Safety Alerts Management Policy

Version Number	1.3	Version Date	March 2020
Policy Owner	Chief Nurse, Director of People and Deputy Chief Executive		
Author	Head of Risk & Compliance		
First approval or date last reviewed	Previously these procedures were part of the Medical Devices Management Policy. This policy Version 1 was written in February 2014. Version 1.1 includes the updates from MHRA and the Medicines Safety Officer role. Version 1.2 was approved in October 2017 to include the subsidiary companies of YDH.		
Staff/Groups Consulted	Chief Nurse, Director of People and Deputy Chief Executive Heads of Departments / Managers / Matrons Procurement and Materials Management Head of Clinical Engineering Chief Pharmacist Director of Estates and Facilities Facilities Manager Medical Devices Committee Patient Safety Steering Group		
Discussed by Relevant Committee / Group	Reviewed through the Incident, Investigation and Learning Group – 15 September 2020		
Approved by Patient Safety Steering Group Committee	16 September 2020		
Next Review Due	August 2022		
Equality Impact Assessment	March 2020		

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1. RATIONALE

1.1 Healthcare organisations are required to report to the Medicines and Healthcare products Regulatory Agency (MHRA) any actual or potential failures or defects of products, medicines and blood products concerns. The MHRA investigates these reports and takes appropriate action which may result in an alert being sent out nationally via the Central Alerting System (CAS). This combined with the Patient Safety Incident reporting process through the National Reporting and Learning Service (NRLS) provides a comprehensive identification of safety issues.

1.2 In January 2014 NHS England formed the National Patient Safety Alerting System (NPSAS) taking over from the closure of the National Patients Safety Agency (NPSA) to communicate safety critical guidance through the CAS system. In September 2019, the MHRA issued an alert (Alert ref: CHT/2019/001) advising all CAS users that the National Patient Safety Alerting Committee (NaPSAC), which consists of representation from all organisations that issue safety information to the NHS, has worked to ensure that all future National Patient Safety Alerts (PSAs) set out clear and effective system-wide actions that providers must take on critical patient safety issues.

1.3 NaPSAC have developed and agreed common standards and thresholds for National PSAs to align all organisations that issue national alerts. A new consistent format for National PSAs had also been agreed by the Committee. The alert advised that each alert issuer is now to undergo the process of reaching these common standards and thresholds and are being assessed to ensure these are met via an accredited process. Once accredited, alert issuers will use the new National PSA template when issuing alerts.

1.4 The NHS Improvement (NHSI) Patient Safety Team were the first alerting body to go through the accreditation process and they were accredited to issue National PSAs for 3 years from July 2019. All alerts that are issued by NHSI Patient Safety will be received in the new format. The safety messages of other issuers will come through in the new format following successful accreditation. This system will build on the strengths of the previous patient safety alerts system.

2. AIM

2.1 Yeovil District Hospital NHS Foundation Trust (the Trust) is committed to protecting patients, staff, and service users, ensuring that safety alerts are acted upon within the required timescales. The purpose of this document is therefore to give comprehensive and clear guidance in the effective, distribution and action requirements of safety alerts, notices and other communication concerning safety that have been issued via CAS.

2.2 This procedural document supports the Risk Management Strategy, Incident Reporting and Investigation Management Policy, Medical Devices Management and Medicines Management Policy.

3. DEFINITIONS

3.1 **The Medicines and Healthcare products Regulatory Agency (MHRA):** - The MHRA is the Executive Agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

3.2 **Central Alerting System (CAS)**: - 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.

3.3 **National Patient Safety Alerting System (NPSAS)**: - NHS England through NPSAS issues 3 stages of alerting and reporting that the Trust is required to action in accordance with the following:

Stage One Alert: Warning

3.4 This stage 'warns' organisations of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information.

Stage Two Alert: Resource

3.5 This alert may be issued some weeks or months after the stage one alert, and could consist of:

- sharing of relevant local information identified by providers following a stage one alert;
- sharing of examples of local good practice that mitigates the risk identified in the stage one alert;
- access to tools and resources that help providers implement solutions to the stage one alert; and
- access to learning resources that are relevant to all healthcare workers and can be used as evidence of continued professional development.

