CCDR Research & Policy Fact Sheet Series

CENTRE FOR COMMUNITY-DRIVEN RESEARCH

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TYPES OF RESEARCH

Fact Sheet 001

Basic research

Basic research seeks to understand the biology of disease and the mechanisms that cause disease. Basic research is conducted in laboratories and gives us fundamental information needed to later conduct research that can be translated into clinical practice.

Questions addressed by basic researchers might include:

- Which genes are most important in specific diseases?
- How do cancer-causing genes function in the cell to control cell growth, replication or death and to promote metastasis?
- How can the immune system be best armed and activated to protect against the development of disease?
- How do stem cells function and can this knowledge be exploited therapeutically?

Clinical research

Clinical research is research that directly involves particular patients and uses materials or information from humans, such as their behavior or samples of their tissue.

It includes clinical trials, but clinical research doesn't always test the effectiveness of a therapy, diagnostic test or device. Clinical research also includes observational studies to assess outcomes in a group of participants.

Questions addressed by clinical researchers might include:

- Is the addition of a new therapy plus standard treatment for pancreatic cancer better than standard treatment alone?
- In older adults , what are the effects of different lifestyles on cardiac health?

Translational research

Translational research takes knowledge obtained from basic research and turns it into diagnostic or therapeutic interventions that can be applied to the treatment or prevention of disease.

Translational researchers use both basic research and clinical research skills in their work to take their lab experiments through to clinical trials.

Questions addressed by translational researchers might include:
- Identifying potential therapeutic targets through assessment of human tissue.
- Identifying biomarkers of prognosis and response to therapy.
- Developing novel therapeutic, diagnostic, screening and chemopreventative strategies.
- Development of molecular imaging techniques.

Epidemiology

Epidemiologists investigate the occurrence, distribution, and control of disease in a population. They research populations to investigate potential links between areas such as diet, lifestyle, genetics, or other factors within populations, and diseases.

They might look at how many people have a specific disease and what factors (such as environment, job hazards, family patterns and personal habits) play a part in the development of specific diseases.

Questions asked by epidemiologists might include:
What are the causes of a specific disease?
Which persons are at greatest risk of specific diseases?

Behavioural research

Behavioural researchers investigate how behaviour relates to whether a person gets a disease and how they cope with illness. It aims to find out why people behave the way they do, why they sometimes behave in unhealthy ways and what motivates them to adopt more healthy behaviours.

Questions addressed by behavioural researchers might include:
- What motivates people to exercise and eat healthy food?
- How do people access health information?
- How do patients make decisions about treatment options?

Psychosocial research

Psychosocial research investigates the psychological and social impact that a disease has on a patient and their family. It also looks at how health professionals and other people can help to reduce this impact.

Psychosocial research is particularly important in diseases that cause a significant amount of distress and disruption at diagnosis and where patients experience ongoing difficulties that can severely affect their quality of life.

Questions addressed by psychosocial researchers might include:

How do people react to being told they have a disease?
Why do some patients decide not to finish their treatment?
What value do patients place on accessing affordable therapeutics?

Health service research

Health service research investigates the quality of health care, how people get access to health care, how much care costs, and what happens to patients as a result of this care.

The main goals are to identify the most effective ways to organise, manage, finance and deliver high quality care; reduce the variation in medical practice and medical errors; and improve patient safety. Research is broad in its approach and considers interventions across the spectrum from health promotion and illness prevention through treatment to rehabilitation, recovery and care of the terminally ill.

Questions addressed by health service researchers might include:
- What is the cost of a specific treatment in a specific patient population?
- How is the quality of health care impacted when new policies are implemented?
- What is the impact on quality and quantity of life of different treatment options?

Each type of research plays an important part in informing how our health system works, and what diagnostic tools and treatment options are available to us. Dedicated researchers help to find the answers to the questions we have about disease and its impact on us as individuals and as a community. However, research can only happen because of the generosity of patients in the community who volunteer to participate in studies. Research starts and ends with patients, and that is why it is important for researchers to listen to the needs of their patient community and develop research projects to address the most urgent problems faced by patients.

