ID: NJLM/2012/3904:1948

View Point

Pharmacy education Section

Knowledge, Attitude And Perceived Skills Before And After A Clinical Research Module

P. RAVI SHANKAR, RAJANI SHAKYA

ABSTRACT

Introduction: Kathmandu University started a three-year post-baccalaureate Doctor of Pharmacy (PharmD) program in 2010. A clinical research module was recently conducted for the first batch of students during the third semester using facilitator presentations, group activities, presentations and audience elicitation sessions to discuss different aspects. The present study was conducted to study participant's perception of their knowledge, attitudes and perceived skills with regard to clinical research before and after the module and also obtain suggestions for further ther improvement.

Methods: The study was conducted in November 2011. 12 of the 13 students participated. Perceptions were obtained using a retrospective-pre questionnaire. Gender was noted and responses were coded according to predetermined scale. Knowledge, attitudes and perceived skills scores were calculated before and after the module. The normality of responses was studied using the one-sample Kolmogorov-Smirnov test and the data was normally distributed. The scores before and after the module were compared using paired samples t-test ($p < 0.05$).

Results: Eight of the twelve respondents (66.6%) were female and four were males. The scores of all individual statements increased after the module. The mean knowledge, attitude and perceived skills scores and the total score increased significantly after the module. The module strengths were group activity and assignments. Internship in a clinical research organization was recommended by all participants.

Conclusions: Student's knowledge, attitudes and perceived skills about different areas significantly improved at the conclusion of the module. The skills scores as perceived by the students were low. Suggestions can be considered while planning future courses.

Key Words: Attitudes, Clinical research, Knowledge, Nepal, Perceived skills

INTRODUCTION

Pharmacists are trained to have extensive knowledge about different aspects of drug therapy and pharmacotherapeutics [1]. They have the ability to provide expertise in many areas of research related to drugs. However, recent studies state that the profession of pharmacy may be underutilizing opportunities for clinical research [2,3]. The American College of Clinical Pharmacy (AACP) white paper outlined the critical need for pharmacists to expand their training in clinical and translational research [1].

Nepal is a developing country in South Asia situated between China and India. Pharmacy education in Nepal is a recent development and di¬ploma in pharmacy was started by the Institute of Medicine (IOM) in 1972 and a Bachelor of Pharmacy (BPharm) was started by Kathmandu University (KU) in 1994 [4]. KU started a three year post-baccalaureate Doctor of Pharmacy (Pharm D) program in 2010. The program has one and half years of basic modules on pharmacotherapeutics of various systems, clinical pharmacy practice, biostatistics and research methodology, clinical pharmacokinetics etc. along with clinical rotation in different departments of the KU teaching hospital,followed by a 6 months project work. Final year students go for a specialization internship in the hospital allotted by the university. Accompanying clinicians on ward rounds, providing information about medicines and research and publications can be activities for pharmacists in teaching hospitals in Nepalin addition to dispensing and counseling [5]. A recent paper has outlined major challenges for the PharmD program in program in Nepal which emphasizes patient care and concentrates on pharmacy practice and pharmaceutical care [4].

Nepal, a developing country has limited resources and starting a super-specialty hospital with ward-based pharmaceutical care provision, well-structured curriculum, an evidence-

based critical literature database, and conducting clinical research projects is a challenging task [4]. Also in Nepal the profession of pharmacy has only recently started emphasizing the provision of pharmaceutical care. Tertiary care teaching hospitals affiliated to medical schools can provide an ideal practice setting but unfortunately most teaching hospitals in Nepal contract out the hospital pharmacy and related services to the highest bidder [6]. This can hamper the rational use of medicines in the hospital and the development of pharmacy practice.

Recently global clinical trials have increased significantly in the Asia-Pacific region and the growth spurt has been led by Japan, Taiwan, Korea and India [7]. Clinical trial pharmacists have an important role in clinical trials. Clinical trials are a complex undertaking involving diverse individuals from different fields. Pharmacists can undertake activities like investigational product (IP) receipt, IP handling, IP storage, IP dispensing, IP return, IP destruction and IP accountability. They can also have an important role in ensuring the safety of the subjects by identifying and reporting adverse drug events. Pharmacists can also work as clinical research coordinators or clinical research associates in a trial [8].

