Health Technology Assessment (HTA) Glossary

Compiled by Dr. Karen Facey
Edited by Leigh-Ann Topfer and Liza Chan

on behalf of the

International Network of Agencies for
Health Technology Assessment

July 5. 2006
First Edition

INAHTA Secretariat, c/o SBU
Stockholm, Sweden

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Page 2 of 55

Introduction

At the annual meeting of the International Network of Agencies for Health Technology Assessment (INAHTA) in 2002, members discussed the need for a list of standard definitions of terms used in health technology assessment (HTA). The purpose was to give the HTA community – both producers and users of assessment information – a common vocabulary for work in this field. Dr Karen Facey kindly volunteered to compile the list, under the direction of Dr Finn Børlum Kristensen and the INAHTA Education and Training Working Group.

Later in 2002 HTA agencies were asked to send in their glossaries for review and compilation. These submissions formed the basis for a draft glossary. In March 2004, the draft was circulated to all INAHTA members and other colleagues with an invitation to review the list and provide suggestions for changes and additional terms. Many further terms and refinements were submitted and subsequently incorporated into the glossary. But a glossary is never really a finished product, and additions and revisions are needed as HTA continues to evolve. The next challenge will be to translate the glossary into other languages and make it accessible to all through the INAHTA web site.

We would like to express our appreciation to Karen Facey for undertaking this work. This first edition of the INAHTA HTA glossary gives us a common reference point for key terms in HTA. Moreover, it will help us to effectively communicate HTA information to others. Any suggestions for additions, changes or deletions to the glossary should be directed to the Chair of the INAHTA Education and Training Working Group.

Don Juzwishin
Chair, Education and Training Working Group
July 5, 2006

Acknowledgements

Many of the definitions in this glossary have been reproduced with permission from Dr. Clifford Goodman's guide *HTA 101: introduction to health care technology assessment.* He also reviewed the draft of this glossary and provided advice. We thank Dr. Goodman for his generous contribution to this glossary.

Other entries in this glossary have been created by selecting terms from existing glossaries and from terms and sources suggested by many individuals working in the field of health technology assessment. Special thanks are due to the many individuals from the following agencies who provided lists of terms and comments on the first draft of this glossary:

- Agency for Healthcare Research & Quality (AHRQ)
- Alberta Heritage Foundation for Medical Research (AHFMR)
- Australian Government. Department of Health & Ageing
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
- Centre for Health Economics and Policy Analysis (CHEPA)
- Cochrane Collaboration
- Comité d'Evaluation de Diffusion des Innovations Technologiques (CEDIT)
- Danish Centre for Evaluation & Health Technology Assessment (DACEHTA)
- Innovus Research Inc.
- Institute of Applied Health Sciences (IAHS), University of Aberdeen
- NHS Quality Improvement Scotland (QIS)
- Swedish Council on Technology Assessment in Health Care (SBU)
- UK Centre for Reviews & Dissemination (CRD)
- UK National Coordinating Centre for Health Technology Assessment (NCCHTA)
- VA Technology Assessment Program (VATAP)

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Page 4 of 55

Sources

The sources used to compile this glossary include:

1. *EBM glossary.* Oxford, UK: Bandolier; April 2004. Available:
   www.jr2.ox.ac.uk/bandolier/glossary.html (accessed 2006 March 31)

2. *Evidence-based medicine glossary.* Oxford, UK: Centre for Evidence-Based Medicine; 2004.
   Available: www.cebm.net/glossary.asp (accessed 2006 March 31)

3. *Glossary / methodology terms.* Wellington, NZ: New Zealand Guidelines Group; 2004.
   Available: www.nzgg.org.nz/index.cfm?fuseaction=glossary (accessed 2006 March 31)

4. *Glossary of terms in The Cochrane Collaboration.* [Denmark: The Nordic Cochrane Centre];
   2000. Available: www.cochrane.org/resources/glossary.htm (accessed 2006 March 31)

5. *Glossary of qualitative research.* Adelaide, Australia: Audience Dialogue; 2004. Available:
   www.audiencedialogue.org/gloss-qual.html (accessed 2006 March 31)

6. *Glossary of qualitative research terms [draft].* Liverpool, UK: The Qualitative Research and
   Health Working Group, Liverpool School of Tropical Medicine; 2003. Available:
   www.liv.ac.uk/lstm/download/glossary.pdf (accessed 2006 March 31)

7. *Glossary of Technology Assessment Terms.* Boston, MA: Department of Veteran Affairs,
   Technology Assessment Program; 2004. Available: www.va.gov/vatap/glossary.htm
   (accessed 2006 March 31)

8. *Glossary of terms.* New York, NY: New York Academy of Medicine; [n.d.] Available:
   www.ebem.org/definitions.html (accessed 2006 March 31)

9. Goodman, C.S. *HTA 101: introduction to health care technology assessment. Bethesda, MD:
   National Library of Medicine.* National Information Center on Health Services Research &
   Health Care Technology; 2004. Available:
   www.nlm.nih.gov/nichsr/hta101/ta101_c1.html (accessed 2006 March 31)

10. Greenhalgh, T. How to read a paper: papers that summarise other papers (systematic
    reviews and meta-analyses). BMJ 1997;315(7109):672-675. Available:
    http://bmj.bmjjournals.com/archive/7109/7109ed2.htm (accessed 2006 March 31)

11. *PharmacoEconomics.* Auckland, NZ: Adis International Ltd.

12. *Research methods glossary.* In: Project GOLD: Guidance Online for those Learning at a
    Distance. Bath, UK: University of Bath; 2000. Available: www.bath.ac.uk/e-
    learning/gold/glossary.html#glossary (accessed 2006 March 31)

13. Wojtczak A. *Glossary of medical education terms.* White Plains, NY: Institute for
    International Medical Education; 2002. Available: www.iime.org/glossary.htm (accessed
    2006 March 31)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 5 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Additional sources for further information

1. Berger, M.L., Bingefors, K., Hedblom, E.C., et al., editors. *Health care cost, quality, and outcomes: ISPOR book of terms.* Lawrenceville, NJ: International Society for Pharmacoeconomics and Outcomes Research (ISPOR); 2003.

2. Dodge, Y., editor. *The Oxford dictionary of statistical terms.* Oxford, UK: Oxford University Press; 2003.

3. *Glossary for evaluation and results based management (presentation).* Paris: OECD, Development Assistance Committee Working Party on Aid Evaluation; 2002. Available: www.oecd.org/dataoecd/29/21/2754804.pdf (accessed 2006 March 31)

4. Last, J.M., Spasoff, R.A., Harris, S.S., et al., editors. *A dictionary of epidemiology.* Oxford, UK: Oxford University Press; 2000.

5. *Glossary.* Brussels, Belgium: European Observatory on Health Systems and Policies; 2005. Available: www.euro.who.int/observatory/glossary/toppage (accessed 2006 March 31)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 6 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

INAHTA HTA Glossary

Term	Definition/Description
Absolute risk reduction	A measure of treatment effect that compares the probability (or mean) of a type of outcome in the control group with that of a treatment group, [i.e.: Pc - Pt (or µc - µt)]. For instance, if the results of a trial were that the probability of death in a control group was 25% and the probability of death in a treatment group was 10%, the absolute risk reduction would be (0.25 - 0.10) = 0.15. (See also **Number needed to treat**, **Odds ratio**, and **Relative risk reduction**)
Access	The degree to which the health care system aids or inhibits an individual or group in gaining entry and receiving necessary services due to constraints in the financing and delivery of care.
Accuracy	The degree to which a measurement (e.g. the mean estimate of a treatment effect) is true or correct. An estimate can be accurate, yet not be precise, if it is based upon an unbiased method that provides observations having great variation (i.e. not close in magnitude to each other). (See also **Precision**)
Acquisition cost	The purchase cost of a drug to an institution, agency or person.
Action research (or participatory action research)	Where a problem is identified, investigated and changes are made; then reassessed and further changes made, until the problem is satisfactorily resolved.
Additive model	A model in which the combined effect of several factors is the sum of the effects produced by each of the factors. For example, if one factor multiplies risk by a and a second factor by b, the combined effect of the two factors is a + b. (See also **Multiplicative model**)
Adverse effect	An undesirable or unintended effect of an intervention. (See also **Adverse event** and **Side effect**)
Adverse event	Any noxious, pathological or unintended change in anatomical, physical or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of a clinical study whether or not considered treatment related. It includes exacerbation of pre-existing conditions or events, intercurrent illnesses, accidents, drug interaction or the significant worsening of disease.
Adverse reaction	Any undesirable or unwanted consequence of a preventive, diagnostic, or therapeutic procedure in a standard clinical setting.
Allocative efficiency	An allocation of the mix of resources for maximal benefit (i.e. such that no change in spending priorities could improve the overall welfare).

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 7 of 55

Term	Definition/Description
Alpha (α)	**Alpha (α):** the probability of a Type I (false-positive) error. In hypothesis testing, the α-level is the threshold for defining statistical significance. For instance, setting α at a level of 0.05 implies that investigators accept that there is a 5% chance of concluding incorrectly that an intervention is effective when it has no true effect. The α-level is commonly set at 0.01 or 0.05 or 0.10. (See also **Hypothesis testing**)
Annualisation	A means of converting capital costs into an annual figure based upon the equipment lifespan, initial cost, end of lifespan value and financial interest rate.
Applicability	The degree to which the results of an observation, study or review hold true in other settings. (See also **External validity** and **Generalizability**).
Analytic perspective	The viewpoint chosen for the analysis (e.g. societal, government, health care system, payer).
Arithmetic mean	See **Mean**.
Assessment	A scientific process of examining and reporting properties of a technology used in health care, such as safety, efficacy, feasibility and indications for use, cost and cost-effectiveness, as well as social, economic and ethical consequences.
Attrition bias	Systematic differences between comparison groups in withdrawals or exclusions of participants from the results of a study. For example, patients may drop out of a study because of adverse reactions of the intervention. Excluding these patients from the analysis could result in an overestimate of the effectiveness of the intervention.
Audit	The process of setting and adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice.
Autonomy	The patient's right of self-determination concerning medical care. It may be used in various senses including freedom of action, effective deliberation and authenticity. It supports such moral and legal principles as respect for persons and informed consent. Making decisions for oneself, in light of a personal system of values and beliefs.
Average cost	Total costs of a treatment or programme divided by total quantity of treatment units provided. (See also **Marginal cost**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 8 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Bayesian analysis	A statistical approach that can be used in single studies or meta-analysis which explicitly incorporates a prior probability distribution based on subjective opinion and objective evidence, such as the results of previous research. Bayesian analysis uses Bayes' theorem to update the prior distribution in light of the results of a study, producing a posterior distribution. Statistical inferences (point estimates, confidence intervals, etc.) are probability based on this posterior distribution. The posterior distribution also acts as the prior distribution for the next study. This approach has many attractive features, but is controversial because it may depend on opinions, and frequently they will vary considerably. However, its use has become commonplace in **Economic evaluation** as it allows creation of complex models with different evidence sources and determination of uncertainty.
Before-and-after study (pre-test/post-test study)	A study design where a group is studied before and after an intervention. Interpretation of the result is problematic, as it is difficult to separate the effect of the intervention from the effect of other factors.
Benchmarking	A quality assurance process in which an organization sets goals and measures its performance in comparison to those of the products, services, and practices of other organizations that are recognized as leaders.
Beta (ß)	The probability of a Type II (false-negative) error. In hypothesis testing, β is the probability of concluding incorrectly that an intervention is not effective when it has true effect. (1-β) is the **Power** to detect an effect of an intervention if one truly exists. (See also **Hypothesis testing**)
Bias	In general, any factor that distorts the true nature of an event or observation. In clinical investigations, a bias is any systematic factor other than the intervention of interest that affects the magnitude of (i.e. tends to increase or decrease) an observed difference in the outcomes of a treatment group and a control group. Bias diminishes the accuracy (though not necessarily the precision) of an observation. Randomization is a technique used to decrease this form of bias. Bias also refers to a prejudiced or partial viewpoint that would affect someone's interpretation of a problem. Double blinding is a technique used to decrease this type of bias. (See also **Attrition bias**, **Detection bias**, **Performance bias**, **Publication bias**, **Selection bias** and **Workup bias**)
Bibliographic database	An indexed computer or printed source of citations of journal articles and other reports in the literature. Bibliographic citations typically include author, title, source, abstract, and/or related information (including full text in some cases). Examples are **MEDLINE** and **EMBASE**.
Binary data (dichotomous data)	Observations with two possible categories such as dead/alive, smoker/non-smoker, present/not present.

