Managing Safety Alerts Procedure

Version number :	1
Consultation Groups	Medical device lead and virtual medical devices group
Approved by (Sponsor Group)	Medical devices group
Ratified by:	
Date ratified:	
Name and Job Title of author:	Risk and Datix Manager
Executive Director lead :	Executive Nurse, Lorraine Sunduza
Implementation Date :	January 2020
Last Review Date	July 2019
Next Review date:	July 2022

Services	Applicable to
Trustwide	x
Mental Health and LD	
Community Health Services	

Contents

Central Alert System (CAS) Procedure

1. Introduction

The Central Alert System (CAS) is an electronic cascade system originally developed by the Department of Health and now delivered by the Medicines and Healthcare products Regulatory Agency and is a key means by which to communicate and disseminate important safety and device alerts information within the NHS. CAS facilitates distribution of Alerts available on the CAS website including National Patient Safety Alerts, NHS England and Improvement Patient Safety Alerts (PSA), Estates Alerts, MHRA Dear Doctor letters, Drug Alerts, Chief Medical Officer (CMO) Alerts, and Department of Health & Social Care Supply Disruption alerts.

Trusts are required to implement and maintain systems for alert dissemination and review in accordance with Care Quality Commission regulations, the DB2011(01) "Reporting Adverse Incidents and Disseminating Medical Device Alerts" and CHT/2020/002 "Changes to MHRA alerts and amendments to the website".

This procedure 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 staff 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) Department of Health Estates and Facilities (DHEF)

c) Department of Health and Social Care (DHSC)

d) NHS England and 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 and lessons learnt.

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 defined timescales in order to safeguard patients, visitors, and staff from harm.

2. Scope

This process applies to all members of staff employed within the Trust who are involved in any aspect of alert dissemination, action, implementation and review.

3. Aims

It is the Trust's intention that there is a robust system for disseminating and providing feedback on the implementation of the Safety Alerts, issued by the MHRA, DHSC, NHS England and Improvement and DHEF.

This procedure will ensure that the Trust has;

- Clearly defined alert communications system for distributing alerts and obtaining responses from identified key leads.
- System for monitoring that actions identified in the alerts have been taken, to ensure the safety of all those who deliver and receive services from the Trust.
- Duties (Roles and responsibilities)
- An out of hours process in place.

4. Responsibilities

The success of the system in reducing harm to patients and litigation relies upon all relevant staff being aware of and acting on alerts and ensuring appropriate documentation is maintained to provide evidence of actions taken.

The **Chief Executive** has overall responsibility for patient safety and patient safety alerts with operational management delegated to the Medical Director and Chief Operations Officer.

The **Medical Director** has responsibility Chief Medical Officer (CMO) Alerts

The **Chief Nurse** has responsibility for alerts relating to medical devices.

The **Medical Director** or **Chief Nurse** will also agree any 'internal alerts' before circulation to confirm appropriate and the level of action required.

Executive Directors have responsibility for Patient Safety Alerts relevant to their area of expertise.

Director of Pharmacy and **Medicines Safety Officer** has specific responsibilities relating to `drug alerts and other pharmaceutical notices.

Director of Estates, Facilities and Capital Development has responsibility for Estates related alerts.

The **Risk and Datix Manager** is responsible for the management of the safety alerts system, responsibilities include;

- Formulating and reviewing procedural guidance for the alert process.
- To provide support, guidance and training to key leads on the Datix Safety Alerts Module.
- Receiving alerts via CAS on behalf of the Trust.

- To identify the key lead(s) to assess each alert.
- Maintaining a central record of alerts using Datix.
- Closing alerts on the CAS when actions have been completed and evidence provided by the Medical Devices Safety Officer / Medication Safety Officer & Pharmacist /Director of Estates, Facilities and Capital Development.
- Provide a monthly report of the status of all alerts to be received by the Quality Committee.
- Notifying the MHRA of any changes to the Medical Devices Safety Officer (MDSO).
- Undertake an annual audit of safety alerts.

