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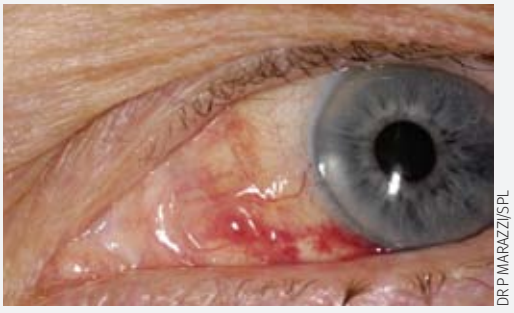
- Novartis takes legal action over trusts' advice to use bevacizumab for wet AMD (*BMJ* 2012;344:e2959)
- Bevacizumab as adjuvant therapy for lung cancer does not help patients over 65 (*BMJ* 2012;344:e2855)
- FDA cancels approval for bevacizumab in advanced breast cancer (*BMJ* 2011;343:d7684)
- Potential withdrawal of bevacizumab for the treatment of breast cancer (*BMJ* 2011;343:d4946)

WHY USING AVASTIN FOR EYE DISEASE IS SO DIFFICULT

Using bevacizumab rather than ranibizumab for wet age related macular degeneration could save substantial sums. But, as **Ingrid Torjesen** reports, the drug company is fighting to protect its profits

RANIBIZUMAB AND BEVACIZUMAB: A COMPLEX STORY

When were they licensed?
Bevacizumab (Avastin) was licensed as a cancer treatment in 2005. Ranibizumab (Lucentis) was licensed for the treatment of age related macular degeneration (AMD) in 2007. Both treatments were developed by Genentech, which was bought by Roche in 2009. Novartis holds the license to sell ranibizumab outside the US. Novartis retains data exclusivity for ranibizumab until 2015.


DR P MARAZZI/SPL

A 72 year old patient with AMD after a Lucentis injection

Why is bevacizumab the cheaper drug?
The dose required for intravenous use in cancer treatment is much larger than that used for intravitreal injection in AMD, which brings the price down. The cost per injection for AMD is about 12 times lower than that for ranibizumab.

What needs to happen for a drug to be available for a specific indication in the UK?
Drug companies must submit their drug for licensing to the MHRA, which decides whether it is effective and safe. A third party can apply for a licence for a generic or biosimilar version but must either wait for the company's exclusive rights to the data to elapse or provide its own preclinical and clinical data. For a drug to be appraised by the National Institute for Health and Clinical Excellence (NICE), it must be referred by the Department of Health. Health commissioners in the UK can still allow the use of a drug even if it is unlicensed for a particular indication and NICE hasn't recommended it. This is what Southampton City, Hampshire, Isle of Wight and Portsmouth City PCT has done in the case of bevacizumab.

What are the key clinical trials for these drugs?
The Comparison of Age Related Macular Degeneration Treatment Trials (CATT) in the US is funded by the National Eye Institute. The first year CATT results were published last May and suggested that bevacizumab and ranibizumab are equally effective. Second year results will be published this month. Also this month comes first year data from another major trial, the Inhibit VEGF in Age Related Choroidal Neovascularisation (IVAN) trial in the UK.

Ranibizumab (Lucentis) and bevacizumab (Avastin) are both commonly used to treat wet age related macular degeneration (AMD) in the United Kingdom. Many primary care trusts, which pay for treatments in England, see little difference between them, other than the price: ranibizumab costs around 12 times more than bevacizumab.[1]

But Novartis insists there are subtle and important differences between them in terms of effectiveness and safety, and, most importantly, ranibizumab is licensed for wet AMD and is recommended by the National Institute for Health and Clinical Excellence (NICE), whereas bevacizumab is not. Some cynics might describe it as clever marketing.

Both drugs were developed by Genentech, which is now owned by Roche. They are derived from the same antibody and work by blocking vascular endothelial growth factor (VEGF) to slow down or stop abnormal growth of blood vessels. Bevacizumab was developed as an anticancer drug and licensed in Europe in 2005. Ranibizumab was licensed for macular degeneration in 2007

Roche holds the licence for bevacizumab and in the US sells ranibizumab via Genentech. Outside the US Novartis manufactures and holds the licence for ranibizumab.

Before ranibizumab was licensed, ophthalmologists realised that bevacizumab was likely to have the same effect and some started using it off-label for wet AMD.

