Introduction to study design and analysis for the MFOM dissertation 2012

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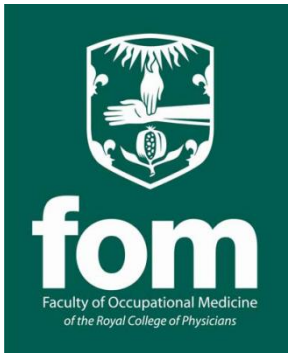


Topics

- Welcome
- Why a dissertation for MFOM?
- Process reminder
- “Equivalent evidence”
- Basic questions and timetabling
- Study design
- Interpretation
- Resources

Why a dissertation?

Why a dissertation?

- 2 population-based specialties, both require a dissertation
  - Occupational Medicine (c 50% by MSc)
  - Public Health (100% by MSc)
- Advisory role to employers
  - Workplaces vary greatly, some are unique
  - Little top-down guidance cf DH, NICE

Examples of specialist advice

- Review an employer's pre-employment screening process and make evidence-based recommendations for revisions
- Investigate an outbreak of unexplained symptoms in one department of an industrial plant
- Write and implement a pandemic 'flu policy for a workplace, taking account of national guidelines
- Undertake a risk assessment of a new lifting and handling procedure, draft guidance, audit the outcomes of the controls, and report to management
- Review the cost-effectiveness of an in-house counselling service and make recommendations about continuance

Why a dissertation?

- Formulate a clear question
- Find and appraise the evidence
- Present information clearly
- Interpret information, place it in context, make policy recommendations
- Write clearly, succinctly, and logically
- Sustain the motivation to run a longterm project over several months or years from concept to conclusion
- Team-working, networking

NOT (necessarily) research

- Research skills are a generic GMC requirement for all specialist training
- MFOM candidates may submit a substantial audit or systematic review
- No requirement to cover ***all*** the curriculum research competencies in the dissertation (because these can be covered elsewhere in the 4 years of training)

Process reminder

- **Supervisor** =educational supervisor, or other(s)
- **Protocol** and Form M2 (standard dissertations)
- FOM obtains two independent advisory **reviews**
  - Rapid feedback
- **Final submission** and Form M3
- FOM obtains a joint **assessment** by two assessors
  - Accept
  - Minor revisions
  - Major revisions & reassessment
  - Reject
- **In difficult cases**
  - Additional assessors, vivas
  - Appeals process

From FOM guidance document

“ … All candidates must accept the responsibility to produce a dissertation of an acceptable standard in a timely fashion. …”

What are assessors looking for?

- Clarity, including a high standard of grammar, spelling, indexing, referencing & other presentational issues
- < 10,000 words
- Relevance to policy or practice
- Substantial piece of work
- Thoughtful discussion of strengths and weaknesses

Assessment proforma

- Presentation and layout
- Clarity of abstract
- Background data and references
- Clarity of study aim
- Methodology – appropriateness and clarity
- Statistical methods - appropriateness
- Presentation of results – clarity; tables and figures
- Discussion of findings, potential bias, strengths and weaknesses
- Contextualisation within Occupational Medicine policy or practice
- Statement of contributions
- Ethical issues
- Specific comments (any issues which need addressing or clarifying

“Equivalent evidence”

“Equivalent evidence”

- FOM makes the concession that work done for other purpose may be submitted instead of a MFOM dissertation (and may be submitted in the same format as for the other purpose)
  - Research dissertation
    - MSc Occupational Medicine/Health
    - Other MSc/MD/PhD etc
  - Substantial published work
- Evidence is assessed by 2 assessors, and it may need to be revised

Basic questions and timetabling

Some dissertation project types

- Case series
- Epidemiological studies
- Opinion surveys
- Intervention studies (trials)Qualitative studies
- Literature reviews
- Audits
- Laboratory-based studies

- Read the journals
- Go to meetings
- Talk to your supervisor
- Talk to your peers
- Read old dissertations

What is the question?

- Must engage your imagination
- Helps if the answers matter to your training organisation
- Is your *"question"* a question, or a design/ method? eg:
  - *"Study how the results of (a test of a work competency) change with age"*
  - Should older workers' competency be assessed more frequently than that of young workers? Competency to do what task, and to prevent what adverse outcome?