Stage Three Alert: Directive

3.6 When this stage of alert is issued, organisations will be required to confirm they have implemented specific solutions or actions to mitigate the risk. A checklist will be issued of required actions to be signed-off in a set timeframe. These actions will be tailored to the patient safety issue.

3.7 **Categories of Alerts**: - As well as those alerts issued through the NPSAS under the 3 stage process there are a number of categories that an alert might fall into under CAS which require a response:

- **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 on the advice
- **Action**: 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 follow up manufacturers Field Safety Notices
- **Update**: 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 beneficial
- **Information Request**: Used to alert users about a specific issue that may become a problem and where feedback is required. These alerts may be sent out with additional questions to be completed

3.8 **CAS Liaison Officer (CASLO)**: - The CASLO receives and disseminates safety alerts through the CAS system. They are the point of reporting for the Trust.

3.9 **Medical Devices**: - Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does not include general workshop equipment such as power or machine tools, or general purpose laboratory equipment. Examples of medical devices can be found in the Trust's Medical Device Management Policy.

3.10 **Medical Device Alerts (MDAs)**: - MDAs are the Medicines Healthcare products Regulatory Agency (MHRA) prime means of communicating safety information to medical device users in health and social care. This includes products purchased through procurement systems.

3.11 **MHRA Drug Alerts**: - Drug alerts are published by the Defective Medicines Reporting Centre at the MHRA with the resulting alerts distributed via a national cascade system.

3.12 There are four types of Drug Alerts:

- **Class 1** - Action now (including out of hours)
- **Class 2** - Action within 48 hours
- **Class 3** - Action within 5 days
- **Class 4** - Caution in use

3.13 **DH Estates and Facilities Alerts (EFA**): – The primary means of communicating safety information relating to non-medical equipment, engineering plant, installed services and building fabric.

3.14 **Ulysses**: - The Trusts on-line risk management system will be used to record and track responses to safety alerts within the Trust. The system has a cascade system which is managed by the CASLO.

3.15 **Field Safety Notices (FSNs)**: - Actions identified by the manufacturers or distributors of medical devices or consumables relevant to the safety performance of the product. These are received through sources outside CAS and may be distributed through the on-line reporting system.

3.16 **Internal Safety Alerts**: - Safety alerts may be cascaded internally to raise issues that require action or information. These will be raised through the Head of Risk & Compliance.

4. RESPONSIBILITIES

Chief Executive

4.1 The Chief Executive has overall responsibility for ensuring effective arrangements are in place for managing risk.

Chief Nurse, Director of People and Deputy Chief Executive

4.2 Responsible for ensuring appropriate systems are in place to enable the effective management of safety alerts. This responsibility is passed down to the Deputy Director of Quality Governance and Patient Safety who ensures the reporting process for safety

alerts are managed and reported through the appropriate committee.

CAS Liaison Officer (CASLO)

4.3 Responsibilities include:

- Receiving and reporting on alerts via CAS on behalf of the Trust
- Maintaining a central record of alerts
- Distributing alerts to responsible persons through on-line systems using Ulysses(the risk management system)
- Liaising with the Leads and managers to monitor status of alerts
- Maintaining records and confirming actions
- Updating the status of alerts within the Trust in the CAS system
- Providing support and guidance to staff regarding alerts
- Reporting medical device adverse events to the MHRA
- Responsible for monitoring the status of alerts to ensure actions are completed and the alert is closed when appropriate
- Providing training regarding alert processes for relevant members of staff
- Maintaining a monthly summary of alerts to the monitoring committee – Patient Safety Steering Group
- Maintaining a quarterly summary of alerts to the Medical Devices Committee and the Quality Governance and Assurance Committee
- Responsible for monitoring the status of alerts to ensure actions are completed and the alert is closed when appropriate
- Ensure that medical device incidents are sent to the NRLS as soon as possible and at least once a week
- Receive and respond to requests for more information from the Patient Safety Domain in NHS England and the MHRA about medical device incident reports

Head of Risk & Compliance

4.4 Responsible for supporting the CASLO and for ensuring the systems for reporting are managed in line with this policy. Where risks are identified from non-compliance the Head of Risk & Compliance is to liaise with those persons responsible for escalating the alert and raising risks to the appropriate level. The Head of Risk & Compliance ensures cover for the CASLO is in place when the CASLO is away.

