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| ACTA | see Australian Clinical Trials Alliance |
| AHP | see Analytical hierarchy process |
| 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. ^{HTAI} |
| Analytic hierarchy process | A multi-criteria decision analytic method used to elicit patients' preferences for specific treatment characteristics or outcomes being assessed in, for example, an HTA. ^{Danner & Gerber-Grote} |
| ANZCTR | see Australian New Zealand Clinical Trials Registry |
| APON | see Australian Patient Organisation Network |
| ARTG | see Australian Register of Therapeutic Goods |
| AusPAR | see Australian Public Assessment Report for prescription medicine |
| Australian Clinical Trials Alliance | An alliance of more than 50 clinical trials networks, coordinating centres and clinical quality registries that works together to promote effective and cost-effective healthcare in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decisions made by health practitioners, policy-makers, and consumers. |
| Australian New Zealand Clinical Trials Registry | An online registry of clinical trials being undertaken in Australia, New Zealand and elsewhere. |
| Australian Patient Organisation Network | A network of patient groups which held its inaugural conference in May 2019 |
| Australian Public Assessment Report for prescription medicine | A publicly available report about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. |
| Australian Register of Therapeutic Goods | The register of therapeutic goods for human use that may be imported to, supplied in or exported from Australia. ^{PBS} |
| Bias | Occurs when a factor influences a research study's outcomes or interpretation of outcomes. There are many types of <i>bias</i> . Some are by accident, some are on purpose, some are caused by the research and some are caused by other factors. Sampling <i>bias</i> occurs when the people or entities chosen to represent the entire <i>population</i> are not representative. For example, a study that enrolls patients on a first-come, first-served basis may be biased towards those who are already receiving better health care. Publication <i>bias</i> 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. ^{HTAI} |
| Carer (care giver) | A person who looks after family, partners or friends in need of help because they are ill, frail or have a disability. The care they provide is unpaid. ^{QIS} |
| CBA | see Cost benefit analysis |
| CCC | see HTA Consumer Consultative Committee |
| CCDR | see Centre for Community-Drive Research |
| CEEU | see Consumer Evidence and Engagement Unit |
| Centre for Community-Drive Research | A non-profit association aimed at changing the way patients and the community engage in decisions about health. |
| CHF | Consumer Health Forum of Australia |
| CI | See Confidence interval |

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| 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. ^{HTAI} |
| Clinical trial | A study to determine whether a treatment is safe and effective. It is carried out with a <i>sample</i> 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 questions. For example, does the treatment cause <i>adverse effects</i> and, if so, how serious are these? Does the treatment result in desired outcomes for patients, and if so, how much improvement takes place? What is the safest dose to avoid serious <i>adverse effects</i> while still achieving the desired outcomes? ^{HTAI} |
| Clinical Trials Network | Groups of practicing clinician researchers (often several 100 per network) that come together to identify important clinical questions and design large multi-centre clinical trials to answer them. Some also conduct trials with industry but the majority have a strong focus on investigator-initiated trials that can provide unbiased, high-quality scientific evidence of the effectiveness or cost effectiveness of interventions. ^{ACTA} |
| Clinical Trials: Impact and Quality | A collaborative of stakeholders interested and involved in clinical trials who share a passion for striving for excellence in clinical trials. |
| Clinically significant | A benefit from treatment that relates to an important <i>outcome</i> , such as length of life, and is large enough to have practical importance to patients and health professionals. Effects that are identified as <i>statistically significant</i> 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 <i>evidence</i> that this leads to an important clinical <i>outcome</i> , such as lower risk of blood clots or heart attack. ^{HTAI} |
| Comparator | The medicine or treatment currently being used which the new medicine or treatment is being compared to in an assessment. If the new medicine or treatment is recommended for the PBS the comparator will usually be replaced by the new treatment. |
| Confidence interval | There is always some uncertainty in research. This is because a small group of patients (called the <i>sample</i>) is studied to predict the effects in the wider <i>population</i> who may 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 <i>population</i> . 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’ <i>population</i> blood pressure is not higher than 150 and not lower than 110; thus 95% CI is 110 to 150’. ^{HTAI} |
| Consumer Evidence and Engagement Unit | The unit established by the Department of Health in 2019 to develop structured projects to engage consumer and patient groups in HTA bodies like PBAC, MSAC and PLAC. |
| Consumer Health Forum of Australia | The national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems. |
| 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 |