SALT&PEPPER
HOW FAR IS IT?
THAT DEPENDS ON WHERE YOU WANT TO GO
OH.. THAT MAKES IT COMPLICATED -LET'S GO BACK HOME

Ways of answering questions

- Literature review ± meta-analysis
- Observational study
  - Survey of current practice and expert opinion
  - Epidemiological study
    - Longitudinal
    - Cross-sectional
    - Case-control
  - Qualitative study
- Intervention/evaluation study ± economic evaluation
  - Experimental
  - Non-experimental
    - Clinical audit

Should older workers' competency be assessed more frequently than that of young workers?

- Literature review ± theoretical simulations
- Survey of SOM members
- Follow-up of a work cohort as it ages
- Survey of variation by age in current workforce
- Comparison of age distribution in cases of competency "failure" and controls
- Qualitative interviews eg managers, experts, workers
- Intervene (ie assess them more frequently) and evaluate the outcome

Timetabling

- Preparations
  - eg reading, discussions, visits, training, ethics approval, permissions, funding
- Outline protocol → FOM
- Data collection and analysis
- Drafting
- Final drafting
- Assessment by FOM
- Revision, resubmission

It is never too early to think about document presentation

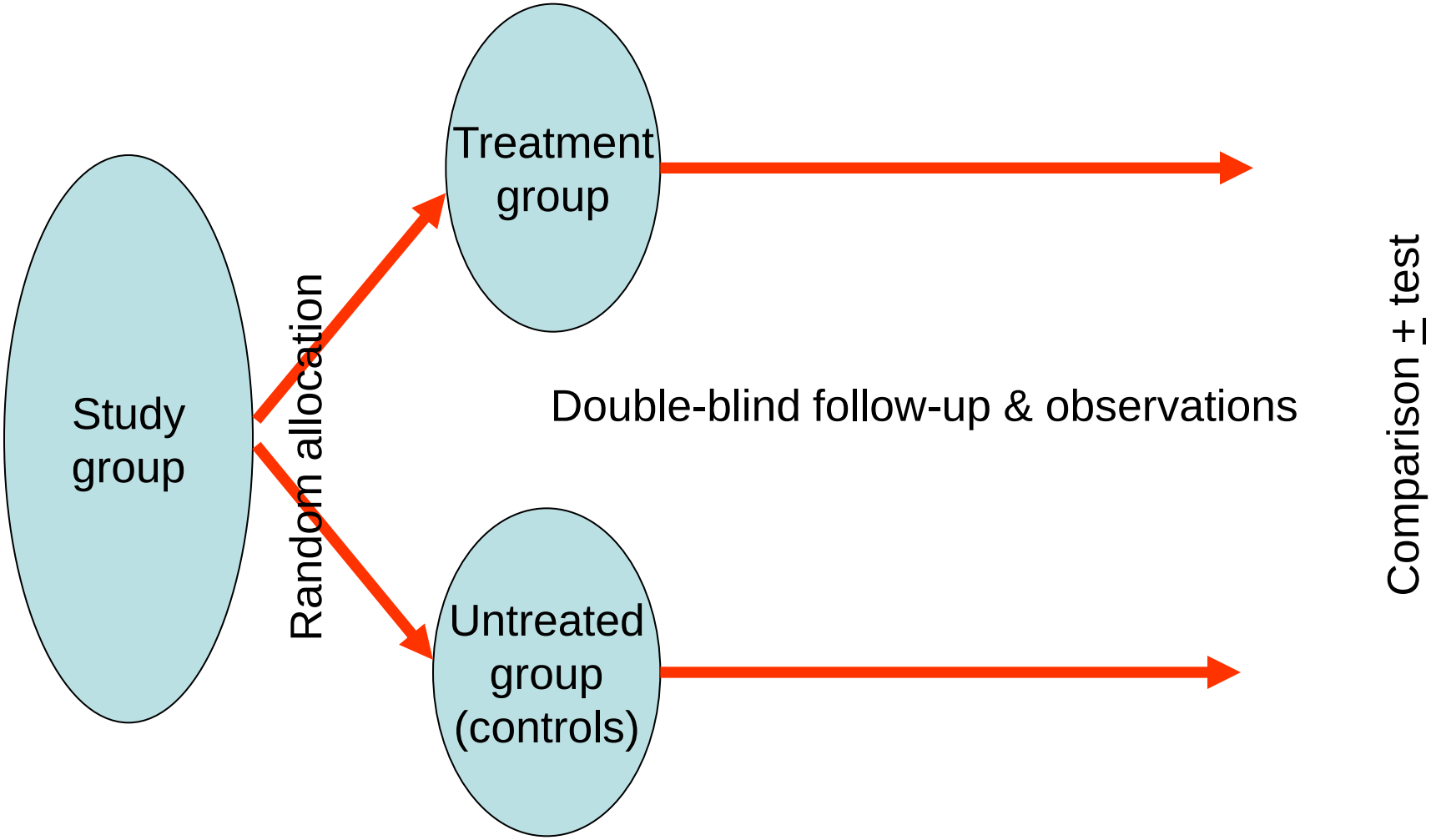
- Word limit – 10,000 words
- Referencing software
- Indexing
- Pagination
- Appearance of tables and figures
- Photographs
- English style, grammar, spelling

