Investigation of identified non-conformances

Executive Summary:

- All non-conformity notices (NCNs) are robustly recorded and followed up using Synnovis' electronic Quality Management Software
- There is a step-by-step process with built-in deadlines for assigned personnel to track and action progress in investigating, identifying root causes and contributory factors, and the action needed to rectify these.
- Actions arising are raised and also tracked to completion
- All NCN and corrective actions are reviewed and approved by appropriate senior staff
- Common and recurring factors are reviewed to identify trends and hotspots at an early stage
- Compliance with this is assessed as part of the Quality Management System compliance for accreditation against ISO 15189 standards

Q-pulse (Quality Management Software | QHSE | Q-Pulse QMS | Ideagen) is an electronic data management system used by Synnovis to store documents, log actions, keep track of audit schedules and equipment logs. It has various modules including storage of Documents, Audit, and Training records.

The CAPA (Corrective and Preventive Action) module in Q-Pulse has been specifically designed to document Non-Conformity Notices (NCNs) identified from any source, including internal and external audits, incidents, including Datix, complaints and user surveys, internal and external quality control procedures, equipment failure, staff comments etc.

They are documented in the CAPA module in accordance with the Adverse Incident and Quality Exception Standard Operating Procedure (SOP), recording the source, type of incident, date and location and each one is allocated an owner. NCNs arising from users' Datix incidents are noted as such.

There are a number of pre-set steps to follow to investigate and resolve each NCN and these must be completed before the record can be approved and closed.

The first of these is remedial action, which is the action taken at the time of the incident to mitigate its immediate effect, and in most cases this would already have taken place and so can be completed by the incident reporter. The target date for completion is within 24 hours of the incident being raised.

Each NCN has a Root Cause Analysis (RCA) done to identify the underlying or main cause(s) and any contributory factors. Various tools are available to assist the investigator including the RCA fishbone, the Five Whys and an incident decision tree, and there is a section in the NCN record for adding the findings of this when the investigation is complete.

A Corrective Action is raised for each cause or contributory factor which details the steps taken to rectify it. Part of this is to select the appropriate fault category which allows for trend analysis and monitoring by the Quality Management team.

Each Corrective Action is allocated to an appropriate operational or clinical owner who receives an email telling them they have been assigned a new action, and each user/owner can track their outstanding actions and the deadlines they have been assigned.

Every CAPA needs to have a manager's approval to ensure it is reviewed by appropriate personnel (Operations Manager / Quality Manager) and the date of sign-off is recorded. Once all stages are complete and evidence has been uploaded to the CAPA record, the entire non-conformity record can be closed.

Information about NCNs and CAPA are shared at staff and team meetings and the outcomes of all Serious Incidents are discussed at appropriate Clinical Governance meetings and escalated across Synnovis, where there is shared learning for other departments to benefit from.

All of the above elements are audited by the regulatory and accreditation bodies that oversee pathology, including the United Kingdom Accreditation Service (UKAS - The UK Accreditation Body - Creating Confidence - UKAS and the MHRA (Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)) as part of their assessment of Synnovis' Quality Management System, and form the backbone of accreditation that provides assurance to our users and their patients that the service provided is safe and meets internationally recognised standards.

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