

MECOR

Methods in Epidemiologic,
Clinical and Operations Research



*“Improving global lung health through development of
local, country and regional lung disease research
capacity”*

The *ATS MECOR Program*

The *ATS MECOR Program* began in Latin America as the International Respiratory Epidemiology (IRE) course in 1994 and transitioned to the MECOR Program—Methods in Epidemiologic, Clinical and Operations Research—in 2004. The primary aim of the *ATS MECOR Program* is capacity building for research, based on the idea that individuals with skills in research are needed develop, design and carry out studies to identify and quantify the burden of lung disease in their country and to develop, implement and evaluate interventions that are likely to be effective in their settings. The *ATS MECOR Program*, now in its 18th year, has developed into a 5-level program with a range of competencies that include basic research design, data analysis, presentation skills and manuscript preparation.



In 2007, an *ATS MECOR Program* was developed for Africa. The first three courses were held in Blantyre, Malawi in collaboration with the Pan African Thoracic Society with funding from the Nuffield Foundation. An *ATS MECOR Program* has also been developed in collaboration with the Turkish Thoracic Society with courses held in 2008, 2009 and 2011. The program model designed for Africa and Turkey introduced the first level of the Program—Level 1, Introduction to Clinical Research Methods—in the initial year, with Levels 1 and 2 in the second year followed by Levels 3 in the successive year the program matured. In 2009, the *ATS MECOR Program* was introduced into India in collaboration with the U.S. Centers for Disease Control and the Indian National Institute of Epidemiology. In 2011 the *ATS MECOR Program* was expanded into Southeast Asia, with a course in Vietnam, sponsored by the Woolcock Institute for Medical Research, the University of Sydney, the Australian Research Council and the Thoracic Society of Australia and New Zealand.

The ultimate goal of the *ATS MECOR Program* is to improve global lung health through the development of local and regional lung disease research capacity. This, in turn, will provide the capacity for collaboration in clinical and epidemiologic projects with a cadre of trained clinicians and scientists. With this in mind, the content of the *ATS MECOR Program* courses

has been carefully chosen to emphasize local and regional respiratory disease problems that are of public health importance.



Through the *ATS MECOR Program*, more than 800 clinicians have received training. The *ATS MECOR Program* model is predicated on the observation that all clinicians can benefit from basic training in research methods, regardless of their ultimate career choices.

The courses have had lasting impact as course graduates have gained specialized knowledge not readily available locally, have translated their knowledge into local research studies that have been presented at major national and international meetings and publications in high-quality peer-reviewed national and international journals, and have gained valuable colleagues and friends within the larger regional and international scientific communities.



Students have advanced their careers through a variety of opportunities including:

- A fellowship sponsored by the Royal College of Physicians in collaboration with the West African College of Physicians for sub-specialty training in pulmonology;
- A KAP study and initiation of ISAAC in Lusaka, Zambia with support from Novartis;
- A Pediatric Pulmonology fellowship at BARTS and London School of Medicine and Dentistry;
- Fogarty fellowship at Northwestern University AIDS International Training and Research Program for a Masters in Clinical Investigation;
- An MPH from the London School of Tropical Medicine, sponsored by the Wellcome Foundation in the UK; and
- A Pediatric Fellowship at the University of Cape Town;

1. Goals and Objectives of the *ATS MECOR Program*

The goals and objectives of the *ATS MECOR Program* were developed recognizing that all clinicians need basic skills in research methodology to improve clinical outcomes in their practices and/or hospitals. In addition, there are clinicians who are able to spend more time on research or are academic leaders or in charge of public health programs need additional skills. The program is designed for both by building upon course material in each level as described below.

The *ATS MECOR Program* is designed to help clinicians and health care professionals to:

- use data from the literature to improve clinical practice,
- develop the skills needed to study local, national, or international problems, and to develop and evaluate interventions, and
- use data to inform public policy and improve clinical practices, academic and teaching programs.

2. Description the *ATS MECOR Program*

The *ATS MECOR Program* is designed for clinicians, investigators, academicians, and public health professionals who primarily work with pulmonary diseases to provide training in research methods. The *ATS MECOR Program* was developed as a “ladder” with the first two levels (levels 1 and 2) designed to provide basic training in research methods and to be relevant for all clinicians. The higher levels (levels 3, 4, and 5) were designed for those who wish to develop more advanced skills in research.

Level 1: Introduction to Clinical Research is appropriate for clinicians and academicians who are engaged in the clinical practice of respiratory and sleep medicine, public health, allergy and critical care and wish to improve their skills in clinical research and investigation.

Level 2: Advanced Clinical Research Methods is a continuation of the Level 1 Course and focuses on clinical epidemiology and advanced clinical research methods. It is recommended for all in pulmonary medicine who are interested in advancing their skills in clinical research. It is also appropriate for individuals who wish to improve their skills in reading the literature and research design.

