Name of Policy: Policy for the dissemination, implementation and management of safety alerts

Effective From: 28/07/2017

<table>
<thead>
<tr>
<th>Date Ratified</th>
<th>08/06/2017</th>
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<tbody>
<tr>
<td>Ratified</td>
<td>SafeCare Council</td>
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<tr>
<td>Review Date</td>
<td>01/06/2019</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Director of Nursing, Quality and Midwifery</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>07/06/2020</td>
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<td>Withdrawn Date</td>
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Unless this copy has been taken directly from the Trust intranet site (Pandora) there is no assurance that this is the most up to date version

This policy supersedes all previous issues.
## Version Control

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<thead>
<tr>
<th>Version</th>
<th>Release</th>
<th>Author/Reviewer</th>
<th>Ratified by Authorised by</th>
<th>Date</th>
<th>Changes (Please identify page no.)</th>
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<td>1.0</td>
<td>01/04/2009</td>
<td>J Edwards</td>
<td>SafeCare Council</td>
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<td>2.0</td>
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<td>3.0</td>
<td>28/07/2017</td>
<td>Paula Brennan, Jac Reaveley, Neil Gammack</td>
<td>SafeCare Council</td>
<td>08/06/2017</td>
<td>Process now managed by The Quality Team. Ulysses has been introduced to disseminate alerts.</td>
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1 Introduction

The Central Alert System (CAS) is an electronic cascade system developed by the Department of Health and is a key means by which to communicate and disseminate important safety and device alerts information within the NHS. The CAS supersedes the SABS (Safety Alert Broadcast System) and Public Health Link (PHL). The CAS facilitates distribution of safety alerts, emergency alerts, NHS Improvement Patient Safety Alerts (NHS-PSA), Medical Device alerts (MDAs), Drug alerts, Estates alerts, field safety notices, Chief Medical Officer messages and Dear doctor letters.

Trusts are required to implement and maintain systems for alert dissemination and review in accordance with Care Quality Commission regulations and the DB2011(01) “Reporting Adverse Incidents and Disseminating Medical Device Alerts”.

This policy is designed to ensure a consistent approach for dealing with the management of alerts received through the Central Alert System (CAS). It is important that all Trust personnel are aware of their roles and responsibilities with regard to dissemination and actions required in complying with alerts.

Alerts originate from the following organisations: -
- a) Medicines and Healthcare products Regulatory Agency (MHRA);
- b) NHS Commissioning Board Special Health Authority
- c) Department of Health Estates and Facilities (DHEF)
- d) Department of Health (DH)
- e) NHS Improvement

It may also be necessary for the Trust to distribute “internal alerts”. These alerts will be used to provide rapid dissemination of information, e.g. medical device/equipment recall. It is the aim of the Trust to ensure that all alerts are communicated promptly to all relevant members of staff employed within the Trust and that action to comply with alerts is taken within Department of Health timescales (these are detailed in each alert) in order to safeguard patients, visitors, and staff from harm.

2. Policy Scope

This policy applies to all members of staff working within Gateshead Health NHS Foundation Trust. Staff are asked to participate in the confirmation of relevance of alerts received, the implementation of recommendations and the provision of compliance statements.

