

Pan African Thoracic Society



Course Schedule

Methods in Epidemiologic, Clinical & Operations Research (MECOR)

≈ Measuring the Burden of Disease ≈

Brackenhurst
Nairobi, Kenya

Monday 10.October - Friday 14.October.2011



Faculty and Students Level 1 PATS MECOR 2010

Rev 21.Sept.2011

ACKNOWLEDGMENTS

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2011 MECOR Course in Kenya

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program

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**MEASURING THE BURDEN OF DISEASE
COURSE SYLLABUS
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Small Group Leaders:

Group 1: Evans Amukoye & Bamidele Adeniyi (TA)

Group 2: Steve McCurdy & Adebola Orimadegun (TA)

Group 3: Peter Wanzala

Group 4: Kevin Mortimer

Group 5: Ezekiel Wafula

Group 6: TBA

Bibliography

EXPECTATIONS *BEFORE* YOU ARRIVE:

First, go to the MECOR resources web page at the American Thoracic Society web page (<http://www.thoracic.org/global-health/mecor-courses/index.php>) or the PATS web page (<http://www.africanthoracic.org/>). Follow the links to the MECOR program and the course resources, including the slides and IUATLD syllabus cited below. Information and resources (syllabus, schedule, slides) may also be available at the regional thoracic society website as well.

1. **Download and/or print and review prior to course:** MECOR Level 1 Course Schedule.
2. **Download and/or print IUATLD Syllabus:** "Research Methods for the Promotion of Lung Health, A Guide to Protocol Development for Low-Income Countries." This is also available at the IUATLD website (<http://www.theunion.org/>). On the horizontal bar click on "Resources." The next page will have a blue box on the left—click on "Lung Health and NCDs." You will see it listed among other publications.

Or, here is a very long URL that will take you directly to the document:

<http://www.theunion.org/index.php/en/resources/scientific-publications/item/166-research-methods-for-the-promotion-of-lung-health-a-guide-to-protocol-development-for-low-income-countries>

3. **Download and/or print Faculty PowerPoint slides:** These will be available prior to the start of the course on the MECOR page of the American Thoracic Society web page or the PATS webpage at http://www.africanthoracic.org/patsmecor/students_important_info.htm
Please be aware that they may be changed by the faculty prior to their presentation. (Such changes are usually modest.)
4. **Download** EpiInfo (free) at www.cdc.gov/epiinfo and complete the tutorial.

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

<p><u>OVERALL GOAL</u></p>	<p>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 biostatistical skills. Students will gain an overview of statistics that will help them to collaborate effectively with statistical co-investigators.</p>
<p><u>EPIDEMIOLOGY</u> Descriptive Epidemiology</p>	<p>Understand basis of epidemiologic approach to disease e.g. prevalence, incidence.</p>
<p><u>RESEARCH DESIGN</u> Research Design Research Questions</p>	<p>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 for the question posed.</p>
<p><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</p>	<p>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</p>

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

Day 1: Monday 10.October.2011

Themes: Study design, statistics, consider research question

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:00 AM	Plenary welcome to students and faculty at all levels	All	
9:00 – 9:30 AM	Intro: Welcome & expectations of students	S Gordon S Buist S McCurdy	
9:30 – 10:00 AM	How can epidemiology make a difference in developing countries?	E Amukoye S Gordon	IUATLD 1.1-1.3, 2.1-2.2 Gordis Ch. 1 Hulley 18 Slides: Getting Started
10:00 – 10:30 AM	Coffee Break		
10:30 – 11:00 AM	Student Introduction & Topics of Interest	All Faculty (faculty to assign to small groups)	
11:00 – 12:15 PM	Study Design: Overview and Cohort Studies	S McCurdy	IUATLD 4.1-4.3 Gordis Ch. 7-10 Hulley 7 Slides: Study Design I
12:15 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Role of Statistics in Research (Statistics 1)	S McCurdy	IUATLD 8.2 Slides: Biostat 1
2:30 – 3:30 PM	Study Design: Cross-sectional Studies	S Buist	IUATLD 4.1-4.3 Gordis Ch. 9, 13 Hulley 8 Slides: Study Design III
3:30 – 4:00 PM	Tea Break		
4:00 – 5:30 PM	Small Groups #1 <i>(Review FINER criteria per Hulley and 2x2 in plenary session; discuss ideas for research question in small groups; group report)</i>	All Faculty	IUATLD 1.1-1.3, 3.1-3.2 Hulley 2