Medical Devices Safety Officer (MDSO)

4.5 The MDSO role is integral to improving medical device incident reporting and learning within organisations. One of the MDSO's key roles is to promote the safe use of medical devices across their organisation and provide expert advice. As well as improving the quality of reporting, the MDSO will be the essential link between the identification and implementation of (local and national) medical devices safety initiatives and the daily operations to improve the safety of medical devices.

4.6 The MDSO will be an active member of the National Medical Devices Safety Network through participation in the National webex meetings.

4.7 The MDSO will improve reporting of and learning from medical devices incidents by participating in the investigation of "equipment/device" related incidents and participating in the Trusts Patient Safety Steering Group.

4.8 The MDSO will manage medical device incident reporting in the organisation and review all medical devices incident reports to ensure data quality for local and national learning and where necessary investigate and obtain additional information from reporters.

4.9 The MDSO will be a member of the Medical Devices Safety Committee and the Patient Safety Steering Group (the Monitoring committees).

4.10 The MDSO will act as an additional senior point of contact for manufacturers and support local actions on Field Safety Notice. The MDSO will review and action "equipment/device" related Field Safety Notices.

4.11 The MDSO is responsible for ensuring that safety alerts for medical devices are acted upon in accordance with this policy and the instructions issued within alerts. They are responsible for liaising with the managers of service areas to act upon Medical Device alerts which are cascaded out via the Ulysses system to departments of the affected devices.

4.12 Alerts from Manufacturers/FSNs received through the MDSO are to be notified to the CASLO and Head of Risk & Compliance to escalate to the service area as appropriate. Where there are technical issues to be addressed as the result of a Device alert or FSN Senior Bio-Mechanical Engineering Technician will action this. If it is a user or consumable issue it will be referred back to the CASLO for distribution.

Chief Pharmacist

4.13 Responsible for safe use of medicines supply and distribution throughout the Trust ensuring actions against managing safety alerts for drugs and medicines are carried out 24/7 in accordance with the regional cascade system and through CAS and the on-line alerts system in Ulysses. Requirements include nominating staff who will be responsible for reporting including having an alternative reporter for continuity.

Estates and Facilities Director

4.14 Responsible for ensuring compliance with the management of CAS alerts relevant to DH Estates and Facilities Alerts managed through the on-line alerts reporting system in Ulysses. Requirements include nominating staff who will be responsible for reporting including having an alternative reporter for continuity.

Head of Procurement including Materials Management

4.15 Responsible for ensuring that products purchased through the procurement systems are recorded and monitored for distribution and use. This is essential when tracking and tracing medical device products used within the Trust.

4.16 The procurement team will receive and manage alerts through the on-line alerts system in Ulysses. Requirements include nominating staff who will be responsible for reporting through including having an alternative reporter for continuity. The Materials Management team are responsible for responding to safety alerts, through the CASLO and through FSNs received outside the CAS system.

Facilities Manager

4.17 Responsible for staff in relation to the distribution of products and consumables in the Trust and acting upon safety alerts through the on-line system in Ulysses.

Heads of Departments/Managers

4.18 Responsible for ensuring that safety alerts are acted upon as notified through the on-line reporting system in the areas they are responsible for and for communicating the nature and seriousness of the alert as appropriate.

4.19 Responsibilities include:

- responding to alerts in the time frames set out in the alert
- ensure the distribution of alerts to appropriate departments/teams
- providing confirmation of actions taken to the CASLO relevant to the alert issued

All staff

4.20 Responsible for acting upon alerts notified to them in accordance with the alert issued. On receipt of an alert they will take the necessary actions within the required timeframes and submit response as required to the CASLO through the alert reporting procedure.

5. MANAGEMENT OF SAFETY ALERTS

Types of Safety Alerts issued through CAS

5.1 CAS is a key means to communicate important safety information to the NHS, requiring action to address risks to patient safety. There is a distinction between the two types of alerts sent via CAS:

- **NON-EMERGENCY ALERTS** – issued on behalf of MHRA, Medical Devices, NHS England and DH Estates and Facilities alerts have set deadlines for acknowledgment and completion of actions. NHS Trusts are required to submit responses on the action they have taken on alerts and are monitored on their compliance with completing such alerts within agreed deadlines.