The PharmD curriculum of KU has a module on clinical research including the new drug development process and pharmacovigilance. In Nepal the pharmaceutical industry at present does not develop new drugs in the country. The clinical trials and research industry is poorly developed. PharmDs could play an important role in clinical research and clinical trials once more clinical trials begin to be conducted in the country. A module on clinical research was recently conducted by the first author for thirteen second year (third semester) PharmD students of KU. There was a total of 34 hour activity-based sessions, assignments and a formal two and half hour written assessment at the end of the module. The module used facilitator tations, group activities, student presentations and audience elicitation sessions to discuss different aspects of clinical research. The thirteen students were divided into two small groups which were kept constant throughout the module. A whiteboard, LCD projector, flip charts were available in the room where sessions were conducted.

The present study was conducted with the following objectives:

[a] Study participant's perception of their knowledge, attitudes and perceived skills with regard to clinical research before and after the module.

[b] Obtain their perceptions about the strengths of the module, suggestions for improvement and for translating the module into practice and

[c] Note any differences in perceptions according to the gender of the participants.

METHODS

The study was conducted in November 2011 among PharmD (Doctorate of Pharmacy) students of Kathmandu University, Nepal. At the end of the clinical research module participants were administered a retrospective-pre questionnaire to obtain their perceptions about knowledge, attitudes and perceived skills about different areas covered during the module. The topics to be included, statements and skills to be identified were decided by the authors through consensus and review of the PharmD curriculum in the area of clinical research. Information about 2 perceived strengths of the session, 2 suggest for further improvement and two suggestions for translating the session into practice were also noted. The questionnaire was reviewed for language and ease of comprehension by 2 postgraduate pharmacists not involved in the study.

Participants were explained the objectives of the study, possible benefits and other issues and were invited to participate. Written informed consent was obtained from all participants. The gender of the participants was noted. Participants were asked to indicate in each subject area their level of knowledge before and after the module using one of three possible responses, 'No idea', 'Have a vague idea' and 'Clear idea'.In a retrospective-pre questionnaire information is collected only once and the participants are asked about their perceived level of knowledge, attitudes and skills at the beginning of and at the end of the module. 'No idea' was scored as 1, 'Have a vague idea' as 2 and 'Clear idea' as 3. For attitudes, participants' degree of agreement with a set of statements was noted using the following scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree with the particular statement. For perceived skills, the scoring system used was 1 = 'Not confident', 2 = 'Somewhat confident', 3 = 'Very confident' and 4 = 'Will be able to do independently in future'. Reliability analysis of the data was carried out using Cronbach's alpha. The alpha value was 0.743. The normality of responses was studied using the one-sample Kolmogorov-Smirnov test. The data was normally distributed. Hence the mean total knowledge, attitude and skills scores and the total scores were calculated. The scores before and after the module were compared using paired samples t-test. A p value less than 0.05 was taken as statistically significant.

The frequency of comments about strengths of the module, suggestions for further improvement, and suggestions for converting the module into practice were noted.

RESULTS

A total of twelve of the thirteen students (92.3%) provided feedback on the module. 8 out of 12 respondents (66.6%)

and 4 were male. [Table/Fig-1] shows the mean scores of individual statements before and after the module. All scores increased after the module. [Table/Fig-2] shows the mean knowledge, attitudes and perceived skills scores and the total score before and after the module. All scores significantly improved after the module.