Key Leads

Medical Devices Safety Officer is responsible for;

- Assessing the relevance of alerts in relation to medical devices.
- Distributing alerts onwards to service directors for cascade.
- Escalating issues to the Medical Devices Group.
- Maintaining records confirming dissemination of alerts and completed action plans.
- Providing a summary of actions taken to Risk and Datix Manager including evidence to be uploaded to the Datix system.

Medication Safety Officer & Pharmacist has responsibility for;

- Assessing relevance of drug alerts.
- Maintaining an up to date list of pharmacy leads and nominated deputies.
- Distributing alerts received across the Trust to Service Directors as necessary.
- Maintaining records confirming dissemination and completed action plans.
- Providing summary of actions taken to Risk and Datix Manager and attaching evidence to the Datix system.
- Providing reports to the Medicines Management Committee when appropriate i.e. when complex action plans are required.

Director of Estates or nominated deputy (Director of Estates, Facilities and Capital Development)

- Assessing relevance of all Estates related alerts.
- Distributing alerts to contractors as appropriate.
- Maintaining records confirming dissemination and completed action plans.
- Providing summary of actions taken to Risk and Datix Manager and attaching evidence to the Datix system.

Directors of Nursing / Medical Directors

- Provide expert advice to support Medical Device Lead / Medication Lead / Estates lead / Service directors as required.
- Lead on complex patient safety alerts as directed by the Medical Devices Committee or Executive Director Lead.

Medical Director CHS & Medical Director Primary Care

- To receive all alerts for information in the first instance
- Assessing relevance of all alerts and distribute and cascade to practices as appropriate.
- Providing a summary of actions taken to Risk and Datix Manager and attaching evidence for upload to the Datix system.

Professional Lead for Allied Health Professionals

- Provide expert advice to support Medical Device Lead / Medication Lead / Estates lead / Service directors as required.
- Lead on complex patient safety alerts as directed by the Medical Devices Committee or Executive Director Lead.

Operational Services

Operational Directorate Managers/ Clinical Directors

Operational Directorate Managers/ Clinical Directors have responsibility to ensure arrangements are in place for the dissemination, action, and implementation of actions required for each alert within directorates as directed by key leads. Operational Directorate Managers / Clinical Directors must provide timely updates to individual alert action plans and maintain a record of implementation and report back to the key specialist lead.

Team leaders / Ward Managers / Matrons

Team leaders, ward managers and matrons are responsible for;

- Checking equipment as directed by the actions required.
- Implementing changes in practice as directed by the safety alert.
- Ensuring that actions are followed up in a timely manner.
- Reporting back to service director.

Committees

Quality Committee

The Quality Committee will receive a monthly CAS report detailing;

- Number of alerts received in month including type.
- Number of Alerts closed in month those where action is complete and those not relevant.
- Number and details of any alerts which remain open.
- Outcomes of any audits.

Medical Devices Group

The Medical Devices Group will support the implementation of patient safety alerts relevant to medical devices and associated action plans where requirements are deemed complex and trustwide. The group will;

- Identify executive director lead if necessary.
- Monitor progress against deadlines
- And where necessary identify further actions to provide assurance that requirements' are met.

Health, Safety and Security Committee

The Health, Safety and Security Committee will support the implementation of patient safety alerts and estates alerts in relation to Health and Security and the Control of Substances Hazardous to Health (COSHH).

5. Actioning Alerts

When a new alert is added to the CAS website, an e-mail notification is sent to the Trust, the Trust has 48 working hours in which to acknowledge receipt of the alerts. The CAS reference number together with the Datix reference should be quoted on all documentation and correspondence.

All alerts carry deadlines for completion that depend on the subject of the alert as follows:

Categories of Alerts

- **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
- **Action**: used where the recipient is expected to take action on the advice where necessary, to repeat warning on long standing problems, or support or follow-up manufacturer's modifications

All CAS alerts are issued with action deadline requirements which relate to the seriousness of the identified safety issue. The Trust is responsible for updating the CAS website in relation to all action deadlines.

