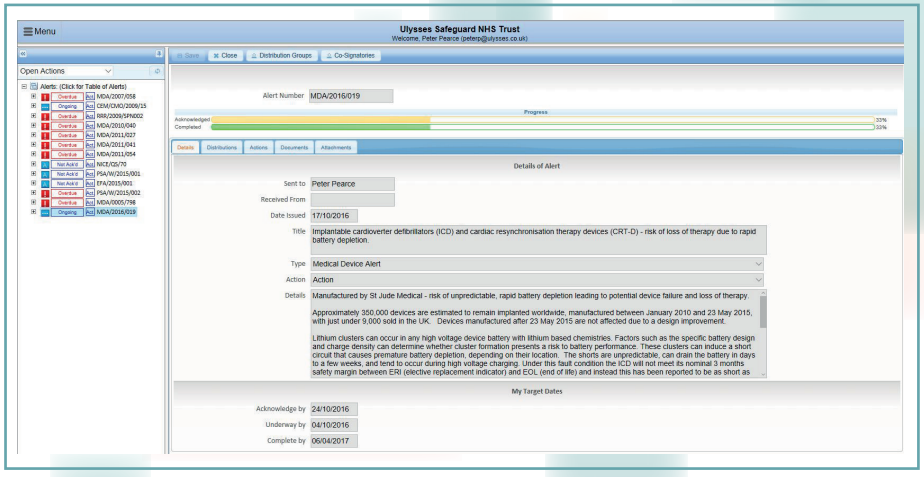
ULYSSES ALERT

INTRODUCTION

Due to the increase in the amount of information to be disseminated and the number of Alerts issued from external agencies, managing the communication process and keeping a full audit of individual responses and actions has become increasingly complex.

Ulysses Alert manages and audits the communication between the Organisation's Information Lead, the coordinators and the staff who determine and implement the actions. The Lead can send email reminders when target dates are nearing and reports can be manually or automatically produced showing performance against targets. Use Ulysses Alert for the dissemination of any information, such as policy documents, NICE Guidance, FSN's (Field Safety Notices) from external agencies e.g. MHRA (Regulating Medicines & Medical Devices). Security within the system ensures that Alerts are only viewable by appropriate staff members.



ULYSSES ALERT

ACTION TRACKING

Action tracking enables the Information Lead and those in receipt of an Alert to communicate with each other via Ulysses Alert. The whole process is audited from the initial dissemination of information, the recipient's acknowledgement and planned actions through to the completion of those actions.

Ulysses Alert updates in real time, ensuring the Information Lead is fully updated with live information on the progress of all Alerts in the system.

DISTRIBUTION (OF ALERTS)

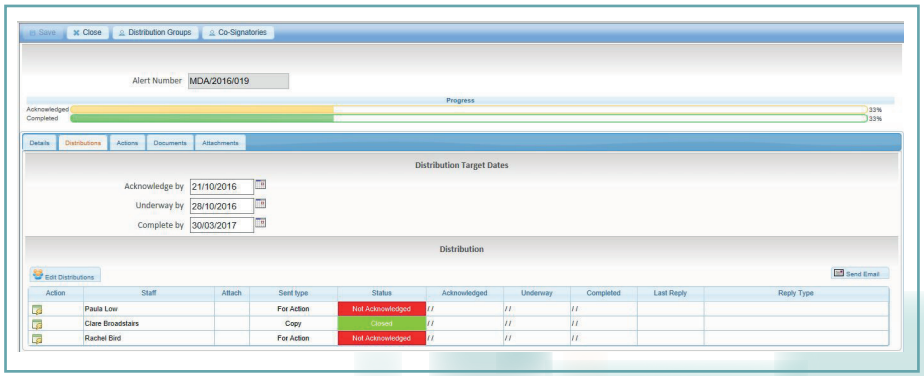
The Information Lead simply selects who needs to be informed and / or implement an action. In many cases action may be requested, and where this is not required the information coordinator responds accordingly, also indicating as a mandatory requirement why action is not needed. Distribution lists can be pre-set to the type of Alert; there could be different coordinators for each type of Alert. Recipients can also appear within 'groups' e.g. Safety, Stores, Clinical.

