

A role in drug development

— work of a clinical trials technician

By Rachel Graham

Many clinical trials are performed in UK hospitals and technicians are becoming increasingly involved in their day-to-day organisation. This article, based on an interview with Nicola Bowles from Guy's Hospital, London, describes the work of a clinical trials pharmacy technician



Reviewing the fees charged for trials is one of the tasks of a clinical trials technician

Two years ago, when Nicola Bowles took up the role of clinical trials technician at Guy's Hospital, London, there were approximately 15 clinical trials being carried out at the hospital at any one time. Now there are about 40 trials under way ("active" trials), with about 20 more planned for some time in the near future ("pending" trials). This article, based on an interview with Miss Bowles, describes the work of a clinical trials pharmacy technician and how the role has developed.

Key tasks

As with many NHS jobs, there is no typical day for a clinical trials technician. Administrative work, multidisciplinary team working, dispensing, staff training and financial management are all part of Miss Bowles' role.

Administrative work Each clinical trial has its own standard operating procedure (SOP) file for pharmacy aspects, and compiling these is the responsibility of the clinical trials technician. A framework document that lists the basic sections of the SOP is available (see Panel 1, p140), which is then tailored for each particular trial. Once written, Miss Bowles signs and dates each

SOP before the clinical trials support pharmacist reviews and signs them. With the large number of clinical trials being carried out at Guy's Hospital, compiling SOPs takes up a considerable amount of time, Miss Bowles explains.

Traditionally, the pharmacy aspects of clinical trials for cancer treatments at Guy's Hospital have been managed by staff at an oncology unit that is separate from the hospital's main pharmacy department. Workforce changes have meant that Miss Bowles has recently taken over some of the day-to-day running of the oncology trials that do not involve aseptically-prepared products. She visits the oncology unit in the afternoons, as and when needed, working either alongside the clinical trials pharmacist or alone.

Multidisciplinary team working To perform her role effectively, Miss Bowles needs to liaise with the many people involved with clinical trials, both at her trust and from external organisations. They include investigators (usually a consultant clinician at the hospital), clinical research associates from the sponsoring organisation (usually pharmaceutical company employees), research nurses, ward-based medical, nursing and pharmacy staff, dispensary staff, oncology unit staff, quality assurance staff at pharmacy preparation units and staff at external suppliers. "I spend quite a lot of time reviewing

documents and compiling SOPs, so interacting with a wide range of people is important to bring a balance to the working day," Miss Bowles says. Working with others also provides the opportunity to acquire specialist knowledge or learn about new practices that can be transferred to everyday work, she adds. For example, she has changed the paperwork used for non-cancer clinical trials so that it is more in line with that which has been used for some time at the oncology unit.

Financial management Clinical trials are sources of income for NHS hospitals. In the current climate of budgetary constraint, this makes it particularly important that trusts ensure they run trials efficiently and charge those sponsoring them appropriately. Part of Miss Bowles' role involves a periodic review of the fees charged by Guy's Hospital for pharmacy services, for example, administration (ie, trial organisation) and dispensing fees. She also checks that reimbursed drugs (ie, drugs that need to be given to trial patients as a supplement to trial medicines, but are not provided by the sponsor, eg, Calcichew) are charged for appropriately. She liaises with finance staff to ensure that invoices are drawn up correctly.

Staff training With the increasing number of trials taking place, together with the other demands being placed on her, it is not

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Panel 1: Framework for pharmacy-related clinical trials standard operating procedures

Section 1: Trial details

- Title of trial
- Details of the primary and secondary objectives
- Summary of study design
- Copies of the randomisation protocol and treatment schedule

Section 2: Location of trial medicines

- List of trial drugs and their location
- Pharmacy file reference number

Section 3: Dispensing procedure

- Trial-specific, step-by-step guide to dispensing procedure
- Details of prescription and stock requirements
- Instructions for booking trial drugs out on the pharmacy computer system
- Labelling directions, sample label and warning labels (eg, storage advice, “for clinical trial use only” and pharmacy address sticker, if necessary)
- Instructions for filling out accountability forms
- Instructions to dispensers to sign the signature log the first time they dispense medicines for that trial