Speculate about the likely study findings

- Implications of range of likely findings
- Skeleton tables and figures
- Headings & sub-headings (IMRAD)
  - What did I do?
  - How did I do it?
  - What does it mean?

Study design

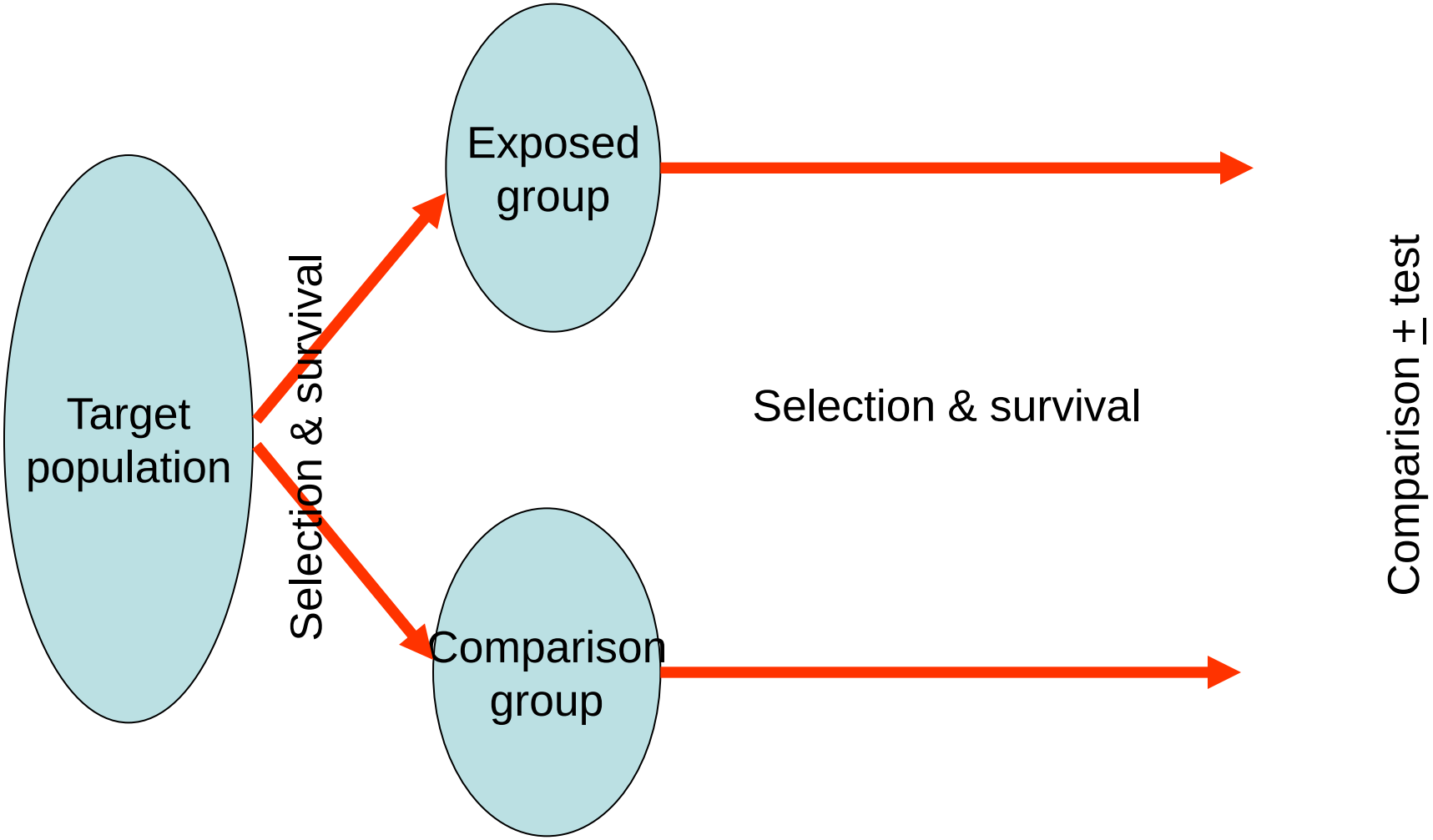
Basic experimental design



Strengths of experimental design

- Random allocation into sub-groups
- Inclusion of untreated control subjects
