

UK NEWS Doctors are asked if “body MOTs” and DNA profiling should be regulated, p 971

WORLD NEWS Patent pools: an idea whose time has come, p 974

bmj.com Protesters force hospital to abandon lecture on euthanasia

Three elderly patients died after being given inappropriate drugs, inquest jury finds

Clare Dyer **BMJ**

Three elderly patients who died at a hospital in Hampshire in the late 1990s were given inappropriate drugs for their condition which hastened their death, an inquest jury has concluded.

Another two patients were found by the jury to have been given the correct drugs but in doses that contributed to their deaths. The deaths of a further five patients were not caused by the drugs they were taking, the jury decided.

The findings at Portsmouth Coroners’ Court follow an unprecedented inquest ordered by the justice secretary, Jack Straw, into the deaths of 10 patients at Gosport War Memorial Hospital between 1996 and 1999.

Mr Straw’s permission was required because seven of the 10 bodies had been cremated. The inquest comes at the end of a decade of inquiries by police and the NHS into 92 deaths at the hospital, where families claimed that relatives who were sent for recuperation died after being given heavy doses of palliative drugs.

The Crown Prosecution Service decided against a criminal prosecution. An investigation by the Commission for Health Improvement, which was taken over in 2004 by the Healthcare Commission, quoted experts consulted by the police as finding “inappropri-

ate combined subcutaneous administration of diamorphine, midazolam and haloperidol, which could carry a risk of excessive sedation and respiratory depression in older patients, leading to death.”

The experts found that there were no clear guidelines to prevent staff making assumptions that patients had been admitted for palliative rather than rehabilitative care, says the commission’s 2002 report. A protocol for palliative care “was inappropriately applied to patients admitted for rehabilitation.”

In 2002 England’s chief medical officer, Liam Donaldson, ordered a review into deaths at the hospital by Richard Baker, professor of clinical governance at Leicester University, but the results have not been made public. The Department of Health has refused a request for access to the report under freedom of information legislation.

The families are angry that the coroner did not allow the Baker report and some expert reports obtained by police to be put before the jury. Relatives are calling for a further investigation, but Hampshire police said they had no plans to reopen the inquiry.

The families said in a statement: “We did not expect this inquest to be transparent, honest, or fair, and our expectations have been met in full.”

Jane Barton, a Gosport GP who worked



Elsie Devine (left) died after being prescribed inappropriate treatment. Dr Jane Barton (right) worked part time at the hospital.

part time at the hospital, may face a fitness to practise hearing by the General Medical Council over her prescribing practices. She said in a statement, “I am pleased the jury recognised that, in all of these cases, drugs were only given for therapeutic purposes.”

Cite this as: *BMJ* 2009;338:b1657

Drug industry protests over need to register trial results

Bob Roehr **WASHINGTON, DC**

Drug manufacturers this week expressed their concern about a new requirement of the world’s leading drug trial registry that the outcomes of all clinical trials have to be posted on the register within 12 months of completion of the trial.

Under a US law passed in 2007, ClinicalTrials.gov (www.clinicaltrials.gov), which opened in February 2000, has expanded to include not just the details of trials being set up but also the outcomes

of completed trials. The requirement came into effect last September.

Deborah Zarin, who heads the service at the National Library of Medicine of the National Institutes of Health (NIH), said that more than 71 000 trials had been registered on the site and that about 300 to 350 new trials were coming in each week. Stakeholders aired their concerns about the registry at a meeting this week on the NIH campus outside Washington, DC.

Katie McCarthy, speaking on

behalf of the trade association Biotechnology Industry Organization, said it supported “access to key clinical trial results information.” But openness also had its limits, she said: “There are some circumstances where wide dissemination of clinical trial results relating to unapproved products may restrain our member companies’ ability to conduct research . . . by releasing information that undermines a company’s competitive position and ability to raise capital to fund research.”

Gordon Johnston, representing the Generic Pharmaceutical Association, also expressed concerns.

He said that clinical endpoint trials conducted by the association’s members did not provide new information and should not be reported before FDA had approved the generic form of a drug.

