Letters to the Editor
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Teaching a module on clinical trial research for PharmD students in Nepal: My experiences

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Dear Editor,

In mid-August 2011 Ms Rajani Shakya, Assistant Professor, Pharmacy, Kathmandu University (KU), Dhulikhel, Nepal asked me to facilitate and teach a module on clinical trial research for the Doctor of Pharmacy (PharmD) students. My experiences of facilitating a module will be of interest to other facilitators and educators who can learn about the challenges I faced, problems while conducting the module and how they were overcome.

Clinical trial research, a new subject area in Nepal: Based on a number of reasons including the small pharmaceutical industry, phase I, II and III clinical trials of new drugs are rarely conducted in Nepal unlike, the clinical trials of already marketed drugs, such as those used for altitude sickness, which are occasionally conducted in the Everest and Annapurna region.

PharmD students and small group learning: I emphasised both the drug development process and the clinical development process of a new drug during the module. The module consisted of 12 sessions with an additional concluding session to wrap up the proceedings and to obtain student feedback (Table 1). I used small group-based activity sessions which I had previously successfully used in teaching undergraduate medical students and other adult learners in various workshops. The module was undertaken in the third semester of the three-year post-baccalaureate PharmD programme. The programme is open to students who have completed a four year Bachelor of Pharmacy (BPharm) The Clinical Research module is a two credits course with a minimum requirement of 32 contact hours in the form of sessions and assignments. The 13 post-graduate students were divided into two smaller groups.

Venue for the sessions: The sessions were held at the University's School of Management campus in the Lalitpur district. The venue provided small tables and chairs which could be easily moved around, as well as a white board. In addition to the white board, the students also used flip charts and we had access to a LCD projector.

Creating an online mailing group: Based on my successful experience with effectively sharing information using an online mailing group with undergraduate medical (MBBS) students, I also created an online mailing group for the PharmD students. The online group was used by the students to submit their assignments and by the facilitator to share reading materials and other clinical trial research resources (e.g. free internet-based textbooks related to clinical trial research, and material from the United States Food and Drug Administration (USFDA) and the European Medicines Agency (EMA) sites among many others)

Assignments and formative assessment: Both group and individual assignments were used during the module. Students were typically given a week to complete and submit their assignments which are shown in Table 2. Both formative and summative assessments were carried out during the module. The formative assessment tasks (worth 40%) evaluated the students' attendance, punctuality, participation, presentation skills and their assignment submissions. Then at the end of the module, a 150 minute short answer examination was used as a summative assessment task (worth 60%) to evaluate the students' knowledge and understanding about clinical trials.

Group work: A 10-15 minute group work activity was an important part of each two hour small group learning session. Important clinical trial issues discussed during these group work activities included: developing a protocol for a clinical trial; focusing on different parts of the protocol; and good clinical trial practice. Table 3 clearly outlines the group work activities conducted during the different sessions. Informal feedback obtained from students indicated that small group activities contributed substantially to the module.

Student feedback on the module: Student feedback about the module was obtained informally at the end of the module. Their perceived knowledge, attitude and skills about different subject areas before and at the conclusion of the module were studied. The author also obtained structured written feedback at the end of each session. The feedback obtained will be used to further improve future sessions.

Possible lessons for other clinical trial research educators: To the best of my knowledge this is the first time a clinical trial research module has been taught in Nepal for pharmacy students. Based on my experience, clinical trial research training modules can be effectively delivered in small group activity-based learning sessions, using white boards, flip charts and the submission of both formative and summative assessment tasks. In addition, the availability of online resources, online group discussion forums and internet sites also contribute to this learning environment which can be successfully used to deliver new and innovative programs such as this one to the PharmD students.

