

Standard Operating Procedure (SOP) for the Management of Central Alert System (CAS) Safety Alerts

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DOCUMENT TRACKING SHEET

Standard Operating Procedure (SOP) for the Management of Central Alert System (CAS) Safety Alerts

Version	Status	Date	Issued to/approved by	Comments
0.1	Draft	August 2023	Trust-wide Patient Safety & Mortality Review Group	New Standard Operating Procedure
1.0	Final	September 2023	Trust-wide Patient Safety & Mortality Review Group	Approved

REFERENCES

CHT/2023/002 Management of the National Patient Safety Alerts [Management of National Patient Safety Alerts \(4\).pdf](#)

RELATED POLICIES/PROCEDURES/protocols/forms/leaflets

Medical Devices Policy	KMPT.CliG.004.10

SUMMARY OF CHANGES

Date	Author	Page	Changes (brief summary)

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1 INTRODUCTION

- 1.1 The Department of Health (DH) Central Alerting System (CAS) is a web-based system for issuing patient safety alerts, important public health messages and other safety critical guidance to the National Health Services (NHS) and to other health and social care providers.
- 1.1.1 The CAS was introduced in September 2008 and brought together the Chief Medical Officer (CMO) Public Health Link (PHL), the Safety Alert Broadcast System (SABS) and the Electrical Safety Notifications systems to provide a robust and streamlined means of distributing safety alerts to the NHS and other health and social care providers, with the potential to expand as needs arise.
- 1.1.2 It enables alerts and urgent patient safety specific guidance to be accessed at any time and communicates vital information to Trusts to enable them to take-action to improve safety.
- 1.1.3 The alerts are based on national learning and issued in areas of great risk, indicating where practices should be stopped or modified, or medical devices withdrawn.
- 1.1.4 Safety alerts, emergency alerts, drug alerts, Dear Doctor letters and Medical Device Alerts are available on the CAS website. They are issued on behalf of the Medicines and Healthcare products Regulatory Agency, the National Patient Safety Agency, DH Estates & Facilities and the Department of Health.

2 PURPOSE

- 2.1 This Standard Operating Procedure describes the processes undertaken when a CAS Alert enters Kent & Medway NHS & Social Care Partnership Trust (KMPT) until it is closed. There are different types of alerts that come into the Trust and as such may require to be sent to different members of staff for advice or support of who to send them to.

3 SCOPE

- 3.1 This Standard Operating Procedure (SOP) applies to all members of staff employed in KMPT who are involved in the management, dissemination, action, response or review of CAS Safety Alerts.
- 3.2 The aim of this document is to ensure that all CAS Safety Alerts are communicated promptly and effectively to relevant members of staff and that appropriate action is taken in a timely manner.

4 DEFINITIONS

4.1

Acronym	Definition
Alert	Communication, normally related to safety, which must be distributed to appropriate personnel. Some alerts may require acknowledgment or actions to take place within a defined timescale.
CAS	Central Alerting System
CEM/CMO	Chief Medical Officer Bulletin
CHT	CAS Helpdesk Team
CMO	Chief Medical Officer
DH	Department of Health
DSI	Device Safety Information
EFA	Estates & Facilities Alerts
EL	Medicines Alert
FSN	Field Safety Notice
KMPT	Kent & Medway NHS & Social Care Partnership Trust
MDI	Medicine Defect Information
MDSB	Medical Devices Safety Bulletin
MSN	Medicines Supply Notification

Acronym	Definition
MDSO	Medical Devices Safety Officer - an Officer of the Trust designated as the lead contact with the Department of Health for receiving and responding to CAS alerts.
MQSO	Medicines Quality & Safety Officer
MHRA	Medicines and Healthcare products Regulatory Agency
Nat/PSA	National Patient Safety Alert
SDA	Supply Disruption Alert
TL	Targeted Letter
TWPHG	Trustwide Physical Health group
TWPS&MRG	Trustwide Patient Safety & Mortality Review Group
UKHSA	UK Health Security Alert