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

Day 2: Tuesday 11.October.2011

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

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:30 AM	Statistics 2	S McCurdy	IUATLD 8.2 Slides: Biostat 2
9:30 – 10:45 AM	Measures of Association	P Hopewell	IUATLD 2.3, 6.5 Gordis Ch. 11 Slides: Measures of Association
10:45 – 11:00 AM	Coffee Break		
11:00 – 12:00 PM	Statistics 3	S McCurdy	IUATLD 8.2 Slides: Biostat 3
12:00 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Sources of Error: Chance, Bias, Confounding	K Mortimer	IUATLD 8.1 Gordis Ch. 14, 15 Hulley 9 Slides: Caveat emptor
2:30 – 3:30 PM	Protocol development	S Buist	IUATLD 3 Slides: Protocol development
3:30 – 4:00 PM	Coffee Break		
4:00 – 5:30 PM	Small Groups #2 <i>(Identify research question, address design; group report)</i>	All Faculty	IUATLD 1.1-1.3, 3.1-3.2

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

Day 3: Wednesday 12.October.2011

Themes: Outcomes, statistics, continue protocol development

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:30 AM	Statistics 4	S McCurdy	IUATLD 5.3, 8.2 Hulley 5,6 Slides: Biostat 4
9:30 – 10:30 PM	Respiratory Disease Outcomes	S Buist	Slides: Respiratory Disease Outcomes
10:30 – 11:00 AM	Coffee Break		
11:00 – 12:15 PM	Population and Sample Selection	K Mortimer	IUATLD 5.1 Slides: Study Populations
12:15 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Questionnaires and their Development	K Mortimer	IUATLD 6.3 Hulley 15 Slides: Questionnaires
2:30 – 3:30 PM	Sample Size and Power Calculations	S McCurdy	Slides: Sample Size and Power: An Intuitive Approach
3:30 – 4:00 PM	Coffee break		
4:00 – 5:30 PM	Small Groups #3: <i>(Continue with outline and protocol development; group report)</i>	All Faculty	

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

Day 4: Thursday 13.October.2011

Themes: Statistics, funding, continued protocol development

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 – 9:30 AM	Systematic literature review	K Mortimer	
9:30 – 12:00 PM (includes coffee break 10:30-11:00 a.m.)	Small Groups #4: (<i>Continue with outline and protocol development.</i>)	All Faculty	
12:00 – 1:30 PM	Lunch		
1:30 – 2:30 PM	Practical Aspects of Research and Funding	S Gordon E Amukoye S Buist	IUATLD 9.2 Hulley 19 Slides: Funding (Gordon, Buist)
2:30 – 5:30 PM (includes tea break 4:00-4:30 p.m.)	Small Groups #5: (<i>Should be almost finished!</i>)	All Faculty	

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

Day 5: Friday 14.October.2011

Themes: Statistics, polishing and presenting protocols

TIME	TOPIC	FACULTY	READINGS* & SLIDES
8:30 AM – 12:00 PM (includes coffee break 10:30 – 11:00 AM)	Small groups #6 <i>(Finish & Polish Protocols)</i>	All Faculty	
12:00 – 1:30 PM	Lunch		
1:30 – 4:00 PM	Presentations of Protocols	All Faculty	
4:00 – 5:00 PM	GRADUATION (Presentation of Certificates)		

* IUATLD readings are required. Other listed material is optional

LEVEL 1 - Course Faculty

A. Sonia Buist, MD

Pulmonary and Critical Care Medicine
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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 Gordon, MD

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Professor Stephen Gordon gained his first degree at Cambridge in 1987 and went on to become an MD in 1998 and a Fellow of the Royal College of Physicians (London) in 2005. He joined the Liverpool School of Tropical Medicine in 2005 and is now a Professor of Tropical Respiratory Medicine. He also holds an Honorary Consultant Contract in General Medicine in the Royal Liverpool University Hospital and University Hospital Aintree and combines Respiratory and General Medicine with research and teaching in the School.

