CPD

Which study design?

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There is a bewildering array of terms for different study designs, such that the average clinician could be non-plussed as to what they mean and which one to choose for one's proposed study. The situation is not helped by the absence of universally agreed classification or definitions of these.

The **study design** is the basic structure or the template one would use to answer a particular question. For any job, before choosing the tool one must be clear about the job you are going to do, and have some understanding of the tools available. This applies in research too.

Research is about asking questions: *so, what is your research question?*

It helps to write it down.

What are you trying to do?

Quantity or quality?

If you are measuring something quantifiable, it is a quantitative study; 99% of medical research belong to this category. Qualitative studies measure quality, which is not (easily) quantifiable, e.g. patients' experiences, expectations, etc. Their importance is being increasingly appreciated; they are very popular amongst nurses.

Rest of this article deals only with *quantitative studies.*

Describe or analyse?

Describe

Your question may simply be an enquiry regarding incidence or prevalence of something or an outcome in a group of people, for e.g.:

'What is the prevalence of Hepatitis B in the pregnant population?'

'What is the outcome of the last 100 vaginal breech deliveries in our Unit?'

Those which simply describe *without comparison* are '**descriptive** studies'.

The important features are:
there is *only one* group;
there is no *preconceived hypothesis.*

Analyse

On the other hand, you may have an idea (hypothesis) you want to test, for e.g.

'Babies of diabetics are more liable to have shoulder dystocia.'

'Suicide is more common amongst teenagers.'

'Antenatal steroids reduce RDS in the baby.'

To do so, you have to study two (or more) groups and *compare* the results. Such comparative studies are called **analytical**, as they analyse an issue as opposed to simply describing it.

The important features are:
there is a *stated hypothesis;*
there are at *least two groups.*

Observe or intervene?

If you simply *observe* and record outcomes, then you are doing an **observational** study, for e.g.

Incidence of Hep B in pregnant women (descriptive);

Birth weights of diabetics vs. non-diabetics (analytical).

If you *do an intervention* and record the outcomes, then you are doing an **interventional** study, for e.g.:

Outcome in 100 cases of TCRE (descriptive);

Outcome in premature babies when mothers received steroids compared to when they did not (analytical).

Observational

Descriptive: These would be case reports, case series, prevalence surveys, etc.

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Analytical: there are two well defined, distinct categories:

Cohort studies, and

Case control studies.

The important features common to both are:

There is a clear *pre-stated hypothesis* to be tested;

Cases are carefully *selected* using clear inclusion and exclusion criteria;

There are *at least two groups* who are *similar* except for the variable in question.

Often there is confusion about these two, but the distinction should be very clear; it depends on *the point of recruitment* of patients:

in a *cohort* study, it is at the point of exposure;

in a *case control* study, it is at the point of outcome.

For e.g., if you recruit two groups of women, one on the pill and the other not, and see how many in each group develop DVT, it would be a cohort study. On the other hand, if you recruit them depending whether they have DVT or not, and find out how many in each group are on the pill, it would be a case control study.

There are some analytical studies which resemble the cohort design but do not satisfy the strict criteria mentioned above, for e.g. extracting data from a large data base and looking for associations between different variables. They are best described as 'Correlational studies'.

Interventional

Descriptive: This includes case series of new procedures, operations, etc. A typical example would be a pilot study to test a new device.

Analytical: The most obvious example is the **randomised controlled study**, which is considered the gold standard in the hierarchy of evidence. Nowadays, any new intervention would not be accepted as effective, unless shown to be so by a rct.

Randomisation eliminates two of the most troublesome errors in research:

Selection bias, and

the effect of *confounders*, both known *and* unknown.

Sometimes randomisation is not practical or ethical; then one would use a **non-randomised controlled study**, sometimes called *'a pragmatic study'*. Another way to avoid selection bias is to do a **cross-over trial**, where each participant receives both treatments (usually in chronic conditions).

If the outcome is subjective and hence open to observational bias, one would introduce blinding (single, double or triple).

When blinding is not possible, it is sometimes called *'an open plan'* study.

Unhelpful labels

1. *Prospective/retrospective:* these by themselves do not constitute study designs, but are additional refinements to a basic design. E.g. 'this is prospective study' is not meaningful, whereas 'this is a prospective cohort study' is.
2. *Cross-sectional study:* this too, is not strictly a basic design but a tool to extract information for different purposes. It simply means 'taking a cross-section at a given point in time or time period'. You could use the information for a descriptive study (incidence of GDM among patients booked during 2010; prevalence of TB in prison inmates) or a complicated analytical study (relationship between maternal BMI and various obstetric outcomes).
3. *Questionnaire study:* same as 2. There is no such design; it is only a tool.

Common mistakes

1. *Mislabelling cohort as case control and vice versa.* You are showing a lack of understanding of the basics of a tool you have used, and therefore compromise the credibility of your method. Cohort studies are more commonly mislabelled than case control.
2. *Using incomplete/imprecise terms* such as 'observational, prospective, retrospective, cross-sectional and questionnaire study.'
3. Describing a study as 'a *prospective* RCT'.

   This is a meaningless statement as a RCT could never be retrospective! Unfortunately, this is very common.

Conclusion

Describing the appropriate study design precisely is important as it illustrates the level of your understanding of the tool you have used to do your 'experiment'. If this is at fault, then your methods and therefore, results and conclusions could be open to question.

Also you do yourself injustice by describing a well-designed cohort study (which is fairy high up in hierarchy) simply as 'an observational study'. When

a subsequent researcher searches for cohort studies for a systematic review, your study will not be picked up and hence not cited.

Lastly, as scientists we should try to be precise.

