Australian Government
AusAID

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Medical Research Strategy

2012

Summary

AusAID will invest in medical research to save the lives of poor people in the Asia Pacific region. Investments will be guided by the Government's assessment criteria:

- Poverty
- National interest
- Capacity to make a difference
- Current scale and effectiveness.

The Australian Government's aid policy statement *An Effective Aid Program for Australia* states that "**the fundamental purpose of Australian aid is to help people overcome poverty**".

Saving lives is one of the five strategic goals of Australia's aid program. This includes saving the lives of poor women and children through greater access to quality maternal and child health services (for example, skilled birth attendants and midwives), and supporting large scale disease prevention, vaccination and treatment.

The Government's aid policy statement also gave in-principle support to **"more aid funding for research by Australian and international institutions, particularly in..... medicine".** This strategy gives effect to that support.

Purpose

AusAID will invest in medical research to save the lives of poor people in the Asia Pacific region.

Criteria for investment

An assessment of:

- Poverty
- National interest
- Capacity to make a difference
- Current scale and effectiveness

Objectives	Approach
AusAID will support medical research that removes or reduces the barriers to achieving priority health outcomes in the Asia Pacific in the shortest possible time.	We will work with development partners to support Product Development Partnerships to undertake research that will make a difference for poor people in our priority health areas. Our initial focus will be on malaria and tuberculosis, potentially contributing to late stage drug and vaccine development, and the development of diagnostics and delivery platforms. We will work in partnership with the National Health and Medical Research Council to support implementation research including operational research to make a difference to the quality of clinical care delivered to poor people. The program will address our priority health issues namely: malaria, tuberculosis, maternal and neonatal health conditions and diarrhoeal diseases and bacterial pneumonia and meningitis.
AusAID's investments will also encourage innovation and collaboration, including by strengthening capacity and institutional links in the region.	We will build on existing AusAID programs to provide support for medical research at the individual, institutional and national level in the Asia Pacific region including through: Australia Awards scholarships & fellowships, core funding to medical research institutions where agreed with partner countries and through the new Government Partnerships for Development program to commence in 2013.

1. The rationale for supporting medical research

The world's poorest and most vulnerable people bear the greatest burden of disease and ill health. In low-income countries, the average number of years of life lost to premature death per person is more than four times higher than in high-income countries[1]. Poverty forces people to live in conditions that encourage the spread of disease; without clean water and adequate sanitation; causes hunger which leaves people vulnerable to disease; and denies people access to reliable health services and affordable medicines when they get sick.

Infectious diseases (such as HIV, tuberculosis and malaria), complications from pregnancy and childbirth, and poor nutrition are major causes of high death rates in low-income countries. In 2010, 287,000 women died during pregnancy or childbirth, 99% of them in developing countries2. In the same year, 7.6 million children under five years of age died from largely preventable causes, 40 per cent in their first month of life3. In 2011, 1.7 million people died from HIV-related causes4 and in 2010, 655,000 people died from malaria, most of whom were children under five years old5. These diseases and complications of pregnancy cause deaths and contribute to morbidity. For example, for every woman that dies another 20 women and girls suffer from pregnancy-related and childbirth-related injury, disability, infection, and disease.6

AusAID's priority is to help countries increase coverage and access to the interventions and health technologies that work. This means working with countries to strengthen the building blocks of equitable health services: such as trained health workers; commodities and drugs; facilities; finances, leadership and health governance. Gains have been made by the international community including increased access to essential medicines and critical health services. With increased coverage of interventions such as immunisation and treatment of common childhood killers, the number of deaths in children under five years of age globally fell by almost 40 per cent between 1990 and 2010. Funding for HIV means eight million people in low- and middle-income countries were receiving treatment in 2011.

However, our ability to combat diseases and health issues could be vastly improved by medical research breakthroughs in cases where effective proven medical interventions don't exist, are not appropriate for use in poor communities, or are just too expensive. Where medical interventions do exist, it is important to understand how they can have the greatest benefit to patients in different contexts.

For example, current treatment for tuberculosis requires patients to take four drugs every day for six months under direct supervision. The difficulties of taking this treatment properly are causing resistance to these drugs, meaning that TB is becoming harder and more expensive to treat, and more likely to spread. This is similarly true of malaria, where substandard drugs and lack of access to quality medicines are driving the emergence of drug-resistant malaria parasites in South-East Asia. Even where they are available, contraceptives are often not used because they are unaffordable, unacceptable to a woman or her partner, have undesirable side effects or require a skilled health

provider to administer them. Effectively addressing these issues is necessary to improve the health of the world's poor and to tackle global health threats.