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 9 of 55

Term	Definition/Description
Blinding (masking)	Also known as "masking," the knowledge of patients and/or investigators about whether individual patients are receiving the investigational intervention(s) or the control (or standard) intervention(s) in a clinical trial. Blinding is intended to eliminate the possibility that knowledge of which intervention is being received will affect patient outcomes or investigator behaviors that may affect outcomes. Blinding is not always practical (e.g. when comparing surgery to drug treatment), but it should be used whenever it is possible and compatible with optimal patient care. (See also **Concealment of allocation**, **Single blind**, **Double blind** and **Triple blind**)
Budget impact analysis	The financial impact of the introduction of a technology or service on the capital and operating budgets of a government or agency.
Capital costs	The non-recurring cost of investment in items that remains useful beyond the period when costs are incurred.
Case	A person in the study group who has the disease or characteristic of interest.
Case-control study	A retrospective observational study designed to determine the relationship between a particular outcome of interest (e.g. disease or condition) and a potential cause (e.g. an intervention, risk factor, or exposure). Investigators identify a group of patients with a specified outcome (cases) and a group of patients without the specified outcome (controls). Investigators then compare the histories of the cases and the controls to determine the rate or level at which each group experienced a potential cause. As such, this study design leads from outcome (disease or condition) to cause (intervention, risk factor, or exposure).
Case-mix	Features of a study population that may influence the outcome or the choice of treatment (e.g. severity of disease, coexisting conditions); such features must be taken into account when assessing treatment outcomes.
Case report (case study)	An uncontrolled (prospective or retrospective) observational study involving an intervention and outcome in a single patient. (Also known as a single case report or anecdote.)
Case series	An uncontrolled study (prospective or retrospective) of a series (succession) of consecutive patients who receive a particular intervention and are followed to observe their outcomes. (Also known as case series or clinical series or series of consecutive cases.)
Categorical data	Data that are classified into more than two categories where there is not necessarily a natural order to the categories; for example treatment centres. (See also **Ordinal data**.)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 10 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Causal pathway	Also known as an "analytical framework," a depiction (e.g. in a schematic) of direct and indirect linkages between interventions and outcomes. For a clinical problem, a causal pathway typically includes a patient population, one or more alternative interventions (e.g. screening, diagnosis, and/or treatment), intermediate outcomes (e.g. biological markers), and health outcomes. Causal pathways are intended to provide clarity and explicitness in defining the questions to be addressed in an assessment; they are useful in identifying pivotal linkages for which evidence may be lacking.
Causality	The relating of causes to the effects they produce. The Bradford Hill criteria for causal association are: consistency; strength; specificity; dose–response relationship; temporal relationship (exposure always precedes the outcome; it is the only essential criterion); biological plausibility; coherence; and experiment.
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	Electronic database covering the literature in nursing and allied health. Years of coverage: 1982 - present.
Citation	The record of an article, book, or other report in a bibliographic database that includes summary descriptive information, e.g. authors, title, abstract, source, and indexing terms.
Clinical effectiveness (effectiveness)	The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.).
Clinical (practice) guideline	A systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances. The development of clinical practice guidelines can be considered to be a particular type of HTA; or, it can be considered to be one of the types of policymaking that is informed or supported by HTA
Clinical outcome	An outcome of major clinical importance that is defined on the basis of the disease being studied (e.g. fracture in osteoporosis, peptic ulcer healing and relapse rates).
Clinical pathway	A multidisciplinary set of daily prescriptions and outcome targets for managing the overall care of a specific type of patient, e.g. from pre-admission to post-discharge for patients receiving inpatient care. Clinical pathways often are intended to maintain or improve quality of care and decrease costs for patients in particular diagnosis-related groups.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 11 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Clinical prediction	A clinical prediction rule is a tool for assisting clinical decision making, which consists of variables obtained from the patient's history, physical exam, or testing that provide the probability of an outcome or suggest a diagnostic or therapeutic course of action.
Clinical significance	A conclusion that an intervention has an effect that is of practical meaning to patients and health care providers. Even though an intervention is found to have 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. In a trial with few patients, an important clinical difference may be observed that does not achieve statistical significance. (A larger trial may be needed to confirm that this is a statistically significant difference.)
Clinical trial	A carefully controlled and monitored research study on human subjects or patients evaluating one or more health interventions (including diagnostic methods and prophylactic interventions). Each trial is designed to answer specific scientific questions.
Cochrane Central Register of Controlled Trials (CENTRAL)	A database of references to controlled trials in health care compiled from the specialised registers of the Cochrane groups and other organisations, searches of MEDLINE, EMBASE and other databases.
Cochrane Database of Methodology Reviews (CDMR)	The CDMR contains two parts: *Cochrane Methodology Reviews* (complete systematic reviews of methodological studies) and Protocols for reviews that are currently in progress.
Cochrane Methodology Register (CMR)	A database of articles and books about methods for conducting systematic reviews of the effects of health care interventions. It is published in The Cochrane Library.
Cochrane Database of Systematic Reviews (CDSR)	This database includes the full text of all available Cochrane Collaboration systematic reviews, and the procotols for reviews that are currently underway. (See also The Cochrane Library)
The Cochrane Library	A collection of databases published on CD-ROM and the Internet and updated quarterly, designed to provide information and evidence to support decision making in health care. The databases are as follows: the Cochrane Database of Systematic Reviews, the Cochrane Database of Methodology Reviews, the Cochrane Central Register of Controlled Trials, the Database of Abstracts of Reviews of Effects, the Cochrane Methodology Register, the Health Technology Assessment database and the NHS Economic Evaluation database.
Cochrane Methodology Register (CMR)	A bibliography of publications which report on the methods used in the conduct of controlled trials. It is published in The Cochrane Library.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 12 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Cohort study	An observational study in which outcomes in a group of patients that received an intervention are compared with outcomes in a similar group i.e. the cohort, either contemporary or historical, of patients that did not receive the intervention. In an adjusted- (or matched-) cohort study, investigators identify (or make statistical adjustments to provide) a cohort group that has characteristics (e.g. age, gender, disease severity) that are as similar as possible to the group that experienced the intervention.
Cointervention	In a randomized controlled trial, the application of additional diagnostic or therapeutic procedures to members of either or both the experimental and the control groups.
Comorbidity	The presence of co-existing or additional diseases to the one being studied.
Comparator	The technology to which an intervention is compared.
Compliance	A measure of the extent to which patients undergo an assigned treatment or regimen, e.g. taking drugs, undergoing a medical or surgical procedure, doing an exercise regimen, or abstaining from smoking.
Concealment of allocation	The process used to assign patients to alternative groups in an RCT in a manner that prevents foreknowledge (by the person managing the allocation as well as the patients) of this assignment. Medical record numbers, personal identification numbers, or birthdays are not adequate for concealment of allocation. Certain centralized randomization schemes and sequentially numbered sealed, opaque envelopes are among adequate methods of allocation concealment. (See also **Blinding**)
Concurrent control	A control group that is observed by investigators at the same time as the treatment group, but that was not established using random assignment of patients to control and treatment groups. Differences in the composition of the treatment and control groups may result.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 13 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Confidence interval (CI)	Depicts the range of uncertainty about an estimate of a treatment effect. It is calculated from the observed differences in outcomes of the treatment and control groups and the sample size of a study. The confidence interval (CI) is the range of values above and below the point estimate that is likely to include the true value of the treatment effect. The use of CIs assumes that a study provides one sample of observations out of many possible samples that would be derived if the study were repeated many times. Investigators typically use CIs of 90%, 95%, or 99%. For instance, a 95% CI indicates that there is a 95% probability that the CI calculated from a particular study includes the true value of a treatment effect. If the interval includes a null treatment effect (usually 0.0, but 1.0 if the treatment effect is calculated as an odds ratio or relative risk), the **Null hypothesis** of no true treatment effect cannot be rejected.
Confidence profile method	A type of meta-analysis based on Bayesian statistics for combining results of multiple studies of various design (e.g. RCTs, observational studies, and others) that adjusts the individual studies for their respective methodological biases before combining their results into a probability distribution for the parameter(s) of interest.
Confidentiality	The professional-client promise not to reveal information without consent.
Conflict of interest	A situation in which the private interests of someone involved in the assessment or evaluation process (e.g. interviewer, rater, scorer, evaluator) have an impact (either positive or negative) on the quality of the evaluation activities, the accuracy of the data, or the results of the evaluation.
Conflict of interest declaration (register of interest)	A statement by a contributor to a report or review of personal financial or other interests that could have influenced the findings or their interpretation.
Confounding factor	A factor that is causally linked to the treatment (exposure) and the outcome under study. For example, if cancer incidence is compared between heavy drinkers and tea-totallers, smoking is a confounder (i.e. more heavy drinkers smoke and this is related to cancer) and so smoking should be carefully ascertained and evaluated in the analysis.
Consensus development	Various forms of group judgment in which a group (or panel) of experts interacts in assessing an intervention and formulating findings by vote or other process of reaching general agreement. These process may be informal or formal, involving such techniques as the nominal group and Delphi techniques.
Consensus report	A statement or practice based on general or majority agreement within a group.

