HTAi HEALTH TECHNOLOGY ASSESSMENT iNTERNATIONAL

Patient and Citizen Involvement Interest Group

HTAi consumer and patient glossary
A guide to words used in health technology assessment

Version: 2
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About this glossary

This glossary explains words that are often used in health technology assessment (HTA) so that they can be more easily understood by anyone, especially patients and consumers. It is hoped that it will inspire clearer communication, and support those patients and consumers taking part in HTA.

Words that are written in *italics* have their own separate entry. Words that are listed as 'see also' give extra information on the topic.

Patients and organisations are encouraged to use this glossary and provide feedback about its usefulness, including the words include and the language used.

Feedback should be sent to: glossaryfeedback@gmail.com

About this Version

Version 2 replaces Version1 published in October 2009. It contains updated contact information for feedback on the glossary and definitions for the following terms:

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A

absolute risk reduction

The likelihood that a particular outcome will happen is called the *absolute risk*. The *absolute risk reduction* is the decrease in the likelihood of that outcome due to a treatment or other *intervention*.

For example, if a treatment reduces the absolute risk of death from 0.25 or 25% to 0.10 or 10%, the *absolute risk reduction* is 0.15 or 15% (that is 0.25 minus 0.10 equals 0.15 or 15%).

The estimate of *absolute risk reduction* often comes from clinical trials. The percentage (%) of people taking part that are receiving treatment (treatment group) who experience a specific outcome is compared to the percentage of people taking part but not receiving treatment (control group) who experience the same outcome.

See *number needed to harm*, *number needed to treat*

adverse effect

A negative or unwanted effect that results from a treatment or *intervention*. Some adverse effects may be predicted as a direct result of the treatment. For example, chemotherapy kills cancer cells but may also kill healthy cells such as red blood cells. This leads to the *adverse effect* of anaemia.

Some adverse effects may be the result of incorrect use. For example the wrong dose of the drug may be given or a needle may accidentally puncture an artery.

See also *side effect*

advocate

Someone who speaks on behalf of themself or another person.

In health, an *advocate* is usually a person who speaks on behalf of a health care consumer or *patient*, or a group of consumers or patients. An example of an *advocate* is a person who is closely involved with consumers or patients or a patient support group, and is able to voice any concerns and views of a *consumer* or *patient*.

analysis	The process of looking for patterns in information to identify cause and effect and/or answer specific questions, such as whether it works and what the risks are. The information is usually collected in research. There are two types of analyses. *Quantitative* analysis looks for patterns in the form of numbers, such as most frequent choice of treatment option or average rating of pain during treatment. *Qualitative* analysis looks for patterns of meaning, feeling, or beliefs, leading to a finding such as 'most people who support paying more for end-of-life therapy also believe society should give more to those with greater need'.
analytical hierarchy process	
ARR	See *absolute risk reduction*
B	
bias	Occurs when a factor influences a research study's outcomes or interpretation of outcomes. There are many types of *bias*. Some are by accident, some are on purpose, some are caused by the research and some are caused by other factors. Sampling *bias* occurs when the people or entities chosen to represent the entire *population* are not representative. For example, a study that enrols patients on a first-come, first-served basis may be biased towards those who are already receiving better health care. Publication *bias* occurs because journals are more likely to publish only the results of studies that show a benefit. Studies that show no effect are often not published, even though their findings are just as important. See also *blinded trial, blinding(masking)*
blinding (masking)	A way to prevent the researchers, doctors and patients in a *clinical trial* from knowing which study group each patient is in so they cannot influence the results. The best way to do this is by sorting patients into study groups randomly, for example by pulling numbers out of a hat or assigning them using a random number list made on a computer. A single-blinded study is one in which patients do not know which study group they are in. A double-blinded study is one in which both patients and the researchers or doctors do not know which

	study group the patients are in. One common method of *blinding* is to give patients in the non-treatment or control group a similar-appearing fake treatment, also known as a *placebo*. For example, one group might be given an active drug treatment and the other group might be given fake (dummy) pills (a *placebo*). See also *bias, randomisation*
C	
capital costs	The cost of buying and using land, buildings or equipment, and developing the skills to provide a service such as health care.
care giver	See *carer*
carer/caregiver	An individual who is the unpaid informal primary or secondary caregiver for a patient.[2]
case-control study	A study to find out the cause(s) of a health *outcome*. This is done by comparing a group of patients who have a disease or condition (cases) with a group of people who do not have the disease or condition (*controls*). The controls should be similar in ways that are not relevant to the causes of the disease or the condition being studied (for example, the same age or living in the same place). This means the researcher can look for those aspects of their lives that differ and may cause the condition. For example, a group of people with lung cancer might be matched with a group of people the same age without lung cancer. The researcher could compare how long both groups had been exposed to tobacco smoke.
case report	An account of a single patient that describes their treatment and the outcome (health condition or disease status). For example the report might record the effect of a new type of operation on a particular patient. See also *case series*
case series	A report on a series of individual patients who have had a specific treatment (such as an operation or a drug). *Case series* do not compare patients with those who have not been given the treatment (*controls*). They are sometimes called a case study. See also *case report*

case study	See *case report*
CCA	See *cost-consequence analysis*
CCT	See *controlled clinical trial*
CEA	See *cost-effectiveness analysis*
CEAC	See *cost-effectiveness acceptability curve*
CI	See *confidence interval*
clinical effectiveness	How well a treatment works in the 'real-world' (for example by a doctor with a patient at home), rather than in a carefully *controlled clinical trial*. A treatment may sometimes be less effective when used outside a trial for many reasons. Patients in the community may be different, may not comply completely with the treatment (because of *side effects* or difficulties in taking the treatment) and may not respond as well as those selected for the *clinical trial*. Treatment recommendations, follow-up and information offered by health care staff may also be different than in the *clinical trial*. See also *efficacy*
clinically significant	A benefit from treatment that relates to an important *outcome*, such as length of life, and is large enough to have practical importance to patients and health professionals. Effects that are identified as *statistically significant* are not always clinically significant, because the effect is small or on an outcome that is unimportant. For example, a treatment may improve blood flow but for that condition, there is no *evidence* that improved blood flow leads to an important clinical *outcome*, such as lower risk of blood clots or heart attack.
clinical pathway	*Clinical pathway* usually refers to the practices, procedures and treatments that should be used with patients with a particular condition to achieve favourable outcomes. Clinical pathways aim to improve the quality of care.
clinical practice guideline	A document that describes and recommends procedures for the *diagnosis*, treatment and management of a health condition. It is developed to help doctors and patients decide on the best course of action for the patient, taking into account the patient's needs and views. *Clinical practice guidelines* are ideally based on the best available *evidence* for each aspect of health care, as well as