- **EMERGENCY ALERTS** - are currently sent by the following originators – MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging. These alerts can be sent out of office hours (24/7) and are issued directly by the alert originator. Although these alerts do have deadlines, these relate to how quickly the

information contained should be cascaded onwards and do not require a response through CAS. As a matter of course these will be monitored through the Trusts reporting process.

Management of NON-EMERGENCY ALERTS - (**Appendix A**)

CAS Liaison Officer - Management of Alerts

5.2 Alerts notification through CAS will be received through email sabs@ydh.nhs.uk by the CASLO who then acknowledges the alert in the CAS system within the prescribed time frame of 48hrs.

5.3 The alert will identify the issues and actions to be taken within a set time frame and will set out who the alert is to be cascaded to for action/information.

5.4 The CASLO assesses the relevance of the alert with assistance through key contact filter as set out in Section 5.3 if necessary. The CASLO then notifies the alert to the relevant person/s. The on-line alerting system in Ulysses is used for this process which allows the status and records of actions to be maintained.

5.5 Dates are set within Ulyssesto ensure internal deadlines are appropriate so that any required action can be followed up against alerts.

5.6 The notification will take one of 3 forms:

- **Action** – Alerts that target specific person/s required to lead and take action against the alert
- **Information (Info)** – Alerts that require to be notified where acknowledgement is required for internal monitoring. The person/s receiving the 'Info' alert are not the responsible person for leading the alert but should ensure their area acts upon the alert and informs relevant staff appropriately
- **Copied** (CC'd) – Alerts that need to be distributed but do not require a response

5.7 For PSAs, the CASLO will send out to the leads responsible.

5.8 The CASLO will monitor all outstanding alerts to receive the responses within the timescales set out in the alert. They are to follow up with the person/s responsible no later than 1 week before the alert is due to end if no action has been received (to trigger this action a date is set within Ulysses).

5.9 The CASLO is to ensure CAS is updated within the specified timescales on actions taken, liaising with the person/s responsible for implementation.

5.10 Section 5.17 sets out the response and action deadlines that are required to be reported through CAS.

The Recipient - Management of Alerts

5.11 The alert recipient will be notified via email when the CASLO enters the alert into the on-line system in Ulysses.

5.12 The person/s receiving the alert for **action** or **information** are those persons who the alert is targeted at within the alert. They are the responsible person/s to act on the alert.

5.13 Those notified are required to login into the managers section of the Ulysses reporting system responding on-line to **acknowledge** the alert noting the deadline dates. The alert has a link that accesses the CAS page where the alert is described in detail with attachments relevant to the alert.

5.14 For all copied alerts (CC'd) via email there is no requirement to acknowledge the alert, but the information must be acted upon as appropriate to that department.

5.15 The responsible person/s must assess the relevance of the alert and then act upon the details set out in the alert.

5.16 If at this point they feel they are not the appropriate person to action the alert they must notify the CASLO immediately.

5.17 The alert may be disseminated as appropriate to others for assessment and relevance however the responsibility remains with the person notified through the on-line reporting system.

5.18 Responses required through Ulysses are as follows:

- Where the alert is **not relevant** details of why the alert is not relevant must be notified to the CASLO at the earliest opportunity
- Where the alert is **relevant** actions must be taken to manage the implementation of alerts as necessary. Ulysses must be updated as soon as possible to inform the CASLO as to the status as follows:
    - Action Not Started
    - Action Required: On-Going

5.19 Once the deadline is reached the actions are to have been **completed**. The person/s responsible for action are to report back through Ulysses. This is to be notified as soon as possible before the deadline is reached providing any information relevant to the implementation of the alert.

Note:

- If the deadline for closure is nearing the closure date but the actions will be **on-going** the CASLO must be informed of the status for reporting through CAS
- Where there are issues implementing the alert within a service or Strategic Business Unit area, the status must be notified through the relevant senior management team at the earliest opportunity for escalation of risk

Key Contact Filter

<u>MHRA Medical Device Alerts</u>

- Procurement
- Materials Management
- Chief Pharmacist or nominated pharmacist

- MDSO
- Senior Bio-Mechanical Engineering Technician

DH Estates and Facilities Alerts

- Maintenance Manager
- Senior Bio-Mechanical Engineering Technician

Patient Safety Alert

- Deputy Director of Quality Governance and Patient Safety
- Head of Risk & Compliance
- Specialist Lead(s)
- Clinical Director of Patient Safety
- Patient Safety Lead

Alert Responses and Action Deadlines

5.20 All non-emergency CAS alerts are issued Monday to Friday with action deadlines requirements which relate to the seriousness of the identified safety issue.