With primary care trusts under financial pressure, an increasing number are considering allowing ophthalmologists to use the cheaper bevacizumab for wet AMD, a move that would affect Novartis's profits dramatically.

Novartis argues that ranibizumab is the more effective and safer product for the indication and points out that there are potential repercussions for doctors and hospitals using bevacizumab off-label rather than ranibizumab, which NICE recommends. Much of this argument is delivered through sponsored meetings and interactions between individual company representatives and ophthalmologists, primary care trust (PCT) staff, or journalists.

And with the imminent move to clinical commissioning groups, Novartis is beginning to target general practitioners who will be holding the purse strings with educational meetings on commissioning in ophthalmology. One is due to be held in London on 14 June.

Independent evidence

Two major non-pharmaceutical company funded trials comparing bevacizumab and ranibizumab are currently underway to clarify whether ranibizumab is really more effective and safer: the Comparison of Age-related Macular Degeneration Treatments Trials (CATT) in the US funded by the National Eye Institute, and the Inhibit VEGF in Age-related choroidal Neovascularisation (IVAN) trial in the UK funded by the Health Technology Assessment Clinical Trials programme of the UK National Institute for Health Research.

The first year results from CATT, published last May, suggest that bevacizumab and ranibizumab are equally effective. Novartis highlighted that the two drugs had different side effect profiles, with a higher risk of stroke and death with bevacizumab.[2] The second year CATT data and first year IVAN data will be unveiled at the Association for Research in Vision and Ophthalmology meeting in Florida in May. In preparation Novartis is briefing key journalists. In April it held a media roundtable to recap the CATT first year data and IVAN trial design and discuss implications for interpreting the final results of these trials.

Legal challenges

The board of North Yorkshire and York PCT has been discussing allowing use of bevacizumab for some time,[3] but, aware that such a decision is likely to elicit a legal challenge from Novartis, in January its board decided to await the outcome of the IVAN and CATT trials.[4] If it does give the green light to bevacizumab, it is likely to create difficulties for some providers. York Teaching Hospital NHS Foundation Trust has received funding from Novartis for a mobile eye unit for patients on the east coast of Yorkshire, so that patients do not have to make an 80 mile round trip to York Hospital once a month for their ranibizumab injections.[5]

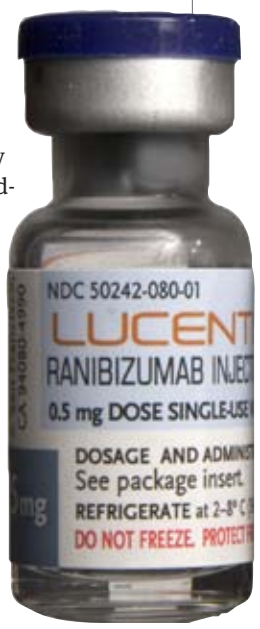
And North Yorkshire and York is right to be wary. Novartis has stared judicial review proceedings against SHIP PCT cluster, which is made up of Southampton City, Hampshire, Isle of Wight and Portsmouth City PCTs, after it agreed in September 2011 to allow ophthalmologists the option of prescribing bevacizumab.

Elsewhere, a meeting organised with ophthalmologists by a PCT in Hertfordshire to discuss the potential use of bevacizumab was followed by a call the next day from a Novartis representative to check that ranibizumab was still the only drug being funded. Two weeks later the Royal National Institute of Blind People, a patient organisation with links to Novartis, made a Freedom of Information request asking whether bevacizumab was commissioned for wet AMD. The accounts for the RNIB show that it received £851 000 (€1m; $1.4m) from Novartis in 2010-11. In September 2011, the RNIB's policy and campaigns manager Barbara McLaughlan joined Novartis as national cancer policy lead.

But even when PCT clusters allow the use of bevacizumab, it does not mean that ophthalmologists will do so. While some may happily use bevacizumab for private patients, who benefit from the cost saving, they are reticent to use it off-label for NHS patients.

A paper issued by the Royal College of Ophthalmologists in December last year concluded that both bevacizumab and ranibizumab "are equally effective in the treatment of AMD and have a similar safety profile."[1] But both the college and patients' representative organisations back the use of ranibizumab for wet AMD because it is licensed and approved by NICE.

