Introduction to medical research:
Essential skills

Iveta Simera

EQUATOR Network, Centre for Statistics in Medicine, NDORMS

EQUATOR – OUCAGS training course
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Iveta Simera
Head of Programme Development
EQUATOR Network; Oxford

Experience:
Laboratory research, systematic reviews, research reporting and reporting guidelines
Writing, reviewing, training, research ethics
Not editor but working closely with journal editors for over 8 years

My talk today:
• Course outline
• Overview of medical research
• Key ethical principles
• Useful resources
Course outline

• Overview of **key steps and common methods** in medical research and its publication

• **4 modules** (introductory basic level, 3½ h):
  - Research planning: before you start your research project
  - Research design and protocol
  - Statistical thinking
  - Research publication and dissemination

• Course is build around **competencies** specified in the **Academic Compendium** of the UK Foundation Programme
Session 1: Research planning

- Objectives - by the end of this module participants should have:
  - Clearer idea 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

- Programme, facilitators

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<th>Time</th>
<th>Activity</th>
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<tr>
<td>9.00</td>
<td>Welcome and introduction</td>
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<tr>
<td>9.15</td>
<td>Overview of research process</td>
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<tr>
<td>9.45</td>
<td>Overview of ethical and governance issues in clinical research</td>
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<td>9.45</td>
<td>Introduction to systematic reviews</td>
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<td>10.30</td>
<td>Break (20 minutes)</td>
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<tr>
<td>10.50</td>
<td>Formulating the research question</td>
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<td>11.50</td>
<td>Literature searching</td>
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<td>12.20</td>
<td>Online resource access</td>
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<td>12.40</td>
<td>Summing up</td>
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<td>13.00</td>
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Medical research: what is it and what does it involve

- Different ways to look at it
- Research as a process: clinical research continuum

Types of clinical research

- Observational studies
  - Case reports
  - Surveys
  - Cohort studies
  - Cross-sectional studies
  - Case-control studies

- Experimental studies
  - Randomised trials
  - Non-randomised studies

- Qualitative research

- Research synthesis (systematic reviews)
Types of studies by research questions / focus

• Treatment evaluations - RCTs
• Disease aetiology, harms, .. - Observational studies
• Prognostic studies
• Diagnostic studies
• Experiences, views, .. – Qualitative studies
• Quality improvement studies
• Economic evaluations
• Patients’ involvement in research
• Some research designs are more suitable for answering a given research question than others - important to choose an appropriate research design!
  – E.g. RCT – treatment evaluation

• Different advantages but also limitations

• Bring different ethical issues
  – E.g. – accepting concept of randomisation

» More in the next session!
Principles guiding medical research

- Ethical guidelines are important in clinical research
  - They safeguard participants’ health, safety and privacy
  - They help in building public trust in medical research (unethical practices lead to wasting time and money and increased regulation – burden)

- Ethics – very broad term
- Demonstrated in the Declaration of Helsinki

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:
- 29th WMA General Assembly, Tokyo, Japan, October 1975
- 35th WMA General Assembly, Venice, Italy, October 1983
- 41st WMA General Assembly, Hong Kong, September 1989
- 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
- 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
- 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
- 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
- 59th WMA General Assembly, Seoul, Republic of Korea, October 2008
- 64th WMA General Assembly, Fortaleza, Brazil, October 2013
Declaration of Helsinki: Key ethical principles

- General principles
- Risks, burdens and benefits
- Vulnerable groups and individuals
- Scientific requirements and research protocols
- Research ethics committees
- Privacy and confidentiality
- Informed consent
- Use of placebo
- Post-trial provisions
- Research registration and publication and dissemination of results
- Unproven interventions in clinical practice
Despite regulation problems occur

Delays in publishing the results of clinical trials harm patients, public health

Misconduct cases source: http://www.slideshare.net/cjrw2/infamous-cases-of-research-misconduct
Research

Increasing value, reducing waste

It has been estimated that 85% of research is wasted, usually because it asks the wrong questions, is badly designed, not published or poorly reported. This diminishes the value of research and also represents a significant financial loss. However, many causes of this waste are simple problems that could easily be fixed, such as appropriate randomisation or blinding of a clinical trial. A first step towards increasing the value of research and increasing waste is to monitor the problems and develop solutions that aim to fix them.

researchwaste.net is a place to share and exchange documentation, information, and resources on how to increase the value of both basic and applied research and reduce or avoid wasting research. It is based on a series of articles that were published in the medical journal The Lancet in 2014.

