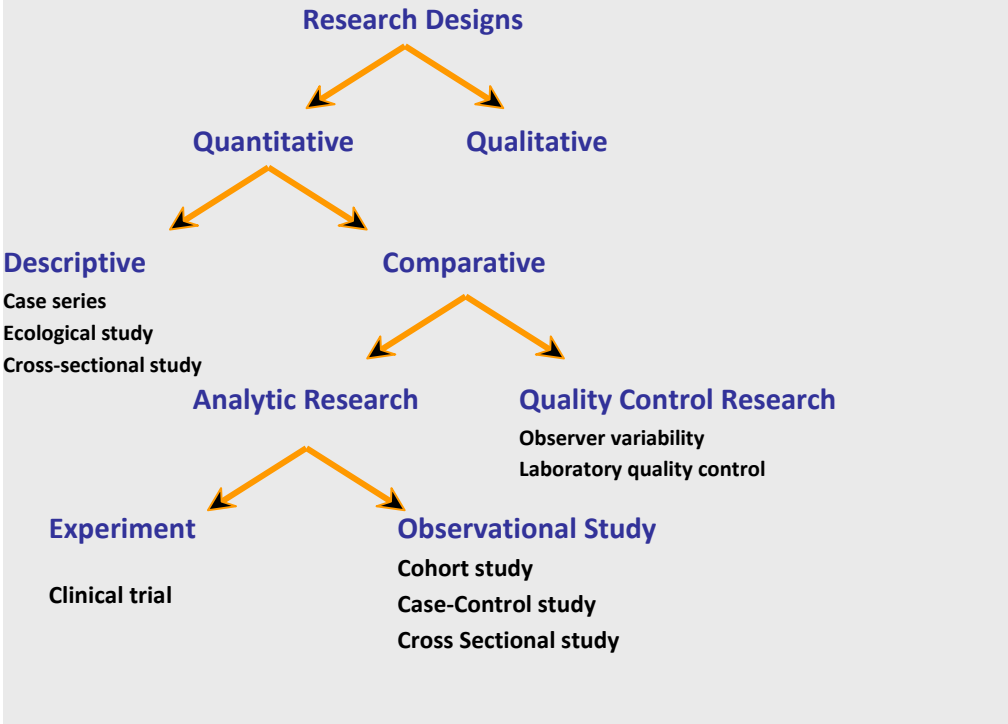
Dissertation Module: Research Skills Program
Topic 4: Research Designs for the Health Sciences

Every research question can be addressed with a study design which is “ideal” for that question. However, the “ideal” research design is sometimes out of reach for us because of resource constraints such as time and money. Hence we may opt for a “feasible” maybe second best design. Such is life!
As we proceed with this research skills program we will discuss different research designs in more depth and we will highlight their main usage and what kind of research questions a design is likely to address best. In Topic 4 we provide an overview of the different research design options at hand.

Classification of Research Designs

Figure 1 provides one possible classification of research studies as applied in the health sciences.

Figure 1: Classification of research designs (based on Feinstein, A. 1985)



Here, the first principal differentiation is between quantitative and qualitative research in the health sciences.

Qualitative research is exclusively descriptive often explorative in nature and usually studies a small – deliberately selected - group of people in detail. Qualitative studies usually address the "why?", "how?", or "what?" questions. Often the sample is formed by key "information-rich" people who are researched using interviews or discussions guided by the investigator. It is not unusual for the questions or discussion points to be modified during the research process. After the completion of the interviews the investigator identifies the main topics and themes raised during the data collection, thus providing a detailed description of the people researched. Qualitative research does not aim to generalise its findings to a wider population.

Quantitative research in contrast, aims to collect information of many people who are representative of the general population rather than a selected group of key people. The intention is to draw inferences from the sample and generalize them to the wider population; in other words, quantitative research aims to state generalizable results. The information gathered is strictly predefined and measured as consistently and accurately as possible. Results are analysed using statistical analysis. Please note qualitative research is concerned with the individual experience or process. Quantitative research is aimed at the wider, general population; the result of quantitative research is information about the "average" person or outcome.

From an historical perspective qualitative research was undoubtedly used before people started to quantify health issues. However, nowadays quantitative research can be regarded as the main branch of studies in the health sciences while qualitative research is seen as a discipline in its own right. The two methodologies complement each other and many researchers conduct studies using both types of methodologies; such studies are called "mixed methods" research.

Descriptive studies do exactly as their name suggests, they describe patterns of disease occurrence in relation to characteristics of persons, place and time. Descriptive research provides data that are used only for descriptive purposes. Descriptive studies are often used in health service research to provide information about cost and apparent need for medical care. Another example of descriptive research is a case report or a case series of interesting or maybe previously unreported symptoms, behaviours, and/or events. Classic examples are the case reports of Kaposi's sarcoma and *Pneumonocystis carinii* pneumonia noted in the early 1980s by the US Centre for Disease Control, which raised the first alarms about the disease we now know as HIV/AIDS (Kanabus, A. & Fredriksson, J., 2010).

Comparison is one of the hallmarks of scientific activity and studies involving a comparison to a control group constitute the **analytic research** approach **-** the main stream of **comparative research.** Analytical studies assess the effect(s) of potential etiologic agents (causes of disease), pathogenic mechanisms, risk factors, prognostic factors, or remedial therapy. Please note the most important feature of comparative research is the definition of a **control group** against which comparisons are carried out.