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 14 of 55

Term	Definition/Description
Consequence(s)	The outcome(s) associated with a disease and/or intervention (e.g. stroke, death, side effects, avoided morbidity).
Consumer (patient, user)	Someone who uses, is affected by, or who is entitled or compelled to use a health related service.
Consumer advocate (patient representative)	Consumer who is actively involved with other consumers and able to represent the perspectives and concerns of that broader group of people.
Contamination	In clinical trials, the inadvertent application of the intervention being evaluated to people in the control group or inadvertent failure to apply the intervention to people assigned to the intervention group.
Context	The conditions and circumstances that are relevant to the application of an intervention, for example the setting [in hospital, at home, in the air], the time [working day, holiday, night-time], type of practice [primary, secondary, tertiary care; private practice, insurance practice, charity], whether routine or emergency.
Context bias	The influence of the study context on the interpretation of test results; for example, in groups with high prevalence of disease, readers may be more likely to interpret test results as abnormal.
Contingency table	A tabular cross-classification of data such that subcategories of one characteristic are indicated horizontally (in rows) and subcategories of another characteristic are indicated vertically (in columns). Tests of association between the characteristics can be readily applied. The simplest contingency table is the fourfold, or 2x2 table, which is used in clinical trials to compare dichotomous outcomes, such as death, for an intervention and control group or two intervention groups.
Contingent valuation	A method for evaluation of benefit or value to individuals of therapy that uses survey methods to establish willingness to pay.
Continuous data	Data with a potentially infinite number of possible values along a continuum. Height, weight and blood pressure are examples of continuous variables.
Contraindication	A clinical symptom or circumstance indicating that the use of an otherwise advisable intervention would be inappropriate.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 15 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Control	1. In clinical trials comparing two or more interventions, a control is a person in the comparison group that receives a placebo, no intervention or standard care. 2. In case-control studies a control is a person in the comparison group without the disease or outcome of interest. 3. In statistics control means to adjust for or take into account extraneous influences or observations. 4. Control can also mean programs aimed at reducing or eliminating the disease when applied to communicable (infectious) diseases.
Control group	A group of patients that serves as the basis of comparison when assessing the effects of the intervention of interest that is given to the patients in the treatment group. Depending upon the circumstances of the trial, a control group may receive no treatment, a "usual" or "standard" treatment, or a placebo. To make the comparison valid, the composition of the control group should resemble that of the treatment group as closely as possible. (See also **Historical control**)
Controlled clinical trial (CCT)	A prospective experiment in which investigators compare outcomes of a group of patients receiving an intervention to a group of similar patients not receiving the intervention. Not all clinical trials are RCTs, though all RCTs are clinical trials.
Controlled vocabulary	A system of terms, involving, e.g. definitions, hierarchical structure, and cross-references, that is used to index and retrieve a body of literature in a bibliographic, factual, or other database. An example is the *MeSH* controlled vocabulary used in **MEDLINE** and other *MEDLARS* databases of the NLM.
Correlation coefficient	A numeric measure between -1 and 1 that expresses the strength of observed linear association between two variables; expressed as r, the value r = 0 indicates either the lack of a linear relationship or a possible nonlinear relationship between the two variables.
Cost-benefit analysis	A comparison of alternative interventions in which costs and outcomes are quantified in common monetary units
Cost-consequence analysis (CCA)	A form of cost-effectiveness analysis in which the components of incremental costs (of therapies, hospitalization, etc.) and consequences (health outcomes, adverse effects, etc.) of alternative interventions or programs are computed and displayed, without aggregating these results (e.g. into a cost-effectiveness ratio).
Cost-effectiveness acceptability curve (CEAC)	A plot of the probability that an intervention is cost effective, as a function of the value assigned to an additional quality adjusted life year (**QALY**).

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 16 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Cost-effectiveness analysis (CEA)	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. (See also **Cost per QALY**)
Cost-minimization analysis (CMA)	A determination of the least costly among alternative interventions that are assumed to produce equivalent outcomes.
Cost of illness analysis	A determination of the economic impact of a disease or health condition, including treatment costs; this form of study does not address benefits/outcomes.
Cost of lost time	The cost of time lost from work and decreased productivity due to disease, disability, or death. Value of time commonly based on the average wage/earnings rate.
Cost per QALY	A measure used in CUA to assist in comparisons among programmes; expressed as monetary cost per unit of outcome.
Cost-utility analysis (CUA)	A form of cost-effectiveness analysis of alternative interventions in which costs are measured in monetary units and outcomes are measured in terms of their utility, usually to the patient, e.g. using **QALY**s.
Critical appraisal	The process of assessing and interpreting evidence by systematically considering its validity, results and relevance.
Cross-sectional study (prevalence study)	A (prospective or retrospective) observational study in which a group is chosen (sometimes as a random sample) from a certain larger population, and the exposures of people in the group to an intervention and outcomes of interest are determined.
Crossover bias	Occurs when some patients who are assigned to the treatment group in a clinical study do not receive the intervention or receive another intervention, or when some patients in the control group receive the intervention (e.g. outside the trial). If these crossover patients are analyzed with their original groups, this type of bias can "dilute" (diminish) the observed treatment effect.
Crossover design	A clinical trial design in which patients receive, in sequence, the treatment (or the control), and then, after a specified time, switch to the control (or treatment). In this design, patients serve as their own controls, and randomization may be used to determine the order in which a patient receives the treatment and control.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 17 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Crossover trial (study)	A trial in which patients receive, in sequence, the treatment (or the control), and then, after a specified time, switch to the control (or treatment). In this design, patients serve as their own controls, and randomization is used to determine the order in which a patient receives the treatment and control. A problem with this design is that the effects of the first treatment may carry over into the period when the second is given and so washout periods between periods are often used.
Cumulative meta-analysis	In cumulative meta-analysis studies are added one at a time in a specified order (e.g. according to date of publication or quality) and the results are summarised as each new study is added. In a graph of a cumulative meta-analysis each horizontal line represents the summary of the results as each study is added, rather than the results of a single study. However, such analyses are subject to bias unless the multiple testing aspects are adequately accounted for. (See also **Sequential trial**)
DALY	See **Disability-adjusted life years**
Database (or register)	Any of a wide variety of repositories (often computerized) for observations and related information about a group of patients (e.g. adult males living in Göteborg) or a disease (e.g. hypertension) or an intervention (e.g. antihypertensive drug therapy) or other events or characteristics. Depending upon criteria for inclusion in the database, the observations may have controls. Although these can be useful, a variety of confounding factors (e.g. no randomization and possible selection bias in the process by which patients or events are recorded) make them relatively weak methods for determining causal relationships between an intervention and an outcome.
Database of Abstracts of Reviews of Effects (DARE)	DARE is a database of quality assessed systematic reviews of the effects of health care interventions. (See also **The Cochrane Library**)
Decision analysis	An approach to decision making under conditions of uncertainty that involves modeling of the sequences or pathways of multiple possible strategies (e.g. of diagnosis and treatment for a particular clinical problem) to determine which is optimal. It is based upon available estimates (drawn from the literature or from experts) of the probabilities that certain events and outcomes will occur and the values of the outcomes that would result from each strategy. A decision tree is a graphical representation of the alternate pathways.
Decision tree	A framework for representing alternatives for use in decision analysis.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 18 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Degrees of freedom	The number of independent comparisons that can be made between the members of a sample. It refers to the number of independent contributions to a sampling distribution (such as chi-square distribution). In a contingency table it is one less than the number of row categories multiplied by one less than the number of column categories; e.g. a 2 x 2 table comparing two groups for a dichotomous outcome, such as death, has one degree of freedom.
Delphi technique	An iterative group judgment technique in which a central source forwards surveys or questionnaires to isolated, anonymous (to each other) participants whose responses are collated/summarized and recirculated to the participants in multiple rounds for further modification/critique, producing a final group response (sometimes statistical). See also **Nominal group technique**
Detection bias	Systematic differences between comparison groups in ascertainment, diagnosis or verification of outcomes.
Diagnosis	Identification of an illness or diseases by means of its signs, symptoms and results of investigations. This involves ruling out other illnesses and causal factors for the clinical manifestations.
Diagnostic accuracy	See **Accuracy**
Diagnostic impact	A characteristic of **Diagnostic test efficacy** describing the effect of test results on diagnosis.
Diagnostic test efficacy	The impact and usefulness of a diagnostic test expressed in terms of its technical properties, **Diagnostic accuracy**, **Diagnostic impact**, therapy, patient **outcome**, or society.
Dichotomous data	See **Binary data**
Diffusion of innovation	The process by which an innovation is communicated through certain channels over time among the members of a social system. In the case of medical technologies this would be the factors influencing the adoption of a new technology within the health care system.
Dilemma	A forced choice between courses of action (usually two) which are equally unacceptable.
Direct costs	The fixed and variable costs of all resources (goods, services, etc.) consumed in the provision of an intervention as well as any consequences of the intervention such as adverse effects or goods or services induced by the intervention. Includes direct medical costs and direct nonmedical costs such as transportation or child care.
Direct medical costs	A medical cost that varies directly with the provision of a health care intervention (e.g. physician salaries).

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 19 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Direct non-medical costs	A non-medical cost associated with provision of medical services (e.g. transportation of a patient to a hospital).
Disability-adjusted life years (DALYs)	A unit of health care status that adjusts age-specific life expectancy by the loss of health and years of life due to disability from disease or injury. DALYs are often used to measure the global burden of disease.
Discounting	The process used in cost analyses to reduce mathematically future costs and/or benefits/outcomes to their present value. These adjustments reflect that given levels of costs and benefits occurring in the future usually have less value in the present than the same levels of costs and benefits realized in the present.
Discount rate	The interest rate used to discount or calculate future costs and benefits so as to arrive at their present values, e.g. 3% or 5%. This is also known as the opportunity cost of capital investment. Discount rates are usually based on government bonds or market interest rates for cost of capital whose maturity is about same as the time period during which the intervention or program being evaluated. For example, the discount rate used by the US federal government is based on the Treasury Department cost of borrowing funds and will vary, depending on the period of analysis.
Disease management	A systematic process of managing care of patients with specific diseases or conditions (particularly chronic conditions) across the spectrum of outpatient, inpatient, and ancillary services. The purposes of disease management may include: reduce acute episodes, reduce hospitalizations, reduce variations in care, improve health outcomes, and reduce costs. Disease management may involve continuous quality improvement or other management paradigms. It may involve a cyclical process of following practice protocols, measuring the resulting outcomes, feeding those results back to clinicians, and revising protocols as appropriate.
Dissemination	Any process by which information is transmitted (made available or accessible) to intended audiences or target groups.
Distribution	A mathematical function describing the variability of a variable.
Dominance	A process of comparing the cost and effectiveness of each alternative which assists in identifying the most cost-effective strategy. A strategy would dominate another strategy if its effectiveness was higher and its costs lower.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 20 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Double blind (double masked)	Neither the participants in a trial nor the investigators (outcome assessors) are aware of which intervention the participants are given. The purpose of blinding the participants (recipients and providers of care) is to prevent performance bias. The purpose of blinding the investigators (outcome assessors, who might also be the care providers) is to protect against detection bias. (See also Blinding, Single blind and Triple blind)
Early warning system	A stable unit with reliable connections and sources which aims to: identify new technologies that have the potential to make a large impact on health services, filter and prioritise these technologies to select those most likely to have a significant impact and make an assessment of likely impact in terms of health, service and financial impact.
Economic evaluation	The comparative analysis of alternative courses of action, in terms of their costs and consequences.
Economic model	In healthcare, a mathematical model of the patient pathway that describes the essential choices and consequences for the interventions under study and can be used to extrapolate from intermediate outcomes to long-term outcomes of importance to patients.
Effect size	1. A generic term for the estimate of effect determined in a study. 2. A dimensionless measure of effect that is typically used for continuous data when different scales (e.g. for measuring pain) are used to measure an outcome and is usually defined as the difference in means between the intervention and control groups divided by the standard deviation of the control or both groups. One type of meta-analysis involves averaging the effect sizes from multiple studies. (See also Standardised mean difference and Treatment effect)
Effectiveness	See also Clinical effectiveness The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home.
Efficacy	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	The extent to which the maximum possible benefit is achieved out of available resources. (See also Allocative efficiency and Technical efficiency.)
Efficient frontier	In a graphical representation of the non-dominated comparators, the incremental cost-effectiveness or cost-utility ratios are formed along the efficient frontier.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 21 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
EMBASE	A biomedical and pharmacological database (Excerpta Medica database). The database has particularly strong coverage of European publications. Years of coverage - 1970 to present.
Emerging health technology	A technology that is not yet adopted by the health care system; pharmaceuticals will usually be in phase II or phase III clinical trials or perhaps pre-launch; medical devices will be prior to marketing, or within 6 months of marketing, or marketed but <10% diffused or localised to a few centres) or a change in indication or use of an existing technology
Empirical	Empirical results are based on experience (or observation) rather than on reasoning alone.
EMTREE	Controlled vocabulary thesaurus for the EMBASE database.
Endpoint	A measure or indicator chosen for determining an effect of an intervention.
Epidemiology	The study of the distribution and determinants of health-related states or events in specified populations.
Equipoise	A state of uncertainty regarding whether alternative health care interventions will confer more favorable outcomes, including balance of benefits and harms. Under the principle of equipoise, a patient should be enrolled in a randomized contolled trial only if there is substantial uncertainty, (an expectation for equal likelihood) about which intervention will benefit the patient most.
Equity	Fairness in the allocation of resources or treatments among different individuals or groups.
Equivalence trial	A trial with the primary objective of showing that the response to two or more interventions differs by an amount which is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences.
Estimate of effect	In studies of the effects of healthcare, the observed relationship between an intervention and an outcome expressed as, for example, a number needed to treat, odds ratio, risk difference, relative risk, standardised mean difference, or weighted mean difference. (See also **Treatment effect**.)
Ethics	A general term for what is often described as the science of morality. In philosophy, ethical behaviour is that which is good. The goal of a theory of ethics is to determine what is good, both for the individual and for society as a whole. http://encyclopedia.thefreedictionary.com

