All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

GLOSSARY OF GENERAL TERMS

Absolute risk reduction
Absolute risk reduction (ARR) is the difference between the event rate in the control group (CER) and the event rate in the treated group (EER).
ARR = CER – EER.

Blinding
The term 'blinding' (also 'masking') is used in randomised controlled trials and includes single blinding and double blinding. Single blinding occurs when the participants are unaware of which intervention they are receiving. Double blinding occurs when both the participants and the health professionals are unaware of who is receiving the assessed intervention and the control interventions.

Case control study
Increasingly used to investigate causes of diseases, especially rare diseases. A case control study involves the comparison of those with a given condition (cases) and those without the condition (controls). Levels of exposure to a factor are compared between the two groups. Case control studies have been called retrospective studies.

Case study
In-depth analysis and systematic description of one patient or group of similar patients to promote a detailed understanding of their circumstance.

Chi-squared
A test statistic used to assess the statistical significance of a finding, based on the difference between the observed frequency of an event and that which would be expected if the null hypothesis were true.

Clinical audit
The systematic and critical analysis of the quality of clinical care, including the procedures used for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient or client.

Clinical effectiveness
The extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do, i.e. maintain and improve health and secure the greatest possible health gain from the available resources. To be reasonably certain that an intervention has produced health benefits, it needs to be shown to be capable of producing worthwhile benefit (efficacy and cost effectiveness) and to have produced that benefit in practice.

Clinical governance
A framework through which NHS organisations are accountable for continuously improving the quality of their services.

Clinical and health outcomes
These refer to the extent to which the expected health benefit (see clinical effectiveness) is achieved and can be attributed to the relevant clinical and health interventions. The NHS Executive uses the following working definition of health outcome: the "attributable effect of intervention or its lack on a previous health state".

Clinical significance
Whether a treatment is relevant to the patient in practice – this is different to statistical significance. For example, a trial could show a statistically significant difference between a treatment and a control, reducing mean length of symptoms from 7 to 6.5 days. Everyone in the treatment group gets better 0.5 days more quickly, which may be statistically significant, but makes little difference in real life. It is therefore unlikely that the new treatment would be widely adopted; it is of little clinical significance.

Cohort study
A cohort study (also known as a follow-up study or a longitudinal study) involves the identification of two groups (cohorts), one of which is exposed and the other not exposed to a potential factor. These cohorts are followed up in time, and the incidence of the outcome in one group compared with the incidence in the other.

Confidence interval (CI)
A confidence interval quantifies the uncertainty in measurement. It is usually reported as 95% CI, which is the range of values within which we can be 95% sure that the true value for the whole population lies.

Controls
Controls in an RCT are people in a comparison group. They are allocated not to receive the new intervention which is allocated to people in the experimental group. They could instead receive a placebo, conventional therapy or no treatment at all.

Control event rate (CER)
This is the event rate or risk in the control group. See also 'Event rate'.

Cost-effectiveness
The cost-effectiveness of a particular form of health care depends upon the ratio of the costs of health care to its health outcomes.

Critical appraisal
The process of assessing and interpreting evidence, by systematically considering its validity, results and relevance to practice.

Crossover study
A type of trial comparing experimental and control interventions in which the participants are divided into two groups. One group starts with the control intervention and switches halfway through the trial to the experimental intervention. The other group does the opposite.

Cross-sectional study
A study in which information on the putative risk factors and the putative outcomes are measured simultaneously at one point in time. A survey is an example, or in epidemiology, a measure of prevalence.

Event rate
Event rate (sometimes called risk) is the proportion of patients in a group in whom the event is observed. Thus, if out of 100 patients, the event is observed in 27, the event rate is 0.27. 'Control event rate' (CER) and 'experimental event rate' (EER) are terms used to refer to event rates in control and experimental groups of patients respectively.

Experiment
An experiment sets out to test causal relationships by contrasting one or more variables and predictions or hypothesised outcomes.

Experimental event rate (EER)
This is the event rate or risk in the experimental group. See also Event rate.

Experimental group
The experimental group are the group of people in an RCT who are subject to an intervention which can be a treatment, a change in practice or procedure or the introduction of a screening programme.

Follow-up
Results obtained from the participants in a trial all the way through the study period. Losing patients in the follow-up phase can distort the results.

Hawthorne effect
Psychological response in which subjects change their behaviour simply because they are participants in a study, not because of the treatment being researched.

Heterogeneity
A statistical test often used in meta-analysis. It determines if there are any differences between studies, in terms of the population, intervention or outcome, which could influence the intervention effect and therefore make it inappropriate to combine the studies statistically.

Homogeneity
Homogeneity means 'similarity'. Studies are said to be homogeneous if their results vary no more than might be expected due to chance. The opposite of homogeneity is heterogeneity.

Incidence
The rate at which new cases occur in a population during a specified period.

Inclusion criteria
The criteria used by authors of a review to decide whether to include studies.

Intervention
An intervention can be a treatment, a change in practice or procedure or the introduction of a screening programme.