Next fact sheet in series: Ethics and patient consent

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ETHICS AND PATIENT CONSENT

Fact Sheet 002

Research ethics

Research that involves people raises unique and complex ethical, legal and social issues. Research ethics allows us to analyse ethical issues that are raised when people are involved as participants in research.

There are three main objectives in conducting an ethical review of research. The first is to protect participants. The second is to make sure that the research being conducted serves interests of patients, groups and/or society as a whole. The third objective is to examine specific research activities and look at issues such as the management of risk, protection of privacy and confidentiality and the process of informed consent.

Informed consent

If you are considering participation in a research study, you will be asked to give informed consent. Informed consent is a process, not just a form.

At a minimum, this should include receiving both an information sheet and a consent form, however the researcher should also take the time to explain the research to you and answer any of your questions.

The information provided should be given without undue inducement or any element of force, fraud, duress or any other form of constraint or coercion. Participants should always be given adequate information on both the possible risks and the potential benefits of their involvement to allow them to make informed decisions about whether or not to participate in the research.

Human Research Ethics Committees

Human Research Ethics Committees (HREC) operate in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007. When a researcher wants to conduct a study involving humans, they submit an application to one of the 200+ HRECs in Australia for ethical review. HRECs are required to have a minimum membership which includes a Chairperson with suitable experience, at least two lay people, at least one person with knowledge of and current experience in the professional care, treatment or counselling of people, e.g. a nurse, doctor or allied health professional, at least one person who performs a pastoral care role in a community, e.g. an Aboriginal elder or minister of religion and at least one lawyer.

If you are a participant in a research study and have a concern about the conduct of a research, you can raise your concern with the researcher responsible for the project, however if you are not comfortable discussing your concern with the researcher or are not satisfied with the response, you can contact the HREC that approved the research project. The contact details for the HREC will have been given to you on either the written information sheet or consent form.

Next fact sheet in series: Clinical trials

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CLINICAL TRIALS

Fact Sheet 003

Clinical trial phases

Clinical trials are separated into different phases. Not every drug goes through a phase 0 trial and not every drug goes through a phase 4 trial, but all drugs go through phase 1, 2, and 3 trials

Phase 0 clinical trials

In some situations, before we do a phase 1 trial, we may elect to do a phase 0 trial.
Phase 0 trials are trials that are conducted in a small subset of patients, usually around 5 to 15 patients. Phase 0 help us understand how a drug is metabolised or whether the drug does what we want it to do in human beings.

Phase 1 clinical trials

A phase 1 clinical trial is the first stage of clinical testing in volunteers after laboratory research. The purpose of a phase 1 clinical trial is to determine the answer to three questions. Is the treatment safe? Are there any side effects? Does the treatment work better than current treatment?

Volunteers for phase 1 trials are the first to try new and innovative treatments. Phase 1 trials typically involve a small number of participants, usually 15 to 100 volunteers. Participants are divided into small groups that are called cohorts. The first cohort receives a low dose of the new treatment. After the first dosage, treatment is adjusted from there. The dose increases until the trial investigators find the most effective and safe dose for future testing. With each increasing dose, doctors test each volunteer to see how well the volunteers are responding.

Clinical trial phases

Not every drug will go through phase 0 trials. The drugs that do go through a phase 0 trial usually have small sample size, low dose of the drug and a single or few exposures to the drug to try and gauge preliminary information that can be used to design future trials.

Phase 2 clinical trials

A phase 2 clinical trial is the second stage of human clinical trials. The purpose of a phase 2 clinical trial is to determine how well the new treatment works, how the treatment affects a larger group, how much of the drug should be given to be most effective, and what types of diseases the treatment can treat.

Normally, phase 2 studies are performed in a large group of volunteers ranging from about 50 to 300 people. Phase 2 studies are sometimes divided into phase 2A and phase 2B.