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 22 of 55

Term	Definition/Description
EuroScan	The European Information Network on New and Changing Health Technologies www.publichealth.bham.ac.uk/euroscan/. The members are HTA agencies that are involved in the identification and assessment of new and emerging health technologies.
Evaluation research	Various research methods that are used to assess a program, agency, policy, etc., particularly with respect to elements such as organization, processes, outcomes and utility.
Event rate	The proportion of participants in a group in whom an event is observed. Thus, if out of 100 patients the event (e.g. a stroke) is observed in 32, the event rate is 0.32.
Evidence-based decision making	The consideration of evidence in the process of making health care decisions. Also known as "evidence-informed decision making".
Evidence-based health care	An extension of the application of the principles of evidence-based medicine to all professions associated with health care, including purchasing and management.
Evidence-based medicine	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, systematically searching the scientific and medical literature, identifying and critically appraising relevant research results, and applying the findings to patients.
Evidence table	A summary display of selected characteristics (e.g. of methodological design, patients, outcomes) of studies of a particular intervention or health problem.
Explanatory trials	Trials that measure the effects of health interventions under ideal conditions, using carefully defined subjects in a research clinic; often evaluating efficacy.
External validity	The extent to which the findings obtained from an investigation conducted under particular circumstances can be generalized to other circumstances. To the extent that the circumstances of a particular investigation (e.g. patient characteristics or the manner of delivering a treatment) differ from the circumstances of interest, the external validity of the findings of that investigation may be questioned. (See also **Applicability** and **Generalizability**)
Extrapolation	Refers to the application of results to a wider population. Means to infer, predict, extend or project the results beyond what was recorded, observed or experienced.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 23 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Factorial design	Most trials only consider a single factor, where an intervention is compared with one or more alternatives, or a placebo. In a trial using a 2x2 factorial design, participants are allocated to one of four possible combinations. For example in a 2x2 factorial, RCT of nicotine replacement and counselling, participants would be allocated to: nicotine replacement alone, counselling alone, both, or neither. In this way it is possible to test the independent effect of each intervention on smoking cessation and the combined effect of (interaction between) the two interventions.
Factual database	An indexed computer or printed source that provides reference or authoritative information, e.g. in the form of guidelines for diagnosis and treatment, patient indications, or adverse effects.
False negative error	Occurs when the statistical analysis of a trial detects no difference in outcomes between a treatment group and a control group when in fact a true difference exists. This is also known as a **Type II error**. The probability of making a Type II error is known as β (beta). (See also **Beta**)
False positive error	Occurs when the statistical analysis of a trial detects a difference in outcomes between a treatment group and a control group when in fact there is no difference. This is also known as a **Type I error**. The probability of a Type I error is known as α (alpha). (See also **Alpha**)
Field evaluation	A study designed specifically to collect primary data about a promising technology for which good evidence is lacking.
Fixed effect model	A statistical model that stipulates that the units under analysis are the ones of interest, and thus constitute the entire population of units. Only within-study variation is taken to influence the uncertainty of results (as reflected in the confidence interval) of a meta-analysis using a fixed effect model. Variation between the estimates of effect from each study (heterogeneity) does not affect the confidence interval in a fixed effect model. (See **Random effects model** and **Peto Method**.)
Focus group	Discussion and opinions on a particular issue presented by a small group of people (approximately 10 participants) led by a moderator.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 24 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Follow-up	The ascertainment of endpoints, events, or other outcomes in patients during or following an intervention, or during the natural course of disease or condition, at one or more stated time intervals after initiating the intervention or other baseline of observation. Also: the ability of investigators to collect data on all patients who were enrolled in or otherwise identified for a study for its full duration. To the extent that data on relevant patient outcomes are lost, e.g., among patients who move away or otherwise withdraw from the study, the results may be affected, especially if there are systematic reasons why certain types of patients are lost to follow-up. Investigators should report on the number and type of patients who could not be evaluated, so that the possibility of bias may be considered. (See also **Intention-to-treat analysis**)
Formulary	A list of drugs reimbursable under a health insurance plan or offered under a capitated or managed care programme or preferred in a particular clinical setting.
Friction cost method	A method of estimating the productivity costs by calculating the value of production losses during the friction period (i.e. between start of absence from work and replacement).
Funnel plot	A graphical display of sample size plotted against effect size that can be used to investigate publication bias.
Future health care costs	Costs which result from the additional consumption of resources (via longer life span, etc.) due to a given intervention.
FY	Fiscal Year
Generalizability	Generalizability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health care situations. (See also **Applicability** and **External validity**)
Gold standard	The method, procedure or measurement that is widely accepted as being the best available against which new interventions should be compared. It is particularly important in studies of the accuracy of diagnostic tests.
Gray/grey literature	Research reports and other literature in print and electronic formats that is not found in traditional peer-reviewed publications or otherwise controlled by commercial publishers. Examples are government agency monographs, symposium proceedings, and industry reports.
Grounded theory	When researchers try to approach a problem without preconceptions, in order to build their theories based solely on the evidence collected.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 25 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Guidance	A document that provides direction or advice as to a decision or course of action. In the UK the term guidance is used to describe guidelines and appraisals for NICE.
Guideline	See Clinical (Practice) Guideline
Handsearching	Planned searching of a journal page by page (i.e. by hand), including editorials, letters, etc., to identify all relevant studies. Normally a person would start by handsearching the current year of a journal, and work backwards until the yield of trials becomes negligible or until volume 1 is reached.
Health economics	The application of the principles and rules of economics in the area of health and health care, including the evaluation of health policy and the health system from an economic perspective; health system planning; the demand for and supply of health care; economic evaluation of medical technologies and procedures; the determinants of health and its valuation, and analysis of the performance of health care systems in terms of equity and allocative efficiency
Health needs assessment	Assessing the health needs of the local community and using this information to set priorities and plan for health care delivery and services.
Health outcomes	The results or impact on health of any type of intervention (or lack of) (e.g. a clinical procedure, health policy or program, etc.).
Health-related quality of life (HRQL, HRQoL, QOL)	Patient outcome measures that extend beyond traditional measures of mortality and morbidity, to include such dimensions as physiology, function, social activity, cognition, emotion, sleep and rest, energy and vitality, health perception, and general life satisfaction. (Some of these are also known as health status, functional status, or quality of life measures).
Health services research	An interdisciplinary field of inquiry that examines the impact of the organization, financing and management of health care services on the delivery, quality, cost, access to and outcomes of such services.
Health status	The level of health of the individual, group or population as subjectively assessed by the individual or by more objective measures.
Health technology	Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organizational systems used in health care.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 26 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Health Technology Assessment (HTA)	Health technology assessment (HTA): the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.
Health Utilities Index (HUI®))	A generic, preference-scored, comprehensive system for measuring health status, health-related quality of life, and producing utility scores (www.fhs.mcmaster.ca/hug/)
Healthy years equivalent (HYE)	The hypothetical number of years spent in perfect health which could be considered equivalent to the actual number of years spent in a defined imperfect state of health.
Hermeneutics	Interpretation of a whole in relation to its parts, and vice versa. (Originally a form of Biblical interpretation).
Heterogeneity	In meta-analysis heterogeneity refers to variability or differences in the estimates of effects among studies. A distinction is sometimes made between "statistical heterogeneity" (differences in the reported effects), "methodological heterogeneity" (differences in study design) and "clinical heterogeneity" (differences between studies in key characteristics of the participants, interventions or outcome measures). Statistical tests of heterogeneity are used to assess whether the observed variability in study results (effect sizes) is greater than that expected to occur by chance. However, these tests have low statistical power. (See also **Homogeneity**)
Hierarchy of evidence	Studies are often grouped into a hierarchy according to their validity or the degree to which they are not susceptible to bias. The hierarchy indicates which studies should be given most weight in an evaluation. There are a various of hierarchies are used in HTA.
Historical control	A control group that is chosen from a group of patients who were observed at some previous time. The use of historical controls raises concerns about valid comparisons because they are likely to differ from the current treatment group in their composition, diagnosis, disease severity, determination of outcomes, and/or other important ways that would confound the treatment effect. It may be feasible to use historical controls in special instances where the outcomes of a standard treatment (or no treatment) are well known and vary little for a given patient population.
Homogeneity	In systematic reviews homogeneity refers to the degree to which the results of studies included in a review are similar. "Clinical homogeneity" means that, in trials included in a review, the participants, interventions and outcome measures are similar or comparable. Studies are considered "statistically homogeneous" if their results vary no more than might be expected by the play of chance. (See **Heterogeneity**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 27 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Horizon scanning	The systematic identification of technologies in development that could have important effects on health care, and which might be considered for Health Technology Assessment.
HTA database	A database of information on ongoing and completed health technology assessments. It is maintained by the Centre for Reviews and Dissemination in collaboration with the Secretariat of INAHTA.
HTAi	Health Technology Assessment International - an international society focusing specifically on HTA, embracing academic institutions health care systems, industry, business, voluntary sector and government: http://www.htai.org
Human Capital Approach (HCA)	A means of calculating the indirect cost of medical illness, based on the remaining lifetime economic value to society of a healthy individual of that age, measured by potential market earnings.
Hypothesis testing	The means of designing and analysing a clinical trial that involves determining the probability that an observed treatment effect could have occurred due to chance alone if a specified hypothesis were true. The specified hypothesis is normally a null hypothesis, made prior to the trial, that the intervention of interest has no true effect, or that there is no difference in effect between the two interventions. Hypothesis testing is used to determine if the null hypothesis can or cannot be rejected.
Impact analysis	Evaluation of the effects of a health technology assessment report, or of a health service or program.
INAHTA	See **International Network of Agencies for Health Technology Assessment**
Incidence	The rate of occurrence of new cases of a disease or condition in a population at risk during a given period of time, usually one year.
Incremental cost	The additional costs that one intervention imposes over another.
Incremental cost effectiveness ratio (ICER)	The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions, e.g. additional cost per **QALY**.
Index Medicus	A bibliographic listing of references to articles from biomedical journals worldwide. Index Medicus is the print equivalent of the **MEDLINE** database.
Indication	A clinical symptom, risk factor, or circumstance for which the use of a particular intervention would be appropriate as determined or specified by, e.g., a clinical practice guideline, standard of care, regulatory body, or other authoritative source.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 28 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Indirect costs	The cost of time lost from work (or leisure) and decreased productivity due to disease, disability, or death. In cost accounting, refers to costs that cannot be attributed to a particular activity but can be allocated across different activities; may be "fixed" regardless of activity intensity (e.g., building maintenance) or "variable" where their magnitude varies with activity (e.g., heating and lighting a building).
Individual patient data	In systematic reviews this term refers to the availability of raw data for each study participant in each included trial, as opposed to aggregate data (summary data for the comparison groups in each study).
Informed choice	A choice made by a competent person, on the basis of comprehensive information regarding an intervention, procedure, or the availability and quality of health services.
Informed consent	The legal and ethical requirement that no significant medical procedure can be performed until the competent patient has been informed of the nature of the procedure, risks and alternatives, as well as the prognosis if the procedure is not done. The patient must freely and voluntarily agree to have the procedure done.
Intangible costs	The cost to include pain and suffering resulting from a disease, condition, or intervention that cannot be quantified.
Integrative study	A study that does not generate primary data but that involves the qualitative or quantitative consolidation of findings from multiple primary studies. Examples are literature review, meta-analysis, decision analysis, and consensus development. (See also **Primary study**).
Intention-to-treat (ITT) analysis	An analysis in which all the participants in a trial are analysed according to the intervention to which they were randomized, whether they: received it or not, completed the study, complied with the study protocol, or crossed over to another group. Intention-to-treat analyses are favoured in assessments of effectiveness as they help to account for the non-compliance and treatment changes that are likely to occur when the intervention is used in practice and because of the risk of attrition bias when participants are excluded from the analysis. However, for equivalence trials, per protocol analyses are preferred as ITT analyses may dilute treatment effects and thus bias towards equivalence. (See also **Per protocol**)
Inter-rater reliability	The degree of stability exhibited when a measurement is repeated under identical conditions by different raters. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of inter-rater reliability may arise from divergences between observers or instability of the attribute being measured. (See also **Intra-rater reliability**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 29 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Interim analyses	At the outset of a trial, the required sample size is determined. Standard statistical analyses are performed when all these patients have completed treatment. In some situations there may be a need for interim analyses to be performed as the trial progresses. This requires special statistical techniques for the interim and final analyses. (See also **Sequential trial**)
Intermediate outcome	See **surrogate endpoint**
Internal validity	The extent to which the findings of a study accurately represent the causal relationship between an intervention and an outcome in the particular circumstances of that study. The internal validity of a trial can be suspect when certain types of biases in the design or conduct of a trial could have affected outcomes, thereby obscuring the true direction, magnitude, or certainty of the treatment effect.
International Network of Agencies for Health Technology Assessment (INAHTA)	An international association of non-profit, health technology assessment agencies, currently representing over 40 agencies worldwide: www.inahta.org
International Society of Technology Assessment in Health Care (ISTAHC)	The first international association for those involved in health technology assessment. The society operated for about twenty years until it was disbanded (circa 2002). A new association, HTAi, is now in operation.
Interrupted time series	Treatment effect is assessed by comparing the pattern of (multiple) pre-test scores and (multiple) post-test scores (after the introduction of the technology) in a group of patients. This design can be strengthened by the addition of a control group which is observed at the same points in time but where the technology is not introduced to that group. Can also use multiple time series with staggered introduction of the technology.
Intervention study	See **Clinical trial**
Intra-rater reliability	The degree of stability exhibited when a measurement is repeated under identical conditions by the same rater. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of intra-rater reliability may arise from divergences between instruments of measurement or instability of the attribute being measured. (See also **Inter-rater reliability**)
Investigational Device Exemption (IDE)	A regulatory category and process in which the US Food and Drug Administration (FDA) allows specified use of an unapproved health device in controlled settings for purposes of collecting data on safety and efficacy/effectiveness; this information may be used subsequently in a premarketing approval application.