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| | <p>disadvantages considered in an analysis depends on the perspective taken. <i>Cost-benefit analysis</i> differs from other forms of economic analysis, like <i>cost-effectiveness analysis</i>, mainly in putting monetary values on outcomes.</p> <p>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.</p> <p>The more challenging part of <i>cost-benefit analysis</i> 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 through willingness to pay. The costs and benefits of a <i>comparator</i> 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 <i>adverse effects</i> such as stomach problems.</p> <p>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 may result in total lower costs to the system. ^{HTAI}</p> |
| <p>Cost effectiveness analysis</p> | <p>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.</p> <p>For example, Drug A for epilepsy results in 90 days without seizure. Drug B costs twice as much, but increases the number of 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 <i>quality-adjusted life-years gained</i>). ^{HTAI}</p> |
| <p>Cost-utility analysis</p> | <p>A study similar to a <i>cost-effectiveness analysis</i>. The costs are measured in units of money and the benefits are stated in a value that reflects patient preferences (known as <i>utilities</i>), such as a <i>quality-adjusted life year</i>. ^{HTAI}</p> |

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| Critical appraisal | <p>A process to find valid and relevant <i>evidence</i> or methods in a <i>systematic review</i> or <i>HTA</i>. <i>Evidence</i> is considered using a system of agreed rules to check its quality and decide if it should be included in the <i>HTA</i> or not.</p> <p>For example, <i>evidence</i> from a particular study may not be included because it is an <i>uncontrolled study</i> or uses a different form of treatment from that studied in the <i>HTA</i>.^{HTAI}</p> |
| CTIQ | see Clinical Trials: Impact and Quality |
| CTN | see Clinical Trials Network |
| CUA | see Cost utility analysis |
| DCE | see Discrete choice experiments |
| Department of Health | The government department responsible for delivering health care. In Australia there are departments of health at the state level and one Department of Health at the federal level, called the Australian Government Department of Health. The Australian Government Department of Health is responsible for the PBS and Medicare. |
| Device | A physical item or artificial body part (called a prosthesis) used to treat a disease or condition or diagnose it. For example, a <i>device</i> might be a pacemaker, knee replacement, xray or blood pressure kit (but not a drug). ^{HTAI} |
| Discrete choice experiments | A method used in economic evaluations to determine the value of a medicine or treatment based on its characteristics or attributes beyond clinical outcome. |
| DoH | see Department of Health |
| Drug Utilisation Sub Committee | A subcommittee of PBAC that primarily advises PBAC on the utilisation and financial analyses in submissions. ^{CoA} |
| DUSC | see Drug Utilisation Sub Committee |
| EBM | see Evidence based medicine |
| Economic analysis | In <i>HTA</i> , an <i>economic analysis</i> is an assessment that compares the costs and benefits of using different tests or treatments for the same condition. Sometimes called an economic evaluation. ^{HTAI} |
| Economic model | A means of estimating the costs and effects of a technology over periods of time or patient groups not covered in a <i>clinical trial</i> . ^{HTAI} |
| Economic Sub Committee (PBAC); | A subcommittee of PBAC that primarily advises PBAC on the cost-effectiveness aspects in submissions. ^{CoA} |
| Evaluation Sub Committee (MSAC) | A subcommittee of MSAC that primarily advises MSAC on the issues and uncertainties arising from the evidence presented in an assessment report. ^{CoA} |
| EMA | see European Medicines Agency |
| ESC | see Economic Sub Committee (PBAC); Evaluation Sub Committee (MSAC) |
| European Medicines Agency | an agency of the European Union in charge of the evaluation and supervision of medicinal products. |
| FDA | see Food and Drug Administration (USA) |
| Food and Drug Administration (USA) | Responsible for protecting public health in the United States of America by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. ^{FDA} |
| Gold standard | In <i>HTA</i> , a <i>gold standard</i> is a method, procedure or measure that is |

