Nottingham University Hospitals NHS
NHS Trust

# Audiology

# Procedure

# CAPA (Corrective And Preventative Actions)

| | |
|---|---|
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| Supersedes: | Version 2 |
| Changes from previous version: | Additional reference to CAPA policy for scoring of actions (6.3.1.1, 6.3.2.1 & 6.4.1) |
| Equality Impact Assessment Date: | 29 November 2020 |
| Target audience: | All Staff |
| Lead Executive: | Claire Benton – Head of Audiology |
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| Consultation with: | Julie Brady - Advanced Audiologist<br>Kevin Hole - Advanced Audiologist |

## Contents

# 1. Introduction

This document details the reporting & review process associated with the CAPA process. It should be used in conjunction with the Trusts requirements for incident reporting via Datix.
It is important to note that the CAPA process DOES NOT replace the Trusts requirements for Datix reporting but runs in tandem with it. All high risk incidents should be raised through Datix – Not via CAPA.

# 2. Executive Summary

This procedure sets out the overall process for the CAPA process. It details how staff can raise both corrective and preventative actions, along with the subsequent investigation & review to be undertaken by members of the CAPA team.
It is important to note that the Preventative action aspect of CAPA is not a method for general feedback, it should only be used when identifying potential risk within a process.

# 3. Procedure Statement

To comply with national recommended procedures and guidance, Audiology staff must meet the responsibilities of their individual roles as defined in Section 5 (Roles & Responsibilities), and must adhere to the practices defined in Section 6 and associated documents defined in Section 11 (References).

# 4. Definitions

| Term | Definition |
|---|---|
| CAPA | Corrective and Preventative Action |
| Corrective Action | Actions to resolve a non-conformance that has occurred. |
| Preventative Action | Actions taken to prevent future non-conformances. |
| Concession | A special approval that is granted to release a nonconforming product or service for use or delivery. Concessions are usually restricted to a specific use and limited by time and quantity. |
| Datix | Trust electronic system for reporting and investigation of incidents and near misses |
| Incident | Any unexpected or unintended event, which could have or did lead to harm, loss or damage. |
| Near Miss | A prevented patient safety incident. |
| Non-conformance | A deviation from a process specifically not meeting some or all of a policy, procedure, guideline or standard. |
| Root Cause Analysis (RCA) | A method of problem solving used for identifying the root causes of faults or problems. |

# 5. Roles and Responsibilities

## 5.1. Senior Leadership Team/Lead Executive

The Senior Leadership Team (SLT) or Lead Executive are responsible for approving this document and ensuring that it is reviewed in line with Trust Policy.

### 5.2. Audiology Staff

Audiology staff are responsible for accessing, reading, understanding and following this document where it applies to their job role.

## 6. Procedure

### 6.1. High risk incidents

Where a high risk incident has occurred, especially one which has resulted in direct harm, or high risk of harm, to a patient or member of staff, it MUST be raised through Datix and not via CAPA.

If a member of staff is unsure of how to raise a Datix, or if an incident should be raised through Datix they are advised to speak to a senior colleague or member of the Integrated Governance team.

CAPA only exists to support in the resolution of green (and in some instances yellow) rated incidents as per the CAPA corrective action scoring index. Any CAPA raised incidents rating above this will be escalated on to Datix following review.

### 6.2. Reporting stage – Corrective & Preventative actions.

Where a member of staff has identified a corrective or preventative action, they should raise the action/suggestion via the CAPA database. When this is not possible, they can also E-mail the existing non-conformance E-mail address, including the following information:

- Whether a patient has been involved
- If a Datix incident has been raised & incident number.
- What area of the service the incident relates to.
- Does it relate to an existing document?
- A description of what happened.

A member of the CAPA team will contact them should additional information be required.

### 6.3. Investigation Stage

At the start of an investigation, the record on the CAPA database should be assessed to see if it is a Corrective or Preventative action. The database will automatically flag when a new record has been created.
A general check of the information should also take place to allow an investigation to commence. After this the subsequent actions should be undertaken.

#### 6.3.1. Corrective Actions

New corrective actions will be flagged in yellow and a due date for completion of the investigation will be populated automatically.
When an investigation has been started, the record's status should be changed to 'under review' and the reviewer & date of commencement recorded.

The action should now be scored and an RCA undertaken. Any noted themes within the action should be recorded on the database for future trend analysis. RCA's should be completed using interrogative techniques (such as 'the five whys') as appropriate.

When the RCA is complete and action plan has been written, the 'review completed' & 'final outcome' sections of the database date should be completed.

Where an investigation has not been initiated by the target date (28 days after the record was created), the investigation section will flag to signify it is behind schedule.