	agreement between experts and stakeholders.
clinical trial	A study to determine whether a treatment (drug, *device* or procedure) is safe and effective. It is carried out with a *sample* of intended patients, usually after laboratory studies and studies with healthy volunteers have been conducted. The trial is set up to answer one or more specific questions. For example, does the drug cause *adverse effects* and, if so, how serious are these? Does the drug result in desired outcomes for patients, and if so, how much improvement takes place? What is the safest dose to avoid serious *adverse effect*s while still achieving the desired outcomes? See also *experimental study, randomised controlled trial, risk factor*
CMA	See *cost-minimisation analysis*
cohort study	A study with two or more groups of people (called cohorts) with similar characteristics. One group receives a treatment, is exposed to a *risk factor* or has a particular symptom and the other group does not. The study follows the two cohorts and records what happens. See also *observational study*
comorbidity	Other diseases or conditions that a patient may have in addition to the disease or condition being treated or studied.
comparative study	A study of two or more subjects of interest such as groups of people who are treated differently for the same condition to find out how each treatment affects the outcome. For example, the groups might be given different drugs. It can also be a study that looks at the same treatment for different groups (such as different ethnic groups). See also *comparator*, *clinical trial, randomised controlled trial (RCT)*
comparator	An alternative, or *control*, that researchers use to compare with the test or treatment that is the subject of the study. For example, it may be an alternative test or treatment for the condition, or it may be a *placebo* or simply no treatment at all. See also *control*

confidence interval (CI)	There is always some uncertainty in research. This is because a small group of patients (called the *sample*) is studied to predict the effects in the wider *population* who will eventually use the treatment. The confidence interval (CI) shows the amount of uncertainty. It gives a range of results from the study that is likely to include the 'true' value for the *population*. The CI is usually stated as '95% CI', which means that the range of values have a 95 in 100 chance of including the 'true' value. For example, a study may state that 'based on our sample findings, we are 95% certain that the 'true' *population* blood pressure is not higher than 150 and not lower than 110; thus 95% CI is 110 to 150'. See also *confidence limits*
confidence limits	The top and bottom values of a *confidence interval (CI)*. They are the values that define the range of a *confidence interval*. In the example above, the limits are 150 and 110.
confidentiality	The promise not to reveal a patient's information to another person without the patient's consent.
conflict of interest	A situation where researchers or HTA developers have other interests at stake that may influence the results and interpretation of the research; for example, financial interests or competition among research institutes or researchers.
confounder	A research study often looks for a relationship between a cause (such as drinking alcohol) and an outcome (such as lung cancer). A *confounder* is a factor that is common to the cause and the outcome of interest (such as smoking while drinking). The *confounder* may hide an actual relationship between cause and outcome or falsely suggest a relationship that does not really exist. For example, researchers used to think that drinking alcohol was related to a higher risk of lung cancer. But, they found that people tend to smoke more when they are drinking alcohol. Smoking is the actual *risk factor* for lung cancer, and is a *confounder* that made it look as if there was a relationship between drinking and lung cancer.
consensus development	The process of gaining agreement between people, such as a group of experts. Statements or guidelines based on agreement between a group of experts are called consensus guidelines.

consumer/user	An individual who uses, has used, or intends to use a particular health technology or service.[2]
consumer advocate	See *advocate* and *consumer member*
consumer member	An individual who has been selected to support the inclusion of the interests of consumers on a committee.
contraindication	A circumstance (such as high blood pressure or use of another medicine at the same time) that increases the risk of a *side effect* from a treatment. As a result, the treatment will not normally be recommended for people with that *contraindication*.
control	A standard or measure for avoiding *bias* from *confounders* in an experiment. In *clinical trials*, the *control* may be a suitable known treatment (or no treatment), test, *risk factor*, etc. In a *case–control study*, the controls are usually the people without the condition. See also *control group*
control group	The group of people in a study who do not receive the treatment or test being studied. Instead, they may receive the usual treatment or a *placebo*. The results for the *control group* are compared with those of the treatment group to check for any differences. The findings are easier to understand if the control group is as similar as possible to the treatment group so that if there is an effect, it is likely to be due to the treatment. See also *control*
controlled clinical trial	A *clinical trial* that includes a *control group* who receive a different treatment from that being tested. For example, the control might be the usual treatment, a *placebo* or no treatment. A *controlled clinical trial* may sort the people taking part into *control* and treatment groups in a random way (based on chance). This is known as a *randomised controlled trial.*
controlled study	A study such as a *cohort study* or *case–control study* in which there is a *control group* matched, for example, by age, sex or where they live. The *control group* does not receive the test or treatment, is not exposed to the *risk factor* or does not have the disease or condition in question. This *control group* is compared with the study group, who do receive the test, treatment or risk factor. See also *control, qualitative research*