“Disclosing [results] prior to approval would give competitors a road map to plans from the generic industry,” he added.

Cite this as: *BMJ* 2009;338:b1652



JOCHEM WIMANDS/ALAMY

Research has shown that women are not willing to take part in randomised trials of place of birth

Home birth is as safe as in hospital for low risk women, study shows

Helen Macdonald *BMJ*

Home birth is as safe as hospital birth for women at low risk of poor outcomes, according to the results of a Dutch cohort study of 529 688 women. But the authors say that a prospective study is needed (*British Journal of Obstetrics and Gynaecology* 2009;116:1-8).

"In our research, we studied more than half a million women in primary care and compared planned home births with planned hospital births," said the lead researcher, Simone Buitendijk, head of the child health programme at the Netherlands Organisation for Applied Scientific Research.

All low risk women who gave birth between January 2000 and December 2006 were included. Just over 60% planned to give birth at home, 30.8% in hospital, and the rest

did not specify. The researchers compared the risk of intrapartum death, neonatal death, and admission to neonatal intensive care, according to the women's delivery plans.

"The number of babies that died or were admitted to a neonatal intensive care unit was the same in both groups, namely, seven per 1000," the researchers found. Poor outcomes were more likely in women who were primiparous, who delivered outside 38-40 weeks' gestation, were under 25 or older than 35, or were not Dutch.

Controversy surrounds the safety of home birth in the Netherlands. Previous cohort studies have produced conflicting results, and the strength of their findings has been limited by small sample sizes. Professor Buitendijk's is the largest study of its kind and has capital-

ised on the high rates of home birth in the Netherlands—about 30%, compared with 2.7% in the United Kingdom in 2006.

"We conclude that women can safely choose where they want to give birth, provided the maternity care system is well equipped for home births," said Professor Buitendijk.

Expanding on that caveat, Philip Steer, obstetrician and gynaecologist, and editor in chief of the *BJOG*, said, "It must be noted that maternity services in the Netherlands are set up to meet the demand for home births, transport is good, and distances short if emergency transfer to hospital is needed. The same advantages are not available in all places in the UK, so the safety of home birth has to be considered in the context of the availability of local services.

"We look forward to the Birthplace in England study, presently being conducted by the National Perinatal Epidemiology Unit, as their data will give us a reasonably accurate picture of the relative safety of home births in the UK for the first time."

As well as the transferability of the finding, Professor Steer explained a limitation of the study design: "Evaluating the safety of home births is difficult because very few studies randomise the place of birth, and thus even after excluding obvious risk factors, women who choose birth at home may differ systematically from women who choose hospital birth."

Professor Buitendijk's research team emphasised the need for prospective study designs. A randomised control trial would produce the best evidence, but research has shown that women are not prepared to participate in a randomised controlled trial of place of birth.

Cite this as: *BMJ* 2009;338:b1616

UK will still publish hospital standardised mortality ratios

Zosia Kmiotowicz *LONDON*

The Department of Health has said it will publish mortality ratios of patients in hospitals in England in the next few weeks despite research indicating that the measures do not help to distinguish between the quality of care provided at different hospitals.

The department has said that the publication of hospital standardised mortality ratios on the NHS Choices website will allow doctors and the public to more easily compare the performance of local services. The site already carries mortality rates for heart surgery and four other procedures, including hip and knee replacements, for every hospital in England.

But a study published online by the *BMJ*

last month (2009;338:b7808, doi:10.1136/bmj.b780) criticised the use of the ratios for rating hospitals in England and other countries because their use distorted results.

Although the figures were standardised, some of the variables, such as primary diagnosis and previous admissions in the past year, were of dubious value, said the researchers, led by Mohammed Mohammed, senior lecturer in the public health unit at the University of Birmingham. Other variables, such as whether patients were admitted as emergencies and whether they had other illnesses, were not safe to use because of different logging and admissions criteria around the country.

Dr Mohammed said, "Any claims that

variations in hospital SMRs [standardised mortality ratios] reflect differences in quality of care are less than credible. They should not be used without a massive warning on them."