A phase 2A trial is designed to determine the best and most effective dose that should be given. A phase 2B trial is designed to study how well the treatment works at the prescribed doses. The goal of a phase 2 clinical trial is to determine if the treatment is as effective as or more effective than current treatments. If it is, then the treatment will move to phase 3.

Phase 3 clinical trials

A phase 3 clinical trial is the third phase of human clinical trials. These trials compare new treatments with the best current available treatment. Normally, phase 3 clinical trials are performed in a larger group of volunteers ranging from about 300 to over 3,000 people. These studies can be run in many different countries all over the world. Only about 18% of phase 2 trials make it to phase 3, meaning the new treatment is quite effective.

The goal of a phase 3 clinical trial is to determine the effectiveness of the new treatment measures against the effectiveness of current treatments. A phase 3 clinical trial might also look into new doses or ways to administer existing therapies. If the treatment is effective, then the new treatment or new medication can be presented to the government for approval.

Phase 4 clinical trials

After a phase 3 trial is complete and the drug is approved and available as a treatment option, we sometimes elect to do phase 4 trials. These are large trials where data is collected to monitor rare events or rare side effects of the drug.

Next fact sheet in series: Risks & benefits of clinical trials

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RISKS AND BENEFITS OF CLINICAL TRIALS

Fact Sheet 004

Benefits

The benefits of participating in a clinical trial are:
* That you may be able to access to new treatments that are not yet available in standard clinical practice.
* You'll be monitored more closely and regularly than you would in standard care.
* You will help generate information that will improve our understanding of the disease and improve our ability to treat the disease so that we can have better options to offer patients in the future. This means that there is a benefit to patient themselves as well as a greater benefit to the community.

Clinical trials and standard treatment

You will never miss out on receiving standard treatment in a clinical trial. Patients who participate in a clinical trial will usually be placed in one of two or more groups. The 'test group' will usually receive standard treatment for the disease or condition plus the new treatment being tested. The 'control group' will be given standard treatment only. If there is no standard treatment they will receive a placebo which is a substance that has no therapeutic effect but will look the same as the test treatment.

Patients may withdraw from a clinical trial at any time for any reason, and without prejudice to further treatment. Patients can also be withdrawn from a clinical trial by the researcher if they feel that the patient is not deriving clinical benefit or because of unacceptable side effects.

Patients who are withdrawn or are removed from the study will usually be followed-up to make sure there are no ongoing side effects.

Risks

The risks of participating in the clinical trial include:
* That there may be side effects of the treatments that are being given as part of the clinical trial. That is why when patients are approached to enrol in a clinical trial, they will always be informed of the potential side effects of the experimental treatment.

* There may be some travel to participate in the trial if the trial is not being conducted at a site near your home.

* It is also important to remember that the treatment being given in a clinical trial may not work for you.

Next fact sheet in series: How clinical trials are regulated

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HOW CLINICAL TRIALS ARE REGULATED

Fact Sheet 005

Financing trials

There are several ways that we can ensure financial support for clinical trials. These may include federal or state funding through grants, funding through the pharmaceutical industry, funding through institutional grants and occasionally, funding through philanthropy.

In addition to sponsoring the trial from a financial point of view, the pharmaceutical industry often work collaboratively to provide the drug that is being tested to researchers outside of their own company.

Regulating clinical trials

To conduct a clinical trial in Australia there are a number of guidelines that need to be followed. All clinical trials must comply with the National Statement on Ethical Conduct in Human Research[1], the Australian Code for the Responsible conduct or research [2], as well as local, State and Territory guidelines. For clinical trials using goods that are not on the Australian Register of Therapeutic Goods, or use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval, there are two additional mechanisms used including the Clinical Trial Notification scheme (CTN) and Clinical Trial Exemption scheme (CTX).