If the action is rejected, it should be detailed as to why within the review notes. Following this the 'final outcome' should be changed to 'rejected' and the status to 'complete'.

If during the RCA further non-conformities are identified these should be raised as new actions.

#### 6.3.1.1. Scoring of corrective actions

All corrective actions must be scored to determine the need for potential further escalation.

The scoring index, potential outcomes and responsibilities can be found in the document 'Policy – Quality' under the CAPA section.

### 6.3.2. Preventative actions

Preventative actions will be flagged in blue and a due date for completion of review will be populated automatically. The target for initiating review of preventative actions is within 84 days of it being raised.

When an investigation has been started, the records status should be changed to 'Under review'. The reviewer should also record their details in the 'review details' section.

Preventative actions should be reviewed in conjunction with other preventative suggestions as well as closed, open & historical corrective actions that fall into the same category. From this investigation it can be assessed if there is a potential need for preventative action or if the record can be closed.

At this point the outcome and review completed sections should be populated.

#### 6.3.2.1. Scoring of Preventative action

All preventative actions must be scored to support risk analysis and determine if there is the requirement for further escalation. A preventative action can score no higher than five/yellow on the scoring index. When transferring the incident to datix it should be classed as a 'near miss'.

The scoring index, potential outcomes and responsibilities can be found in the document 'Policy – Quality' under the CAPA section.

## 6.4. Action Planning Stage

If a Corrective or Preventative action has been identified as requiring an update or change in process, an action plan should be created.

Following the RCA or review it may be possible for the team member to identify a simple action plan, these should be discussed with the larger CAPA team before escalation to the SLT. Any pertinent notes should be included in the 'action plan details' column of the record.

The CAPA database will be reviewed in CAPA team meetings and in larger Quality group meetings, this is to support in the development of action plans and assess any wider trends that may be occurring.

Action plans are passed on to the SLT for review and ratification. The outcome should be logged on the CAPA database, filling in the 'final outcome' & 'date closed or completed' column.

Where a record is deemed to require no further action it should have its status changed to 'Closed', where a record is deemed to require an action, it should remain under review until the action has been deemed completed. At this point it should be changed to 'complete'.

Should the outcome of an action plan be a concession, a concession number should be generated and recorded on the CAPA database.

### 6.4.1. Additional considerations for Corrective actions

CAPA team members should refer to the full CAPA policy (found within the Audiology Quality policy) for additional considerations regarding the cessation of activity for Corrective actions of concern.

### 6.4.2. Concessions

When a concession is generated, it must be given a set length of time to be in place. This period is deemed to start on the date the record was created.

The concession length should be recorded as a number of days on the 'concession length' column, from here a date for review of the concession will be generated.

These dates should be periodically checked, with the nature of the concession reviewed 20 working days before its expiry. The concession will Flag orange within this timeframe, changing to red when the expiry date has been breached.

Whilst a concession is in place, a record should maintain its 'under review' status.
Concessions should only be used for Corrective actions.

## 6.5. Review of Action Plans for Effectiveness Stage

Following completion of an action plan (for both Corrective and Preventative actions) The CAPA will monitor the database for any further same/similar instances and review the original action plan and carry out a further root cause analysis if necessary.

Following this, the CAPA team will contact the SLT to review the action plan, if it has not been effective.

If action plan has been effective, The CAPA team will change the records status to complete & add any relevant comments.

# 7. Training and Implementation

## 7.1. Training

Procedure issued and discussed at induction. Ongoing updates provided as required

## 7.2. Implementation

Procedural documentation implemented through document readership.

## 7.3. Resources

No additional resources are required.

## 8. Equality Impact Assessment (EQIA) Form

An equality impact assessment has been undertaken on this document and has not indicated that any additional considerations are necessary.

| **Q1. Date of Assessment: November 2019** | | | |
|---|---|---|---|
| **Q2. For the document and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the document or implementation down into areas)** | | | |
| **Protected Characteristic** | **a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups experience? i.e. are there any known health inequality or access issues to consider?** | **b) What is already in place in the document or its implementation to address any inequalities or barriers to access including under representation at clinics, screening** | **c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality** |
| **The area of the document or its implementation being assessed:** | | | |
| Race and Ethnicity | No issues identified | | |
| Gender | No issues identified | | |
| Age | No issues identified | | |
| Religion | No issues identified | | |
| Disability | No issues identified | | |
| Sexuality | No issues identified | | |
| Pregnancy and Maternity | No issues identified | | |
| Gender Reassignment | No issues identified | | |
| Marriage and Civil Partnership | No issues identified | | |
| Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation) | No issues identified | | |

