

# Learning sessions on critical appraisal of randomised clinical trials: Student feedback

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## Abstract

Critical appraisal skills are essential for students to become rational prescribers. Evidence-based medicine requires the ability to appraise articles critically. The Manipal College of Medical Sciences, Pokhara, Nepal mainly admits students from Nepal, India and Sri Lanka for the undergraduate medical (MBBS) course. Pharmacology is taught during the first four semesters. The department recently started learning sessions on the critical analysis of published randomized clinical trials for the third and fourth semester students. Student feedback about the sessions was obtained using a questionnaire. Basic demographic information about the respondents was collected and the degree of agreement with a set of 16 statements was noted. A total of 117 students participated (overall response rate was 81.8%). Nepalese and Indians were the major nationalities. The median score was 54. No significant difference in scores was seen among different subgroups. Student opinion about the sessions was positive. Lack of knowledge of statistics among the students was a limitation. A student elective on reading and writing science can be considered.

**Keywords:** *Critical appraisal, Medical students, Randomized clinical trial*

## Introduction

In the early 1990s the concept of evidence-based medicine (EBM) started to gain importance. Evidence-based medicine (EBM) states that well-formulated questions about medical management can be answered by carrying out randomized, high quality, controlled clinical trials, tracing all the available evidence, systematically analyzing the evidence, determining the validity and usefulness of the evidence and applying the evidence to the management of the individual patient (Aronson, 2006).

EBM has been defined as 'the conscientious, explicit and judicious use of current evidence in making decisions about the care of individual patients' (Sackett, 1996). A critical skill for the practice of EBM is the ability to appraise articles critically (Sackett & Rosenberg, 1995). EBM has been included as a part of the undergraduate medical curriculum in medical schools all over the world (Wanvarie, 2006; Weberschock, 2005; Holloway, 2004). In Nepal, however, the concept of EBM is still in its infancy.

Critical appraisal skills are crucial for students to become rational prescribers (Hogerzeil and Barnes, 2001). Medical students should be equipped with skills to critically review not only medical literature but also promotional material and the prescribing patterns of fellow clinicians (Hogerzeil and Barnes, 2001). The department of pharmacology at the

Manipal College of Medical Sciences teaches medical students to critically analyze drug advertisements and other promotional material (Giri & Shankar, 2005). The department has been able to introduce students to the concept of rational use of medicines (RUM) and influence students during the first two years of their training but the influence gets eroded once students enter the clinical phase of training (Shankar, 2007).

## Learning design

The Manipal College of Medical Sciences (MCOMS), Pokhara, Nepal is affiliated to the Kathmandu University for the undergraduate medical (MBBS) course and mainly admits students from Nepal, India and Sri Lanka. A few students are from other countries. This year, the department started learning sessions on the critical analysis of published randomized clinical trials for the third and fourth semester students. The students were informed of the topic of the learning session a week in advance.

The faculty members (PRS and PS) introduced the students to published scientific research papers. The different parts of a paper, Abstract, Introduction, Materials and Methods, Results and Discussion were briefly discussed. The IMRaD format was highlighted. The tips for efficient reading described in

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'Guide to good prescribing' were highlighted. Then we discussed with the students, the various phases of clinical trials and the process of new drug development and its progress through pre clinical and clinical testing. The gold standard of the randomized, double-blind, placebo-controlled, clinical trial was discussed. With the involvement of the students a checklist to assess published clinical trials was drawn up.

Each group was given a published clinical trial from a scientific journal to analyze using the developed checklist. The coursework given to the students was to familiarize themselves with all the trials given to the various groups. The student group of 37 or 38 students was divided into five groups of 7 or 8 students each for the session.

In the next practical session, the various groups first described their allotted trial in brief. Then they analyzed the strengths and weaknesses of the trial using the checklist. Then the discussion was opened to the house. After all the five groups presented their findings, the facilitators elaborated points which they felt were not covered adequately.

Student feedback about the sessions was obtained using a questionnaire. Basic demographic information was obtained and student attitude towards the sessions was studied.

## Methods

At the end of the second learning session student feedback was collected using a questionnaire. The objectives of the study were explained to students and they were invited to participate. Verbal consent was obtained from all participants.

Basic demographic information of gender, nationality, method of financing of medical education, occupation of parents, semester of study and place of family residence were noted. The degree of agreement of the respondents with a set of 16 statements was noted using a modified Likert-type scale. The questionnaire used is shown in Appendix 1.

The total score was calculated by adding the scores of the individual statements. Statements 3, 5, 6, 7 and 12 were negative and their scores were reversed while calculating the total score. The median total score was calculated. The median scores were compared among different subgroups of respondents. Mann-Whitney test was used for dichotomous variables and Kruskal-Wallis test for the others. A p value less than 0.05 was taken as statistically significant.

