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Obituary—Anna Donald

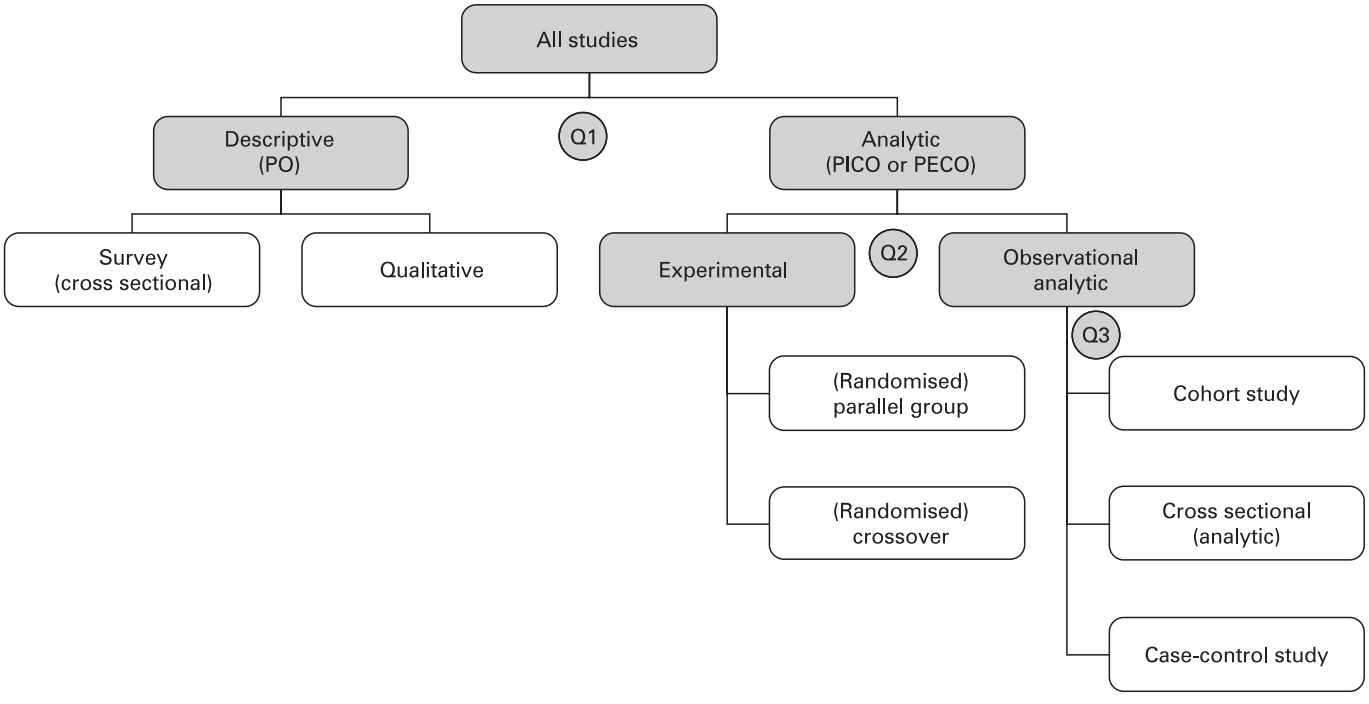
Anna Donald, a pioneer of evidence-based medicine (EBM) in the UK, died recently after a protracted struggle with breast cancer. Anna originally worked as a physician and lecturer in epidemiology and public policy at University College London and was a founding Clinical Editor of the *British Medical Journal's* groundbreaking compendium, Clinical Evidence. A former Rhodes Scholar, Kennedy Fellow, Caltex Scholar, and Menzies Scholar, in 1999 she co-founded Bazian—a company that could act as an independent source of evidence provision and that produces many evidence resources, including *Evidence-Based Mental Health* and much of the material for Clinical Evidence. She was a great ambassador for EBM and creative force within it. She coined the term "Evidology: A new medical specialty that enables medical research to be incorporated systematically into clinical practice [Latin *videre* to discern, comprehend; *evideri* to appear plainly]," and believed that we need to train a cohort of evidologists with a deep understanding of the nature of evidence.

Anna was a warm and wonderful person who, during treatments for cancer, freely discussed her plight, hopes, and fears on her blog on the BMJ: recommended reading for doctors and patients alike. Anna brought a smile and light into the lives of all those around her.