- Double-blind observation

Basic epidemiological design



Experiment *vs* observation

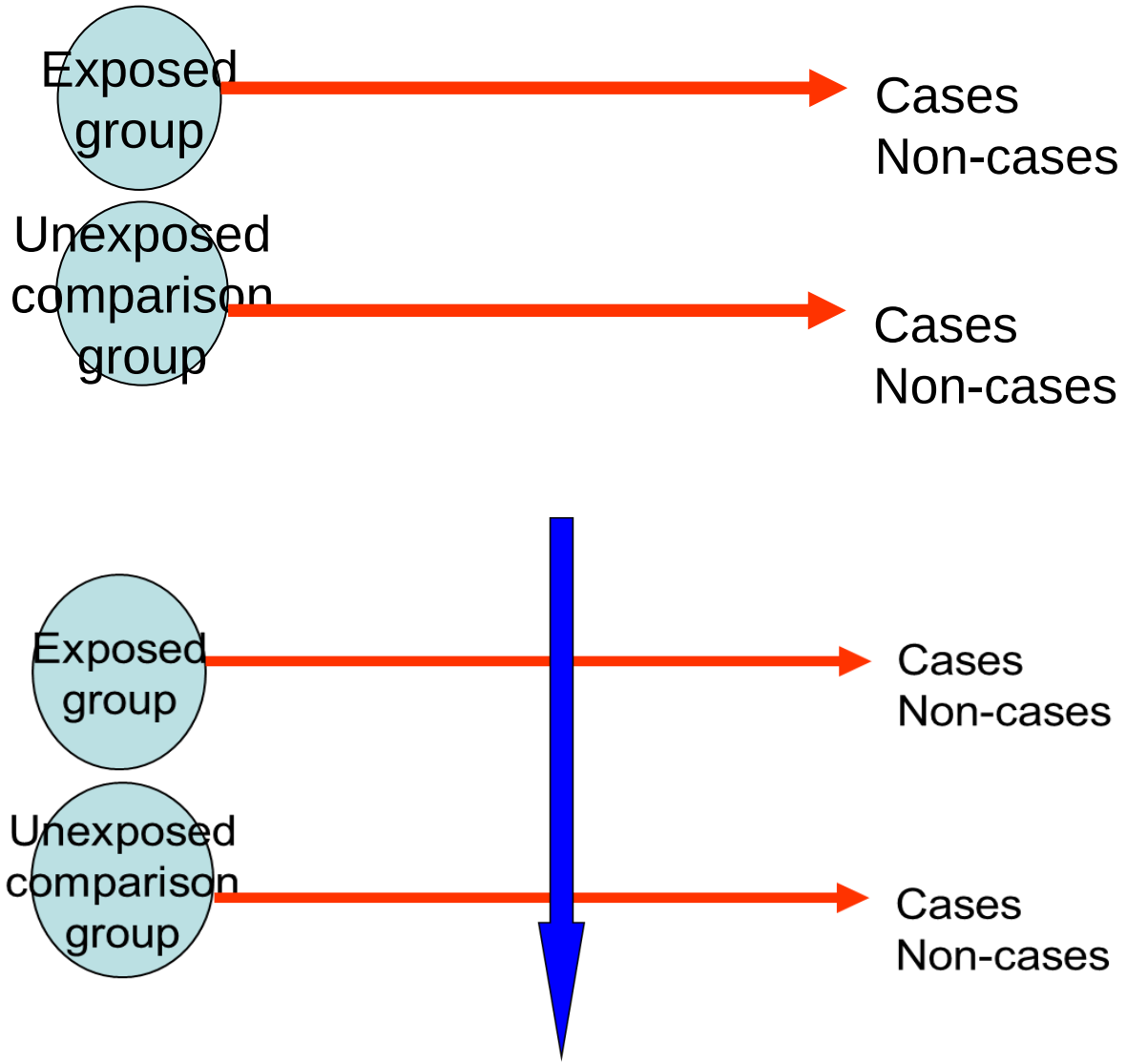
- Weaknesses of experiments (eg clinical trials) in human disease
  - Specially selected subjects
  - Interventions and observations different from "real life"
- Observational studies
  - Representative of real people
  - Real exposures
  - Realistic observations