Clinical trial notification

The majority of clinical trials receive approval to commence through the CTN. Through this notification scheme, Human Research Ethics Committess bear the responsibility of assessing ethical acceptability of the study and approving the trial protocol. Notification is sent to the CTN for each site where the study will be conducted. A study cannot commence until this process is complete.

Special access scheme

Therapeutic goods that have undergone an evaluation for quality safety and efficacy are listed on the Australian Register of Therapeutic Goods (ARTG). However, because there are circumstances where patients need to access treatments outside this system, the Therapeutic Goods Administration (TGA) manages the Special Access Scheme (SAS) on a case-by-case basis. Applications under the SAS are made to the TGA by registered medical practitioners, preferably the patient's treating doctor.

Clinical trial exemption

The Clinical Trial Exemption scheme (CTX) is not used often, but is available in situations where an application to conduct a clinical trial is submitted to the TGA for evaluation and comment (as opposed to notification through the CTN). The TGA decides whether or not the proposed usage of the therapy or device in the trial is within the guidelines for the product. If there are any objections or issues, the trial cannot commence until these have been resolved.

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Next fact sheet in series: The Pharmaceutical Benefits Scheme

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THE PHARMACEUTICAL BENEFITS SCHEME (PBS)

The Medical Benefits Schedule (MBS)

Fact Sheet 006

What is the PBS?

The Pharmaceutical Benefits Scheme (PBS) is an Australian Government program that provides subsidised prescription drugs to residents of Australia. It provides access to necessary and lifesaving medicines at an affordable price. The scheme assumes responsibility for the cost of drugs to patients in the community setting rather than in hospital, which is the responsibility of each state and territory. The PBS Schedule is part of the wider Pharmaceutical Benefits Scheme managed by the Department of Health and administered by Department of Human Services. PBS and Medicare make up key components of the Australian healthcare system and represent a large proportion of expenditure within the health budget.

What is the MBS

The Medical Benefits Schedule (MBS) is an Australian Government program that provides access to medical and hospital services. The MBS is a list of services that are subsidised under Medicare. Services might include things such as GP visits, blood tests, x-rays.

It is important to remember that Medicare rebates do not always cover the full cost of medical services. There is often a gap between what patients pay for services and the amount that Medicare reimburses . This gap is known as an out-of-pocket expense, as the patient makes up the difference. As an example, if you go to a GP that doesn't bulk bill, they are free to set their own prices for services. In this case, a patient will pay for their treatment and receive a rebate from Medicare.

WHAT IS THE OBJECTIVE OF THE PBS?

The main objective of the scheme is delivering safe, affordable and clinically effective medicines to all Australians as well as assuring value for taxpayers.

References

www.humanservices.gov.au

Next fact sheet in series: PBS concessions

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PBS CONCESSIONS AND SPECIAL SCHEDULES

Fact Sheet 007

Who is eligible for PBS concessions?

Individuals who hold the following cards are eligible for PBS concessions:
a) A pensioner concession card, Commonwealth seniors health card or a Healthcare card. These are issued by Centrelink.
b) A DVA White, Gold or Orange card issued by the Department of Veterans Affairs.

Concession card entitlements

Concession cardholders are entitled to all PBS medicines under the concessional rate. DVA concession cardholders are entitled to all PBS medicines at a concessional rate and also medicines under the Repatriation Pharmaceutical Benefits Scheme (RPBS) depending on DVA entitlement. All medicines supplied under the RPBS are dispensed at the concessional rate (or free if the patient has reached their Safety Net threshold) [1].

If you have a DVA white card, it entitles you to-
• RPBS and PBS medicines at the concessional rate for a specific medical condition (which is at your doctor's discretion) war or service related [1].
• Receive all other PBS medicines at the general rate.
If you have an orange card
• Receive all RPBS medication that are pharmaceutical medications, exclude other healthcare expenses [1].
If you have a DVA gold it entitles you to-
- All RPBS and PBS medicines at the concessional rate, including clinically necessary treatment whether related to war service or not [1].

DVA pension cardholders are entitled to concessional rate for PBS however, are not eligible for RPBS medicines [1].