Access articles
Typical research process: key steps

- Conception
- Design
- Execution
- Analysis
- Publication and reporting

See research flowchart handout for more details
Key elements of good research

- Turning idea into a research question (clear research aim, rationale, hypothesis)
- Treatment – clinical equipoise
- Consult study with ‘users’ – patients’ input (questions, design - outcomes, process, ..)
- Systematic review of existing evidence
- Consider research participants: practicalities; wellbeing; courtesy; respect
Key elements of good research

- CONSULT with a STATISTICIAN
- Develop appropriate design to answer question
- Adequate sample size
- Adequate steps to reduce bias
- Carefully balance risk and benefits; inclusion and exclusion criteria
- Develop a protocol
- Ethical approval – informed consent, PIS, questionnaires, ..
Key elements of good research

- Participants’ recruitment and **consent** form – trained personnel (voluntary, avoid coercion, right to withdraw, fully informed, ..)

- Good clinical practice conduct, research integrity principles (data collection, data protection and confidentiality)

Conception

Design

**Execution**

Analysis

Publication and reporting

You can find the latest version of this guidance on our website at www.gmc-uk.org/guidance.

**Good practice in research and Consent to research**
Key elements of good research

- Data analysis should be hypothesis driven (statistical analysis plan)
- A statistician should be employed from the study conception
- Avoid any data fabrication / falsification
Key elements of good research

- Research only has **value** if
  - Study methods have validity
  - Research findings are published in a usable form

- The goal should be **transparency** and honest account
  - Should not mislead
  - Should allow replication (in principle)

- **Impact** - research paper needs to be usable, ‘fit for purpose’
  - we need to think beyond our own work

- **Reporting guidelines:**
  www.equator-network.org
Useful resources
Clinical Trials and Research Governance

The Clinical Trials and Research Governance (CTRG) team supports University Clinical Researchers. CTRG has a role in promoting and supporting high quality research within the University, and ensuring the University meets its requirements as Sponsor and host institution.

About CTRG •

Research Classification and Procedures •

Research Governance •

Sponsorship and Ethics Applications •

Resources •

Training •

Contacts

› Contact the CTRG team

Find us

› Directions to CTRG team, Joint Research Office (836kb)

Map

› Click here for a Google Map

Documents

› Glossary of acronyms used on this site (141kb)

Related links

› Safety Reporting (Serious Adverse Events)
› Clinical Trial Units
We provide free advice on research design to researchers in the South Central region who are developing proposals for national, peer-reviewed funding competitions for applied health or social care research.

How we can help

If you have a research question you would like to turn into a fully developed funding proposal, we can help. Our experienced Research Advisors have expertise in key aspects of preparing grant applications, including:

- Design
- Methodology
- Identifying an appropriate funder
- Involving patients and public
- Costing your research project

Who we can help

Read on and find out if you are eligible for our support.

Find out more about who the RDS can help and how it supports researchers in the RDS leaflet

What you can expect from us

The RDS Charter provides information about the services we offer.
Planning a study

Information, tips and pointers to other resources to help your research team plan an effective study.

Specialist advice on specific aspects of a study

Follow the links on the right.

Getting started

For a general overview of what's involved when planning a study, get started with our Information Pack for Health and Social Care Researchers

This highlights some of the key issues to consider when making a research grant application, including:

- Refining your research idea
- Examining the current literature
- Getting your methodology right
- The usual structure of a grant application, and what a reviewer would expect to see in each section
- Logistical issues to consider, including time and money
- Types of costs typically requested
- Ethics and governance procedures required of all NHS research
- What Patient and Public Involvement is, and how to do it well
- Other organisations which may be useful to you.

This list is not definitive; your Research Advisor can provide advice specifically tailored to your application.

Download the full Information Pack for Health and Social Care Researchers

Share the knowledge

If you discover a useful resource not mentioned here, please drop us a line at rds.sc@nihr.ac.uk

Planning a study

- Successful application
- Don’t miss the NIHR benchmark
- Costing your research project
- Health Economics
  - DIRUM database: resource for health economics research
  - Economic Evaluation
- Study Design
  - Cross-over trials
  - EQUATOR
  - Help with methodological approaches
  - Qualitative Research Design
    - Discourse Analysis
    - Quantitative studies
    - Clinical Trials
      - Cluster randomised trials
      - Complex Interventions
      - Cross-over Trials
      - Factorial design clinical trials
      - Meta-analysis
      - Non-Inferiority Trials
      - Parallel Group Study
      - Phase I and Phase II Trials
      - Systematic Review
      - Systemic Reviews
Welcome to INVOLVE...

