



**American Thoracic Society
and
Turkish Thoracic Society**

Level 1 Course Schedule

Methods in Epidemiologic, Clinical & Operations Research (MECOR)

Pine Bay Hotel
Kuşadası, Turkey
16-21.November.2009



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MECOR Course in Kuşadası, Turkey**

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program**

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2008 ATS MECOR Course Staff

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**LEVEL 1 COURSE – SYLLABUS
TABLE OF CONTENTS**

	Pages
Introductory Materials	
Course Acknowledgements	1
Syllabus Table of Contents	2
Bibliography	3
Helpful Web Sites	3-4
MECOR Level 1 Competencies	5-6
Course Schedule Level 1	7-12
Course Faculty	13-16
Appendix	
FINER Criteria for assessing study questions	16
Conceptual framework for study design	17
Outline for précis of study proposal	18

Bibliography

Primary Resources:

First, go to the MECOR resources web page at

<http://www.thoracic.org/sections/meetings-and-courses/mecor-courses/courses.html>

Then . . . scroll toward the bottom of the page to “Level 1.”

1. **Download and/or print and review prior to course:** MECOR Level 1 Course Schedule. (This is item d.)
2. **Download and/or print:** IUATLD Syllabus: “Research Methods for the Promotion of Lung Health, A Guide to Protocol Development for Low-Income Countries.”
You will find this at the American Thoracic Society MECOR website at <http://www.thoracic.org/sections/meetings-and-courses/mecor-courses/courses.html>. Scroll down to Level 1; you will see a link through which you can download the Guide directly.
3. **Download and/or print:** Faculty PowerPoint slides: These will be available prior to the start of the course on the MECOR website at <http://www.thoracic.org/sections/meetings-and-courses/mecor-courses/courses.html>. Please be aware that they may be changed by the faculty prior to their presentation. (Such changes are usually modest.)

Supplemental Resources

1. Gordis L. Epidemiology. Third edition. Elsevier Saunders, Philadelphia, PA 2004.
2. Glantz, Stanton A. Primer of biostatistics / Stanton A. Glantz. 6th ed. New York : McGraw-Hill Medical Pub. Division, 2005.
3. **Highly recommended:** Hulley SB, et al. Designing clinical research : an epidemiologic approach. Third edition. Philadelphia : Lippincott Williams & Wilkins, 2007. (Note: The earlier 2nd edition is available used at lesser cost and is perfectly suitable.)

Helpful websites:

Statistics at Square One (British Medical Journal):

<http://bmj.bmjournals.com/collections/statsbk/> This is an excellent review of basic medical statistics.

Southwest Oncology Group for clinical trials: <http://www.swogstat.org/statoolsout.html>

This site is primarily designed for clinical trials work but can be used for other analyses. Designs covered include one-sample and two-sample binomial, normal and survival calculations, plus two-stage clinical trials designs. Does not cover regression models. Logistic regression works only for one dichotomous predictor (via two-sample binomial). Note that it also has some simple statistical calculations (2x2 tables) and probability calculations (binomial, normal).

UCLA: http://socr.ucla.edu/htmls/SOCR_Analyses.html UCLA's statistical calculators run JAVA applets to estimate sample size needs for two-sample Poisson, ANOVA, Fisher's exact test, correlation/regression, t-test with unequal variances, nonparametric rank sum and sign tests, and other features.

Dartmouth-Hitchcock Norris Cotton Cancer Center:
<http://biostat.hitchcock.org/MeasurementError/Analytics/PowerCalculationsforLogisticRegression.asp> This site does logistic regression with a continuous exposure variable and one additional continuous covariate or confounder.

Vanderbilt University: <http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize>
This site is posted by Vanderbilt's CTSC group, which has developed a downloadable free program for Power and Sample Size calculation.

University of Iowa: <http://www.stat.uiowa.edu/~rlenth/Power/index.html>
Russ Length's excellent website covers many ANOVA and regression designs, repeated measures, and a lot more. This is a superb resource with the ability to work out power for contrasts, generate power curves, and so on.