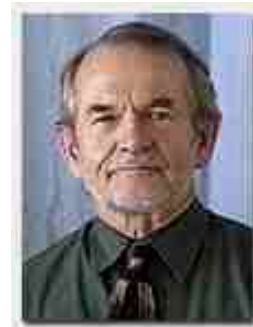
His remit at the Liverpool School of Tropical Medicine was to establish laboratory and clinical research on susceptibility to pulmonary infections. His previous research in Sheffield and Malawi focused on susceptibility to respiratory infection and in particular, on the effect of HIV infection on susceptibility to pneumococcal disease. The work demonstrated that pulmonary mucosal defence is regulated differently than systemic defence against infection, and can be perturbed by environmental exposures including indoor air pollution.

The Respiratory Infection laboratory now focuses on mechanisms for antigen presentation to the mucosal surface leading to effective mucosal defence against bacterial infections. Additionally team members also study the effect of biomass fuel smoke on defence against infection. Recent work includes a study of inhaled pneumococcal polysaccharide vaccine, assessment of the pulmonary response to pneumococcal conjugate vaccine and the current study of experimental pneumococcal carriage as a pulmonary antigen challenge. Work on biomass fuel smoke indicates that acute and chronic exposures result in very different immune responses, probably leading to altered defence against infection and COPD by different mechanisms.

Professor Gordon is a member of the PATS Committee and founded the PATS MECOR course where he has been a faculty member since 2007.

Phillip Hopewell, MD

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Dr. Hopewell was born in West Virginia and 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 got his first taste of public health as a medical officer in the Division of Tuberculosis Control at the Centers for Disease Control. Subsequently he worked with CDC serving as a consultant in tuberculosis control to the Nigerian Government during and after the Biafran war. In addition to Nigeria, Dr. Hopewell has worked with the national tuberculosis control program in Peru and with the Stop TB Department at the World Health Organization. Recently he co-chaired with Mario Raviglione of the World Health Organization, the committee that developed the *International Standards for Tuberculosis Care (ISTC)*. Since completion of the *ISTC*, he has conducted pilot studies of implementation of the Standards in India, Indonesia,

Kenya, Tanzania, and Mexico. Because of his close collaboration with the Indian Medical Association he was awarded honorary membership in the organization.

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 and with Peter Small, formerly at Stanford University and now with the Bill and Melinda Gates Foundation. 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.

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 (MPH) program. He received his medical degree from the University of California, San Diego School of Medicine, and his education included a Master of Public Health (MPH) degree from the University of California, Berkeley School of Public Health. After a clinical residency in internal medicine and a year as Chief Medical Resident at the University of California, Davis Medical Center, he completed a fellowship in Occupational and Environmental Medicine at UC Davis and subsequently joined the faculty at the School of Medicine. His research interests include general occupational medicine, occupational hazards in semiconductor manufacturing and agricultural industries. He has a strong interest in teaching, and his teaching activities include the preventive medicine and epidemiology curriculum for the UCD School of Medicine's preclinical medical students, small-group leadership in the third-year Doctoring curriculum, and the Introduction to Public Health and Public Health Practicum courses for graduate MPH students. He is also the director for a one-week intensive clinical epidemiology course similar to MECOR for UC Davis fellows and new faculty. He has participated since 1998 in previous MECOR courses as faculty and Level One Course director in Argentina, Brazil, Peru, Ecuador, Uruguay, Turkey, Malawi, and Kenya. Hobbies include music (guitar, recorder), international culture (fluent in German and moderate fluency in Spanish), and, yes, riding a unicycle.