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| | 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 <i>gold standard</i> . ^{HTAI} |
| 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. ^{HTAI} |
| Health technology | Any form of <i>intervention</i> to improve health, such as drugs, <i>devices</i> , medical equipment and procedures relating to health care and its services, including prevention, <i>diagnosis</i> and treatment of a condition. ^{HTAI} |
| Health technology assessment | The systematic evaluation of the <i>clinical effectiveness</i> and/or cost effectiveness and/or the social and ethical impact of a <i>health technology</i> 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 <i>health technology</i> 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 <i>risks</i> of using the technology. They also look at costs and any wider impacts that the technology might have on a <i>population</i> or on society. ^{HTAI} In Australia, PBAC, MSAC, PLAC and hospitals do health technology assessments. |
| Health Technology Assessment international | the global, non-profit, scientific and professional society for all those who produce, use or encounter. |
| 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. ^{HTAI} |
| Healthy-year 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. ^{HTAI} |
| Highly specialised drug | A medicine that is listed in the PBS to treat chronic conditions but to which only public and private hospitals with appropriate specialist facilities are allowed access because of its clinical use or other specialised features. Funding is provided under the HSD Program within s. 100 of the <i>National Health Act 1953</i> . ^{CoA} |
| HRQoL | see Health-related quality of life |
| HSD | see Highly specialised drug |
| HTA | see Health technology assessment |
| HTA Consumer Consultative Committee | The committee – made up of the consumer representatives from PBAC, MSAC, PLAC and their subcommittees – helps the Department of Health work more closely with consumers and communities in HTA decision making; brings consumer and community evidence and views into HTA processes; informs policy on consumer and patient matters in HTA of significance to Australian consumers and community; creates opportunities to promote |

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| | greater public understanding of HTA processes and enhances methods for formal patient inputs. |
| HTAi | see Health Technology Assessment international |
| HYE | Healthy-year equivalent |
| ICER | see Incremental Cost Effectiveness Ratio |
| Incidence | The number of new cases of a disease among a certain group of people during a specific period of time. ^{HTAI} |
| Inclusion criteria | A set of conditions that must be met for a person to take part in a <i>clinical trial</i> , 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 <i>evidence</i> is included in a <i>systematic review</i> or <i>HTA</i> . ^{HTAI} |
| Incremental cost | The extra cost linked to using one test or treatment over another or the additional cost of increasing the <i>rate</i> of activity. ^{HTAI} |
| 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 <i>outcome</i> . ^{HTAI} |
| Intention to treat | A principle of analysis that includes data from all participants allocated to a specified clinical management group as representing that group irrespective of whether they received or completed the prescribed regimen, or whether they were followed for the full duration of the trial or study. This involves following up participants to contribute data and/or prespecifying procedures to deal with missing data. ^{CoA} |
| 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. ^{HTAI} |
| Intervention group | In a <i>clinical trial</i> , the group receiving the treatment (<i>intervention</i>) in question, as opposed to the <i>control group</i> , which receives either no treatment or another treatment. ^{HTAI} |
| ITT | see Intention to treat |
| Length of stay | The time a patient must stay in hospital or at the treating facility |
| licensing | A marketing authorisation for drugs that assesses quality of production (manufacture), <i>safety</i> and <i>efficacy</i> . ^{HTAI} |
| Life Saving Drugs Program | The program through which the Australian Government provides fully subsidised access for eligible patients with rare and life-threatening diseases to essential medicines (currently 16 medicines eligible patients with one of 10 conditions). |
| 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 <i>systematic review</i>) of all published studies on a specific topic. ^{HTAI} |
| LOS | see Length of stay |
| LSDP | see Life Saving Drugs Program |
| MA | see Medicines Australia |
| MBS | see Medicare Benefits Scheme |
| Medical Research Futures Fund | A \$20 billion fund for health and medical research sector to ensure sustainable funding for vital medical research. |

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| Medical Services Advisory Committee | An independent HTA advisory committee of the Australian Government that primarily advises the health minister on whether it supports the public funding of proposed health technologies and other medical services. ^{CoA} |
| Medicare Benefits Schedule | Under the authority of the <i>Health Insurance Act 1973</i> , a listing and description of the professional services for which a Medicare benefit is payable by the Australian Government, the amount of a patient's cost that is met through a government rebate, and any conditions applying to the use of that service. ^{CoA} |
| Medicines Australia | The representative body for the pharmaceutical industry in Australia, responsible for the Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines. |
| MRFF | see Medical Research Futures Fund |
| MSAC | see Medical Services Advisory Committee |
| National Medicines Policy | cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines. The term "medicine" includes prescription and non-prescription medicines, including complementary healthcare products. ^{DoH} |
| National Products Price List | Under the authority of the National Blood Agreement, a listing and description of blood products and blood-related products that are funded by Australian governments. ^{CoA} |
| NMP | see National Medicines Policy |
| NPPL | see National Products Price List |
| Pathology Services Table | Lists the pathology tests for which Medicare benefits are available, their Schedule Fees and conditions for use. ^{PBS} |
| Patient-based evidence | Evidence from research into patients' experiences, preferences and perspectives, conducted using robust scientific methodology and able to be critically assessed like other scientific evidence. |
| Patient input | Information provided by patients, their representative groups or caregivers. It can be written or verbal and is based on knowledge gained from living with a condition. It is not mediated by researchers and aims to aid value judgements and add value to decision-making in an assessment like PBAC. |
| Patient involvement | In HTA the term is often used for two different activities which complement each other: (1) patient participation (two way communication with patients including patient input such as taking Consumer Comments and enabling patients to take part in HTAs, to enable committees and patients to learn from each other and solve problems before, during and after an HTA); (2) research into patient aspects (patient based evidence from primary or secondary research into patients' experience, preferences and perspectives using robust, scientific methodology) |
| Patient preference research | A range of methods to measure the values of patients with a particular condition to explore how they perceive treatments and to understand what is most important to them. |
| Patient reported outcome measures | a measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. PROM is the instrument or tool, typically a questionnaire or diary, used to gather the health status of the patient. ^{FDA} |

