

Why Audit? The Cambridge CRF Experience

Carolyn Sexton, QA Manager NIHR/Wellcome Trust Clinical Research Facility, Cambridge

Background

The Cambridge CRF implemented a robust system of document control. The next step was to find out the answers to the following questions:

- Were the documents meaningful?
- Did staff follow the procedures put in place?
- Was training up to date?
- Was equipment fit for purpose?
- Was there evidence that the systems were working?

These questions formed the basis for audit.



What is Audit?

According to GCP audit is:

"A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data recorded, analysed and accurately reported according to the protocol, sponsors written procedures, GCP and applicable regulatory requirements".

In simple terms: Are we are doing what we say we do?



Methodology

To find out the QA manager devised a vertical audit plan to audit the Cambridge CRF's approved documented procedures. Followed by some horizontal audits.

What audit was carried out?

A **Vertical Audit** examines all the procedures in the context of the process

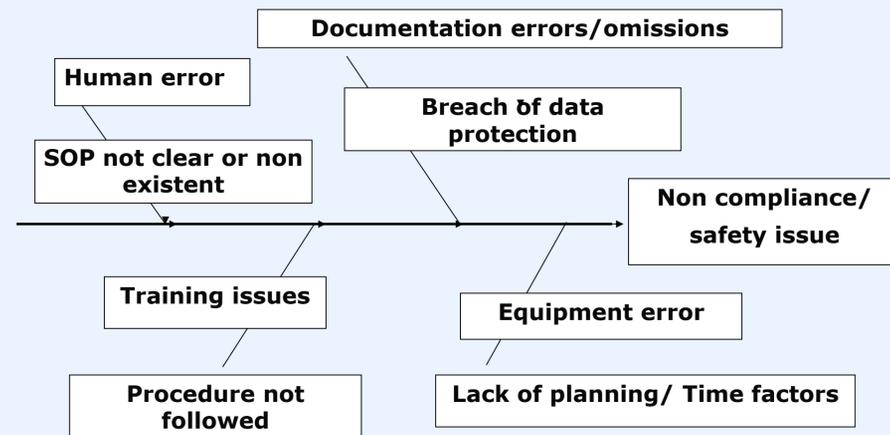


A **Horizontal Audit** examines procedures. Non-compliance with any part of a process would trigger a horizontal audit of that procedure across the department



Findings

Overall the agreed processes were working well, but there were also some findings that required improvement (see below).



The findings were discussed with the relevant staff. All staff involved were encouraged to contribute to identification and implementation of Corrective and Preventive Actions (CAPA).

Outcomes resulting from the audit

- Identification of gaps in processes
- Implemented new SOP's to address the gaps
- Update of processes and the relevant SOP's
- Update and review of forms and checklists
- Improvement in the quality of documentation
- New training needs identified, such as training to updated processes and SOP's
- Increased staff involvement in the audit process
- Improved working practice

Conclusion

Audit is a powerful tool for service improvement



Contact: carolyn.sexton@addenbrookes.nhs.uk