

### **Clinical research methodology. A course report**

The Second Annual Intensive Course on Clinical Research Methodology organized by the Research Committee of the Department of Surgery in collaboration with the Medical Education Center, King Saud University Medical College and the Saudi Medical Journal was held in King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia on 9th January 2003. Similar to last year's activity, this well-attended course focused on how to plan and perform a clinical research study and how to write and present a scientific report. The program provided a comprehensive review of several relevant topics and as evidenced by the participation of the audience, it aroused a great deal of interest.

Professor Basim A. Yaqub reviewed the uniform requirements for submission to biomedical journals outlined by the International Committee of Medical Journal Editors in Vancouver, Canada in 1979 and highlighted its latest update in 1997. He, also, showed how the impact factor as a citation measure has moved, recently, from being an obscure bibliometric indicator to become the chief quantitative measure of the quality of a journal. However, other issues may be considered depending on type of publication, speed of publication and the real objectives of the publishing author. On how to prepare a manuscript and ensure a better chance of its acceptance, Professor Yaqub gave the advice not to repeat the abstract in introduction and discussion. The introduction should discuss the literature and highlight the researcher's queries. In the results section, overuse of tables should be avoided; tables are used to simplify complex data. Short data do not need tables and should be included in the text. Bar and pie charts should only be used if they cannot be accommodated as tables. Data in tables and figures should not be repeated in the results section. Conclusions ought to be linked with the goals of the study but avoid unqualified statements and conclusions if not completely supported by data. Particularly, authors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such. Appropriate conclusion and recommendations should be your final goal in any publication. In another contribution, Professor Yaqub emphasized that, in medical literature, the reader should look critically at all publications and recognize its values and limitations. The conclusions coming from clinical reviews (reviews of patient notes) and meta-analysis reviews (reviews of all previously published studies) should be interpreted carefully as

they deal with heterogeneous data; trends rather than firm conclusions should be drawn out of these studies. Similarly, authoritative recommendations coming from scientific reviews (usually written by a researcher of wide experience and publications on a controversial topic) are usually biased and depend on the author experience and selectivity of the data.

Professor Mansour Al-Nozha gave a comprehensive review of his experience in planning, designing and conducting an extensive multidisciplinary community-based epidemiological and multi-centered hospital study sponsored by King Abdul-Aziz City for Science and Technology aiming at establishing the prevalence of coronary artery disease and its risk factors in the Saudi population. The presentation emphasized the importance of an initial feasibility study and the need for proper organization with meticulous attention to all details together with adequate liaison between different research teams in different disciplines with regular updating and progress-evaluation meetings.

In his comprehensive talk on who should qualify for authorship in medical publications, Professor Abdel Galil Abdel-Gader classified authors into 2 categories: firstly those who qualify for authorship being the key persons responsible for the article and fulfilling the 3 principles explained by the International Committee of Medical Journal Editors known as the Vancouver Group (hence this category of persons can be described as Vancouver Group positive) and, secondly, those who do not qualify (Vancouver Group negative) but are considered for acknowledgment. However, concern started to increase, recently, about the number of authors who do not meet these strict criteria for authorship (substantial contribution to: 1. the idea and design or analysis and interpretation of data, 2. drafting the article or revising it critically for important intellectual content and 3. final approval of the version to be published). The need, thus, arose for a new definition for who qualifies for authorship, as the existing strict definition of what constitutes authorship is becoming unworkable. Consequently, a conference on authorship in biomedical science was held in Nottingham, United Kingdom in 1996. The Editors of Lancet followed by BMJ suggested abandoning the Vancouver Group definition and instead introduced the concept of "contributorship". Contributors are defined as those who "have added usefully to the work." Contributors should decide "who did what" in a written signed statement. Contributors should accept credit and accountability for: the idea of the research, literature search, design of the research project, collecting and analyzing data, interpretation of results and writing the paper. Prof. Abdel-Gader concluded his interesting presentation by prescribing a blend of science, honesty and high moral standards as a remedy which could work better than any guidelines or restrictions.

In the time allocated for biostatistics, Dr. Ashry Gad Muhammad enlightened the audience on how to plan a case/control study classifying it into exploratory type, particularly useful at the early stage of inquiry for the generation of research hypothesis and explanatory type to test specific cause and effect relationships where we begin with determination of disease status and then trace the subjects backwards in time for prior exposure history. In the selection of cases he advised researchers to choose incident (newly diagnosed) cases where exposure is recent; hence, easy to recall and also where the etiological milieu is relatively homogeneous and we can avoid the possibility that in long term survivors the exposure to the characteristic may occur after the onset of the disease. The selection of control group(s), whether by matching for relevant criteria (pair-wise or frequency matching) or through random or stratified sampling, should be carefully carried out to select persons who do not have the specified disease condition in order to obtain estimates of the frequency of the attribute or risk factor for comparison with its frequency among cases. The comparison is estimated by means of the odds ratio, which is the ratio of odds of exposure among diseased to the odds of exposure among controls.

Regarding developing the skills needed for presenting scientific papers, Dr. Mamoun Kremli updated the audience with a comprehensive practical guide to digital photography. The presentation vividly showed the importance of digitalizing old audio visual collections (35 mm slides, photographic prints or x-ray films). With hardly any need for extra space, this will achieve a far better storage capacity, more superior quality, easier organization and greater resourcefulness. Detailed advice was given on different types of scanners and digital cameras available for that purpose and for acquiring fresh digital images. The review also included image-management software, different storage media, card readers and inkjet printers.

Besides vividly pointing out the power points of PowerPoint, Dr. Khalid Kalantan gave an A to Z

practical guide on how to get the best out of this fantastic software in creating a slide show for scientific presentations. However, he recommended that the basic principles of a presentation should not be overshadowed by the power of the software. Consideration should, still, be given to the size of audience and their knowledge of the topic. The objectives and contents should be matched with the time given. Based on equipment availability, the appropriate output option should be selected ahead of time. However, always be ready for electronic surprises. Effects should only be used if really needed; then, they should be simple, clear and relevant. No amount of animation or clever sound can make a disorganized presentation succeed.

In his lecture on evidence-based clinical practice, Professor Jamal Al-Jarallah emphasized the need to evaluate properly the efficacy of diagnostic and therapeutic procedures before accepting them as standard clinical practice. He discussed the various ways of efficient literature searching and critical evaluation of different varieties of published medical evidence. It is crucial that critical appraisal issues arise from patient problems the clinician is currently confronting.

The course concluded with a lively Panel-Discussion Session. At the outset, the panelists critically evaluated 2 dummy run presentations and then responded to questions and comments from the audience. The discussion reflected the enthusiasm and interest in clinical research of all participants from various hospitals in Riyadh who represented a wide spectrum of biomedical specialties at all levels of seniority.

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