Deadline: Action underway: at the time of acknowledgment of the alert the Trust registers that it is assessing relevance, after it has been established the Trust is responsible for the issues raised. Deadlines are set by the Department of Health for this part of the process.

Deadline: Action completed: the date the Department of Health requires the Trust to have had completed any necessary action.

All alerts are centrally logged and managed via the Datix Integrated Risk Management system. The Risk and Datix Team will forward each alert to the relevant specialist lead;

- DH/Estates and Facilities Alerts will be forwarded to Director of Estates, Facilities and Capital Development and nominated deputies to access relevance.
- Patient Safety Alerts relevant to medical devices will be forwarded to the Medical Device Lead / Physical Health Lead to access relevance.
- Patient Safety Alerts will be forwarded to the appropriate Executive Director Lead / Directors or Nursing / Medical Directors / Medical Device Lead / Physical Health lead as directed by the alert instructions.
- Drug Alerts and Supply Disruption Alerts will be forwarded to the Medication Safety Officer & Pharmacist.
- CMO / DDL Alerts: will be circulated to the Medial Director and Deputy Medical Director for sharing with relevant Clinical Directors.

Upon receipt of an alert it is the responsibility of the key lead to review the alert and decide if it is relevant or applicable to the Trust taking advice from speciality leads where necessary. The key lead must monitor the implementation of the actions required, in conjunction with lead nurses and service directors or appropriate contractors within the required timescales as identified in the alert. Completed action plans and supporting evidence must be forwarded to the Risk and Datix Team and uploaded onto Datix.

Appendixes 1 to 6 detail overarching and directorate processes and template forms

6. Out of Hours

Whilst it is rare to receive a patient safety alert out of hours for immediate action the Trust is required to have processes in place to facilitate the distribution and action of patient safety alerts. Such alerts will normally relate to Class 1 Drug Recalls. The national CAS Team will email any out of hour's alerts to the Director on Call via emergencies@elft.nhs.uk. In turn the Director on Call will contact the on-call pharmacist in the first instance who will identify

whether an alert applies to the Trust. The on-call pharmacist can request help from the director on-call if required.

