

OUTCOMES ASSESSMENT, RATIONAL DRUG THERAPY AND PHARMACY
PROGRAMME FOR May 26-27, 2014

Alan Lyles, ScD, MPH, RPh

Monday May 26 (**Room to be announced**)

- 9.15-12 Opening remarks
Introduction to outcomes research
- Background and brief history
 - Key concepts
 - o Costs: Economic considerationsⁱ
 - o Treatments: Clinical Considerations
 - o Bias
 - o Managing Conflicts of Interest
 - Procedures and Methods
 - o Registering Clinical Trials
 - o Alternative Analytic techniques
 - Outcomes measures
 - o Efficacy vs. Effectiveness
 - o Cost-Effectivenessⁱⁱ
 - o Cost-Utility
 - Selection of outcomes measures
 - o ECHO Model
 - o Resources for validated instruments
 - Medical Outcomes Trust (<http://www.outcomes-trust.org/>)
 - ISPOR (www.ispor.org)
- 12-13 Lunch
- 13-14.30 Evidence-based medicine (EBM) – is there really evidence?
- Peer review & assessing the strength of accumulating evidence
 - The role of therapeutic guidelines in EBMⁱⁱⁱ
 - Examples of study designs, case studies
 - o Randomized Clinical Trials
 - o Pragmatic Clinical Trials
 - o Cohort Studies
 - o Quasi-Experimental Design: Administrative Database Studies
 - Recommended readings and resources:
Note Retraction Watch <http://retractionwatch.wordpress.com/>
- 14.30-14.45 Coffee break
- 14.45-15.30 Outcomes assessment of pharmaceutical services: What is known about outcomes of medication reviews?
- Analysis of study designs and methodology

- Outcomes measures applied
- DRPs and PIMs as outcomes measures
- Session is based on the literature review of Dr. Saija Leikola's dissertation:
Development and Application of Comprehensive Medication Review Procedure to
Community-Dwelling Elderly (<https://helda.helsinki.fi/handle/10138/30203>)
Dr. Saija Leikola, Association of Finnish Pharmacies (to be confirmed)

15.30-16.15 Outcomes research in hospital settings
Lotta Tynismaa, MSc(Pharm), HUS Pharmacy (to be confirmed)

16.15-17 Consulting hour for assignments

Tuesday May 27 (Room to be announced)

9.15-12 Workshop: Study design decisions (Practical exercises)
Alan Lyles and Marja Airaksinen

12-13 Lunch

13-14 Selected examples of student projects

14-14.30 Comparative Effectiveness research (CER)
The Patient Centered Outcomes Research Institute (www.pcori.org)
Priorities
Methodology
<http://www.pcori.org/research-we-support/research-methodology-standards/>

Guidelines for Comparative Effectiveness. Value in Health Special Issue
2009; 12(8)
http://www.ispor.org/publications/value/valueinhealth_volume12_issue8.pdf

