

Contribution to global health

In the last century revolutionary advances in healthcare have helped to improve health and increase life expectancy. Yet ill health and disease continue to place a huge burden on society: from the AIDS epidemic in Africa and Asia, to the health needs of an ageing population in the developed world and the huge global growth in chronic diseases such as diabetes. Additionally, emerging diseases such as pandemic flu pose potentially serious threats. Ill health is also expensive, it can increase healthcare costs and reduce economic productivity.

Headlines

- Supplied 1.1 billion vaccine doses, of which 78 per cent were shipped for use in developing countries
- In 2007, GSK had products listed in 17 out of 27 therapeutic areas on the WHO Essential Medicines List
- Launched a major new treatment for breast cancer and a vaccine to help prevent cervical cancer
- Invested £3,327 million in R&D in 2007
- We have over 150 prescription medicines and vaccines in clinical development
- Created two new research Centres of Excellence
- Funded basic medical research to increase understanding of the human body and the impact of disease

Our business makes a significant contribution to society through the research, development, manufacture and marketing of products that address the medical needs of patients. How we respond to society's healthcare needs is the most important responsibility issue for GSK. It is also central to our commercial success. Our portfolio and product pipeline include medicines and vaccines for serious diseases prevalent in developed and developing countries, as well as health-related consumer products.

This section explains our approach to:

- Preventing disease: GSK is one of the world's largest vaccines businesses
- Treating ill health: our products treat some of the diseases that place a high burden on society
- Investing in R&D: our pipeline includes new medicines and vaccines that are needed in developing and developed countries
- Contributing to scientific understanding: we participate in partnerships that advance scientific knowledge and lay the ground for future medical advances

Our products are only beneficial if they are accessible and affordable to patients. This section of the report should be read in conjunction with [Access to medicines](#), which explains our efforts to increase access to our key products in developing and developed countries and the Community investment section (page xx) which summarises our work with communities to improve healthcare.

Preventing disease

Disease prevention can play a critically important role in reducing the global disease burden and the economic costs of ill health.

The value of vaccines

Vaccines play a major role in preventing disease and are the cornerstone of public health programmes around the world. Immunisation is acknowledged by WHO as being 'among the most cost-effective of health investments'¹.

GSK is among the world's top vaccine providers. We have over 30 vaccines approved for marketing and over 20 in our pipeline, one third of which target diseases particularly prevalent in the developing world. Over 1,500 scientists work in vaccine research at GSK and we believe our vaccine pipeline is the largest in the industry.

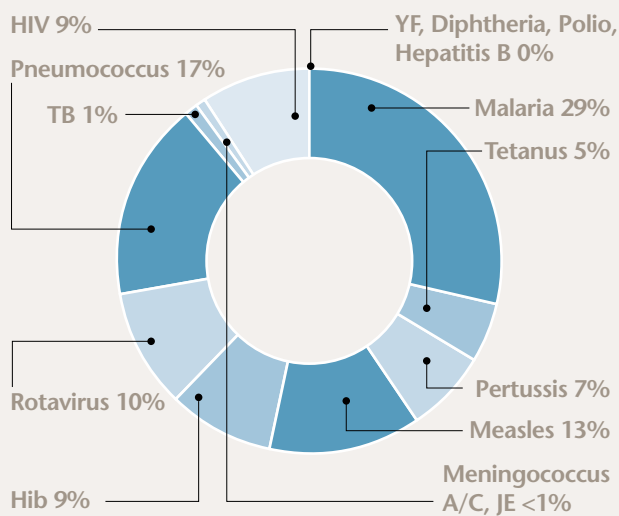
In 2007 we supplied 1.1 billion vaccine doses. Of these 78 per cent were shipped for use in developing countries. For more on our [tiered pricing system for vaccines](#), see page 41.

¹WHO fact sheet No. 208

Our vaccine portfolio

Our vaccine portfolio addresses the medical needs of developing and developed countries. GSK vaccines are included in immunisation campaigns in 169 countries worldwide. Our portfolio covers most of the leading causes of childhood mortality, as defined by the World Health Organization.

Deaths from infectious diseases in children under – five 2002



Source: World Health Report 2004: Data are the latest available (2002), 10.6 million total annual deaths in children under the age of five.