5.21 The CASLO is responsible for updating the CAS website in relation to the action status:

- **Acknowledgement**: all alerts received are to be acknowledged within 48hrs (Monday to Friday)
- **Assessing Relevance**: this option is available to record that enquiries are being made as to the relevance of the alert within the Trust
- **Action Not Started**: this option indicates that there is an agreement that the alert is relevant and actions are required to address the issues raised in the alert
- **Action Required – On-Going**: this option identifies that action is needed and these are being implemented, but on-going action is anticipated. The deadline for action completed may have been reached but not yet fully implemented. In this case supporting text should be documented within CAS
- **Action Not Required**: this option may be selected if there is no relevance to the alert having consulted as necessary. Supporting text should be documented in CAS to support this status
- **Action Completed:** this option is the date the DoH requires the Trust to have had completed any necessary action. Reporting the alert completed means the Trust is fully compliant with the alert and processes are to be in place to address on-going requirements, including training and awareness as necessary

Management of EMERGENCY ALERTS

5.22 Emergency alerts sent out through the Central Alerting System (CAS) will be received through notification via the central email sabs@ydh.nhs.uk

5.23 MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging alerts are not required to be acknowledged through CAS but will be cascaded internally for action and information through the on-line reporting system in Ulysses.

5.24 All alerts whether emergency or not, will be cascaded through the CASLO (Monday to Friday) Out of hours emergency alerts will be notified to the Clinical Site Team on clinicalsite.team@ydh.nhs.uk who will escalate to the On Call Manager and if required the On Call Director.

5.25 MHRA Drug alerts will be received directly through the pharmacy team 24/7 via the South West Medicines Information and Training (SWMIT) service for action in line with the alert category.

Management of PSAs

5.26 As required with the MHRA's Alert ref: CHT/2019/001 dated 17 September 2019 (see section 1.2 for more information), all CAS users were required to identify appropriate escalation routes for National PSAs to ensure senior oversight. On a weekly basis, the Trust holds a Senior Incident Review Group that meets to discuss any incidents that may require investigation. The Group consists of the Chief Nurse, Director of People & Deputy Chief Executive, Chief Medical Officer, Clinical Director of Patient Safety, Deputy Chief Nurse, Deputy Director Quality Governance and Patient Safety and the Head of Risk & Compliance. It was agreed by the Group that all Patient Safety Alerts would be taken to the newly named Senior Incident & Alert Review Group (SIARG) from mid-September 2019 onwards. This ensures the alert is escalated to senior management as required under Alert CHT/2019/001. It would be agreed at the SIARG who should receive the alert and who would be the most appropriate members of staff to address the actions within the alert.

5.27 For all PSAs, the PSA tracker template (Appendix C) is populated by the CASLO with the actions required by the Trust. This is sent to the recipients of the PSA to complete. The recipients must complete the tracker supplying evidence to demonstrate the actions have been addressed. The PSA trackers are held by the CASLO on the Clinical Governance secure T Drive, a copy uploaded onto the alerts module on Ulysses and included within the quarterly PSSG and GQAC papers.

Management of MHRA Alerts for Drug Updates

5.28 For Drug safety updates issued through the MHRA, the Medication Safety Officer (MSO) will receive updates via email through subscription through the MHRA site. The relevance of each alert will be assessed by the MSO and then cascaded through the Ulysses Alerts module. The MSO will feed back on the relevant alert action to the Medicines Committee. Refer to **Appendix B**.

6. REPORTING TO THE MHRA

6.1 Defective medical devices and reporting of adverse blood reactions/events to the MHRA will follow the procedures set out in the Medical Devices Policy and the Blood Transfusion Policy. The Incident Reporting and Investigation Management Policy identifies the requirements for externally reporting incidents.