MECOR Level 1 Competencies	
<u>OVERALL GOAL</u>	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.
<u>EPIDEMIOLOGY</u> Descriptive Epidemiology	Understand basis of epidemiologic approach to disease e.g. prevalence, incidence.
<u>RESEARCH DESIGN</u> Research Design Research Questions	Understand basic design of different types of studies: cross-sectional, case-control, cohort, clinical trial, including their respective measures of effect. Be able to pose simple research questions and know which study design is appropriate.
<u>RESEARCH METHODS</u> Sampling/population selection Sample size and power Questionnaires, measures, & measurement procedures Quality Control Ethics & Informed Consent Development of a full research proposal	Difference between populations and samples and how these may affect study results Importance of adequate power and the factors that affect power Importance of valid and reliable measurements; sensitivity, specificity, predictive value Techniques for maximizing data quality Importance of ethical conduct of human research Four stages of study proposals: one-sentence hypothesis, two-page summary, full proposal, manual of operations

MECOR Level 1 Competencies	
<u>STATISTICS</u>	
Descriptive Statistics	Summarize continuous and categorized data; understand and use measures of central tendency; understand and use measures of dispersion.
Measures of association and effect	Prevalence, incidence rate, cumulative incidence, odds; ratios for these
Sources of error	Bias, confounding chance; type I and II errors, standard error and confidence intervals
Univariate & bivariate analyses	T test and ANOVA; Wilcoxon and Kruskal-Wallis; chi-squared
Multivariate analyses	General concept behind multiple linear regression
Logistic regression	General concept behind multiple logistic regression
<u>READING & WRITING</u>	
Reading a scientific paper	Addressed in subsequent MECOR levels
Evidence-based medicine	Addressed in subsequent MECOR levels
Writing a scientific paper	Addressed in subsequent MECOR levels
<u>PRESENTATION</u>	
Protocol	Be able to present research protocol developed in course

Small Group Leaders:

Group 1: Sonia Buist

Group 2: Banu Çakir

Group 3: Ahmet Demir

Group 4: Phil Hopewell

Group 5: Steve McCurdy

METHODS IN EPIDEMIOLOGIC, CLINICAL & OPERATIONS RESEARCH (MECOR)

**Level 1 Course
Kuşadası, Turkey 2009**

Day 1 (Monday, 16.November.09)

Themes: Study design, statistics, consider research question

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:00 AM	Intro: Welcome & expectations of students	S Buist S McCurdy	
9:00 – 9:30 AM	Epidemiology: Making a difference in your world	S McCurdy	IUATLD 1.1-1.3, 2.1-2.2 Gordis Ch. 1 Hulley 18 Slides: Getting Started
9:30 – 10:30 AM	Student Introduction & Topics	All faculty (Faculty to develop small-group assignments)	
10:30 – 11:00 AM	Coffee Break		
11:00 – 12:00 PM	Assignment to small groups	All faculty	
12:00 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Study Design I: Overview and Cohort Studies	S McCurdy	IUATLD 4.1-4.3 Gordis Ch. 7-10 Hulley 8 Slides: Study Design I
2:30 – 3:30 PM	Writing a research protocol	S Buist	IUATLD 8.2
3:30 – 4:00 PM	Tea Break		
4:00 – 5:30 PM	Small Groups #1 (Plenary review of FINER criteria per Hulley & 2 x 2 table; small groups discuss ideas for research question.)	All Faculty	IUATLD 1.1-1.3, 3.1-3.2 Hulley 2 Appendix

*** IUATLD readings are required. Other listed material is optional.**

Day 2 (Tuesday, 17.November.09)

Themes: Study design, statistics, association and testing, developing research question

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:45 AM	Role of Statistics in Research (Statistics 1: Descriptive Statistics)	S McCurdy	IUATLD 8.2 Slides: Biostat 1
9:45 – 10:45 AM	Measures of Association	P Hopewell	Slides: Measures of Association Diagnostic Tests
10:45 – 11:00 AM	Coffee Break		
11:00 – 12:00 PM	Study Design II: Cross-sectional Studies	S Buist	IUATLD 4.1-4.3 Gordis Ch. 10 Hulley 8 Slides: Study Design II
12:00 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Study Design III: Case-Control Studies	B Çakir	IUATLD 4.1-4.3 Gordis Ch. 9, 13 Hulley 7 Slides: Study Design III
2.30-3.30PM	Diagnostic and Screening Testing	A Demir	IUATLD 8.1 Gordis Ch. 4 Slides: Diagnostic Tests
3:30 – 5:30 PM (includes tea break 3:30-4:00 p.m.)	Small Groups #2 (<i>Identify research question, address design.</i>)	All Faculty	IUATLD 1.1-1.3, 3.1-3.2

* IUATLD readings are required. Other listed material is optional.