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 30 of 55

Term	Definition/Description
Investigational New Drug Application (IND)	An application submitted by a sponsor to the US FDA prior to human testing of an unapproved drug or of a previously approved drug for an unapproved use.
ISTAHC	See International Society of Technology Assessment in Health Care
Justice	The principle that states that fairness requires equals to be treated equally.
Kappa statistic	κ a measure of the degree of agreement that occurs between the diagnostic test and the gold standard over and above that which would have occurred by chance alone.
Knowledge brokering	Brokering is the active, relationship-building aspect of knowledge transfer, a third-party role dedicated to linking researchers and research users so information, innovation and support can flow freely between them.(Canadian Health Services Research Foundation www.fcrss.ca/brokering/pdf/Montreal_Report_e.pdf)
Language bias	A form of bias that may affect the findings of a systematic review or other literature synthesis that arises when research reports are not identified or are excluded based on the language in which they are published.
Large simple trials	Prospective, randomized controlled trials that use large numbers of patients, broad patient inclusion criteria, multiple study sites, minimal data requirements, and electronic registries; their purposes include detecting small and moderate treatment effects, gaining effectiveness data, and improving external validity.
Levels of evidence	See Hierarchy of evidence.
Licensing	A marketing authorisation for medicines which meet standards of safety, quality and efficacy.
Likelihood ratio	1. Compares the chance of positive (or negative) test results in those with the disease to the chance in those without the disease. The likelihood ratio for a positive test result is sensitivity/(1 minus specificity). The likelihood ratio of a negative test result is (1 minus sensitivity)/specificity. 2. A statistical indicator comparing the adequacy of two related models to data, allowing hypothesis testing in a large number of situations.
Literature review	A summary and interpretation of research findings reported in the literature. May include unstructured qualitative reviews by single authors as well as various systematic and quantitative procedures such as meta-analysis. (Also known as overview.)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 31 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Logistic model	A statistical model of an individual's risk as a function of a risk factor or intervention. This model has attractive statistical features and is widely used as a regression model for dichotomous outcomes. In meta-analysis (or meta-regression) the logistic model can be used to explore the relationship between study characteristics and study results. The treatment effect is measured by the log odds ratio.
Log-odds ratio	The (natural) log of the odds ratio. It is used in statistical calculations and in graphical displays of odds ratios in systematic reviews.
Magnitude of treatment effect	Refers to the size (or the distance from the null value indicating no treatment effect) of the summary measure (or point estimate) of the treatment effect and the values included in the corresponding 95% confidence interval.
Malpractice	Negligent professional conduct or the improper discharge of professional duties that fails to meet the standard of care, resulting in harm to a person.
Mantel-Haenszel test	A summary chi-square test for stratified data and used when collecting for confounding. In meta-analyses the Mantel-Haenszel test is used to analyse data stratified (grouped) by study.
Marginal benefit	The additional benefit (e.g. in units of health outcome) produced by an additional resource use (e.g. another health care intervention).
Marginal cost	The additional cost required to produce an additional unit of benefit (e.g. unit of health outcome).
Markov chain Monte Carlo (MCMC)	Markov chain Monte Carlo. A markov model captures the transitional probabilities between various states. This can be combined with probabilistic analysis using Monte Carlo techniques to analyse the interaction between the probability distributions attached to each variable. This will inform on uncertainty in the model. Widely used in Bayesian analysis to build or update models of the joint distributions of variables.
Markov model	A type of quantitative modeling that involves a specified set of mutually exclusive and exhaustive states (e.g. of a given health status), and for which there are transition probabilities of moving from one state to another (including of remaining in the same state). Typically, states have a uniform time period, and transition probabilities remain constant over time.
Masking	See **Blinding**
Mean (arithmetic mean)	The average value, calculated by summing all the observations and dividing by the number of observations.