ISPOR Task Force Reports

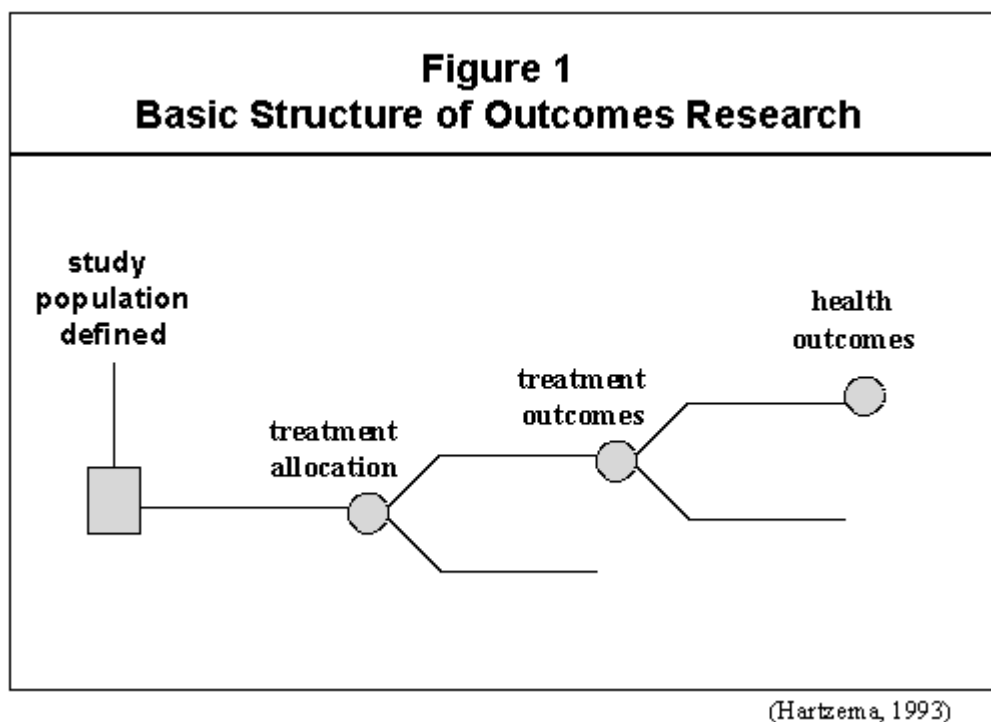
- 1) <http://www.ispor.org/workpaper/Interpreting-Indirect-Treatment-Comparison-Studies-for-Decision-making.asp>
- 2) <http://www.ispor.org/workpaper/conducting-indirect-treatment-comparison-and-network-meta-analysis-studies.asp>
- 3) <http://www.ispor.org/workpaper/Prospective-Observational-Clinical-StudiesGRP.asp>

Prof. Alan Lyles

14.30-15 Coffee break

15-15.45 CER Examples/Discussion
The National Institute for Health and Welfare
http://www.thl.fi/en_US/web/en/aboutus/organisation/units/centre_for_health_and_social_economics
Prof. Alan Lyles

15.45-16 Closing remarks
Prof. Marja Airaksinen



Resources:

Agency for Healthcare Research and Quality. Outcomes of Pharmaceutical Outcomes Research. <http://www.ahrq.gov/clinic/pharmimp/pharmi4.htm>

Agency for Healthcare Research and Quality. Effective Health Care Program: Methods Guide for Effectiveness and Comparative Effectiveness Reviews, 2013. <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=318&pageaction=displayproduct>

Johnson ML¹, Chitnis AS. Comparative effectiveness research: guidelines for good practices are just the beginning. Expert Rev Pharmacoecon Outcomes Res. 2011 Feb;11(1):51-7. doi: 10.1586/erp.10.93.

GRACE Principles: <http://www.graceprinciples.org/index.html>

ISPOR. Pharmaceutical Outcomes Research and Policy in Canada - Context and Recent Developments. <http://www.ispor.org/news/articles/june08/por.asp>

ISPOR. Using 'Real World' Data in Coverage and Reimbursement Decisions Task Force. http://www.ispor.org/workpaper/RWD_TF/ISPORRealWorldDataTaskForceReport.pdf

National Cancer Institute. Theory at a Glance: A Guide to Health Promotion Practice. Available at: <http://www.cancer.gov/PDF/481f5d53-63df-41bc-bfaf-5aa48ee1da4d/TAAG3.pdf>

PhD in Pharmaceutical Outcomes Research and Policy: University of Washington, Department of Pharmacy. Curriculum contents. <http://depts.washington.edu/porpp/gradpage.html>