Sincerely,

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Table 1: Different sessions conducted during the clinical trial research teaching module

Session number	Topic	Learning objectives (At the end of the session the student will be able to)
One	Drug development process	Describe the different stages in the drug development process Explain lead optimisation and toxicity testing
Two	Drug development process 2 & Ethics	List components of an Investigational New Drug (IND) application Recognise the relationship between phases of drug development and clinical trials Understand ethics and its importance in clinical trial research Describe the functions of Institutional Review Boards (IRBs) Recall the guidelines of Nepal Health Research Council
Three	Introduction to clinical trials	Provide a brief history of clinical trials Understand the importance of randomization and masking in clinical trial research Recall ethical issues, and data monitoring in clinical trials Describe the general principles of clinical trials Recognise different trial designs
Four	Phase I studies and pharmacokinetics	Relate human phase I clinical trial studies to animal studies Describe the selection process for volunteers, how to obtain informed consent, where to conduct clinical trials and what type of

		insurance is required for phase I clinical trials Describe the importance of medication dosing schedules in phase I clinical trials
Five	Postmarketing surveillance and phase IV studies	Understand postmarketing surveillance Explain the relationship between clinical trials and drug safety Describe the spontaneous reporting of Adverse Drug Reactions (ADRs) Understand the difference between case control and cohort studies Design an ADR reporting form Describe parts of the protocol for clinical trial research
Six	Ethical issues in clinical trial research	Understand ethical principles for conducting clinical trial research Describe the process for obtaining informed consent Design a participant informed consent form Describe the role of an institutional review board Discuss the national guidelines for clinical trials Recognise potential vulnerable groups in clinical trials Describe the responsibilities of different individuals involved in clinical trials
Seven	Good clinical trial practice	Understand what is Good Clinical Practice (GCP)? Describe initiatives towards GCP Familiarise themselves with the World Health Organization (WHO) handbook on GCP and International Conference on Harmonization (ICH) on GCP Describe the Case Record Forms (CRFs) Describe multicentric trials List the essential documents required for clinical trials
Eight	Responsibilities of various individuals in a clinical trial	Describe the responsibilities of the sponsor in terms of manufacturing, packaging, coding of investigational products and ADR reporting in clinical trials Describe the responsibilities of the clinical trials investigators, monitors and research associates

Nine	Data management in clinical trial research	Understand how data is generated during a clinical trial Have an overview of the data management process Understand the process of managing and tracking CRFs Describe the steps required for data review and clarification Understand issues relevant to validation, data queries, query tracking and resolutions Understand the importance of quality assurance and archiving
Ten	Drug regulatory environments in Nepal, India and certain developed nations	Understand the historical background of drug regulation Have an overview of the clinical trial regulations with reference to the European commission, the United Kingdom, Nepal, the United States, Japan, the European medicines agency, and the Central Drugs Standard Control Organization (CDSCO) of India Obtain information about the control of clinical trials by regulators Describe the end points in clinical research
Eleven	Phase III clinical trials	Describe Phase III clinical trials under the headings of objectives, subtypes, study population and study design Understand the publication guidelines for clinical trials Describe the Institutional Review Board (IRB) clearance of the clinical trial protocol, monitoring of the clinical trial, initiation meeting and other issues relevant to phase III clinical trials
Twelve	Miscellaneous issues	Describe how to complete an Abbreviated New Drug Application (ANDA) application Describe the components of a drug master file Recognise the importance of type 1 and type 2 errors Understand how to conduct a systematic review and list the steps involved in undertaking one Describe the importance of confidentiality in clinical research Understand the relevance of ghost writing, and negative results in clinical trials Describe phase II clinical trials

Thirteen	Concluding session	Present concept maps about the topics discussed during the module Describe the steps in translating knowledge into practice Carry out a Strength, Weakness, Opportunity, Threat (SWOT) analysis on clinical research in Nepal Reflect on the strengths and weaknesses of the module

Table 2: Group and individual assignments used during the module

Group assignments	1) What are the four ethical principles mentioned in the national ethical guidelines for health research in Nepal? How will you ensure these guidelines are followed in clinical trials? (to be submitted within a week of completion of session three) 2) Group A – Prepare an outline protocol for a phase I clinical trial of a new drug for tuberculosis Group B – Prepare an outline protocol for a phase III clinical trial of a new anticancer drug. (to be submitted within a week of completion of session eleven) 3) On a chart paper prepare a concept map of the issues discussed during the module on clinical trial research (to be presented during session thirteen)
Individual assignments	1) Develop a protocol for conducting a phase I clinical trial study of a new antihypertensive at the Kathmandu University (to be submitted within a week of completion of session four) 2) Develop a protocol for conducting a phase I clinical trial study of a new antidiabetic drug at the Kathmandu University (to be submitted within a week of completion of session four) 3) List the essential documents to be made available before the phase I of the clinical trial commences. List the additional essential documents to be made available after completion or termination of the trial. (to be submitted within a week of completion of session seven)