**Area of service/strategy/function**

| | | | |
|---|---|---|---|
| **Q3. What consultation with protected characteristic groups inc. patient groups have you carried out?**<br>None | | | |
| **Q4. What data or information did you use in support of this EQIA?**<br>None | | | |
| **Q.5 As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?**<br>None | | | |
| **Q.6 What future actions needed to be undertaken to meet the needs and overcome barriers of the groups identified or to create confidence that the document and its implementation is not discriminating against any groups** | | | |
| **What** | **By Whom** | **By When** | **Resources required** |
| | | | |
| **Q7. Review date** | Not applicable | | |

## 9. Values and Behaviours

The Trust's TEAM NUH Values and Behaviours describe the principals and beliefs of our people and show that 'we listen, we care'. The TEAM NUH Values and Behaviours have been considered in relation to this document.

Please rate each value from 1 – 3 (1 being not at all, 2 being affected and 3 being very affected)

| Value | Score (1-3) |
|---|---|
| **1. Polite and Respectful**<br>Whatever our role we are polite, welcoming and positive in the face of adversity, and are always respectful of people's individuality, privacy and dignity. | 1 |
| **2. Communicate and Listen**<br>We take the time to listen, asking open questions, to hear what people say; and keep people informed of what's happening; providing smooth handovers. | 1 |
| **3. Helpful and Kind**<br>All of us keep our 'eyes open' for (and don't 'avoid') people who need help; we take ownership of delivering the help and can be relied on. | 1 |
| **4. Vigilant (patients are safe)**<br>Every one of us is vigilant across all aspects of safety, practices hand hygiene & demonstrates attention to detail for a clean and tidy environment everywhere. | 1 |
| **5. On Stage (patients feel safe)**<br>We imagine anywhere that patients could see or hear us as a 'stage'. Whenever we are 'on stage' we look and behave professionally, acting as an ambassador for the Trust, so patients, families and carers feel safe, and are never unduly worried. | 1 |
| **6. Speak Up (patients stay safe)**<br>We are confident to speak up if colleagues don't meet these standards, we are appreciative when they do, and are open to 'positive challenge' by colleagues | 1 |
| **7. Informative**<br>We involve people as partners in their own care, helping them to be clear about their condition, choices, care plan and how they might feel. We answer their questions without jargon. We do the same when delivering services to colleagues. | 1 |
| **8. Timely**<br>We appreciate that other people's time is valuable, and offer a responsive service, to keep waiting to a minimum, with convenient appointments, helping patients get better quicker and spend only appropriate time in hospital. | 1 |
| **9. Compassionate** | 1 |

| | |
|---|---|
| We understand the important role that patients' and family's feelings play in helping them feel better. We are considerate of patients' pain, and compassionate, gentle and reassuring with patients and colleagues. | |
| **10. Accountable**<br>Take responsibility for our own actions and results | 1 |
| **11. Best Use of Time and Resources**<br>Simplify processes and eliminate waste, while improving quality | 1 |
| **12. Improve**<br>Our best gets better. Working in teams to innovate and to solve patient frustrations | 1 |
| **TOTAL** | 12 |

## 10. Monitoring Matrix

| **Minimum requirement to be monitored** | **Responsible individual/ group/ committee** | **Process for monitoring e.g. audit** | **Frequency of monitoring** | **Responsible individual/ group/ committee for review of results** | **Responsible individual/ group/ committee for development of action plan** | **Responsible individual/ group/ committee for monitoring of action plan** |
|---|---|---|---|---|---|---|
| Service evaluation/ monitoring audits | SLT<br>All staff | Audits | Various | SLT<br>CAPA | SLT<br>CAPA | SLT<br>CAPA |
| Adverse Incident Surveillance | SLT<br>Audiology Clinical Governance Lead/ CAPA team | Datix incidents/ CAPA reporting | Monthly | SLT<br>Audiology Clinical Governance Lead/ CAPA team | SLT<br>Audiology Clinical Governance Lead/ CAPA team | AMG<br>Audiology Clinical Governance Lead/ CAPA team |
| Peer review | SLT<br>All staff | Peer review | Various | SLT<br>Line manager<br>CAPA team | SLT<br>Line manager<br>CAPA team | SLT<br>Line manager<br>CAPA team |

## 11. References

**Local documents:**

- (0)001 Policy – Quality
- (0)004 Audiology Quality Manual

**Trust documents (available on Trust intranet):**

- NUH Incident Reporting and Management Policy

# 12. Appendices

## 12.1. The five Whys

Five whys (or 5 whys) is an iterative interrogative technique used to explore the cause-and-effect relationships underlying a particular problem. The primary goal of the technique is to determine the root cause of a defect or problem by repeating the question "Why?" five times. The answer to the fifth why should reveal the root cause of the problem.