A spotter's guide to study designs

When searching for evidence to answer our clinical questions, the ability to rapidly recognise different types of studies is helpful for finding the one that best answers the question. The "Levels of evidence" tables make suggestions for which design is best for which type of question. For instance, you would naturally consider a randomised controlled trial as the most appropriate study design for intervention decisions. But for potential harms of interventions, we may need case-control studies. And for aetiology we often need to use cohort studies: you wouldn't randomise someone to cigarette smoking to see if they did worse—this would also be unethical. But you would want investigators to follow up cigarette smokers and non-smokers for a long time, just as Richard Doll did.[1]

This short article is a brief guide to the different study types and their advantages and disadvantages. In trying to understand why the investigators chose a particular study type, several factors need to be taken into account. The first thing to recognize is that both clinical questions and study designs have similar components (as we'd expect from PICO):



Simplified classification of different types of studies (Q1, Q2, & Q3 refer to the 3 questions above).

- a defined population (P) from which groups of subjects are studied
- outcomes (O) that are measured

This "PO" is sufficient for questions about frequency, such as the prevalence of hepatitis C in specific groups. But for experimental and analytic observational studies, we need 2 extra elements:

- interventions (I) or exposures (E) that are applied to different groups of subjects
- a comparison (C) or control group to which the intervention is compared

A SIMPLE CLASSIFICATION

The figure shows the tree of possible designs, branching into subgroups of study designs by whether the studies are descriptive or analytic and by whether the analytic studies are experimental or observational. The list is not completely exhaustive but covers most basics designs.

Our first distinction is whether the study is analytic or non-analytic. A *non-analytic* or *descriptive* study does not try to quantify the relationship but tries to give us a picture of what is happening in a population (eg, the prevalence, incidence, or experience of a group). Descriptive studies include case reports, case-series, qualitative studies, and survey (cross-sectional) studies, which measure the frequency of several factors, and hence the size of the problem. They may sometimes also include analytic work (comparing factors—see below).

An analytic study attempts to quantify the relationship between 2 factors—that is, the effect of an intervention (I) or exposure (E) on an outcome (O). To quantify the effect we need to know the rate of outcomes in a comparison (C) group as well as the intervention or exposed group. Whether the researcher actively changes a factor or imposes an intervention determines whether the study is considered to be observational (passive involvement of researcher) or experimental (active involvement of researcher).

In *experimental* studies, the researcher manipulates the exposure—that is, he or she allocates subjects to the intervention or exposure group. Experimental studies, or randomised controlled trials (RCTs), are similar to experiments in other areas of science. That is, subjects are allocated to ⩾2 groups to receive an intervention or exposure and are then followed up under carefully controlled conditions. Such controlled trials, particularly if randomised and blinded, have the potential to control for most of the biases that can occur in scientific studies, but whether bias is actually controlled depends on the quality of the study design and implementation.

In *analytic observational* studies, the researcher simply measures the exposure or treatments of the groups. Analytical observational studies include case–control studies, cohort studies, and some population (cross-sectional) studies. These studies all include matched groups of subjects and assess associations between exposures and outcomes.

Observational studies investigate and record exposures (such as interventions or risk factors) and observe outcomes (such as disease) as they occur. Such studies may be purely descriptive or more analytical.

We should finally note that studies can incorporate several design elements. For example, the control group of a randomised trial may also be used as a cohort study, and the baseline measures of a cohort study may be used as a cross-sectional study.

SPOTTING THE STUDY DESIGN

The type of study can generally be worked out by looking at 3 issues (as per the Tree of design shown in the figure):

Q1. Was the aim of the study to simply describe a population (PO questions)—descriptive—or to quantify the relationship between factors (PICO questions)—analytic.

Q2. If analytic, was the intervention randomly allocated?

Yes ⇒ randomised controlled trial

No ⇒ observational study

For observational studies, the main types will then depend on the timing of the measurement of outcome, so our third question is:

Q3. When were the outcomes determined?

(a) Some time after the exposure or intervention ⇒ cohort study ("prospective study").

(b) At the same time as the exposure or intervention ⇒ cross-sectional study or survey.

(c) Before the exposure was determined ⇒ case-control study ("retrospective study" based on recall of the exposure).

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