James Talks, a consultant ophthalmologist at Royal Victoria Infirmary in Newcastle and a member of the college council says: "From a lot of doctors' point of view, the effectiveness evidence appears very similar, but then you are then trying to persuade the patient that they should have a treatment that is not the NICE approved one. Essentially it is a cheaper drug, but there isn't really any benefit from the individual patient's point of view, it is a benefit from the community point of view. Doctors want reassurance that it is not going to come back to haunt them."



Novartis is keen to point out the medicolegal pitfalls for both doctors and hospitals of opting to use an off-licence drug instead of one that is licensed and recommended by NICE. Last May, it held a meeting

on establishing safety and examining the medicolegal implications of unlicensed prescribing.

The current General Medical Council guidelines, *Good Practice in Prescribing Medicines*, state that in order to use a medicine off-label doctors must "be satisfied that it would better serve the patient's needs than an appropriately licensed alternative." These guidelines are being revised, and one of the proposals is to allow doctors to take the cost of the medicine into account for the benefit of the wider health system. Publication has been delayed repeatedly and is now expected in June, but without the controversial chapter on off-label and unlicensed prescribing, on which the GMC is seeking legal advice.

"A PCT meeting to discuss bevacizumab was followed by a call the next day from a Novartis representative to check that ranibizumab was still the only drug being funded"

Talks adds that even revised GMC guidance will not resolve the issue completely: "The hospital doesn't want to get sued because someone gets an infection using something that is against the current NICE guidance. It is probably very unlikely, but it is possible. The process of manufacture, the process of distribution, is not the same as it would be for a licensed product."

Infection is a risk whenever any drug is injected into the eye, but Novartis argues that the risk is greater with bevacizumab because it distributes it in quantities that are much too large for injection. Special compounding pharmacies have to split it into smaller dose, and this process increases the infection risk. There have been cases in Florida linked to a compounding pharmacy and outbreaks at two Veterans Affairs hospitals in the US. In the UK, Moorfields Pharmaceuticals was forced to recall batches of bevacizumab in March after suspected cases of sterile endophthalmitis.[6]

In the wake of the Moorfields incident the European Alliance for Access to Safe Medicines, a patient safety group that receives funding from Novartis,[7] stated there was an urgent need to address patient safety around the use of unlicensed and off-label medicines, which should be used only when there is no licensed product available.

Pricing pressure

Helen Jackman, chief executive of the Macular Disease Society, says there is anecdotal evidence that when patients pay for wet AMD treatment privately, they are usually happy to have bevacizumab rather than ranibizumab, but she emphasises that the NHS should be using ranibizumab because it has been fully appraised and licensed.

"There are a number of conditions that ranibizumab is not available for—diabetic macular oedema, retinal vein occlusion, and so on—and we are quite happy to support patients to try to receive bevacizumab for those conditions," she says.

Novartis is understood to be in discussion with the Department of Health and NICE about lowering the price of ranibizumab in exchange for recommendation by NICE for a wider range of indications. Such a deal would certainly be in Novartis's interest given that, in the UK, there are around 100 000 patients a year with diabetic macular oedema compared with 20 000-25 000 with wet AMD.[8] Last year NICE decided it could not recommend ranibizumab for diabetic macular oedema because it was too expensive. In October last year Novartis cut the cost of ranibizumab in Switzerland by 30%.[9]

"We know how cash strapped PCTs are at the moment and ranibizumab is an expensive treatment. If the Department of Health or NICE or whoever can come to an agreement with Novartis that lowers the cost of ranibizumab and makes it available to a wider set of indications and those patients could benefit, we would strongly urge the department to pursue those discussions with energy," Jackman says.

The imminent launch of another more competitively priced VEGF blocker may make a price cut more likely. Aflibercept, codeveloped by Bayer and Regeneron Pharmaceuticals, was licensed in the US for wet macular degeneration in November last year. In the US, it costs $1850 per dose versus $2000 for ranibizumab. However, as aflibercept requires bimonthly injection rather than monthly, the annual cost of aflibercept is estimated to be $16 000 compared with $24 000 for ranibizumab.[10]

In 2010 the Department of Health asked NICE to explore the feasibility of appraising bevacizumab for wet AMD. NICE concluded that a technology appraisal would be possible if the Department of Health referred it and the Medicines and Healthcare Products Regulatory Agency (MHRA) did an assessment of safety and quality.[11] Both the Macular Disease Society and the Royal College of Ophthalmologists have urged the Department of Health to refer bevacizumab for appraisal,[1 12] but it has not.