Selection and survival

- Selection into a job
  - Workplace factors
  - Worker factors
- “Survival” in a job
  - Workplace factors
  - Worker factors

- Selection into a study
  - Availability of records
  - Participation
    - organisations
    - Individuals
  - Selection criteria
    - inclusion
    - exclusion

Longitudinal, cross-sectional, and case-control designs



	Case	Non-case
Exp+	a	b
Exp-	c	d

Measurement: types of variable

- Determinant
  - (independent, stimulus, exposure)
- Outcome
  - (dependent, response, disease)
- Modifying variables, including confounders
  - eg age, sex, smoking

Examples of ways of measuring occupational exposure

- Body burden eg kidney cadmium
- Measured personal exposure eg radiation film badges
- Area measurements eg asbestos fibre counts
- Modelled/estimated exposure
- Job-exposure matrices
- Ordinal scales
- Categories eg job titles
- Duration of job
- Ever/never worked in industry

Measurement

- Time relations?
- Natural format/scale of the variable
- Definitions
  - Concrete, unambiguous
- Independent data collection
- Information quality
  - Valid, repeatable
- Procedures
  - Acceptable, safe, practicable

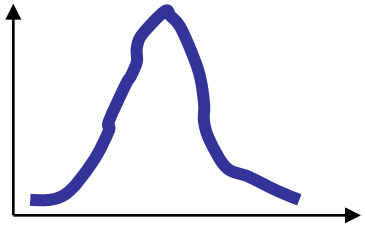
Validity and repeatability

Validity and repeatability

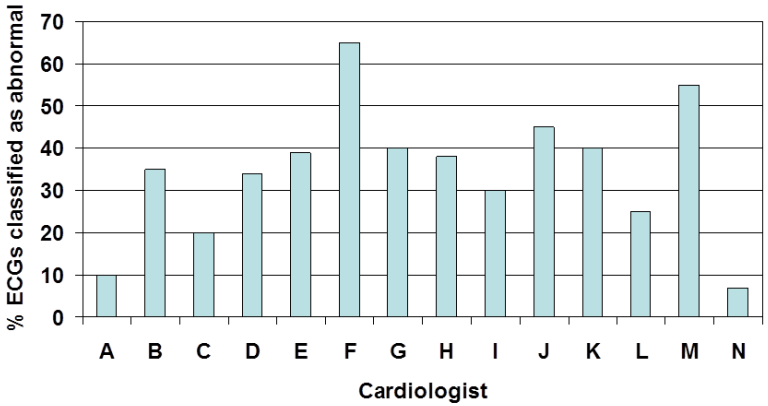
- Validity: does the index I chose measure what it is supposed to measure?
  - Criterion – compared with the “gold standard”
  - Predictive
  - Consensus
  - Face
- Repeatability: does it give similar findings on different occasions?