We are funded by the National Institute of Health Research (NIHR) to support public involvement in NHS, public health and social care research.

Resource centre
- View our publications and our libraries of references
- Visit our databases and resources for researchers

News and events
- Public engagement funding within research grants – new video from Wellcome Trust
  9 September, 2014

Keep in touch
- How to contact us and keep in touch.
  - Follow @NIHRINVOLVE
Our Committees
Quick links to our committees for research ethics, gene therapy and confidentiality – please make sure you are familiar with the content for the research community before applying.

Our committees ➤

End of study guidance
New guidance for information to participants at the end of a study is open for comment until 30 September 2014 – we need your views.

HRA Approval
Find out the latest news, including our plans for recruitment

More about HRA Approval ➤

About the HRA
The HRA was established in
Resources

Resources pages provide additional detail on important topics. This includes links to external sites, reference documents and explanatory text.

Many pages also provide links to other areas of the site, where related information can be found.

We have created these to give you extra detail on key themes, and many of them can be reached from more than one page in the site.

You can find information in this section using the alphabetical list below, the categories in the menu on the left or using the search box.

List of Resources

- Adding new sites to a study
- Administration of Radioactive Substances
- Adults Unable to Consent for Themselves
- Amendments
- Applying for Approvals: Template Documents
- Care After Research
- Chief Investigator
- Clinical Research Networks
- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Confidentiality Advisory Group (CAG) – Annual Review Template
- Confidentiality Advisory Group (CAG) – Meeting Dates
- Confidentiality Advisory Group (CAG) – Pre-application Decision Tool
- Confidentiality Advisory Group (CAG) – Standard Conditions of Support
- Confidentiality Advisory Group (CAG) – Application Advice
- Confidentiality Advisory Group (CAG) – Proportionate Review
- Confidentiality Advisory Group (CAG) – Section 251 form for non-research applications
- Confidentiality, Privacy and Data Protection
- Consent and Participant Information
- End of Study Notification – Clinical Trials of Investigational Medicinal Products (CTIMPs): EudraCT form
- End of Study Notification – Studies other than Clinical Trials of Investigational Medicinal Products
- Ethical Considerations in Research
- Ethical Review for Private and Voluntary Health Care
Guidelines

The following are our latest guidelines - freely available to everyone.

Looking for presentations from recent workshops? If you are an AfRE member, simply log in. If not, please contact us to find out more about membership, or click here.

Key aspects of health research ethics: simple practical checklists

General Considerations
Specific Considerations
Participant Information Sheets
Consent Forms
Withdrawn Consent
Reenumeration
Mental Capacity
Research with Children
Internet Mediated Research
Internet Mediated Research - Top Tips
Clinical Trials of Cell Therapies
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Enhancing the QUAlity and Transparency Of health Research

The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Search for reporting guidelines
Visit the library for more resources

Key reporting guidelines

- CONSORT
- STROBE
- PRISMA
- STARD
- COREQ
- ENTREQ
- SQUIRE
- CARE
- SAMPL
- SPIRIT

Full Record | Checklist | Flow Diagram

EQUATOR highlights

13/08/2014 - Videos now available from the scientific meeting in Paris: Improving reporting to decrease the waste of research

The 6th annual lecture, presentations and roundtable discussion were recorded and are now available to watch Read More

13/08/2014 - Interview with Iveta Simera about the EQUATOR Network

The plagiarism detection software company iThenticate recently interviewed EQUATOR’s Head of Programme Development, Iveta Simera Read More

13/08/2014 - Declaration of transparency

News

COMET initiative: Group seeks standardization for what clinical trials must measure
3/09/2014

STRATOS initiative
3/09/2014

New actions by PLoS Medicine Editors to advance research transparency – focus on observational studies
27/08/2014

Montreal Statement (on research collaboration) is now available in Spanish
27/08/2014
• Resources for planning and design

• Reporting guidelines
  – Know principles of responsible reporting early to prevent problems later