EAHP Academy

Seminar 2014

An ACPE knowledge and application based activity

"Pharmacoepidemiology – methodology and tools"
ACPE Universal Activity Number (UAN): 0475-0000-14-033-L04-P/CEUs: 1.375

Academy Camp General Abstract

The need

Activity in pharmacoepidemiology is among the most requested tasks of hospital pharmacists at the interface of research & development and of practice. It is widely interpreted as a

population- (thus the term epidemiology) and public health-oriented preventing task which is guided by accurate and diligent analyses of existing public health and clinical study data. Pharmacoepidemiological research is a promising tool to improve long-term outcome of preventive and therapeutic measures.
The EAHP Scientific Committee has identified the hospital pharmacists' need to manage health data to perform research which can be submitted to the EAHP (and other associations) as congress contributions and as well as articles for publication in EJHP (and other journals). Thus, a hospital pharmacist can perform translational research in pharmacoepidemiology in the practice of hospital pharmacy and in this way contribute to improve long-term clinical and public health outcomes.

Objectives of the Academy Camp and the Workshop

It is the declared objective of this Academy Camp
- to teach current study hierarchy, databases, methods and tools of pharmacoepidemiology research
- to apply individually in break out sessions or interactively in the plenary these methods and tools
- to train delegates in performing literature research and meta-analysis, and combine it with drug utilization data to estimate population attributable risks (PARs)

Presentations and workshop follow a predefined track which starts with the concepts, methods and tools of analytical epidemiology i.e. introduction to study hierarchy, use of current databases, methods, tools, and hints on how to manage bias and confounding. In a workshop series, these concepts will be theoretically and practically applied, i.e. in systematic literature research, meta-analysis, as well as its combination with drug utilisation data to estimate population attributable risks (PARs).

Target group of the seminar

The target group comprises hospital pharmacy managers at the interface of R&D and practice, mainly heads and/or deputy heads of pharmacy, particularly those from the new EU countries and new members of EAHP.

Didactic tools

There will be introductory lectures about the most relevant pharmacoepidemiology topics right before the interactive part will start. The messages delivered during the introductory lectures will be applied and practiced in breakout sessions or plenary discussions. In general, the interactive part will be done in couples of 2 persons. Groups are randomly selected . Mixing / mingling is preferred. For the workshop, every couple or group needs a laptop computer with the Cochrane Collaboration's program Revman® (latest version, freely available on the web) being installed. The interactive parts and the work with the Revman® application is done online.
To facilitate reporting and multiplying knowledge in the national associations, delegates will receive slides for a general presentation made by the workshop coaches.

Key competences and skills of the speakers / tutors according to learning objectives

Speakers will have
- To possess didactic seniority in study design / epidemiology and supervision of epidemiology / computer labs
- To have available a track record with meta-analysis
- To be senior pharmacoepidemiologists
- To dispose of extensive knowledge of EU registries / pharmacoepidemiology
- To know how Revman® software works
- To act out epidemiological excellence for doing meta-analysis and estimated PARs
- To apply their experience in teaching epidemiology labs to students
- To supervise and help the couples during the interactive part

Contents, Teaching Goals, and Learning Objectives of the lectures and workshops

"Introduction into pharmacoepidemiology & EU pharmacoepidemiological databases"

Frank de Vries, Maastricht University Medical Centre, the Netherlands

Abstract / Workshop content
General introduction to pharmacoepidemiology. It will focus on its main areas and applications. Public Health needs reliable data for description and assessment of the population's health problems. They will be described in several types of clinical studies. Pharmacoepidemiology estimates the unintended effects of drugs in very large populations. It will also give a brief overview of widely pharmacoepidemiological databases in the European Union.

Teaching goals
In this section, the presenter and workshop coach will
• Give an overview of major applications of pharmacoepdemiology
• Give a brief overview of EU pharmacoepidemiological databases

Learning objectives
At the end of this session, participants will be able

• To overlook applications of pharmacoepidemiology as of 2014
• To navigate in the most important European pharmacoepidemiological datasources

"Epidemiological Study Designs & Critical Appraisal of Scientific Papers"

Rolf Groenwold, University Medical Center Utrecht, the Netherlands

Abstract / Workshop content
The art of reading a pharmacoepidemiological paper relies on the knowledge of the different designs of clinical studies such as cross-sectional, case control and cohort studies. During this session, the differences and similarities between the different study designs will be explained. In the interactive part, selected papers will be handed out. The study design will have been wiped out/masked and delegates will be asked to identify and discuss the study designs in these scientific papers.

Teaching goals
In this section, the presenter and workshop coach will
- Disseminate knowledge by interactive lecture
- Explain the differences and similarities between study designs
- Demonstrate how to unravel study designs
- Activate participants by ‘buzz groups’ (i.e., one minute discussions among participants with the one sitting next to them)
- Work on short exercises and have plenary discussion

Learning objectives
At the end of this session, participants will be able
- To differentiate between the cohort and the case-control design
- To name pro’s and con’s of commonly used study designs in pharmacoepidemiology, notably the cohort and the case-control design
- To calculate measures of association (risk ratio, odds ratio, risk difference) and explain their differences
- To recognize study designs, exposures, and outcomes in scientific publications

"Classification of Exposure and outcome"

Patrick Souverein, Utrecht University, the Netherlands

Abstract / Workshop content
Classification of exposure and outcome will focus on the principles measuring and classifying pharmacoepidemiological research. Issues with respect to misclassification when using data from electronic health care data will be described.
The interactive parts of classification of exposure and outcome and of bias & confounding will be held in one single block.