7. MONITORING OF ALERTS

7.1 A monthly status report will be provided by the CASLO to the monitoring committee (Patient Safety Steering Group) to identify the status of alerts and actions required to close down the alerts. Outstanding actions must be followed up through Heads of Service or Strategic Business Unit senior teams. Alerts and incidents will be provided to the Medical Devices Committee for review on a quarterly basis. The GQAC will also receive a quarterly report detailing the progress with the PSAs.

8. TRAINING

8.1 Training on the on-line system in 'Ulysses' will be provided to users through the CASLO on a needs basis.

9. APPLICABILITY

9.1 This policy applies to all staff employed by the Trust, whether on a permanent or temporary basis. Failure to action alerts will mean that the safety issues may not be implemented and put the Trust in breach of its license to safeguard patients. Disciplinary action may be taken for failure to follow this policy.

10. SUBSIDIARY COMPANIES OF YEOVIL DISTRICT HOSPITAL (YDH)

10.1 Any employees of subsidiary companies of YDH will adhere to this policy and will receive consistent training in relation to policy implementation.

11. REFERENCES AND ACKNOWLEDGEMENTS

- MHRA Central Alerting System Website
- Medicines and Healthcare Products Regulatory Agency
- An Introduction to the NHS England Patient Safety Alerting System, published: 31 January 2014 (NHS England)
- Care Quality Commission (CQC), Core Standards
- MHRA Defective Medicines Products

12. EQUALITY IMPACT ASSESSMENT

12.1 This policy has been assessed and implemented in line with the policy on procedural documents and an equality impact has been carried out to ensure the policy is fair and does not discriminate any staff groups. A completed Equality Impact Assessment can be found at **Appendix D.**

APPENDIX A – PATHWAY FOR ALERTS REPORTED THROUGH CAS

Receive Alert

Central Alerting System (CAS) Liaison Officer (CASLO) receives an alert via email through the CAS system at sabs@ydh.nhs.uk. The alert is **acknowledged** on CAS within 48hrs

Assess Relevance and Category of Alert

CASLO assess relevance with key contacts if required, otherwise distribute to one of the following individuals/teams through the alerts module in 'Ulysses' within the appropriate category

- **MHRA Medical Device Alerts**
  Procurement for products and consumables
  MDSO & Senior Bio-Mechanical Engineering Technician for equipment
  Chief Pharmacist or nominated pharmacist for related devices/alerts/MHRA Drug Alerts
- **DH Estates and Facilities Alerts**
  Estates and Facilities Director
  Maintenance Manager or nominee
  Senior Bio-Mechanical Engineering Technician
- **National Patient Safety Alerting System**
  Deputy Director Quality Governance and Patient Safety
  Head of Risk & Compliance
  Relevant specialist leads/Business Units
  Clinical Director for Patient Safety
  Patient Safety Lead

Is the alert applicable to the Trust?

NO → Update CAS – Action not required providing reason why in the text box

YES or MAYBE

CASLO – Issues alert through on-line 'Ulysses' system with internal deadlines to responsible person for **Action** or **Information**

Note: Alerts may be CC'd where there is no requirement for acknowledgement. The responsibility to act on information rests with the person who the alert is cascaded to.

Responsible person receiving alert email **acknowledges** the alert in the 'Ulysses' system as prompted and then **assesses the relevance**.

Responsible person to **action** alert and cascade as necessary to others and **update** the CASLO through the on-line system in 'Ulysses' with information as follows:

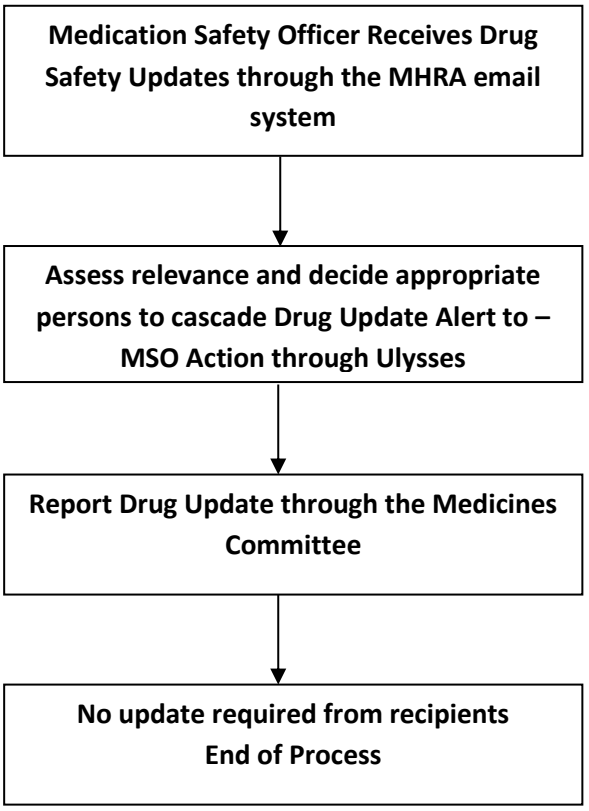
- Action **Not Started**
- Action required: **On-going**
- Action **Not Required**