As well as fostering conditions which cause ill-health, poverty means that there is little financial incentive for commercial investment in the diseases which primarily affect the poor. This is 'market failure' where very little of the total medical research effort is directed to the diseases which affect the largest number of people. For example, between 1974 and 2004, of the 1,556 new drugs that came onto the market, only 21 were for neglected diseases and poverty related diseases: eight for malaria, three for tuberculosis, and 10 for neglected tropical diseases (such as Chagas disease and river blindness).[7]

AusAID already makes big investments in The GAVI Alliance (GAVI) and The Global Fund for AIDS, TB and Malaria (Global Fund) which act to correct this market failure by signalling to industry that there is a reliable market for products for the poor. This has encouraged better development and production of appropriate medical interventions. However, this signalling does not work well for all types of research. Development of new medical technologies is expensive, and researchers need funding to pay for the resources to do the research.

The benefits of medical research can be game-changing. Research can deliver a better understanding of how people are affected by diseases and how they could be treated. It can create new vaccines to prevent diseases, new drugs to treat them, and new tools to diagnose them. It can also investigate how to get the best results for patients by using these tools. However, choosing how to invest to achieve these results is complex and highly technical. Developing a single new vaccine requires investigation of a large number of candidates (most of which are not successful), can cost $600-800 million, and take 10-15 years, so we must ensure that we are making the best decisions to achieve real outcomes for the poor. This means taking into account the benefits and risks of different investments, the likelihood of success, the financial costs, and the time it will take for research to have an impact on the health of the poor.

This strategy outlines how AusAID will respond to this challenge and support research to create new medical products such as diagnostics, drugs or vaccines, and to improve the clinical treatment of people in poor communities.

2. Principles for investing in medical research

Purpose

AusAID will invest in medical research to save the lives of poor people in the Asia Pacific region.

Objectives

AusAID will support medical research that removes or reduces the barriers to achieving priority health outcomes in the Asia Pacific in the shortest possible time.

AusAID's investments will also encourage innovation and collaboration, including by strengthening capacity and institutional links in the region.

Criteria for investment

The Government's criteria for allocations to medical research are an assessment of:

- **Poverty**: we will focus on the diseases and health issues which have a large global burden and, and where the burden falls disproportionately on low-income and lower middle-income countries.

- **National interest**: we will focus on diseases and health issues which have the greatest impact on AusAID's programming–where they have a large burden in our priority countries; where emerging problems (such as drug resistance) pose a threat; and where Australia can make a contribution to research efforts.

- **Capacity to make a difference**: we will choose research which is more likely to improve the health of the poor quickly–where there is a high likelihood of the research succeeding, and a short time (up to 5 years) to an outcome for poor people.

- **Current scale and effectiveness**: we will make investments which are more likely to make a real impact for poor people, including by using competitive mechanisms, managing risk well, and by working in partnership with others who can contribute other resources and expertise.

3. What is medical research?

Medical research is a specialised part of research for health. The hallmark of medical research is that it is focused on finding solutions for individual patients, rather than for the broader population (Although, as in the case of vaccines, it can have benefits for the broader population). It is generally considered to refer to laboratory and clinical research-the continuum from laboratory to bedside which designs interventions and how they should be used–and excludes health system concerns, such as how to make medicines available in health clinics.

This Strategy considers medical research in three categories:

basic research: the experimental or theoretical work undertaken to acquire new knowledge about diseases and health issues and, unlike product development or operational and implementation research, is not directed at any particular application.

product development includes the research and development activities that translate basic research knowledge into new tools to tackle disease including prevention, treatment and/or cure. It covers the spectrum of discovery, pre-clinical research, clinical trials (Phase I to III trials), and registration and pharmacovigilance–monitoring product safety (Phase IV trials).

implementation research including operational research: understanding how to achieve the best outcomes for patients using existing or new health interventions. Implementation research aims to develop strategies for available or new health interventions (for example, testing the best way for pregnant women to take an existing malaria treatment). Operational research aims to develop solutions for specific service delivery problems (for example, determining how many samples from a patient should be tested to diagnose tuberculosis).

Medical research will form part of AusAID's investment in research for health.

4. Our priorities

Diseases and health issues

AusAID will invest in diseases and health issues which have a need for new and/or improved medical interventions for use in poor communities and which are not being supported by the market. It will do this by supporting medical research in key areas which have **the greatest potential to alleviate poverty, and best align with Australia's national interests**.