5 RESPONSIBILITIES

- 5.1 The Chief Executive has overall responsibility for patient safety and patient safety alerts.
- 5.2 The Medical Director has responsibility of the Chief Medical Officer (CMO) Alerts.
- 5.3 The Chief Nurse has responsibility for alerts relating to medical devices.
- 5.4 Executive Directors have responsibility for Patient Safety Alerts relevant to their area of expertise.
- 5.5 The Patient Safety Lead will have oversight of all relevant patient safety alerts and will have links to the Medicines Quality and Safety Officer (MQSO) and the Medical Devices Safety Officer (MDSO).
- 5.6 The Chief Pharmacist and the Medicines Quality and Safety Officer (MQSO) have responsibilities relating to medicines recall, medicines notifications, supply disruption alerts and other pharmaceutical notices.
- 5.7 The Director of Estates and Facilities has the responsibility for Estates related alerts.
- 5.8 The Inphase Manager is responsible for the management of the safety alerts system and responsibilities include:
 - 5.8.1 Formulating and reviewing procedural guidance for the alert process.
 - 5.8.2 To provide support, guidance and training to key leads on the Inphase CAS Alerts module.
 - 5.8.3 Notify the MHRA of any changes to the Medical Device Safety Officer.
- 5.9 The Medical Devices Coordinator holds the role of the Medical Devices Safety Officer (MDSO) for KMPT. Responsibilities include:
 - 5.9.1 Receiving alerts via CAS on behalf of the Trust.
 - 5.9.2 Assessing the relevance of the alerts in relation to medical devices
 - 5.9.3 Distributing the alerts onwards to services.
 - 5.9.4 Escalating issues to the Matrons, Service Managers and Heads of Nursing
 - 5.9.5 Maintaining a central record of alerts using Excel and Inphase, recording actions taken.
 - 5.9.6 Closing alerts on the CAS when actions have been completed and evidence provided by the Executive Lead / Medication Quality & Safety Officer & Chief Pharmacist / including those who the alert is sent out to.
 - 5.9.7 Provide a quarterly report for the Trustwide Patient Safety and Mortality Review Group (TWPS&MRG) and Integrated Care Board (ICB) and a bi-monthly report for the Quality Digest.

6 SPECIFIC PROCEDURE

- 6.1 See Appendix A CAS Alert Procedure for KMPT and Appendix B National Patient Safety Alert Procedure from the MHRA. Appendix C is process that is informed to staff in the Medical Devices Policy.
- 6.2 Check the designated email inboxes for new CAS alerts at least once each working day.
 - 6.2.1 kmpt.cas.alerts@nhs.net

- 6.3 Add the CAS alert to the CAS Excel database including the CAS alert reference, title, issue date and deadline if applicable to the Excel database.
- 6.4 Identify what type of alert has been received i.e. medications, Field Safety Notice (FSN) for medical devices, National Patient Safety Alert (Nat/PSA), etc.
- 6.5 Determine appropriate actions, with clinical support if necessary, and date for completion.
 - 6.5.1 The Senior Management Team consists of: Emergency Planning Lead; Emergency Planning Single Point of Contact (SPOC); Director of Quality & Safety; Head of Patient Safety; Chief Nurse & Director for Infection Prevention & Control; Deputy Director for Nursing & Deputy Director of Infection Prevention & Control; Chief Pharmacist; Head of Nursing for Physical Health; Executive Medical Director.
 - 6.5.2 National Patient Safety Alert (Nat/PSA), Chief Medical Officer Bulletins (CEM/CMO), UK Health Security Alert (UKHSA) are always sent to the Senior Management Team in the first instance who will advise if the alert is to be sent out and who it is sent to. They will also advise on the content of the e-mail for staff.
 - 6.5.3 Device Safety Information (DSI), Field Safety Notice (FSN), Supply Disruption Alert (SDA) usually refer to specific medical devices. In this case the Medical Devices Coordinator will check the Trust Asset List and also check with the Procurement Team to see if the device has been purchased by a team in the Trust. The alert is then sent to the specific team(s) with the device with the actions to follow.
 - 6.5.4 Medication alerts (EL), Medicine Defect Information (MDI), Supply Disruption Alert (SDA) are sent to the Pharmacy Team who will advise on who to send the alert to and when to close it.
 - 6.5.5 Targeted Letters (TL) are usually for the Doctors. The Senior Management Team will also advise on this type of alert.
- 6.6 Ensure that a folder is created for each type of alert and within that the numbered alerts for that category.
 - 6.6.1 a copy of each CAS alert is saved in the appropriate folder
 - 6.62 e-mail received with the alert is saved in the appropriate folder
 - 6.63 the e-mails sent out to teams with the alert is saved in the appropriate folder
- 6.7 All staff who receive a CAS Safety Alert must ensure it is read and understood and appropriate actions are taken forward to comply.
- 6.8 When the alert is closed on the CAS website, close on Excel database and add on to the Inphase database.