Michael Summers, vice chairman of the Patients' Association, said the move to publish the ratios was very welcome. But he added that a "more professional and more standardised publication would be of greater benefit to patients."

However, Bruce Keogh, the NHS's medical director, defended the use of such ratios.

A high hospital standardised mortality ratio (HSMR) of 127, for 2005-6, was one of the indicators that had prompted the NHS watchdog, the Healthcare Commission, to investigate Mid-Staffordshire NHS Foundation Trust (*BMJ*

Doctors warn government against removing benefits from alcoholics who refuse treatment

Adrian O'Dowd LONDON

Experts have warned that plans to withdraw benefits from alcoholics could drive the problem underground and put people off seeking help.

The UK government is considering withdrawing benefits from people who are addicted to alcohol unless they consent to take part in a treatment programme.

Experts, however, are sceptical about the idea, saying that treatment services available are insufficient and that taking benefits away could deter people with a problem from coming forward.

The scheme, similar to one already being piloted among people with drug addiction, could be extended to alcoholics, said James Purnell, work and pensions secretary.

Mr Purnell said that the government was commissioning new research, with an internal review by the Department of Health and the Department for Work and Pensions, to explore how to make the benefits system work for alcoholics.

"We have introduced a new policy that will mean heroin and crack addicts get treatment in return for benefits," said Mr Purnell during a visit to a community centre in Dewsbury Moor in West Yorkshire this week.

"We will actually help them rather than simply handing them money which ends up in pockets of drug dealers.

"But we can't abandon anyone to long periods on benefits without help to over-

come problems. So that's why we are going to look at the arrangements for alcoholics on benefits, just as we did for problem drug users, so that people get the help they need to get sober, to get their life back and get back to work."

Martin Plant, professor of addiction studies and co-director of the alcohol and health research unit, University of West of England in Bristol, said that he was surprised by the idea.

"There is a shortage of treatment services in England and Wales and in Scotland for people with drinking problems. To penalise people for not using services that do not exist would be a very unwise thing to do.

"The first thing to do would be to consider what gaps there are in treatment services and to fill those gaps.

"What this idea [removing benefits] might do is to deter people with alcohol problems from putting their head above the parapet, approaching agencies or going to a GP or local alcohol clinic to disclose the fact that they have an alcohol problem lest their benefits be put at risk. It could drive the problem underground."



Penalising people for not using services that don't exist "would be unwise"

Ian Gilmore, president of the Royal College of Physicians, said that focusing on the lack of treatment services was most important.

"We would not support any form of coercion on patients with alcohol problems," said Professor Gilmore.

"However, we would welcome people with alcohol problems being given more opportunities to access treatment services. The provision of treatment services is currently patchy, and there would need to be a major expansion to meet

any improvements in access."

A spokesman for Addaction, a drug and alcohol treatment charity, said, "We agree it is a good idea to get people back into the labour force and get them into treatment to enable them to do that. However, you would need a lot more investment in alcohol treatment programmes in order for this to be practical. The idea of taking benefits away is useless because the people who would lose out would be people who are dependent on the person getting the benefits, such as children or partners."

Cite this as: *BMJ* 2009;338:b1591

despite criticism

2009;338:b1141, 18 Mar). Last month, in its report into the deaths in the emergency department at the Mid-Staffordshire trust, the Healthcare Commission concluded that 400 more people died than would have been expected at the hospital between 2005 and 2008.

Professor Keogh said, "It is a moral and social duty for all healthcare organisations to know what they're doing and how well they're doing it. The HSMR is one of many measures that will help them do this, but it is not enough on its own.

"The HSMR is an aggregate measure of mortality for the organisation and hence a rather blunt, but useful, indicator of trouble."

Cite this as: *BMJ* 2009;338:b1641

Doctors are asked whether "body MOTs" should be regulated

Jacqui Wise LONDON

The Nuffield Council on Bioethics has launched a consultation on the ethical issues concerning commercial technologies such as DNA profiling and body imaging that increasingly mean that patients bypass their GP.