Evans Amukoye, MBChB. Mmed (Paediatric)

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Dr Amukoye is the Director of the Centre for Respiratory Diseases Research, Department of Kenya Medical Research Institute. He obtained a Bachelor of Medicine and Surgical and Master of Medicine in Paediatrics from the University of Nairobi. He has done several courses and attached in the field of respiratory medicine in various institutions, including the Institute of Child Health/Great Ormond Street Children's Hospital, UK, University of Kyorin (Japan) and University of Sapporo (Japan). He is a member of the Executive Board of KAPTLD and interim Executive Council of PATS. He is a member of the Scientist Committee of the Centre and the Institute. He has participated as a student in similar courses held in Kenya. He has been involved in the supervision of Masters and PhD students at Jomo Kenyatta University of Agriculture and Technology and the University of Nairobi.

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After obtaining his medical degree from the University of Cambridge Kevin continued his medical training in Nottingham. Along the way he did a PhD in Respiratory Medicine, completing three clinical studies and a case-control study exploring the potential systemic adverse effects of inhaled corticosteroids. He spent the last two years of his specialist training in a Clinical Lecturer post at the University of Nottingham helping to develop clinical research projects, contributing to teaching and obtaining further training in clinical trial design, implementation and analysis through an MSc in Clinical Trials at the London School of Hygiene and Tropical Medicine. He now works at the Liverpool School of Tropical Medicine with particular research interests in non-communicable respiratory disease and the adverse health effects of biomass fuel smoke exposure.

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Dr. Adeniyi is a consultant physician (respiratory medicine) at the Federal Medical Centre, Owo in Ondo state, Nigeria. His areas of research interest include asthma, COPD, TB and other chronic lung conditions. He is also interested in sleep medicine. He has completed the level three of the PATS-MECOR program and looks forward to giving back to the program with great passion.

**Adebola E. Orimadegun, M.B;B.S, MSc (Ibadan),
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Dr. Orimadegun is a Medical Research Fellow in the Institute of Child Health, College of Medicine at the University of Ibadan and Honorary Consultant Paediatrician, in the Children Emergency Unit at the University College Hospital, Ibadan, Nigeria. He coordinates the Master in Public Health (Child and Adolescents Health) programme. His research interests include epidemiology and control of childhood diseases, risk factor for mortality and clinical trials of interventions. He has attended Levels 1, 2 and 3 MECOR courses in Malawi and Kenya.

Ezekiel Wafula, M.Med, MB.ChB

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Dr Wafula graduated from the University of Nairobi with an MB.ChB in 1974 and an M.Med in Paediatrics in 1979 and attended a Fellowship in Clinical Epidemiology in the University of Pennsylvania in 1989 to 1980. He has worked as the Provincial Paediatrician for Coast Province between 1979 and 1980, and joined the Department of Paediatrics as lecturer in 1980. He was promoted to position of Senior Lecturer in 1987 and to that of Associate Professor in 1992.

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Dr. Wanzala is a research scientist at the Kenya Medical Research Institute's Centre for Public Health Research. His former affiliations are the Royal Dental College in Copenhagen Oral Medicine and Pathology programs (1987-1993) and the University of Washington Department of Public Health Sciences (1989-1999). Currently he is the Research Methodology Course coordinator in the Institute of Tropical Medicine and Infectious Diseases at Jomo Kenyatta University of Agriculture and Technology. He is currently the Editor in Chief of the African Journal of Health Sciences (Website: ajhsjournal.or.ke). His interests include dental public health research, epidemiology, biostatistics, oral medicine, oral pathology, and virology.