7 EQUALITY IMPACT ASSESSMENT SUMMARY

- 7.1 The Equality Act (2010) places a statutory duty on public bodies to have due regard in the exercise of their functions. The duty also requires public bodies to consider how the decisions they make, and the services they deliver, affect people who share equality protected characteristics and those who do not. In KMPT the culture of Equality Impact Assessment will be pursued in order to provide assurance that the Trust has carefully considered any potential negative outcomes that can occur before implementation. The Trust will monitor the implementation of the various functions/policies and refresh them in a timely manner in order to incorporate any positive changes. The Equality Impact Assessment for this document can be found on the Equality and Diversity pages of the Trust i-Connect.

8 HUMAN RIGHTS

- 8.1 The Human Rights Act (1998) sets out fundamental provisions with respect to the protection of individual human rights. These include maintaining dignity, ensuring confidentiality and protecting individuals from abuse of various kinds. Employees and volunteers of the Trust must ensure that the trust does not breach the human rights of any individual the trust comes into contact with.

9 MONITORING COMPLIANCE WITH AND EFFECTIVENESS OF THIS DOCUMENT

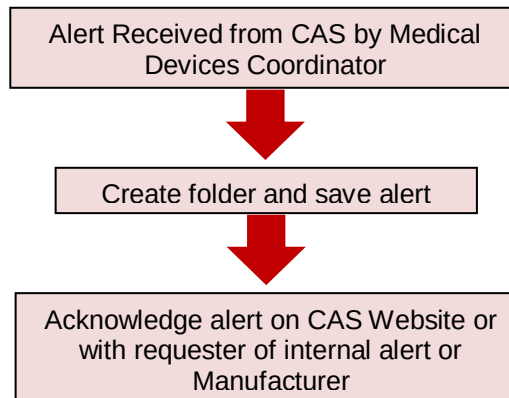
9.1 This is an example of a Heading 2 please type over me.