Statement	Mean score (before the module)	Mean Score (after the module)
Knowledge scores (maximum 3):		
Process of new drug development	1.92	2.83
Randomization & blinding in clinical trials (CT)	2.08	2.83
Ethical issues in clinical research	1.67	2.92
Use of placebos in clinical trials	2.17	2.92
Phase I and III studies	1.92	2.67
Postmarketing surveillance	2.00	2.92
Roles of sponsor, contract research organization (CRO), investigators in CT	1.00	2.83
Good clinical research practice	1.33	2.67
New drug application (NDA) and Abbreviated New Drug Application (ANDA)	1.00	2.67
Data management in CT	1.25	2.50
Attitude scores (Maximum 5):		
New drug development is a long & expensive process.	4.75	4.92
Blinding reduces bias in CT.	4.17	4.75
Doing CT in developing countries raises more ethical issues.	3.42	4.25
Using a placebo in a CT can be unethical sometimes.	3.25	4.67
Phase III studies approximates the use of the drug in practice.	3.75	4.58
Postmarketing surveillance is not important.	3.92	4.50
A sponsor can transfer legal responsibility for the trial to a CRO.	3.00	4.33
Good clinical practice I feel is a waste of time.	4.00	5.00
ANDA is an unethical shortcut procedure for generics.	2.92	3.17
Data management is an important process in a CT.	3.83	4.92
Perceived skills (Maximum score 4)		
New drug development	1.25	2.33
Writing a clinical trial protocol	1.17	2.83
Considering ethical issues while doing clinical research.	1.25	3.00
Conducting phase I studies	1.00	1.83
Reporting adverse drug reactions (ADRs) occurring during CT	1.92	3.25
Drafting an agreement with investigators	1.17	2.17
Designing a protocol according to International Conference of Harmonization Good Clinical Practice (ICH GCP)	1.08	2.75
Managing data generated during clinical research	1.17	2.17
Conducting clinical research in Nepal	1.08	2.33

[Table/Fig-1]: Mean scores of individual statements before and after the module

Characteristic	Before the module	After the module	P value
Knowledge (Maximum score 30)	16.33	27.75	0.000
Attitudes (Maximum score 50)	37.00	45.08	0.000
Perceived skills (Maximum score 36)	11.08	22.67	0.000
Total (Maximum score 116)	64.42	95.5	0.000

[Table/Fig-2]: Mean knowledge, attitudes, perceived skills and total scores before and after the module

Among the commonly mentioned strengths of the module Among the strengths of the module were group activity and assignments (6 respondents), participatory approach (4 respondents), activities on designing trials (4 respondents) and provided an idea about the drug development process (3 respondents). Among the suggestions for further improvement were practical exposure to clinical research, more group activities and use of video clips during the sessions. Among

the suggestions to translate research into practice were exposure to real practice situations (7 respondents), collaboration with clinical research organizations (3 respondents) and involvement in ADR reporting and postmarketing surveillance (1 respondent). Among other comments were a request for internship in clinical research organizations, more time should be devoted to this topic, and participants liked the friendly learning environment.

DISCUSSION

Overall student perception about the module was positive. The mean scores in individual learning areas increased after the module. The mean knowledge, attitude, skills and total scores increased significantly after the module. Participants were in favor of internship in a clinical research center or organization to apply their knowledge into practice and know the practical aspects of clinical trials [9].

At Purdue University in the United States a two credit hour elective course in clinical research was offered to second year and 3rd year PharmD students [1]. 15 classes of 2 hour sessions were conducted using a mixture of lectures, workshops and in class presentations by students. The authors concluded that students who pursued the elective had greater familiarity with research related topics, training options and career opportunities. They had greater interest in pursuing a career in clinical research. In Nepal clinical research is a very new subject area and to the best of the authors' knowledge a formal module on clinical research has not previously been offered in the country. A certain amount of training has been provided to doctors and other health professionals who had been involved in clinical trials. The module broadly followed the PharmD curriculum of KU. [Table/Fig-3] lists the topics covered during the module.