Day 3 (Wednesday, 18.November.09)

Themes: Outcomes, statistics, continue protocol development

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:30 AM	Study Design IV: Clinical Trials	A Demir	IUATLD 4.1-4.3 Gordis Ch. 7,8 Hulley 10, 11 Slides: Study Design IV
9:30 – 10:45 AM	Statistics 2: Confidence Intervals	S McCurdy	IUATLD 5.1 Slides: Caveat emptor
10:45 – 11:00 AM	Coffee Break		
11:00 – 12:00 PM	Sources of Error: Chance, Bias, Confounding	A Demir	IUATLD 8.2 Slides: Biostat 2
12:00 – 1:30 PM	Lunch		
1:30 – 5:30 PM (includes tea break 3:30-4:00 p.m.)	Small Groups #4: (<i>Continue with outline and protocol development.</i>)	All Faculty	

* IUATLD readings are required. Other listed material is optional.

Day 4 (Thursday, 19.November.09)

Themes: Statistics, avoiding error, questionnaires, continued protocol development

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30– 9:30 AM	Respiratory Disease Outcomes	S Buist	Slides: Respiratory Disease Outcomes
9:30 – 10:45 AM	Statistics 3: Fundamentals of Testing	S McCurdy	IUATLD 8.2 Syllabus III Slides: Biostat 3
10:45 – 11:00 AM	Coffee Break		
11:00 – 12:00 PM	Population Selection	B Çakir	IUATLD 8.1 Gordis Ch. 14, 15 Hulley 9 Slides: Population Selection
12:00 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Questionnaires and their Development	B Çakir	IUATLD 6.3 Hulley 15 Slides: Questionnaires
2:30 – 6:00 PM (includes tea break 4:00-4:30 p.m.)	Small Groups #5: (<i>Continue with outline.</i>)	All Faculty	

* IUATLD readings are required. Other listed material is optional.

Day 5 (Friday, 20.November.09)

Themes: Statistics, funding, continued protocol development

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:45 AM	Statistics 4: Which test to use?	S McCurdy	IUATLD 5.3, 8.2 Hulley 5,6 Slides: Biostat 4
9:45 – 12:30 PM (includes coffee break 10:30-11:00 a.m.)	Small Groups #6: (<i>Continue with outline and protocol development.</i>)	All Faculty	
12:30 – 1:45 PM	Lunch		
1:45 – 2:45 PM	Practical Aspects of Research and Funding	S Buist	IUATLD 9.2 Hulley 19
2:45 – 6:00 PM (includes tea break 4:00-4:30 p.m.)	Small Groups #7: (<i>Should be almost finished!</i>) (<i>Sign up for order of presentations on Saturday</i>)	All Faculty	

* IUATLD readings are required. Other listed material is optional.

Day 6 (Saturday, 21.November.09)

Themes: Statistics, polishing and presenting protocols

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:30 AM	Statistics 5: Multivariable Methods	S McCurdy	IUATLD 8.2 Slides: Biostat 5
9:30 – 10:30 AM	Finish & Polish Protocols	All Faculty	
10:30 – 11:00 AM	Coffee Break		
11:00 – 12:30 PM	Finish & Polish Protocols	All Faculty	
12:30 – 2:00 PM	Lunch		
2:00 – 5:30 PM	Presentations of Protocols	All Faculty	
5:30 – 6:15 PM	GRADUATION (Presentation of Certificates)		

* IUATLD readings are required. Other listed material is optional.

LEVEL 1 - Course Faculty

A. Sonia Buist, MD

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Dr. Sonia Buist is currently Professor Emerita of Medicine at the Oregon Health & Science University. Dr. Buist obtained her medical degree from St Andrews University in Scotland, did her residency at the University of Colorado School of Medicine in Denver, and completed fellowships in pulmonary medicine and pulmonary physiology at the University of Oregon Medical School. Dr. Buist has been a member of numerous federal and international advisory groups. She is a past member of the New England Journal of Medicine Editorial Board and is a current member of the editorial board of Thorax and the Clinical Respiratory Journal. She has held numerous positions in the American Thoracic Society and was President in 1990-91. Dr. Buist's research interests are primarily in the areas of asthma and COPD, with particular emphasis on the epidemiology and management of these diseases.

Dr. Buist, together with Dr. Jon Samet, started the ATS IRE Program in 1994. Since then, the program, now called the MECOR (Methods in Epidemiologic, Clinical & Operations Research) Program has been held annually in Latin America (Mexico, Chile, Brazil, Argentina, Peru, Uruguay and Ecuador). In 2007, the MECOR Program started in Africa, in conjunction with the Pan African Thoracic Society (PATS-MECOR). The MECOR Program started in Turkey in 2008 and in India in 2009.

