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TEACHING BIOSTATISTICAL CONCEPTS AND METHODOLOGY TO MEDICAL PROFESSIONALS: VARIOUS ALTERNATIVES

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1. Introduction

Physicians and other medical professionals are increasingly aware of their need for biostatistical knowledge, not only if directly involved in research activities, but also if, as a clinical practitioner, one wishes to keep abreast of advances in the field.

The traditional approach involves incorporating biostatistical research concepts within the medical school instruction. The curricula in most medical schools in the United States and in other countries now include at least a session on introduction to biostatistics, although it may be called epidemiological research or research methods. Such courses are typically short (one rotation or one semester) and cover basic information with the intent of introducing the general concepts of descriptive and inferential statistics, but are not intended to prepare the physician for conducting clinical research. Most medical students do not envision a career as investigators but as practitioners, and thus tend to concentrate on the traditional medicine subjects and therefore to disregard the importance of the statistical instruction. It would seem that the timing of this instruction should come at a stage in their medical career when the professional accepts the importance of basic biostatistical knowledge.

For the few medical professionals who do choose a career in research, it is imperative that additional in-depth research methods instruction be obtained. In some cases, they are able to pursue a post-graduate master's of public health (MPH) degree, typically in a department of epidemiology. The University of North Carolina at Chapel Hill offers MPH degrees in the Departments of Biostatistics and of Epidemiology of the School of Public Health. However, many physicians do not have the opportunity to pursue such post-graduate training and may either be self-taught or often disregard the need for further training and merely "forge-ahead". This latter approach has been greatly facilitated since the last decade with the widespread availability of statistical software for

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personal computers, so that anyone "armed" with these tools can be their own biostatistician. Numerous examples exist of the pitfalls of such activities.

Another alternative is to rely on a biostatistician and to blindly accept the answers obtained from such collaboration. This is not a healthy approach either as the biostatistician is placed on a pedestal, viewed as a necessary evil that must provide significant results, and there is no semblance of a collegial collaboration.

The end results of such alternatives is often poorly planned, poorly conducted, poorly analyzed or poorly presented medical research. It is in the best interest of the medical research profession and the biostatistical profession that medical professionals planning to be clinical researchers obtain relevant, targeted statistical education. This is not to argue that the biostatistically-trained medical professional should be able to be their own biostatistician, but that if they have a basic understanding of the statistical issues present in their research, they will be able to better collaborate with a statistician and, therefore, to be better researchers.

This paper presents four non-degree post-graduate alternative statistical education approaches that aim to provide medical professionals with the biostatistical research tools necessary to be effective clinical investigators. They range in coverage, time commitment, cost and depth of training. The goals of each approach are presented and compared, especially in terms of the expectations of the biostatistical abilities of the course participants upon completion of training. The experience of the author as instructor in all four different teaching approaches is presented.

2. Clinical Scholars training: two years in-depth

The Clinical Scholars training program is a Robert Wood Johnson Foundation funded program in the United States that competitively selects physicians nationwide for a two-year post-graduate training program in clinical research methods. Fellows attend training centers within selected medical schools at research universities. This training is quite similar in time commitment to pursuing an MPH degree, except that it is offered by a school of medicine and is more focused on clinical research rather than epidemiology. Its goal is to produce excellent clinical researchers.

The biostatistical training provided at the University of North Carolina through this approach is divided into two components. Fellows take a one-year intensive core curriculum of research methods, in which ten sessions are directly on basic biostatistics. These sessions compress a one-

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semester introduction to probability, descriptive and inferential statistics into 30 hours of instruction. In addition, the remainder of the core curriculum covers other biostatistical topics indirectly as they pertain to specific study designs like case-control studies or clinical trials. The second component comes from enrollment in regular graduate level courses in the Departments of Biostatistics or of Epidemiology, where fellows take intermediate subjects like multiple regression, clinical trial methodology and multivariate methods.

This approach is quite costly in terms of time commitment on the part of the physician, but has demonstrated success in producing excellent clinical researchers. They are still dependent on biostatistical support, but are conversant with statistical terminology and concepts. They are able to critically appraise the medical literature.

3. International Clinical Epidemiology Network training: one year in-depth

The International Clinical Epidemiology Network (INCLEN) training program is originally a Rockefeller Foundation funded worldwide program that competitively selects physicians from 26 selected medical schools in developing countries for a one-year post-graduate training program in clinical research methods (Halstead *et al.*, 1991). Fellows attend training centers within selected medical schools at research universities in Canada, Australia or the United States. This training is similar in intent to the Clinical Scholars program, but with a reduced time commitment.

The goals of the INCLEN program are to develop units of excellence in clinical epidemiology research at the participating medical schools in the developing countries. As such, the program not only provides training to the future investigators, but also time protection for conducting research activities and the necessary biostatistical and other support required upon their return to their home institutions.

The biostatistical training provided at the University of North Carolina through this approach is almost identical to the Clinical Scholars program. The reduced time-in-residence limits the possibility of more in-depth biostatistical courses that the physicians can take. The medical professional thus may not be as independent statistically as an MPH in epidemiology or as a Clinical Scholar, but the Network is designed so that the necessary biostatistical support is available at the home Clinical Epidemiology Unit (CEU).

