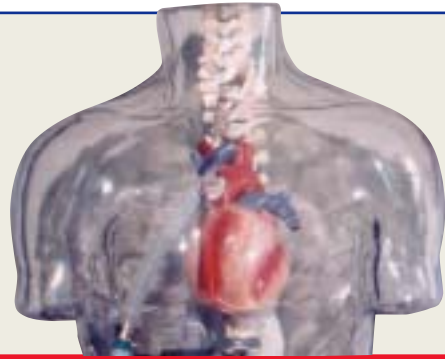


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## Adverse drug reactions

### Cases cost thousands and take up 4% of beds

Although most patients do not react badly to prescriptions, a new study has found that one in 16 hospital admissions (in two hospitals) were caused by adverse drug reactions, and these resulted in an average of 8-day inpatient stays, using 4% of the hospitals' bed capacity. Therefore, in all, adverse drug reactions alone could cost the UK's healthcare service about £466m per annum.

Gastrointestinal bleeding was found to be the most common reaction seen, and among the most commonly implicated drugs were low dose aspirin, diuretics, warfarin, and non-steroidal anti-inflammatory drugs, in a new study by researchers at Liverpool University (pub: *British Medical Journal*).

For their survey, the drug history and symptoms of 18,820 patients aged over 16 years, were assessed after they had been admitted to two Merseyside hospitals over a six-month period. 1,225 admissions (a prevalence of 6.5%) were due to adverse drug



reactions. Most of the patients recovered, but 28 (2.3%) died as a direct result of the reaction, yet the researchers pointed out that about 70% of their reactions could have been definitely - or possibly -

avoidable during prescribing: 'Simple measures, such as a regular review of prescriptions, computerised prescribing and the involvement of pharmacists in assessing prescribing behaviour, may all reduce the burden caused by adverse drug reactions.'

The study also implied that, nationally, 5,700 patients may be dying due to adverse drug reactions, but the number might be even higher, because the research did not include numbers who died from adverse reactions to drugs received during hospital stays. The team concluded that measures are urgently needed to reduce this healthcare burden.

In the UK, the safety of drugs is continuously monitored by the Medicines and Healthcare Products Regulatory Agency (MHRA), which investigates all and any emerging safety issues. The country's Department of Health is now considering the introduction of an 'online yellow card' and modernising the way reactions to drugs are reported.

## First implants of absorbable metal stents

**Germany** - Following positive results in numerous animal studies and the first human implantations of the Biontronic Absorbable Metal Stent (AMS) in below-the-knee arteries that confirmed device safety, at the end of July the first patients (worldwide) received AMS implants. Professor Raimund Erbel, Director of the Cardiology Clinic, Essen University, and Professor Michael Haude, carried out the procedures as part of a 'Progress-AMS' study.

'This technology combines - for the first time - the short term vessel support of a metal stent with the advantage of removing the long term presence of an implant,' explained Dr Claus Martini, Vascular Intervention CEO at Biotronik GmbH & Co KG, Essen.

The four-month follow up will determine the great potential of this technology, the firm added. 'We also believe that AMS has the potential to overcome the future hurdle of non-invasive imaging, because it doesn't create artifacts under X-ray and allows successful utilisation of non-invasive vessel imaging with computed tomography CT or multi-slice CT (MSCT). In addition AMS stents are magnetic resonance compatible, because no artifacts are produced.'

## Oncology Equipment sales

From 2000-2003, the UK alone purchased 204 CT Scanners, 88 MRI scanners and 91 linear accelerators, as well as 44 computers for radiotherapy planning, 23 simulators and over 600 devices for breast screening.

However, whilst some EU countries plough ahead with their cancer detection programmes, others appear to drag their feet about adopting important new technologies, or even setting up national breast screening programmes.

On pages 10-15 European Hospital asks why, and feature the political, economic and technical influences on approaches to cancer care today - particularly focusing on **mammography**. In this special new section, we also highlight current research and technological advances.