Section 4: Checking procedure

- Instructions to ensure that the dispensing procedure is followed and that documents are appropriately signed and dated
- Instructions for storing prescriptions
- Details of any patient leaflets to be distributed with the trial medicines

Section 5: Returns

- Instructions to put any returned trial medicines in returns box in dispensary

Section 6: Unblinding procedure

- Instructions to, for example, refer to protocol

Section 7: Ordering of study medicines

- Information as to whether new stock is automatically or manually ordered

Section 8: Receiving deliveries

- Details of any storage requirements (eg, temperature) that need to be met

Section 9: Contact details

- Contact details of investigator, research nurses and sponsor’s clinical research associates

Copies of the significant event record sheet (where, for example, information about any deviations from the protocol or patient withdrawals is recorded), accountability forms and prescriptions are placed in each SOP file

possible for Miss Bowles to dispense the medicines needed for all of the trials herself. Her role therefore includes training other dispensary staff to dispense clinical trial drugs. An accreditation programme is in place in the department, whereby dispensary staff need to dispense the medicines for 20 different clinical trials without error, before they are deemed competent. If dispensers do not regularly perform clinical trials work (as evidenced by signatures in the log of SOPs — see Panel 1) then they need to be re-accredited.

Details of the dispensing procedure are listed in each SOP, assisting dispensary staff to dispense medicines for that particular clinical trial. Improvements to training procedures and SOPs mean that dispensary staff are now more willing to get involved in dispensing for clinical trials.

Miss Bowles also presents an overview of clinical trials procedures as part of the induction programme for new pharmacists and technicians.

As well as training others, Miss Bowles ensures that her own knowledge is up to date by attending good clinical practice training sessions regularly. She also attends

meetings of the Clinical Trials Network Group, based at King’s College Hospital, London, and is a member of the Institute of Clinical Research.

Dispensing and returns For trials that have just started, Miss Bowles dispenses the medicines herself on the first two or three occasions that they are needed, so that she can check that the SOP is easy to follow.

When the bottles and boxes of dispensed clinical trials medicines are returned to the pharmacy department, they are placed in a “returns box”. Miss Bowles reviews the returned medicines on a twice-weekly basis, recording the relevant details (eg, whether patients received all of their doses) on accountability forms.

Future developments

Recent changes to legislation have resulted in even more clinical trials-related paperwork being generated, Miss Bowles explains. The development of databases to store and retrieve clinical trials-related information would be a step forward. However, databases will be unlikely to solve the

problem of “excessive paperwork” completely, she points out, because hard-copy back-ups will most likely still be needed.

Challenges

Miss Bowles’ current post requires her to split her time between clinical trials work (in the mornings) and general dispensing duties (in the afternoons). “This can be a difficult arrangement,” Miss Bowles explains, “because it is just not possible to switch off from clinical trial work at midday.” For example, she receives telephone calls relating to clinical trials in the afternoons. Moreover, as mentioned above, Miss Bowles now spends some afternoons at the hospital’s oncology unit dealing with their clinical trials issues. However, Miss Bowles is keen to carry on her dispensary-based role. “I am an accredited checking technician, and I need to make sure I do enough dispensing so I can continue with this role,” she says.

One potential drawback of working as a clinical pharmacy technician is that there is less scope for interacting directly with patients than, for example, technicians involved in ward-based medicines management work. However, as Miss Bowles explains, her work is ultimately of benefit to patients, because the clinical trials she plays an important part in running can result in new treatments becoming available, or can prevent medicines that do not prove themselves to be safe and effective being further developed.

Conclusion

The number of clinical trials performed in UK hospitals looks set to increase, bringing opportunities for pharmacy technicians to become involved. While the work of a clinical trials technician might not bring as many chances to interact directly with patients as do some other technician’s roles, it is full filling, requires a wide range of skills to be developed and used, and is ultimately of benefit to patients.

“Focus on technicians” articles

This series exists to report on how pharmacy technicians are pushing forward their traditional boundaries and making a full contribution to the profession. Any pharmacist or technician who is involved in any new developments in work undertaken by technicians is asked to consider writing an article for publication. Advice on the publication process can be obtained by telephoning the *Hospital Pharmacist* editorial office on 020 7572 2425/2419.

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