Teaching goals
In this section, the presenter and workshop coach will
- Outline the principles of exposure and outcome measurement
- Demonstrate how definitions matter in the context of classifying exposure and outcome
- Explain the impact of misclassification on risk estimation
- Instruct how to critically appraise exposure and outcome definitions in medical literature

Learning objectives
At the end of this session, participants will be able
- To critically appraise pharmacoepidemiological papers with respect to exposure and

outcome definitions
- To recognize the implication of using definitions in the process of classification exposure and outcome
- To assess the effect of misclassification on risk estimation

"Bias and confounding"

Rolf Groenwold, University Medical Center Utrecht , the Netherland

Abstract / Workshop content
Bias and confounding will focus on the most frequent errors and falsification pitfalls encountered in pharmacoepidemiological research (notably confounding and selection bias). Methods to detect and control for these biases will be discussed. The potential for bias in several clinical examples will be discussed.
The interactive parts of classification of exposure and outcome and of bias & confounding will be held in one single block.

Teaching goals
In this section, the presenter and workshop coach will
- Instruct how to uncover pitfalls in the study interpretation such as misclassification of exposure and outcome, bias and confounding
- Disseminate knowledge by interactive lecture
- Activate participants by ‘buzz groups’ (i.e., one minute discussions among participants with the one sitting next to them)

Learning objectives
At the end of this session, participants will be able
- To classify different sources of bias into confounding, selection bias and information bias.
- To list possible design and analytical solutions for each bias
- To assess the potential for bias in reports of pharmacoepidemiologic studies

"Systematic literature research, meta-analysis & estimation of pooled risks of side-effects"

Hein van Onzenoort, Nijmegen University Medical Centre, the Netherlands

Abstract / Workshop content
Retrieving data by means of systematic literature research is the basis for writing successfully reviews and meta-analysis. This task can be aided by a suitable dedicated software such as the open access tool Revman®. Delegates will have to download this software from http://tech.cochrane.org/revman/download [1] and install before the Academy Camp will start. In the break-out session delegates will perform a meta-analysis by application of existing papers and Revman®.

Teaching goals
In this section, the presenter and workshop coach will

- Disseminate knowledge by interactive lecture
- Provide insight regarding various aspects of systematic reviewing the literature
- Provide skills to apply these insights
- Describe how to transcribe retrieved data into Revman®
- Demonstrate how to use Revman®
- Evaluate the mini meta-analyses performed

Learning objectives
At the end of this session, participants will be able
- To distinguish between narrative review, systematic review, and meta-analysis with their advantages and disadvantages
- To recognize the steps of a systematic review
- To apply quantitative data extraction and calculation of summary measures of effect
- To prevent and diagnose bias in systematic reviews
- To apply the principles and methods of dealing with sources of heterogeneity
- To apply Revman®

"Drug utilisation data sources in the EU"

Daniel Prieto-Alhambra, Oxford UK / Barcelona Spain

Abstract / Workshop content
There are some excellent European data sources for retrieving data on drug utilisation. These sources will be presented and assessed. In the interactive part a selection of drug utilisation data will be searched.
For availability as of 2011 see http://www.imi-protect.eu/documents/DUinventory_2011_6_WORD97-2003.pdf appendix 7. [2]

Teaching goals
In this section, the presenter and workshop coach will
- Demonstrate how nationwide drug utilization data can be found
- Navigate in European drug utilisation data sources
- Instruct on how to retrieved practice-oriented epidemiologic expertise

Learning objectives
At the end of this session, participants will be able
- To identify and access a number of publicly available online EU drug utilisation data sources
- To estimate DDDs / 1000 inhabitants use of a certain medication or group of medications
- To analyse and assess the relevance of population-related health data

"Population attributable risks"

Hans Petri, St Albans UK

Abstract / Workshop content
This session will demonstrate how to combine drug utilisation data of a selected European

country and data from meta-analyses to estimate population attributable risk of a side effect. The workshop will start from drug utilisation data of benzodiazepines (Khong TP et al. Potential impact of benzodiazepine use on the rate of Hip fractures in five large European countries and the United States. Calcif Tissue Int 2012;91:24-31), as well as from Revman®-aided meta-analysis of the hip fracture side effect, to estimate the population attributable risk (PAR) of this side-effect as a result of the drug use in the selected European country.

Teaching goals

In this section, the presenter and workshop coach will

- Outline the methodology to estimate population attributable risk from the combination of pooled risk estimation and drug utilisation data
- Demonstrate how specific nationwide drug utilization data can be combined with data from meta-analysis to estimate population attributable risks (PARs)
- Reproduce step by step the population attributable hip fracture risk as a result of an adverse drug reaction to benzodiazepines

Learning objectives

At the end of this session, participants will be able

- To learn how to combine pooled risk estimates with web-available drug utilisation data of a selected European country
- To transform available data on drug utilisation to an estimated prevalence of use figure
- To estimate the possible population impact of a drug, combining literature data on risk with drug utilisation data
- To list limitations of estimating population attributable risk

Last update: 10 July 2014

Links

[1] http://tech.cochrane.org/revman/download [2] http://www.imi-protect.eu/documents/DUinventory_2011_6_WORD97-2003.pdf