For example, a number of companies offer to analyse an individual's DNA for a range of health risks. The consultation document says that the disease risks associated with some of the genes being tested have not been well researched, potentially leaving people with

misleading or inaccurate results.

It is also possible to go to private healthcare companies for magnetic resonance imaging or computed tomography to look for abnormalities that indicate disease. The document says that these "body MOTs" (akin to Ministry of Transport vehicle tests) can produce large numbers of false positive results.

Christopher Hood, chairman of the report's working party and professor of government at the University of Oxford, said that GPs may have to pick up the pieces: "The NHS may end up having to do follow-up tests to reassure the patient."

Medical Profiling and Online Medicine: The Ethics of "Personalised" Health Care in a Consumer Age is available at www.nuffieldbioethics.org. The closing date for responses is 21 July 2009.

Cite this as: *BMJ* 2009;338:b1646

IN BRIEF

Telemedicine can reduce carbon

footprint: A study of videoconference users at a telemedicine service designed to improve cancer services in Wales shows that in one month at one centre a total of 20 800 km of car travel was avoided, equivalent to 2590 kg of carbon dioxide emissions. "We estimate that 48 trees would take a year to absorb that quantity [of carbon dioxide]," say the authors (*Journal of Telemedicine and Telecare* 2009;15:137-8).

Teenage admissions for alcohol poisoning rise in Netherlands:

More and younger Dutch teenagers are being admitted to hospital with alcoholic poisoning, a national register of paediatricians from 60 hospitals throughout the country has reported. Last year 337 young people aged between 11 and 17 were admitted, a rise of 13% on 2007, while the average age dropped slightly to 15 years.

Restraint and drug use in care homes vary widely across world:

Data from 14 504 long term care facilities in five countries have found that the use of physical restraint varies widely. Use of physical restraint ranged from an average 6% of facilities in Switzerland and 9% in the United States to 20% in Hong Kong, 28% in Finland, and more than 31% in Canada (*International Journal of Geriatric Psychiatry* doi:10.1002/gps.2232).

Occupational health workers feel pressured to reveal employees' health information:

Around half of occupational health nurses and doctors feel under pressure from managers to reveal confidential health information about employees, shows a survey of 248 private and public sector specialist staff published in *Occupational Health at Work* (2009;5:12-20). Almost a tenth (8%) of the NHS respondents reported that inappropriate breaches of medical confidentiality occurred "frequently or very frequently."

Brains wanted for research into Parkinson's disease:

The UK Parkinson's Disease Society is calling on people to sign up to the Parkinson's brain donor register (www.parkinsons.org.uk/brainbank) to help scientists find a cure for the condition. A shortage of donors is hindering research, it says. The doctor Jane Asher (the society's president) and the television presenters Jeremy Paxman and John Stapleton have pledged to donate their brains.

Cite this as: *BMJ* 2009;338:b1633

Amnesty fears for safety of human rights activists in Sudan

Peter Moszynski LONDON

Concern is growing for the welfare of human rights activists and victims of torture in Sudan after last month's security service raids on the offices of organisations that provide rehabilitation to survivors of torture.

The raids occurred within hours of an arrest warrant being issued by the International Criminal Court against President Omar al Bashir for war crimes and crimes against humanity, which also led to the expulsion of numerous international humanitarian charities.

Amnesty International last week warned that Mohamed Al-Mahjoub, director of the Amal Centre for Treatment and Rehabilitation for Victims of Torture in North Darfur, was arrested on 11 April and taken to a National Intelligence and Security Services detention centre in El Fasher. So far he has not been allowed any personal visits, nor has he been given access to a lawyer.

Amnesty International says that it "fears for his safety and is concerned that Mr Al-Mahjoub is at risk of torture or other forms of ill treatment. Torture or other forms of ill



AFP/STRINGER/GETTY IMAGES

Egypt's intelligence chief, Omar Suleima (left), talks to Sudan's intelligence chief, Salah Gosh, who says he will "cut off the head" of anyone who gives information to the International Criminal Court

treatment of human rights activists by the NISS [National Intelligence and Security Services] is often reported in Sudan, in particular when those detained are not given access to the outside world." The charity says it has documented "many such cases."

