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TRAINING OF STATISTICIANS AND CLINICAL RESEARCHERS WORLDWIDE TO COLLABORATE AS CO-INVESTIGATORS WITHIN COUNTRY CLINICAL EPIDEMIOLOGY UNITS: THE EXPERIENCE OF THE INTERNATIONAL CLINICAL EPIDEMIOLOGY NETWORK (INCLEN)

Clinical researchers rely on biostatisticians in order to design, conduct and analyse observational and experimental studies involving populations of subjects. In many countries, trained biostatisticians are not readily available. There are many possible approaches to this problem, including educating the medical or health professional to be a researcher with an understanding of statistical methodologies, as well as training statisticians to be biostatisticians with an understanding of clinical considerations. The International Clinical Epidemiology Network (INCLEN) embarked on such an endeavour by creating clinical epidemiology units that included both approaches, trained clinical epidemiologists as well as biostatisticians. The specific statistical training needs of both types of students are described.

1. INTRODUCTION

Physicians and other health 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.

One alternative for the clinical researcher is to completely rely on a trained biostatistician and to blindly accept the answers obtained from such collaboration. For the clinicians reading the latest scientific journals in their field, this is equivalent to ignoring the methods section of the research articles. This is evidently not a healthy approach, for the obvious reason that an uneducated researcher is not in a position to critically appraise the literature or to effectively collaborate in a research team.

In addition, this approach is undesirable because 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 result of this alternative is often poorly planned, poorly conducted, poorly analysed, or poorly presented medical research, which is as unethical as recommending inadequate treatment for their patients.

Evidence of such inadequate collaboration can be seen in reviews of the often poor quality of the methodology and statistics used in peer-reviewed medical journals (Altman, 1994; Coste, Fermanian, & Venot, 1995). Training of the health professional in proper understanding of statistical concepts is not easy. For example, Estepa and Sánchez-Cobo (2001) point out the difficulty in properly teaching the concept of 'association,' an important concept in the health professions. In addition, given the increasing complexity and new methods emerging in the statistical field, there is an

increasing clear need for statistical support in medical research at an early stage (Hand, 1994; Altman, 1998).

It is in the best interest of the health research professions 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 health 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 biostatistician and to therefore be better researchers (Bangdiwala, 1989). The central role of statistics in epidemiology and public health requires that all health professionals acquire competence in the use and interpretation of statistics.

The availability of a trained biostatistician is often not the case in many developing countries (Crivisqui & Abruzzini, 2001). There usually are many trained statisticians, especially in the areas of econometrics and official statistics, or more commonly, well-trained mathematical statisticians with little or no understanding of epidemiological research design, methodologies, or substantive issues of the fields of application (Ospina & Ortiz, 2001).

One alternative for these statisticians, if called to interact with medical researchers, is to completely rely on the physician and to blindly accept the answers obtained from such collaboration. Similarly as the situation described above, this is not a healthy approach. The statistician must also be trained and appreciate the nuances of the field of application if they are to collaborate efficiently. It is thus necessary that the statistician become a biostatistician.

Individuals trained in clinical epidemiology research or in biostatistics are often uncommon professionals in many countries. This can have advantages from a scarce commodity standpoint, but more often they face special challenges. In some countries their special skills may not be recognised as relevant to the country's health priorities. Clinical researchers face the challenge of the pressing needs for their clinical expertise, and often their research skills go under-utilised as they are pressured to treat patients by their institutions or government.

On the other hand, trained biostatisticians are sought by research institutions, international agencies and private enterprise, and may be difficult to retain in academic research medical schools, especially since a non-physician in a medical school may not be considered as an equivalent colleague by the medical doctors. In addition, they often face 'professional isolation' as they have few, if any, colleagues to discuss issues with, and may not be able to maintain themselves current with the advances in their field given the relative lack of resources such as journals and the competing demands for their time. The challenge is thus not only to train these individuals, but to provide them with a career path appropriate to their training, and continued nurturing during their early careers.

This paper presents the experience of the International Clinical Epidemiology Network (INCLEN) training program in training both types of professionals, physicians to be clinical epidemiologists, and statisticians to be biostatisticians. Section 2 describes the biostatistical training for physicians, while section 3 describes the biostatistical training for statisticians. The underlying assumption is that both types of scientists would be collaborating in medical research as part of a clinical epidemiology unit located in a country with not much additional expertise available. Finally, the success of this training is subjectively assessed in section 4.

