Safety Alerts Procedure

March 2018
<table>
<thead>
<tr>
<th><strong>Version</strong></th>
<th><strong>Changes</strong></th>
</tr>
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<tbody>
<tr>
<td>1.0</td>
<td></td>
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<tr>
<td>2.0 –</td>
<td>Renamed Central Alerting System Procedure</td>
</tr>
<tr>
<td></td>
<td>Document has undergone significant change to reflect the increase in the type of alerts that may be received, the source of the alerts, changes in personnel, job roles and meetings. The process has been simplified &amp; flow chart added.</td>
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<tr>
<td>3.0</td>
<td>Renamed Safety Alerts Procedure</td>
</tr>
<tr>
<td></td>
<td>Sharing an alert with another organisation may be an appropriate response to an alert.</td>
</tr>
<tr>
<td></td>
<td>‘Appointed person from the Quality and Governance Team’ now defined as the Clinical Effectiveness Facilitator</td>
</tr>
<tr>
<td>Safety Alerts Spreadsheet now being updated by first line recipients</td>
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<td>---------------------------------------------------------------</td>
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<tr>
<td>New Home Care Manager role acknowledged</td>
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<tr>
<td>Safety Alerts Spreadsheet to be completed initially by first line recipients within 7 days.</td>
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</tr>
<tr>
<td>Flow chart updated to reflect above changes</td>
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1. INTRODUCTION

1.1 Statement of Intent

This procedure relates to all types of safety alerts and updates issued by the Central Alerting System (CAS), Medicines and Healthcare Regulatory Authority (MHRA), internally generated or from any other source.

The type of alerts on the CAS website include:

- Safety alerts
- Chief Medical Officer messages
- Drug Alerts
- Dear Doctor Letters
- Medical Device Alerts (MDAs)

This procedure must be followed in the event of receiving any safety alert or update which has been disseminated by the appointed person from the Quality and Governance Team or their deputy.

The organisation seeks to have a pro-active culture; working with staff and other healthcare providers to prevent and manage potential safety hazards. Other local healthcare providers may also be signed up to receive alerts from CAS and the MHRA. Whilst it is not Family Nursing & Home Care’s responsibility to keep other organisations appraised of alerts, this may be an appropriate action to take when responding to an alert.

In the event of an alert being pertinent, the Family Nursing & Home Care (FNHC) will take any immediate or remedial action and review the issues highlighted to minimise the chance of hazardous incidents occurring in the future. If the organisation cannot take action itself it will, where appropriate, make other agencies aware of issues which they may need to address.

This procedure is a risk management tool designed to protect patients, clients, staff and the organisation. A flow chart of the process is in appendix 1.

1.2 Definitions and Explanations

Central Alerting System (CAS) - “The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.” (Central Alerting System, 2016).

Dear Doctor Letters – these come from the Chief Medical Officer and generally convey emergency or international/national key messages

Drug Alerts – These are generated by the Medicines and Healthcare Regulatory Authority (MHRA).

Estates and Facilities Alerts (EFA) – These are issued by NHS Estates to communicate safety information about engineering, installed services and building fabric. These alerts are unlikely to be relevant to Family Nursing & Home Care (FNHC).

Field Safety Corrective Action (FSCA) – this is undertaken by a manufacturer when there are technical or medical concerns about the characteristics or performance of their product which could cause death or serious injury (Cumbria Partnership NHS Foundation Trust, 2014).
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The Medicines and Healthcare Regulatory Authority assesses all FSCA and if required issues a Medical Device Alert (MDA).

Field Safety Notices – These are used by manufacturers to communicate with their customers about FSCA providing advice or action that needs to be undertaken. The MHRA publishes manufacturers’ FSNs on their website however, the majority of these will not be relevant to FNHC. Those that are may need to be disseminated to staff for information/awareness and action if required. If contacted directly by the manufacturer a FSN would need to be actioned. Not all FSNs result in a Medical Device Alert (MDA).

Internally Generated Alerts – These are issued to share local learning or raise awareness about safety issues. They will be managed in the same way as alerts from the Central Alerting System and the Medicines and Healthcare Regulatory Authority.

Medicines and Healthcare Regulatory Authority (MHRA) – A UK Department of Health (DH) executive agency, it regulates medicines, medical devices and blood components for transfusion to ensure their safety, quality and effectiveness.