Among these types of diseases, AusAID will focus on those which are of priority based on the following criteria:

- **A high global burden of disease**[1]: we will look for solutions to the biggest health development problems
- **A high burden of disease in AusAID priority countries**[2]: we will consider how these diseases and health issues impact on the countries in the Asia Pacific, particularly those where we provide the most aid
- **High inequity of disease burden:** we will consider how much more of the burden is borne by low- and middle-income countries compared to high-income countries
- **Strategic importance to Australia**: we will consider other strategic issues, such as where disease could reverse health gains, such as emerging drug-resistance, or regional cross-border implications.
- **Can build on Australian research expertise**: Australia has existing research expertise in many areas which we can leverage to provide global results.

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1 In assessing the burden, we used data on Disability-Adjusted Life Years (DALYs) Lost–a measure of the years of life affected by illness or disability or lost as a result of premature death. This measure is commonly used to show the total effect of diseases. **Error! Bookmark not defined.**

2 AusAID's top 12 aid recipient countries are all in Asia and the Pacific, and as noted in *Helping the World's Poor through Effective Aid: Australia's Comprehensive Aid Policy Framework to 2015–16* are: Indonesia, Papua New Guinea, Solomon Islands, Afghanistan, Vietnam, Philippines, Bangladesh, East Timor, Pakistan, Cambodia, Burma, and Vanuatu.

Consistent with these criteria, our disease and health issue priorities are outlined below:

Table 1: Disease and health issue priorities

Priorities	Justification
Malaria	> Malaria has a high burden on the poor- 99% of the global burden of disease occurs in low and lower middle income countries. > Gains in controlling malaria are being threatened by areas of emerging resistance to existing drugs. > The type of malaria parasite which is particularly common in the Asia Pacific region–*Plasmodium vivax*–is not as well understood, and treatment in the Pacific can be complicated. > Australian universities and medical research institutes have substantial expertise which could be leveraged to address the needs of our partner countries.
Maternal health conditions and **Neonatal health conditions**	> Have a large burden in the Asia Pacific region, which has 44 per cent of the world's maternal mortality > They account for more than one third of deaths of children under five. > Both groups of conditions have a particularly high burden in AusAID's priority countries. > The burden of both groups is also around 20 times higher in poorer countries.
Diarrhoeal diseases and **Bacterial pneumonia and meningitis**	> High global burdens of disease, together accounting for around a third of deaths of children under 5 years old. > Have a very high burden in AusAID's priority countries.
Tuberculosis	> Has a high burden in our region and in our priority countries: South East Asia and Western Pacific combined have the highest numbers of people with tuberculosis, as well as the highest rates of new infections globally. > Resistance to existing drugs, and co-infection with HIV is complicating tuberculosis control efforts. > Australia also has substantial research expertise in tuberculosis which could be leveraged to address the needs of our partner countries.

a. Maternal health conditions include haemorrhage, sepsis, hypertensive disorders, obstructed labour, and unsafe abortion
b. Neonatal health conditions include prematurity and low birth weight, birth asphyxia and birth trauma, and neonatal infections
c. Diarrhoeal diseases include rotavirus, E. coli, cholera, and shigella

Research framework

AusAID will support medical research that removes or reduces the barriers to achieving priority health outcomes in the Asia Pacific region in the shortest possible time. In order **to make a difference**, we will focus on investments that have:

- a high likelihood of the research succeeding, and
- a short time (up to five years) to an outcome for poor people.

In line with these criteria, our research priorities are:

Priorities	Justification
Late stage clinical trials **(drugs and vaccines)**	> These studies test the effectiveness of safe, promising candidates to take them to registration and make them available for use. > As products progress along the development pipeline, the risk of failure decreases, as does the time to completion. > Late-stage products have a much higher success rate than early stage research (around 75 per cent of Phase III products are successful, compared to as few as 10 per cent of products in Phase I trials). > By the time products enter late stage trials, the time to health impact is shorter.
Diagnostics and **Delivery platform technologies**[3]	> Development of diagnostics and delivery platforms has a higher chance of success than vaccines or drugs. > They also have a shorter total development time which falls within our acceptable boundaries: diagnostic tests take around 2-7 years to develop, shorter than new drugs (7-10 years) or vaccines (10-15 years)[8].
Implementation and operational research	> Have a high likelihood of success–that is, likely to deliver the intended outcome, particularly where it is focused on a particular project or program. > Time to health impact can vary, but is short where research is focused on a particular program or place, or where there is a focus in the research program on uptake of evidence into medical practice on a broader scale.