In Darfur, rape victims have often been arrested for reporting sexual assaults to the police, and several international agencies were indicted or expelled for commenting on the extent of sexual violence in the region.

Now human rights activists fear that something similar could happen to those who have reported abuse at the hands of the authorities as the intelligence services trawl through the agencies' records, which contain the names and details of hundreds of people who have been tortured.

The Khartoum Centre for Human Rights and Environmental Development, which provides legal aid to victims of torture and offers human rights training to lawyers, was also targeted, with security forces raiding its offices and confiscating a safe, computers, and classified documents.

The centre's staff have since fled Sudan, including its legal aid coordinator, Ali M Agab, who complained that files containing the names and details of victims would now be in the hands of the security forces. "Those people's lives are in danger," he said.

Ahmed Adam Hussein, spokesman for the largest rebel group in Darfur, the Justice and Equality Movement, said that there was genuine cause for concern, because Sudan's security chief, General Salah Gosh, had publicly threatened to "cut off the arms and heads of anyone suspected of passing information to the International Criminal Court."

Cite this as: *BMJ* 2009;338:b1636

FDA puts restrictions on a clinical trial review

Janice Hopkins Tanne NEW YORK

The US Food and Drug Administration said last week that Coast Institutional Review Board, of Colorado Springs, Colorado, had agreed to stop some aspects of its operations overseeing clinical trials because of "concerns about the company's ability to protect human subjects participating in clinical trials."

The FDA issued a warning letter to the company (www.fda.gov/cder/warn/2009/Coast_IRB_letter.pdf), and the company sub-

sequently agreed that no new studies, subject to certain requirements, would be approved.

The issue began when the Government Accountability Office (GAO), the regulator of the US Congress, found that the institutional review board (IRB) system "was vulnerable to unethical manipulation, which elevates the risk that experimental products are approved for human subject tests without full and appropriate review."

In the past, institutional review boards



CLAUDE MAHOUE/MSF

Women are vaccinated by staff from Médecins Sans Frontières in the Zinder region of Niger

Meningitis toll rises as west Africa faces its worst epidemic for 10 years

Chibuzo Odigwe CALABAR, NIGERIA

More than 40 000 cases of meningococcal meningitis have been recorded in west Africa in an epidemic that has been raging for three months despite international humanitarian efforts to bring it under control.

In Nigeria, Niger, and Chad the international charity Médecins Sans Frontières (MSF) is working with local health authorities to carry out a vaccination campaign among a target population of around eight million people who are at risk.

This year's epidemic is the largest in more than 10 years, with more than 1600 deaths having been recorded in Nigeria and Niger, the two worst affected countries. Vaccination has brought the situation under control in many areas, but there are still large areas where vaccination teams have not yet arrived.

In Nigeria more than 37 000 cases of meningitis have been recorded by the joint MSF and Ministry of Health teams.

The outbreak began around the start of the year, during the dry season, when dust and winds and cold nights are more common and there is a greater incidence of coughs and colds.

In Niger the areas most affected are in the southern part of the country. A total of 4591 cases of meningitis and 161 deaths have been registered in the Dosso, Maradi, and Zinder regions.

More than 2.7 million people have already been vaccinated—1.1 million in Nigeria and 1.6 million in Niger—and additional campaigns to vaccinate around 5.5 million people are ongoing or planned in all three countries. Epidemiologists are saying that numbers of cases are falling two weeks after each vaccine programme is completed.

International health authorities have released 2.3 million doses of vaccine to Nigeria and 1.9 million doses to Niger.

Cite this as: BMJ 2009;338:b1638

board after secret investigation reveals faults

were often based at hospitals or big medical centres. Now many are independent, profit making enterprises. More than 6000 such boards are registered in the US.

The GAO selected three independent review boards from an online search and submitted a made-up protocol to each board for review.

“Coast IRB . . . was the only IRB selected that reviewed and approved the research protocol and did so with only minor edits

to the submitted materials,” said the warning letter. The letter says that Coast failed to verify the false assertion that the FDA had already cleared the device for marketing, which could have been done by searching the FDA's online database.