Quality control research, the second branch of comparative research, deals with methods to assess and maintain measurement quality - mainly with respect to instruments in the medical laboratory but also with respect to intra- and inter-observer agreement in general. Please note that *any* measurement including measurements obtained using an instrument or data collected by questionnaire or recorded by a person should be valid and reproducible. Using validated and published data collection tools is a recommended approach. Thus quality control research forms the basis for any quantitative research. The methodologies of quality control research follow established principles, they are very specific and specialised. One important example of quality control research is studies which assess sensitivity and specificity of a screening or diagnostic tool.

Mainstream analytic research studies are further divided into the major branches of **experimental studies** and **observational studies**. In experiments the exposure (= study factor; often an intervention such as a medication) under study is actively and deliberately managed by the investigator; for example, one group is given the new drug; the control group receives an inert placebo. In contrast, in observational studies the investigator only observes exposure without actively managing it; for example, a group of smokers is compared to a group of non-smokers; both groups are observed and compared with respect to a certain outcome which could be coronary artery disease.

Box 1: Examples of different study designs

Example 1: Researchers investigated the effect of community-led total sanitation (CLTS) on child diarrhoea and child growth in rural Mali. The study population included households in rural villages from the Koulikoro district of Mali; every household had to have at least one child aged younger than 10 years. Villages were randomly assigned to receive CLTS or no programme.

Comments:

(1) This comparative study is an experimental study; a cluster-randomised controlled trial. The study factor was the community-led total sanitation intervention which was either implemented in a village or not (= managed by researchers).

(2) Randomising “clusters” in this case villages and not individual children is often decided on practical grounds such as feasibility and expected level on contamination.

Source: Pickering, A.J. et al (2015)

Example 2: Investigating the growing issue of obesity, researchers in Dunedin looked at the association between childhood sleep time and the long term risk for obesity. The cohort used was the general-population birth cohort of 1037 participants born between April 1972 and March 1973 in Dunedin. Within the study group, parental reports of sleeping times at different ages were associated with measured adult body mass index.

Comments:

(1) This comparative study is an observational study, a so called cohort study. The "exposure" (study factor) was sleep time during childhood and the outcome was "adult obesity". The researchers did not manage the study factor i.e. the childhood sleeping time of their participants (this would have been very impractical and maybe even unethical). The childhood sleeping time was just "observed" - this defines the study as observational.

(2) Please note from a design point of view, experimental studies are preferable to observational studies as they allow a certain control during the study which we do not have in observational designs. However, it is very often impractical or even unethical to vary the exposure level and to conduct an experimental study. Imagine you would like to conduct a study on the effects of smoking in people. An experimental design would imply that you allocate the number of cigarettes smoked by your participants; so according to your allocation some people would smoke 20 cigarettes per day, others 50 and again others none at all…..for several years of follow-up. Naturally such a design is completely unacceptable and the only way left to study the effect of smoking is observation!

This restriction applies to numerous human behaviours, such as alcohol consumption, sun exposure, or safe sex.

Source: Landhuis, C.E. et al (2008)

Example 3: A study conducted by Macquarie University, NSW, compared children with specific language impairment (SLI) and children with specific reading disability (SRD) with a control group of children with no language or reading disabilities for their processing of passive auditory event-related potentials to tones, rapid tones, vowels and consonant-vowels. The study concluded that impaired auditory processing is a potential risk factor for both SLI and SRD.

Comment:

This study is a comparative, observational study, a so called case-control study. The "exposure" (study factor) was impaired auditory processing and the outcome was "SLI" and "SRD". Obviously, the researchers did not vary impaired auditory processing of their participants. Rather the impaired auditory processing was just "observed" (measured). This defines the study as observational.

Source: McArthur, G. et al (2009)

Example 4: A study was conducted in Ghana to investigate the use of antimalarial drugs in the management of fever. A random selection of 370 households was generated in Kintampo, Ghana. All household members present at the time of the survey in the eligible households were interviewed based on a two weeks reported fever recall and the use of antimalarial for the management of fever. A finger-prick blood sample was also obtained from each member of the household present and later examined for malaria parasites.

Comment:

This study was descriptive, a so called cross-sectional study. The results of the study were prevalence of fever as well as of antimalarial drug usage. The study had no comparative

hypotheses and no control group.

Source: Abokyi, L.N. et al (2015)

Example 5: Researchers at the Queensland University of Technology developed a valid and reliable instrument to measure substance-related expectations in relation to cannabis, the Cannabis Expectancy Questionnaire, specifically for Men who have Sex with Men (MSM).

Comment:

This study is an example of quality control research. The researchers developed a questionnaire which reliably (comparisons of repeated applications to the same people give identical results) and validly (the questionnaire measures what it is supposed to measure) assess substance–related expectations. This questionnaire can now be used in studies of MSM in Australia.

Source: Mullens, A.B. et al (2010).

Example 6: A study was conducted to explore access and influences on sexual health care seeking among bisexual men in Vientiane, Laos. In 2013, behaviourally bisexual men were recruited from bars, clubs and dormitories for 5 focus group discussions and 11 in-depth interviews.

Comment:

This study is an example of a qualitative study exploring the experiences of a specific group of people in Laos.

Source: Bowring, A.L. et al (2015)

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