Jackman says: "This could potentially set a difficult precedent in terms of being a sort of backdoor approach to the regulation of medicine, which you know is not something that would necessarily be a good thing. Talks agrees, adding that the department "wants pharmaceutical company investment in this country; we are losing a lot of it as it is."

So could another body refer bevacizumab to NICE? Not unless it is licensed, and Roche is unlikely to submit an application to the MHRA for wet AMD.

"An application (generic/biosimilar) by an independent third party referring to bevacizumab may not be accepted until the 10 years' data exclusivity period for bevacizumab has elapsed," a spokesman for the MHRA said. "In the interim, should a third party wish to apply for a product containing the active substance bevacizumab, the applicant would be required to submit results of their own pharmaceutical, preclinical, and clinical data to fully support their application."

By the sound of it, unless the Department of Health is successful in pushing for a lower price for ranibizumab, we may have to wait until after 2015 to see a really competitively priced anti-VEGF for wet AMD licensed and recommended to the NHS.

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Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

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Cite this as: *BMJ* 2012;344:e3012

BMJ Group Improving Health Awards In association with MDDUS

Technological approaches to improving care

Kathy Oxtoby introduces the individuals shortlisted for the Transforming Patient Care using Technology award

Advances in technology are transforming health services, with innovators constantly coming up with new ways to use information technology in primary and secondary care. But for an innovation to be outstanding, it should get to the heart of problems faced by healthcare providers— such as patient safety and accuracy of results. At a time when service providers are being required to cut costs, schemes also need to be cost effective and improve efficiency.

Nottingham wireless working system for out of hours care

Concerns about out of hours hospital care are usually communicated through pagers and landline phones. But this approach can result in long delays, and the noise from phone calls and bleeps disturbs other patient on the wards.

To tackle these difficulties, Nottingham University NHS Trust has introduced a wireless communication system that works across ward desktop computer, a tablet computer held by the hospital at night coordinator, and mobile phones held by the junior doctors.

Nurses log a job on to the ward computer and send details to the night coordinator, who forwards them to a smart phone held by a doctor. "The beauty of this unique system is that a server stores all the job details so staff know if a job is urgent or complex, and it's given us a real insight into exactly what happens in the hospital out of hours," says Dominick Shaw, associate professor at the University of Nottingham and Nottingham University NHS Trust.

Met Office Healthy Outlook alert service

To help people with chronic obstructive pulmonary disease cope with the effect that extreme weather conditions can have on their health, the Met Office has developed a forecast alert service. Those who sign up to the Healthy Outlook service, which is funded by individual primary care trusts, receive a patient pack that contains advice about how to keep well.

When the weather conditions may pose greater risks for their health, the alert service reminds patients of this advice via a recorded telephone call from the Met Office.

More than 21 000 people with chronic obstructive pulmonary disease have used the Healthy Outlook service, and feedback has been positive. Results from 30 primary care trusts showed a 20% average reduction in hospital admissions. In a survey of 3000 patients taking part in the scheme, 90% reported finding it useful, while 36% requested repeat prescriptions in response to receiving a Met Office alert call.

Patrick Sachon, business manager for health at the Met Office says, "We're not looking to make large profits—we're looking to keep people well."

Oxford University Hospitals electronic laboratory medicine communication system

Mislabelling of specimens causes problems for the NHS, such as delays in treatments. To minimise the risk of mislabelling, staff at Oxford University Hospitals NHS Trust have designed a communications system for laboratory medicine orders that allows staff to identify patients by barcode scanning their wristbands and to print specimen labels from the bedside.

Doctors, nurses, or phlebotomists use a workstation on wheels, which they take to the patient. These workstations include a laptop, which has access to the trust's electronic patient record (EPR) system, a wireless specimen label printer, a barcode scanner, and specimen tubes and bags. Staff scan patients' wristbands, which opens up their electronic patient record. They then check the specimen request, print out labels, and collect the specimen.

The system, which on peak days processes some 1500 requests, has removed the need to write request cards by hand and the associated clinical risks of transcription errors and illegible handwriting.

John Skinner, EPR programme director for the trust, adds: "We wanted to achieve a gold standard for positive patient identification, and this whole process has been about improving patient safety."

Barts and The London NHS Trust Cardiac Recovery from Operation Quality Assessment System (C-ROQAS)

Robust systems are required to help ensure cardiac surgery patients recover safely after their operation.

