PHARMACY PRACTICE

Pharmacy Technician Support of Clinical Drug Trials and Drug Use Evaluation

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INTRODUCTION

Pharmaceutical Care has been embraced by virtually all major pharmacy organizations as the preferred model for the practice of pharmacy. Pharmacists are being told that they must assume more responsibility for a patient's outcome and that this can be accomplished through Pharmaceutical Care.[1] The challenge facing hospital pharmacy departments and practitioners is how to implement the Pharmaceutical Care model at a time of financial constraint. Most hospital pharmacy departments in Canada are currently facing staff freezes if not cuts to their staffing and, therefore, services. The full implementation of Pharmaceutical Care will, however, require pharmacists to substantially increase the amount of time spent on direct patient care. This has been identified as one of the barriers to the implementation of Pharmaceutical Care.[2]

It is apparent that implementation of Pharmaceutical Care will require a redeployment of pharmacists' time from non-patient care functions to those more directly related to patient care. In doing so, pharmacy departments will have to shift work which is currently being done by pharmacists to technical staff. As predicted by Anderson in 1987,[3] pharmacy technicians are vital to the future development of the profession of pharmacy.

Pharmacy technicians have traditionally been used to perform routine drug distribution functions that do not require the professional judgement of the pharmacist.[4] Hospital pharmacy departments have, to a large extent, maximized the use of technicians to perform these functions. This makes it necessary to consider if there are other functions within hospital pharmacy that could be assumed by technicians. Recent articles indicate that this process is underway in selected institutions.[5,6]

Hospital pharmacists have traditionally coordinated and carried out the majority of functions associated with pharmacy support of clinical drug trials and retrospective drug use evaluations.[7,8] However, when one examines the role of pharmacists providing these services, it is apparent that the majority of these functions are performed without the intent of producing specific outcomes for individual patients. As such, they do not directly contribute to the provision of Pharmaceutical Care and, therefore, could be considered to be a barrier to its implementation.

This paper describes the development and initial results of an initiative to have a pharmacy technician assume significant responsibilities for pharmacy services to support clinical drug trials and drug use evaluations.

Program Development

This program was introduced at a 490-bed, tertiary care, teaching hospital. The pharmacy department offers a full range of contemporary drug distribution and clinical services.

Prior to 1992, pharmacy services to support clinical drug studies were coordinated by an Assistant Director with the day to day workload distributed among the teams of pharmacists, according to their area of speciality (eg., studies in Alzheimer's were serviced by pharmacists assigned to cover the Neurology Service). An Assistant Director was responsible for billing the investigator for charges associated with pharmacy support of the study. The pharmacy was involved in approximately 15 studies and billed investigators approximately $12-15,000 per year. Problems encountered with this method included variability in the

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commitment to the service by the 15 staff pharmacists involved, poor tracking of drug accountability due to the number of individuals involved and complaints from the pharmacists that their involvement with clinical trials detracted from their patient care activities. Due to these problems, the management of the pharmacy department set an objective to develop a position dedicated to and responsible for the day to day operation of the investigational drug service.

Prior to 1992, drug utilization evaluations were performed annually on selected antibiotics. These evaluations were primarily conducted by pharmacy residents as part of their projects. In response to increased demand by the Medical Advisory Committee and hospital administration to control drug costs, the Pharmacotherapeutics Committee and its Subcommittee on Antibiotics developed "Criteria for Use" for several drugs. As the pharmacy department was given the responsibility to ensure that these criteria were adopted, pharmacists were educated on their intent, rationale, and content. The management of the pharmacy department also identified the need to audit adherence to these criteria using retrospective and/or concurrent drug use evaluation. Again, it was decided that this could be best accomplished by having an individual dedicated to data collection for the audits.

Funding for pharmacy support of clinical drug trials could only be obtained through monies brought in by billing investigators. These monies are placed in a trust fund managed by the pharmacy department for the promotion of pharmacy-initiated research activities. Due to financial constraints within the hospital, administration was not willing to provide funding for personnel for drug utilization review, but agreed not to cut pharmacy staff (as was being done in many other departments) if drug use evaluations contributed significantly to the overall drug budget restraint program. In other words, pharmacy would have to increase their capacity to carry out drug use evaluations without adding staff. It was apparent that a dedicated position for clinical drug study support and drug use evaluation would have to be done in a cost effective manner.

To accomplish this, a proposal to have a pharmacy technician assume these tasks was approved. It was agreed that this would initially be a 0.5 FTE position responsible to an Assistant Director of Pharmacy. The position would be funded by fees for the reimbursement for pharmacy services to clinical drug trials and by monies raised by the department to conduct drug use evaluations and continuing education on antibiotic drug use evaluation for other hospital pharmacy departments in the region. The latter was partially supported by pharmaceutical manufacturers. The half-time position was posted internally; the qualifications included demonstrated organizational skills, preparation of sterile products, experience with personal computers and the ability to work independently. The successful candidate was hired in the May 1992. Since that time, this individual has worked half-time on these activities and half-time on other technical activities within the department. Where necessary, training was done through on-the-job meetings and discussions with the Assistant Director.

The responsibilities of the pharmacy technician include the following:

Investigational Drug Service

-Review of protocols with Assistant Director.

-Preparation of protocol summary sheets which briefly review the protocol and dispensing procedures. This summary is made available to all pharmacy staff to inform them of the protocol.

-Assisting the Assistant Director with educating specific pharmacy personnel who will be involved in the protocol.

-Preparation and dispensing of study drugs. This includes 24 hour on-call coverage for drug preparation outside of regular weekday hours. This on-call service is exclusive of the on-call provided by the pharmacists in the department. Responsibility for these activities of the technician is assumed by the Assistant Director.

-Maintenance of drug accountability records.