conventional treatment	A currently accepted and widely used treatment for a disease or condition.
cost-benefit analysis	This analysis is a method of considering the advantages and disadvantages of alternative health care technologies. The scope of the advantages and disadvantages considered in an analysis depends on the perspective taken. Cost-benefit analysis differs from other forms of economic analysis, like cost-effectiveness analysis, mainly in putting monetary values on outcomes. For example, the costs of an insulin injection may include the costs of the drug, the needle, the nursing time, the monitoring tests and the patient's time. The outcomes (both positive and negative) are also given in terms of money. For example, one outcome may be the savings in potential costs to manage severe diabetes, including kidney failure, circulation and cardiovascular complications, foot problems, and time in hospital. The outcomes might also include the patient's contribution at work, lack of social welfare costs, and increased cost of healthy foods. The more challenging part of cost-benefit analysis is that it assigns money values to outcomes such as better health or improved access. For example, the outcomes might include a monetary value of the expected health gain measured though willingness to pay. The costs and benefits of a comparator treatment are also worked out. For example, the cost of insulin taken by mouth includes the higher cost of the drug, but no cost for needles, and increased cost for more monitoring tests, but no cost for nursing time to make sure patients take it as prescribed. The outcomes of the treatment being compared are expressed as money. For example, insulin taken by mouth saves the cost of being in hospital and long-term organ failure because more patients take it as prescribed. Also included in the outcomes may be the cost of drugs to treat *adverse effects* such as stomach problems. The difference in costs and the difference in benefits of the two treatments can be directly compared. For example, the total cost of insulin taken by mouth may be more than the total cost of insulin given by needle, but the total savings due to increased benefits result in total lower costs to the system.

cost-consequence analysis	A type of *analysis* that compares the costs (such as treatment and hospital care) and the consequences (such as *health outcomes*) of a test or treatment with a chosen suitable alternative. Unlike *cost-benefit analysis* or *cost-effectiveness analysis*, it does not attempt to summarise outcomes in a single measure (like the QALY) or in money terms. Instead, outcomes are listed in their natural units (some of which may be monetary) and it is left to decision makers to determine the overall balance of advantage and disadvantage.
cost-effectiveness acceptability curve	A method to measure and show as a graph whether a treatment will provide value for money (that is, be 'cost effective') compared with another treatment. It provides more detail about uncertainty in the *cost-effectiveness analysis* than a *confidence interval*. It is based on an *outcome* measure such as a *QALY*. See *cost-effectiveness analysis*
cost-effectiveness analysis	This analysis compares two or more drugs, devices, tests, or procedures to find out which provides more outcomes for the cost of treatment or which has the lowest cost for a given outcome. This means that the outcomes of all treatments being compared must be measured in the same units. For example, Drug A for epilepsy results in 90 days without seizure. Drug B costs twice as much, but increases the days without seizure to 240. So Drug B gives better outcomes for the money spent as 240 (the outcome) divided by two (the cost) equals 120, which is more than Drug A's 90 days. Examples of other uniform outcome measures are reduced blood sugar levels, days without cancer symptoms progressing, and years of survival. The more specific an outcome measure the less useful it is in making comparisons between technologies. For example, a measure in terms of cancer symptoms will be less useful in comparing cancer drugs with drugs for multiple sclerosis, so there is a preference for common measures such as life years gained (or quality-adjusted life-years gained). See also *outcome*
cost-minimisation analysis	An analysis that compares the costs of two or more treatments, where the treatments have similar effects and only their cost might be different. Costs are, in principle, *opportunity costs* and wherever possible are expressed in money. The aim is to find out which treatment costs the least.

cost-of-illness analysis	An attempt to place a value on the costs, financial and other, of a disease or condition, including *direct costs* (such as the cost of treating it) and *indirect costs* (such as time off work). It does not usually consider the wider costs to society or benefits and outcomes.
cost-of-lost time	The value of the time lost from work due to disease or disability. It is usually based on the average wage/earnings *rate* before tax.
cost-per-QALY analysis	Another name for a cost-effectiveness analysis which results in benefits of different treatments or tests being stated as a *quality-adjusted life years* (QALYs). See also *cost-effectiveness analysis*
cost-utility analysis	A study similar to a cost-effectiveness analysis. The costs are measured in units of money and the benefits are stated in a value that reflects patient preferences (known as *utilities*), such as a *quality-adjusted life year*. See also *health utilities index*
critical appraisal	A process to find valid and relevant *evidence* or methods in a *systematic review* or *HTA*. *Evidence* is considered using a system of agreed rules to check its quality and decide if it should be included in the *HTA* or not. For example, *evidence* from a particular study may not be included because it is an *uncontrolled study* or uses a different form of treatment from that studied in the *HTA.*
CUA	See cost-utility analysis
D	
DALY	See *disability-adjusted life year*
data	Data are the information collected through research. They can include written information, numbers, sounds and pictures. Data are usually stored on computer, so that they can be analysed, interpreted and then communicated to others, for example in reports, graphs or diagrams.[2]
deliberation	
deliberative framework	
Delphi method (or technique)	A technique to obtain agreement from a group, often experts in their field, on a question of interest. For example, in *HTA* it can be used to find out how a technology is being used. The experts

	answer at least two rounds of written questions about their experiences and current practices in the area of the topic. The goal is to agree on a final group answer (or consensus) on a topic. See also *consensus development*
device	A physical item or artificial body part (called a prosthesis) used to treat a disease or condition or diagnose it. For example, a *device* might be a pacemaker, knee replacement, x-ray or blood pressure kit but not a drug.
diagnosis	The process of identifying a disease or condition using a test or tests, or by studying the symptoms.
discrete choice experiments	
direct costs	The cost to an organisation of providing the test, treatment or procedure. For example, the cost of the drug or the cost of bringing a patient to or from a hospital for treatment. Direct costs can be non-medical. See also *indirect costs*
disability-adjusted life year	A measure of the impact of a disease or injury in terms of healthy years lost. For example, the global average burden of disease across all World Health Organization regions in 2004 was estimated as 237 disability-adjusted life years per 1000 *population*, of which about 60% was due to premature death and 40% to non-fatal health outcomes.[4]
disease management	The process of managing health and health care and improving *quality of life*, particularly for people with long-term (chronic) conditions. The focus is on trying to reduce the symptoms of a disease and prevent complications, rather than trying to cure it (which may not always be possible).
double blind	See *blinding*
double masked	See *blinding*