Our vaccine range includes products that protect against the following diseases:

- Cervical cancer
- Chickenpox
- Diphtheria
- Hepatitis A and B
- Influenza
- Measles
- Meningitis
- Mumps
- Polio
- Rotavirus
- Rubella
- Tetanus
- Typhoid
- Whooping cough (Pertussis)
- Pneumonia, otitis media and bacterial meningitis

Vaccination campaigns can play a very significant role in reducing ill health. For example, it is estimated that at least six million deaths are prevented and 750,000 children are saved from disability due to vaccines every year². The number of deaths in Africa from measles fell 91 per cent between 2000 and 2006 due to better coverage of routine immunisation programmes and targeted campaigns to ensure that children had a second chance to be vaccinated³.

However, despite this progress, it is estimated that the lives of over two million children could be saved each year if existing vaccines were made accessible to all who need them.

Disease awareness and education

Better disease awareness among healthcare professionals and the public can help to prevent ill health. We support patient education through our work with [patient groups](#) and through our own disease awareness campaigns. These campaigns are run around the launch of a new product. This can have a positive impact on public health and create commercial benefits for GSK.

For example, *Cervarix* is our vaccine against cervical cancer. It helps to prevent infection from the most common cancer-causing types of the Human Papilloma Virus (HPV) which can lead to cervical cancer. A year before we launched *Cervarix* in Europe, research in this region showed that as few as two per cent of women knew of the link between HPV and cervical cancer. We ran disease awareness campaigns across our International Region and in many European countries to highlight this link and educate people on the importance of screening to help prevent cervical cancer. The campaigns targeted healthcare professionals, media, policy makers and women through press articles, educational events for

healthcare professionals and support for cervical cancer patient groups and their activities, such as the European Cervical Cancer Prevention Week.

Rotarix is our vaccine against rotavirus, a leading cause of gastroenteritis infection. Rotavirus is associated with 25 million clinic visits, two million hospitalisations and more than 600,000 deaths worldwide among children under five every year⁴. Its launch in Mexico in 2004 and other Latin American countries was preceded by a widespread disease awareness campaign. To achieve this, GSK educated journalists about gastroenteritis infection caused by rotavirus, its causes and how to prevent it; for example through vaccination and how to detect its symptoms early. Rotavirus can quickly become fatal if a child becomes dehydrated and does not receive treatment. Our educational materials emphasise the importance of vaccination and give guidance on prompt detection and treatment methods.

²Ehret J. The Global Value of Vaccination. *Vaccine* (2003); 21 (7-8):596-600

All GSK-led disease awareness activities and campaigns are non-promotional and comply with our ethical marketing codes.

Other disease prevention work

Other areas of our work that contribute to better disease prevention include:

- **Smoking cessation** – smoking is a major public health problem, contributing to around five million premature deaths every year. Our nicotine replacement brands (including *NiQuitin CQ/NicoDerm*, *Commit lozenge* and *Nicorette*) have helped more than 6.3 million people stop smoking since 1996.
- **Community investment** – we are participating in the Global Alliance to Eliminate Lymphatic Filariasis, a leading cause of disability in tropical countries. Our PHASE hand-washing programme helps to prevent the spread of diarrhoea-related disease in children in developing countries. See page 112
- **Obesity** – obesity is a major cause of ill health and diseases such as diabetes. *alli* is our over-the-counter weight-loss treatment, see [page 67](#).

Treating ill health

Our key products target serious diseases in seven main areas:

- Anti-bacterials (antibiotics) and anti-malarials: infections, malaria
- Anti-virals: HIV/AIDS, herpes and hepatitis B
- Cardiovascular and urogenital: heart failure, hypertension, deep vein thrombosis,
- Central nervous system: migraine, epilepsy, depression and Parkinson’s disease
- Metabolic: diabetes and osteoporosis
- Oncology: breast, cervical, lung and ovarian cancer, non-Hodgkins lymphoma, leukaemia
- Respiratory: asthma and chronic obstructive pulmonary disease, rhinitis

We also make vaccines which prevent serious diseases, see page xx.

Our products help to improve health in a number of ways:

- **Prolonging life** – our anti-retrovirals (ARVs) such as *Combivir* help patients to control the effects of HIV infection for many years. We sell our ARVs to the Least Developed Countries and to countries in sub-Saharan Africa at not-for-profit prices. See [Access to medicines](#), page 40
- **Preventing complications** – many diseases such as diabetes are progressive – if patients do not receive the right treatment they can suffer severe complications. For example, every day in the US diabetes is the cause of an estimated 225 lower limb amputations, up to 66 cases of blindness, and 117 people experiencing kidney failure.