Table 3: Group activities used during different sessions

Topic	**Group activities**
Drug development	1) Do you think medicines, in general, are expensive in Nepal? How does Nepal compare with other countries in terms of medicine costs? (5 minutes) 2) What toxicity tests should a new drug undergo during preclinical testing? (10 minutes)

Drug development process 2 & Ethics	1) Prepare an outline IND application for a new drug developed from Yarshagumba to treat male impotence. (Group A) (15 minutes) Prepare an outline IND application for a new drug developed to treat typhoid fever. (Group B) (15 minutes) 2) Kindly list the various points to be mentioned while completing an IND application. (10 minutes) 3) What ethical problems do you foresee while conducting clinical trial research in Nepal? (10 minutes)
Introduction to clinical trials	1) What systems of post-marketing surveillance are available in Nepal? How can these systems be strengthened? (10 minutes)
Phase I studies and pharmacokinetics	1) Outline the steps for conducting a phase I study of a new NSAID (Group A)(10 minutes) 2) Outline the steps for conducting a phase I study of a new antibiotic among healthy humans (Group B) (10 minutes)
Postmarketing surveillance and phase IV studies	1) In your group design a spontaneous ADR reporting form for medicines in phase IV trials on one side of the flip chart (15 minutes)
Ethical issues in clinical trial research	1) Group A: Design an informed consent form (patient participation consent form) for a pharmacokinetic study which involves drawing repeated blood samples at frequent intervals over a two day period Group B: Design an informed participant consent form for a study among college students to ascertain their attitudes towards premarital sex. (15 minutes) 2) Identify ten vulnerable groups and justify why they are considered as vulnerable for purposes of participation in clinical trials (10 minutes)
Good clinical trial practice	1) Group A Kindly read the ICH GCP, WHO GCP and CDSCO GCP guidelines and define fifteen terms beginning with the letters from A to I Group B Kindly read the ICH GCP, WHO GCP and CDSCO GCP guidelines and define 15 terms beginning with the letters from J to Z (15 minutes) 2) *Group A: Referring to the WHO handbook answer the following questions:* • *What types of changes may require formal amendment of the protocol for all phases of a clinical trial?* • *When is unblinding of the trial by the investigator permissible? How should unblinding be accomplished (in those situations where it would be allowed)?* • *Who is responsible for determining that the risk/benefit profile of a clinical trial study is acceptable or unacceptable?* Group B: *Referring to the WHO handbook answer the following questions:* • *How is compliance with the protocol ensured and documented within GCP?* • *How should serious unexpected adverse events (SAEs) be reported during phase I and phase II studies and to whom?* • *What should be done if the benefit-risk profile of a study becomes unfavourable?* (15 minutes)
Responsibilities of various individuals in a clinical trial	1) Using the ICH GCP guidelines list the responsibilities of monitors of clinical trials (Group A)(15 minutes) Using the ICH GCP guidelines list the responsibilities of AUDITORS of clinical trials (Group B) (15 minutes) 2) Group A: Can you start a Contract Research Organization (CRO) in Nepal? If yes, how will you ensure the CRO is financially viable?

