

## **GLOSSARY**

### **Clinical significance<sup>(1)</sup>**

A conclusion that an intervention has an effect that is of practical meaning to patients and healthcare providers. Even though an intervention has a statistically significant effect, this effect might not be clinically significant. In a trial with a large number of patients, a small difference between treatment and control groups may be statistically significant but clinically unimportant. Conversely, in a trial with few patients, an important clinical difference may be observed that does not achieve statistical significance. In this case, a larger trial may be needed to confirm that this is a statistically significant difference.

### **Cost-effectiveness analysis<sup>(1)</sup>**

A comparison of alternative interventions in which costs are measured in monetary units and outcomes are measured in non-monetary units (e.g. reduced mortality or morbidity).

### **Effectiveness, effective<sup>(1)</sup>**

The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions (e.g. by a physician in a community hospital or by a patient at home).

### **Efficacy, efficacious<sup>(1)</sup>**

The benefit of using a technology for a particular problem under ideal conditions; for example, in a laboratory setting, within the protocol of a carefully managed randomized controlled trial, or at a “center of excellence”.

### **Efficiency, efficient<sup>(2)</sup>**

An ability to perform well or achieve a result without wasted energy, resources, effort, time, or money. Efficiency can be measured in physical terms (technical efficiency) or in terms of cost (economic efficiency). Greater efficiency is achieved when: the same amount and standard of services is produced for a lower cost; a more useful activity is substituted for a less useful one at the same cost; or needless activities are eliminated.

### **Evidence-based medicine<sup>(1)</sup>**

The use of current best evidence from scientific and medical research to make decisions about the care of individual patients. It involves formulating questions relevant to the care of particular patients, searching the scientific and medical literature, identifying and evaluating relevant research results, and applying the findings to patients.

### **Follow up<sup>(3)</sup>**

Observation over a period of time of an individual, group, or initially defined population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables.

### **Health Technology Assessment (HTA)<sup>(1,4)</sup>**

The systematic evaluation of the properties, effects, and/or other impacts of healthcare technology. Its primary purpose is to provide objective information to support healthcare decisions and policy making at the local, regional, national, and international level.

### **Incidence<sup>(3)</sup>**

The number of new cases of illness commencing, persons falling ill, or adverse events during a specified time period in a given population. **Prevalence:** the proportion of persons with a particular disease, risk factor, or adverse event within a given population at a given time.

### **Levels of evidence** (adapted from 5)

- Strong** – consistent findings from at least two good quality randomized control trials (RCTs).
- Moderate** – consistent findings from:
  - one good quality RCT, and/or;
  - at least two average quality RCTs, and/or;
  - at least two poor quality RCTs or controlled clinical trials (CCTs), and/or;
  - one average quality and one poor quality trial (RCT or CCT).
- Limited** – findings from one average RCT or one poor quality trial (RCT or CCT).
- Conflicting** – inconsistent findings among multiple trials (RCTs or CCTs) of any quality.

### **Meta-analysis<sup>(1)</sup>**

The use of statistical methods to combine results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. The combined results may produce a stronger conclusion than can be provided by any individual study. (Also known as data synthesis or quantitative overview.)

### **Observational study<sup>(1)</sup>**

A study in which the investigators do not manipulate the use of an intervention (e.g. do not randomize patients to treatment and control groups), but merely observe patients who are (and sometimes patients who are not) exposed to the intervention, and interpret the outcomes. There are three types of observational study: cross-sectional (prevalence), cohort (longitudinal), and case-control.

### **Pain<sup>(6)</sup>**

An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. **Chronic pain** is defined as pain that has persisted beyond the normal tissue healing time (usually taken to be 3 months).

### **Placebo<sup>(1)</sup>**

An inactive substance or treatment given to satisfy a patient's expectation of treatment. In some controlled trials (particularly investigations of drug treatments), placebos that cannot be distinguished by patients (and providers when possible) from the true intervention are given to the control group to be used as a comparator for determining the effect of the investigational treatment.