Patient Safety Alerts – These are issued by NHS England and are derived from patient safety incident data from the National Reporting and Learning System (NRLS). There are three stages of patient safety alerts

  - **Stage one** – a “warning” alert to make healthcare staff aware early of emerging concerns
  - **Stage two** – this is a “resource” alert which follows if the stage one alert requires further action. It contains more information and advice
  - **Stage three** – This type of alert is a “directive” and UK healthcare organisations are mandated to respond to confirm that they have undertaken the necessary action to reduce the risk. There is no requirement for FNHC to send confirmation, however, the organisation should complete the requirements of the ‘directive’ where this is relevant.

1.3 Scope/Responsibility

This procedural document applies to all staff working for Family Nursing & Home Care or seconded to work within the organisation.

**Chief Executive Officer (CEO)**

The CEO has overall responsibility for ensuring that FNHC has appropriate arrangements in place to respond to and manage safety alerts.

**Quality and Governance Lead**

The Quality and Governance Lead has delegated responsibility for ensuring that appropriate processes and procedural documentation are in place to address all safety alerts.

**Clinical Effectiveness Facilitator**

The Clinical Effectiveness Facilitator is responsible for:

- Receiving alerts via CAS and the MHRA through daily monitoring of their emails (Monday to Friday with the exception of bank/public holidays)
- Assessing the relevance to FNHC of the alerts received via CAS and the MHRA
- Electronically disseminating alerts that are relevant or potentially relevant.
- Recording the alerts on the centrally held Safety Alert database including action taken
Safety Alerts Procedure

- Monitoring the database and closing the alerts when all areas have completed their response to them and all practicable remedial action to reduce risk has been undertaken.
- Undertaking ‘exceptional reporting’ of safety alerts to the Operational Governance Group and the Health and Safety Group.
- In collaboration with the Quality and Governance Lead, agreeing who should lead any specific alerts.
- Responding on behalf of FNHC to any Field Safety Notices received directly from a manufacturer
- Informing their ‘Deputy’ when they will be away from work

First Line Recipients of Alerts (Operational Leads, Home Care Manager and other relevant Managers/Personnel)
In most instances the Operational Leads and Home Care Manager will be the first line recipients of safety alerts. It is their responsibility to manage the alert process within their areas and this includes:

- Assessing the relevance of alerts received to their areas
- Disseminating alerts to the appropriate personnel
- Ensuring that there are processes in place within their areas of responsibility for actioning alerts and monitoring that agreed actions have been completed.
- Recording the action they have taken regarding alerts on the safety alert spreadsheet on central filing within 7 days of receiving the alert or within any other required timeframe.
- Providing an update to the Clinical Effectiveness Facilitator where requested.
- Ensuring a deputy is appointed when required and communicating this person’s name to the Clinical Effectiveness Facilitator.

Second Line Recipients of Alerts
Second line recipients of alerts are staff receiving an alert from a ‘first line’ recipient. Responsibilities include:

- Dissemination to other team members if appropriate
- Taking the appropriate action as per the alert and/or as requested by the first line recipient
- Adhering to time lines
- Providing feedback as requested

Third Line Recipients of Alerts
Third line recipients of alerts are staff receiving an alert from a ‘second line’ recipient. Responsibilities include:

- Taking the appropriate action as per the alert and as requested by the sender
- Adhering to time lines
- Providing feedback as requested
2. PROCEDURE

The particular circumstances of the safety alert/update will influence the immediate actions to be taken.

The Clinical Effectiveness Facilitator and their deputy will be signed up to receive automatic alerts from both CAS and the MHRA.

The Clinical Effectiveness Facilitator will monitor their emails daily (Monday to Friday with the exception of bank/public holidays) for safety alert notices.

When alerts are received, the Clinical Effectiveness Facilitator will determine which alerts are likely to be relevant to Family Nursing & Home Care (FNHC). Where there is uncertainty about the relevance of any alert it should be sent anyway to the relevant people stated below.

All alerts thought to be relevant/possibly relevant will be entered onto a spreadsheet which will be held centrally.

The Clinical Effectiveness Facilitator will email safety alerts/updates, thought to be relevant/possibly relevant, to first-line recipients or their deputy (as appropriate to the alert). This may include:

- Quality and Governance Lead (only if the alert highlights significant risk to the Association (for whatever reason) and requires immediate financial, legal or other action or is relevant to their team)
- Operational Lead - Adult Services
- Operational Lead - Child & Family Services
- Operational Lead - Rapid Response and Reablement
- Home Care Manager
- Finance Director
- Storeman (if the alert may be relevant to products stocked in FNHC Stores)

Emails sent will be flagged for the recipient indicating that a response is required within one week (or earlier if indicated).