9.1.1 This is an example of a Heading 3 please type over me.

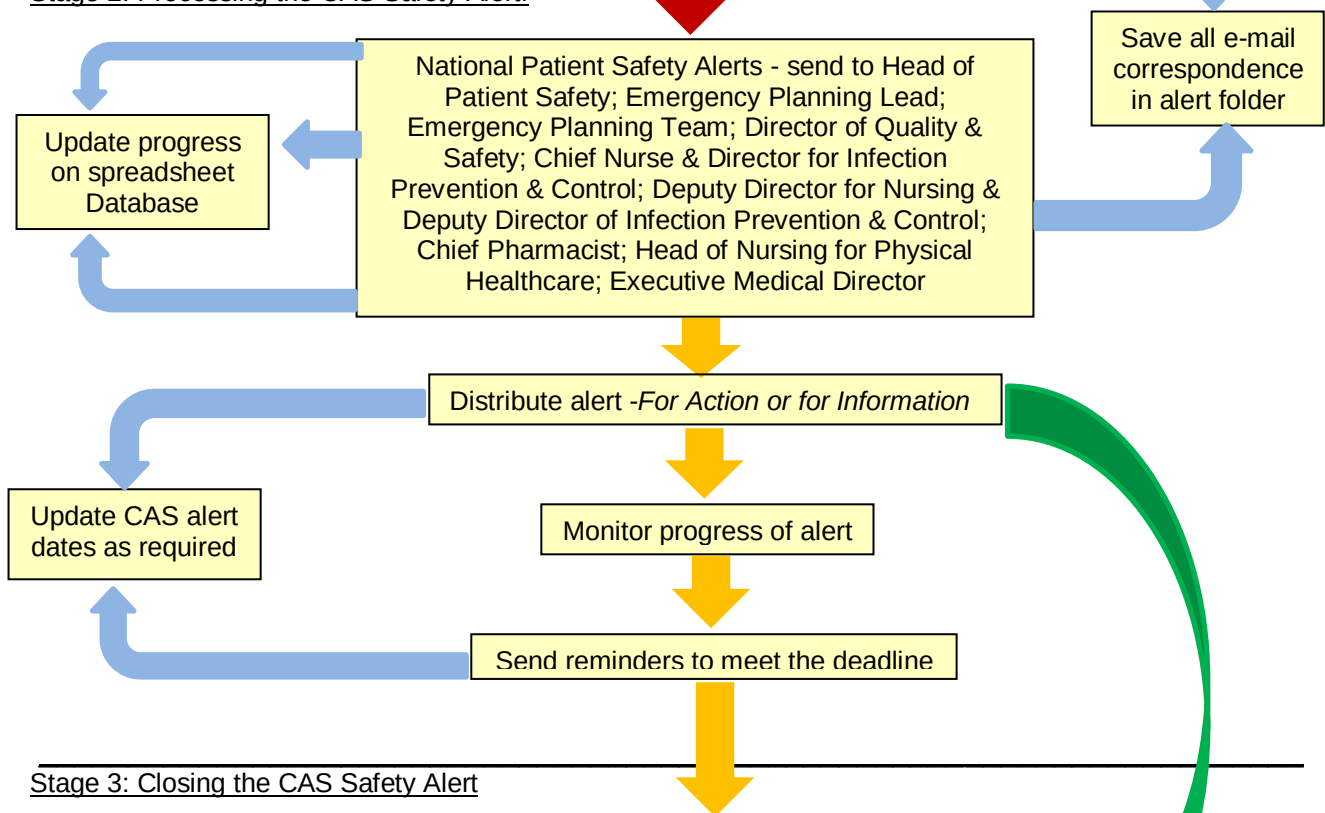
<i>What will be monitored</i>	<i>How will it be monitored</i>	<i>Who will monitor</i>	<i>Frequency</i>	<i>Evidence to demonstrate monitoring</i>	<i>Action to be taken in event of non-compliance</i>
The number of CAS Safety Alerts closed each quarter	Quarterly report to TWPS&MRG; TWH&RG; and the ICB	Medical Devices Coordinator	Quarterly	Report	To be escalated to relevant leads
Excel database and Inphase to be updated	Logging in to Inphase. Accessing Excel database	Medical Devices Coordinator	Weekly	Databases updated	To be escalated to Physical Health Team Manager
Acknowledgement on CAS website within 2 working days of receipt of CAS Safety Alert	Logging into CAS website	Medical Devices Coordinator	Daily	CAS website up to date	Senior Management Team

