Introduction to medical research: Essential skills

Module 2: Research design and protocol

EQUATOR – OUCAGS training course
4 October 2014

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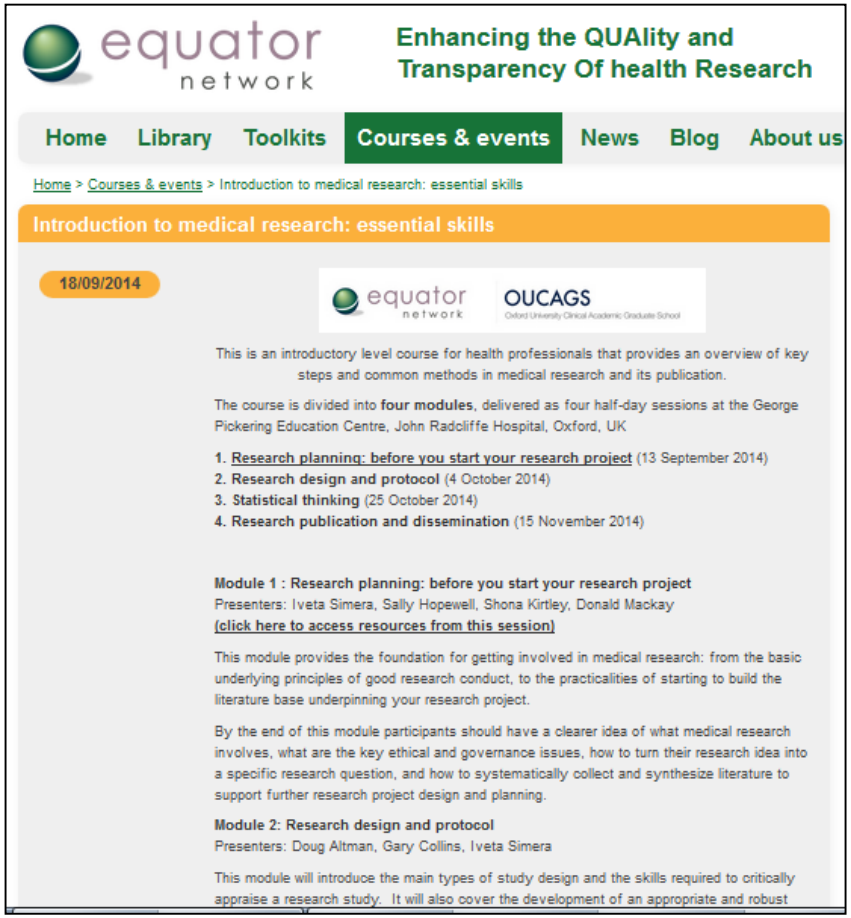
CSM

Module 1

- Focus on:
  - Overview of what medical research involves
  - What are the key ethical and governance issues
  - How to turn research idea into a specific research question
  - How to systematically collect and synthesise literature to support further research project design and planning
- Slides & resources online



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Home > Courses & events > Introduction to medical research: essential skills

Introduction to medical research: essential skills

18/09/2014

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This is an introductory level course for health professionals that provides an overview of key steps and common methods in medical research and its publication.

The course is divided into **four modules**, delivered as four half-day sessions at the George Pickering Education Centre, John Radcliffe Hospital, Oxford, UK

1. **Research planning: before you start your research project** (13 September 2014)
2. **Research design and protocol** (4 October 2014)
3. **Statistical thinking** (25 October 2014)
4. **Research publication and dissemination** (15 November 2014)

Module 1 : Research planning: before you start your research project
Presenters: Iveta Simera, Sally Hopewell, Shona Kirtley, Donald Mackay
(click here to access resources from this session)

This module provides the foundation for getting involved in medical research: from the basic underlying principles of good research conduct, to the practicalities of starting to build the literature base underpinning your research project.

By the end of this module participants should have a clearer idea of what medical research involves, what are the key ethical and governance issues, how to turn their research idea into a specific research question, and how to systematically collect and synthesize literature to support further research project design and planning.

Module 2: Research design and protocol
Presenters: Doug Altman, Gary Collins, Iveta Simera

This module will introduce the main types of study design and the skills required to critically appraise a research study. It will also cover the development of an appropriate and robust

http://www.equator-network.org/2014/09/18/introduction-to-medical-research-essential-skills/

Module 2

- Focus on choosing appropriate research design and protocol preparation

- **Prof Doug Altman**
  - Director, Centre for Statistics in Medicine
  - Co-Director, OCTRU
  - Director, EQUATOR Programme

- **Dr Gary Collins**
  - Associate Professor
  - Head of Prognosis Methodology
  - Deputy Director, Centre for Statistics in Medicine

Developing a research question

Sally Hopewell

The research question

- The research question for a **systematic review** should specify the types of population (participants), types of interventions (and comparisons), and the types of outcomes that are of interest.

Selection Criteria

- Type of participants
- Type of interventions (and comparisons)
- Type of outcome measures
- Type of studies

- The acronym PICO (**P**articipants, **I**nterventions, **C**omparisons and **O**utcomes) helps to serve as a reminder of these.

P Types of participants

- How is the disease/condition defined?
- What are the most important characteristics that describe these people (participants)?
- Are there any relevant demographic factors (e.g. age, sex, ethnicity)?
- What is the setting (e.g. hospital, community etc)?
- Who should make the diagnosis?
- Are there other types of people who should be excluded from the review (because they are likely to react to the intervention in a different way)?
- How will studies involving only a subset of relevant participants be handled?

I/C Types of interventions

- What are the experimental and control (comparator) interventions of interest
- Does the intervention have variations (e.g. dosage/intensity, mode of delivery, personnel who deliver it, frequency of delivery, duration of delivery, timing of delivery)?
- Are all variations to be included (for example is there a critical dose below which the intervention may not be clinically appropriate)?
- How will trials including only part of the intervention be handled?
- How will trials including the intervention of interest combined with another intervention (co-intervention) be handled?

O Types of outcomes

- Main outcomes, for inclusion in the 'Summary of findings' table, are those that are essential for decision-making, and should usually have an emphasis on patient-important outcomes.
- Primary outcomes are the two or three outcomes from among the main outcomes that the review would be likely to be able to address if sufficient studies are identified, in order to reach a conclusion about the effects (beneficial and adverse) of the intervention(s).
- Secondary outcomes include the remaining main outcomes (other than primary outcomes) plus additional outcomes useful for explaining effects.
- Ensure that outcomes cover potential as well as actual adverse effects.
- Consider outcomes relevant to all potential decision makers, including economic data.
- Consider the type and timing of outcome measurements.

S Types of studies

- Different types of studies have different methodological issues to consider
- May need to consider different statistical analysis techniques according to the type of included studies
- Parallel randomised controlled studies (common in Cochrane systematic reviews) are the 'easiest' inclusions.
- Non-randomised studies may suffer from bias
- Cross-over studies may have issues with wash-out periods
- Studies with multiple sites (eg many fingers measured per person) would need statistical adjustments
- Etc…. beyond the scope of this session