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| Patient Voice Initiative | An incorporated association which brings together patients, patient groups, researchers and industry to promote and improve the use of the patient voice in healthcare decision making in Australia. |
| PBAC | see Pharmaceutical Benefits Advisory Committee |
| PBS | see Pharmaceutical Benefits Scheme |
| Pharmaceutical Benefits Advisory Committee | An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the health minister on the listing of medicines in the PBS. ^{PBS} |
| Pharmaceutical Benefits Scheme | Under the authority of the National Health Act 1953, a listing and description of the medicines that are subsidised by the Australian Government, the amount of that subsidy and any conditions applying to the use of that medicine. ^{PBS} |
| phase I, II, III and IV studies | Different phases of <i>clinical trials</i> 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 <i>safety</i> 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 <i>adverse effects</i> . ^{HTAI} |
| PI | see Product information or patient involvement |
| PICO | see Population, intervention, comparator, outcome |
| PL | see Protheses List |
| PLAC | see Protheses List Advisory Committee |
| PMS | see Post Market Surveillance |
| 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 <i>clinical trial</i> 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 <i>clinical trial</i> need to be typical of the whole population of interest. ^{HTAI} |
| Population, intervention, comparator, outcome | A framework used, especially in evidence-based medicine, to guide research questions and literature searches. |
| Post Market Surveillance | The activity of monitoring the performance of a health technology post-approval. ^{CoA} |
| PPI | Patient and public Involvement |
| prevalence | How common a disease or condition is within a <i>population</i> 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 health boards varied from 3.7% to 4.6%. ^{HTAI} |
| Prevalence study | A study that looks at how common a disease or condition is in a <i>population</i> . ^{HTAI} |
| Primary outcome | The result(s) of most interest to the researchers. A test or treatment can give results for several <i>outcomes</i> , but primary outcomes are of greatest importance when assessing the outcome. ^{HTAI} |
| Primary research | A study that collects data and analyses it. It can refer to either laboratory research or <i>clinical trials</i> . ^{HTAI} |

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| Probability | <p>The likelihood that an event will occur. In statistics, the probability (or <i>P</i>-value) shows the likelihood that a research result could have occurred by chance alone.</p> <p>For example, a <i>P</i>-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 <i>P</i>-values of 0.05 or less are usually considered to be a reliable indication of an effect in the wider <i>population</i> and are called <i>statistically significant</i>.^{HTAI}</p> |
| Product Information | A document that provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine. |
| PROM | see Patient reported outcome measure |
| Protheses List | Under the authority of the <i>Private Health Insurance Act 2007</i> , a listing of the prostheses that private health insurers must fund and the benefits payable for them. ^{CoA} |
| Protheses List Advisory Committee | An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the health minister on appropriate listing of, and benefits for, prostheses in the Protheses List. ^{CoA} |
| PSD | see Public Summary Document |
| PST | see Pathology Services Table |
| Public Summary Document | Information available to the public about recommendations from PBAC or MSAC. |
| PVI | see Patient Voice Initiative |
| QALY | see Quality-adjusted life year |
| QES | see Qualitative evidence synthesis |
| Qualitative evidence synthesis | A method used to bring together multiple studies into patients attitudes, belief and feelings about a treatment or condition to provide decision-makers with a diverse range of experiences found in robust research. Also known as qualitative systematic review. |
| qualitative research | <p>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 <i>focus groups</i> and <i>interviews</i>.⁸</p> <p>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.^{HTAI}</p> |
| quality-adjusted life year | <p>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).</p> <p>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.^{HTAI}</p> |
| quantitative research | Researchers collect <i>data</i> in the form of numbers, that is, they measure things or count things. Quantitative research might ask a question like how many |

