

An Audit of Clinical Trial Delegation Logs Within a District General Hospital

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Introduction

Appropriately qualified and trained personnel are required to ensure the satisfactory conduct of research studies at a site. Staff involved in the study may be delegated duties by the Principal Investigator (PI). These people must be appropriately experienced and qualified to assist in the management of the study for the task that they have been delegated. The allocation of duties to appropriately qualified persons should be recorded in a study specific delegation of duties log with specimen signatures and the initials of all involved. There are many different templates for delegation logs and this can lead to confusion and errors when completing these essential documents. Despite sponsor monitoring and review errors can still occur.

Methods

A Nuffield research student on placement within the Clinical Research Unit at Yeovil District Hospital conducted an audit of the trial delegation logs. Due to time constraints only 80 logs were picked at random. 40 were oncology studies and 40 were studies involving other disciplines. Each log was checked in a systematic way looking at signatures, dates, correct amendments of mistakes, whether the GCP certificate and CV were available and tasks delegated for errors or discrepancies.

Results

- 77.5% of delegation logs had errors suggesting that errors occur commonly
- 62/80 had either
 - Missing PI signature
 - Study task delegation missing
 - No record of GP or CV in the site file or master file
 - Non compliant with GCP (amendments not crossed out correctly etc)
- 65% errors were from oncology logs
- 8 trials with 3 or more errors on them (25% of total errors)
- 26/32 PI's made an error
- 42.1% of errors were task delegation discrepancies

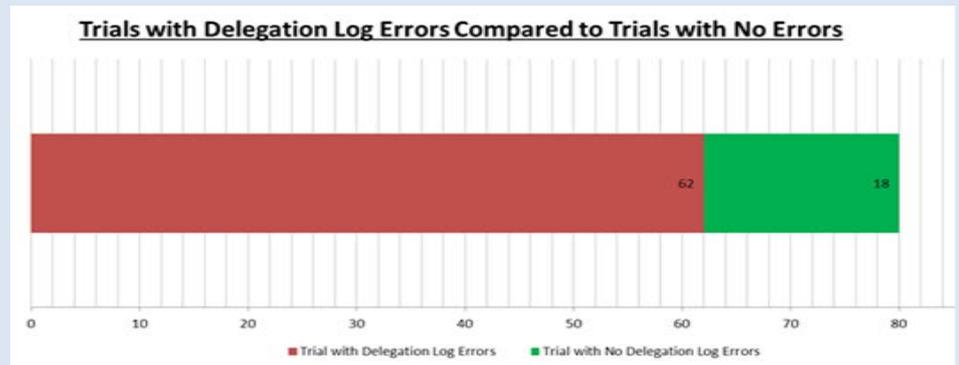


Fig 1 Errors in delegation logs

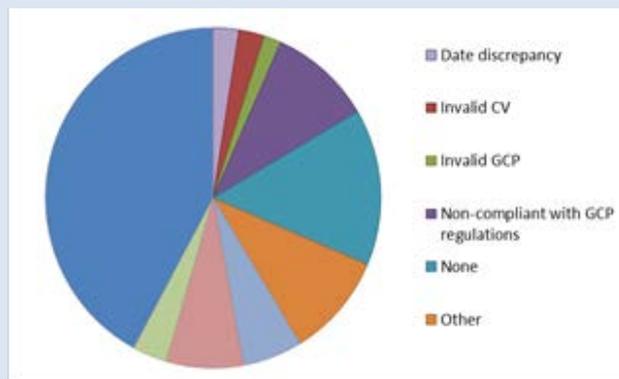


Fig 2 Types of error found

Discussion

Despite monitoring of study delegation logs by sponsors there were still errors occurring on such an essential document. There is little training available for PI's on completion of delegation logs except in GCP training. The highest proportion of errors was in the task delegation and were things such as no team member delegated archiving or screening etc. This could be due to the lack of a standardised delegation log. Often the tasks are varying between trials and sometimes require teams writing them in potentially leading to more mistakes. Long running complex oncology trials with multiple changes of staff appeared to lead to more errors. Lack of knowledge about the completion of logs correctly was evident. By auditing we can tailor education to the clinical teams that require it most.

Recommendations for practice

- Complete delegation log at SIV when majority of team present
- Ensure all duties are delegated if applicable
- Education sessions for PI's and research staff
- Regular reviews of delegation logs and a re-audit
- Standardised delegation logs separate for CTIMPS and non CTIMPS