3. Aim

The aim of this policy is to provide a structure to effectively and efficiently deal with all safety alerts and consequently provide a safer organisation for users and providers within the establishment. The policy aims to give guidance to staff involved within the process of identifying and delivering safer systems.
4. **Trustwide Roles and Responsibilities.**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust board</td>
<td>The Trust Board is responsible for supporting the CAS Liaison Officer in their role to ensure the post holder has the authority, expertise and available resources to enable the Trust to effectively manage the risk areas highlighted by the safety alerts. The Board will formally review the systems and processes for ensuring safety alerts are managed effectively.</td>
</tr>
<tr>
<td>Assistant Director of Quality</td>
<td>The Assistant Director of Quality will ensure sufficient provision of resources are available to ensure the Trust can undertake the function required to effectively manage Safety Alerts this includes identifying a Deputy Liaison Officer to act in the absence of the regular post holder.</td>
</tr>
</tbody>
</table>
| Service Line Manager / Head of Service  | Will oversee the role of the Safety Alert Lead and will be responsible to;  
  - Provide justification at the Risk and Safety Council as to why delays have occurred or any barriers to full implementation.  
  - Escalate to SafeCare council, with a full risk assessment and add any risk to the Risk Register. |
| Ward or Department Managers             | Are responsible for ensuring all actions that impact on current practice are implemented. Ensure alerts are cascaded to all relevant staff and implemented locally within the designated time frames. Managers will also provide feedback to the service line managers detailing completion of implementations or barriers / delays to compliance. |
| CAS Liaison Officer                     | Carry out work Trust wide supporting the leads to ensure compliance and assurance of the CAS Process.                                                                                                                                                        |
| CAS Safety alert leads                  | Leads will identify personnel to locally implement actions and manage the process ensuring compliance is reached by the deadline or escalate anticipated or actual problems or delays. The lead will also be responsible for providing assurance to the CAS liaison officer that actions have been undertaken and provide relevant evidence (See Appendix 2 CAS Safety Alert named delegates/deputies) |
| CAS Review Group                        | The CAS review group will;  
  - Receive alerts via CAS liaison officer for consideration  
  - Review all new alerts published during the previous month  
  - Identify or review formerly identified leads to coordinate and implement recommended actions stated within new alerts.  
  - Review live or outstanding alerts  
  - Liaise with identified leads and receive regular feedback to populate a Progress Report, which will notify the Safe Care Council of the current position, organisational gaps, or any identified barriers to implementation, which may pose a significant risk to the Trust.  
  (See Appendix 3 CAS review group terms of reference) |
<table>
<thead>
<tr>
<th>Department</th>
<th>Role and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement / Logistics department</td>
<td>The supplies department shall assist in identifying the relevance of alerts appertaining to equipment and supplies used in the Trust.</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>The Pharmacy department will respond and action all medication safety alerts in line with the below standard operating procedure and all alert will be retrospectively added to the Ulysses system for completeness.</td>
</tr>
<tr>
<td>Pharmacy</td>
<td><a href="#">Drug Alert SOP (Jan 16 DG).doc</a></td>
</tr>
<tr>
<td>Patient Safety Facilitator (CAS Liaison Officer Deputy)</td>
<td>The Patient Safety Team is responsible for the central administration and co-ordination of Safe care Alerts. They will work with the identified lead author of the Alert to produce an alert in a standard format. They are also responsible for sending the approved Alert to either the Director of Nursing and Midwifery or Medical Director or the Chief Executives PA for distribution by email to the relevant personnel. The Patient Safety Team will archive all disseminated alerts. (See Appendix 4 CAS review group flow chart)</td>
</tr>
<tr>
<td>Individual staff</td>
<td>Responsible for ensuring their practice conforms to guidance stipulated within alerts and support the further dissemination for info to colleagues to ensure full compliance is consistently maintained to enhance patient safety. Any Field safety notices (FSN) received into the Trust must be forwarded to the CAS Liaison Officer in the safe care dept.</td>
</tr>
<tr>
<td>Bank staff</td>
<td>The Nurse bank administrative team are to inform Bank nurses of risks and risk management responsibilities identified in alerts to ensure all care is delivered as recommended. Bank staff must ensure all duties carried out are within the remit of the Trust risk management process.</td>
</tr>
<tr>
<td>Patient Safety Facilitator</td>
<td>Will interrogate the Datix system to identify similar incidents or near misses as those identified in alerts, and provide relevant data to the CAS Liaison officer and Head of Corporate Risk.</td>
</tr>
</tbody>
</table>

### 5. Definition of terms

- **Compliance** - the state or act of conforming with or agreeing to do something
- **Dissemination** - to distribute or spread something, especially information, widely, or become widespread
- **Alerts** - an alarm or warning of danger, to make somebody aware of a possible danger or difficulty
6 Process for Identification and Dissemination of Safety Notices and Alerts.

This section gives a break-down of each type of alert, i.e.
- National alerts via the Central Alerting System;
- Safe care alerts coordinated by the Trust's internal Safe Care team
- Field safety notices (FSN) those received direct from manufacturers warning of potential of manufacturing incidents and how they are received into the Trust and managed internally.