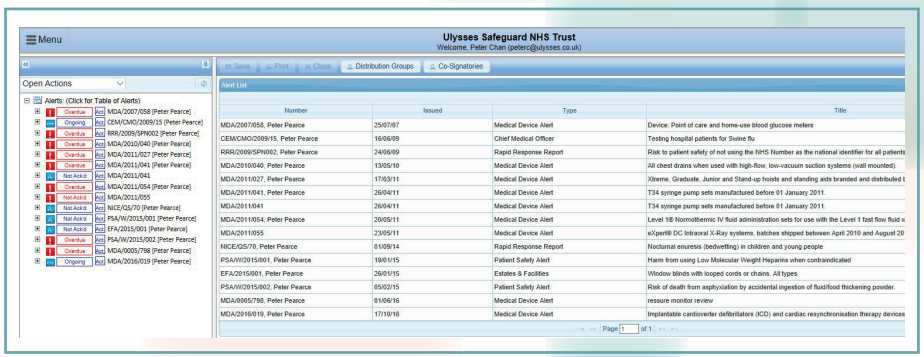
Once the initial emails are sent, the Information Lead waits for the coordinators to respond and indicate their status – it may be "assessing the need for action", "action started", or simply an acknowledgement. Should there be a delay in the process, the Lead can automatically remind the coordinators via email that action is required, therefore saving time administering and chasing information. The final notification process ensures all respondents are notified when the alert is closed; this process also concludes any open actions related to that alert.

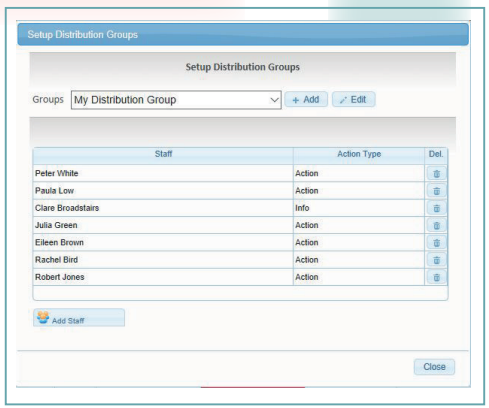
DISTRIBUTION (OF ALERTS) CONT.

Ulysses Alert allows recipients to cascade alerts onwards, with the leads and coordinators each having their own distribution lists. This means the Information Lead can deal with a smaller number of staff and the recipients using the cascading function to further the distribution and responsibility within the organisation. Therefore, Ulysses Alert provides one repository for all information, simplifying audit and accountability.

Information recipients are able to allocate Co-Signatories enabling others to respond to alerts on their behalf ensuring the process is continued in their absence. More than one co-signatory can be allocated, if required. This means the Information Lead can send an alert to a small number of staff who then cascade the alert onwards passing responsibility for responding to their own distribution list.







ULYSSES ALERT

ALERT ACTION RESPONSES

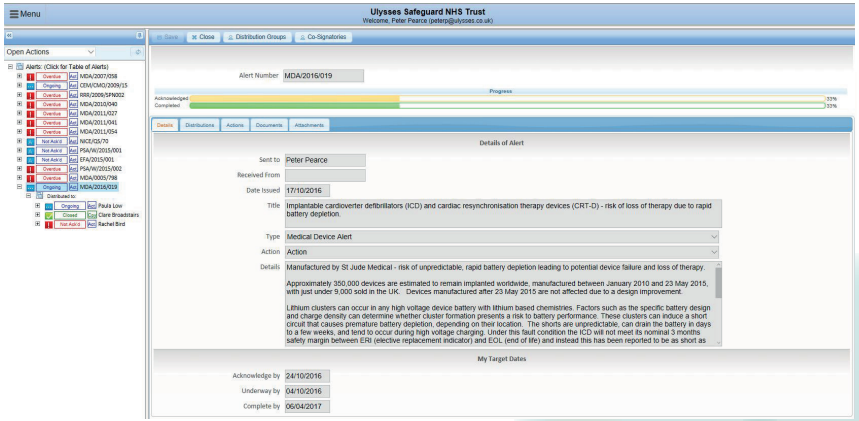
At any stage of the process the Information Lead can see the action status of recipients, when they last responded and any attachments. Ulysses Alert also indicates when all the actions for an alert are complete and the alert is ready to be closed.