2. INTERNATIONAL CLINICAL EPIDEMIOLOGY NETWORK TRAINING OF PHYSICIANS

The International Clinical Epidemiology Network (INCLEN) training program began in 1984, and was originally funded by the Rockefeller Foundation as a world-wide program that competitively selected physicians from developing countries for a one-year post-graduate training program in clinical research methods (Halstead et al 1991). The selected physicians were faculty from 27 specific medical schools that were participating in the network. These medical schools were initially selected because of their willingness to establish a Clinical Epidemiology Unit (CEU) as an independent organisation within the medical school, responsive only to the Dean of the School of Medicine.

The idea was that trained clinical researchers, after returning home from training, would have a 'second home' in which to pursue careers in clinical research, in addition to, but separate from their clinical discipline. There was protected time for research - 20% or one day a week – so that their skills in research would be used and the clinical demands would not overcome their entire time. The CEU was comprised of various clinical researchers from a variety of medical disciplines, plus a biostatistician, a health economist, and a health social scientist. The idea was to have a multidisciplinary team of researchers to collaborate effectively. Since its inception, the INCLEN program has trained over 500 health professionals world-wide.

The goals of the INCLEN program were to develop units of excellence in clinical epidemiology research at the participating medical schools in the developing countries. The ultimate hope is that with qualified researchers in a country, the country's pressing health priorities would be adequately researched. 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.

For their training, physicians attended centres at research universities in Canada, Australia, or the United States, for 12-18 months of training. Most physicians did not have any statistical training prior to their participation in the program. Currently, INCLEN has regionalised the training by creating Clinical Epidemiology Research and Training Centres (CERTC) in those CEUs that have progressed in their infrastructure, in such diverse countries as Brazil, Chile, Colombia, Thailand, Philippines, and India. The training curriculum is basically the same as at the original training centres, only with a different venue and faculty. However, at the regional training centres, it was decided to provide a greater emphasis on statistical training for the health professional, since it was less likely that they would be able to obtain the necessary biostatistical support at their home institutions.

Specific aspects of the statistical training of the clinical researchers at the University of North Carolina CERTC are presented in Table 1. The curriculum varied somewhat among the original four training centres and the current regional training centres, but the core elements are quite comparable. The statistical training, aside from the topics of epidemiological research methods, aimed at providing basic training in statistical concepts and methods.

The physicians took the Supplemental Course concurrently with Course I at the beginning of their training, since it was considered fundamental that they have basic statistical software knowledge in order to perform the work required for the biostatistics course. The biostatistics course was offered also at the beginning since it was felt

necessary in order to perform well in the core courses of clinical epidemiology research methods as well as in other courses they took during the academic year.

Table 1: Curriculum Topics of the Statistical Training of Physicians

Topic	Details
Supplemental Course: Introduction to STATA	4 lectures
Creation of data files and data entry, create new variables, subset data files	
Produce graphs	
Perform simple statistical descriptive analyses	
Draw random samples	
Practice	Use software for Course I homework
Course I: Introduction to Biostatistics	12 lectures
Introduction to statistics	Dealing with uncertainty and variability
Types of data	
Elementary probability theory	
Samples and populations	Random sampling
Probability distribution functions	Binomial, Poisson, Gaussian
Descriptive and exploratory data analysis	Graphs, tables, summary statistics
Concepts of statistical inference	Hypothesis testing, confidence intervals, Central Limit Theorem
Methods for one sample	Parametric and non parametric
Methods for two samples	Parametric and non parametric
Analysis for contingency tables	Chi-squared tests
Assessing independence and correlation	Simple linear regression, correlation, diagnostics
Introduction to multiple regression and ANOVA	Issues of multiple comparisons
Course II: Regression models	10 lectures
Exploring relationships	
Logistic regression	
Survival analysis	
Course III: Various topics	
Issues in biostatistical critical appraisal of the medical literature	Articles selected by the clinicians
Study design	Discussion of alternatives and of implications of chosen design
Study conduct, quality assurance	Ensuring adequate data quality
Appropriateness of analyses methodologies	Discussion of alternatives and of possible other results; interpretation of statistical importance of findings
Practices: Relevant project in clinical field of student	Self-chosen project (2-3 weeks) with oral presentation

The biostatistics training took place intensively over a 4-week period prior to the academic semester, but it consisted of the complete topics of the regular 3-credit introductory course offered by the Department of Biostatistics (BIOS 150).

In the first and second semester of the academic year, the physicians took a Core Curriculum on clinical and epidemiological research methods (see Table 2 below). The statistical concepts were already covered in Course I and thus they were able to apply them to the various commonly used epidemiology study designs.