E

early warning system	A process for health policy makers and planners that identifies which new tests and treatments are most likely to have the biggest impact on people's health and the cost of providing health care. See also *cost-of-illness analysis*
economic analysis	In *HTA,* an *economic analysis* is an assessment that compares the costs and benefits of using different tests or treatments for the same condition. See also *pharmacoeconomics*
economic evaluation	See *economic analysis*
economic model	A means of estimating the costs and effects of a technology over periods of time or patient groups not covered in a *clinical trial*.
effect size	A measure that shows the magnitude of the *outcome* in one group, such as the study group, compared with that of the *control group*. The effect size is usually tested, using statistics, to find out how likely it is that it is due to chance alone (that is, it is *statistically significant*). For example, if the *absolute risk reduction* is shown to be 5% and it is the outcome of interest, the effect size is 5%. See also *magnitude of effect*
efficacy	The benefit of a test, treatment or procedure gained under ideal conditions, such as in a *controlled clinical trial*.
efficiency	Efficiency refers to either gaining the greatest benefit from a test or treatment using the available resources, or achieving a given benefit in a way that minimises costs. For example, health organisations seek to obtain *efficiency* savings by maintaining the same level of diagnostic service but reducing the number of hospital visits a patient needs to make to for the service.
emerging health technology	A drug, procedure, equipment or item that is not yet commonly used in health care. An example is a drug or piece of equipment that is still being tested in *clinical trials* and is yet to be approved.

epidemiology	The study of the diseases that exist in a *population*, their distribution and the factors that aid or prevent their spread. Epidemiology considers the possible *risk factors* for a whole *population* or area, not just the *risk factors* for individual patients.
equity	The principle of treating everyone fairly— that is, not discriminating unjustly against some people. It means recognising that not all people have the same access to opportunities. This may be due to gender, class, religion or age, for example. Equity is different from equality. Equality means treating everyone the same. For example, consider access to care. If all patients are given written information about a test in a country's most common language, the patients are being treated equally. But, it more equitable if each patient is given written information about a test in their language. See also *justice*
equivalence trial	A trial that aims to show that the difference between two tests or treatments is not large enough to matter to patients (that is, it is not *clinically significant*). When this is the case, the tests or treatments are called 'noninferior', and a *cost-minimisation analysis* can be used to find out whether one is cheaper.
ethics	The study of values and customs to understand the principles according to which humans should live. Health ethics describes the principles of good medical practice that determine what is good for individual people and society as a whole. These principles include relationships between patients and doctors, and the use of technology.
evidence	Findings from research and other sources, such as experience, that may serve as a useful basis for decision-making in public health and health care.[5] See also *evidence-based decision making*, *evidence-based health care*, *evidence-based medicine*
evidence-based decision making	The process of making decisions about health care informed by the best available *evidence*. See also *evidence-based medicine*, *shared decision making*
evidence-based health care	The process of making decisions about all areas and aspects of health care, such as management and administration, informed by the best available *evidence*.

evidence-based medicine	The use of the current best *evidence* from scientific and medical research to inform the care of individual patients. The *evidence* is used by doctors and other health professionals to inform the health services they provide, and the treatment they offer people who use these services.
exclusion criteria	The features used in *critical appraisal* to decide whether a study is relevant to the assessment. See also *clinical trial, inclusion criteria*
experimental study	A study in which the people taking part are sorted into two or more groups to be given a treatment or test, and then followed up under carefully controlled conditions. Experimental studies, rather than *observational studies*, are the best choice for medical studies because they use *control groups* and minimise *bias*. See also *quantitative research*

F

false negative error (Type II error)	When the statistical *analysis* of a trial detects no differences in outcomes between a treatment group and a *control group*, when in fact a true difference exists in the *population*.[5]
false positive error (Type I error)	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 in the *population*.[5]
focus group	A focus group is a small group of people brought together to talk about a specific topic. Having recorded the focus group, the purpose is to analyse systematically the discussion. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.[2] Talking in a group results in a different kind of data from that collected in one-to-one interviews.

G

gold standard	In HTA, a *gold standard* is a method, procedure or measure that is widely agreed among the medical profession to be the best available to test for or to treat a disease. New tests or treatments are often compared against the *gold standard*.
gray/grey literature	Information that is not available through traditional peer-reviewed publications, such as scientific journals or books.

	Examples include conference proceedings, academic report, newsletters, and industry and technical reports. See also *peer review*
guideline	See *clinical practice guideline*

H

health economics	The use of the principles of economics to study health, health policy and the health care system.
health needs assessment	A method of reviewing the top health issues facing a certain group of people. It results in an agreed list of priorities that will improve health care in that area.
health-related quality-of-life measures	A measure of the effects of an illness to see how that illness affects a person's day-to-day life.
health status	The level of health of a person or group of people that is measured either by the person or people themselves and/or by scientific means. The level is usually based on the patients' ability to carry out everyday activities such as dress and feed themselves or freedom from pain. For example, the status may be measured according to whether a person can walk by themselves, walk with a stick, needs a wheelchair or is bedridden.
health technology	Any form of *intervention* to improve health, such as drugs, *devices*, medical equipment and procedures relating to health care and its services, including prevention, *diagnosis* and treatment of a condition.
health technology assessment	The systematic evaluation of the *clinical effectiveness* and/or cost-effectiveness and/or the social and ethical impact of a *health technology* on the lives of patients and the health care system. Its main purpose is to inform health care policy makers. The process advises whether a *health technology* should be used, and if so, how it is best used and which patients will benefit most from it. Assessments vary, but most look at the health benefits and *risks* of using the technology. They also look at costs and any wider impacts that the technology might have on a *population* or on society.