-Storage and security of drugs for clinical investigation.

-Tracking pharmacy expenses for costs incurred to support studies and billing investigators semi-annually.

All of these activities are supervised by the responsible Assistant Director of Pharmacy.

Drug Use Evaluation

-Preparation of a monthly report on the utilization of the 50 most expensive drugs in the hospital. This is prepared from the pharmacy usage reports available from the inventory program. This information is forwarded to the Director and Assistant Director of Pharmacy for use by the Pharmacotherapeutics Committee to guide the drug utilization evaluation program.

-Review of patients' charts to document information necessary to carry out drug utilization evaluation. In the first year, the technician collected patient-specific information for a concurrent vancomycin and a retrospective liposomal amphotericin B audit. All case summaries were submitted to the Assistant Director of Pharmacy for review and, if necessary, further data collection or clarification. The Assistant Director of Pharmacy summarized the data by comparing the audit results with predefined criteria for drug use and presented it to the Subcommittee on Antibiotics and the Pharmacotherapeutics Committee.

PROGRAM EVALUATION

Investigational Drug Service

In the fiscal year April 1, 1992 to March 31, 1993, the technician was actively involved in 17 clinical drug trials involving the following areas: AIDS, Anesthesia, Cardiology, Infectious Diseases, Neurosurgery, Oncology, Respirology, and Vascular Surgery. The technician received 18 after-hours call-backs for drug preparation. Billings to investigators for the 1992-93 year totalled $19,355. There have been no instances of errors in drug accountability since the technician assumed responsibility for this area.

The response to the development of this position has been very favourable from both the pharmacy staff and clinical investigators. Pharmacists and technicians appreciate having a primary contact for questions relating to clinical drug studies. Pharmacists spend less time dealing with clinical drug trials which provides them with additional time for patient care. The Assistant Director of Pharmacy also now spends significantly less time with individual clinical drug studies and this provides more time for other activities. Pharmacy's reputation for providing a quality investigational drug service to investigators has also improved. For example, we were recently asked to coordinate the randomization, blinding, and distribution for a study involving a medical device. The primary investigator stated that this was done in recognition of our expertise in supporting clinical trials.

Drug Utilization Evaluation

In the fiscal year 1991-92 our hospital spent $220,000 on vancomycin. This prompted the development of criteria for use of vancomycin which were approved by the Pharmacotherapeutics Committee and the Medical Advisory Committee (June 1992). Projected annual expenditures based on data from April to November, 1992 were $187,000. Although this represented an improvement, the Subcommittee on Antibiotics felt that additional savings were possible and asked that a drug utilization evaluation be conducted using the criteria for use. A drug utilization evaluation of 63 cases of vancomycin use was conducted by the technician and Assistant Director and the results and recommendations were subsequently presented to the Pharmacotherapeutics Committee. Based on data from April 1 - July 31, 1993, our annual projected expenditure for vancomycin is $81,000.

The technician also collected data on the use of liposomal amphotericin B within our hospital. Data included indications for therapy, dose, duration, mortality, and cost. These data indicated that we had used the drug in 11 patients with an associated drug acquisition cost of $171,900. Based on this and other information, the Medical Advisory Committee has approved that this drug no longer be available for use within the institution.

DISCUSSION

If pharmacists are to practice pharmaceutical care, there will have to be an increased reliance on pharmacy technicians to perform additional activities that do not require the professional judgement of the pharmacist. This paper describes the successful use of a pharmacy technician to support pharmacy-based investigational drug and drug utilization evaluation services. To our knowledge, this is the first report of such use of a pharmacy technician.

The most important benefits derived from this initiative are that: 1) pharmacist's time is freed up to perform additional patient care contributions; and 2) the pharmacy does not needlessly pay a pharmacist to perform activities which can be competently performed by a technician. We are also very satisfied with the improved efficiency of our investigational drug service and the quality of data collection for drug use evaluations which have made significant contributions to the drug budget restraint program.

Pharmacy technicians have traditionally been assigned technical repetitive tasks associated with the drug distribution system. Today, many of these tasks can be performed by new technology (e.g., unit dose bin filling machines, bar code technology). Coincidentally, pharmacists are being strongly encouraged to focus on activities that require their professional judgement and are directly linked to patient care. These influences create the potential for pharmacy technicians

to assume many of the activities currently performed by pharmacists. To facilitate this, the following initiatives are recommended:

-recognition by pharmacists of the number of activities which they perform and which do not require their expertise;

-recognition by pharmacists that, with the proper training, instruction and supervision, technicians are capable of performing many of these activities;

-development of enhanced training programs by hospital pharmacy departments and community colleges to prepare technicians for these responsibilities;

-adjustments of job descriptions and salary scales to reflect the responsibilities of various levels of technicians.

These initiatives would also create the potential for greater career advancement by pharmacy technicians. Job satisfaction amongst hospital pharmacy technicians has been reported to be relatively poor.[9] The creation of additional job opportunities and the potential for career advancement should alleviate some of this dissatisfaction.

The expansion of the role of the technician should not be viewed as a threat by pharmacists. For drug use evaluation, the expertise of the pharmacist is required to develop the criteria for drug use, analysis and interpretation of results, and communication of recommendations to the appropriate individuals and committees within the hospital. Similarly, for investigational drugs, pharmacists are required for protocol evaluation and some aspects of problem solving. Appropriate use of technicians will augment the capacity of the pharmacist to manage the many tasks and opportunities presented to them.

In summary, we have demonstrated that a pharmacy technician is capable of competently performing many of the activities traditionally assigned to a pharmacist in the areas of an investigational drug service and a drug utilization evaluation program. We recommend further expansion of the role of the technician to facilitate improved patient care by the pharmacist and hospital pharmacy departments.

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