Session	Topic	Areas covered
One	Drug development process	Drug development process, pre-clinical and clinical phases, lead optimization, toxicity testing
Two	Drug development process 2 & Ethics	Investigational New Drug (IND) application, phases of drug development and clinical trials, ethics, guidelines of Nepal Health Research Council
Three	Introduction to clinical trials	Brief history of clinical trials, randomization and masking, ethical issues, data monitoring, general principles of clinical trials, trial designs
Four	Phase I studies and pharmacokinetics	Relationship of phase I studies to animal studies, selection of volunteers, informed consent, place, insurance, protocol, single rising dose and repeated administration
Five	Postmarketing surveillance and phase IV studies	Postmarketing surveillance, clinical trials and drug safety, spontaneous reporting of ADRs, case control and cohort studies, designing an ADR reporting form, seeding studies, Introduction to the protocol
Six	Ethical issues in clinical research	Ethical principles, informed consent, informed consent form, institutional review board, national guidelines for clinical trials, vulnerable groups, responsibilities
Seven	Good clinical practice	What is GCP? Initiatives towards GCP, WHO handbook on GCP, ICH GCP, Principles of ICH GCP, medical care of trial subjects, Case record forms (CRFs), multicentric trials, essential documents
Eight	Responsibilities of various individuals in a clinical trial	Responsibilities of sponsor, manufacturing, packaging, coding of investigational products, ADR reporting, responsibilities of investigator, monitor and clinical research associate
Nine	Data management in clinical research	Data generated during a clinical trial, data management process, managing and tracking CRFs, data review and clarification, validation, data queries, query tracking and resolution, quality assurance, archiving
Ten	Drug regulatory environments	Historical background of drug regulation, European commission, United Kingdom, Nepal, United States, Japan, European medicines agency, Central drugs standard control organization, control of clinical trials, end points in clinical research
Eleven	Phase III clinical trials	Phase III trials, objectives, subtypes, study population, study design, publication guidelines for clinical trials, Institutional Review Board (IRB) clearance, monitoring, initiation meeting, other issues

Twelve	Miscellaneous issues	ANDA application, drug master file, type 1 and type 2 errors, systematic reviews, confidentiality in clinical research, ghost writing, negative results in clinical trials, clinical trial in the Khumbu (Nepal), phase II clinical trials
Thirteen	Concluding session	Presentation of concept maps about the module, translating knowledge into practice, strength, weakness, opportunity, threat SWOT analysis on clinical research in Nepal, reflections on the module, presentations on systematic reviews

[Table/Fig-3]: Topics covered during the clinical research module

All sessions used a mixture of facilitator presentations, audience elicitation sessions, group work and student presentations. Reading assignments and presentations were used widely. Before the module student's knowledge of issues like the process of new drug development, ethical issues in clinical research, phase I and phase III studies, role of sponsors, contract research organizations and investigators in clinical trials, good clinical research practice, new drug application, and data management in clinical trials was particularly low. These improved after the module.

In the US, a research elective was conducted to engage pharmacy students in research activities. Hands-on learning activities, including discussions on experimental design, development of collective diagrams, research planning, results analysis, data evaluation, and presentation design, were used during the course as team-based learning experiences. Training in research has been stated as an important objective of PharmD courses. During their BPharm course KU students do a six months project work in different areas (pharmacy practice, formulations, pharmacognosy etc) and their work has been published in different national and international journals. And also during PharmD (Postbacc) there is a six months period in fourth semester allotted for doing research work.

The PharmD students had done their Bachelors training from different universities within and outside the country. The emphasis on research during the Bachelor's course varies. Pokhara University requires all students to develop and carry out a research project during the eighth semester of the Bachelor of Pharmacy (BPharm) course [10]. Many students have published their projects in different journals in Nepal and abroad.

In our study knowledge scores as perceived by the students at the end of the module were satisfactory with a mean score of 27.75 out of a maximum possible score of 30. The attitudes score was also good (mean score 45.08; maximum score 50). The skills score as perceived by the students was low (mean score 22.67 and maximum possible score 36). A major problem is that clinical research is a new discipline in the country and has not been developed. There are at present no places within the country where students can be sent for practical training in clinical research. With this limitation development of practical skills may be difficult. The authors are exploring the possibility of arranging internship for students with organizations in the neighboring country of India. This may be more difficult in terms of logistics and the costs involved.

The clinical research module is a 2 credit course and can only serve as an introduction to a complex topic. More hours should be allotted and facilities for practical training developed. Developing clinical research in Nepal can be a challenge. A major limitation could be Nepal is not a big market for medicines and pharmaceuticals. Also facilities will have to be built up from scratch. The benefit could be the genetic diversity of the Nepalese population with different ethnic and other groups being concentrated in a small geographic area.