[3] These are technologies to deliver drugs to a patient or to the site in the body where they act, and can potentially be applied to a range of diseases and products.

5. How will AusAID invest?

Research Programs

AusAID will **support the most efficient and effective funding mechanisms** and work with selected Australian and international partners who can deliver. As AusAID is new to funding medical research (in contrast to capacity building which it funds already), **the scale of our investment will be very focused,** with a view to increasing over time, and we will consider future investments based on early experiences and lessons learnt.

We recognise that the types of research we have prioritised–especially late stage product development–are more likely to achieve a health impact for the poor, but they are also more costly. AusAID will therefore use mechanisms that pool funds with other donors to achieve better outcomes, or are able to leverage additional resources or activity.

AusAID will consolidate effort by supporting existing mechanisms that pool research efforts, and have the internal capacity to efficiently and effectively manage investments in this complex area. We will prioritise effective mechanisms that:

- **Focus on health impact for the poor**: understand the needs of poor communities, work with these needs in mind, and promote uptake of results into medical practice for these communities
- **Have sound risk management:** manage the financial, scientific, and ethical risks of doing medical research
- **Encourage capacity building:** promote sustainable effects of doing research, by fostering partnerships and building knowledge and skills of researchers and institutes
- **Are globally competitive:** seek out the best research and researchers in the world in order to achieve the best results
- **Encourage innovation**: by drawing on knowledge and expertise from different partners, some mechanisms encourage new solutions to problems and better ways of working
- **Leverage more resources or activity:** work with partners to increase available funding or create an environment which enables more research.

Using these criteria, AusAID will invest in:

Priorities	Justification
Product Development Partnerships (PDPs)[4] with partners and through existing mechanisms where possible	> portfolio management approach increases the likelihood of success compared to funding the development of single candidates > ensuring new products are acceptable and usable in their target environment, and can support uptake of products into national health systems[9] > overseen by a scientific advisory group that ensures that only the best prospects continue to be funded > involving partnerships with researchers in developing countries promote capacity building and increase the sustainable benefits of research > drawing on global expertise from a range of partners including pharmaceutical companies, biotechnology companies, research institutes, and NGOs > leveraging resources from their network partners, such as in-kind donations of human resources or access to intellectual property.
Partnership with the National Health and Medical Research Council (NHMRC) through a competitive funding process which will award grants to partnerships of researchers and organisations from Australia and developing countries	> funding research that will be used to improve patient outcomes through influencing clinical practice in partner countries > priority projects will focus on the needs of partner countries, and the uptake of evidence into practice > partnership with the NHMRC will leverage the existing high level of technical expertise, well established research governance processes, including peer review of applications to determine merit, and financial management of grants > funding will complement the investments that the NHMRC make in global health and medical research > supporting partnerships between Australian and partner country researchers and institutions, will build the capacity to do and use clinical research.

AusAID's initial priorities for 2012-13 will be funding PDPs for malaria and tuberculosis research. AusAID also aims to begin funding through its partnership with the NHMRC and envisages rolling priorities.

PDPs are not-for-profit organisations which combat diseases of the poor by acquiring and managing portfolios of product development activities within a disease and/or technology area. While PDPs vary in their form and operation, they have five characteristics in common: they target one or more 'neglected diseases'; they use some private sector approaches to attack research and development challenges including in particular variants of the multicandidate/ portfolio management approach; their primary objective is public good rather than a commercial goal; they are focused on products suited for use in developing countries; they advocate for their focus area(s).

In 2011-12 AusAID's investment in health research was $20 million, and focused largely on health policy and systems research. In future years, medical research will represent approximately 30 per cent of the health research budget.

Capacity building

AusAID will support innovation and collaboration, including by strengthening capacity and institutional links in the region. C**apacity building will be a priority for AusAID's research investments, not only to undertake research, but to stimulate demand for and use of research for development decision making**. This approach is consistent with AusAID's broader strategy for investing in research.

AusAID already invests in medical research programs that encompass capacity building in research and research associated skills. These programs support capacity building by working with partners in developing countries to define needs, perform research, and promote uptake. The ability to embed research into health systems requires competent scientists and a supporting and enabling environment that allows research communities to grow and deliver research goods.[10]

To date, AusAID has provided core funding to medical research institutes in some partner countries, as well as providing scholarships and fellowships and funded government to government cooperation through the Public Sector Linkages Program to increase capacity. Where medical research is an agreed priority with partner countries, we will continue our support for capacity building in medical research.