### **Quality assessment (QA) of randomized controlled trials (RCTs)<sup>(7)</sup>**

QA of the individual RCTs synthesized in systematic reviews (SR) is necessary to limit bias and guide the interpretation of findings. QA includes the measurement of validity (the extent to which a variable or intervention measures what it is supposed to measure or accomplishes what it is supposed to accomplish), and represents the extent to which the design and conduct of the study prevented bias. Differences in study validity can explain variation in the results of RCTs included in a SR. Different checklists (criteria) for assessing the quality of studies are available in the literature.

The RCTs in the 'Evidence in Brief' summaries were rated with respect to quality criteria as follows:

- Good** - at least 80% of the criteria met
- Average** - between 50% and 80% of the criteria met
- Poor** -  $\leq$  50% of the criteria met

### **Quality assessment (QA) of systematic reviews (SR)<sup>(4, 7)</sup>**

It is important to assess the quality of a SR to ensure that all measures have been taken to avoid bias. There are items that evaluate the quality of reporting information in the SR (such as clear presentation of: inclusion and exclusion criteria, search strategy, data extraction, quality assessment, potential methodological limitations, and clinical applicability of the results), and items that evaluate the quality of the SR (such as the

comprehensiveness of the search strategy, independent data extraction and QA by at least two reviewers, and presentation of conclusions that are supported by the results). Usually the process of assessing the quality of a SR involves independent reviewers (at least two) who apply QA criteria to the SR and use consensus methods to resolve any disagreement.

The SRs in the 'Evidence in Brief' summaries were rated with respect to six essential quality criteria as follows:

- Good** - six criteria met, or five met and one criterion only partially met
- Average** - one criterion not met, or one criterion not met and one criterion only partially met, or two criteria only partially met
- Poor** - at least two criteria not met

### **Randomized controlled trial (RCT)<sup>(1)</sup>**

A true prospective experiment in which investigators randomly assign an eligible sample of patients to a control group and one or more treatment groups, and track patient outcomes (also known as a randomized clinical trial).

### **Safety, safe<sup>(1)</sup>**

A judgment of the acceptability of risk (a measure of the probability of an adverse outcome and its severity) associated with using a technology in a given situation, e.g. for a patient with a particular health problem, by a clinician with certain training, or in a specified treatment setting.

### **Statistical significance<sup>(1)</sup>**

A conclusion that an intervention has a true effect, based upon observed differences in outcomes between the treatment and control groups that are sufficiently large for it to be unlikely that the differences occurred by chance (as determined by a statistical test). Statistical significance indicates the probability that the observed difference was due to chance if the null hypothesis is true; it does not provide information about the magnitude of the treatment effect. (Statistical significance is necessary but not sufficient for determining **clinical significance**.)

### **Study design<sup>(7)</sup>**

There are different types of study design, but for particular research questions certain study designs are superior. For example, **randomized controlled trials** are considered to be essential for addressing questions regarding therapeutic efficacy. **Case-control studies** and **cohort studies** are better for deciding questions relating to etiology or risk factors. In addition, other aspects must be considered before reviewing a study, such as

the comparison groups used (**placebo** or another active treatment/intervention), the evaluation of outcomes in an unbiased manner, and the length of **follow up**.

### **Systematic review (SR)<sup>(8)</sup>**

A review that meets all of the following criteria:

- 1) focused clinical question;
- 2) explicit search strategy;
- 3) use of explicit, reproducible, and uniformly applied criteria for article selection;
- 4) critical appraisal of the included studies encompassing the use of a quality tool or checklist;
- 5) qualitative or quantitative data synthesis.

### **The Cochrane Collaboration<sup>(9)</sup>**

An international non-profit, independent organization dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. The Cochrane Collaboration was founded in 1993 and named after the British epidemiologist Archie Cochrane. The major product of the Collaboration is the Cochrane Database of Systematic Reviews,<sup>(10)</sup> which is published quarterly as part of The Cochrane Library. A password and fee is required to view full-text reviews.

## References:

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