EAHP Academy Seminar 2017

An ACPE application based activity

"Hospital Pharmacy Practice Research? Scientific Quality"

About Pharmaceutical Research

Hospital Pharmacists are generally well familiar with GXP Quality requirements, mainly with cGMP and PIC/s Guidelines, GDP, GSP. As related to GCP, its knowledge among Hospital Pharmacists is much less current. The reason might be that Randomised Clinical Trials are a treatment, therefore under the responsibility of physicians and Contract Research Organisations (CRO) / Clinical Research Associates (CRA, also referred to as Clinical Monitor). It is highly associated to major risk and threats for the patients' life, as repeated incidences occur and do harm to study participants:

- BIAL clinical trial Rennes (France) 2015/2016 with compound BIA 10-2474 (pain relief by acting on cannabinoid receptors)
    - 1 brain dead
    - 5 persons hospitalised with neurological symptoms
    - 90 healthy volunteers enrolled in trail

- Tegenero trial of TGN 1412 (London 2006)
    - six volunteers experienced cytokine storm after receiving a CD28-targeting superagonist

Even if not involved in Randomised Clinical Trials (RCT), Hospital Pharmacist are not excluded from performing Research and Development. Numbers of data are arising from daily practice waiting for being analysed, systematically interpreted and being concluded to improve practical work. Opportunities to actively do research can be found all along the pharmaceutical supply chain from active pharmaceutical ingredients (API) via manufacturing, trade, provision, procurement, clinical needs to clinical, financial, and the patient's quality of

life.

About the catalytic leverage and added values provided by hospital pharmacy researchers

Being researcher and eventually teacher provides numbers of skills and points of view which are highly precious for hospital pharmacy practice.

Research is not basically a top-down task nor a matter of institutional management, but requires bottom-up professional excellence. Knowledge, which is not available, must be provided by those professionals who are placed best to dispose specific research skills, notonly in University hosptials, but also in smaller hospitals for their specificity of the patient mix. The hospital pharmacist as generalist is one of the medical and health professionals being able to integrate chain elements into the provision of evidence and new knowledge.

The items covered by the Academy Seminar topics' are

- Research leadership and management
- Innovation
- Creativity
- Interpretation and anticipation of research by third parties
- Workshops and Interactive Sessions

The Educational Need

Topics of EAHP events are fixed both in a **top-down** manner by the Scientific Committee and directly arising from the fields the members daily are moving in, such as

- Politics
- Practice
- Education
- Current research and development
- New professional opportunities
- New technology
- New medicines
- New methodologies
- New treatments
- Research and development

and in a **bottom-up** manner by

- Proposals from members
- Surveys (544 responses at the 2014 Congress' Cyber Café) / Questionnaires (every five years)
- National associations based on their national strategies
- Focus groups
- Joint commissions
- Mandated members of the Scientific Committee.

Generally, topics will be approved by the EAHP Board. Educational need and gaps between best and current practice and actual versus desired skills respectively can be easily screened by the Scientific Committee from

- EC resolutions
- EAHP surveys (by Survey Monkey® or Adobe Acrobat® form generator)
- FIP statements
- Current tractanda of the Board
- The Scientific Committee Meetings
- The General Assembly
- Evaluation of submitted abstracts for poster or oral presentation
- Past congresses' evaluations
- Existing data such as surveys, questionnaires, etcetera

The aim of this Academy Seminar is to provide tools which improve the position of the hospital pharmacist in Research & Development activities adapted to the own institution's environment.

Links to the EAHP mission & goals and to the European Statements of Hospital Pharmacy

The main EAHP goal covered by the Academy Seminar on Pharmaceutical Reserch and Development is to promote research & development activities of hospital pharmacists and to provide essential tools to facilitate these activities.