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 32 of 55

Term	Definition/Description
Median	The middle value in a ranked group of observations. This can be a better estimate of the average value if there are extreme outlying values that may skew the arithmetic mean.
MEDLARS	*M*edical *L*iterature *A*nalysis and *R*etrieval *S*ystem comprising about 40 computer databases managed by the National Library of Medicine.
MEDLINE (MEDlars onLINE)	An electronic database produced by the United States National Library of Medicine. It currently indexes over 12 million references from more than 4,600 biomedical journals. Years of coverage – 1966 to present.(See also **PubMed**)
MeSH	*Me*dical *S*ubject *He*adings, the controlled vocabulary of about 19,000 terms used for **MEDLINE** and certain other US National Library of Medicine *MEDLARS* databases.
Meta-analysis	Systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. (Also known as data synthesis or quantitative overview.)
Meta-regression	Multivariate meta-analytic techniques, such as logistic regression, used to explore the relationship between study characteristics (e.g. allocation concealment, baseline risk, timing of the intervention) and study results (the magnitude of effect observed in each study) in a systematic review.
Methodological quality	The extent to which the design and conduct of a study are likely to have prevented systematic errors (bias). Variation in quality can explain variation in the results of studies included in a systematic review. More rigorously designed (better 'quality') trials are more likely to yield results that are closer to the 'truth'. (See also **External validity** and **Validity**)
Minimization	A method of allocation to intervention used to provide comparison groups that are closely similar for several variables. It can be done with or without a component of randomization. It is best performed centrally with the aid of a computer program to ensure allocation concealment.
Misclassification	The erroneous classification of an individual, a value, or an attribute into a category other than that to which it should be assigned.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 33 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Monte Carlo simulation	A technique used in computer simulations that uses sampling from a random number sequence to simulate characteristics or events or outcomes with multiple possible values. For example, this can be used to represent or model many individual patients in a population with ranges of values for certain health characteristics or outcomes. In some cases, the random components are added to the values of a known input variable for the purpose of determining the effects of fluctuations of this variable on the values of the output variable.
Mortality rate	The proportion of a population who die of a particular cause, usually expressed within a time interval of one year (i.e. death rate).
Moving target	Term used to describe a technology that has properties which are changing rapidly.
Moving target problem	Changes in health care that can render the findings of HTAs out of date, sometimes before their results can be implemented. Included are changes in the focal technology, changes in the alternative or complementary technologies i.e. that are used for managing a given health problem, emergence of new competing technologies, and changes in the application of the technology (e.g. to different patient populations or to different health problems).
Multiple regression	See **Regression analysis**
Multiple testing	Standard statistical tests are based on the principle that a single null hypothesis will be tested once at the end of the study, when all data are gathered. The sample size, alpha and beta are set according to this principle. If more than one statistical test is undertaken e.g. with pairwise comparisons of several interventions, testing different variables, testing at different timepoints, different, parameterizations or sub-groups, there will be an inflation of the planned type I error rate (alpha), i.e. the test is more likely to find a significant effect in the study sample, when in fact in the entire population there is no effect. Special statistical methods are available to take account of the multiple testing of several interventions and for testing data as they accumulate in a study. (See also **Sequential trial**)
Multiplicative model	A model in which the joint effect of two or more factors is the product of their effects. For example, if one factor multiplies risk by a and a second factor by b, the combined effect of the two factors is a x b. (See also **Additive model**)
N of 1 trial	A clinical trial in which a single patient is the total population for the trial, including a single case study. Random allocation may be used to determine the order in which an experimental and a control intervention are given.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 34 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Narrative review	An overview of primary studies which have not been identified or analysed in a systematic (standardised and objective) way.
Natural history	The course of a disease from onset (inception) to resolution. Many diseases have well-defined stages such as pathological onset, presymptomatic and clinically manifest disease.
Negative predictive value	An operating characteristic of a diagnostic test; predictive value negative is the proportion of persons with a negative test who truly do not have the disease, determined as: [true negatives ÷ (true negatives + false negatives)]. It varies with the prevalence of the disease in the population of interest. (See also **Positive predictive value**)
Negative study	A term often used to refer to a study that does not have "statistically significant" (positive) results indicating a beneficial effect of the intervention being studied. The term can generate confusion because it refers to both statistical significance and the direction of effect. Studies often have multiple outcomes, the criteria for classifying studies as "negative" are not always clear and, in the case of studies of risk or undesirable effects, "negative" studies are ones that do not show a harmful effect. (See also **Positive Study**)
Net benefit	Benefit (in monetary units) minus total cost (in monetary units): a basic decision criterion in CBA.
New Drug Application (NDA)	An application submitted by a sponsor to the FDA for approval to market a new drug (a new, nonbiological molecular entity) for human use in US interstate commerce.
Nominal group technique	A face-to-face group judgment technique in which participants generate silently, in writing, responses to a given question/problem; responses are collected and posted, but not identified by author, for all to see; responses are openly clarified, often in a round-robin format; further iterations may follow; and a final set of responses is established by voting/ranking. (See also **Delphi technique**)
Non-experimental study	A type of epidemiologic study that is based on existing exposure conditions without investigator intervention; this type of study is commonly used, but provides weaker evidence of a causal link between the intervention and outcome (s) of interest. (See also **Observational study**)
Nonrandomized controlled trial	A controlled clinical trial that assigns patients to intervention and control groups using a method that does not involve randomization, e.g. at the convenience of the investigators or some other technique such as alternate assignment.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 35 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Null hypothesis	In hypothesis testing, the hypothesis that an intervention has no effect, i.e. that there is no true difference in outcomes between a treatment group and a control group. Typically, if statistical tests indicate that the *P* value is at or above the specified a-level (e.g. 0.01 or 0.05), then any observed treatment effect is not statistically significant, and the null hypothesis cannot be rejected. If the P value is less than the specified a-level, then the treatment effect is statistically significant, and the null hypothesis is rejected. If a confidence interval (e.g. of 95% or 99%) includes zero treatment effect, then the null hypothesis cannot be rejected.
Number needed to harm (NNH)	With reference to adverse effects, the number needed to harm (or, more correctly, the number needed to treat to harm) is the inverse of the absolute risk difference. The term was created as a variant of **Number needed to treat**.
Number needed to treat (NNT)	A measure of treatment effect that provides the number of patients who need to be treated to prevent one outcome event. It is the inverse of absolute risk reduction (1 ÷ absolute risk reduction); i.e. $1.0 \div (P_c - P_t)$. For instance, if the results of a trial were that the probability of death in a control group was 25% and the probability of death in a treatment group was 10%, the number needed to treat would be $1.0 \div (0.25 - 0.10) = 6.7$ patients. (See also **Absolute risk reduction**, **Relative risk reduction**, and **Odds ratio**)
Observational study	A study in which the investigators do not manipulate the use of, or deliver, an intervention (e.g. do not assign patients to treatment and control groups), but only observe patients who are (and sometimes patients who are not as a basis of comparison) exposed to the intervention, and interpret the outcomes. These studies are more subject to selection bias than experimental studies such as randomized controlled trials. (See also **Non-experimental study**)
Odds	Odds are the ratio of the number of people in a group with an event over the number without an event.
Odds ratio (OR)	A measure of treatment effect that compares the probability of a type of outcome in the treatment group with the outcome of a control group, i.e. $[P_t \div (1 - P_t)] [P_c \div (1 - P_c)]$. For instance, if the results of a trial were that the probability of death in a control group was 25% and the probability of death in a treatment group was 10%, the odds ratio of survival would be $[0.10 \div (1.0 - 0.10)] \div [(0.25 \div (1.0 - 0.25)] = 0.33$. (See also **Absolute risk reduction**, **Number needed to treat**, and **Relative risk**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 36 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Open clinical trial	A clinical trial in which the investigator and participant are aware which intervention is being used for which participant (i.e. not blinded). Random allocation may or may not be used in such trials. Open trials are also used when there is only one intervention, for unblinded long-term follow-up studies or in situations where blinding is difficult, impossible or unethical (e.g. surgical vs medical treatment of a disease).
Opportunity cost	The amount that could be spent on alternative healthcare strategies if the health technology in question was not used.
Ordinal data (ordered categorical data)	Data that are classified into more than two categories where there is a natural order to the categories; for example, non-smokers, ex-smokers, light smokers and heavy smokers. Ordinal data are often reduced to two categories to simplify analysis and presentation, which may result in a considerable loss of information or if there are many categories data are considered as continuous – again this can lead to erroneous distributional assumptions.
Outcomes	Components of patients' clinical and functional status after an intervention has been applied.
Outcomes research	Evaluates the impact of health care on the health outcomes of patients and populations. It may also include evaluation of economic impacts linked to health outcomes, such as cost effectiveness and cost utility. Outcomes research emphasizes health problem- (or disease-) oriented evaluations of care delivered in general, real-world settings; multidisciplinary teams; and a wide range of outcomes, including mortality, morbidity, functional status, mental well-being, and other aspects of health-related quality of life. It may entail any in a range of primary data collection methods and synthesis methods that combine data from primary studies.
Outlier	An observation differing so widely from the rest of the data as to lead one to suspect that a gross error may have been committed.
p value	In hypothesis testing, the probability that an observed difference between the intervention and control groups is due to chance alone if the null hypothesis is true. If p is less than the α-level (typically 0.01 or 0.05) chosen prior to the study, then the null hypothesis is rejected.
Paired design	A study in which participants or groups of participants are matched (e.g. based on prognostic factors) and one member of each pair is allocated to the experimental (intervention) group and the other to the control group.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 37 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Parallel group trial	A trial that compares two contemporaneous groups of patients, one of which receives the treatment of interest and one of which is a control group (e.g. a randomized controlled trial). (Some parallel trials have more than one treatment group; others compare two treatment groups, each acting as a control for the other.)
Participatory action research	See Action research
Patient	See Consumer
Patient information leaflet	A document targeted at patients and the general public, which clearly describes key facts about a treatment or procedure. It should include clear explanations of any technical terms.
Patient pathway	See Clinical pathway
Patient representative	See consumer advocate.
Patient selection bias	A bias that occurs when patients assigned to the treatment group differ from patients assigned to the control group in ways that can affect outcomes, e.g. age or disease severity. If the two groups are constituted differently, it is difficult to attribute observed differences in their outcomes to the intervention alone. Random assignment of patients to the treatment and control groups minimizes opportunities for this bias.
Peer review	The process by which manuscripts submitted to health, biomedical, and other scientifically oriented journals and other publications are evaluated by experts in appropriate fields (usually anonymous to the authors) to determine if the manuscripts are of adequate quality for publication.
Per protocol	Analysis of efficacy variables that excludes patients who were not compliant with protocol procedures (e.g. were not compliant with the intervention regimen, took prohibited concomitant treatments). This produces a very controlled population that is not affected by factors that may dilute any treatment effect and so is likely to produce a larger estimate of treatment effect. (See also Intention-to-treat analysis)
Performance bias	Systematic differences in care provided apart from the intervention being evaluated. For example, if patients know they are in the control group they may be more likely to use other forms of care, patients who know they are in the experimental (intervention) group may experience placebo effects, and care providers may treat patients differently according to what group they are in. Blinding of study participants (both the recipients and providers of care) is used to protect against performance bias.
Peto method	A way of combining odds ratios that has become widely used in meta-analysis. The calculations are straightforward and understandable but in some circumstances the Peto odds ratio can differ substantially from the exact odds ratio. It is a fixed effect model.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 38 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Pharmacoeconomics	Economic analyses (such as, cost-benefit, cost-effectiveness, cost-minimisation or cost-utility) that are used to assess different drugs (or drugs to non-drug therapies) used in treatment.
Phase I, II, III, and IV studies	Phases of clinical trials of new technologies (usually drugs) in the development and approval process required by regulatory agencies. Phase I trials usually involve approximately 20-80 healthy volunteers to determine a drug's safety, safe dosage range, absorption, metabolic activity, excretion, and the duration of activity. Phase II trials are controlled trials in approximately 100-300 volunteer patients (with disease) to determine the drug's efficacy and adverse reactions (sometimes divided into Phase IIa pilot trials and Phase IIb well-controlled trials). Phase III trials are larger controlled trials to determine efficacy and monitor adverse events during longer-term use (sometimes divided into Phase IIIa trials conducted before regulatory submission and Phase IIIb trials conducted after regulatory submission but before approval). Phase IV trials are postmarketing studies to monitor long-term effects and provide additional information on safety and efficacy, including for different regimens patient groups.
Placebo	An inactive substance or treatment given to satisfy a patient's expectation for treatment. In some controlled trials (particularly investigations of drug treatments) placebos that are made to be indistinguishable by patients (and providers when possible) from the true intervention are given to the control group to be used as a comparative basis for determining the effect of the investigational treatment.
Placebo effect	The effect on patient outcomes (improved or worsened) that may occur due to the expectation by a patient (or provider) that a particular intervention will have an effect. The placebo effect (also known as the Hawthorne effect) is independent of the true effect (pharmacological, surgical, etc.) of a particular intervention. To control for this, the control group in a trial may receive a placebo.
Point estimate	The results (e.g. mean, weighted difference, odds ratio, relative risk or risk difference) obtained in a sample (a study or a meta-analysis) which are used as the best estimate of what is true for the relevant population from which the sample is taken. A confidence interval is a measure of the uncertainty (due to the play of chance) associated with that estimate. (See also **Confidence interval**)
Positive predictive value	An operating characteristic of a diagnostic test; predictive value positive is the proportion of persons with a positive test who truly have the disease, determined as: [true positives ÷ (true positives + false positives)]. It varies with the prevalence of the disease in the population of interest. (See also **Negative predictive value**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 39 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Positive study	A term used to refer to a study with results indicating a beneficial effect of the intervention being studied. The term can generate confusion because it can refer to both statistical significance and the direction of effect, studies often have multiple outcomes, the criteria for classifying studies as negative or positive are not always clear and, in the case of studies of risk or undesirable effects, "positive" studies are ones that show a harmful effect. (See also **Negative study**)
Power	The probability of detecting a treatment effect of a given magnitude when a treatment effect of at least that magnitude truly exists. For a true treatment effect of a given magnitude, power is the probability of avoiding Type II error, and is generally defined as $(1 - \beta)$.
Pragmatic trials	Trials that measure the effects of health interventions in routine clinical practice. Such trials are used to evaluate effectiveness.
Precision	1. The degree to which a measurement (e.g. the mean estimate of a treatment effect) is derived from a set of observations having small variation (i.e. close in magnitude to each other). A narrow confidence interval indicates a more precise estimate of effect than a wide confidence interval.. A precise estimate is not necessarily an accurate one. 2. A measure of the likelihood of random errors in the results of a study, meta-analysis or measurement. Confidence intervals around the estimate of effect from each study are a measure of precision, and the weight given to the results of each study in a meta-analysis (typically the inverse of the variance of the estimate of effect) is a measure of precision (i.e. the degree to which a study influences the overall estimate of effect in a meta-analysis is determined by the precision of its estimate of effect). 3. The proportion of relevant citations located using a specific search strategy, i.e. the number of relevant studies meeting the inclusion criteria for a trials register or a review) divided by the total number of citations retrieved. (See also **Accuracy**)
Preference	Preference is a generic term and a concept that refers to the desirability of a health outcome. Both utility and value are special cases of the general term/concept of preference. (See also **Utility** and **Value**)
Premarketing Approval (PMA) Application	An application made by the sponsor of a health device to the FDA for approval to market the device in US interstate commerce. The application includes information documenting the safety and efficacy/effectiveness of the device.
Pre-test/post-test study	See **Before and after study**.