Health Utilities Index®	A system for measuring *health status*, *health-related quality of life*, and producing *utility* scores.[7] (Source Health Utilities Inc, http://www.healthutilities.com, 4 June 2009). See also *quality-adjusted life year*
healthy years equivalent	The number of years spent in good health that a patient would see as equal to the actual number of years they spend in ill health. For example, if someone spent 10 years ill, they may see it as equal to five years spent healthy. See also *quality-adjusted life year*
HRQoL	See *health related quality-of-life measures*
HTA	See *health technology assessment*
HTAi	Health Technology Assessment international, a non-profit society that supports the growth of HTA community by providing a global forum for the exchange of information, methods and expertise.[8]
HUI	See *Health Utilities Index®*
HYE	See *healthy years equivalent*
I	
ICER	See *incremental cost-effectiveness ratio*
impact analysis	Evaluation of the affect of an *HTA* on health service organisations or patients.[5]
INAHTA	See *International Network of Agencies for Health Technology Assessment*
incidence	The number of new cases of a disease among a certain group of people during a specific period of time.[8]
inclusion criteria	A set of conditions that must be met for a person to take part in a *clinical trial*, such as gender, age and type or stage of disease, as well as medical history. It may also be a set of rules to decide if *evidence* is included in a *systematic review* or *HTA*. See also *exclusion criteria*, *critical appraisal*
incremental cost	The extra cost linked to using one test or treatment over another or the additional cost of increasing the *rate* of activity.

incremental cost-effectiveness ratio	A ratio that shows the extra cost of a more expensive test or treatment, compared with a cheaper treatment or no treatment, divided by the difference in health *outcome*. See also *incremental cost*
indirect costs	The costs that are not directly related to providing the test or treatment. They can be all the goods, services and other resources that are used to provide a test or treatment, or in dealing with side effects or other current or future aspects linked to it. See also *direct costs*
individual patient data	In a *clinical trial*, it refers to the data available for each patient, as opposed to summarised data for a group of patients.
informed choice	A choice made by a person who is judged to be capable of understanding the information available about a test or treatment, as well as its *risks* and benefits. See also *informed consent*
informed consent	The process of a patient or *carer* learning the key facts about a treatment, test or study before deciding whether to agree to it or to take part (such as in a study). Informed consent is an ongoing process throughout the treatment or study to provide information to people, including the potential *risks* and benefits. Informed consent is not a contract, and the person may stop (withdraw consent) at any time. See also *informed choice*
intangible costs	A term often used for a patient's pain and suffering due to disease or illness that cannot be understood as a cost in terms of money.
intention-to-treat analysis	An assessment of the people taking part in a *clinical trial* based on the group they were first put into, regardless of whether they dropped out, followed their treatment to the end of the trial or moved to another treatment. This *analysis* is useful in effectiveness assessments because these changes are similar to the ways patients behave in the 'real world' rather than a *controlled study*.
interim analysis	A report of study data before the study is complete.
International Network of Agencies for Health Technology Assessment	A non-profit organisation that provides a forum for HTA agencies to share information and help stop activities being repeated unnecessarily.

intervention	A procedure, such as treatment with medicine drug, surgery, behaviour change (such as diet or exercise), psychotherapy (such as counselling), early detection (such as screening) or use of patient educational materials.
intervention group	In a *clinical trial*, the group receiving the treatment (*intervention*) in question, as opposed to the *control group*, which receives either no treatment or another treatment.
intervention study	A study that looks at how well a test or treatment (an *intervention*) works. *Randomised controlled trials* are often thought to be the most useful type of *intervention* study to show a difference between *intervention*s.
interview	In research, an *interview* is a conversation between two or more people, where a researcher asks questions to obtain information from the person (or people) being interviewed. Interviews can be carried out in person (face-to-face) or over the phone.[9] The *data* from the recorded *interview* would then be systematically analysed.

J

justice	The principle that all people must be treated fairly and equally. See also *equity*

L

lay	An individual who has no professional healthcare qualifications or expert healthcare knowledge.[2]
levels of evidence	Ranking given to studies based on how well they are designed and conducted. *Clinical trials* with the best levels of *evidence* (that is, trials that have eliminated most *bias*) can then be given the most weight in a review of *evidence*. See also *bias, validity, weighted*
licensing	A marketing authorisation for drugs that assesses quality of production (manufacture), *safety* and *efficacy*.
literature review	A summary of the information published in books, journals, etc (the literature) on a topic. A literature review may be a general overview and interpretation of the research, or a more formal review (such as a *systematic review*) of all published studies on a specific topic.

M

magnitude of treatment effect	A term that describes the difference between the changes in the study group and *control group* at the end of a *clinical trial* (the *effect size)*.
marginal benefit	The extra benefit in health *outcome* as a result of adding another test, treatment or resource.
marginal cost	The extra cost needed to produce more benefit. The benefit is usually measured as workload or a health *outcome*.
masking	See *blinding*
meta-analysis	A method often used in *systematic reviews* to combine results from several studies of the same test or treatment to estimate the overall effect of the treatment. See also *quantitative research*
meta-regression	An extension of a *meta-analysis*. A meta-regression looks at the relationship between one or more study characteristics (eg dose, length of treatment) and the *effect size* seen in the studies.
methodology	Describes how research is done, including how information is collected and analysed, as well as why a particular method has been chosen.[3]
minimisation	A way of putting patients into treatment groups in a *controlled clinical trial* that balances the groups in terms of chosen characteristics such as age, sex and severity of disease.
mortality rate	The proportion of a *population* that dies within a particular timeframe, for example one year. The *rate* is often given as a certain number per 1000 people.