Level 3: Advanced Clinical Research Methods is designed for the individual who would like to do clinical research and/or pursue an academic career and who is in the process of considering or planning a particular research study and would like to work on this with faculty consultation.

Level 4: Advanced Clinical Research Methods is a continuation of Level 3. It is designed for the individual for who has collected research data and is ready to analyze the data or write a paper. This work is conducted under the supervision of MECOR faculty.

3. Competencies:

The competencies for the *ATS MECOR Program* are listed in **Table 1** below.

As the *ATS MECOR Program* was developed for each country, region or (sub) continent, the program design has taken into consideration the local/regional respiratory disease research needs and has, inevitably, been shaped by the availability of resources.

Prerequisites for all *ATS MECOR Program* courses include:

- Fluency in the language of the course as demonstrated by submission of an essay written in that language as part of the application process.
- Medical degree or advanced degree in related areas such as public health, nursing, physical therapy etc.
- Participants are required to attend class for the full week and are expected to do preparation before the course and in the evenings. The week's course work is demanding and participants must be willing to free themselves of all other commitments for the week of the course and participate in all class work.
- Participants must be prepared and willing to present their research protocols or week's work on the last day.

Table 1: Competencies for all levels

COMPETENCY	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
OVERALL GOAL	Level 1 is designed for academic physicians who will be involved in producing medical research. Students will learn the fundamentals of posing a testable research question, the various study design options for generating and testing hypotheses, and basic analytic skills. Students will gain an overview of statistics that will help them to collaborate effectively with statistical co-investigators.	The Level II course is designed to build on the concepts learned in the Level I course and apply them to the clinical realm. There are 3 major educational goals: (1) To learn advanced concepts of bias, confounding, and chance as applied to clinical research, (2) To develop a research idea into a research protocol and (3) To apply epidemiologic concepts to a critical review of clinical research studies.	The Level 3A course is designed to enable students to apply concepts and skills from the Level 1 and 2 courses to the design of a specific research study they wish to conduct. There are four major educational goals: (1) To further develop an understanding of the advantages and disadvantages of alternative study designs for answering a specific research question; (2) To develop and refine the protocol and Manual of procedures for a study the student plans to carry out; and (3) To provide an opportunity to critique/defend student research studies.	The purpose of this course is to develop skills in presentation of original, scientific research findings for peer-review manuscripts. Ideally students would bring completed analyses and focus their time on writing up their results, though faculty often assist student in completing analyses during the week as well as writing up results. Lectures focus on how to write the various sections of a paper, but also include some statistics lectures.	This course is for the individual who has collected research data and is ready to analyze them. Ideally taking the 3C course, with its focus on analysis, would be a prelude to taking the 3B course, where the focus is more on writing up results in manuscript form. Students are expected to bring their own statistical analysis program and to have a familiarity with how to use it. Though not a “competency” per se, students must bring their own dataset and work on data analysis under faculty supervision.
EPIDEMIOLOGY					
Descriptive Epidemiology	Understand basis of epidemiologic approach to disease e.g. prevalence, incidence	Understand the basis of clinical epidemiology as an approach to diagnosis, prognosis, and treatment of disease	Apply epidemiologic principles appropriately as relevant to the proposed study		Not applicable
RESEARCH DESIGN					

Research Design	Understand basic design of different types of studies: cross-sectional, case-control, cohort, clinical trial, including their respective measures of effect	Understand the application of study design to clinical studies	Identify alternative research designs that might be used to answer the research question of interest; describe their respective strengths and weaknesses in terms of internal and external validity, generalizability, and feasibility	Clearly report study design and rationale	Not applicable
Research Questions	Be able to pose simple research questions and know which study design is appropriate	Apply and adapt epidemiologic questions to clinical and health services problems	Select the optimal design to answer the research question or test the research hypothesis, specifying the inclusion & exclusion criteria, sample size, intervention procedures (if relevant), measures, measurement & data management procedures and data analysis strategy	Clearly articulate the study question(s) and/or hypothesis(es) in best location in the manuscript	Students are expected to arrive with data in hand (and hence an already defined research question). This question may be refined, however, through the process of analysis and interaction with faculty.