## Sleep apnoea study may alter stroke management

**Spain** - New research suggests that sleep apnoea is a new risk factor for death from stroke.

Sleep apnoea describes repeatedly interrupted breathing when asleep. Sufferers may stop breathing for 10 seconds and, in some, this may occur over 300 times a night. The syndrome affects some 20% of people.

During their 30-months study (pub: *European Respiratory Journal*) Dr Olga Parra, and researchers at Barcelona University Hospital, began monitoring the breathing of 161 stroke patients soon after their hospital admittance due to strokes. An apnoea index was used for each patient. The team found that the higher the patient scored on the apnoea scale, the greater the risk of dying from stroke. In that period, about 50% suffered a second stroke, and 22 patients died.

The team also pointed out that the risk of a stroke and death was

more obvious in those with obstructive sleep apnoea, in which the upper airways collapse.

The team do not explain why sleep apnoea raises the risk of stroke death, but they do indicate that the syndrome can be treated by using a nasal mask to give continuously pressurised air, which reduces breathing interruptions. A study in several Spanish centres is now underway to find out whether treating sleep apnoea could indeed cut the death rate from stroke. Although results from this will not be published for about five years, Ludger Grote, at the Sahlgrenska Hospital, Sweden, commenting in the same journal, said that the Spanish study represents '... a milestone in our understanding of the potential role of sleep apnoea in stroke patients' and that the initial Spanish results could have considerable implications for future stroke management.

**Respiratory reports: pages 16-17**

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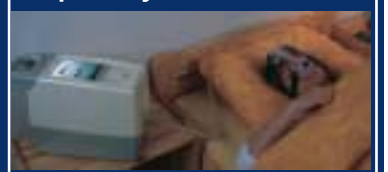


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Now, tell us more about your work, so that we can plan future publications with your needs in mind. Please put a cross  in the relevant boxes.

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Other institution (eg medical school) \_\_\_\_\_

### 2. YOUR JOB

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Medical practitioner/type \_\_\_\_\_

Other/department \_\_\_\_\_

### 3. HOW MANY BEDS DOES YOUR HOSPITAL PROVIDE

Up to 150  151-500  501-1000  more than 1000  
 None, (not a hospital/clinic)

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 Nursing: new aids/techniques  Laboratory equipment, refrigeration, etc.  
 Hospital furnishings: beds, lights, etc.  Hospital clothing and protective wear  
 Hygiene & sterilisation  Nutrition and kitchen supplies  
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Other information requirements - please list \_\_\_\_\_

### ESPECIALLY FOR DOCTORS:

Please complete the above questions and we would like you to answer the following additional questions by ticking yes or no or filling in the lines as appropriate.

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Are you head of the department?  Yes  No

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relatively modern  Yes  No

state-of-the-art  Yes  No

Do you use/buy second-hand equipment?

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Is your department linked to an external computer network?  Yes  No

Is your department involved with telemedicine in the community?  Yes  No

Do you consider your department is under-staffed?  Yes  No

Are you given ample opportunities to up-date knowledge?  Yes  No

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This information will be used only in an analysis for European Hospital, Höherweg 287, 40231 Düsseldorf, Germany, and for the mailing out of future issues.

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Date \_\_\_\_\_

EH 4/04

## NEWS

**Austria. 6-9 October** - Challenges of the new EU Member States will be high on the agenda of this year's EHFG. The forum, timed to coincide with the constituent meetings of the European Parliament committees, expects 600 participants from over 45 countries, and reports that 56 government members have been invited, with acceptances confirmed by EU Commissioner David Byrne and WHO Regional Director Marc Danzon confirmed, as well as Roel Bekker (General Secretary of the Health Ministry, Netherlands), Chien-Jen Chen (Taiwan, R.O.C), Julio Frenk (Mexico), deputy state secretary Mojca Gruntar Cinc

background of the Lisbon Strategy. 'Certainly, our commitment to health cannot stop at the Schengen borders,' Dr Leiner said, 'Infectious diseases don't respect borders either. We cannot ignore the fact that HIV rates in the Ukraine are twelve times as high as in the bordering countries of Poland or Hungary, or that TB cases are five times as high as in neighbouring Hungary. The EU must in its own interest undertake all efforts to help the states at the outer borders of a larger EU to cope with their health problems.' Dr Leiner said the European healthcare debate must turn glob-