N

natural unit	The actual unit, such as kilogram (for weight), millimetre of mercury (for blood pressure) and score (for pain), that *clinical trial* results are measured in. This is in contrast to units such as *disability-adjusted life years* and *quality-adjusted life years* (which are based on further calculations of the actual measurements).
net benefit	The cost of the benefit from a test, treatment or procedure, minus its total costs. For example, if a patient's illness costs $1000 each year in reduced earnings and a treatment costing $100 reduces this by $200 to $800 each year, then the net benefit would be $100

	(that is the saving of $200 in earnings minus the cost of treatment of $100).
number needed to harm	A measure of how many patients need to have a treatment or be exposed to a *risk factor* for one to have a bad outcome. Ideally this number should be as high as possible because the larger the number the less often bad outcomes occur. It is the opposite *of absolute risk reduction*. For example, if you give a 100 mg stroke prevention drug to 100 people and two of those people experienced the *adverse effect* of joint pain, the number needed to harm is 50 (that is 100 divided by two equals 50). See also *number needed to treat*
number needed to treat	The number of patients that need to receive a treatment to prevent one additional bad outcome from their medical condition. The smaller the number, the better the *intervention*. For example, if you give a stroke prevention drug to 20 people before one stroke is prevented, the number needed to treat for that stroke-prevention drug is 20. See also *number need to harm*, *absolute risk reduction*
nonrandomised controlled trial	A *clinical trial* with a *control group* in which patients are not put in the study group or *control group* by chance (randomisation). Instead, they are sorted by other methods. For example, they may be put in groups alternately when they arrive for treatment. These methods do not eliminate *bias*. See also *controlled clinical trial*

O

observational study	A study in which a researcher looks at and records exposures (such as tests, treatments or *risk factors*) and observes results (such as the presence of a disease) as they naturally occur. Observational studies can be loosely sorted into two types: • descriptive studies (such as *case reports* and *case series*) that record how often a disease or condition occurs, so researchers can see the size of a problem • analytical studies (such as case–control studies and cohort studies) that look at any links between exposures and results.

	In social science, *observational studies* refer to researchers using a system to study people in natural environments to find patterns in their behaviour.
opportunity cost	The increased value of the most highly valued alternative use of a resource. In a fixed budget health care system like that in Canada or the United Kingdom, the true *opportunity cost* of using a resource, such as a nurse's work time, in one way rather than another is the health gain that could have resulted if the resource had been used in the alternative way.
outcome	A test or treatments impact on health or wellbeing. Some examples of outcomes are the number of patients who fully recover from an illness, the amount of weight that patients lose or the number of hospital admissions. Outcomes are called continuous when the results vary along a continuous scale, such as weight or blood glucose level. They are called binary or dichotomous when the result is either one thing or another, such as improved or not improved, have cancer or no cancer. Surrogate outcomes are those measured in the short-term that predict longer-term patient-focused outcomes. For example, reducing blood pressure reduces the likelihood of death. See also *patient-focused outcomes*
outcomes research	Research that seeks to understand the results of particular health care practices and *interventions* in terms of their impact on health and wellbeing — that is *outcomes*.
P	
participant	A person who takes part in the research, such as a *clinical trial* in either the *study group* or in the *control group* or a *focus group* or *interview*. Sometimes, participants are called respondents, patients, subjects, volunteers or consumers.
patient	An individual with a disease or disorder who is using some aspect(s) of the healthcare system because of this disease or disorder.[2]
patient advocate	An individual who represents and advocates for the interests of a particular group of patients on a committee, e.g. patients with breast cancer[2]
patient-based evidence	2017

patient input	2017
patient involvement	2017
patient member	An individual who has been selected to support the inclusion of the interests of patients in Health Technology Assessment processes on a committee[2]
patient participation	2017
patient pathway	A plan worked out by a doctor, based on the best *evidence* and patient *preferences*, to manage a disease or condition. The patient pathway specifies each stage of the patient's care, from one point to the next. For example, the pathway starts from before the patient is treated or admitted to hospital, to follow-up after they are treated or home from hospital.
patient preference study	
patient reported outcome	
patient reported outcome measures	
patient representative	See *patient advocate* and *patient member*
patient selection bias	A type of *bias* where patients are sorted into groups for a *clinical trial* based on factors such as how ill they are, their age or ability to follow their treatment. This may mean that the *control group* is different from the *treatment group.* In this case, any differences the researchers find might be caused by the differences between the groups rather than the test or treatment being studied.
peer review	The critical review of a study by other experts in the area to make sure the study results are accurate and valid. It cannot guarantee that the results of the study will not be flawed (that is, prone to *bias*).
pharmacoeconomics	The *economic evaluation* of the different drugs used to treat a disease or condition, and how much value for money they provide. See also *economic analysis*
phase I, II, III and IV studies	Different phases of *clinical trials* that are run to develop a new test or treatment, such as a drug. Phase I (one) involves using healthy human volunteers to check the *safety* of the test or treatment. In

	phases II–IV (two to four), patients with the disease that the researchers are interested in are given the treatment and the optimal dose is worked out. Researchers study these patients to see whether it works, how long the effects last and whether there are any *adverse effects*. See also *clinical trial, safety, efficacy*
placebo	A fake procedure or dummy treatment, which looks the same as the real test or treatment, which the people in a *control group* receive. This is to make sure that a study's results show the true effect of the test or treatment.
placebo effect	Any effects in the *control group* that occur because patients expect to get better when they are receiving medical care or due to the extra care given in a *clinical trial*. Researchers must decide whether the effect of the real treatment is greater than the placebo effect. The placebo effect can be measured by treating *control group*s with a *placebo*.
population	A group of people with a common link, such as the same medical condition or living in the same area or sharing the same characteristics. The population for a *clinical trial* is all the people whom the test or treatment is designed to help (such as adults with diabetes, women at high risk of breast cancer). The group taking part in a *clinical trial* need to be typical of the whole population of interest.
preference	A *patient* or *consumer's* personal choice of health care procedures. This choice may be related to lifestyle and other factors that change from one person to another. Doctors need to take account of the patient's preferences when they are developing a treatment plan (*patient pathway*).
prevalence	How common a disease or condition is within a *population* either at a point in time or over a given period of time (it includes new and existing cases). For example, in 2007, the prevalence of diabetes in Scottish NHS boards varied from 3.7% to 4.6%.
prevalence study	A study that looks at how common a disease or condition is in a *population*. See also *prevalence*
primary outcome	The result(s) of most interest to the researchers. A test or treatment can give results for several *outcomes*, but primary