INAHTA – The International Network of Agencies for Health Technology Assessment
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org
Page 40 of 55

Term	Definition/Description
Prevalence	The number of people in a population with a specific disease or condition at a given time, usually expressed as a proportion of the number of affected people to the total population.
Prevalence study	See **Cross-sectional study**
Primary (research) study	1. "Original research" in which data are first collected. The term primary research is sometimes used to distinguish it from "secondary research" (reanalysis of previously collected data), meta-analysis, and other ways of combining studies (such as economic analysis and decision analysis). However, because systematic reviews can provide answers not possible from individual studies they can also be considered to be primary research. 2. An investigation that collects original (primary) data from patients, e.g. randomized controlled trials, observational studies, series of cases, etc. (See also **Integrative study**.)
Priority setting	The criteria (explicit or implicit) used in HTA to select technologies for assessment.
Probability distribution	Portrays the relative likelihood that a range of values is the true value of a treatment effect (or other outcome or result). This distribution may follow the form of a particular function, e.g., a normal, chi square, binomial, or Poisson distribution. An estimate of the most likely true value of the treatment effect is the value at the highest point of the distribution. The area under the curve between any two points along the range gives the probability that the true value of the treatment effect lies between those two points. Thus, a probability distribution can be used to determine an interval that has a designated probability (e.g. 95%) of including the true value of the treatment effect.
Prognosis	An assessment of the expected future course and outcome of a person's disease.
(Cox's) Proportional hazards model	A statistical model in survival analysis that asserts that the effect of the study factors (e.g. the intervention of interest) on the hazard rate (the risk of occurrence of an event, such as death, at a point in time) in the study population is multiplicative and does not change over time.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 41 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Prospective study	1. In evaluations of the effects of healthcare interventions, a study in which people are divided into groups that are exposed or not exposed to the intervention(s) of interest before the outcomes have occurred. Randomized controlled trials are always prospective studies and case control studies never are. Concurrent cohort studies are prospective studies, whereas historical cohort studies are not (see cohort study), although in epidemiology a prospective study is sometimes used as a synonym for cohort study. 2. A study in which the investigators plan and manage the intervention of interest in selected groups of patients. As such, investigators do not know what the outcomes will be when they undertake the study. (See also **Retrospective study**)
Protocol	The plan or set of steps to be followed in a study. A protocol for a systematic review should describe the rationale for the review; the objectives; and the methods that will be used to locate, select and critically appraise studies, and to collect and analyse data from the included studies.
Pseudorandomization	See **Randomization** and **treatment allocation**
Publication bias	Unrepresentative publication of research reports that is not due to the scientific quality of the research but to other characteristics, e.g. tendencies of investigators to submit, and publishers to accept, positive research reports (i.e. ones with results showing a beneficial treatment effect of a new intervention). Thus, for example, systematic reviews that fail to include otherwise qualified unpublished studies may overestimate the true effect of an intervention.Other potential sources of publication bias include reputation or affiliation of authors and language of publication.
PubMed	A service of the National Library of Medicine that includes over 14 million citations for biomedical articles back to the 1950's. These citations are from **MEDLINE** and additional life science journals. PubMed includes links to many sites providing full text articles and other related resources. PubMed includes more than just the **MEDLINE** database. It also includes OLDMEDLINE, publisher supplied records & in process records, & is available free of charge via the Internet. (PubMed web site: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi). (See also **MEDLINE**)
Quality	Dimensions of quality include client quality, management quality and professional quality (Ovretveit). Total Quality Management is based on the definition from Deming that quality is to meet or exceed the needs and expectation of the user. In healthcare it is often related to standards of health care that have been set in order to improve patient outcomes and provide equitable care for all.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 42 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Quality-adjusted life year (QALY)	A unit of health care outcomes that adjusts gains (or losses) in years of life subsequent to a health care intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems. Quality-adjusted life year (QALY): a unit of health care outcomes that adjusts gains (or losses) in years of life subsequent to a health care intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems. Analogous units include Disability-adjusted life years (DALYs) and Healthy-years equivalents (HYEs).
Quality assessment	A measurement and monitoring function of quality assurance for determining how well health care is delivered in comparison with applicable standards or acceptable bounds of care. (See also Quality assurance and Quality of care)
Quality assurance	Activities intended to ensure that the best available knowledge concerning the use of health care to improve health outcomes is properly implemented. This involves the implementation of health care standards, including quality assessment and activities to correct, reduce variations in, or otherwise improve health care practices relative to these standards. (See also Quality assessment and Quality of care)
Quality of care	The degree to which health care is expected to increase the likelihood of desired health outcomes and is consistent with standards of health care. (See also Quality assessment and Quality assurance)
Quality of evidence	Degree to which bias has been prevented through the design and conduct of research from which evidence is derived.
Quality of life (QOL)	See Health-related quality of life
Quasi random allocation	See Treatment allocation
Quality score	A value assigned to represent the validity of a study either for a specific criterion, such as allocation concealment, or overall. Quality scores can use letters (A, B, C) or numbers.
Random effects model	A statistical model sometimes used in meta-analysis in which both within-study sampling error (variance) and between-studies variation are included in the assessment of the uncertainty (confidence interval) of the results of a meta-analysis. If there is significant heterogeneity among the results of the included studies, random effects models will give wider confidence intervals than fixed effect models. (See also Fixed effect model)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 43 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Random error	The tendency for the estimated magnitude of a parameter (e.g. based upon the average of a sample of observations of a treatment effect) to deviate randomly from the true magnitude of that parameter. Random variation is independent of the effects of systematic biases. In general, the larger the sample size is, the lower the random variation is of the estimate of a parameter. As random variation decreases, precision increases.
Random permuted blocks	A method of randomization that ensures that, at any point in a trial, equal numbers of participants have been allocated to all the comparison groups. Permuted blocks are often used in combination with stratified randomization.
Random sampling	A method of obtaining a representative, unbiased group of people from a larger population.
Randomization	The process of allocating patients to intervention and control groups in clinical trials using a truly random mechanism such as a random number table or a computer generated random number list under blinded conditions. Proper randomization of patients reduces potential bias in patient assignment because it tends to neutralize known and unknown patient prognostic factors by spreading them evenly among intervention and control groups. Randomization is necessary for valid use of many statistical tests. Pseudorandomization methods (or systematic allocation) based on events such as day of the week, name, date of birth, etc are not equivalent to randomization and can lead to serious biases. (See also **Blinding**)
Randomized controlled trial (RCT)	An experiment of two or more interventions in which eligible people are allocated to an intervention by randomization. The use of randomization then permits the valid use of a variety of statistical methods to compare outcomes of the interventions. (See also **Explanatory trial** and **Pragmatic trial**.)
Receiver operating characteristic	See **ROC curve**
Recurrent costs	Costs that occur each year. (See **Capital costs**)
Referee process	System by which a document goes out for review to editors and external parties with content, methodological or user expertise. These people are sometimes called external peer reviewers or referees. (See also **Peer review**)
Reference list	A list of items cited within a piece of work. Usually found at the end of a work and includes the elements author(s), title, source and year of publication.
Register	See **Database**

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 44 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Registry	System of ongoing registration for compiling data concerning all cases of a particular disease or other health-relevant conditions in a defined population such that the cases can be related to a population base
Regression analysis	An approach that uses the best mathematical model (e.g. linear, logistic) to describe or predict the effect of independent variable "X" on dependent variable "Y"; "multiple" regression involves estimating the effect of several independent variables on the dependent variable.
Relative risk (RR) (risk ratio)	The ratio of (statistical) risk in the intervention group to the risk in the control group. A relative risk of one indicates no difference between comparison groups. For undesirable outcomes an RR that is less than one indicates that the intervention was effective in reducing the risk of that outcome.
Relative risk reduction	A type of measure of treatment effect that compares the probability of a type of adverse outcome in the treatment group (t) with that of a control group (c), i.e.: (Pc - Pt) ÷ Pc. For instance, if the results of a trial show that the probability of death in a control group was 25% and the probability of death in a control group was 10%, the relative risk reduction would be: (0.25 - 0.10) ÷ 0.25 = 0.6. (See also **Absolute risk reduction**, **Number needed to treat**, and **Odds ratio**)
Reliability	The extent to which an observation that is repeated in the same, stable population yields the same result (i.e. test-retest reliability). Also, the ability of a single observation to distinguish consistently among individuals in a population.
Resolution	The ability of an imaging device to distinguish two objects that are separate in either physical distance (spatial resolution) or in composition (contrast resolution).
Retrospective study	A study in which investigators select groups of patients that have already been treated and analyze data from the events experienced by these patients. Retrospective studies are subject to selection bias because investigators can select groups of patients with known outcomes or exposures or that are otherwise not truly representative of the broader population of interest. Case control studies are always retrospective, cohort studies sometimes are, randomized controlled trials never are. (See also **Prospective study**. Contrast with **prospective study**.)
Revealed preference	Preferences revealed by the choices that individuals make. The choices may be those made by individuals in natural settings or responses to choices in questions posed by an investigator.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 45 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Review	1. A systematic review. 2. A review article in the medical literature which summarises a number of different studies and may draw conclusions about a particular intervention. Review articles are often not systematic. Review articles are also sometimes called overviews. (See also Peer review)
Reviewer	Somebody responsible for preparing and, in the case of Cochrane Reviews, keeping up-to-date a systematic review. The term "reviewer" is also sometimes used to refer to an external peer reviewer, or referee.
Risk	The risk is the ratio of people with an event in a group to the total in the group.
Risk assessment	The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences.
Risk factor	An aspect of a person's condition, lifestyle or environment that increases the probability of occurrence of a disease. For example, cigarette smoking is a risk factor for lung cancer.
Risk ratio	See Relative risk
Receiver operating characteristic (ROC) curve	A graphical depiction of the relationship between the true positive ratio (sensitivity) and false positive ratio (1 - specificity) as a function of the cut-off level of a disease (or condition) marker. ROC curves help to demonstrate how raising or lowering the cut-off point for defining a positive test result affects tradeoffs between correctly identifying people with a disease (true positives) and incorrectly labelling a person as positive who does not have the condition (false positives). The area under the ROC curve is an expression of the diagnostic potential of a marker independent of the patient population and can be used to compare two or more markers.
Safety	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.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 46 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Sample size	Sample size: the number of patients studied in a trial, including the treatment and control groups, where applicable. In general, a larger sample size decreases the probability of making a type I (false-positive) error (α) and increases the power of a trial, i.e. decreases the probability of making a type II (false-negative) error (β). Large sample sizes decrease the effect of random variation on the estimate of a treatment effect. In designing a study, the desired sample size can be calculated using statistical formulae based on the acceptable levels of α and β, the difference between intervention groups considered to clinically relevant, and the associated variance. See Alpha and Beta.)
Sampling error	See **Random error**
Screening	A public health service in which members of a defined population, who do not necessarily perceive they are at risk of a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment.
Search strategy	The combination of sources, terms and limits used in the literature search to identify information for the systematic review or health technology assessment.
Secondary research	Research that does not generate primary data but that involves the qualitative or quantitative synthesis of information from multiple primary studies. Examples are literature reviews, meta-analyses, decision analyses and consensus statements.
Selection bias	1. Error due to systematic differences in characteristics between those who are selected for study and those who are not. It can invalidate conclusions and generalizations which might otherwise be drawn from such studies. Random allocation with adequate concealment of allocation protects against selection bias. 2. Selection bias is sometimes used to describe a systematic error in reviews due to how studies are selected for inclusion. Publication bias is an example of this type of selection bias.
Sensitivity	An operating characteristic of a diagnostic test that measures the ability of a test to detect a disease (or condition) when it is truly present. Sensitivity is the proportion of all diseased patients for whom there is a positive test, determined as: [true positives , (true positives + false negatives)]. (See also **Accuracy**, **ROC curve**, and **Specificity**).