This approach is slightly less costly in terms of time commitment,

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and fellows are prepared to not only be critical appraisers of the medical literature, but to function as independent clinical researchers within a team at the CEU.

4. Clinical Vision Research short course: two-day introduction

The National Eye Institute of the United States' National Institutes of Health sponsors two-day intensive short courses in clinical vision research methodology for ophthalmologists in developing countries. These short courses are offered in conjunction with major regional scientific professional meetings so as to attract a broad-based audience.

The goals of this course are to introduce ophthalmologists to clinical research methods and develop skills to evaluate clinical research protocols. This is achieved through an overview of basic epidemiologic and statistical principles, and seminars/discussions on the major issues to consider in the design, conduct, analysis and interpretation of clinical research. Participants thus develop a critical approach to clinical research.

The biostatistical methodological topics and concepts are not directly offered in such short courses given the time limitations, but through applications to particular study designs and the conduct and analysis of epidemiologic studies. An integral component of the short course is a detailed critical appraisal of two selected ophthalmology research articles.

This approach does have the potential of reaching a large section of the medical professionals in a given field with relevant specific instruction. It requires minimal time commitment and involves less costs as well. However, it also is limited in the depth of statistical understanding that the participants acquire. Participants cannot be expected to gain in-depth appreciation of statistical issues, but should acquire a critical appreciation of medical research in their field. Those participants who wish to pursue careers as researchers would seek further in-depth training.

5. Extended short course: one-month intermediate

The final alternative is an intermediate approach to the ones presented above, an intensive but short course. In the United States, several institutions offer summer continuing education programs with the intent of providing an intensive introduction to epidemiology and biostatistical methods for health professionals planning careers in research, teaching or practice in a particular field. The Council on Epidemiology and

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Prevention of the American Heart Association offers a 10-day seminar focused on methods for cardiovascular diseases (19th session in 1993); the New England Epidemiology Institute and Tufts University offers a 3-week series of 14 courses on Epidemiology (13th session in 1993); the University of Michigan School of Public Health offers 1-week and 3-week courses as part of their Graduate Summer Session (28th session in 1993). These are but a few examples of alternative instructional possibilities for acquiring research tools. These relatively short courses are viable alternatives for the medical professional seeking such training but unable to commit larger amounts of time. They are intensive, vary in-depth, and provide continuing education credits as well as graduate level credits if desired. The biostatistical concepts are presented either as a basic introduction course (ex. Fundamentals of Biostatistics), indirectly as part of an applied epidemiology topic (ex. Clinical Trials - Analytic Methods), or as a special in-depth statistical topic (ex. Introduction to the Logistic Model).

The Department of Anesthesia and Intensive Care of the John Hunter Hospital in Newcastle, Australia, chose the intensive 1-month approach for training its clinical residents in the fundamentals of biostatistics in June 1991. They contacted the Centre for Clinical Epidemiology and Biostatistics of the University of Newcastle to offer the course. Four in-class sessions over a 4-week period were conducted, coupled with critical appraisal readings and exercises, with the goal of providing an understanding of commonly used statistical methods encountered in the current medical literature (with an emphasis on anesthesiology). The extension over a 4-week period enabled participants to complete readings and exercises, but also to develop in-depth questions and to better "digest" the statistical topics. It also allowed for minimal disruption of their clinical duties, and by being offered on-site, accommodated potential clinical emergencies.

At the end of the course, participants had a basic understanding of a few commonly used statistical methods, and were better equipped for critically appraising the anesthesiology literature.

6. Discussion and conclusion

The four alternatives presented above all aim to provide the medical or health professional with training in biostatistical methods and concepts. Choosing a particular approach depends on the time commitment on the part of the potential participant, which should be directly related to their interest in conducting clinical research. Those medical professionals

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wishing to pursue careers in research should obviously choose thorough training, either with a post-graduate degree or competitively applying for training fellowships such as the Clinical Scholars or the INCLEN programs. However, the most practical approach is to participate in short courses, since selection only depends on one's ability to pay (or obtain a scholarship). A 2-day course is limited in its training potential, and should be considered as one to reach a large group of medical professionals with a basic critical appreciation for the importance of biostatistics, but only to stimulate the potential researcher to pursue further training. An extended but still short approach seems the preferred alternative. It is quite flexible and accommodating to the medical professional's schedule, and the statistical content can be varied from the basic introduction, to intermediate topics or even advanced topics. The typical short course summer sessions in the United States offer several courses to choose from. Tailor-made courses for specific medical professions can focus on the statistical issues particular to that field and may be also a valid alternative.

The goal of educating the medical professional consumer of statistics is a lofty one, but attainable. The approaches presented in which the author has been an instructor have all met their stipulated training goals. Training health and medical professionals in statistical methodology is not a threat to the statistical profession, but actually enhances our profession. Given the potential abuses of statistical methods made easy by the proliferation of statistical software readily available, the potential danger to the profession from the ill-trained casual user is great. Thus, an educated consumer is the best client for our statistical profession.

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