Our study had limitations. The number of students in the course was small but 12 out of 13 students had participated in the study. The retrospective-pre nature of the questionnaire carries the risk of student's knowledge, attitudes and skills at the end of the course influencing their perceptions about these at the beginning of the module. The questionnaire used was developed by the authors and was not validated. Student feedback was collected only using a questionnaire and other methods were not employed.

CONCLUSION

Student's knowledge, attitudes and skills about different areas of clinical research significantly improved at the conclusion of an activity-based module conducted in small groups. The skills scores as perceived by the students at the end of the module were low despite significant improvement. Practical training in clinical research organizations and devoting more time to the topic were suggested. These can be considered while planning clinical research modules for the next batch of PharmD students.

ACKNOWLEDGEMENT

The authors would like to acknowledge the help of the Kathmandu University School of Management, Balkumari, Lalitpur for providing rooms for conducting the sessions. They would like to acknowledge the help of Dr. Medha Joshi, Head, Quality Assurance, Health Sciences, Gokula Education Founda-

tion (Medical), Bangalore, India for her intellectual resources. They thank all students who participated in the study.

REFERENCES

[1] Overholser BR, Foster DR, Henry JR, Plake KS, Sowinski KM. The influence of an elective introductory clinical research course on pharmacy student interest in pursuing research-based careers. *Am J Pharm Educ*. 2010;74(9):165.

[2] Fagan SC, Touchette D, Smith JA, et al. The state of science and research in clinical pharmacy. *Pharmacotherapy.* 2006;26:1027-40.

[3] Robles JR, Youmans SL, Byrd DC, Polk RE. Perceived barriers to scholarship and research among pharmacy practice faculty: survey report from the AACP Scholarship/Research Faculty Development Task Force. *Am J Pharm Educ*. 2009;73(1):Article 17.

[4] Bhuvan KC, Subish P, Mohamed Izham MI. PharmD education in Nepal: The challenges ahead. *Am J Pharm Educ*. 2011;75(2):38c.

[5] Bhandari DR, Subish P, Mishra P, Alam K. Do pharmacists have a scope in south Asian hospitals? An experience from Nepal. *Pharmacologyonline* (Newsletter) 2006;3:146–55.

[6] Thapa HS, Shrestha RK, Shankar PR. Hospital pharmacies should be run by the hospital under the supervision of the Medicine and Therapeutics committee. *Journal of Medicine Use in Developing Countries* 2009;1:52-9.

[7] La HO, Choi S, Lee SK, Ryu BE, Han OY. *Current status and future directions for clinical trials pharmacy*. Yakugaku Zasshi. 2011;131:969-75.

[8] Ganachari MS, Shah SP, Zalavadia NM. Pharmacist: A crucial part of clinical Research. *Journal of Pharmacy Research* 2010;3:444-50.

[9] Ramsauer VP. An elective course to engage pharmacy students in research activities. *Am J Pharm Educ*. 2011;75(7):Article 138.

[10] Pokhara University. *Syllabus Bachelor of Pharmaceutical Sciences* (BPharm). Pokhara: 2005.

AUTHOR(S):

1. Dr. P. Ravi Shankar
2. Dr. Rajani Shakya

PARTICULARS OF CONTRIBUTORS:

1. Corresponding Author,
2. Assistant Professor, Department of Pharmacy, Kathmandu University.

INSTITUTION TO WHICH THIS STUDY IS ASSOCIATED WITH:

Kathmandu University.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. P. Ravi Shankar
KIST Medical College, P.O. Box 14142,
Kathmandu, Nepal.
Ph: 977-1-5201680, Fax: 977-1-5201496
Email: ravi.dr.shankar@gmail.com

FINANCIAL OR OTHER COMPETING INTERESTS:
None.

Date of Submission: **Jan 03, 2012**
Date of Peer Review: **Mar 12, 2012**
Date of Acceptance: **Apr 23, 2012**
Date of Publishing: **Jun 30, 2012**