Acknowledgement

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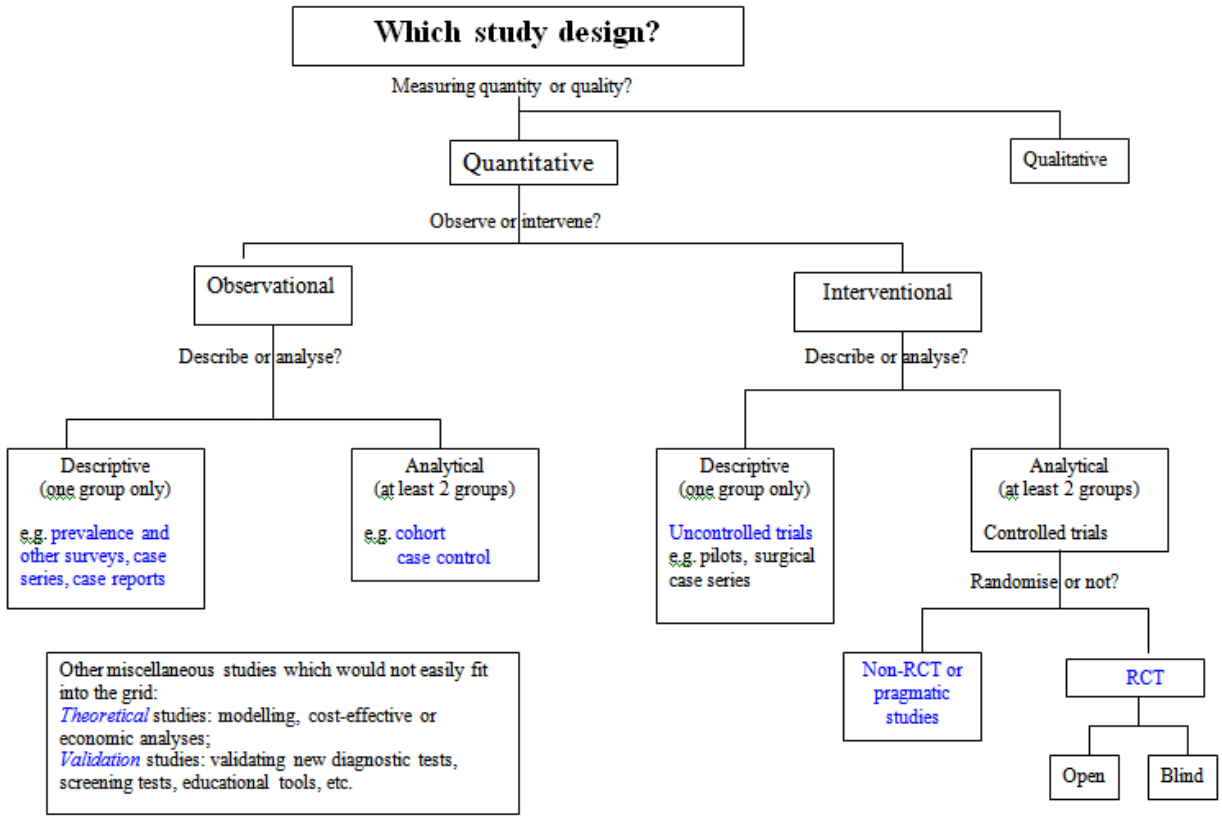

Revision exercise

1. List the advantages and disadvantages of cohort and case control studies. In which situations would you prefer one to the other?

2. Give two examples of a situation where randomisation would not be appropriate.

3. For randomisation to be ethical, what should be the state of mind of the researcher and the patient? One word answer please.

4. What is Zelen randomisation? What does it purport to do?

5. Which of the following are descriptive studies:
   a. Prevalence of GDM among the patients booked in an ANC in 2010 was 12%;
   b. Mean birth weight of 50 babies born to GDM mothers in a Unit was 3.8 kg (3.6-4.0), compared to the national average birth weight of 3.1 kg (2.8-3.4). Conclusion: GDM results in bigger babies;
   c. Mean Hb of 100 tea pluckers on oral iron was 10.8 g/dl (10.5-11.1), compared to 8.5 g/dl (8.0-9.0) for the estate sector. Conclusion: oral iron is effective in treating anaemia in the estate population?

6. Which of the following are observational studies:
   a. Does betel chewing by the mother affect birth weight? Mean birth weight in 100 women chewing betel habitually was compared with that of 100 women who do not;
   b. A paediatric registrar was interested to find the effect of surfactant on very premature babies (<28 weeks). He compared the NNMR in such babies in 2009 (when surfactant was routinely given), with similar figures for 2007 when it was not;
   c. In a multi-centre trial of women undergoing amniocentesis, two groups of women were identified: those with a history of a miscarriage and those without. There was no difference in the miscarriage rate following amniocentesis, in the two groups?

7. Which study design would you use in the following instances/to test the following hypotheses:
   a. Calcium supplements are effective in hyperemesis
   b. Use of 'ecstasy' in early pregnancy causes gastroschisis in the fetus
   c. You have come across three cases of extra-pelvic endometriosis presenting differently
   d. Maternal weight gain during pregnancy affects birth weight
   e. In transferring a case of cord prolapse, filling up the bladder improves foetal outcome
   f. A past history of TB affects fertility
   g. TVT is at least as good as colposuspension
   h. In massive PPH as a last resort, uterine artery embolisation is as effective as hysterectomy
   i. You want to test a cheap locally made equivalent to the TVT tape
   j. You have come across a case of a 'lost coil' retrieved from the rectum, after extensive search in the abdomen failed to find it.
   k. Nifedipine is better in treating premature labour than ritodrine?