6.1 Department of Health Central Alerting System (CAS)

The 3 main types of alerts disseminated via the CAS system originate from Medicines and Healthcare Regulatory Agency (MHRA), NHS improvement or DH Estate and Facilities

- **The MHRA** - As an executive agency within the Department of Health, aims to enhance and safeguard the health of the public by ensuring that medicines and medical devices function effectively and are acceptably safe. No product is risk-free, and underpinning all the work carried out by the MHRA lies robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. They therefore take an overview, and take any necessary action to protect the public promptly if there is a problem. These alerts on the whole are managed by QEF's medical devices team, or procurement as they often relate to recalls or maintenance issues.

- **DH Estates and Facilities** department issued alerts to the NHS via CAS to manage risks relating to non-medical equipment, engineering, plant installed services and building fabric in the NHS. Alerts are categorised into the same categories as those issued by the MHRA i.e. Immediate action, action, update and information request. These alerts are on the whole managed by QEF’s Estates dept. as they often relate to building issues.

- **NHS Improvement** (On 1 April 2016 the statutory patient safety functions previously delivered within NHS England transferred to NHS Improvement.) Patient safety alerts are a crucial part of the work carried out by NHS improvement to rapidly alert the healthcare system to risks and provide guidance on preventing potential incidents that may lead to harm or death. These incidents are identified using their reporting system (NRLS) to spot emerging patterns at a national level, so that appropriate guidance can be developed and issued to protect patients from harm. These alerts on the whole require formulation of a project team, central coordination from the patient safety team and often impact trust wide.

6.1.1 CAS electronic database

Information contained within the Department of Heath CAS database can be accessed using a password unique to the Trust; this password is held by the CAS liaison officer, or deputy. Information relating to the number of live, complete or outstanding alerts as detailed by the trust can be viewed via this...
site. This information is then utilised to populate the safety and indicator within NHS choices.

6.1.2 Receipt of CAS alerts into the Trust
The Trust’s CAS liaison officer is an individual allocated within the Trust’s patient safety team; to receive safety alerts automatically via the Departments of Health’s electronic (CAS) dissemination system.

Upon receipt the CAS liaison officer will investigate the alerts relevance on the Trust’s provision of healthcare. Utilising Ulysses the liaison officer will source the Trusts current status, from the Business Unit delegate/deputy. This will involve liaising with specialist teams across the organisation (e.g. medical devices, procurement, SLM’s, Estates etc.) to ensure significance is not overlooked. Once a relevance status is obtained the liaison officer must respond via the Department of Health’s CAS electronic reply system indicating acknowledgement and level of application required by the Trust.

6.1.3 Internal Dissemination and acknowledgement of CAS alerts to appropriate staff members across the organisation
It is important that all alerts are not disseminated to leads but only those that are relevant; or ‘alert fatigue’ is likely to occur, leading to staff potentially neglecting those alerts that hold significance to their working practice.

Level 1 dissemination i.e. CAS liaison officer to disseminate to the business unit safety alerts lead & their deputy. Following a declaration of affirmed relevance the CAS Liaison Officer will need to formally issue alerts for necessary action; this will be undertaken via Ulysses to enable full traceability.

The CAS liaison office is responsible for formulating and maintaining a dissemination register within Ulysses. Associate Directors have nominated leads within the divisional unit/ service that hold necessary levels of responsibility to influence service delivery.

Level 2 dissemination
Once the safety alert leads receive an alert they need to consider the required actions and identify who within the service or business unit needs to be involved to support the implementation of required actions at local level. It is then up to the safety alert leads to further disseminate the alert (via Ulysses) to those individuals within the business unit or service required to implement recommendations or develop plans accordingly.

All alerts shall be discussed at the subsequent CAS review group to ensure they have been circulated appropriately and efficiently.
6.1.4 Acknowledgement of CAS alert

Acknowledgement to external bodies
This relates to the CAS liaison officer reporting back to CAS indicating acknowledgement and consequently feeding back any update status. The pre-defined status categories are:

- Acknowledged
- Assessing relevance
- Action not required
- Action required on-going
- Action complete

The system also provides free text fields which allows the CAS liaison officer to submit updates for future reference.