	Group B: Why are few clinical trials being conducted in Nepal? How could you ensure more clinical trial research is conducted in the country? (10 minutes)
Data management in clinical trial research	1) What are the common problems with data that may arise at the entry stage? (5 minutes)
Drug regulatory environments	1) How can regulators exert control over clinical trials? (15 minutes)
Phase III clinical trials	1) Group A – Create an outline proposal for conducting a multicentric phase III study of a new antidiabetic drug in Nepal. (10 minutes) Group B- Create an outline proposal for conducting a multicentric phase III study of a new anticancer drug in Nepal.
Miscellaneous issues	There were no group activities during this phase. There was a presentation by a student on her home assignment on ghost writing and negative results in clinical trials. Students also presented an outline of their completed group assignments.
Concluding session	1) SWOT analysis of the clinical trial research scenario in Nepal

Audio files enhance classroom learning among medical students in Oman

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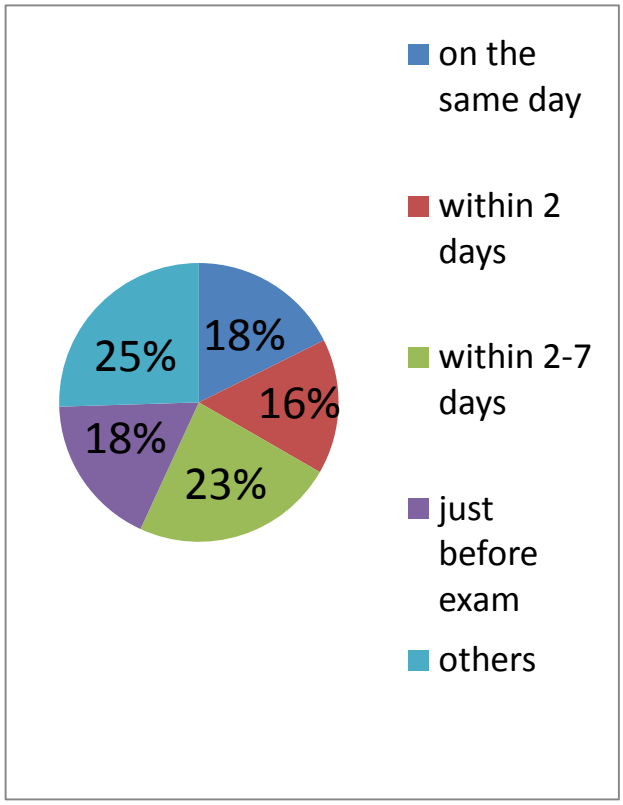
Dear Editor,

The students at Oman Medical College (OMC) are mostly Arabic speaking, with English as the medium of instruction at college and university. Since the curriculum at OMC is designed in the Western style and faculty from US lecture for a variety of courses, a good knowledge of English is essential. A variety of learning styles have previously been described and studied, with research demonstrating that the medium through which course content is disseminated may impact learning.[1] Hence, complete understanding of lecture material presented in English may become difficult for many of the students. Audio recordings of lecture material which can be accessed through the internet or downloaded to a portable media player, have been suggested to be 'an educational revolution in the making'.[2] In December 2005, Harvard became the first medical school to make its whole syllabus of lectures downloadable as MP3/4 files on the university intranet.[3] Listening to audio files of course material helped students improve their grades.[4] We therefore decided to make use of this educational tool to enhance understanding and learning of course material in medical pharmacology.

Audio recording of the lecture material using a Philips MP3 recorder was performed during regular lecture sessions and students were encouraged to listen to them. The file in MP3 format was then uploaded to the online site available to the students to access course material. The students downloaded them to an MP3 player or directly listened to them on their laptops. At the end of eight months of training an objective structured questionnaire was prepared to assess the effectiveness of usage of audio files. The questionnaire had close-ended questions as well as questions with options "strongly agree" to "strongly disagree". All students who attended pharmacology lectures took part in the survey. Results were compiled and analysed.

Eighty out of 110 students (77%) responded to the survey. 49/80 (62%) agreed that they used these audio recordings to enhance their understanding of the material in pharmacology. A high proportion of the students (83%) used their own laptops to listen to these and 10% of the students downloaded them to a mobile phone or an MP3 player. While 14% of the students listened to all the lectures, a significant number (83%) listened to selected lectures only. Lack of time was a factor for not listening to the lecture in its entirety.