Dental and optometrical schedules

Dentists are not able to prescribe general PBS items, but have a separate Dental Schedule from which they can prescribe dental care medicines for their patients [2]. Optometrists are not able to prescribe general PBS items, but have a separate Optometrical Schedule from which they can prescribe eye care medicines for their patients [2].

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2. Australian Department of Health and Ageing. About the PBS The Pharmaceutical Benefits Scheme (Available from www.pbs.gov.au/info/about-the-pbs - What_is_the_PBS) [Accessed 5 August 2015]

Next fact sheet in series: Safety net

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THE SAFETY NET

Fact Sheet 008

The PBS and Medicare Safety Net[1]

* There are two safety nets, the Medicare Safety Net and the Pharmaceutical Benefits Scheme (PBS) Safety Net.
* Under the Medicare Safety Net, Medicare will pay 100% of the out of pocket costs for medical services provided out of hospital after a threshold of $453.20 is reached per calendar year. There are different thresholds depending on your circumstances (see www.humanservices.gov.au)
*The PBS Safety Net entitles people to cheaper medicines if they spend more than a certain amount on PBS prescription medicines in a calendar year. The current Safety Net threshold as of 1 January 2017 is $1,494.90. Once you spend this amount, you reach the 'Safety Net threshold' and your payments will be reduced to the concessional rate for the rest of the calendar year.
* If you combine your family's PBS amounts, you will possibly reach the PBS Safety Net threshold sooner.
* If your medicine isn't covered by the PBS, your doctor may write you a private prescription. These types of medicines don't count towards your PBS Safety Net threshold and you'll need to pay full price for the medication at the pharmacy.

PBS

There are two types of prescription record forms to record PBS prescription items. A blue form, used for items obtained at community pharmacies and available from community pharmacies, Medicare Service Centres and the Department of Human Services; and a grey form, used by out-patients who pay for items at public hospital pharmacies and available from hospital out-patient departments or the Department of Human Services.

1. https://www.humanservices.gov.au

The safety net

The safety net is to prevent high overall costs of medication. Once the safety net has reached a specific threshold during the calendar year, the price of medications listed on PBS is reduced.

The PBS safety net for general patients is $1,494.90 and $378.00 for concession holders.

The MBS safety net for all Medicare card holders is $453.20.

Before you can become eligible for free or cheaper medicines under the PBS Safety Net scheme, you must have a record of how much you have spent on PBS medicines that year.

If you always use the same pharmacy, ask your pharmacy to record your spending on their computer. You can ask for a print-out of your spending from the pharmacy at any time.
If you use different pharmacies, you can:

* obtain a print-out of your spending from each, or
* record all your spending on a prescription record form

The Safety Net applies to a calendar year, so ask for a form the first time you buy a PBS medicine in the new year. Hand your prescription record form to the pharmacist each time you have a prescription filled that year.

If you have a family, ask your pharmacy to combine the amounts spent on each person's medicines into one Safety Net total or use one prescription record form for the entire family.

Brand Premiums

In an effort to limit the cost of PBS, the Australian Government introduced Brand Premiums on medications where cheaper generic brands were available. The Brand Premium is usually the price difference between the premium brand and the generic brand. The patient pays the Brand Premium in addition to the normal contribution if they prefer not to buy the generic brand. The Brand Premium doesn't count towards the safety net threshold.

Therapeutic Group Premiums

Therapeutic Group Premiums (TGPs) was introduced by the government in 1998 to limit the cost of medications that were priced significantly higher than the cheapest medication in a defined therapeutic sub-group where the drugs were considered to be similar in safety and efficacy. The TGP is the price difference between the premium brand and the benchmark (base) price for drugs in the class. The patient must pay this TGP in addition to the normal patient co-payment contribution if they have been prescribed such a medication. The TGP paid does not count toward the Safety Net threshold.