Should the CAS liaison officer fail to respond or delay acknowledgement they will receive daily email reminders with simultaneous recording of non-compliance in the CAS system.

Internal acknowledgement

Level 1 acknowledgement follows level 1 dissemination
Upon receipt of alerts the safety alert leads must complete the required fields within Ulysses stipulating acknowledgement and detailing proposed implementation plans. This information is fed back through Ulysses to the CAS liaison officer, offering assurance the alert has been received and measures are being implemented locally.

Level 2 acknowledgements follows level 2 dissemination i.e. local acknowledgement of alerts further cascaded by safety alert leads to relevant personnel believed capable of implementing recommendations locally.
Upon receipt of alerts the recipient must acknowledge via Ulysses and detail anticipated strategies to delivery recommendations, detail additional resources including required input from other stakeholders. Should the recommendations be beyond the capabilities of the identified support this must also be detailed within Ulysses. All level 2 acknowledgements and free text information must be fed back to the corresponding safety alert leads.

Local failure to respond to or delay in responding to internal processes will incur reminder emails via Ulysses and automated reports escalated to service line managers, detailing individuals showing non-compliance.
6.1.5 Description of actions
The MHRA and DH estates and facilities have developed the following formats to their alerts for the dissemination of advice and solutions to NHS staff:

<table>
<thead>
<tr>
<th>Immediate Action</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action</td>
<td>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.</td>
</tr>
<tr>
<td>Update</td>
<td>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.</td>
</tr>
<tr>
<td>Information Request</td>
<td>Used to alert users about a specific issue that may become a problem and where we are requesting feedback. These alerts will be sent out with additional questions to be completed.</td>
</tr>
</tbody>
</table>

NHS Improvement however present alerts with the following categories assigned:-

<table>
<thead>
<tr>
<th>Warning Alerts</th>
<th>Typically issued in response to a new or under-recognised patient safety issue with the potential to cause death or severe harm. They aim to issue warning alerts as soon as possible after becoming aware of an problem and identify that healthcare providers could take constructive action to reduce the risk of harm. Warning alerts ask healthcare providers to agree and coordinate an action plan, rather than to simply distribute the alert to frontline staff.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resource Alerts</td>
<td>Typically issued in response to a patient safety issue that is already well-known, either because an earlier warning alert has been issued or because they address a widespread patient safety issue. Resource alerts are used to ensure healthcare providers are aware of any substantial new resources that will help to improve patient safety, and ask healthcare providers to plan implementation in a way that ensures sustainable improvement. Highlighted resources will usually have been developed by national bodies, professional organisations or networks.</td>
</tr>
<tr>
<td>Directive Alerts</td>
<td>Typically issued because a specific, defined action to reduce harm has been developed and tested to the point where it can be universally adopted, or when an improvement to patient safety relies on standardisation (all healthcare providers changing practice or equipment to be consistent with each other) by a set date.</td>
</tr>
</tbody>
</table>
Each local safety alert lead will coordinate their local teams planning and implementation of recommended actions. Evidence of actions undertaken and associated outcomes is required to offer assurance of compliance, this level of compliance must be fed back to the CAS liaison officer so compliance reports can be formulated accordingly.

6.1.6 Compliance of CAS alert actions

Once the recommended actions contained within an alert are complete a chain of compliance must be followed. The chain of compliance is the chain of dissemination in reverse i.e. local personnel responsible for implementing the actions and monitoring outcomes must report compliance (via Ulysses) and forward associated evidence to the safety alert leads. The safety alert leads then forward a compliance statement and associated evidence to the CAS liaison officer.

The CAS liaison officer will then review the evidence and make a trust wide compliance decision and formulate assurance reports for the Trust and at Business Unit level.

If the implementation of recommended actions is delayed or deemed unachievable the safety alerts lead must inform the CAS Liaison Officer, stating any alternative measures implemented and/or evidence that risks have been addressed or added onto the local risk register.