In addition to the European Statements of Hospital Pharmacy, the need is also arising from hospital pharmacy practice, since the topic "Medication Review" has been proposed in the Cyber Café Needs Assessment Survey at the EAHP Congress 2014 at Barcelona and from the EAHP Scientific Committee's experience when evaluating submitted abstracts.

Education and research is covered by section 6, items 6.1 ? 6.5 of the European Statements of Hospital Pharmacy ("Pharmacy practice research - designing your study").

Assessment of Learning Success

To evaluate the learning success as requested by ACPE and as defined by teaching goals and learning objectives, a Survey Monkey® driven online questionnaire will be used. This form can be completed online on day 2 subsequent to the Academy Seminar, et cetera. The link will be communicated to the delegates. A participation certificate will be delivered by link after anonymous submission of the completed questionnaire.

Contents, Teaching Goals, and Learning Objectives of the lectures

The Academy Seminar and Workshops show a main track from a general overview to national clinical implications. The focus is put and centred on the patient and on processes. To clarify terms and obtain a commonality of understanding, some definitions might be outlined as far as they are needed to exclude misunderstandings. However, a broad discussion and philosophy on the terms is excluded. Kind reminder: The second slide of each presentation will give the disclosure of conflicts of interest. The last slides of presentation should give a summary.

"Inspiring example(s) of pharmacy practice research"

Dr Mary Tully[1], University of Manchester, Manchester, United Kingdom

Abstract
Research studies in hospital pharmacy practice have been conducted internationally over the past few decades. This presentation will start with a description of what we mean by pharmacy practice research in hospitals and then move on to a detailed description of several different, high quality pharmacy practice studies conducted in hospital. Using existing research about prescribing errors as the example topic, these inspiring studies will highlight both descriptive and interventional studies that have produced impact on professional practice and hence improved patient safety.

Learning objectives

At the end of this session, participants will be able:
? to know the definition of pharmacy practice research in hospital practice;
? to recognise three different purposes of pharmacy practice research;
? to think about some different examples of high quality pharmacy practice research;
? to recognise ways of which pharmacy practice research can impact on professional practice.

Link to Hospital Pharmacy Statements

The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Formulation of research question"

Prof Dr Eric van Roon [2], Medisch Centrum Leeuwarden, Leeuwarden, The Netherlands

Abstract
In this lecture the importance of a good research question is presented. The moment of defining a research question in the broader spectrum of designing the trial is discussed. The components of a research question and the first steps in the operationalisation of the research question are discussed, Finally, the quality check of the research question is presented and discussed with the audience. During the presentation examples of research questions are used to illustrate the goals of the presentation.

Learning objectives

At the end of this session, participants will be able:
? to recognise tools to formulate a research question;
? to understand tools to check the quality of a research question;
? to think of considerations on the planning of a trial and the moment a research question must be formulated.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Study design and outcome measures"

Prof Dr Patricia van den Bemt[3], Erasmus University Medical Center, Rotterdam, the Netherlands

Abstract
A good study protocol is essential before you start your research. Moreover, it will form a solid basis for publication. In this presentation, the following parts of the study protocol will be covered: study design, study population and outcome measures. Several study designs will be introduced: not only the well-known randomized controlled trial design, but also several observational designs. Such observational designs are in general better achievable but may suffer from risk of bias and confounding. As for outcome measures, the distinction between primary and secondary outcome measures will be explained. Furthermore, variables necessary to characterize the study population will be dealt with. It will also be clarified to the participants that in the protocol a description on how to measure the population characteristics and outcome measures needs to be included.
The presentation will end with an explanation of the case report form as the way to collect data. Integrity of data is vital to the provision of sound study results and therefore the topic of data monitoring will be covered as well.