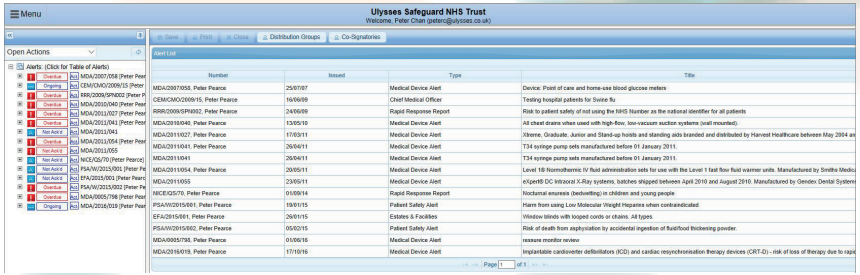
Responses of Completed, Compliant and Not Compliant can be entered.

ULYSSES ALERT

COMMUNICATION

As the communication process is cascaded through the organisation, the system fully audits the responses and actions at all levels. All staff involved have access to the on-line system to input their own actions and responses, and the automatic reminders prompt staff to complete within their target dates. Ulysses Alert indicates when all staff have responded and the alert can be closed.





ULYSSES ALERT

INVENTORY

Ulysses Alert includes a full equipment inventory that can be linked to your external Equipment Register. For each piece of equipment, inspections and the locations can be recorded. As soon as a Medical Device Alert is issued the Organisation can check if the equipment is present and where. In addition, the inventory will be shared with Ulysses Incident enabling the Organisation to see straight away if that piece of equipment has been involved in any incidents or near misses.

EXAMPLE REPORTS

Outstanding Alert Responses

Ref. No.:	MDA/2016/019
Title:	Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid

Alert Type:	Medical Device Alert	**Alert Action:**	Action

Trust Alert Deadline Dates	
Acknowledge By:	24/10/2016
Underway By:	04/10/2016
Complete By:	06/04/2017

Details:

Manufactured by St Jude Medical - risk of unpredictable, rapid battery depletion leading to potential device failure and loss of therapy.

Approximately 350,000 devices are estimated to remain implanted worldwide, manufactured between January 2010 and 23 May 2015, with just under 9,000 sold in the UK. Devices manufactured after 23 May 2015 are not affected due to a design improvement.

Lithium clusters can occur in any high voltage device battery with lithium based chemistries. Factors such as the specific battery design and charge density can determine whether cluster formation presents a risk to battery performance. These clusters can induce a short circuit that causes premature battery depletion, depending on their location. The shorts are unpredictable, can drain the battery in days to a few weeks, and tend to occur during high voltage charging. Under this fault condition the ICD will not meet its nominal 3 months safety margin between ERI (elective replacement indicator) and EOL (end of life) and instead this has been reported to be as short as 24 hours.

To date only 0.2% of affected devices are reported to have experienced premature battery depletion due to this mechanism. However, the failure rate as implant duration increases beyond 6 years is as yet unknown. Worldwide there have been 10 reported incidents of syncope (fainting) and 2 deaths (1 of which was in the UK) from lack of defibrillation therapy that may have been linked to lithium cluster induced short circuits.

Although most devices will reach ERI due to normal battery depletion, it is not possible for centres to quickly differentiate these from the few that are affected by this failure mechanism. There is no way to predict which devices will suffer a lithium cluster induced short circuit and so it is important to detect ERI as soon as it occurs and replace the device as quickly as possible. At present, the risk of patient harm from revision surgery is generally greater than that of device failure, so prophylactic explant is not recommended. The relative risks, however, should be assessed on an individual patient basis taking account of their unique clinical circumstances. If the decision is made to replace an affected device St. Jude Medical will provide a replacement device at no cost.

Acknowledged ? (Information Only & Staff Action Emails):

Type:	Name:	Acknowledged (Y or N):	Acknowledged Date:	Days to Acknowledge:
Action	John Smith	N	/ /	
Info	Mike Blake	N	/ /	
Info	Donna Adams	N	/ /	
Action	Rachel Bird	N	/ /	

Underway ? (Only staff sent Action Email):

Name:	Underway (Y or N):	Underway Date:	Days to Underway:
Peter Pearce	Y	30/01/2017	81
John Smith	N	/ /	
Lynne Partridge	N	/ /	
Tim Barnes	N	/ /	
Paula Low	Y	30/01/2017	81

EXAMPLE REPORTS

Average Report

Your Logo Here NHS
NHS Trust

Alert Reference	MDA/2016/019

Alert Issued:	17/10/2016	Alert Received:	17/10/2016	Alert Closed:	

Alert Title:

Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid battery depletion.