Mean
The average value, which is calculated by adding all the measurements and dividing by the number of measurements.

Median
Is the value on the scale that divides the distribution into two equal parts. Half of the observations have a value less than or equal to the median, and half have a value greater than or equal to the median.

Meta-analysis
A statistical technique which summarises the results of several studies into a single estimate, giving more weight to results from larger studies.

Methodology
Methodology is the approach or design, including the methods used in a piece of work.

Mode
The most frequently occurring value in a set of observations.

Null hypothesis
The proposition that there is no difference between, for example, two treatments other than that due to chance.

Number needed to harm (NNH)
NNH is the number of patients who need to be treated to cause one additional bad outcome (eg side effects). For example, in a trial where side effects are one of the outcomes, if NNH = 10, for every 10 people treated one extra person will suffer side effects.

Number needed to treat (NNT)
NNT is the number of patients who need to be treated to benefit one additional person. For example, if the NNT in a trial looking at giving up smoking by using nicotine replacement therapy = 14, you need to treat 14 people for one additional person to stop smoking.

Odds
The quantified probability of an event happening.

Odds ratio (OR)
The odds in the treatment group divided by the odds in the control group. It is one measure of a treatment's clinical effectiveness.

Outcome
Result of an intervention. Outcomes can be desirable, such as improvement in the patient's condition or quality of life, or undesirable, such as side effects.

Peer-reviewed
Of an article published in a journal, checked by other experts to ensure that the authors have used sound methods and described their methods in sufficient detail to allow others to try and reproduce their results.

Placebo therapy
Placebo therapy is a biologically inert treatment, often given to controls in trials. It can help 'blinding' if patients in the control group are given dummy inactive tablets which look and taste like the real intervention, so that patients do not know which treatments group they are in.

Population
The people that you or the researchers are interested in. Information about them might include their age, gender and state of health.

Prevalence
The proportion of a population that are cases at a point in time.

Prognosis
The expected outcome, predicted on the basis of the normal course of a disease.

P-value
The probability that an observed difference in the results of a study could have occurred by chance. The convention is to believe that if p is greater than 5% (0.05), then the difference may have occurred by chance and not be due entirely to the intervention.

Randomisation
In an RCT, subjects in a population are randomly allocated to groups, usually called treatment and control groups. Allocation of participants to groups is therefore determined by chance. Robust randomisation procedures means that all individuals have the same probability of being allocated either to the experimental or to the control groups.

Randomised controlled trial (RCT)
A RCT is a trial in which subjects are randomly assigned to two groups: one (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control group) receiving an alternative treatment. The results of the trial are assessed by comparing the outcomes in the different groups. The RCT is the 'gold standard' for assessing the effectiveness of an intervention because this study design has the aim of reducing bias and confounding.

Random error
Random error or random variation refers to the differences in results that are due to chance rather than to one of the other variables being studied. Differences caused by random error cause results to be scattered randomly about the mean or best estimate.

Reliability
In naturalistic research, reliability is the process of establishing that data analysis and coding remain constant when reviewed at different times by the same researcher (stability) or another researcher (reproducibility).

Reproducible
Capable of being reproduced. Authors of research reports should describe their methods thoroughly so that others can try to reproduce their results.

Review
Any summary of a particular topic.

Risk
The chances of something happening. Researchers often use the work 'risk' to denote the proportion of patients in a group in whom an event is observed. Another phrase used for 'risk' in this sense is 'event rate'.

Risk ratio
The ratio of risk in the treated group to the risk in the control group: Risk ratio is the risk in the experimental or treatment group (EER) divided by that in the control group (CER). Sometimes called relative risk (RR). RR = EER divided by CER.

Sampling
The process of selecting participants for research on the basis that they can provide detailed information relevant to the enquiry.

Screening
A diagnostic test (used on a person or group) for the presence or absence of a disease, or for risk factors for an increased probability of disease.

Secondary publication
A publication that selects and publishes evidence from other publications, usually with expert commentary. An example could be a book or journals, such as Evidence-Based Medicine, which use primary publications as resources.

Sensitivity analysis
Sensitivity analysis is a statistical technique used to see how the results of a trial or review might be changed by doubt about the data, participants who have dropped out during the course of the research or changes in research methods.

Sets
Groups of related items.

Standard deviation
The mean, median and mode are measures of central tendency and are useful for summarising a frequency distribution, but they do not indicate the spread of values. The standard deviation measures the amount of scatter in results. Approximately two-thirds of the values will fall within one standard deviation of the mean and 95% fall within two standard deviations of the mean.

Statistically significant
A result that is very unlikely to have happened by chance is often described as statistically significant. Researchers often use statistical tests such as chi squared and the probability value to check whether their results are statistically significant.

Systematic review
A review in which evidence on a topic has been systematically identified, appraised and summarised according to predetermined criteria.

Transferability
The extent to which findings from the data can be applied to other settings or groups.

Validity
Refers to the soundness or rigour of a study. A study is valid if the way it is designed and carried out means that the results are unbiased – that is, it gives you a 'true' estimate of clinical effectiveness.