Free text comments from the respondents regarding the sessions were elicited and the common comments were noted.

## Results

A total of 117 students participated in the study. Fifty two of the 75 third semester (69.3%) and 64 of the 68 fourth semester (94.1%) students participated. The overall response rate was 81.8%. Seventy one students were male. Nepalese and Indians were the major nationalities. The majority of students was self-financing, did not have doctor parents and were from urban areas.

The median score was 54 and the interquartile range was 6. The maximum possible score was 80. Table I shows the

median scores of different subgroups of respondents. The median score of the Sri Lankans was lower compared to other nationalities. No other significant difference in scores was seen between different subgroups.

**Table I: Median total scores of respondents according to demographic characteristics**

Characteristic		Median score (interquartile range)	p value
<b>Gender</b>	Male (n = 71)	54 (6)	0.510
	Female (n = 45)	54 (7)	
<b>Nationality</b>	Nepalese (n = 45)	54 (5.5)	0.028
	Indian (n = 66)	53 (7.25)	
	Sri Lankan (n = 4)	39.5 (20.5)	
<b>Financing</b>	Scholarship (n= 23)	54 (4)	0.409
	Self-financing (n = 84)	53.5 (7.75)	
<b>Occupation of parents</b>	Both doctors (n = 12)	53 (9.5)	0.974
	One doctor (n = 20)	53.5 (9.5)	
	None doctors (n = 77)	54 (5.5)	
<b>Semester</b>	Third (n = 52)	54 (6.75)	0.822
	Fourth (n = 64)	53 (5.75)	
<b>Place of family residence</b>	Urban (n = 100)	54 (6)	0.239
	Rural (n = 13)	52 (7.5)	

Table II shows the median scores of individual statements. The students were of the opinion that the sessions made them aware of the technique of critical analysis of a journal article. They agreed that clinical research is a big growth area in South Asia. They were in agreement with the statement that the introduction is the first section to look at when reading a published trial. The students were not in agreement with the statement that doctors do not require knowledge of statistics. They also showed a high degree of agreement with Statement 9 that the abstract is the first part of a research paper to be read. They were in favour of similar sessions in the future.

The common free text comments were grouped together. The students were not in favour of this exercise being included in the assessment examination. They were in favour however, of more such interactive, interesting and short PBL sessions.

## Discussion

The overall student opinion regarding the sessions was positive. The students were in favour of similar sessions in the future.

In our institution, the undergraduate medical (MBBS) course is divided into nine semesters. Pharmacology is taught during the first four semesters as already detailed. Clinical subjects are taught during the last five semesters. Community medicine learning starts from the first semester and continues till the seventh semester. The compulsory internship training of one years duration follows the ninth semester.

The medical literature is a commonly used information source

for students and practicing health care professionals trying to keep up-to-date. Critical appraisal skills are important for medical students (Hogerzeil and Barnes, 2001). Medical literature must be analyzed critically to confirm the validity of the results and conclusions. Students must learn to form their own conclusions after careful, critical review and must learn to challenge exaggerated and unjustified claims (Hogerzeil and Barnes, 2001). The skill of efficient reading has been emphasized in the 'Guide to good prescribing' (De Vries, 1994). The students should be taught to identify at an early stage articles which are worth reading.

**Table II: Median scores of individual statements**

Statement Number	Median Score (Inter-quartile range)	Statement Number	Median Score (Inter-quartile range)
One	4 (1)	Nine	4 (2)
Two	4 (1)	Ten	4 (0)
Three	4 (1)	Eleven	4 (1)
Four	3(1)	Twelve	2 (1)
Five	2 (1)	Thirteen	4 (1)
Six	3 (1)	Fourteen	3 (1)
Seven	3 (1)	Fifteen	3 (1)
Eight	4 (1)	Sixteen	4 (1)

\*The scores of statements 3, 5, 6, 7 and 12 were reversed while calculating the total score

The steps of efficient reading were discussed with the students. The first step is to look at the title of the paper to decide whether it would be of interest to the reader. Then the abstract should be read. If the reader thinks the paper may be of interest then the Materials and Methods section should be considered. The method of the study is important in deciding about the validity of the findings.

We had instructed the respondents to respond to all the statements in the questionnaire. However, two students did not denote their agreement with certain statements. Some respondents did not fill in all the demographic details. If the respondent did not indicate his/her degree of agreement with a particular statement we gave the statement a value of 0. This may have accounted for the lower score of the Sri Lankan students regarding the sessions.

A major problem was the lack of knowledge of biostatistics

among the respondents. The students are only taught the measures of central tendency and the measures of dispersion and the remainder of the biostatistics course is covered in the seventh semester.