On receiving confirmation that actions are complete or otherwise, the CAS Liaison Officer will inform the Department of Health via the CAS system of the Trust’s progression towards compliance.

Information presented to the CAS liaison officer in regard to difficulties, non-compliance, barriers must then be fed back to the CAS review group. It is the responsibility of the CAS Liaison Officer to ensure difficulties are escalated to SafeCare Council accordingly.

6.1.7 Failure to comply with safety alerts issued via the central alerting system

NHS Choices now publish non-compliance data on their website in relation to Trusts failing to declare compliance by the stipulated due date. Failure to comply is likely to be used by the CQC as part of their Intelligent Monitoring System and as an integral part of commissioners’ responsibilities for improving quality. Failure to comply with Directive level alerts in particular will be a cause for significant concern on the part of regulators, commissioners and most importantly, patients. Should the implementation of safety actions be delayed or unachievable this must be escalated to SafeCare Council with a full risk assessment completed and added to the Trusts risk register by Service Line Manager or Chief Matron.

6.2 Manufacturer Recall Notices

6.2.1 Receipt and internal dissemination of manufacturer alerts within the Trust

Manufacturers often send out field safety notices (FSN); these can be received directly by clinical departments or via supplies and procurement
All notices must be forwarded via email or post to the trust’s CAS liaison officer in safe care; who will then liaise with the relevant people in the organisation to determine relevance. This process of determining relevance must be orchestrated via Ulysses. Often FSN require direction from supplies and procurement to advice if the trust has procured items implicated in the notice and the locations or wards affected. The CAS Liaison Officer will add any applicable alerts to Ulysses and disseminate.

Upon confirmation of relevance the CAS Liaison Officer will further cascade the alert following the same process as detailed above for CAS alerts i.e. dissemination via Ulysses to safety alert leads.

A significant number of field safety notices advocate the quarantining and return of devices in relation to specific lot, batch, serial numbers. In most instances QEF logistics will, upon receiving the alert via Ulysses retrieve affected items and manage accordingly.

If procurement is managing the actions of quarantining and returning affected items then FSN may just be disseminated to clinical areas for information only.

6.2.2 Acknowledgement receipt of manufacturer alert
The Trust’s internal recipients of the alert disseminated via CAS Liaison Officer must demonstrate acknowledgement via Ulysses as detailed above for CAS alerts. Automatic reminders are sent daily via Ulysses if recipients reach the designated deadline, they will continue until individuals sign off the appropriate status.

6.2.3 Compliance of manufacturer alert actions
Once the recommended actions contained within a notice are complete the recipient of the notice or other identified lead must feedback to the CAS Liaison Officer indicating completion. This must be done using Ulysses.

The Supplies Dept. will take responsibility for communicating with manufacturer to arrange collection of affected devices and replacement products.

The CAS Liaison Officer will take responsibility for ensuring compliance communicating with manufacturers once all actions are complete.

If the implementation of recommended actions is delayed or unachievable the recipient of the notice or other identified lead must inform the CAS Liaison Officer, stating any alternative measures implemented and evidence that details have been addressed and added onto the local risk register.

Each lead designated with the responsibility of further cascading the alert or implementing the recommendations should retain evidence of this.
6.3 Internal alerts
Local safety information requiring rapid dissemination within the Trust may be distributed in the format of a standard Safe Alert Bulletin or Good Practice Bulletin.

6.3.1 Development of Alerts
When information is received that highlights a potential impact upon the quality and safety of care or service delivery within the Trust, appropriate staff will be advised through the distribution of a Safe Care Alert to inform them of necessary actions required to minimise risk to patients, staff and the organisation.

The information to be distributed should be sent to the Clinical effectiveness team, who shall work with the author to produce a Safe Care Alert. Prior to dissemination, approval of the alert should be obtained from the Director of Nursing and Midwifery or Medical Director, or a deputy in their absence.

6.3.2 Dissemination of alerts to appropriate staff members
Approved Safe Care Alerts will be sent out via Ulysses from the Director of Nursing and Midwifery or Medical Director, to relevant staff.