Learning objectives
At the end of this session, participants will be able:
? to recognise that a good protocol is the start of good research;
? to understand which study designs are applicable to different research questions;
? to have an idea of the definition of primary and secondary outcome measures;
? to think about ways to measure various outcomes;
? to understand what a case report form is.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Qualitative research"

Dr Liset van Dijk*[4], NIVEL, Institute for scientific research, Utrecht, The Netherlands

Abstract
Qualitative research is primarily exploratory in nature. It is used to gain an understanding of reasons, opinions, and motivations that are underlying human behaviour. It can help to develop ideas or hypotheses for potential quantitative research. Qualitative research is increasingly being used in pharmacy practice research. The sample size in qualitative research is typically small, and the selection of respondents is not necessarily representative for the study population as a whole. Yet, the variation within the study population needs to be covered. Qualitative data collection methods vary from quantitative methods because of their use of unstructured or semi-structured techniques. Commonly used methods are individual interviews (open or semi-structured), focus groups (including online focus groups), and participatory observation. In this presentation, we will address research questions for which a qualitative research design is suitable. We also discuss the commonly used data collection

methods and what their pros and cons are. Finally, we also touch upon the way to analyse and interpret qualitative research data.

Learning objectives
At the end of this session, participants will be able:
? to recognise that qualitative research can be a valuable contribution to quantitative research;
? to understand when to perform qualitative research;
? to think of research questions that can be answered using qualitative techniques;
? to have a idea of how to perform qualitative research;

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Examples of research and development without patients involved"

Prof Dr Helena Jenzer [5], EAHP Member of the Scientific Committee, Switzerland

Abstract
Unlike physicians, in many countries hospital pharmacists are not allowed to be principal investigators in clinical studies that investigate treatments that are under the responsibility of physicians such as pharmacotherapies. This is particularly the case for prospective clinical trials of treatments that involve personally identifiable patient data or biological material. However, retrospective anonymised studies such as drug use evaluations are options for hospital pharmacists to be actively involved in clinical research. Further options can be found among epidemiological projects, development of analytical methods or medicines development within the hospital laboratory, where the research is outside human research acts and ordinances.
There are global medicines-related complex problems waiting to be unravelled by researchers collaborating in interdisciplinary research such as medicines shortages. Pharmacoeconomic studies can be performed as well. Instead of statistical tests used in randomised clinical trials, other methodologies are suitable such as meta-analyses or data mining. The latter combines public health data for example of non-communicable diseases which can be linked to drug use databases. Care however has to be considered if data from different populations are trying to be correlated.

Learning objectives
At the end of this session, participants will be able:
? to recognise a number of research options suitable for hospital pharmacists;
? to understand the limitations of research being or not being in the scope of human research acts;
? to identify research options in their professional environment;
? to reproduce reflections and legal restrictions stipulated in research acts that has the purpose of protecting patients' rights.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Statistical considerations and pitfalls"

Prof Dr Helena Jenzer

[5], EAHP Member of the Scientific Committee, Switzerland

Abstract
Evaluation of research results is more than processing figures and creating nice graphs. As many studies examine study participants, it is important to determine which participants have been included in a study. Results are strictly valid for the population examined but not for any others. Therefore, conclusions coming from dedicated environments being extrapolated to wider populations are highly error prone. Even in a population, individuals do not become standardised patients. The other way around, applying study results on an individual patient can deviate from expectations due to genomic, transcriptomic, proteomic, or transcriptomic diversity. There are many examples of medicines which have had to be withdrawn from the market as patients treated after a market admission differed from patients treated in clinical study phases.

Learning objectives
At the end of this session, participants will be able:
? to recognise limitations of validity of clinical trials;
? to understand reasons for diversity of outcomes;
? to identify risks bound to uncritical application of standardised therapies on individuals with a metabolism deviating from a mean metabolism of study populations.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"Medical ethical aspects"

Prof Dr Eric van Roon [2], Medisch Centrum Leeuwarden, Leeuwarden, The Netherlands

Abstract
In this lecture, various aspects of ethics in medical research are presented. In the start of the lecture the reason for the current importance of ethics are presented, including some disastrous examples. The current roles of medical ethical committees is discussed. In this discussion, the connection is made to the impact of this role for the individual researcher in designing and conducting the study.