7. Audit and Review

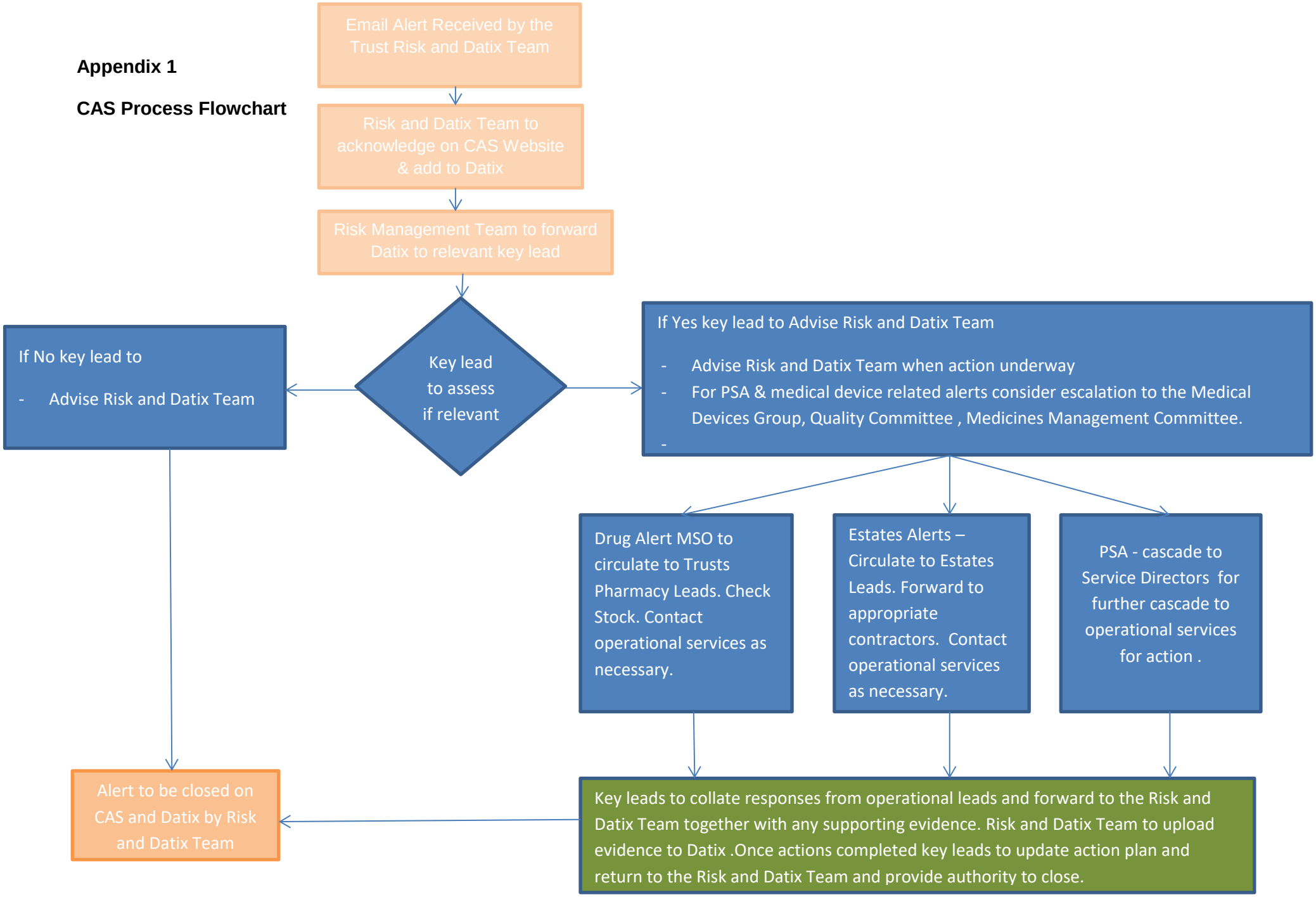
A monthly report is provided to the Quality Committee detailing all open and closed safety alerts.

The Risk and Datix Manager will undertake an annual audit of the Safety Alert process and this will be reported to the Quality Committee.

The Managing Safety Alerts Procedure will be reviewed every three years.

Appendix 1

CAS Process Flowchart



Appendix 2 – Overarching action plan template for National Patient Safety Alerts

CAS Title			
CAS Ref		Type of Alert	
Action Underway date		Deadline for Completion	

Alert relevant to	Trustwide / Community Health Services / Community Health Services Inpatients / Mental Health Community / Mental Health Inpatients
To be communicate to……	Trustwide / Community Health Services / Community Health Services Inpatients / Mental Health Community / Mental Health Inpatients

