Managing Safety Alerts Procedure

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Consultation Groups	Medical device lead and virtual medical devices group, pharmacy, Directors of Nursing, Estates, Pharmacy, Clinical Directors.
Approved by (Sponsor Group)	Quality Committee
Ratified by:	Quality Committee
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Executive Director lead :	Executive Nurse
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Services	Applicable to
Trust wide	X
Mental Health and LD	
Community Health Services	
Primary Care	

Version Control Summary

Version	Date	Author	Status	Comment
1	December 2020	Joanne Sims	Ratified	New document to capture CAS process encompassing latest guidance and key roles including the Patient Safety Specialist
2	March 2021	Joanne Sims	Final	Updated to reflect changes to national reporting detailed in CH/2021/001 and CH/2021/002 noted within report to the Quality Committee
3	December 2023			Updated to include InPhase as new reporting system

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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, MHRA Dear Doctor letters and Chief Medical Officer (CMO) 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", CHT/2020/002, CH/2021/001 and CH/2021/002, "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.

Drug recall and drug notifications are now issued by the MHRA via email and not via the CAS System. However alerts meeting the criteria for national patient safety alerts in relation to both drugs and medical devices will continue to be issued via CAS.

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 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 hour's 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.

The **Patient Safety Specialist** will have oversight of all relevant patient safety alerts and will maintain key relationships with the Medicines Safety Officer and the Medical Devices Safety Officer linking into the Trusts Patient Safety Agenda and national networks.

Chief Pharmacist, Medicines Safety Officer and **Lead Procurement Pharmacy** Technician has specific responsibilities relating to drug recall, drug notifications, supply disruption alerts and other pharmaceutical notices.

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

The **Risk and InPhase 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 InPhase 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 InPhase.
- Closing alerts on the CAS when actions have been completed and evidence provided by the Executive Lead / Medical Devices Safety Officer / Medication Safety Officer & Chief 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 InPhase Manager including evidence to be uploaded to the InPhase system.

Medication Safety Officer, Chief Pharmacist and Lead Procurement Pharmacy Technician 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, clinical directors, prescribers including NMPs and nurses as necessary.
- Maintaining records confirming dissemination and completed action plans.
- Providing summary of actions taken to Risk and InPhase Manager and attaching evidence to the InPhase system.
- Providing reports to the Medicines Management Committee when appropriate i.e. when complex action plans are required.

- Maintaining the on-call pharmacist procedure and rota, to include actions for out of hour's drug alerts.

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 InPhase Manager and attaching evidence to the InPhase system.

Directors of Nursing / Medical Directors / Patient Safety Specialist

- Provide expert advice to access relevance and support the 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 InPhase Manager and attaching evidence for upload to the InPhase 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.

<u>Operational Services</u>

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 safety alerts and associated actions within their directorate as directed by key leads.

Operational Directorate Managers / Clinical Directors must have systems in place to provide timely updates to individual alert action plans and maintain a record of implementation. Progress and assurance updates must be provided to the key specialist lead and the Risk and InPhase Team in line with mandated timescales.

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 / clinical 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 trust wide. 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).

Medicines Committee

The medicines committee will support the implementation of safety alerts relevant to medicines and develop associated action plans where requirements are complex and trust wide. The group will:

- Identify executive director lead/clinical director if necessary.
- Oversee the development of action plans to address medicines related National Patient Safety Alerts and Supply Disruption Alerts, monitor progress and make recommendation for closing alerts.
- Monitor progress against deadlines drug recalls and drug notifications as appropriate.

- And where necessary identify further actions to provide assurance that requirements' are met.
- Provide expert knowledge and experience to the trust on medicines and medicines safety actions needed.

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 InPhase 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 nationally 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 InPhase Integrated Risk Management system. The Risk and InPhase Team will forward each alert to the relevant specialist lead;

- **National Patient Safety Alerts relevant to medical devices** will be forwarded to the CMO / Chief Nurse / Medical Device Lead / Physical Health Lead to access relevance.
- **National Patient Safety Alerts and Supply Disruption Alerts relevant to medicines** will be forwarded to the CMO , Chief Pharmacist, Medicines Safety Officer (MSO) and the Pharmacy Procurement Technician. The Pharmacy Procurement Technician will liaise with the MSO to agree a response to each alert.
- **All other National Patient Safety Alerts** will be forwarded to the appropriate Executive Director Lead / Directors or Nursing / Medical Directors / Medical Device Lead / Physical Health lead / Chief pharmacist as directed by the alert instructions.
- **Drug Notifications and Drug Recalls and Supply Disruption Alerts** will be forwarded to the Chief Pharmacist, Medication Safety Officer & Lead Procurement technician.