Dan Duebner, president and chief executive of Coast IRB, said that the company had “implemented a 30 day suspension of the processing of new study submissions.”

Cite this as: BMJ 2009;338:b1618

Obama hopes to cut healthcare costs and increase coverage

Bob Roehr WASHINGTON, DC

The opportunity for health reform in the United States is greater now than it has been in more than 50 years, according to a government adviser on health in the country.

The director of the White House Office of Health Reform, Nancy-Ann DeParle, told a breakfast meeting of reporters this week that the twin goals are to lower costs and extend coverage to people who are uninsured.

Ms DeParle, whose background includes Harvard Law School, a master's degree from Oxford University as a Rhodes Scholar, and extensive national experience with health-care finance, is a counsellor to the president, Barack Obama.

“All of the groups who were at different sides of the table 15 years ago are now at the same table working together and talking about how we can reach these goals. No one wants the status quo,” said Ms DeParle. This was substantially different from when reform was discussed during the Bill Clinton administration, she said.

Additionally, Congress had “put its money where its mouth is” by adding a \$634bn (£430bn; €480bn) healthcare reserve fund to the budget, she added.

Ms DeParle reiterated President Obama's scepticism towards taxing health insurance coverage that is provided through the workplace as part of regular personal income but did not rule out the possibility of doing so.

A central controversy is whether or not reform should include a “public plan,” whereby the federal government acts as an insurance provider for people under 65, as it currently does for older people.

Supporters say that this is a necessary component of reform, but opponents fear that in the long term it will drive out private insurers. Ms DeParle said that a compromise may not be possible for people who are philosophically opposed to such a government role, but others are more concerned with the details of such a programme.

Cite this as: BMJ 2009;338:b1580



JIM YOUNG/REUTERS

Nancy-Ann DeParle is a health adviser to President Obama

New funding mechanism is launched to expand access to

Peter Moszynski LONDON
Fighting malaria is part of the United Nations' sixth millennium development goal, yet a new generation of frontline drugs remains out of reach of most patients, so a new £150m (€170m; \$220m) scheme has been developed to subsidise their cost.

Launched last week in Oslo, the Affordable Medicines Facility for Malaria is an innovative financing mechanism designed to expand access to artemisinin based combination drugs, the

most effective treatment.

In 2006 about 250 million people developed malaria, of whom nearly a million died. Malaria parasites are becoming increasingly resistant to older drugs, such as chloroquine and pyrimethamine with sulfadoxine, which are still often used because they are relatively cheap.

"The age when the world had effective drugs against infectious diseases but let millions die each year because they couldn't afford them is over," said Norway's foreign

minister, Jonas Gahr Støre, at the launch.

He said, "Thanks to new commitments, collaboration, and finance built up over the last decade, we are making these deaths history. The results will go beyond saving lives: malaria is costing developing countries billions of dollars each year in lost economic output.

"By controlling malaria we can improve school attendance and productivity, open new areas to business and tourism, and reduce health costs."



WHO delegates visit a farm in Tanzania where *Artemisia annua* plants are being grown

SURKHEI/CHATTBAR/AP/PA

Patent pools: an idea whose time has come

As GlaxoSmithKline places 500 patents into a pool for use by other drug makers against the payment of royalties, **Elizabeth Sukkar** looks at further developments in patent sharing

Elizabeth Sukkar SCRIP WORLD
PHARMACEUTICAL NEWS

How do you persuade drug companies to invest in drugs for diseases that mainly affect poor people, whose purchasing power is negligible? One possible solution emerging within the industry is patent pools.

GlaxoSmithKline (GSK) has just set one up for neglected tropical diseases, and UNITAID, an international body that buys drugs for developing countries, is creating one for AIDS treatments.

Patent pools have been around for about 150 years, used successfully in other industries, such as information technology, but their move into the drug industry is a new development. Will they work in creating better treatments for neglected diseases in developing countries?