	outcomes are of greatest importance when assessing the outcome.
primary (research) study	A study that collects data and analyses it. It can refer to either laboratory research or *clinical trials*. See also *secondary study*
probability	The likelihood that an event will occur. In statistics, the probability (or *P*-value) shows the likelihood that a research result could have occurred by chance alone. For example, a *P*-value of 0.05 means there is a five in 100 chance that the effect observed in the trial could have been due to chance. Results with *P*-values of 0.05 or less are usually considered to be a reliable indication of an effect in the wider *population* and are called *statistically significant*.
prognosis	The expected health *outcome* for a person in the future, taking into account their current disease stage, condition or symptoms.
prospective study	A study design where groups of people taking part are followed forward in time. For example, a group of people may be watched to see whether they develop a disease and to see whether this disease can be related to exposure to a possible *risk factor*. Prospective studies are slower and sometimes have to be run over many years for diseases that develop slowly. They also cost more to run than *retrospective studies*. Prospective studies give more accurate results because they are less likely to have *bias*.
protocol	A plan that provides the reasons for, and methods of, a study, which must be followed strictly so that the study can be repeated and checked.
public	A community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process[2]
public member	An individual who has been selected to support the inclusion of the interests of the society at large on a decision-making committee in HTA[2]

Q

QALY	See *quality-adjusted life year*
qualitative evidence synthesis	
qualitative research	The act of exploring and understanding people's beliefs, experiences, attitudes or behaviours. It asks questions about how

	and why. Qualitative researchers use methods like *focus groups* and *interviews*.[9] For example, in a qualitative research study, a researcher might ask people why they want to stop smoking, rather than asking how many people have tried to stop.
quality-adjusted life year	A measure of the state of health of a person or group of people in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. That is, a year of active normal life gained as the result of a treatment is rated higher than a year of living with reduced quality (such as being in extreme pain or being in hospital). It is often measured in terms of the level of a person's ability to perform activities of daily living, their freedom from pain and mental disturbance. The patients, or observers with knowledge in the area, rate these various states by giving them scores.
quality of care	The level of health care provided to a *patient* or *consumer*. Actions to improve quality of care aim to improve a person's health and meet health care standards.
quality of evidence	How much the results of studies can be relied on to describe a true effect (*validity*). For clinical studies, quality is directly related to the extent to which *bias* has been taken out of the study, which, in turn, depends on how the study was designed and run. See also *critical appraisal*
quality of life	See *health-related quality of life*
quantitative research	Researchers collect *data* in the form of numbers, that is, they measure things or count things. Quantitative research might ask a question like how many people visit their GP each year, or what proportion of children have had a particular vaccine, or whether a new drug lowers blood pressure more than the drugs that are usually used. Quantitative researchers use methods like surveys and clinical trials. [9] See also *experimental study*
R	
randomisation	A method of assigning patients to one of several groups in a study by chance, similar to tossing a coin. This method usually uses a computer-generated random number list.

	See also *random sample*
randomised controlled trial	A study in which the people taking part are assigned by chance (*randomisation*) into groups (such as the *control group* or the study group). The groups are managed in exactly the same way except they are given different treatments, or exposed to a *risk factor* of interest. *Outcomes* are measured at specific time points and any difference in response between the groups is assessed statistically. This method is used to reduce *bias*. See also *controlled clinical trial*
rapid review	A form of HTA done in a shorter time than the usual HTAs produced by the organisation. It may have a narrower focus than the usual HTA, made possible by restricting the specific clinical question(s) asked in the review.
rate	A measure of how often a specific event happens in a given amount of time. For example, during the trial the *side effect rate* was 0.45 (45% of patients experienced a *side effect*).
RCT	See *randomised controlled trial*
recurrent costs	Costs that occur regularly, such as each year, rather than just once, such as staff costs.
reference list	A record of the studies, journals, books, etc, that are used to support a piece of work (such as a study, literature review or article). The reference list is usually found at the end of the publication and provides enough detail for the reader to find and read the pieces of work.
regression analysis	A mathematical or statistical model to work out the effects of an independent *variable* (such as a treatment) on a dependent variable (such as the disease or condition).
relative risk	The *risk* of an unwanted *outcome* in the study group compared with the same outcome in the *control group*, described as a ratio. A relative risk of one indicates no difference in risk between the two groups. A relative risk of less than one means that the test or treatment being studied was effective in reducing the risk of a particular unwanted outcome. For example, if 10% of patients died on the new treatment compared with 15% on the control treatment, this is a relative risk of 0.10 divided by 0.15 equals 0.67.

reliability	The ability to repeat a study to get the same result. A reliable study gives a similar result each time the study is repeated with a different *population* or group.
retrospective study	A study that brings together groups of patients with a disease or condition of interest and looks backwards in time. The study examines past exposure to suspected *risk factors* for the disease or condition. Retrospective studies are faster and cheaper than *prospective studies*, but are more likely to have *bias* and *confounding* than *prospective* studies. They are useful if the *outcome* of interest is rare.
risk	The *probability* of an event is the risk of it occurring. Another meaning of risk is the chance that a test or treatment will cause injury or harm. Risks are a product of the effect of a hazard and the level of exposure. See also *risk factor*
risk assessment	A process used to work out what a person's chances are of having a disease or other health condition. Risk assessments usually include four steps: 1. identifying the *risk factor* or hazard (for example, what causes this disease or health condition?) 2. working out how much of the risk factor is dangerous (for example, how high a dose of a toxic chemical is needed to cause injury?) 3. working out how people might be exposed to the risk factor (for example, how and how often, do people come into contact with it?) 4. combining the first three steps to characterise the risk and describe how certain the link is between the risk factor and the *outcome*.
risk factor	Any aspect of a person's lifestyle, environment or pre-existing health condition that may increase their risk of having a specific disease or condition.
risk ratio	See *relative risk*
RR	See *relative risk*