Learning objectives
At the end of this session, participants will be able:
? to obtain insight in the reason for the prominent role of ethics in medical research;
? to obtain insight in current practices concerning the role of medical ethical committees;
? to obtain insight in the most important guidelines and laws on ethics in medical research.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

"In search of evidence for the added value of hospital pharmacists ? turning mistakes into learning points!"

Dr Ulrika Gillespie [6], EAHP Member of the Scientific Committee, Uppsala University Hospital,

Uppsala, Sweden.

Abstract
When designing and running a research study, there are numerous pitfalls to avoid. Hospital pharmacists are increasingly pushed to show evidence of effectiveness for the services they provide but excellent practitioners are not always excellent researchers. The term "research-waste" can be used for example when a research study is performed that is underpowered, using the wrong outcome measures or when the results are not disseminated. Our research group has for the last 15 years conducted numbers of studies; anything from student master projects - measuring for example medication errors before and after service implementation - to randomized controlled trials. We have not always managed to avoid the pitfalls however, and some of the studies can be classified as research waste in more than one way. It is important for our profession to show the (hopefully) added value of including hospital pharmacists in an already establish health care structure, and to do so using a robust scientific methodology. In this presentation experiences and learning points will be shared with the participants using examples and international reflection.

Learning objectives
At the end of this session, participants will be able:
? to list the most obvious, avoidable mistakes that can be made when conducting a research study;
? to describe measures to avoid these mistakes and strengthen the scientific quality of the study.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 1.2 - 1.3
? 6.1 - 6.5

Contents and Learning Objectives of the workshops

Abstract
Scope and purpose
The overall idea of the Seminar is that the four subgroups of participants follow several workshops in which they gradually develop their own study protocol.
Workshops Workflow
In the first workshop delegates will come up with the study question, in the second workshop they will chose the study design, the primary and secondary outcomes and other data to be collected, all in line with the previously chosen study question. The first draft of their study protocol is then ready. In the third workshop each group works first on the ethical and statistical considerations of their protocol. Finally, in the second part of this workshop, two groups join together with one group acting as a Medical Ethical Board and the other group defending their study protocol to this board, and vice versa.

Workshop "Formulation of research question"
? Formulation of research question in 4 subgroups
? Presentation of the formulated research questions with feedback
? Operationalisation of research question in subgroups
? Resulting in draft study protocol

Workshop "Fine-tuning the study protocol"
? Medical ethical aspects of the draft study protocol of the previous day
? Statistical aspects of the draft study protocol of the previous day

Workshop "The Medical Ethical Committee"
? "Ethical and statistical considerations"
Presenting the resulting protocols to each other and giving feedback
? "Role play: The Medical Ethical Committee"
Playing the role of the medical ethics committee

Learning objectives
At the end of this sessions, participants will be able:
? To formulate a research question;
? To develop a study protocol;
? To optimise the study protocol in terms of ethical and statistical requirements;
? To assess study protocols from ethical and statistical points of view.

Link to Hospital Pharmacy Statements
The following chapters of the Hospital Pharmacy Statements are applied within this topic:
? 6.1 - 6.5

* Indicates speaker or SC member has stated a conflict of interest.

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Links
[1] http://www.eahp.eu/content/dr-mary-patricia-tully#overlay-context=content/dr-ulrika-gillespie-1
[2] http://www.eahp.eu/content/prof-dr-eric-nico-van-roon#overlay-context=
[3] http://www.eahp.eu/content/prof-dr-patricia-van-den-bemt#overlay-context=content/dr-mary-patricia-tully
[4] http://www.eahp.eu/content/dr-liset-van-dijk
[5] http://www.eahp.eu/content/prof-dr-helena-jenzer#overlay-context=content/prof-dr-eric-nico-van-roon
[6] http://www.eahp.eu/content/dr-ulrika-gillespie-1