- **CMO / DDL Alerts**: will be circulated to the Medial Director and Deputy Medical Director for sharing with relevant Clinical Directors and/or Chief Pharmacist.
- **Medical Device Bulletins** will be forwarded to the Medical Devices Team and if relevant will be communicated to teams via the cascade system set out in appendixes 4 – 6 and via the communications department as appropriate.

The Patient Safety Specialist will be copied into all national safety alerts.

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 InPhase Team and uploaded onto InPhase.

Executive Director oversight is required for all National Patient Safety Alerts and authority to close will be provided by either presentation to the Quality Committee or directly by the Chief Medical Officer or Chief Nurse.

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

Field safety notices received directly from manufacturers will be logged by the Medical Devices Team and actioned with individual services. Internal Alerts may be created if deemed necessary to action a field safety notice trust wide.

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.

Working in parallel to this internal process for drug alerts, there is a Regional Drug Alert Procedure which covers London and other geographical areas, documenting a cascade; whereby hospitals notify other healthcare organisations/professionals of drug alerts. The regional procedure documents that the Homerton University Hospital on call pharmacist will

cascade any relevant drug alerts out of hours to the East London Foundation Trust on call pharmacist.

7. Audit and Review

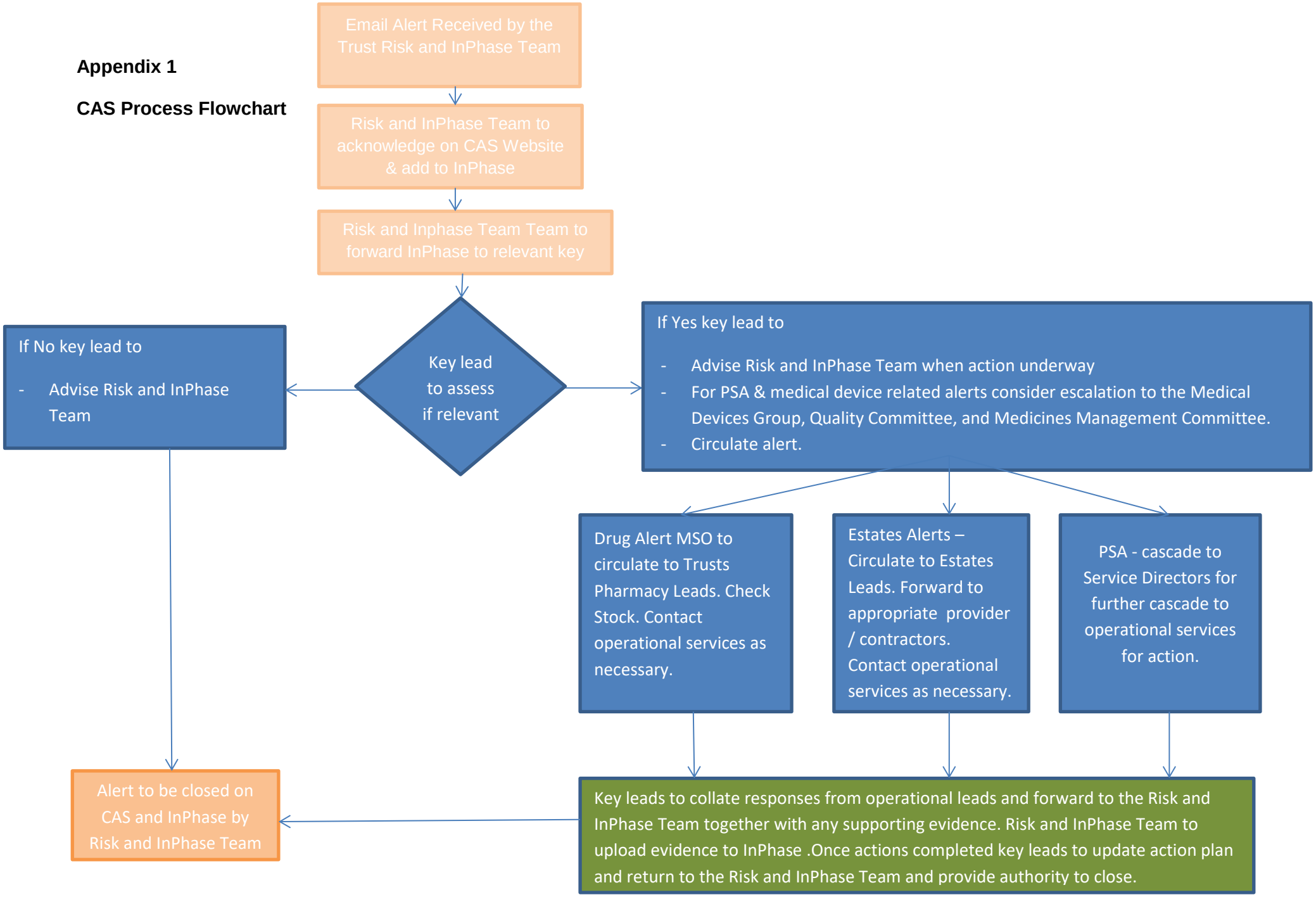
A monthly report is provided to the Quality Committee detailing all open and closed safety alerts.