Avandia, our diabetes treatment, helps patients to control their symptoms, delays the progression of the disease and prevents complications. *Avandia* has now been used by more than seven million people worldwide. For our response to questions about *Avandia* see page 60.

- **Improving quality of life** – many of our medicines such as those for asthma and diabetes help patients with chronic diseases live full and productive lives. GSK preventative treatments for asthma such as *Seretide/Advair* control the symptoms of asthma and prevent asthma attacks
- **Curing infection** – we produce antibiotics that treat respiratory tract and other infections. We donate antibiotics to help relief efforts in disaster areas

The cost of disease

Ill health is expensive for the individual and for society. Ill health is often a result of poverty but it is also an important cause of poverty. For patients it can mean loss of quality of life, loss of earnings and shortened life expectancy. It can place a great burden on families – for instance the need to care for sick relatives can reduce attendance at school or work. For governments, employers and tax payers it can mean increased healthcare costs and loss of workforce productivity.

In Africa and parts of Asia, AIDS has had a serious effect on human and economic development, undermining progress towards the [Millennium Development Goals](#) and poverty reduction efforts. The World Bank estimates that the deaths of working age adults from HIV/AIDS may subtract one per cent a year from GDP economic growth in some sub-Saharan African countries. In South Africa HIV/AIDS may depress GDP by as much as 17 per cent over the next decade⁵. Malaria is estimated to cost African nations about \$12 billion a year in lost economic output⁶.

According to the US government’s Centers for Disease Control and Prevention (CDC) the costs of chronic disease in the US alone include⁷:

- \$132 billion a year in direct and indirect costs due to diabetes
- \$22 billion in annual medical care costs for arthritis and total costs (medical care and lost productivity) of almost \$82 billion
- \$129 billion in lost productivity due to cardiovascular disease

Vaccines and medicines have direct and indirect socio-economic values. They help to prevent

Continued on page 27

death, disease and disability, and improve quality of life for patients. They can reduce the burden on healthcare systems by preventing disease and helping patients to control their symptoms and make fewer visits to hospital. They can also contribute to better economic prosperity by enabling people with chronic diseases to work, reducing absence and increasing productivity.

³Progress in Global Measles Control and Mortality Reduction, 2000-2006 can be found at www.who.int/wer/2007/en

⁴Parashar UD, *et al* – Global illness and deaths caused by rotavirus disease in children. *Emerg Infect Dis* 2003; 9:565-72

⁵See WHO www.who.int/trade/glossary/story051/en/index.html. Accessed at November 2007.

⁶See www.millenniumpromise.org/site/PageServer?pagename=malaria_poverty. Accessed at November 2007

⁷See CDC, 'Chronic Disease Overview: Costs of Disease' available at www.cdc.gov/nccdphp/overview.htm. Accessed at November 2007

Investing in R&D

Despite advances in healthcare there are still many diseases for which there is no cure or for which treatments could be improved. Continued research and innovation is essential. Our investment in R&D into new medicines and vaccines is at the core of our business.

Research and development at GSK

The total R&D spend for GSK in 2007 was £3.3 billion. £2.8 billion was invested in pharmaceutical R&D with the remainder funding vaccine and Consumer Healthcare R&D.

We have over 150 prescription medicines and vaccines in clinical development (see our [Annual report](#)). Our pipeline includes research into many diseases including many forms of cancer, infections, respiratory diseases, autoimmune disorders, metabolic and cardiovascular disease, psychiatric disorders and neurological diseases.

Product approvals and submissions

New products approved for the first time in 2007 were:

- *Altabax* – topical treatment of bacterial skin infections including impetigo. *Altabax* represents the first new class of prescription topical anti-bacterials to be approved by the FDA in nearly two decades.
- *Cervarix* – our vaccine to help the prevention of cervical cancer
- *Daronrix* – a flu vaccine for use once a pandemic has been declared
- *Tykerb* – oral treatment for refractory breast cancer
- *Veramyst* – nasal spray for the treatment of allergic rhinitis in adults and children

Approvals were also received for a number of significant new indications and formulations for marketed products including:

- *Arixtra* – for the treatment of unstable angina and myocardial infarcts (acute coronary syndrome)
- *Requip modutab* – once-daily controlled release formulation for Parkinson's disease
- *Seretide TORCH* – for use in a broader population of patients with the lung disease COPD

Over 15 first submissions for new products and product line extensions were made in 2007. Notable first submissions included:

- *Promacta* – for the treatment of short-term idiopathic thrombocytopenia purpura
- *Volibris* – for the treatment of pulmonary hypertension
- Oral *Hycamtin* – for second-line treatment of small cell lung cancer
- *Lamictal* – oral disintegrating tablets for the treatment of epilepsy and bipolar disorder
- Flu pandemic and flu pre-pandemic, both prophylactic vaccines for the prevention of pandemic influenza
- *Kinrix* – a paediatric booster vaccine
- *Synflorix* – a vaccine for the prevention of childhood infections such as bacterial meningitis, otitis media and pneumonia

Of course, R&D is an inherently risky venture. Only one in ten molecules that start human clinical trials ever reaches regulatory approval. Late stage projects terminated during 2007 included *Ariflo* for COPD and *odiparcil* for stroke prevention in atrial fibrillation.

Late stage pipeline continues to grow

In 2007, five products moved into the Medicines Development Centres from Drug Discovery. All these products have completed clinical proof of concept studies by this stage; *solabegron* for irritable bowel syndrome, *totrombopag* for thrombocytopenia, *darotropium* (233705) for chronic obstructive pulmonary disease, 742457 for dementia and 773812 for schizophrenia. Five further products were in-licensed to late-stage development; 1838262 (XP13512) for restless leg syndrome, *otelixizumab* (TRX4) for type 1 diabetes, *elesclomol* (STA-4783) for metastatic melanoma, 1363089 (XL880) for cancer and *Lunivia* for insomnia.

Expanding our research capabilities

We have created two new research Centres of Excellence for Drug Discovery (CEDD) to focus on areas where there are emerging scientific opportunities. The Infectious Diseases CEDD will help us to build on our long tradition of providing anti-virals and anti-bacterials. The Immuno-inflammation CEDD will research disease pathways that are common to a number of auto-immune diseases and may be important in various other diseases.

We opened a new R&D facility in China which will focus on R&D into neurodegenerative disorders such as Parkinson's disease, multiple sclerosis and Alzheimer's disease. [See page 61.](#)

We invest in technology with the potential to extend our research into new areas. For example, in 2007 we acquired a biopharmaceutical company called Domantis, which is helping us build the next generation of antibodies called domain antibodies. We also acquired Praecis, a small company of dedicated experts skilled in expanding chemical libraries to boost our compound collection.

Contributing to scientific understanding

We fund basic medical research conducted outside GSK to increase understanding of the human body and the impact of disease. This is often the foundation for future advances in the diagnosis, treatment and prevention of disease. Often this research is conducted in partnership and uses very new technologies. Recent examples include:

Investing in new imaging technology

We have invested £46 million in a new Clinical Imaging Centre (CIC) at Imperial College, London. Modern imaging technology provides a 'window' to study in fine detail disease processes. Researchers use the CIC to develop new medicines across a broad range of diseases including cancer, cardiovascular disease, and psychiatric and neurological disorders. The CIC has been established in partnership with the UK government, Imperial College and the UK Medical Research Council. We will invest an additional £11 million in the centre every year for the next ten years.

Structural Genomics Consortium

We are a sponsor of the Structural Genomics Consortium (SGC) – an international public-private partnership established to determine and make freely available the structures of proteins relevant to human disease. Through the SGC, 165 scientists at universities in Oxford, Toronto and Stockholm have placed more than 500 structures of proteins into the publicly accessible World Wide Protein Data Bank. This includes proteins associated with diabetes, cancer and infectious diseases such as malaria.

Stem Cells for Safer Medicines

GSK is participating in the Stem Cells for Safer Medicines public-private collaboration with the UK government and other pharmaceutical companies. The consortium is researching the potential for using human stem cells to evaluate the effect of a potential new medicine in the body and accurately predict its safety. This project has the potential to help scientists determine the safety of new medicines earlier in the research process and reduce the need for animal testing.

Serious Adverse Events Consortium (SAEC)

We are members of the newly launched SAEC, an international partnership of leading pharmaceutical companies, the FDA, and academic institutions addressing patient safety and

drug-related side effects. See [Research practices](#) for more information.