Table 2: Curriculum Topics for Clinical Epidemiology Training of Physicians and Statisticians. Course in Clinical Epidemiology

Topic	Details
Introduction to basic epidemiology	5 lectures per week; two semesters
Epidemiology study designs	Cross-sectional, case-control studies, cohort studies, clinical trials
Measures of disease frequency	Probabilities and odds; prevalence, incidence
Measures of association	Relative risk, odds ratio, incidence density ratio
Measures of impact	Attributable risk
Diagnosis	
Sensitivity and specificity	Test characteristics, predictive values
Likelihood ratios	ROC curves
Biases	Selection, measurement, ascertainment
Research structure/measurement	
Cause-effect evaluation	
Observer variability	
Quality of life	
Clinical measurement	Risk, prognosis, validity
Quantitative research methods	
Interaction	
Confounding, Matching	
Social science methods	
Scale development	Reliability, internal consistency
Measuring social structure	
Qualitative research methods	
Epidemiology of medical care	
Outcomes research	
Quality of care	
Practical research skills	
Data collection, data management	
Human subjects and medical ethics	
Health policy and health economics	
Introduction to health policy analysis	
Health economics	
Cost-benefit and cost-effectiveness analysis	
Miscellaneous topics	
Medicine and culture	
Disease in historical perspective	
Medical anthropology	
Clinical decision making	
Meta analysis	
Cost effectiveness	
Professional development	
Writing a grant proposal	
Writing an abstract, writing a paper	
Writing statistical sections for papers	

The intensive 2-week course in data management and statistical software at the beginning of their training prepared them for the computer analytic requirements of the methods and statistical courses. They were thus equipped to handle the assignments and use the computer for their class work.

The second course on statistical methods was also tailored to the needs of the physicians. Course II was taken in the second semester of the academic calendar, and it provided them with the necessary tools to understand statistical regression models commonly used in clinical epidemiology research. This course was given as an intensive 2-week course and consisted of models such as logistic regression and proportional hazards regression models. In addition, students could choose to supplement Course II with a standard semester-long course on multiple regression techniques (BIOS 163).

During the second semester, a biostatistical critical appraisal course was offered. The innovation of this course was that it differed from the standard critical appraisal of the medical literature in that the clinical importance of the article was not reviewed, and the discussion focused instead on the statistical methods chosen. Importance was stressed on the fact that for all situations, one is faced with alternative choices, and that the selected method needs to be justified statistically.

Physicians appreciated this approach, given the analogy with diagnosis and treatment decisions they must make when faced with a particular patient during their clinical work. The selected statistical method also implies specific results, and these were the focus of discussions. Another innovation is that this course was attended by both the physicians being trained to be clinical researchers as well as the statisticians being trained to be biostatisticians, so that the interactions and the discussions were also a learning experience for all involved. A list of the contents of the 'biostatistical critical appraisal' is given in Table 3.

As shown in Table 1, the biostatistical training provided to physicians at the CERTCs is somewhat limited in the number of in-depth biostatistical courses that the physicians can take.

Table 3: Contents of a Biostatistical Critical Appraisal of the Medical Literature

Topic	Discussion questions
Study design	Is the chosen study design the most appropriate (given practical limitations) to answer the research questions and hypotheses?
Sampling	Is the Population sampled reproducibly described?
	Is the Sampling method reproducibly described?
	Are the inclusion and exclusion criteria clearly defined?
Sample size	Is the sample size justified?
	Is it adequate to answer the research questions with sufficient power?
	Are there non-response, non-compliance, and loss to follow-up?
Significance level	Is it adequate, adjusted for multiple testing?
Quality of data	Are procedures standardised; is staff trained adequately?
	Are data entry and management appropriate?
	Is handling of missing data adequate?
	Are possible biases discussed?
Variables	Are they clearly defined and objectively measured?
	Are transformations / categorisations justified?
Statistical procedures	Are they adequately described?
	Is their choice justified; according to types of variables?
	What alternative procedures are possible?
	What implicit / explicit assumptions are needed, justified?
Results and interpretations	Are they supported by the statistical procedures?
	Is statistical terminology properly used?

The medical professional is thus not considered to be independent statistically, but the Network is designed so that the necessary biostatistical support is available at the home Clinical Epidemiology Unit (CEU). This approach enhances the functioning of the CEU by encouraging a close collaboration among members of a CEU.

