Clinical Trials and Good Clinical Practice (GCP)
– Design and Review of a Training Package

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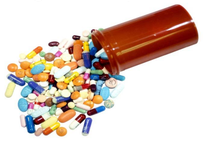
INTRODUCTION

The conduct of clinical trials is subject to UK law[1] and is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

The Good Clinical Practice (GCP) Inspectorate is part of the MHRA and aims to assess the compliance of pharmacies conducting clinical trials using investigational medicinal products (IMPs).

GCP is a set of scientific, ethical and quality standards that are a legal requirement for the safe conduct of clinical trials. Adherence to GCP protects the rights, safety and well-being of human subjects. GCP specifies that each individual involved in the conduct of a trial should be qualified by education, training, and experience to perform his or her respective task(s)[2].



Pharmacy plays an integral role in the running of clinical trials involving IMPs.

All pharmacy staff play a part in the running of a clinical trial, including administration staff receiving post, stores staff accepting deliveries, many of which are fridge items, reception staff being approached by patients with their clinical trial prescription and we haven't even mentioned the dispensing staff!

The Pharmacy Clinical Trials team considered currently available training packages to be over comprehensive for pharmacy staff not routinely involved in clinical trials. A need was identified to develop a training package that would enable all pharmacy staff groups to achieve appropriate standards of GCP training in a time efficient manner. This project aimed to design and evaluate a training package that facilitates pharmacy in meeting GCP standards.

METHOD

A working group consisting of the lead pharmacists and technicians for pharmacy clinical trials was set-up to develop training that was suitable for all pharmacy staff groups.

The working group met on a number of occasions to determine requirements of training. After discussion it was decided that a training package should be developed.

This would be divided into three different documents which when used together formed the clinical trials training package:

1)**A Standard Operating Procedure (SOP**), as GPC requires SOPs as part of a Quality Management System.

2)**A Workbook,** which when completed is kept by the staff member for reference.

3)**A Checklist,** to record evidence of training each staff member.

The training package was delivered as:

i. A pre-training set of questions to determine baseline knowledge.

ii. Reading of the SOP.

iii. A training session delivered by a member of the Clinical Trials team, but guided by the workbook and the participants.

iv. A post-training test to assess competency and improvement in knowledge.

v. Completion of the checklist to document training.

The questions within the training package covered terminology, principles, documentation and the safe handling issues surrounding pharmacy clinical trials. Participants were also timed on completion of the package to determine the subsequent impact on the department.

Presented as a poster at the Association of Pharmacy Technicians UK Conference 2012 in Birmingham, UK.
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RESULTS

A total of 30 people answered the pre-training questionnaire containing 10 multiple choice questions worth 40 points.

- An average score of 86.3% (34.5/40) was achieve pre-training.
- The lowest score was 52.5% (21/40).
- The highest score was 100% (40/40).
- Post- training all participants achieved 100%.

The participants results were the further sub-divided into the different departmental staff groups, with the results detailed in the table below.

Staff group:	Number of Participants	Average score (%)	Range (out of 40)
Pharmacists	6	88.8	29-39
Technicians	12	81.3	27-40
Students	10	89.5	31-38
Dispensers	2	80.0	32

Of the 30 participants, 19 were timed:

- The quickest time was 20 minutes, the slowest was 40 minutes.
- The total time taken 590 minutes, with an average of 31 minutes.

The participants results were further sub-divided into the different departmental staff groups, with the results detail below in the table below.

Staff group:	Number of Participants	Average time (minutes)	Range (minutes)
Pharmacists	4	31.3	30-35
Technicians	5	32.0	30-35
Students	8	28.1	20-30
Dispensers	2	40.0	40

DISCUSSION

There is evidence of a good level of underlying knowledge of GCP within the pharmacy department (mean score pre-training = 86.3%). The lowest pre-training mark was 52.5%, but one person achieved 100% without undertaking the package. This may indicate that the questions within the workbook are too easy or inappropriate for some staff groups who completed with ease. However, despite these initial high scores an increase in knowledge was still demonstrated post training by all staff groups in the study, with the biggest improvement seen in the dispensers. This fulfils the initial aim of designing a training package suitable for all staff groups, including those with limited baseline knowledge of clinical trials.

The department employs 167 people: 70 people have undertaken the training package with 30 of those entering the review. These 30 represent a cross section of dispensary and ward based staff, but do not capture clerical or stores staff. These two sets of staff carry out important behind the scenes duties. They will be the next staff groups to be trained. From these results the training package can be developed according to the needs of each staff group.

The advantage of a workbook led session is that it can be attended by a number of people across different staff groups at one time. With an average time of around 30 minutes to complete, our training package is more time efficient than other currently available external courses. As with all GCP, training is on going and ever evolving. The aim of the Clinical Trials team is to have the entire pharmacy staff of SWBH NHS Trust trained to our workbook standard by early 2013.

REFERENCES
1. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 Statutory Instrument 2006 No. 1928
2. ICH GCP (E6) (International Conference on Harmonisation)

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