6.3.3 Compliance to alert
Safe care Alerts are disseminated to heighten staff awareness of potential situations and do not require a formal reply to the Quality Department. However, it is the responsibility of the Safe Care leads within each department and division to highlight and discuss any relevant Safe Care Alerts through their local Safe Care Structures.

6.4 Drug alerts

6.4.1 Receipt of alerts into the trust
It may be necessary for the Pharmaceutical Industry to recall certain products following reports about faulty and/or incorrect labelling and packaging, quality assurance and adverse drug reactions. The process is cascaded by the Medicines Control Agency using the DRUG ALERT to hospitals via Regional Drug and Therapeutic Centre (RDTC).

The RDTC allocates the next sequential cataloguing number to the alert and clearly states the degree of urgency with which it should be dealt with. The DRUG ALERT states the proprietary and generic name of the medicines involved and batch number and expiry dates together with the dates of issue from the manufacturers.

During normal office hour Monday to Friday The DRUG ALERT is received by fax in the pharmacy office and will be dealt with immediately by office staff. Outside these hours the RDTC on call service will cascade through the Trust pharmacist on – call service. The RDTC routinely checks each year to ensure Trust contact details remain unchanged. Equally as part of their procedures, trusts are required to update them of any changes in contact details.
6.4.2 Dissemination of alerts within the Trust
Pharmacy staff will search the pharmacy computer data bases to determine whether or not the affected product has ever been ordered through the trust pharmacy department.

This search will check carefully for the product name, strength & affected pack size & will include checks for brand names no longer stocked.

All stock located in the pharmacy will be located & quarantined. An issue report to identify all locations across the Trust where the product has been issued to will be generated.

Pharmacy staff will be sent to visit the onsite areas shown by the computer to have received the items detailed by the DRUG ALERT to collect the stock and return it to the pharmacy. For “off-site” wards most senior member of staff on the ward will be telephoned to advise them of the batch number, expiry date, name and strength of the product to be withdrawn. They will be advised to quarantine the product and clearly mark it for return to pharmacy in the ward box. They will be given a pharmacy contact & requested to call back to advise of the outcome of their search.

A follow up e-mail will be sent to all ward sister/charge nurses advising them of the actions taken and requesting them to quarantine any further stock which may be later found for return to pharmacy. This memo will also give advice of suitable alternative products should this be necessary.

6.4.3 Acknowledgement of alert
All alerts received are recorded on the pharmacy master log. As all alerts are numbered in sequence by the RDTC, staff entering a new alert must ensure that it is the next sequential number. If any alerts are missing, the RDTC must be contacted immediately.

When all the actions for an alert have been completed, a senior member of the pharmacy department must sign off the master record sheet to indicate that all necessary actions have been completed.

6.4.4 Description of actions
These are detailed in the pharmacy department local Standard operating procedure. All drug alerts will be retrospectively added to the Ulysses system for completeness.

6.4.5 Compliance of alert actions
When an alert has been completed, an e-mail is sent to the Pharmacy services manager to advise of the reasons for the alert and the actions taken.

6.5 Process for Implementing Change
Implementing changes that are influenced by Safety Alerts will be discussed at Business Unit Level and it shall be the responsibility of the Service Line Manager /
Heads of Service or other identified lead, to determine the level of change required to comply with the recommendations issued within the alert, to develop an action plan, containing details of how the actions are to be implemented, by whom and by when. The date of completion must be within the deadline stipulated within the alert. If this is not possible consideration of the problem highlighted in the alert must be given for entry onto local risk registers. Consequential action plans must be conveyed to the CAS Liaison Officer; hence the gap analysis and progress report can be populated.

7. Training

The implementation of some alerts may warrant training particularly if a change in process or procedure is required, training will then be incorporated into the local actions to ensure the correct knowledge, experience etc. becomes embedded with the implementation of the alert.