S

safety	The study of *adverse effects* from treatments.
sample size	The number of people needed for a study or *clinical trial*, including the treatment group and the *control group.* In *quantitative*

	research, the smaller the *effect size* to be detected, the larger the sample size must be. In qualitative research, the sample size may be quite small. The depth in the findings is more important. See also *significant*
secondary research	An academic review of *primary research studies* to gain new insights on a specific topic (such as a *systematic review*).
sensitivity	The *probability* of a positive test result given the patient has the disease being tested for. See also *specificity*
sensitivity analysis	A process that researchers use to check how much the results of a trial would change if the methods for running it were changed or if the *analysis* did or did not include certain data.
serious adverse event	An unwanted effect from a treatment that causes a serious health problem often resulting in the person needing to go to hospital. See also *side effect*
sham procedure	A procedure designed to resemble the real one that is performed on the patient to assess its effectiveness. See also *placebo*
shared decision making	Decisions that are shared by doctor and patient and informed by best *evidence*, not only about risks and benefits but also patient specific characteristics and values.[10]
side effect	Any extra effects from a drug, treatment or procedure that are not planned, even when used as instructed. They do not necessarily cause harm. See also *serious adverse event*
significant	Either: • the difference between results that statistics show are unlikely to have been caused by chance alone (this is called *statistical significance*) • changes in a person's health condition that make a difference to their overall *quality-of-life* (this is called *clinical significance).*

specificity	The *probability* of a negative test result given the person does not have the disease being tested for. See also *sensitivity*
staging	Grading how severe a disease is based on well-recognised signs and symptoms and diagnostic tests.
stakeholder	An individual with an interest in the outcome of the HTA process final decision.[2]
standard treatment	See *conventional treatment*
statistically significant	The *probability* of observing a treatment effect as large as that seen in the sample (such as in *randomised controlled trial)*, when there is no treatment effect in the wider *population*, is less than 0.05. See also *probability*, *significant*
survey	A list of structured questions to collect information on a topic. A *survey* can be done in a variety of quite different ways, such as sent through the mail, delivered face to face or on-line.
systematic overview	See *systematic review*
systematic review	Work that aims to bring together the results of all studies that address a particular research question. They provide a comprehensive and unbiased summary of the research. For example, one *clinical trial* may not give a clear answer about the effectiveness of a treatment. This may be because the difference between the treatments being tested was very small, or because only a small number of people took part in the trial. So systematic reviews are used to bring the results of a number of similar trials together, to piece together and assess the quality of all the *evidence*. Combining the results from a number of trials (using *meta-analysis)* may give a clearer picture.[3] See also *evidence-based medicine*

T

technology	See *health technology.*
treatment	A procedure administered to improve a health condition.
Type I error	See *false positive error*

Type II error	See *false negative error*

U

uncontrolled study	A study that does not include a *control group*. As a result, these studies tend to be biased and can only be used to help indicate which treatments may be useful. A *case-series* is an example of an uncontrolled study. See also *bias*
utility	A measure of how desirable an *outcome* is, generally expressed as a number between zero and one. For example, a full healthy life would be given a value of one, whereas death is given a value of zero. Utility can also mean a patient's preferred outcome.

V

validity	In a study, *validity* is the degree to which the conclusions that the researchers make can be considered to be 'true', based on how well the study was designed and how well the study matched 'real-life' situations. See also *validity, external; validity, internal*
validity, external	The extent to which the cause-and-effect relationships in a study are true for a wider *population* beyond the study. For example, the external validity of the study may be questioned if the *population* is people in Australia and the study was in Spain, or for old people if the study was in young people. See also *validity*
validity, internal	The extent to which the cause-and-effect relationships in a study are true for the people and conditions of the study. See also *validity*
value	A measure of the desirability or worth of a particular health *outcome* or *intervention*.
variable	A measurement that can vary within a study. Common variables include age, sex and genetic backgrounds of patients.
variance	A measurement of the spread of values for an outcome in a study group. A large variance suggests greater uncertainty in the estimate of the *effect size*, whereas a small variance suggests that a more

	precise estimate can be obtained.

W

weighted	The influence given to a study or set of data, based on *validity*, size and accuracy or precision.

Sources

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Background to this glossary

In June 2007, the HTAi Interest Group of Patient and Citizen Involvement in HTA (now called HTAi Patient and Citizen Involvement Interest Group) decided to compile an HTAi glossary of terms for HTA for *consumers* .Three members of the sub-group reviewed six existing glossaries to assess their suitability for adoption by HTAi in their entirety or as sources for a compilation. These glossaries were:

1. Australian Safety and Efficacy Register of New *Interventiona*l Procedures – Surgical, date. *Glossary* Adelaide: Australian Safety and Efficacy Register of New *Interventiona*l Procedures – Surgical
2. Richard P & De Wit M (Eds), 2004. *The OMERACT glossary for patient research partners* Ottawa: OMERACT
3. INAHTA *Health Technology Assessment (HTA) Glossary*, 2006
4. The Cochrane Collaboration, May 2005. *Glossary of terms in The Cochrane Collaboration*, Version 4.2.5, The Cochrane Collaboration
5. National Institute for Health and Clinical Excellence, June 2007. *Interventiona*l Procedures Programme: Methods guide. London: National Institute for Health and Clinical Excellence
6. National Library of Medicine, Downloaded 9 October 2007. *HTA 101: Glossary*, www.nlm.nih.gov/nichsr/hta101/ta101014.html

The glossaries were reviewed using the following criteria.

- Readability
  Is the language suitable for a non-specialist? Is there *evidence* that it has been assessed for readability?
- Accuracy
  Is the term defined accurately or could the definition be misleading? Is there evidence that it has been checked for accuracy?
- Usefulness
  Are the terms included of interest to consumers? Is there any evidence of consumer input/involvement?
- Applicability
  Is the term often used by HTAi organisations? Is there general agreement on the term by HTAi organisations?
- Comprehensiveness
  Is the glossary in its entirety suitable for adoption by HTAi?
- Other sources of credibility
  References, descriptions of development processes, etc

More than 1000 terms were reviewed, but few definitions were suitable for a non-specialist audience. Of these terms approximately 200 were considered to be important and applicable for this project and a further 300 terms of potential interest. With funding from the HTAi Board, Biotext Pty Ltd was contracted to prepare a first draft of the glossary. Following a review, this draft was presented to the Interest Group for feedback at HTAi's annual meeting in 2008 and following further work presented again at HTAi's annual meeting in 2009.

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