The students agreed with the statement 'The sessions made me aware of the technique of critical analysis of a journal article'. However, we spent a lot of time discussing the basic parts of a scientific paper and of the methodology of a randomized trial. The two sessions only served as an introduction to the complex topic of critical analysis of information. We discussed only clinical trials and did not consider meta analysis and systematic review which are important means of synthesizing information. The students' agreement with Statement 3 is a matter of concern. We discussed the steps of efficient reading with the students and emphasized that they should first look at the Abstract and then the Methods section. However, students tended to agree with Statement 9. These results are conflicting. We plan to emphasize critical analysis of clinical trials again in a future session.

The students did not agree with the first point that conclusions from clinical trials carried out in western countries can be applied to South Asian patients. The Indian clinical trials market of US\$ 30-35 million is projected to grow 8-10 times to US\$ 250-300 million by 2010 (Borfitz, 2003). In 2005, the government of India enacted a rule that allows foreign pharmaceutical companies to conduct trials of new drugs in India at the same time that trials of the same phase are being conducted in other countries (Nundy & Gulhati, 2005). Nepal may consider the possibility of making clinical trials of newly introduced drugs in a Nepalese population necessary before giving marketing permission.

The students were not in agreement that most clinical trials in South Asia are conducted to high standards. Low cost and easy availability of patients are major reasons for the growth of the clinical trial industry. Mechanisms to safeguard the interests of patients should be developed. The sessions made the students aware of the fact that published clinical trials in reputed journals may have flaws. The issue of the pharmaceutical industry and the sponsors influencing clinical trials was also brought out. The concept of 'conflict of interest' was also introduced to the students.

The respondents agreed that the session was informative and interesting. The importance of statistics for medical doctors was also highlighted. To make medical students and future doctors more effective researchers, many medical schools have started undergraduate research electives. In Canada, the Queen's University conducts a mandatory critical enquiry elective in the second year. The elective increased the number of students expressing an interest in pursuing a research career (Houlden, 2004). Other benefits were development of critical appraisal skills and information literacy (Houlden, 2004). A mandatory course in teaching students to read and write science is taught at the University of Zagreb School of Medicine in Croatia (Marusic & Marusic, 2003).

Critical appraisal and research are being encouraged in the medical curriculum. The concept of critical appraisal should be incorporated into the problem-based learning (PBL) system (Karina & Nooriah, 2002). The introduction of the 'journal

club' concept can be helpful (Houlden, 2004). Journal clubs and letter writing exercises have been used in a medical school in the United Kingdom to teach critical appraisal (Edwards, 2001). In Cape Town, South Africa two students present their joint critical appraisal of a relevant article from a reputable, peer reviewed journal at the beginning of each pharmacology tutorial (Hogerzeil & Barnes, 2001).

As already discussed statistics is important for critical analysis. Medical statistics courses should focus on critical appraisal skills rather than on the ability to analyze data (Karina & Nooriah, 2002). Problem based small groups, data interpretation exercises and objective structured clinical examinations can be more productive. A rethinking of the teaching of statistics in our institution can be considered.

### Limitations

Student opinion was obtained using a questionnaire. Detailed information on student opinion was not collected. Student knowledge of the topic following the sessions was measured using a few statements in the questionnaire. Objective assessment of knowledge was not carried out. The response rate of the third semester was low. Certain respondents did not complete all the responses and did not provide certain demographic details.

### Conclusions

Student opinion about the sessions was positive. The sessions served to introduce students to critical appraisal. Lack of knowledge of statistics among students was a major problem in teaching critical appraisal. Restructuring of the teaching of statistics can be considered with more of the subject being taught during the second semester. A student elective on research methodology and critical analysis can be a possibility.

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Appendix: Questionnaire used to elicit student response about the sessions

Sex:

Nationality:

Method of financing:

Both parents doctor/One doctor/None doctor

Semester:

Urban/Rural:

*For the following statements score using the following key (1 = strongly disagree with the statement, 2= disagree with the statement, 3= neutral, 4= agree with the statement, 5= strongly agrees with the statement.) Use whole numbers only.*

1. The sessions made me aware of the technique of critical analysis of a journal article.
2. Clinical research is a big growth area in South Asia.
3. When reading a published clinical trial I will look at the introduction section first.
4. Scientific papers follow the IMRaD format.
5. The conclusions from clinical trials carried out in the west can be applied to patients in South Asia.
6. In South Asia most clinical trials are carried out to high ethical standards.
7. The published clinical trials in medical journals are of high quality
8. The pharmaceutical industry can influence clinical trials.
9. The abstract is the first part of a research paper to be read
10. The session was informative and interesting.
11. Doctors should learn to critically analyze journal articles.
12. Doctors do not require knowledge of statistics.
13. Randomization is an important procedure in a clinical trial.
14. The facilitators performed their roles effectively.
15. Post-marketing surveillance is a type of clinical trial.
16. I would welcome similar sessions in the future.