Training on the Ulysses system can be supported by QEF medical devices support officer or the Trusts CAS liaison officer

8. Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

9. Process for monitoring compliance to this policy

<table>
<thead>
<tr>
<th>Standard/process/issue Monitoring and audit</th>
<th>Standard/process/issue Monitoring and audit Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated desk top reporting via Ulysses identifying compliance levels to issued alerts within the specified time line</td>
<td>Issued electronically via Ulysses to SLM’s and CAS leads per business unit</td>
<td>The CAS Liaison officer</td>
<td>CAS review group</td>
<td>Monthly</td>
</tr>
<tr>
<td>The CAS review group shall meet quarterly to discuss all live, outstanding or delayed alerts as well as those closed since the previous meeting</td>
<td>Forum, will review all alerts and actions taken</td>
<td>Chaired by The CAS Liaison officer</td>
<td>CAS review group</td>
<td>Quarterly</td>
</tr>
<tr>
<td>The CAS liaison group must ensure that delayed implementation or inability to implement is recorded on the relevant risk register</td>
<td>communication with the relevant business unit safe care leads or SLM’s</td>
<td>The CAS Liaison officer</td>
<td>Safe care Committee</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Standard/process/issue Monitoring and audit</td>
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</tr>
<tr>
<td>Assurance reports to be provided for safe care committee detailing relevant reports and compliance levels to this policy.</td>
<td>Assurance Reports to be formulated form data retrieved via Ulysses and communication from safety alert leads.</td>
<td>The CAS Liaison officer</td>
<td>Safe care Committee</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Internal audit has a 3 year program to look at the effectiveness of safety alert dissemination and compliance.</td>
<td>Audit</td>
<td>Internal audit</td>
<td>Safe care</td>
<td>3 yearly</td>
</tr>
</tbody>
</table>

**Drug alerts**

On an Annual basis the pharmacy will be requested, by the CAS Liaison officer for assurance that all alerts have been appropriately addressed in the preceding 12 months, this information shall be incorporated into the CAS annual report which is monitored via Safe Care Council.

10. **Consultation & review of this policy**

This policy has been presented to SafeCare Council and recommendations have made to the policy. Subsequent policies will be reviewed and consultation will happen at the CAS Review Group, then the policy will be ratified at SafeCare Council.

11. **Implementation of this policy**

The policy will be widely available following ratification via the trust intranet. CAS liaison officer will inform safety alert leads identified on distribution list for each division.

12. **References**

- The Central Alerting System [www.cas.dh.gov.uk/Home.aspx](http://www.cas.dh.gov.uk/Home.aspx)
- Regional Drug and Therapeutic Centre [www.nyrdtc.nhs.uk/](http://www.nyrdtc.nhs.uk/)
- Safety First Report 15th December 2006.
- NHS Estates & Facilities Division [www.ic.nhs.uk/about-us](http://www.ic.nhs.uk/about-us)
- MHRA Reporting adverse incidents and disseminating medical devices alerts DB2011 (01).

13. **Associated documents**

Risk management Policy RM01
Appendix 1 – Process Flowchart for CAS Alerts and CAS Review Group

Nominated CAS Liaison Officer receives safety alerts Via CAS or direct from manufacturers

CAS Liaison officer/Deputy:-
- Determines the relevance of the safety alert or notice by sending to specialist teams such as procurement, medical devices, or patient safety team via Ulysses
- Presents a list of alerts to the CAS Group
Pharmacy will action all Drug alerts and they will be added to Ulysses in retrospect.

CAS review group:-
- Discuss alerts, review identified leads and confirm distribution to ensure actions are initiated by the most pertinent people within the Trust

Notified leads develop/agree a suitable action plan to implement recommendations

CAS Liaison Officer will liaise with identified leads for progress updates within the specified time scale. Delays should be disclosed and risk registers undated accordingly

Final action plans will be produced with the business unit and presented to the CAS Review group to populate a progress report

Development of quarterly progress reports presented to the Safe Care Council will highlight compliance and non-compliance of the implementation of recommendations.

Action plans will require monitoring until all recommendations implemented.

Department of Health CAS team will be informed when the action has been completed by the CAS Liaison Officer.
On occasions the Trust will receive important safety information direct from manufacturing establishments, or suppliers, this information requires the same level of significance as those received via CAS.