Stephen McCurdy, MD, MPH

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Dr. McCurdy is a Professor in the Division of Environmental & Occupational Health in the Department of Public Health Sciences at the University of California, Davis School of Medicine, where he directs the Master in Public Health program. His research interests include general occupational medicine, occupational hazards in semiconductor manufacturing and agricultural industries. He has participated since 1998 in previous MECOR courses in Argentina, Brazil, Peru, Ecuador, Uruguay, Turkey, and Malawi.

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Dr Hopewell received both his undergraduate and M.D. degrees from West Virginia University. He trained in internal medicine and pulmonary diseases at the University of California, San Francisco and has remained on the faculty at UCSF, working at San Francisco General Hospital where he was Chief of Pulmonary and Critical Care Medicine and, subsequently, Associate Dean, responsible for University activities at SFGH. He stepped down from the associate deanship in 2004 to pursue international tuberculosis control activities. Currently he is professor of medicine at UCSF and Director of the Francis J. Curry National Tuberculosis Center at San Francisco General Hospital.

Dr. Hopewell continues to direct an active research program in clinical and epidemiological aspects of tuberculosis in close collaboration with the San Francisco Tuberculosis Control Program. He also directs the Curry National Tuberculosis center, which includes a CDC funded Regional Training and Medical Consultation Center as well as projects funded by WHO, TDR, USAID, and the Gates Foundation. In addition he continues to be a practicing pulmonologist and critical care physician at SFGH.

Dr Hopewell is a past President of the American Thoracic Society and was the recipient of the Society's E.L. Trudeau Medal in 2004 and its World Lung Health Award in 2007.

Banu Çakir, MD, MPH, PhD

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Upon obtaining her medical degree from Hacettepe University Medical School, in 1989, Dr. Çakır continued to the residency program in the Department of Public Health (Community Medicine) at the same university, between years 1990 and 1994. Dr. Çakır obtained her M.P.H. degree from the Department of Epidemiology of the Rollins School of Public Health, Emory University, Atlanta, GA, U.S.A. (May 1996) and her Ph.D. degree in Epidemiology from the University of North Carolina at Chapel Hill, Chapel Hill, NC, U.S.A. (January 2000). She has been working with the Department of Public Health at the Hacettepe University since February 2000; where, she obtained a speciality degree in Public Health (Community Medicine) in 2002 and her Associate Professor title in 2004. Dr. Çakır is currently an Associate Professor in the

Department of Public Health at the Hacettepe University Faculty of Medicine, Ankara, Turkey. She teaches public health and epidemiology to undergraduate and graduate students; provides technical consulting and support to different governmental and non-governmental organizations in the field of chronic diseases-, cancer-, genetic-, infectious diseases-, and clinical epidemiology, pharmacoepidemiology, and violence; and also conducts/provides consultancy to a variety of different clinical and field research activities.

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Dr. Ahmet U. Demir completed his medical education in 1992 in Hacettepe University. He received specialty training in Pulmonary Diseases from 1992 to 1999 in Hacettepe University Chest Diseases Clinics. Dr. Demir attended to McGill University Dept of Epidemiology and Biostatistics during his residency with a scholarship, in the period from 1996 to 1998, and received the degree of MSc in Epidemiology and Biostatistics. He is involved in investigations of asthma epidemiology, work-related respiratory diseases, tobacco addiction, and related health problems. Dr. Demir has attended and has been a Faculty member in post-graduate courses of research methodology at international conferences organized by the International Union of Tuberculosis and Lung Diseases in Istanbul. Dr. Demir works as a responsible physician in the Sleep Lab, mainly on sleep-related breathing disorders. He is a member of the Turkish Thoracic Society, and a member of the Executive Committee of Turkish Sleep Research Society. He organized a one-day introductory course on research methodology in epidemiology in the last annual Congress of Turkish Sleep Research Society. His main research interest and recent objective is the epidemiology of sleep disorders in the Turkish general population.