Barts and The London NHS Trust has developed C-ROQAS (Cardiac Recovery from Operation Quality Assessment System)—a database designed to predict the normal progress of a patient's recovery after cardiac surgery and flag up when individuals are not recovering as expected so that staff can quickly respond to their needs.

The system takes into consideration preoperative morbidity and the type of operation. Patients' details are entered at the time of their surgery, and a member of the ward round team records their progress every day after surgery.

If a patient is not progressing as expected, doctors can identify problems by looking at data about others who have had cardiac surgery at the trust—nearly 1000 since the scheme began18 months ago. The information is being used to audit practice; it has helped reduce the length of patient stay and resulted in savings of almost £82 000. The system could also be developed for use in other specialties.

But David McCormack, a specialist registrar in cardiothoracic surgery says, "It allows us to intelligently look at what happens to patients after surgery, minimise risks, and optimise care."

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Cite this as: *BMJ* 2012;344:e2936

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What will a doctor bring to the World Bank?

A popular public health doctor has been appointed to the hotly contested position of president of the World Bank. **Bob Roehr** looks at his credentials and what is expected of him

ERALDO PERES/AP/PA

Why the World Bank matters

What is commonly referred to as the World Bank is technically a handful of agencies whose primary focus has become helping developing countries through technical assistance, low interest or interest free loans, and grants.

It works with governments, non-governmental organisations, and the private sector.

Capital comes from assessments paid by wealthier nations, the repayment of loans, and agreements with charities such as the Bill and Melinda Gates Foundation.

Kim faces at least three major challenges:

Maintaining the financial commitment of developed nations, which are in the midst of economic recession, slow recovery, and budgetary austerity.

Integrating emerging economic powerhouses led by Brazil, Russia, India, and China into the financing and governance of the bank and its development activities.

Shaping development strategies that are environmentally sound, sustainable, and embraced by the developing nations and their governments.

These will affect progress towards meeting the millennium development goals and funding more focused activities such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Jim Yong Kim, announced last week as the new president of the World Bank, is the first doctor to lead the large development agency. While it continues the hegemony of an American at the head of the nearly 60 year old organisation, in many other ways it represents an important change from what has gone before.

"The World Bank is more than just a bank. It's one of the most powerful tools we have to reduce poverty and raise standards of living in some of the poorest countries on the planet," said US president, Barack Obama. "Nobody is more qualified to carry out that mission than Dr Jim Kim."

Kim, 52, was born in South Korea and came to the US with his parents at the age of 5, growing up in the middle of the country in Iowa. A graduate of Brown University, he earned both a medical degree and a PhD in anthropology from Harvard University. He taught at the Harvard Medical School and School of Public Health before becoming president of prestigious Dartmouth College in 2009. He was elected to the US Institute of Medicine in 2004.

Much of Kim's career has focused on diseases of the developing world. He created a model programme to treat drug resistant tuberculosis in Peru. And he coordinated the HIV/AIDS programme at the World Health Organization during a campaign to ramp up access to antiretroviral drugs.

Kim cofounded the non-profit organisation Partners in Health with Paul Farmer and other Harvard colleagues. The organisation pioneered delivery of advanced healthcare to impoverished, rural communities in the developing world, such as Haiti, by working with local residents and officials.

Kim was the operational brains of Partners in Health, which has now grown to 13 000 employees worldwide. "He's sort of a natural executive in a certain way that Paul Farmer is not. Farmer is a saint and a visionary. But Jim could see the vision and turn it into action," is how surgeon and public scholar Atul Gawande described it to *Washington Post* columnist and blogger Ezra Klein.

Kim may be driven, but he is not rigid. He is amicable, does not take himself too seriously, and is remarkably willing to adapt to his environment—an extreme example being the rap video he made at Dartmouth as one way of connecting with its students.

Contested election

Kim was a late entry into the race to become president of the World Bank. Two candidates had already come forward, the Nigerian finance minister Ngozi Okonjo-Iweala, who had served as the bank's managing director, and former Columbian finance minister Jose Antonio Ocampo. Both have fine credentials in the developing and middle income world.

This first contested election was a challenge to the tradition that reserved the bank presidency for an American while its sister organisation, the International Monetary Fund, is headed by a European. The US is the largest shareholder in the bank and voting power is allotted by contribution.