APPENDIX A CAS PROCEDURE

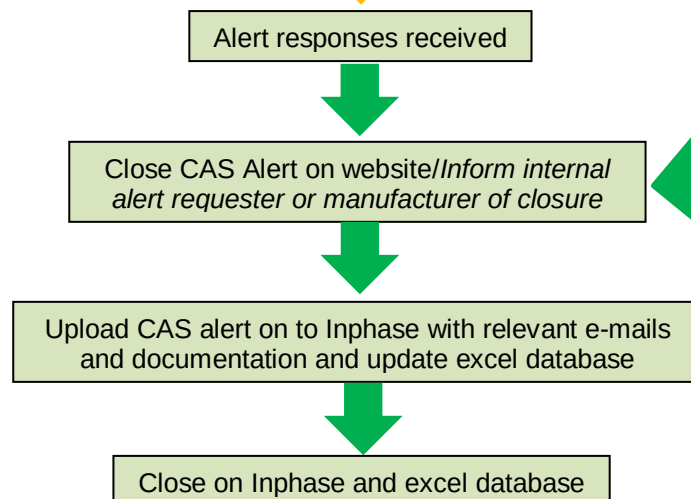
Stage 1: Receiving the CAS Safety Alert



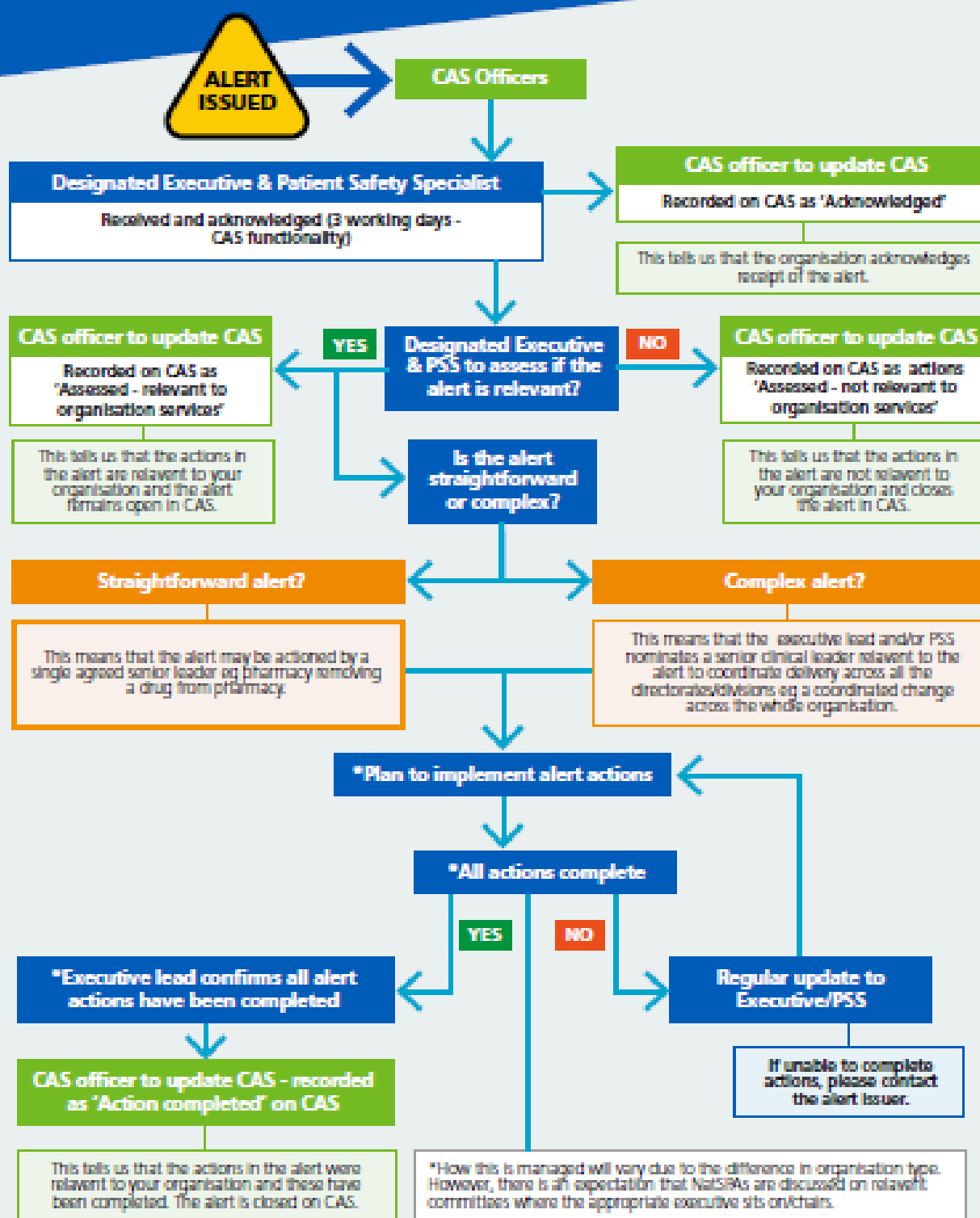
Stage 2: Processing the CAS Safety Alert:



Stage 3: Closing the CAS Safety Alert



Provider process flow for National Patient Safety Alerts



APPENDIX C

CENTRAL ALERTING SYSTEM PROCESS INFORMATION FOR STAFF

Procedure followed when CAS Safety Alert Received by
Medical Devices Coordinator