FINER Criteria for Evaluating Study Questions

Feasible

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope

Interesting

- To the investigator

Novel

- Confirms or refutes previous findings
- Extends previous findings, such as to new geographic areas or populations
- Provides new findings

Ethical

- Must go through institutional human subjects review board

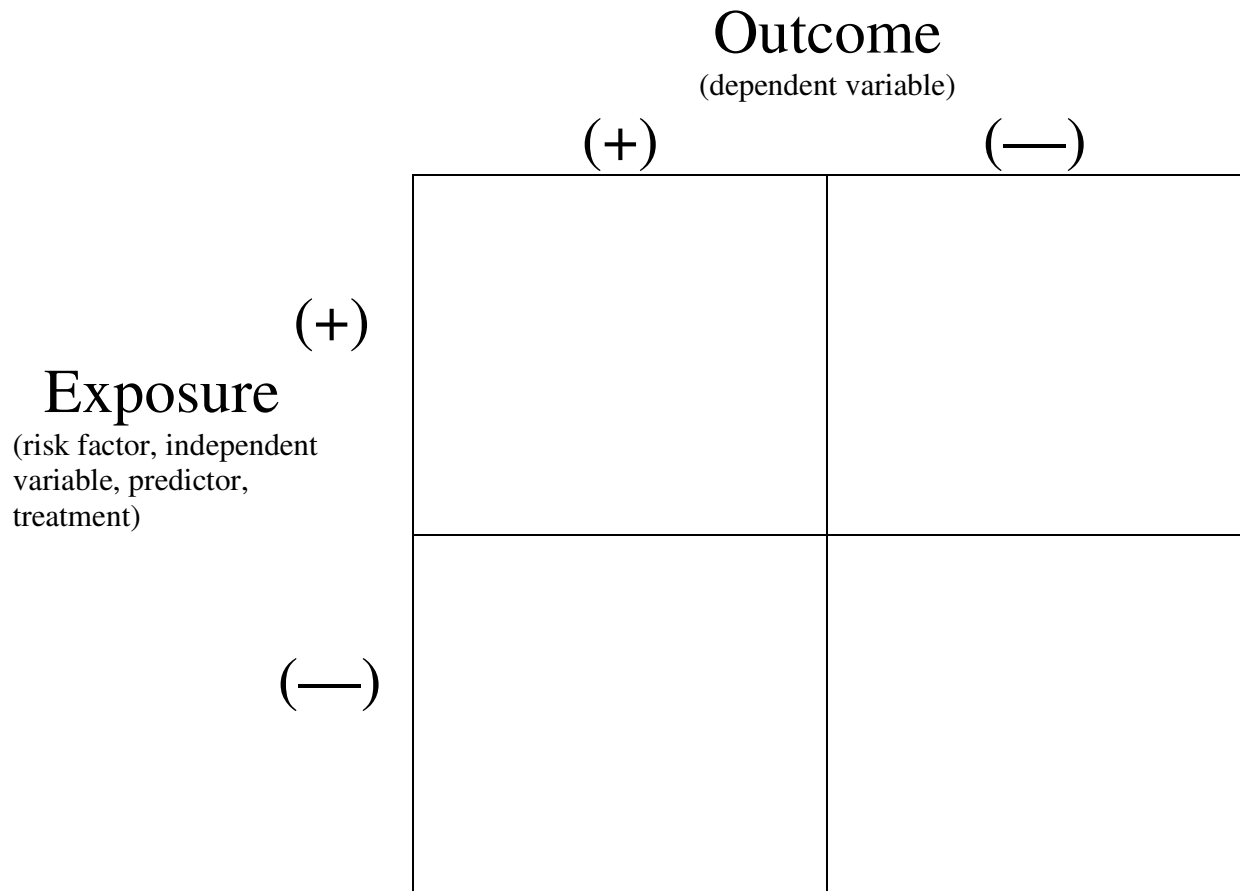
Relevant

- To scientific knowledge
- To clinical and health policy (e.g., affects treatment or prevention)
- To future research (e.g., improves understanding of mechanism)

I.e., what are the implications of finding out the answer to your question?

(Adapted from Hulley et al.: Designing Clinical Research: An Epidemiologic Approach, Table 2.1)

Conceptual framework for study design



Population/sample:

Potential confounders:

Outline of a study
(1-2 pages for dissemination and comment by colleagues)

Title:

Clear and descriptive

Research Question:

One sentence concisely stating your question

Significance:

One to several paragraphs indicating why the question is important

Design:

Cross-sectional vs. case-control, vs. cohort, etc.

Subjects:

Entry and exclusion criteria:

Recruitment:

Variables:

Outcome (dependent variable):

Exposure (risk factor, independent variable, predictor):

Potential confounders:

Method of data collection and quality control:

E.g., questionnaire, medical record review, etc.

Statistical issues:

Hypothesis:

Sample size and power:

Budget:

Personnel:

Supplies:

Equipment:

Travel:

(Adapted from Hulley et al.: Designing Clinical Research: An Epidemiologic Approach, Appendix 1.1, page 15)