Medicare Safety Net

Individuals don't need to register for the Medicare Safety Net as out of pocket medical expenses are automatically kept. However, couples and families need to register for the Medicare Safety Net (even if all of your family members are listed on the same Medicare card), if you want to combine your total medical expenses (Register at www.humanservices.gov.au)

The Medicare Safety Net covers a range of doctor visits and tests that you receive out-of-hospital. Some examples of services that count towards the Safety Net are:

* GP and specialist consultations
* Ultrasounds
* Pap tests
* Blood tests
* CT Scans
* X-rays

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DECISION-MAKING AND THE PBS

Fact Sheet 009

The Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC is an independent body established under The National Health Act to make recommendations to list new medicines on the Pharmaceutical Benefits Scheme (PBS) [1]. The PBAC consists of experienced health professionals and one consumer representative. A PBAC recommendation must be given to medicines prior to being listed on PBS. Submissions are examined for the clinical efficacy, safety, and value for money [2]. Within the PBAC there are two sub-committees, which aid PBAC in decision-making, the Drug Utilization Sub-Committee and the Economics Sub-Committee [2].

Therapeutic Goods Administration (TGA)

TGA is Australia's governing authority for therapeutic goods. TGA implements various assessment and monitoring tools to ensure all therapeutic goods available in Australia meet industry standards. TGA aims to ensure that therapeutic goods are reviewed within a reasonable time frame so that the Australian public has access to therapeutic advances [3] Only medicines approved by the TGA can be submitted to the PBAC for PBS listing.

Medical Services Advisory Committee (MSAC)

MSAC provides the Health Minister with advice on whether a new or existing medical service should be publicly funded through listing on the Medicare Benefits Schedule (MBS) [4]. MSAC takes into consideration value for money of the service, clinical effectiveness, safety and overall cost of the medical service or technology [4]. MSAC only looks at medical services, not prescription medicines [4].

Advisory Committee on Prescription Medicines (ACPM)

ACMP provides recommendations to the TGA on prescription medicines [5]. The recommendations include

- The inclusion of a prescription medicine on the Register
- Changes to a prescription medicine on the register
- Inclusion or exclusion of a prescription medicine from the register

Through the TGA, ACPM provides advice to the Health Minister regarding all concerns relating to prescription medicine [6]. ACMP does not make decisions, ultimately the decisions are made by the TGA [5].

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Next fact sheet in series: PBS challenges

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PBS CHALLENGES

Fact Sheet 010

Access and Affordability

The Pharmaceutical benefits scheme (PBS) is an important aspect of Australian healthcare [1]. PBS however does face a number of challenges, mostly in the process of listing new medications, affordability and access. The pharmaceutical benefits advisory committee (PBAC) recommends which medicines should be listed to the Minister of Health by using a 'value for money' system [2].

Pharmaceutical pricing is currently governed by an agreement between Department of Health and pharmaceutical industry body, Medicines Australia. Due to increased costs of PBS, 'price disclosure' was introduced to reduce costs [3]. Price disclosure requires pharmaceutical companies to disclose to the government, the sell price of medication to pharmacies. Prices are then set through the weighted average of these disclosed prices[4]. Although price disclosure does allow for some reduction in price, the process for price adjustment takes a minimum of 12 months[5].

Timely access

Additional challenges apply to the process of listing new medicines. The processing time involved prior to submission to PBAC can take up to 17 months [6]. For a new drug to be considered it must first be reviewed for safety through Advisory Committee on Prescription Medicines (ACPM) which then advises the Therapeutic goods administration (TGA). It is only after approval from TGA that a new drug can be submitted to the PBAC [6]. While these steps are necessary, the time that it takes for approval often prohibits timely access to therapeutics.

TRANSPARENCY

The decision-making process and reason for acceptance or decline of specific medicine listings is not always clear and needs to be communicated to the public [7]. There is also a need for more meaningful community involvement including providing feedback to the community about decisions that are made [7].