On receipt of the email, the recipient will assess the safety alert and make a decision on whether it is relevant/potentially relevant for their area and the action they need to take.

The action taken must be recorded on the safety alert spreadsheet within one week (or earlier if indicated) of the alert being sent to them.

Some alerts will only require dissemination to relevant staff for information whilst others may involve the withdrawal of equipment, a change in practice or other appropriate action.

Where equipment/medicines might potentially be in use by patients on the caseload but are not used/administered by FNHC staff, the alert should be disseminated anyway to all relevant staff in case they identify the equipment/drug in use by a patient.

Where an alert requires ongoing action, the Operational Leads and the Home Care Manager will feedback progress at the monthly Operational Management meetings and will keep the Safety Alerts spreadsheet updated. For alerts relevant to other areas, the Clinical Effectiveness Facilitator will periodically request updates from the appropriate person/s. A log of this progress will be recorded on the ‘Safety Alerts’ spreadsheet.

When action in response to an alert has been completed, the Clinical Effectiveness Facilitator will indicate on the spreadsheet that the alert is ‘closed’ and record the date that this happens.
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The Clinical Effectiveness Facilitator will undertake ‘exceptional reporting’ on safety alerts at the quarterly Operational Health and Safety meeting and at the Operational Governance meetings.

Where specific issues have been identified as likely to be of significant risk to FNHC (for whatever reason) and may require financial, legal or other action, the Chief Executive Officer (CEO) and Finance Director will be appraised by the Quality and Governance Lead.

3. NON COMPLIANCE

Family Nursing & Home Care expect all staff who receive an alert to respond within the timeframes identified as failure to do this may compromise patient safety.

At any stage of the process, where there is a failure to respond to the alert in the appropriate timeframe the staff member should be contacted by telephone to request an immediate reply.

Should no response be received within 2 working days, a final reminder will be sent by email flagged ‘important’.

If still no response within 2 working days, the situation should be escalated to the Senior Management Team and logged on Assure as a patient safety incident.

4. CONSULTATION AND RATIFICATION

4.1 Consultation Schedule

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title or Team</th>
<th>Date Sent for Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judy Foglia</td>
<td>Quality and Governance Lead</td>
<td>17/11/17</td>
</tr>
<tr>
<td>Tia Hall</td>
<td>Operational Lead – Adult Nursing</td>
<td>17/11/17</td>
</tr>
<tr>
<td>Adrian Blamped</td>
<td>Finance Director</td>
<td>04/12/17</td>
</tr>
<tr>
<td>Michelle Cumming</td>
<td>Operational Lead – Child and Family Services</td>
<td>04/12/17</td>
</tr>
<tr>
<td>Clare Stewart</td>
<td>Operational Lead – Rapid Response and Reablement</td>
<td>04/12/17</td>
</tr>
<tr>
<td>Isabel Freitas</td>
<td>Home Care Manager</td>
<td>04/12/17</td>
</tr>
<tr>
<td>Lindy Henesy</td>
<td>Sister – Children’s Community Nursing Team</td>
<td>14.01.18</td>
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4.2 Ratification Process

<table>
<thead>
<tr>
<th>Name of Committee/Group</th>
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<tr>
<td>Procedural Document Group</td>
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<td></td>
</tr>
<tr>
<td>Chief Executive Officer</td>
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</tbody>
</table>
5. REFERENCES


Department of Health, Central Alerting System Homepage www.cas.dh.gov.uk?Home
(accessed 7.6.16)

6. BIBLIOGRAPHY

Department of Health Medicines and Healthcare Products Regulatory Agency, About us,

(accessed 7.6.16)

NHS England (2013) Policy for managing alerts in primary care,
Alert received via the Central Alerting System, Medicines and Healthcare Regulatory Authority or alert internally generated

Relevance of the alert decided and the alert sent to relevant first-line recipients.

Relevance of the alert for that particular area is determined. Response detailing the action taken to be entered onto the safety alert spreadsheet within 1 week or earlier if indicated

Alert disseminated for staff information/action/vigilance as appropriate. Timescale for action to be given

Feedback on progress with the actions to be recorded on the safety alerts spreadsheet.

Exceptional reporting to the Operational Health and Safety Group and Operational Governance Group when required.

Where specific issues have been identified as likely to be of significant risk to the Association (for whatever reason) and may require financial, legal or other action, the CEO and Finance Director will be appraised by the Quality and Governance Lead.

When all responses received and all action completed, safety alert closed and dated on spreadsheet on central filing.