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| | 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. 8 |
| randomised controlled trial | A study in which the people taking part are assigned by chance (<i>randomisation</i>) into groups (such as the <i>control group</i> or the <i>study group</i>). The groups are managed in exactly the same way except they are given different treatments, or exposed to a <i>risk factor</i> of interest. <i>Outcomes</i> are measured at specific time points and any difference in response between the groups is assessed statistically. This method is used to reduce <i>bias</i> . ^{HTAI} |
| rate | A measure of how often a specific event happens in a given amount of time. For example, during the trial the <i>side effect rate</i> was 0.4 (4 in every 10 patients experienced a <i>side effect</i>) ^{HTAI} |
| RCT | Randomised controlled trial |
| Real world data | The data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example: electronic health records, claims and billing activities, product and disease registries, patient-generated data including in home-use settings, and data gathered from other sources that can inform on health status, such as mobile devices. ^{FDA} |
| Real world evidence | The clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real world data. Real world evidence can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective). ^{FDA} |
| Research4Me | A social enterprise to speed up access to better treatments by making sure people are empowered with a knowledge of clinical trials and how to get involved, and are not alone in their journey to learn about, take part in, and partner with researchers to make trials a better experience, accessible, faster and more relevant. |
| Risk | The <i>probability</i> 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. ^{HTAI} |
| Risk Sharing Arrangement | An arrangement agreed between the supplier of a PBS-listed medicine and the Australian Government that adequately monitors identified risks (or undesired events such as cost-ineffective use or greater-than-expected use) and manages them by appropriate mechanisms for sharing the impact of these risks between the supplier and the government should they arise. ^{CoA} |
| RSA | see Risk Sharing Arrangement |
| RWD | see Real world data |
| RWE | see Real world evidence |
| safety | The study of <i>adverse effects</i> from treatments. ^{HTAI} |
| SAS | see Special Access Scheme |
| secondary research | An academic review of <i>primary research studies</i> to gain new insights on a specific topic (such as a <i>systematic review</i>). ^{HTAI} |
| 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. ^{HTAI} |

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| Special Access Scheme | The government scheme which provides for the import and supply of an unapproved therapeutic good to a single patient on a case-by-case basis. |
| Sponsor | The organisation that makes a submission to PBAC or MSAC or PLAC to have a health technology (such as a medicine or treatment) assessed. It is usually the manufacturer, but patient groups can be sponsors. |
| statistically significant | The <i>probability</i> of observing a treatment effect as large as that seen in the sample (such as in <i>randomised controlled trial</i>), when there is no treatment effect in the wider <i>population</i> , is less than 0.05. ^{HTAI} |
| Systematic review | <p>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.</p> <p>For example, one <i>clinical trial</i> 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 <i>evidence</i>. Combining the results from a number of trials (using <i>meta-analysis</i>) may give a clearer picture. ^{HTAI}</p> |
| TGA | see Therapeutic Goods Administration |
| Therapeutic Goods Administration | part of the Australian Government Department of Health responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. |
| Utility | A measure of how desirable an <i>outcome</i> 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. ^{HTAI} |
| validity | <p>In a study, <i>validity</i> 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.</p> <p>External validity is the extent to which the cause-and-effect relationships in a study are true for a wider <i>population</i> beyond the study. For example, the external validity of the study may be questioned if the <i>population</i> is people in Australia and the study was in Spain, or for old people if the study was in young people.</p> <p>Internal validity is the extent to which the cause-and-effect relationships in a study are true for the people and conditions of the study. ^{HTAI}</p> |
| Weighted | The influence given to a study or set of data, based on <i>validity</i> , size and accuracy or precision. ^{HTAI} |
| WHO | see World Health Organisation |
| Willingness to pay | The maximum amount of money that an individual is prepared to give up to ensure that a proposed beneficial change occurs. A beneficial change could include an improved health outcome or ensuring that the proposed health technology is substituted for its main comparator based on valuing the resulting difference(s) in outcomes. ^{CoA} |

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| World Health Organisation | Part of the United Nations which focuses on international public health |
| WTP | see Willingness to pay |

Definitions used with the thanks to the following sources:

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<http://www.clinicaltrialsalliance.org.au/about-acta/clinical-trials-network/>

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