Figure 1: Pie-chart showing when the students listened to the recordings



Regarding the period during which the students listened to the lectures, 18% listened to them on the same day of the lecture, 18% accessed them just before an exam and 39% of the students accessed them within seven days of the lecture. The remaining 25% listened to them whenever they liked (Figure 1). When asked how many times they accessed the files, 60% listened only once while 29% listened to them two or three times and a small number of students (11%) listened to them several times to understand the material. Of the students 84% agreed that listening to audio recordings helped them to understand and learn the lecture material in detail (Figure 2). A further 76% of the students indicated that listening to the recordings improved their understanding of medical terminologies and their language in general. Moreover 44% of the students who used the recordings agreed that repeated listening was necessary to enhance their overall knowledge of the subject. The majority of the students 46/49 (94%) who listened to these files recommended usage of this learning tool in other courses also (Figure 3). There were 38% of students who did not use the audio recordings and they had various reasons for not doing so. The major factors responsible were lack of

time (60%)[1,2] and 23% were happy with the clarity of the lectures that they did not have to listen to the audio recordings.

Figure 2: Student opinion on whether listening to audio recordings has helped them understand the lecture material

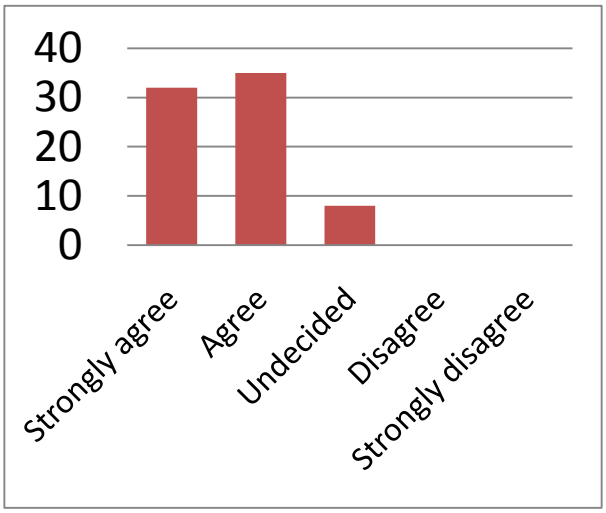
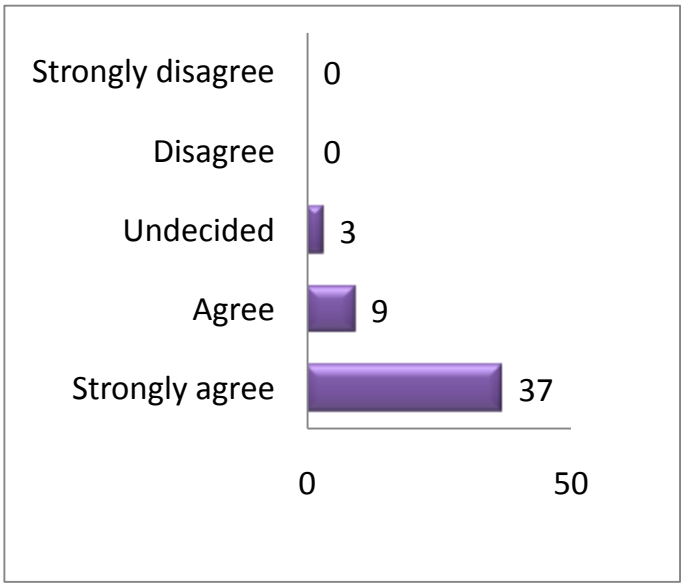


Figure 3: Student opinion on whether audio files should be made available for other courses



In order to fully understand the potential value of audio recordings as a supplementary learning tool a detailed understanding of students' experiences with the use of audio recordings is required. As medical educators, it is important in the context of a demanding curriculum to provide alternative resources and a supportive academic environment to facilitate individual success. This is especially true in this situation where the educational and cultural background is very different from the West. Furthermore, the medium of instruction and language also differs from that which is familiar and comfortable for this group of students.

Our findings are similar to reports mentioned in the literature.[1] The use of audio recordings of lecture material has definitely improved understanding and learning the pharmacology subject in this small group of students. In future it is worth studying the value of this tool in a larger population to define a relationship between the use of this educational tool and performance in assessments.

Sincerely,

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