We will build the research capacity in our partner countries by:

- fostering partnerships between Australian and partner country researchers and universities
- providing a mix of core and project funding to key researchers in our partner countries to develop their capacity to undertake and use research.

AusAID will also provide support at the individual, institutional and national level in the Asia Pacific region through:

Australia Awards	> Australia Awards for medical research study can be awarded through the **Australian Development Scholarships, and the Australian Regional Development Scholarships**, to provide opportunities for people from developing countries to undertake full time postgraduate study at participating Australian universities or selected education organisations in the Pacific region. > The **Australian Leadership Awards Fellowships** awards fellowships to Australian organisations to host leaders or mid-career professionals for short-term research, study, leadership or training, to develop appropriately trained leaders who can influence policy objectives and increase institutional capacity in partner countries. > Australia Awards develop the capacity to do, use, and manage research and leadership skills, and to build people-to-people linkages. > Where it is an agreed priority with partner countries, AusAID will fund Australia Awards across the spectrum of medical research.
Fund medical research institutions in partner countries	> Where it is an agreed priority between AusAID and partner countries, AusAID will provide core funding to medical research institutes. > Core funding to research institutes can support training, infrastructure, and policy development to increase the capacity to manage research and build institutional linkages.
Government Partnerships for Development (GPFD)	> Where it is a priority agreed with partner countries, AusAID can also build institutional and national capacity through GPFD. > GPFD is a new competitive grants program which will facilitate partnerships between Australian public sector organisations and their counterparts to enable exchange of skills, experience and knowledge in support of Australia's aid program objectives. GPFD is expected to begin in 2013.

6. Results

AusAID will establish a robust monitoring and evaluation system. This system will enable results from implementation of the Medical Research Strategy to be fed into Australia's Comprehensive Aid Policy Framework including: its contribution to saving the lives of poor people in the Asia Pacific region; and its contribution to our Research Strategy's aim to build capacity to perform and use research in Australia and in our partner countries. Preliminary indicators are outlined in the following table.

Purpose	**Impact (more than 5 years)**		
AusAID will invest in medical research to save the lives of poor people in the Asia Pacific region.	Improved prevention, treatment and cure of priority diseases/health issues for poor people in the Asia pacific region. Use of, new or adapted products and/or processes, relating to priority diseases/health issues in the Asia Pacific.		
Objectives	**Inputs**	**Outputs**	**Outcomes**
AusAID will support medical research that removes or reduces the barriers to achieving priority health outcomes in the Asia Pacific in the shortest possible time.	AusAID enters (or varies) MOU to collaborate with partner donors and NHMRC to fund medical research. Number, and value of, investments in medical research in line with priorities.	Completion of: - late stage clinical trials - diagnostic & platforms development - operational & implementation research	Registration for patient use of new or modified product in the Asia Pacific region Adoption (e.g. guidelines) of the research findings by a priority country partner and/or multilateral body e.g. WHO.
AusAID will encourage innovation and collaboration, including by strengthening capacity and institutional links in the region.	Number, and value of investments, in: -scholarships -fellowships -core funding to research institutions - partnerships (under GPFD) which relate to medical research.	Increase in proportion of research funding allocated directly to partner country institutions Number of successful competitive grant applications from local research institutions Participants in research capacity development activities value and use new skills Awareness and use of AusAID funded research by users in partner countries	Partner country researchers using research skills. Strengthened partner country research institutes. Research evidence informs partner decisions.

AusAID will undertake a review of its investment in early 2014/15. This review will contribute to its consideration of future investments in medical research.

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[1] World Health Organization. World Health Statistics 2010.

[2] WHO, UNICEF, UNFPA and The World Bank. Trends in maternal mortality:1990 to 2010.

[3] UN Inter-agency Group for Child Mortality Estimation, Levels & Trends in Child Mortality: Report 2011.

[4]UNAIDS. Together we will end AIDS (2012).

[5] World Health Organization, *World Malaria Report 2011.*

[6] UNICEF, SOW 2009.

[7] Pierre Chirac, Els Torreele, 2006, Global framework on essential health R&D. *Lancet 2006*, **367**(9522):1560 - 1561.

[8] Program for Appropriate Technology in Health (PATH), Staying the Course? Malaria Research and Development in a Time of Economic Uncertainty (2011).

[9] William A Wells and Alan Brooks (2011). Adoption of new health products in low and middle income settings: how product development partnerships can support country decision making. Health Research Policy and Systems, **9** (15).

[10] Mary Ann Lansang, Rodolfo Dennis (2004). Building capacity in health research in the developing world. Bulletin of the World Health Organization, **82**(10):764-770.