Despite advances in communication and the vast resources available through the internet, most researchers in many developing countries continue to feel isolated from technological advances in the statistical field, and the efforts of providing continuing education to medical researchers and biostatisticians is an integral part of the program. The topics and types of continuing education courses offered to physicians and biostatistician are quite varied, but concentrate on methodological issues pertinent to their clinical research activities.

Thus, topics have ranged from epidemiological methods [meta analyses, diagnostic tests, issues in clinical trials], research methods [management of multi centre studies, scientific writing, grantsmanship], to statistical methods [interim analysis for early stopping, multiple imputation for missing data, modelling longitudinal repeated measures data].

The continuing education courses are essential to the continued nurturing of the trained professionals, and thus tend to be more inclusive rather than exclusive by discipline. Thus clinical researchers may opt to take a short course on a more statistical topic, and a biostatistician may choose to take an epidemiology methods short course.

The courses are typically 1-week long short courses offered by faculty from one of the original training centres in collaboration with faculty from a regional CERTC. In a given year, from 1-3 courses may be offered in different regions globally, hosted by a local CEU or CERTC. In addition, regions of the INCLEN network have annual professional meetings, and the opportunity for offering short courses to a larger audience with less travel expenses is often taken. The short courses offered in conjunction with these annual meetings will typically be only 1-2 day workshops, since it is difficult for the professionals to be away for an extra week in addition to the time away for the conference.

The continuing education courses are offered on a sporadic basis, usually upon request from a group of CEUs, and based on the availability and expertise of the faculty of the training centres. The topics are not selected through a structured process, although periodically the members of the network are polled as to possible future topics of interest.

As part of the continuing training in the future, web based distance learning courses similar to those presented by Lee (2001) and Stangl (2001), but using ‘case studies,’ are currently being developed by the regional training centres. Researchers will be able to post problems on a web site. Through an interactive ‘chat’ process, alternatives will be discussed, exploratory data analysis will be conducted and evaluated, strategies for statistical modelling will be discussed and evaluated, and analyses will be conducted and interpreted.

3. INTERNATIONAL CLINICAL EPIDEMIOLOGY NETWORK TRAINING OF BIOSTATISTICIANS

Originally, the training of statisticians into biostatisticians was naïvely thought by the network to be analogous to the training of physicians to be clinical epidemiologists.

Thus, the INCLEN program funded a single year of post-graduate training for statisticians as well.

However, most statisticians seeking further graduate-level training already had adequate master's level training in mathematical statistics, and thus a further master's degree was not useful to their personal careers. Furthermore, given that upon return to their countries, the statisticians were expected to be integrated members of the CEU, not having a doctoral degree was a clear professional handicap for the statistician. Administratively, a non-physician in a medical school faced institutional difficulties in even getting an appointment in the medical faculty.

Professionally, not having a doctoral degree made interactions in the 'close collaborating team' of the CEU not completely collegial. Eventually, the need for doctoral level training was recognised by the Network as many individuals opted for doctoral training after seeking additional support beyond the one-year provided by the Rockefeller Foundation.

The content and methods for the training of the statisticians are presented below. Many individuals opted for either a traditional master's degree in biostatistics, or for a doctoral degree in biostatistics. These individuals took the standard curriculum from the Department of Biostatistics as any other student in those degree programs. The details of these *curricula* are presented in Table 4 for the University of North Carolina at Chapel Hill. Also, students seeking the MS, DrPH, or PhD degree must meet the following additional requirements for intermediate or advanced biostatistics or statistics course-work:

- *Master of Science (MS):* Three hours of courses numbered above l65 in Biostatistics, or equivalent;
- *Doctor of Public Health (DrPH):* At least 12 hours of courses numbered 200 or above in Biostatistics, or equivalent;
- Doctor of Philosophy (PhD): At least 12 hours of courses numbered 200 or above in Biostatistics, or equivalent.

In addition, Table 2 above provides the details of the non-standard curriculum course taken by the participants as part of the INCLEN training. The statisticians took this Core Curriculum in clinical epidemiology research methodology, an intensive 9-hour credit course for 2 semesters. The physicians also took the same Core Curriculum, and thus all individuals had a uniform understanding of a common language for their future interactions and collaborations.

Although there is no perfect formula that works for training all statisticians, there is general agreement that statistical training for collaborators in applications of statistics should be driven by the specific considerations of the fields of application. In addition, special supplementary courses were imparted on critical appraisal of the medical literature from a biostatistical viewpoint (see Table 4 above).