Responsible person to **escalate risk of possible non-compliance** to SBU / Head of Service if there is to be a delay to the alert deadline.

CASLO to **Monitor** and follow up internal deadlines set before alert deadline is reached

Action **Complete** – CASLO closes the action on the CAS
(Details to be included on how the alert has been actioned in the free text section)

APPENDIX B – PATHWAY FOR MHRA DRUG SAFETY UPDATES



APPENDIX C – PSA TRACKER TEMPLATE

Alert reference number & title: **Date issued:**
Date response required to CAS: R**eview date:**
Status:

	Number of Actions	**Identified Leads**	**Date due by**	**Action taken**	**Date completed**	**Any other comments**
1						
2						
3						
4						

Somerset Equality Impact Assessment

Before completing this EIA please ensure you have read the EIA guidance notes – available from your Equality Officer

Organisation prepared for	**Yeovil District Hospital NHS Foundation Trust**		
Version	**1**	**Date Completed**	**13 March 2020**

Description of what is being impact assessed

Policy for the Development and Management of Procedural Documents

Evidence

What data/information have you used to assess how this policy/service might impact on protected groups? Sources such as the Office of National Statistics, Somerset Intelligence Partnership, Somerset's Joint Strategic Needs Analysis (JSNA), Staff and/ or area profiles,, should be detailed here

No impacts on protected groups

Who have you consulted with to assess possible impact on protected groups? If you have not consulted other people, please explain why?

Equality & Diversity Lead

Analysis of impact on protected groups

The Public Sector Equality Duty requires us to eliminate discrimination, advance equality of opportunity and foster good relations with protected groups. Consider how this policy/service will achieve these aims. In the table below, using the evidence outlined above and your own understanding, detail what considerations and potential impacts against each of the three aims of the Public Sector Equality Duty. Based on this information, make an assessment of the likely outcome, before you have implemented any mitigation.

Protected group	Summary of impact	Negative outcome	Neutral outcome	Positive outcome

APPENDIX D – EQUALITY IMPACT ASSESSMENT

Age	• n/a	☐	✓	☐
Disability	• n/a	☐	✓	☐
Gender reassignment	• n/a	☐	✓	☐
Marriage and civil partnership	• n/a	☐	✓	☐
Pregnancy and maternity	• n/a	☐	✓	☐
Race and ethnicity	• n/a	☐	✓	☐
Religion or belief	• n/a	☐	✓	☐
Sex	• n/a	☐	✓	☐
Sexual orientation	• n/a	☐	✓	☐
Other, e.g. carers, veterans, homeless, low income, rurality/isolation, etc.	• n/a	☐	✓	☐

Negative outcomes action plan
Where you have ascertained that there will potentially be negative outcomes, you are required to mitigate the impact of these. Please detail below the actions that you intend to take.

Action taken/to be taken	Date	Person responsible	How will it be monitored?	Action complete
n/a	Select date			☐

If negative impacts remain, please provide an explanation below.

n/a

APPENDIX D – EQUALITY IMPACT ASSESSMENT

Completed by:	**Samantha Hann, Head of Risk & Compliance**
Date	**13/03/2020**
Signed off by:	**Bernice Cooke, Deputy Director Quality Governance and Patient Safety**
Date	**13/03/2020**
Equality Lead/Manager sign off date:	**Not required as no significant service change as a result of this policy**
To be reviewed by: (officer name)	**Not required as no significant service change as a result of this policy**
Review date:	**n/a**