agencies, which is monitored at an organisational level by the Quality and Nursing team.

The types of alerts and nature PHW will receive are:

Reference	Originator	Type
MHRA	MHRA Medical Devices Alerts	Medical equipment, medical substances, medical implants.
DHEFD	Department of Health Estates and Facilities	non-medical equipment (but can overlap with medical, e.g. hoists/wheelchairs, etc) substances.
HSE	Health and Safety Executive	Medical & Non-medical work equipment. Can relate to injury or ill health
CMO	Chief Medical Officer	Urgent medical message from the CMO

6. Grades of Alerts and Deadlines

Alerts normally fall into four categories as follows:

Grades of Alert	Description
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 bases, and where further follow-up safety information is judged to be beneficial
Information Request	Used to alert users about specific issues that may become a problem and where feedback is requested.

7. Alerts Procedure

As outlined in [Appendix A](#), the Corporate Quality & Nursing Team in Public Health Wales will:

Step 1: Acknowledgement of the alert receipt

The Alert Corporate Facilitator will acknowledge the alert within the prescribed timeframe as required.

Step 2: Assessing Relevance to Public Health Wales

In collaboration with the Alert Lead for QNAHPS/PHW Assess PSS and other Alerts for relevance to the organisation

Health & Safety Alerts – All of these alerts are initially reviewed by the Health & Safety Lead in PHW

Step 3: Action Underway

The Alert Corporate Facilitator will populate the template indicated in Appendix B and load onto the Alerts Summary Spreadsheet.

Forward the Alert link to either the key directorate leads /contacts as appropriate to the alert requirements, for their action.

Directorate Leads/ Key contacts will assess the relevance of the alert to the services based on its category and their expertise

Directorate Leads /Key contacts will confirm whether the alert is relevant to the organisation with the corporate facilitator

Recipients will then respond to the Alert by indicating in the Alert metadata on Sharepoint that the Alert has been actioned within the alert deadlines.

Step 4: Action Complete

The Alert Corporate Facilitator will ensure that actions for the alert requirements are completed within the alert deadlines and will monitor the responses on the Alerts Summary Spreadsheet.

Collated information will be uploaded onto a register known as the Alerts Summary Spreadsheet (ASSH) of all alerts and related actions taken as evidence

Step 5 Organisational Changes and Assurance

In the event actions outlined in Patient Safety Alerts require an overview and a change or amendment in PHW policy or procedure/guidance, these are escalated to the Assistant Director of Quality & Nursing for discussion & action.

Alert Corporate Facilitator will provide quarterly reports for assurance to the Business Executive Team as required and to the Public Health Wales Quality, Safety and Improvement Committee on the performance of the system

Alert Corporate Facilitator will audit the system to ensure compliance and provide analysis of data as required including:

- a) Timeliness of acknowledgment, issuing and actioning of the alerts.
- b) Number of Alerts that have invoked a formal response.
- c) Number of actions completed.

An annual report will be produced to inform the Annual Quality & Clinical Audit plan

8. Alerts Template

Public Health Wales has developed an Alerts Response Form (ARF) template (Appendix B) which records the Alert details and is disseminated via a sharepoint link as instructed by the Corporate Lead.

The nominated Directorate/Divisional lead must record the actions taken on the form by completing the Metadata column on the Alerts Summary Spreadsheet which is held on sharepoint.

The Alerts response can be completed by the following or their nominated deputy:

- Corporate Facilitator (CF)
- Corporate Lead (CL)
- Health & Safety Lead (HSL)
- Divisional Lead (DL)

If there are any delays with within the required timescales, the CF must be informed immediately by the nominated Lead.

9. Alerts received Out of Hours

It is noted that the process for monitoring all alerts is only operational Monday-Friday during the working week. The process is not active on weekends or bank holidays. Any alerts received outside of the working week core hours will be prioritised for action on the next first working day.

10. Monitoring compliance and effectiveness of this procedure

The Quality & Nursing Division within QNAHPS will monitor the effectiveness of the policy and procedure for alerts and will provide assurance and/or report on any necessary improvements that need to be made to the Business Executive as necessary (or any agreed delegated group) and the Quality, Safety & Improvement Committee.

A quarterly report will be provided to the Quality, Safety and Improvement Committee on the performance of the system.

In addition, a bi-annual audit will be conducted of the system to ensure compliance.

An annual report will be provided for the Annual Quality & Clinical Audit.

11. References

[Patient Safety Solutions: Alerts & Notices - Delivery Unit \(nhs.wales\)](#)

12. Appendices

Process for dealing with Alerts	<u>Appendix A</u>
Alerts Response Form	<u>Appendix B</u>
Process for dealing with Health & Safety Alerts	<u>Appendix C</u>
Key contacts form	<u>Appendix D</u>