Academic collaborations

We invest in research capabilities at universities, fund leading edge academic research projects and support science students. We have more academic collaborations than any other UK-based company with support totalling £16 million in 2007.

Our support benefits the academic institutions through increased funding, technology transfer and access to our research facilities and expertise. It contributes to better scientific understanding and a stronger science base in the countries where we operate. It also benefits GSK by enabling us to tap into R&D expertise and activity outside the company and expands our potential recruitment pool through better trained scientists.

Our support in 2007 included:

- Alliances with discovery units at leading universities to help accelerate drug discovery. For example, we have invested over £10 million to support research at 14 leading UK universities
- A partnership with the Wellcome Trust to train clinicians in translational medicine (translating basic medical research findings into treatment advances)
- A collaboration with the UK Engineering and Physical Sciences Research Council to help researchers acquire advanced chemistry techniques
- Financial support for 300 undergraduate, PhD and post doctoral students in the UK
- Training in GSK laboratories for undergraduates

We also support research in middle-income countries. For example, the INDOX Cancer Trials Network is a collaboration between the University of Oxford and India's top six cancer centres, supported by an educational grant from GSK. By 2020, 70 per cent of all cancer cases will be in middle-income and developing countries and a quarter of these will be in India. The collaboration aims to recruit and retain the highest calibre medical graduates into oncology research through funding research and providing educational opportunities.

The intellectual property rights relating to academic collaborations are typically held by GSK but our partner institutions are free to use the outcome of the collaboration for their own future research. The university also receives a percentage of any financial returns derived from the new intellectual property.

The future

R&D productivity is a major strategic focus for GSK. We anticipate a renewed focus in a number of areas, including oncology (cancer) and vaccines. We have committed to deriving 20 per cent of our pipeline from biopharmaceuticals (large molecules produced in cells) by 2015 and will continue to focus on neurosciences, which will become increasingly important as the population ages.

Helping to manage chronic diseases in the US

Healthcare costs in the US are a concern for patients, healthcare payers and the pharmaceutical industry alike. The increase in prevalence of many chronic diseases such as asthma, diabetes and heart disease is a major contributory factor.

We are working with governments and employers to find new ways to address the problem of chronic diseases while reducing healthcare costs. Our approach, known as the 'triple solution', has three focus areas:

- Prevention – addressing the causes of chronic diseases, such as obesity and smoking
- Intervention – properly managing chronic diseases to prevent complications, avoid hospitalisation costs and reduce time away from work
- Innovation – developing new treatments for costly unmet medical needs such as Alzheimer's disease and stroke (see page x)

Our current programmes include:

The Diabetes Ten City Challenge

Each day in the US, diabetes causes an estimated 225 lower limb amputations and up to 66 people to lose their sight. However with the right treatment these complications can be prevented.

The Diabetes Ten City Challenge, supported by GSK, is a partnership of city governments and private employers in ten cities, the American Pharmacist Association (APhA) Foundation, and pharmacists. It helps employees with diabetes manage their condition through nutrition and medication and by adopting a healthy lifestyle. It aims to prevent serious side-effects and reduce associated healthcare costs.

Key features include:

- Lower co-pays (the portion of prescription costs paid for by the patient) this makes medicines more affordable and makes it more likely that patients will adhere to their prescribed treatment regimen
- Regular meetings between patients and pharmacists to discuss symptoms and identify any potential complications as early as possible

- Help for participants to set and achieve nutrition, exercise and weight loss goals through printed materials and meetings with pharmacist coaches

The programme is based on the APhA Foundation's Asheville Project, which helped reduce healthcare costs for participating employees by over 34 per cent and cut absenteeism by 50 per cent on average.

Findings and resources are being shared with other employers outside the ten cities through a dedicated website.

Working with employers

In the US, healthcare is a major source of expenditure for employers. Absence from work due to ill health can also be a significant cost. We are working closely with many large employers across the US to help them create health management programmes that remove barriers to healthcare access, reduce healthcare costs and improve health.

Our team has worked with more than 200 employers to:

- Identify diseases that put the greatest burden on healthcare budgets
- Encourage employers to provide preventive services to workers. For example regular health screening to detect early signs of disease awareness campaigns and initiatives to help employees adopt a healthy lifestyle such as 'quit smoking' clinics and gym membership
- Develop disease management programmes which help employees control their symptoms and stick to their treatment regimens

We may advise employers to create new incentives for better health management; for example, reducing the co-pay element of prescription medicine charges. This can increase the total amount employers pay for pharmaceuticals in the short term. However, by improving patient medication adherence rates, it can prevent costly complications and time away from work in the longer term – and help to lower overall healthcare costs.