Alert Description:

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Response Breakdown:

	Acknowledged		Underway		Completed		Total Responses	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Early	0	0%	0	0%	0	0%	**0**	**0%**
Awaiting Response	7	78%	7	78%	9	100%	**23**	**85%**
Late	2	22%	2	22%	0	0%	**4**	**15%**
Total Sent Out	9		9		9		**27**	

ACKNOWLEDGE (Staff with Outstanding Responses)

Staff Name	Acknowledge Deadline	Response Status
John Smith	24/10/2016	

Ulysses

EXAMPLE REPORTS

High Level Exception Report For Cascaded Alerts

Your Logo Here NHS
NHS Trust

Staff Name	Cumulative total of Overdue Alerts	Alert Type	Reference No.	Alert Title	Date Issued	Deadline Dates	
						Underway	Completion
Clare Broadstairs	1	Medical Device Alert	MDA/0005/798	ressure monitor review	01/06/2016	25/10/2016	14/12/2016
John Smith	2	Medical Device Alert	MDA/0005/798	ressure monitor review	01/06/2016	25/10/2016	14/12/2016
		Medical Device Alert	MDA/2016/019	Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid battery depletion.	17/10/2016	04/10/2016	06/04/2017
Paula Low	2	Medical Device Alert	MDA/0005/798	ressure monitor review	01/06/2016	25/10/2016	14/12/2016
		Medical Device Alert	MDA/2016/019	Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid battery depletion.	17/10/2016	04/10/2016	06/04/2017
Peter Pearce	2	Medical Device Alert	MDA/0005/798	ressure monitor review	01/06/2016	25/10/2016	14/12/2016
		Medical Device Alert	MDA/2016/019	Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid battery depletion.	17/10/2016	04/10/2016	06/04/2017
Rachel Bird	2	Medical Device Alert	MDA/0005/798	ressure monitor review	01/06/2016	25/10/2016	14/12/2016
		Medical Device Alert	MDA/2016/019	Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) - risk of loss of therapy due to rapid battery depletion.	17/10/2016	04/10/2016	06/04/2017

Date Printed: 30/01/2017
Ulysses Report Reference - ULY041

Underway Deadline Date or Completion Deadline Date has Expired

Underway Deadline Date or Completion Deadline Date has NOT been reached

ULYSSES ALERT

Ulysses

CUSTOMER / USER FEEDBACK

North East Ambulance Service NHS Foundation Trust

The Ulysses Alerts System has created the perfect solution to the requirement of a fully auditable trail for passing urgent and secure communications throughout the Trust. The use of the system has been well received by all staff and improved the Trusts compliance statics overall both internal and external.

NEAS covers a wide geographical area, by using the Ulysses Alerts System, we have gained assurance that important communications are reaching all our staff.

Risk Management Systems Officer
North East Ambulance Service NHS Foundation Trust

ULYSSES ALERT

Ulysses

CUSTOMER / USER FEEDBACK

Leicestershire Partnership NHS
NHS Trust

The Ulysses Alerts module provides a framework for the management of the Central Alerting System (CAS) system. It allows the organisation to track the progress and report on the different alert types including patient safety alerts, medical device alerts and others deemed critical to the organisation by providing the basis for a structured dissemination and assurance process. Each alert can be issued for action (allowing the recipient to cascade further); for information (which requires acknowledgement of receipt) or copy.

At each dissemination layer the distributer is able to develop their distribution lists and the system allows them to see the progress of those to whom they have distributed an alert as well as to those who may have received in the subsequent layers. Consequently, the lead on the alerts process has an “all seeing eye” over the whole distribution of each alert. Other benefits include co-signatories (allowing a colleague to act on behalf of another) to ensure that alerts can progress in the absence of a staff member.

We have a developed a number of reports which provide progress and assurance information on alerts as well as statistics as to how many staff members received an alert in total and how many of those responded.

Risk Manager
Leicestershire Partnership NHS Trust