Actions	Lead	TCD	Progress	Status

Appendix 3 Central Alert System (CAS): Feedback Form

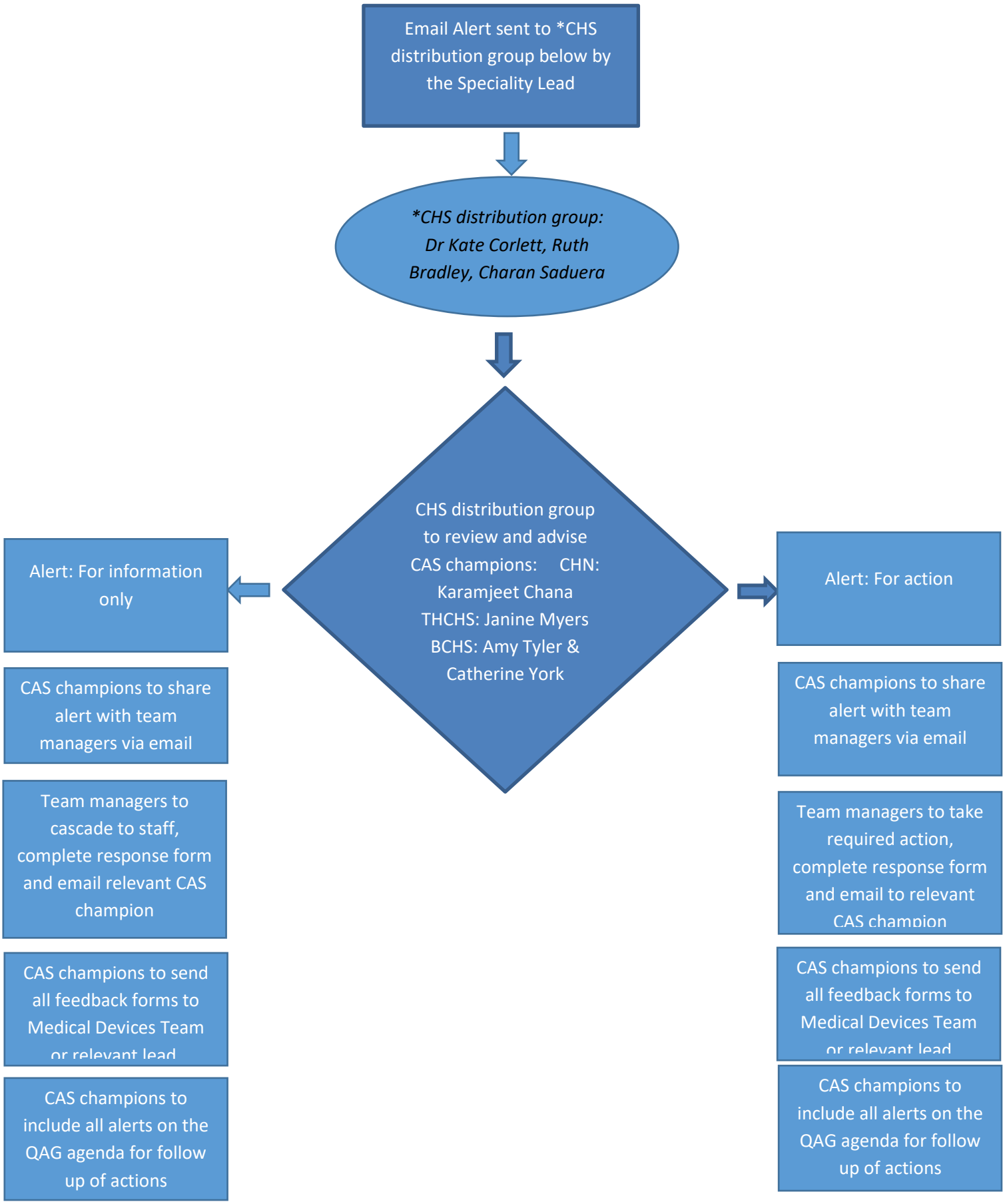
Title of the Alert	
CAS Reference	
Datix Reference Number	
Original Source of Alert	
Action Type (For Information or For Action?)	
Deadline for Completion	
Deadline to return this feedback form to the CAS champion / practice manager	

Service/s	
Name of Person completing this form	
Job Title / Role	
Date Form completed	

