



Epidemiology, Biostatistics & Occupational Health
EPIDEMIOLOGY SEMINAR SERIES
Fall 2013

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***Safety trials of long-acting beta-agonists in asthma:
methodological issues***

**Monday, 16 September 2013
4:00 pm - 5:00 pm - Purvis Hall,
1020 Pine Ave. West, Room 25**

ALL ARE WELCOME

SYNOPSIS:

Long acting beta-agonists (LABA) have for two decades been associated with increased asthma death risks in several observational studies and randomized trials, even when added to inhaled corticosteroids (ICS). In reaction, the FDA recently mandated the manufacturers of LABAs to conduct five large non-inferiority randomized trials of the LABA+ICS combination involving thousands of asthma patients. We will review the literature and discuss several methodological issues in the design of these trials that could lead to inaccurate results.

OBJECTIVES:

- 1)** To review observational and randomized studies of beta-agonist safety in asthma
- 2)** To introduce and define non-inferiority randomized trials
- 3)** To discuss methodological issues with recently launched safety trials in asthma

BIO:

Professor Suissa is the Director of Clinical Epidemiology at the Jewish General Hospital's Lady Davis Institute and of the McGill Pharmacoepidemiology Research Unit, and is Professor of Epidemiology and Biostatistics and of Medicine at McGill University, in Montreal, Canada. He heads the Canadian Network for Observational Drug Effect Studies (CNODES)

Prof. Suissa received the Distinguished Investigator award from the Canadian Institute of Health Research (CIHR) of Canada and the prestigious FC Donders Professorship Award from Universiteit Utrecht, Netherlands.

He has conducted several epidemiological studies on the risks and benefits of medications for the treatment of many chronic diseases, including asthma, COPD, rheumatoid arthritis and cardiovascular diseases, and has developed methods for their proper conduct. He has lectured extensively throughout the world and is the author of over 330 peer-reviewed research papers published in scientific journals.

Professor Suissa has served on the Board of Directors of several societies, including the International Society of Pharmacoepidemiology and the Canadian Association for Pharmaceutical Therapeutics. He serves on several scientific advisory boards and on the editorial boards of the European Respiratory Journal, Lancet Respiratory Medicine and Pharmacoepidemiology and Drug Safety, and served on the Journal of Disease Management and Health Outcomes as well as Treatments in Respiratory Medicine. He is a Section Head editor in Statistical methodologies and health informatics for F-1000 Medicine.