

CRITICAL APPRAISAL ROUNDS: A NEW TRAINING MODEL FOR CLINICAL PHARMACOLOGISTS

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ABSTRACT

A new training model for critical appraisal in therapeutics is presented. Postgraduate trainees in Clinical Pharmacology are assigned to critically appraise scientific papers that faculty members were asked to review by Journals. The manuscripts were discussed in group rounds, allowing teaching of all aspects of therapeutics research. Formal evaluation of this model by trainees revealed high marks for “critical thinking”, “learning study design”, and “how to write / not to write”.

The postgraduate training of physicians and clinical pharmacists in the subspecialty of clinical pharmacology entails a complex range of knowledge, skills, and attitudes.¹⁻⁶

In view of the rapid development in therapeutics, clinical departments, hospitals, governments and the pharmaceutical industry expect clinical pharmacology consultants to be able to continuously evaluate new data and put it in an appropriate context. Hence, critical appraisal becomes one of the most pivotal functions of clinical pharmacologists. The development of the capacity to critically appraise scientific data involves synthesizing knowledge (e.g., pharmacology, epidemiology, and clinical research design), skills (e.g., pharmacokinetics, statistics, and grant writing), and attitudes (e.g., ethics). While all these elements are taught in different ways, it is typically the “Journal Club” forum that brings together the three pillars by examining specific scientific papers. We present a new training model in Critical Appraisal established in our training program and its evaluation by trainees and faculty.

Setting

The University of Toronto has the largest program in Clinical Pharmacology in Canada with over 40 faculty members in different aspects of Clinical Pharmacology. The Program is an accredited subspecialty-training site by the Royal College of Physicians and Surgeons of Canada. The Hospital for Sick Children has 4 full-time geographically-

based clinical pharmacology physicians, 7 additional cross appointed fully trained pediatricians-clinical pharmacologists in other clinical programs, as well as laboratory based pharmacology members, and several clinical pharmacists. The Division of Clinical Pharmacology is the primary site worldwide to train pediatricians in clinical pharmacology at the postdoctoral level, (in addition to a large Graduate program in Pharmacology).¹ Since its inception in 1979, the Program has trained over 60 physicians and pharmacists from 32 countries in Clinical Pharmacology.

The Program’s curriculum includes pharmacokinetics, pharmacodynamics, epidemiology and study design, bioethics, therapeutic drug monitoring, clinical toxicology, maternal fetal toxicology, and clinical consultations, in addition to participating in basic pharmacology rounds (e.g., placental transfer, drug transport, analytical toxicology). In 1995, as part of the Program, we established a weekly Critical Appraisal rounds. This weekly forum is attended by all trainees and 4-6 faculty members.

This forum serves two functions:

1. Reviewing research protocols for formal scientific reviews before submission to the institution’s Research Ethics Board (REB). Each trainee is asked to read the protocol and comment on the statement of current state of

knowledge, scientific importance, relevance and novelty of the research question, feasibility of the proposed study in respect of cohort assembling, sample size, measures, results, funding, budget, timeline, validity of the proposal, ethics, and public health significance. The review is performed using REB standard forms.⁶ After the review meeting, the Principal Investigator (PI) of the discussed protocol is expected to address all scientific issues raised by attendees and to revise/rebuttal. Signature by the Chair of the meeting is needed before the protocol can proceed to the REB. This forum is open to any program in the Hospital who has a protocol related to Therapeutics, although over 80% of all protocols discussed are generated in the Division of Clinical Pharmacology. This forum is an effective teaching means for grant reviewing and writing.

2. Critical review of papers submitted for publication in scientific journals, where our faculty members were asked to review the papers. We receive 1-2 such papers every week from 10-15 different journals dealing with therapeutics. The Journals were informed that a trainee is involved, and the trainees are acknowledged as co-reviewers. The presentation of the paper included anonymous names of authors and institutions. Trainees are advised about and adhere to the complete confidentiality required.

The postdoctoral trainee assigned to a specific paper is asked to review it confidentially in depth, present it to the faculty member addressing the advantages and weaknesses, in the context of other literature published on the specific topic. Subsequently, the trainee presents the review and selected issues to the

group without disclosure of any identifying details. Fellows assigned for the review are instructed that all materials and discussions must remain strictly confidential, and that no photocopies should be made. The format of the discussion is open, and attendees are encouraged to ask and comment throughout the one hour process on any aspect of the paper. The mentor uses the scientific paper for didactic comments, and to highlight specific concerns or advantages. The fellow is expected to comment whether the research question was novel and whether the actual design was appropriate to answer the study question⁶, whether the methods and the intervention⁶ were appropriate, whether the data were appropriately analyzed, the internal and external validity of the results, and the ethicality of the project.