RESEARCH METHODS

Sampling/population selection	Difference between populations and samples and how these may affect study results	Develop feasible & valid approaches to sampling	Develop appropriate eligibility (inclusion and exclusion criteria) for the proposed study	Properly describe methods	Not applicable
Sample size and power	Importance of adequate power and the factors that affect power	Know basic methods to determine sufficient sample size for planned study.	Apply statistical principals/methods correctly to determine the appropriate sample size and/or estimate the power/confidence intervals in the proposed sample	Provide sufficient detail about sample size and power assumptions	Retrospective power calculations based on observed std. errors of model estimates may be discussed.
Questionnaires, measures, & measurement procedures	Importance of valid and reliable measurements; sensitivity, specificity, predictive value	Balance precision & accuracy in measurements; Be able to design & pre-test a study questionnaire.	Select/develop appropriate, valid, and reliable measures & measurement procedures for the proposed study	Describe measurement tools and approaches used in the study	Learn which statistical programs are best suited to what types of study designs and outcomes.
Quality Control	Techniques for maximizing data quality	Know effective approaches to monitoring quality of data gathering & data entry.	Develop a detailed quality control plan for all aspects of the study (e.g., recruitment, assessment, intervention/treatment, data management,		Discuss approaches to data cleaning

Ethics & Informed Consent	Importance of ethical conduct of human research	Know& follow current standards of ethical treatment of human subjects; understand role of IRB.	analysis) Develop detailed plan to ensure informed consent and ethical treatment of participants and their health information	Report information about consent and IRB approval, where applicable	Not applicable
Manual of Procedures	Four stages of study proposals: one-sentence hypothesis, two-page summary, full proposal, manual of operations	Develop a detailed Manual of Procedures for the planned study.			Not applicable

STATISTICS

Descriptive Statistics	Summarize continuous and categorized data; understand and use measures of central tendency; understand and use measures of dispersion	Review statistical methods in level 1; understand bivariate and multivariable techniques used commonly in clinical studies	Develop a specific plan for preparation of descriptive statistical information on the study population and relevant sub-populations		Basic descriptive statistics and presentation of data are discussed.
Measures of association	Prevalence and odds ratios; incidence rates, relative risks and 95% confidence intervals	Review measures of association from Level 1 and understand how prevalence affects the relationship between risk, odds, and hazard ratio	Develop a specific plan for descriptive or analytic use of measures of association, as relevant to the research aims and hypotheses		Learn how to use statistical programs to estimate basic epidemiologic concepts such as odds ratios and relative risks.
Sources of error	Bias, confounding chance; type I and II errors, standard error and confidence intervals	Bias, confounding chance; type I and II errors. Reliability, validity, accuracy & precision	Consider specific sources of potential bias and confounding and plan experimental &/or statistical means of minimizing or adjusting for these factors		Not applicable
Univariate & bivariate analyses	T test, Wilcoxon, chi-squared	T test, Wilcoxon, chi-squared, risk ratios	Develop a specific plan for appropriate univariate/bivariate analyses if appropriate to the research hypotheses, and be able to justify the model chosen	Describe methods used in methods section, Select and apply appropriate tests, select appropriate means to summarize findings, clearly display findings in tables and figures	Different analyses are discussed for normally distributed data and for various types of nonnormal data. Lectures include linear, logistic and Poisson regression and survival analysis
Multivariate analyses	General concept behind multiple linear regression	Understand role of multivariate modeling including logistic regression and survival analysis	Develop a specific plan for appropriate Multivariate analyses if appropriate to the research hypotheses, and be able to justify the model chosen.		

Logistic regression	General concept behind multiple logistic regression	Understand appropriate role for logistic regression and sample size issues
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READING & WRITING

Reading a scientific paper		Conduct critical analysis of RCT, survey study, prognosis study, and diagnostic study	Critique/defend their own and others' research protocols with regard to their validity and feasibility	Critique of examples from published medical literature	Students should be better able to evaluate the appropriateness of the statistical methods used in published research studies.
Evidence-based medicine	To be determined	Understand roles and methods of systematic review, meta-analysis	Provide a sound rationale for the proposed research question(s) and study design in light of the existing state of knowledge and the clinical importance of the question		
Writing a scientific paper				Develop a systematic approach to writing: 1. Title; 2. Abstract; 3. Introduction; 4. Methods; 5. Results; 6. Discussion; 7. References; 8. Figures, Tables and Graphs	Students should be able to adequately describe their statistical methods and should gain a greater appreciation for how to create good figures and tables.

PRESENTATION

Protocol	Be able to present research protocol developed in course	Be able to present research protocol developed in course	Present the purpose, design, and procedures of the planned study;	Present summary of research findings and draft of manuscript	Give presentation appropriate for scientific meeting.
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4. The *ATS MECOR Program* Faculty



All *ATS MECOR Program* courses include faculty from North America as well as from the sponsoring regional or country Thoracic Societies and sponsoring organizations (foundations, government agencies, academic institutions, NGOs, etc.)

5. Textbooks

Textbooks recommended for use in the *ATS MECOR Program* include:

- *Epidemiology*, Leon Gordis (3rd Edition Elsevier Saunders, 2004)
- *Designing Clinical Research: an Epidemiologic Approach*, Hulley SB (3rd Edition 2006, Lippincott Williams & Wilkins).