"The bank is not doing a terrible job on health, but it is not doing as good a job as it needs to be doing"

Jim Yong Kim "does not take himself too seriously" as this You Tube clip of him (above) as a rapping spaceman at a college event shows

But Kim's résumé, coupled with a whirlwind tour of global capitals, quickly lined up support from Japan, Russia, Mexico, and other major players. "I am not a politician. I come to this as a development expert," Kim said at his last stop in Peru. "I am very eager to have a discussion about increasing the voice of developing nations."

The bank formally announced his selection on 16 April without any details on how the 25 member governing board voted. In June, Kim will assume leadership of the bank and its affiliates.

Health and development

"Health is now seen as essential to development strategies," part of the investment in human capital, said Andy Haines, a professor at the London School of Hygiene and Tropical Medicine. Twenty years ago health expenditures were deemed to be a drag on growth that should be deferred.

But Haines believes health has remained "a little bit of a side issue at the bank." He called Kim's selection "a real acknowledgement that health is now centre stage. [It is] a tremendous opportunity for Jim to ensure that the bank puts human health and welfare at the centre of development, and not just economic growth."

"The bank is not doing a terrible job on health, but it is not doing as good a job as it needs to be doing," said Katie Malouf Bous a policy adviser on education and health in the Washington office of the international development organisation Oxfam.

She noted that Kim has worked in very fragile states and experienced first hand the multidimensional complexities of poverty, with health often at its centre. "He has been an activist working for change in those difficult and unstable situations. I don't think you can beat that kind of first hand experience."

Bous hopes that Kim's appointment will give health concerns "a shot in the arm" and help cut through some of the layers of bureaucracy at the bank.

"Our priority is to see the bank move more proactively in removing user fees" as an element of financing healthcare, said Oxfam policy adviser Elizabeth Stuart. While the bank has agreed to this in principle, it often ignores it in practice.

"It needs to spend more time looking for solutions" and offer examples that are tailored to the needs of individual countries. She said the bank's series of case studies on education, and how user fees have been successfully removed, provides a good model of what should be done for health.

International AIDS activist Gregg Gonsalves called Kim "Outstanding. He has the potential to be transformative for millions of people living in poverty and sickness around the world and for those of us who care about human rights and social justice."

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Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* 2012;344:e2921

BMJ.COM BLOGS **Gabriel Scally**

Flying doctors and Sylvia Pankhurst

The Flying Doctors Service of East Africa sounds like an echo from a romantic, and bygone age.

But its formation in 1957 was the first step in the creation of a major African health development organisation that has been given the World Federation of Public Health Associations' Institutional Award at the 13th World Congress of Public Health in Addis Ababa.

The African Medical and Research Foundation (AMREF) works in the remotest communities and works alongside those communities to build the knowledge and skills to transform their own health, how it provides training every year to more than 10 000 health professionals, and how it set up the international campaign Stand Up for African Mothers with its demand that no woman should die giving life. Oh, and it still provides a flying doctor and emergency evacuation service over much of eastern and central Africa.

One of the proud boasts of Ethiopians is that they were never colonised. Being Irish, I very much understand the importance they attach to that achievement. They had to fight for their freedom.

One prominent supporter in the fight against Italy's ambition to colonise this part of Africa was Sylvia Pankhurst, the suffragette leader, who became a friend and supporter of Emperor Haile Selassie and in addition opposed the British government's machinations.

She moved to live in Addis Ababa and received a state funeral when she died in 1960. She is buried in a very prominent spot in the grounds of Holy Trinity Cathedral.

Here in Addis Ababa, the WHO Regional Director for Africa, Luis Sambo, reminded the congress of the contrast between Africa where the maternal death rate is 620 per 100 000 k births, and Europe where the equivalent rate is 21.

He pointed out that Africa is on track to fail to achieve the Millennium Development Goal of reducing maternal mortality by three quarters by 2015.

Sambo went on to draw attention to four new things that public health in Africa had to deal with:

- Adapting to climate change, particularly in the horn of Africa and the Sahel.
- The rapid pace of urbanisation with all its attendant effects
- Changes in wild animal-human interactions and the increased risk of new diseases
- The emergence of further antibiotic resistance.

Quite an agenda for African colleagues to take on in addition to their current priorities.

Gabriel Scally is a public health physician and holds visiting chairs at the University of the West of England and the University of Bristol.

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