This process entails all aspects pertaining to the paper from pharmacokinetic or analytical choices to ethicality, epidemiological methods, sample size considerations etc. At the end of the process the learner is expected to summarize in writing all findings and criticism made by him/her or by other group members during the discussion. This written report is reviewed and revised by the faculty mentor and the learner is then expected to revise his/her report. The hypothesis underlying this learning module was that conducting a “real” critical review of protocols and manuscripts (rather than journal club of already published papers) would increase the sense of responsibility, seriousness, and commitment by trainees.

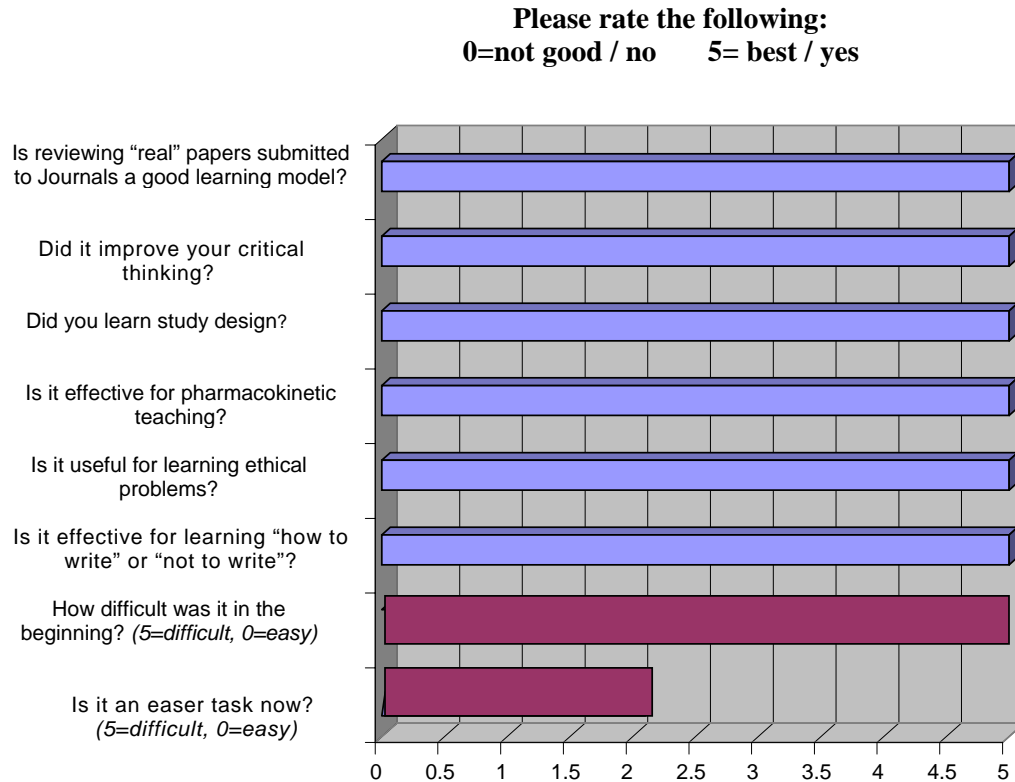
Evaluation by Trainees

We present herein anonymous evaluation of this program by 15 postgraduate trainees (14 physicians and 1 pharmacist) and 4 regular faculty participants that took place twice: in April 2004 and in July 2006. The questionnaire used for the evaluation is shown in Table 1.

TABLE 1 Evaluation of Critical Appraisal Rounds

1. Before doing your Clinical Pharmacology Fellowship - in what medical field was your clinical training?
2. How long have you been in our Program?
3. How many papers have you reviewed?
4. How long does it typically take you to review a paper?
5. How long does it take you to write the report?
6. How long does it take you to revise the report?