Gateshead Health NHS Foundation Trust will fulfil all statutory and organisational requirements related to the acknowledgement, implementation or compliance to applicable safety alerts. This policy should be read in conjunction with the Trust’s Risk Management Policy (RM 01).
Appendix 2 - Named Delegates

The current nominated delegates and deputies for each area are listed below;

Medical Devices – Jac Reaveley and Mark Lowes
Procurement – Lynne Symington and Sharon Whitlie
Estates – David Jones and Kevin Smeaton
Pharmacy and Diagnostics and screening services – Linda Morgan and Neil Gammack
Medical Services – Tom Monaghan, Janet Thompson and Nicola Kenney
Surgical Services – Pam Knowles and Gareth Armstrong
Community – Gareth Johnson and Julie Cockburn
## Terms of Reference

### Central Alerting System (CAS) Review Group

#### Constitution and Purpose
The CAS Review Group carries out its duties as an assurance group of the SafeCare Council in co-ordinating, implementing and monitoring all safety notices, alerts and reports received by the Trust ensuring appropriate actions are taken within the required timescales.

The purpose of the Group is to act as a focal point for all CAS related activity across the Trust. The group will report to the SafeCare Council and provide assurance that Safety Alerts are being effectively actioned across the organisation.

<table>
<thead>
<tr>
<th>Date Adopted</th>
<th>April 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Frequency</td>
<td>Annually</td>
</tr>
</tbody>
</table>

### Core Accountabilities

<table>
<thead>
<tr>
<th>Terms of reference drafting</th>
<th>SafeCare Lead – Patient Safety and Incident Management.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review and approval</td>
<td>CAS Review Group</td>
</tr>
<tr>
<td>Adoption and ratification</td>
<td>SafeCare Council</td>
</tr>
</tbody>
</table>

### 1. Membership and attendance at meetings

#### Membership
- SafeCare Lead – Patient Safety and Incident Management (CAS Liaison Officer) -Chair
- Head of Medical Devices
- Pharmacy Services Manager
- Supplies Manager
- CAS Leads

In addition to core membership the Group may co-opt additional members as appropriate to enable it to undertake its role.

#### Attendance
1.1 The CAS Review Group will meet quarterly.

1.2 It is expected that members will appoint a nominated deputy who will attend meetings in the absence of full members. Attendance will be monitored and measured against the agreed expected standard. The standard shall be that group members or their nominated deputy MUST attend all meetings.

1.3 Non-attendance for 3 consecutive meetings will result in a letter from the Chair.

### Quorum
To be quorate there should be at least one member from each business unit.

### 2. Roles and responsibilities
The key responsibilities of the Group are to:

- Receive and consider all Safety Alert Bulletins received into the Trust via the CAS System Liaison Officer;
  - Newly published CAS documents:
    - review and assess all new Alerts received by Trust within the previous month
    - identify and appoint appropriate lead(s) for the co-ordination of guidance assessment/planning and implementation, and disseminate all documentation to the lead(s)
- Maintain a central electronic database of information pertaining to alerts, including the actual alert and any action plans or other progress/discussion documentation.
- Administer an efficient electronic centralised monitoring system for all alerts received within the organisation, to ensure that the system meets the requirements of the organisation.
- Have the authority to approve clinical guidelines and policies associated with the business of the Group ensuring the appropriate consultation process has been followed
- Provide an annual update on the activities of the group to the SafeCare Council through an annual report.
- Escalate to the SafeCare Council any identified unresolved issues arising within the scope of these Terms of Reference that require executive action or that pose significant threats to the operation, resources or reputation of the Trust.
- Periodically review its own Terms of Reference and effectiveness and report the results of that review to the SafeCare Council.

### 3. Conduct of business

#### 3.1 Sub-Groups & Review
- The Group will have the authority to set up and disband groups in order to effectively discharge its function.
- In establishing groups there should be clear Terms of Reference, appropriate membership and reporting arrangements.

#### 3.3 Monitoring & Compliance
- The CAS Review Group will be monitored by the SafeCare Council.
- The Group will carry out annual self-assessment reviews of its effectiveness and functioning, to include reporting arrangements to the SafeCare Council and frequency of meetings.
- The Group’s members’ attendance is monitored throughout the year.

### 4. Monitoring

4.1 Compliance with these Terms of Reference will be undertaken through an annual self-assessment review.