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 47 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Sensitivity analysis	A means to determine the robustness of a mathematical model or analysis (such as a cost-effectiveness analysis or decision analysis) that tests a plausible range of estimates of key independent variables (e.g. costs, outcomes, probabilities of events) to determine if such variations make meaningful changes the results of the analysis. Sensitivity analysis also can be performed for other types of study; e.g. clinical trials analysis (to see if inclusion/exclusion of certain data changes results) and meta-analysis (to see if inclusion/exclusion of certain studies changes results).
Sequential trial	A trial in which the data are analysed after groups of participant's results become available, not in the usual manner of waiting until the number of patients determined in the sample size calculation have completed treatment. Analyses are performed according to a pre-defined stopping rule as the data accumulate. The stopping rule takes account of the multiple testing of the data and may be constructed to continue until a clear benefit is seen in one of the comparison groups, or it is unlikely that any difference will emerge. The main advantage of sequential trials is that they will be shorter than fixed length trials when there is a large difference in the effectiveness of the interventions being compared or can lead to early termination of a trial if a safety issue emerges. As a sequential trial generally requires unblinding of the treatment groups before the finalisation of the study, special procedures are required to govern the analysis and dissemination of interim results. (See also **Meta-analysis**)
Series	See **Case series**
Side effect	See **Adverse event** and **Adverse reaction**
Single-arm studies	Usually refers to an analysis or evaluation where groups receiving the new technology and the standard (control) are taken from different studies for comparison. The groups may be from different RCTs and therefore probably assembled following a strict protocol.
Single blind (single masked)	The investigator is aware of the treatment/intervention the participant is getting, but the participant is unaware. (See also **Blinding**, **Double blind**, and **Triple blind**)
Social constructivism (social constructionism)	Understanding the interaction between socially constructed reality and interpretation, knowledge and actions.
Specificity	An operating characteristic of a diagnostic test that measures the ability of a test to exclude the presence of a disease (or condition) when it is truly not present. Specificity is the proportion of nondiseased patients for whom there is a negative test, expressed as: [true negatives ÷ (true negatives + false positives)]. (See also **Accuracy**, **ROC curve**, and **Sensitivity**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 48 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Summary receiver operating curve (SROC)	An SROC plots the sensitivity and (1-specificity) from the invidivdual studies involving the same test in the ROC space. A regression line can be fitted through these points.
Staging	The classification of the severity of a disease in distinct stages on the basis of established signs and symptomatic criteria.
Standard gamble (SG)	A method of directly measuring utility, founded directly on the fundamental von Neumann-Morgenstern axioms of expected utility theory. A utility score is revealed by finding the probabilities in the gamble for which the respondent is indifferent between an uncertain alternative (the gamble) and a certain alternative.
Standardised mean difference (SMD)	The difference between two means divided by an estimate of the within-group standard deviation. When an outcome (such as pain) is measured in a variety of ways across studies (using different scales) it may not be possible directly to compare or combine study results in a systematic review. By expressing the effects as a standardised value the results can be combined since they have no units. Standardised mean differences are sometimes referred to as a d index.
Statistical power	See **Power**.
Statistical significance	(See **P-value**) **Statistical significance:** 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 so that these differences are unlikely to have occurred due to 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 a treatment effect. For example, a p-value of 0.05 for a risk difference of 10% means that there is less than a one in 20 (0.05) chance of a risk difference as large or larger having occurred if there was really no difference in risks. It is then stated that the risk difference is "statistically significant" at p = 0.05. A typical cut-off for statistical significance is p = 0.05, or 0.01 for meta-analyses or 0.10 for assessment of interactions. However, these cut-offs are arbitrary and have no specific importance. (See **P-value**.)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 49 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Statistical test	A mathematical procedure (or function) that is used to determine if the difference in outcomes of a treatment and control group is great enough to conclude that the difference is statistically significant. Statistical tests generate a value that is associated with a particular *P* value. Among the variety of common statistical tests are: *F, t, Z,* and *chi-square* tests. The choice of a test depends upon the conditions of a study, e.g. what type of outcome variable used, whether or not the patients were randomly selected from a larger population, and whether it can be assumed that the outcome values of the population have a normal distribution or other type of distribution.
Stratified randomization	Stratified randomization is used to ensure that equal numbers of participants with a characteristic thought to affect prognosis or response to the intervention will be allocated to each comparison group, in order to avoid confounding. For example, in a trial of women with breast cancer, it may be important to have similar numbers of pre-menopausal and post-menopausal women in each comparison group. Stratified randomization could be used to allocate equal numbers of pre- and post-menopausal women to each treatment group. Stratified randomization is performed either by performing separate randomization (often using random permuted blocks) for each strata, or by using minimisation.
Strength of evidence	Magnitude, precision and reproducibility of the intervention effect (includes magnitude of the effect size, confidence interval width, *p-* value and the exclusion of clinically unimportant effects). In the case of nonrandomized studies, additional factors such as biological plausibility, biological gradient and temporality of associations may be considered.
Study base	The study population of interest over a specified period of time.
Study validity	The degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalizability).
Subgroup analysis	The process of analyzing data from subpopulations of patients. Sub-group analyses should be planned at the outset of the study and even then their results should only be considered as exploratory. Any significant sub-group effects should be verified in other studies. (See also **Multiple testing**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 50 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Surrogate endpoint (intermediate outcomes; surrogate outcomes)	(See P-value) **Statistical significance:** 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 so that these differences are unlikely to have occurred due to 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 a treatment effect. For example, a p-value of 0.05 for a risk difference of 10% means that there is less than a one in 20 (0.05) chance of a risk difference as large or larger having occurred if there was really no difference in risks. It is then stated that the risk difference is "statistically significant" at p = 0.05. A typical cut-off for statistical significance is p = 0.05, or 0.01 for meta-analyses or 0.10 for assessment of interactions. However, these cut-offs are arbitrary and have no specific importance. (See P-value)
Synthetic study	See **Integrative study**
Systematic error	See **Bias**
Systematic review (systematic overview)	A form of structure literature review that addresses a question that is formulated to be answered by analysis of evidence, and involves objective means of searching the literature, applying predetermined inclusion and exclusion criteria to this literature, critically appraising the relevant literature, and extraction and synthesis of data from evidence base to formulate findings. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies. (See also **Cochrane Review**)
Technical efficiency	The production of the greatest amount or quality of outcome for any specified level of resources.
Technology	The application of scientific or other organized knowledge – including any tool, technique, product, process, method, organization or system – to practical tasks. In health care, technology includes drugs; diagnostics, indicators and reagents; devices, equipment and supplies; medical and surgical procedures; support systems; and organizational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation. (See also **Health technology**)
Technology assessment	See **Health technology assessment**
Technology diffusion	See **Diffusion of innovation**

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 51 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Technological imperative	The inclination to use a technology that has potential for some benefit, however marginal or unsubstantiated, based on an abiding fascination with technology, the expectation that new is better, and financial and other professional incentives.
Therapeutic impact	A characteristic of **Diagnostic test efficacy** that describes the effect of a diagnostic test on therapeutic choices.
Therapeutic trial	See **Clinical trial**
Time lag bias	A form of bias that may affect identification of studies to be included in a systematic review; occurs when the time from completion of a study to its publication is affected by the direction (positive vs. negative findings) and strength (statistical significance) of its results.
Time series	A set of measurements of the same variables taken over time. An interrupted time series is generated when a set of measurements is taken before the introduction of an intervention, or some other change in the system, followed by another set of measurements taken over time after the change.
Time trade-off (TTO)	A method of measuring value by finding the point at which the respondent is indifferent between two health states for different lengths of time. For chronic states, the choices are the index health state for time *t* followed by death, or perfect health for a shorter time followed by death. For temporary states, the choices are the index health state for time *t* followed by an explicitly specified outcome (usually healthy), or a worse health state for a shorter time followed by the same specified outcome.
Transition probability	The probability that the health of a patient changes from one health state to another health state within a given period.
Treatment allocation	The process used to prevent foreknowledge of group assignment in a randomized controlled trial, which should be seen as distinct from blinding. The allocation process should be impervious to any influence by the individual making the allocation by having the randomization process administered by someone who is not responsible for recruiting participants; for example, a hospital pharmacy, or a central office. Using methods of assignment such as date of birth and case record numbers (called quasi random allocation or pseudorandomization) are open to manipulation. Adequate methods of allocation concealment include: centralized randomization schemes; randomization schemes controlled by a pharmacy; numbered or coded containers in which capsules from identical-looking, numbered bottles are administered sequentially; on-site computer systems, where allocations are in a locked unreadable file; and sequentially numbered opaque, sealed envelopes. See **Randomization**

INAHTA – The International Network of Agencies for Health Technology Assessment Page 52 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Treatment effect	The effect of a treatment (intervention) on outcomes, i.e. attributable only to the effect of the intervention. Investigators seek to estimate the true treatment effect using the difference between the observed outcomes of a treatment group and a control group. (See also **Effect size**)
Trials register	A database of bibliographic references to randomized controlled trials and controlled clinical trials in the Cochrane Collaboration. It includes information about unpublished and ongoing trials.
Triple blind (triple masked)	An expression that is sometimes used to indicate that knowledge of which study participants are in which comparison group is kept secret from the statistician doing the analysis as well as from the study participants and investigators (outcome assessors). (See also **Blinding**, **Single blind**, **Double blind**)
Type I error	See **Alpha**
Type II error	See **Beta**
Unit of allocation	The unit that is assigned to the alternative interventions being investigated in a trial. Most commonly, the unit will be an individual person but, in some trials, people will be assigned in groups to one or other of the interventions. This is done to avoid contamination or for convenience and the units might be, for example, hospitals or communities. In other trials, different parts of a person (such as the left or right eye) might be assigned to receive different interventions.
Unrelated costs	Costs not specifically attributable to the therapeutic pathway and its consequences.
User	See **Consumer**
Users of reviews	Patients or healthcare professionals or policy makers using a review to make practical decisions about healthcare, and researchers conducting or considering further research.
Utility	1. In economic and decision analysis, the desirability of a specific level of health status or health outcome, usually expressed as being between zero and one (e.g. death typically has a utility value of zero and a full healthy life has a value of one). Often used interchangeably with the term **Preference**. 2. The relative desirability or **Preference** (usually from the perspective of a patient) for a specific health outcome or level of health status. (See also **Preference** and **Value**)

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 53 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Validity	The degree to which a result (of a measurement or study) is likely to be true and free of bias (systematic errors). Also, the degree to which a measure or parameter accurately reflects or assesses a concept of interest. Multiple types of dimensions of validity are recognized in research. Internal validity refers to the extent to which the observed cause-and-effect relationship in a study is true for the people and conditions of a study; whereas external validity or generalizability refers to the extent to which the effects observed in a study truly reflect what can be expected in a population and set of conditions those of the study. Among other types of validity are: construct, content, and face validity. (See also Internal validity, External validity, and **Methodological quality**)
Value	A cardinal measure of the preference for, or desirability of, a specific level of health status or a specific health outcome, measured under certainty. (See also **Utility** and **Preference**.) Also used to give an overall description balancing the positive and negative (costs) of a situation (e.g. value for money).
Variable	Any quantity that varies. A factor that can have different values.
Variance	A measure of the variation shown by a set of observations, defined by the sum of the squares of deviations from the mean, divided by the number of degrees of freedom in the set of observations.
Verification bias	See **Workup bias**
Weighted least squares regression	A regression technique for estimating the parameters of a multiple regression model, wherein each study's contribution to the sum of products of the measured variables (study characteristics) is weighted by the precision of that study's estimate of effect.
Weighted mean difference (WMD)	A method of meta-analysis used to combine measures on continuous scales (such as weight), where the mean, standard deviation and sample size in each group are known. The weight given to each study (e.g. how much influence each study has on the overall results of the meta-analysis) is determined by the precision of its estimate of effect and, in the statistical software in RevMan and CDSR, is equal to the inverse of the variance. This method assumes that all of the trials have measured the outcome on the same scale. (See also **Standardised mean difference**)
Willingness to pay (WTP)	The maximum amount that a person is willing to pay: (i) to achieve a particular good health state or outcome, or to increase its probability of occurrence; or (ii) to avoid particular bad health state or outcome, or to decrease its probability.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 54 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org

Term	Definition/Description
Workup bias	Also called verification bias. Occurs when patients with positive (or negative) diagnostic procedure results are preferentially referred to receive verification by the gold standard procedure. The bias can substantially distort the reported accuracy of the test. This bias is avoided if all consecutive subjects who have the test are verified by the reference standard, or subjects are sampled by reference standard results before test results are known.

INAHTA – The International Network of Agencies for Health Technology Assessment   Page 55 of 55
Address: c/o SBU, Box 5650, SE-114 86 Stockholm, Sweden
Website: www.inahta.org • Email: info@inahta.org