What factors do you consider when prioritising your R&D efforts?

There are three main interrelated factors – science, patient need and commercial potential.

We assess scientific opportunities to determine how advances in scientific and disease understanding may lead to innovative new ways to treat or prevent disease. We continually evaluate the scientific information we obtain on our compounds to help us predict whether they can be developed into effective and well tolerated medicines.

Assessing patient need is fundamental to R&D at GSK. It ranges from looking for medicines that will treat diseases for which there are no current effective treatments, to the development of medicines that improve on existing treatments in terms of safety, efficacy or ease of use.

Our assessment of the commercial potential of possible new treatments includes: how our product would be differentiated from those of our competitors; the size of the potential market for any new treatment; and the range of conditions it may be suitable for treating.

The better able we are to meet patient needs, the more likely it is that a product will be commercially successful. However, it is not always possible to achieve a return on investment, for example when developing treatments for diseases that are prevalent in the developing world. In some cases, where commercial potential is limited but patient need is high, we may seek ways to share the costs and risks associated with drug development, see [Access to medicines](#).

Are you researching drugs into serious diseases?

Yes. Our pipeline and product range includes products against most of the major causes of mortality and morbidity (disease).

Our product launches in 2007 included *Tykerb* our new breast cancer treatment, and *Cervarix* our cervical cancer vaccine. Our top-selling products in 2007 were designed to treat asthma and chronic obstructive pulmonary disease, epilepsy and bipolar disorder, diabetes, herpes and migraine. Our vaccines portfolio which includes vaccines to prevent influenza, hepatitis, rotavirus and many childhood illnesses such as measles and rubella, is also growing very strongly.

How do you measure R&D productivity?

The ultimate measure of our productivity is the delivery of new medicines to meet patients' needs. In 2007, GSK launched five products based on new chemical or biological entities and a number of product line extensions that benefit patients. However, given that research and development can take longer than ten years, we measure productivity in a number of ways during the R&D process, including:

- The number of compounds in our pipeline, and the emerging risks and benefits of these compounds
- Our success at progressing compounds in our pipeline through clinical trial Phases I, II and III and to market registration
- The speed of progress through our pipeline, which is an indication of the efficiency of our R&D processes.

Is it true that research productivity is falling in large pharmaceutical companies? How is GSK managing this?

Investment in pharmaceutical R&D has risen while the number of new medicines gaining regulatory approval has remained relatively constant or decreased. We believe there are many reasons for this including:

- An increasing focus on R&D into chronic degenerative diseases such as Alzheimer's which are scientifically challenging, require longer clinical trials and have increased failure rates
- Significant investment by industry in new technologies which will help deliver innovative medicines in the longer term, for example systems biology tools, genome wide association scans, new *in vitro* and *in vivo* models and sophisticated imaging equipment
- More extensive requirements from regulators and healthcare payers including the need to conduct larger clinical studies to evaluate the long term outcome of treatment with a medicine

Our approach is to focus on meeting patients' needs and increasing the effectiveness and efficiency of R&D. For example, we have established a number of Centres of Excellence for Drug Discovery (CEDDs) and Medicine Development Centres each focused on discovering innovative medicines for a particular therapeutic area. These organisations combine the entrepreneurial approach of a small company with the resources and reach of a larger organisation. In 2007 we established two new CEDDs to focus our work in immuno-inflammation and infectious diseases. We take advantage of scientific excellence and talents outside GSK through scientific partnerships and collaborations, such as through the Centre of Excellence for External Drug Discovery (CEEDD).

Links

In this report:

- [Access to medicines](#)
- [Research practices](#)
- [Community investment](#)

On our website

- [Our products](#)
- [Our pipeline](#)
- [Our annual report and accounts](#)

Other resources

- Centers for Disease Control and Prevention www.cdc.gov
- Diabetes Ten City Challenge www.aphafoundation.org/Programs/Diabetes_Ten_City_Challenge/
- GAVI www.gavialliance.org
- World Health Organization www.WHO.int
- UNICEF www.unicef.org/