Sources of unwanted variation

- Random



- Systematic



- Subject
- Instrument
- Observer

} Intra- or inter-

Minimising unwanted variation

- Subject
  - Design study to minimise sources of variation eg do tests at same time of day
  - Multiple tests and use an average
- Instrument
  - Same instrument, calibration, adjustment, multiple readings
- Observer
  - Eliminate where possible, simple instructions, training, multiple observers

Interpretation

Overestimation of risk from the exposure or other determinant

- Information bias
  - eg hazardous job → more frequent health surveillance
  - eg symptoms → better recall of exposure
- Confounding
  - eg smoking is one of the causal factors for the disease and is also more common in the exposed group

Underestimation of risk

- Small sample size (ie low power)
- Study group of “survivors” in employment
- Chosen population has exposure which is too low, or too short
- Follow-up is shorter than the latent interval
- High random variation in exposure or outcome variable chosen for the study
- Over-estimation of exposure
- Inappropriate comparison group
  - General population
  - Occupational population with other exposures causing the disease
- Confounding

Interpretation

- Write for an intelligent, educated layperson
- Respect the reader – grammar, layout etc
- Know your topic well – no excuse for not knowing about the latest HSE guidance, the recent Cochrane review, the classic paper
- Discuss your project's strengths and weaknesses
- Make it clear why your findings matter


do what
you love
love what
you do

Resources/reserves

Relevant FOM resources

- Searchable database of dissertation abstracts
- Library of accepted dissertations
- (For candidates ***not*** undertaking a MSc) feedback on the protocol from 2 reviewers
- Regulations for Membership (MFOM) April 2008
- Question and Answer Sheet on Changes to the Faculty Examinations
- Question and Answer Sheet on Changes to the MFOM Dissertation
- Guidance on Research Dissertations Written for Purpose

FOM research competencies: knowledge

Be able to understand:

- How to design a research study.
- How to use appropriate statistical methods.
- The principles of research ethics.
- How to write a scientific paper.
- Sources of research funding.
- The principles and application of epidemiological methods in research and in problem solving
- The application of medical statistics and the interpretation of statistical analysis methods in scientific research.
- Computer based systems for data collection and analysis.
- Ethical considerations in research.

FOM research competencies: skills

- Be able to define a problem in terms of needs for an evidence base.
- Be able to undertake systematic literature search.
- Be able to undertake a systematic and critical appraisal and review of scientific literature.
- Be able to produce an evidence based digest of the literature.
- Be able to frame questions to be answered by a research project.
- Be able to develop protocols and methods for research.
- Be able to execute an appropriate study design.
- Plan data collection for simple surveys including sample selection and methods of recording and storing data.
- Be able to use databases.
- Be able to accurately analyse data statistically.
- Have good written and verbal presentation skills.
- Present investigation and results in the format of a research based report.
- Be able to write a scientific paper for peer-reviewed publication.

FOM research competencies: attitudes

- Demonstrate curiosity and a critical spirit of enquiry, and where appropriate a critical attitude towards current practice.
- Acceptance of the need for critical review and for research so as to found a solid base for good practice.
- Ensure patient confidentiality.
- Demonstrate knowledge of the importance of ethical approval and patient consent for clinical research.
- Respect individual confidentiality when presenting data.
- Disposition to cooperation and liaison with statisticians and other research colleagues.

Bradford Hill criteria for causation

- Strength of association
- Consistency in different studies
- Specificity of exposure, of disease
- Relationship in time
- Biological gradient
- Biological plausibility
- Coherence of all the evidence
- Experimental or semi-experimental evidence
- Reasoning by analogy

- **S** trength
- **C** onsistency
- **S** pecificity
- **T** ime
- **G** radient
- **P** lausibility
- **C** oherence
- **E** xperimental
- **A** nalogy

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- Statistics
- Can
- Sometimes
- Teach
- Good
- Principles,
- Can
- Epidemiology
- Also?