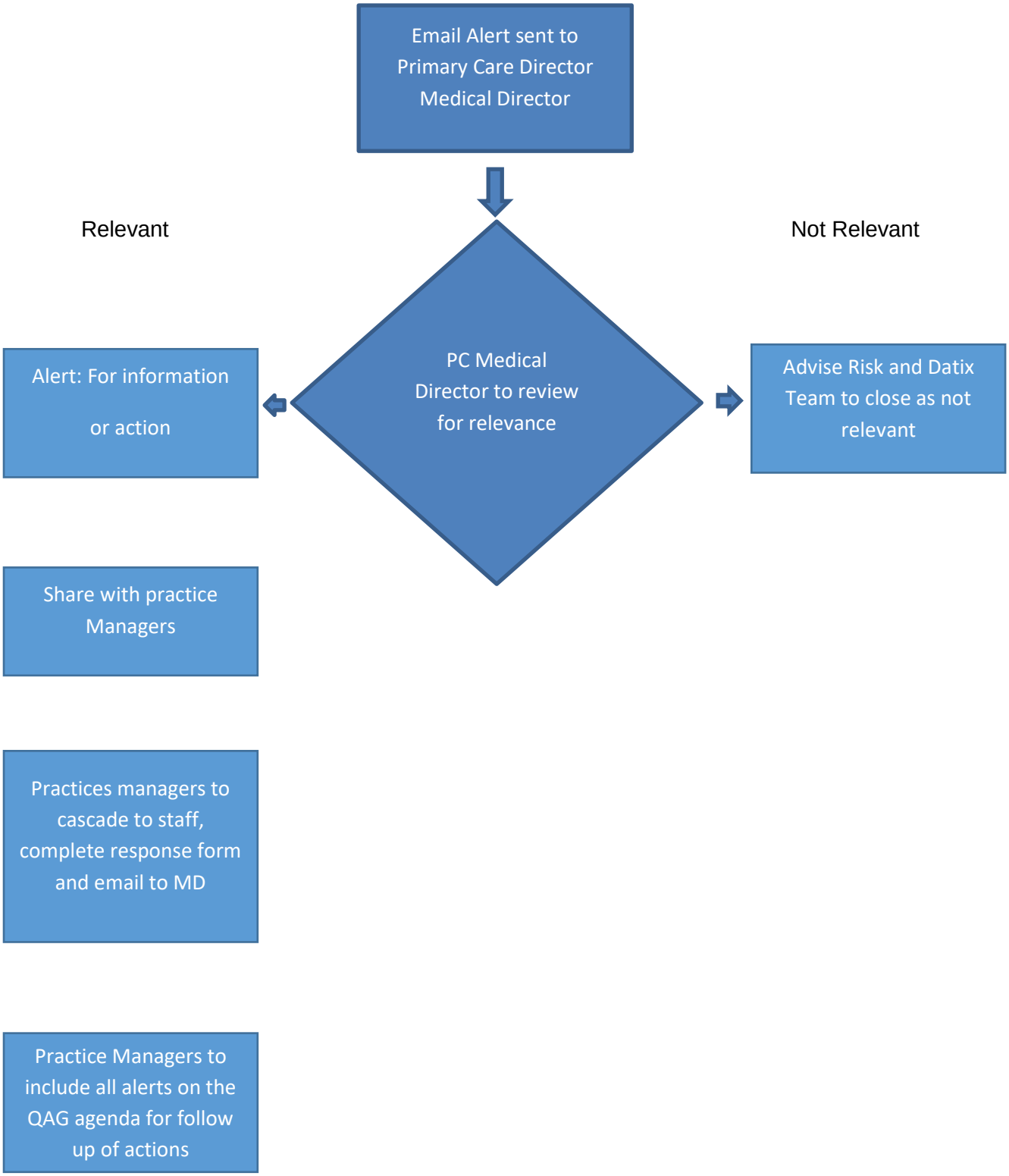
Actions *(Please tick/ indicate yes to only one of the actions outlined below)*		
1	**Action is necessary.** Please give brief details below	
2	**Action/s are all completed and matter resolved.** Please give brief details below	
3	**No action required, for information only.** Please give brief details below	

Please give details of any ongoing actions or completed actions	1 & 2 - If action is necessary please describe what action(s) you have taken or plan to take and by when? Please attach evidence to this form. Also consider: How many patients are affected? How many patients have been contacted? How was this communicated? (phone letter, email etc) 3 - If the alert is for information only, has the alert been cascaded to all relevant staff? Please attach evidence to this form.

Appendix 4: Local dissemination process for central alerts across Community Health Services



Appendix 5: Local dissemination process for central alerts across Primary Care Services



Appendix 6 **Local dissemination process for central alerts across Mental Health Services**