FIG. 1 Evaluation of the Educational Process



Before enrolling in Clinical Pharmacology training the trainees specialized in pediatrics (7), internal medicine (2), neurology (1), obstetrics (2), anesthesia (2) and pharmacy (1). They graduated in 10 different countries. In April 2004, they had been involved in Clinical Pharmacology training for a period ranging from 9 months to 3.5 years (median 1.3 years). During this time period they reviewed in this forum between 3 and 20 scientific papers (median 6). It has typically taken trainees between 1 and 10 days to review a paper (median 4 days). Writing of the report took between 1 hour and 2 days, (median 5 hours), and revision of the report between 15 minutes and 2 days (median 1 day).

Trainees were asked to evaluate different aspects of the educational process from 0 (not good / no) to 5 (the best / yes) (Figure 1). They invariably felt that reviewing "real" papers submitted to journals was an excellent learning experience (median 5, range 3-5). One learner

commented that it was, "an excellent way to understand study design". All 15 trainees believed this model improved their critical thinking (median 5, range 4-5). All trainees felt it had allowed them to learn study design (median 5, range 3-5), pharmacokinetics (median 3, range 2-5), ethical issues (median 5, range 3-5), and "how to write/not to write" (median 5, range 4-5).

In answering the question "how difficult was it in the beginning", trainees felt it was "very difficult" (median 4, range 3-5). At the time of delivering the questionnaire they felt they had improved dramatically, and the review was substantially easier (median 2, range 1-4) ($P < 0.01$).

Evaluation by Faculty

The 4 faculty members comprised of 3 physicians-clinical pharmacologists, all graduates of the Toronto Program, and one analytical toxicologist. All four have attended these rounds

regularly since their inception. Their evaluations of the effectiveness of this program closely resembled those of the learners.

DISCUSSION

As with any other medical specialty and subspecialty, postgraduate training in clinical pharmacology aims at preparing individuals to function at a consultant level.⁵ Many of the “real life” functions of clinical pharmacologists entail critical review and evaluation of experimental and clinical data pertaining to therapeutic or toxic agents. The range of activities is very wide and rapidly growing, from molecular medicine (e.g., pharmacogenetics) to behavioral sciences (e.g., patient adherence).

The learning model presented here allows one to estimate the initial levels of knowledge, skills, and attitudes of trainees and subsequently to follow their progress during active teaching. This model expects trainees to review critically a variety of expertise on a weekly basis throughout their postgraduate training. The academic viability of clinical pharmacologists depends in part on their ability to publish their own data and to write effective grants. As evidenced by the learners’ response, they felt that this model is unique, as it deals with real-time protocols and papers, where they feel that their participation is a useful part of the decision regarding the paper. While the common, “Journal club” review of papers already published, is based typically on high quality, selected papers, this new model includes papers and protocols with a large range of quality, deficiencies, and need for revision. The review of such submissions is one step closer to the author, and hence makes it more relevant to the trainee. Finally, the review process is constructive with defined outcomes and follow-up, rather than moot.

For most aspects of this new model, the trainees exhibited a high degree of agreement among themselves, with relatively narrow range of evaluation. Only for pharmacokinetic learning the answer range was between 2-5, possibly reflecting different needs of trainees with varying backgrounds. The present study analyzed trainees’ evaluation of a new educational technique, and

therefore, cannot address whether this method has increased their long term level of scientific analysis and writing. Eventually the decisions regarding the reviewed paper remain solely with the faculty member originally asked to review the manuscript. The faculty member reviews the paper independently, which allows him/her to also review the potential and progress of the learner in critical review. As important, it allows for identification of areas of weakness and for planning remedial learning. Moreover, this module allows the mentor to assess the performance of other trainees during the review, either through free discussion or by directing questions to specific individuals.

There is paucity of information on educational methods for training postgraduate Clinical Pharmacology fellows, in contrast to impressive development in teaching methods for undergraduate medical pharmacology.⁷⁻¹¹ A recent study focused on study design and rationale in a mock phase I trial as an educational tool for clinical pharmacology. The technique, however, deals with a dummy pharmaceutical company, and is written as a future plan and not as a working method.¹²

In conclusion, we describe a novel method for training postgraduate clinical pharmacology fellows in critical appraisal of drug studies. Because many (if not all) practicing clinical pharmacologists are reviewing scientific papers for peer review journals, this model can be adopted by training programs elsewhere.

Acknowledgements

Dr Koren is a holder of the Ivey Chair in Molecular Toxicology, Department of Medicine, The University of Western Ontario

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