Basic tools for Research

Large study populations/database

What are they?

- Registers
- Routinely collected data
- Healthcare activity records
- Financial or administrative data

Large study populations/database

Why use them?

- Possible to study small or rare populations as well as uncommon adverse events
- Gives a view of "real life" situations
- Possible to recreate cohorts or case-control studies based on this
- Costs of setting up the study are much smaller (in comparison)
- Intelligent data mining for associations

Large study populations/database

Any problems?

- Researchers do not control the method of data collection nor the data collected
- Changes over time on definitions or data collection
- Chances of finding spurious associations
- Complete characterization on disease morbidity/severity is not always available (incomplete confounders)
- Data often missing - not necessarily at random
- Selective reporting is common

Large study populations/database

Can we do anything?

- Insider knowledge of how the data was collected is necessary
- Compare findings across several databases - register of related databases
- In routinely collected databases - lobbying for improvement on the way the data is collected and input on its collection is of high importance.

Randomised Controlled Trials

To answer which question?

- Trials for single treatment (drug intervention)
- Trials on treatment combinations (several drugs)
- Non-drug trials - particular focus on modification of health care delivery

Randomised Controlled Trials

Why use them?

- Highest level of evidence for treatment interventions
- Well conducted means that bias is minimised
- Good understanding of the important methodological aspects to carry out a “good trial”
- Hypothesis testing (not hypothesis generating)

Randomised Controlled Trials

Any problems?

- Applying results from single to multiple conditions
- Drug-drug and condition-condition interactions
- Defining adequate intervention and control arms as well as a relevant outcome (internal validity)
- Flexibility vs Repeatibility
- External validity – temporal and spatial differences
- Costs!

Randomised Controlled Trials

Can we do anything?

- Identify effect sizes in individual drug trials and verify (test) in large databases on relevant populations
- Integration of other forms of evidence to develop not only interventions but also control arm (TAU)
- Theoretical basis for intervention components that facilitates generalisability
- Careful evaluation for the need of an RCT!