In July 2008 UNITAID's executive board gave the go ahead to create a patent pool for AIDS treatments and started negotiating with drug companies. Then in February this year GSK's chief executive, Andrew Witty, made the surprise announcement that his company would be setting

one up, making it the first drug company to do so, and invited other firms to join (*BMJ* 2009;338,b686, 18 Feb).

A patent pool is when a number of patent rights held by different owners, including companies, governments, and academic bodies, are brought together by one organisation and made available on a non-exclusive basis to manufacturers and distributors of drugs against the payment of royalties.

One of the advantages of a patent pool is that it can act like a "one stop shop," allowing other companies such as manufacturers of generic drugs to make use of the patents after paying a royalty, as the licensee does not have to seek the approval of each patent holder.

The UK's Department for International Development, which has encouraged the drug industry to consider UNITAID's pool, says it "will make a real difference to HIV patients, including children." It hopes that GSK will participate in the UNITAID pool, although it welcomes the firm's own scheme. "The onus is now on . . . pharmaceutical companies to demonstrate their

readiness to adopt new approaches," the department adds.

The UNITAID pool: stimulating development of fixed dose combinations for AIDS

The UNITAID patent pool, which will be voluntary, aims to stimulate the development of affordable fixed dose combinations of first line and second line AIDS treatments for adults and children in developing countries. Fixed dose combinations enhance patients' adherence, improve health outcomes, and reduce resistance, say advocates of the scheme.

With a growing number of AIDS patients failing on first line drugs, there is an urgent need to find affordable second line treatments; and boosting the number of suppliers should increase competition and bring down drug prices.

One of the main difficulties for UNITAID, which is holding informal talks with drug firms, is getting the firms on board and deciding the licensing terms and royalty rates.

Another key area for discussion is determining which patents to include. The charity Médecins Sans Frontières (MSF) recommends the inclusion of a fixed dose combination of tenofovir, lamivudine, and either nevirapine or efavirenz, because it is the combination that WHO recommends as the first line antiretroviral treatment and is currently unavailable.



Andrew Witty, chief executive of GSK, announced the pool in February

artemisinin based combination drugs

The facility is hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria, and key financial support comes from the United Kingdom and UNITAID (a French founded international funding mechanism that raises money for health care through a tax on air travel), as well as Norway.

The World Health Organization recommends artemisinin based combination drugs as the first line treatment for uncomplicated *Plasmodium falciparum* malaria (the deadliest form of the disease).

However, these drugs account for only a fifth of antimalarials being taken today.

By increasing access to them and displacing artemisinin monotherapies from the market, the facility not only intends to reduce the impact of the disease but also to delay resistance to the active ingredient, artemisinin. There is concern that widespread use of artemisinin monotherapies could cause the emergence of resistance to the only cure for *P falciparum* malaria.

The facility will be launched

in 11 countries at first (Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania, and Uganda). The two year trial is intended to assess the scheme's effectiveness and to enable lessons to be learnt before expanding it to other countries where malaria is endemic.

"Every year nearly one million people living in developing countries die from malaria," said the UK's minister for international development, Ivan Lewis.

Cite this as: *BMJ* 2009;338:b1627

The UNITAID pool will eventually be run as a separate entity, which should help to gain the trust of the industry. UNITAID hopes the scheme will go live this year.

GSK's pool: promoting research into tropical diseases

GSK's patent pool, which came into effect in March, will promote research into 16 neglected tropical diseases, including malaria, tuberculosis, leprosy, and leishmaniasis.

The company has placed more than 500 granted patents on small molecules and more than 300 pending applications into the pool. It will not charge fees for the development of treatments for the world's least developed countries; for other countries it may either grant a royalty bearing licence or sell any product itself on payment of royalties or a one-off fee to patent pool licensees.

The Drugs for Neglected Diseases initiative (DNDi), which develops treatments for neglected diseases and plans to use the GSK scheme, says it would like the firm to include a wider range of countries, noting that although India is not a least developed country it is the nation most affected by leishmaniasis. Furthermore, royalties should be no higher than 3%, it says.