The Risk and InPhase 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

NHS
East London
NHS Foundation Trust

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 from operational services

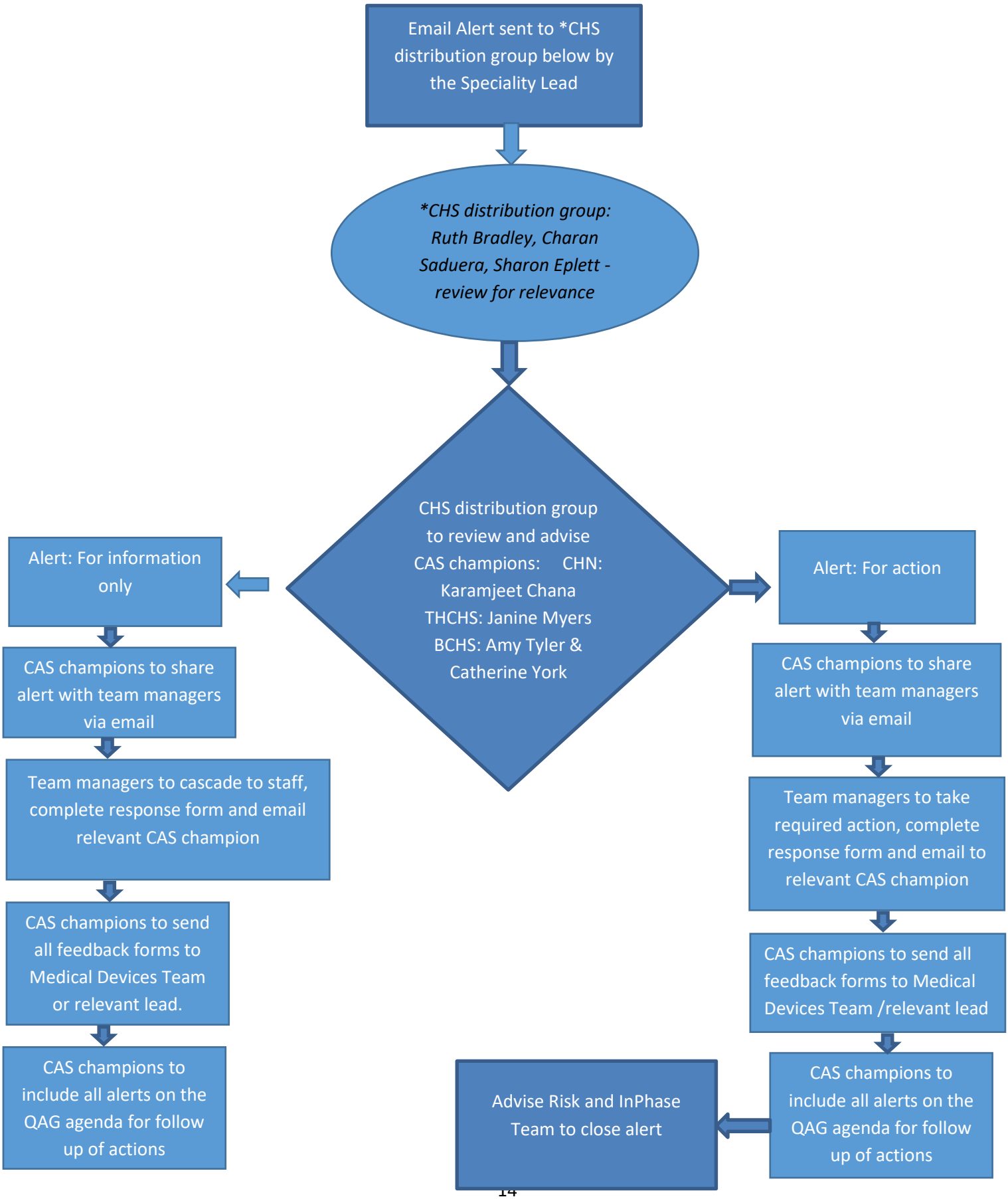
Title of the Alert	
CAS Reference	
InPhase Reference Number	
Original Source of Alert	
Action Type (For Information or For Action?)	
Deadline for Completion	
Deadline to return this feedback form to the CAS champion / Lead / practice manager	