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

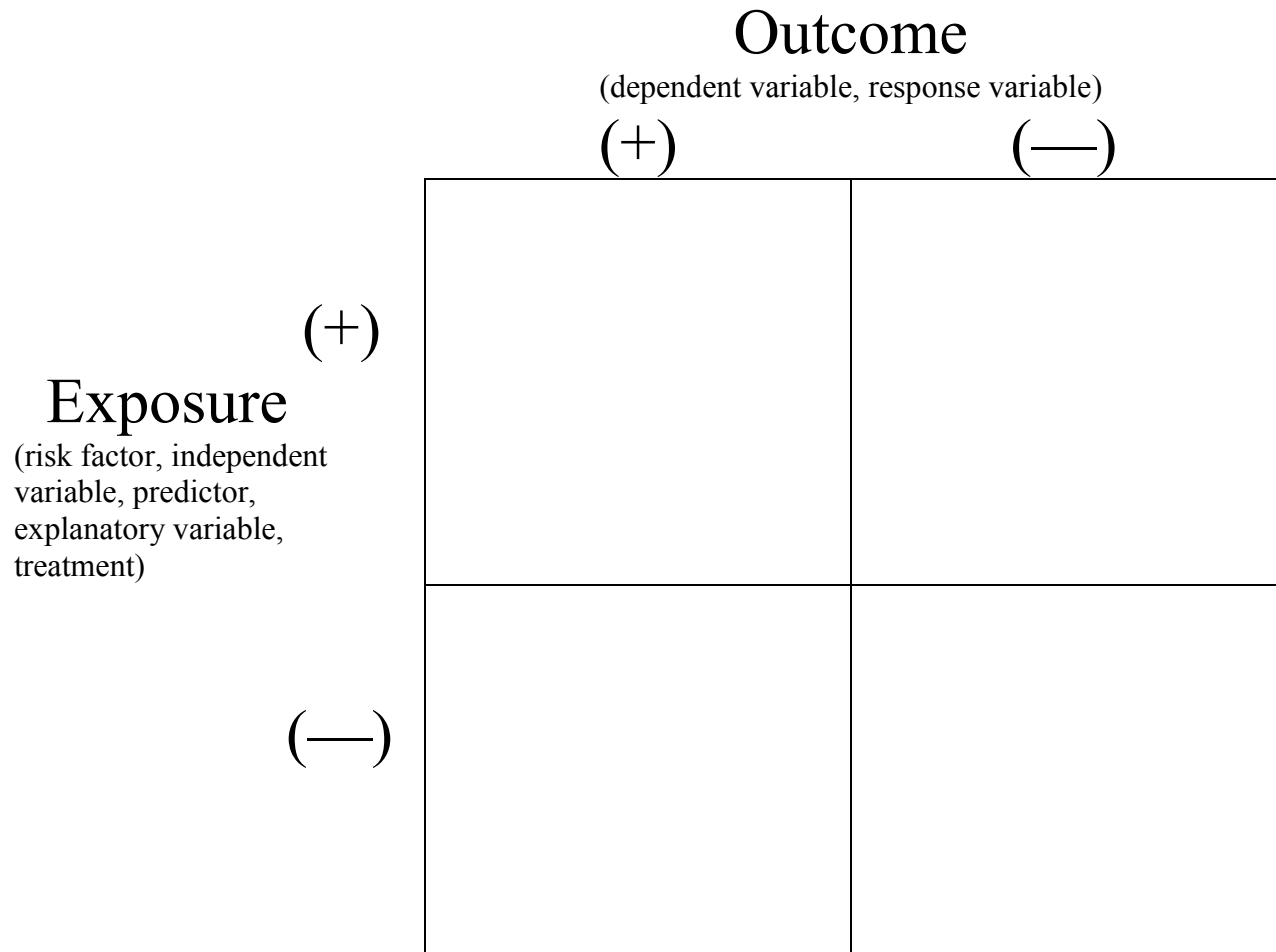
Relevant

- 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:

Important covariates (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, response variable):

Exposure (risk factor, independent variable, predictor, explanatory variable, treatment):

Potential confounders and covariates:

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)