DNDi would also like GSK to include Chagas' disease on its list of neglected diseases, while MSF wants the inclusion of AIDS and the firm's commitment to working with UNITAID.

But GSK does not believe AIDS to be a neglected tropical disease and says that the aims of UNITAID's pool, which is to improve access to existing antiretrovirals, can be achieved in a "simpler manner" through

GSK's not-for-profit pricing and voluntary licensing schemes, for example.

UNITAID counters: "The benefit of the UNITAID pool is in the collaboration by all. Individual licensing does not bring the benefit of enabling the development of fixed dose combinations that are needed, nor will it bring the benefit of a one stop shop that truly increases the number of producers."

Improving the industry's image

For the drug industry patent pools have several advantages. Some charities that campaign for better access to drugs believe they may be one way for the industry to prevent governments from issuing compulsory licences to tackle public health emergencies, something the industry strongly dislikes.

Moreover they may improve the industry's public image. GSK's scheme has generally been given a good press, not the negative coverage that drug firms usually face over intellectual property conflicts. Thirdly, such pools may also give firms access to new markets.

If the patent pool idea fails, other ideas are on the table: the research and development treaty, whereby a committee would decide what money would go into research and development for each disease; and the medical prize fund, where a cash prize is given instead of a patent.

But the industry is not keen on changing the fundamentals of the patent system itself to redress the imbalance of research into neglected diseases. The patent pool keeps the patent system intact.

Elizabeth Sukkar is world editor of *Scrip World Pharmaceutical News* (www.scripnews.com).

Cite this as: *BMJ* 2009;338:b1619

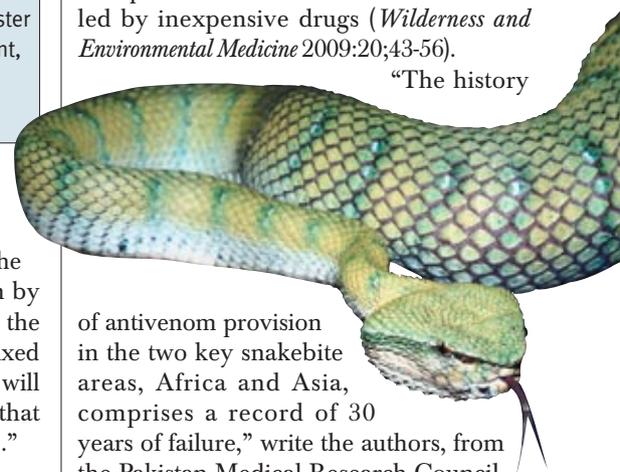
WHO policy on snakebite treatment may result in more deaths

Roger Dobson ABERGAVENNY

Treatment of snakebites has not improved for 30 years, with no significant reductions in mortality or morbidity, a new report says.

The authors criticise the World Health Organization for recommending that countries move to better quality antivenoms, when many countries cannot afford to do so and when the side effects of much cheaper antivenoms can often be tackled by inexpensive drugs (*Wilderness and Environmental Medicine* 2009;20:43-56).

"The history



of antivenom provision in the two key snakebite areas, Africa and Asia, comprises a record of 30 years of failure," write the authors, from the Pakistan Medical Research Council and Stanford University Medical Center.

"The current World Health Organization approach to increase quality standards in an uncontrolled and economically uninformed way, with a subsequent increase in cost in countries without the resources to purchase current products, will be counterproductive and will ensure that either less antivenom is purchased and used or that the standards will be ignored."

They say that no major work has been done to adequately quantify the incidence of adverse reactions, effects on morbidity and mortality, or the cost-benefit comparison between a cheaper antivenom supported by readily available and inexpensive drugs to treat the adverse reactions and a more expensive product with fewer reactions.

They write: "While some antivenoms produced in the developing world tend to generate a higher rate of adverse reactions than those produced in the developed world they can be readily handled with cheap drugs.

"The single most important factor in supply in the developing world is cost. Many underdeveloped countries or states within the more advanced developing countries simply cannot afford an increase in the cost."

Cite this as: *BMJ* 2009;338:b1629