Other innovative aspects of the training included the involvement of the biostatisticians in consultation and co-teaching of workshops, since the biostatisticians required such experiences in order to effectively provide such services at their respective CEUs.

Table 4: UNC Biostatistics Degree Requirements (in Effect During INCLEN Training at UNC, 1986-1995)

	Statistical Courses by Type	Degree for which Required			
Computing		MPH	MS	DrPH	PhD
BIOS 111	Introduction to statistical computing and data management	X	X	X	X
Probability and Statistical Inference					
BIOS l50	Elements of probability and statistical inference		X		
BIOS l60, l6l	Probability and statistical inference I and II			X	X
STAT 134, l35	Intermediate statistical theory I and II				X
Biostatistical Applications					
BIOS l45	Principles of experimental analysis	X[a]			
BIOS l62	Introductory applied statistics	X[b]	X	X	X
BIOS l63	Introduction to linear models		X	X	X
BIOS l64	Sample survey methodology	X	X	X	X
BIOS l65	Analysis of categorical data		X	X	X
BIOS l67	Applied stochastic processes				X
BIOS 263	Advanced linear model theory			X	X
BIOS 266	Advanced linear model methods			X	X
Professional Biostatistics					
BIOS l9l	Field observations in biostatistics	X	X	X	X
BIOS 341	Principles of statistical consulting (2)	X	X	X	X
BIOS 342	Practice in statistical consulting (2)	X	X	X	X
BIOS 350	Training in statistical teaching in the health sciences (3)			X[c]	X
Paper/Dissertation					
BIOS 392	Master's paper	X	X		
BIOS 394	Doctoral Dissertation			X	X

Notes:
a - Or BIOS l63
b - Or a BIOS course numbered above l64
c - Three extra credit hours of BIOS 342 may be substituted for this requirement.

4. DISCUSSION AND CONCLUSION

The success of this endeavour in training physicians to be clinical epidemiologists and in training statisticians to be biostatisticians has been mixed. One of the original intents of the INCLEN program was to establish these CEUs as centres for excellence in various countries so that local well-trained clinical researchers would study the health problems faced in those countries. Other training programs with such lofty goals have failed in the past, as trainees did not return to their countries, thus creating a 'brain drain.' The establishment of a CEU that provided a career path in research, coupled with a variety of monetary and travel incentives, was the planned answer. This has worked in some situations, but in others, given the value of these trained individuals, internal brain drain has meant that the qualified trained clinical researchers and biostatisticians have

left the CEUs for more lucrative positions within private enterprise and international organisations. This is especially true for the biostatisticians within the team, primarily since biostatisticians are a rare commodity in many countries, but also because they do not have high salaries within the medical faculty since they are not clinicians.

The goal of educating the medical professional to be a researcher with an understanding of statistical methodologies and issues is a lofty one, but attainable. There are many possible training methods (Bangdiwala 1993), and the specific methods of the INCLEN training program have achieved reasonable success in many countries. 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.

The training of statisticians to work effectively as team collaborators with the clinicians has been a harder battle to win. Challenges exist in many institutions from an administrative standpoint, such as in reduced possibility of an academic appointment in a medical school, and limited ability to get promoted within the medical faculty as a biostatistician, coupled with reduced salaries because of no clinical practice. Biostatisticians are thus more likely to be lured away by private enterprise, and thus the CEU suffers. From a training standpoint, this INCLEN model requires 3-4 years for training a doctoral statistician contrasted with just one year for a clinical epidemiologist. This expense is not covered by the original funding agency and has meant that not all statisticians desiring a doctoral degree have been able to attain it. Finally, from a professional standpoint, the career development of the biostatistician requires continued contact and interactions with other biostatisticians and especially continued education. In addition to the training received during the degree program, given the professional isolation of the biostatisticians, continuing education training is still an important part of the program. Biostatisticians participate in the same continuing education opportunities as described above for clinical epidemiologists. However, there is still a gap in updating the training with the recent advances in computer intensive methodologies in the statistical field, by the fact that trainers within the Network may not be in a position to provide such continuing education, while outsiders command high honoraria.

The challenges in training professionals to research the pressing health priorities of developing countries are numerous. The INCLEN model includes training physicians in statistics, and training statisticians in clinical epidemiology methods. The complementary roles are institutionalised into clinical epidemiology units, and despite some pitfalls encountered, has been an effective way to increase the clinical research capability of these countries. Until a critical mass of biostatisticians are available within a country, continued education courses for the statisticians on advances in the field are essential for their career development.

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