Biology of disease

As we learn more about the biology of disease, the PBS is being asked to subsidise higher costing drugs [8]. For example, as new subtypes of cancer are recognised, different drugs will be needed to be effective. This means that there will be more and more drugs that are effective for smaller populations and not the wider population [9]. It is also a challenge because there are some drugs that improve quality of life without providing a cure. These drugs may be extremely valuable to patients but they do not always demonstrate the same economic value.

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HEALTH TECHNOLOGY ASSESSMENT IN AUSTRALIA

Overview

Health Technology Assessment

In Australia the Government regulates therapeutic goods, and subsidises the cost of health related goods and services to improve access to medical and surgical procedures, diagnostic tests, prostheses and medical devices, through different programs.

The three main questions asked in relation to Health Technology Assessment are:

- Is it safe?
- Does it improve health outcomes?
- Is it cost effective?

What is a therapeutic good?

A therapeutic good is any product that makes a claim to have a therapeutic use.

Health Technology Assessment in Australia

The Health Technology Assessment process in Australia comprises three main components: regulation, reimbursement and post market surveillance. All components are governed by the **Department of Health and Ageing** (DoHA) under a legislative, policy and program framework.

Regulation

The **Therapeutic Goods Administration** (TGA) is a regulatory and surveillance body responsible for ensuring that all therapeutic goods are safe before they enter the market and become available to the public. Once a therapeutic good is available, the TGA are also responsible for ongoing surveillance and removal of goods that are found to be unsafe are removed from the market.

To lawfully supply a therapeutic good in Australia it must be listed on the **Australian Register of Therapeutic Goods** (ARTG). Therapeutic goods must be listed on the ARTG before they are imported into Australia, exported from Australia or supplied within Australia. There are two types of entry on the ARTG – registered products and listed products. Registered products are prescription and over the counter medicines, vaccines and some complementary therapies, and have an AUST R number on their label. Listed products are complementary therapies such as vitamins and mineral supplements, nutritional supplements, traditional Chinese medicines and aromatherapy oils, and have an AUST L number. The TGA decides if products are suitable for listing or require registration.

Reimbursement

There are three mechanisms in which subsidies are offered to patients and the community. These include the **Pharmaceutical Benefits Scheme** (PBS)/**National Immunisation Program** (NIP), **Medicare Benefits Schedule** (MBS) and the **Prosthesis List**.

Decisions in relation to which medicines are reimbursed through the PBS and which vaccines are listed on the NIP are made by the **Pharmaceutical Benefits Advisory Committee** (PBAC). The PBAC have two sub-committees which support the decision-making process. These include the Drug Utilisation Sub Committee and the Economics Sub Committee.

Decision in relation to the medical services, devices, consultations or allied health services that are subsidised through Medicare and the **Medical Benefits Schedule** (MBS) are made by the **Medical Services Advisory Committee** (MSAC). If the MSAC needs additional advice to effectively undertake its role, it may establish sub-committees to support the decision-making process.

The Prostheses List contains prostheses and the benefit to be paid by private health insurers.

Products on the Prostheses List include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue. The list does not include external legs, external breast prostheses, wigs and other such devices.

Post market surveillance

The TGA have three main post market surveillance mechanisms including:

Monitoring and Alerts: The TGA monitor claims made in advertisements and issue fines, sanctions and alerts if advertising claims can not be supported.

Adverse events: The TGA records reports of adverse events and subsequent recall actions. Reports of adverse events are made by consumers, health professionals and industry.

Manufacturing: The TGA have mechanisms to inspect manufacturers of therapeutic goods to ensure compliance with Australian codes and the safety of therapeutic goods. These include sampling (TGA Laboratories undertake a continuous sampling program in all states of Australia. Products are purchased in the marketplace, or obtained from manufacturers or sponsors, and subjected to analysis and regulatory scrutiny); Good Manufacturing Practice Audits (inspections by the TGA's Manufacturer Assessment Section) and the Surveillance Unit of the TGA (The Surveillance Unit investigates breaches of the legislation and coordinates prosecutions).