Articles

1. ALLHAT. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial. <http://allhat.sph.uth.tmc.edu/>
2. Cardinal H, Monfared AA, Dorais M, LeLorier J. A comparison between persistence to therapy in ALLHAT and in everyday clinical practice: a generalizability issue. *Can J Cardiol*. 2004 Mar 15;20(4):417-21.
3. Lyles A. Pharmacoeconomics: Applying Science to the Business of Drug Evaluation. *Dosis* [Finland] Farmaseuttinen Aikakauskirja 2006;22(4):276-288.
4. Volpp KG and Das A. Comparative Effectiveness – Thinking Beyond Medication A versus Medication B. *NEJM* 2009;361(4):331-333.
5. Lexchin J, Bero LA, Djulbegovic B, and Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003;326:1167-1170 (31 May), doi:10.1136/bmj.326.7400.1167
6. Sullivan SD, Lyles A, Luce B and Gricar J. AMCP Guidance for Submission of Clinical and Economic Evaluation Data to Support Formulary Listing in United States Health Plans and Pharmacy Benefits Management Organizations. *Journal of Managed Care Pharmacy* 7(4):272-282,2001.
7. Taylor RS, Drummond MF, Salkeld G, Sullivan SD. Inclusion of cost effectiveness in licensing requirements of new drugs: the fourth hurdle. *BMJ* 2004;329:972-975 (23 October), doi:10.1136/bmj.329.7472.972

Editorials

1. Vandenbroucke, JP and Psaty BM. Benefits and Risks of Drug Treatments: How to Combine the Best Evidence on Benefits With the Best Data About Adverse Effects *Journal of the American Medical Association* 2008;300(2):2417-2419
2. Harris G. Medical Journal Changes Its Policy After Criticism By Group. *The New York Times* January 8, 2009
3. Zermansky AG and Silock J. Is Medication Review by Primary-Care Pharmacists for Older People Cost Effective? A Narrative Review of the Literature, Focusing on Costs and Benefits *Pharmacoeconomics* 2009; 27 (1): 11-24
4. Psaty BM and Burke SP. Protecting the Health of the Public – Institute of Medicine Recommendations on Drug Safety. *New England Journal of Medicine* 2006;355(17):1753-1755.
5. Lyles A. The Reference Case Ten Years Later: Has Comparing Cost Effectiveness Analyses Improved? *Clinical Therapeutics* 2006;28(8):1182-1183.
6. Lyles A. Making ‘Real World’ Studies Relevant for Evidence-Based Decisions. *Clinical Therapeutics* 2005;27(7):1090-1091.
7. Lyles A. Must an Interest Be a Conflict? *Clinical Therapeutics* 2005;27(3):344-345.
8. Lyles A. Evidence- or Opinion-Based Pharmaceutical Policy? *Clinical Therapeutics* 2004;26(11):1922-1923.
9. Lyles A. Pharmaceutical Economics and Health Policy Research Using Administrative Data. *Clinical Therapeutics* 2004;26(7):1122-1123.

10. Lyles A. Research Results: Balancing Access with Relevance for Patient Decisions. *Clinical Therapeutics* 2003;25(9):2450-2452.
11. Lyles A. Comparative Information for Evidence-Based Drug Decisions. *Clinical Therapeutics* 2003;25(7):2086-2087.
12. Lyles A. Peer Review and Evidence-Based Decisions. *Clinical Therapeutics* 2002;24(10):1646-1647.

Optional, Additional Resources

The Canadian Agency for Drugs and Technologies in Health (CADTH). Available at:
<http://www.cadth.ca/en>

National Institute for Health and Clinical Excellence (NICE). <http://www.nice.org.uk/aboutnice/>
National Institute for Health and Welfare (www.thl.fi)

ⁱ ISPOR. Report Of The ISPOR Task Force On Use Of Pharmacoeconomic/ Health Economic Information In Health Care Decision-Making. Available at:
<http://www.ispor.org/workpaper/healthscience/TFdecision2002.pdf>

ⁱⁱ Rawlins MD and Culyer AJ. National Institute for Clinical Excellence and its value judgments. *BMJ* 2004;329:224-227 (24 July), doi:10.1136/bmj.329.7459.224 available at:
<http://www.bmj.com/cgi/content/full/329/7459/224>

ⁱⁱⁱ ISPOR. Evidence Based Medicine and Outcomes Research Task Force. Available at:
http://www.ispor.org/councils/Decision_making.asp