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

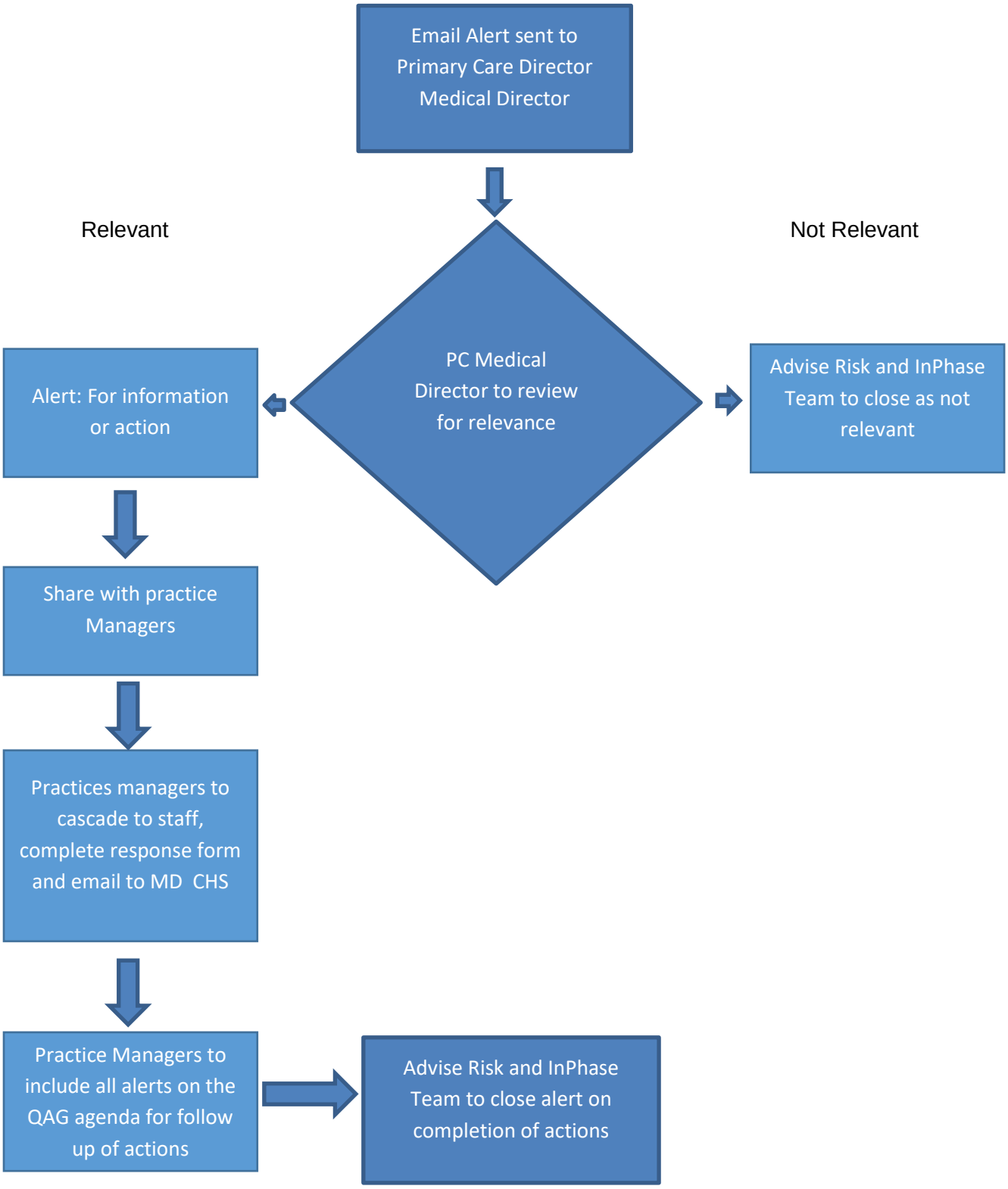
Actions *(Please tick/ indicate yes to only one of the actions outlined below)*		
1	**Action is necessary.** Please give brief details below	
2	**Action/s are all completed and matter resolved.** Please give brief details below	
3	**No action required, for information only.** Please give brief details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