# Challenges for the new EU member states

## 7th European Health Forum Gastein

(Slovenia), and Maria Rauch-Kallat (Austria), Mihály Kökény (Hungary), Mitalip Mamytov (Kirghizia), Michéal Martin (Ireland).

Borders disappear, yet health gaps remain - The EHFG organisers point out that not all EU citizens have equal access to optimal medical care. Many must live and work under conditions likely to cause physical and mental disease. Many suffer from health disorders that could have been avoided through sufficient information and prevention. Despite the economic and political integration of the old and new EU Member States, the differences in life expectancy and health of the citizens within the European Union remain blatant: Swedish men live an average of 77 years, but the average Latvian man will die when aged 64. In Hungary, lung cancer numbers are five times higher than in Sweden. In Lithuania, TB cases are 17 times higher than in Sweden. 'Can we accept such discrepancies in a united Europe?' the EHFG asks.

EHFG President Dr Günther Leiner said: 'It is not primarily a question of fate whether people stay healthy or become ill. It is necessary to examine the reasons behind such health inequalities and develop strategies to counteract any undesirable developments.' The EHFG said it could make a substantial contribution to improve health in Europe as a competitive factor against the

al, and that, in this context, the forum had convinced the OECD to become a partner of the 7th European Health Forum Gastein. 'After the World Bank and the WHO, the OECD is now the third globally operating organisation that actively contributes to the European health debate at the EHFG. From the European side, the EHFG receives support from the EU Committee of the Regions (CoR), from the European Commission, General Directorate for Health and Consumer Protection, and from the European Observatory on Health Systems and Policies.'

**Mental health** - The 7th EHFG will also examine the current situation of people with mental diseases, define targets, discuss solution approaches, and work on the development of networks to better support sufferers and families.

According to a report by the European Commission, the EHFG pointed out, mortality due to suicide and self-inflicted injuries reached a rate of 42 for every 100,000 inhabitants (76.5% men, 12.6% women) in Lithuania in 1999, the highest rate in the entire European region and four times higher than the EU average. This figure is just as alarming as it is inconclusive in understanding the underlying problems and adequately counteracting these. All in all, there are too little resources for the research, prevention, and treatment of mental diseases, the

# Asylum seekers and healthcare

**UK** - Over 100,000 asylum seekers have been relocated throughout London and England's southeast, to spread the cost of their medical care. However, because many of these people are from countries where HIV and AIDS are rife, many doctors have pointed out that their dispersal may lead to increased HIV transmission in the UK. Additionally, the relocations might not only harm those who might contract the disease, but the asylum seekers themselves, i.e. those already undergoing medical investigations, or beginning antiretroviral therapy, or alternative therapy after drug regimes had failed, or whose care involves multiple medical specialities. Dispersal should also not be considered for those with full-blown AIDS.

A survey of 56 employees in sexual health clinics in London revealed concern that dispersal of asylum seekers was often done within just 48 hours of their arrival, and often without the transfer of their medical details. Only three centres reported appropriate transfer of care.

The doctors argued that before the decision to disperse, the National Asylum Support Service (NASS) should consider expert medical advice, as well as consider the impact on the infrastructure and staffing of sexual health clinics taking over these cases.

However, the Home Office said that the NASS did consider medical conditions and dispersed asylum seekers with hi considerations into there was no evidence that dispersal increased the likelihood of onward transmission of HIV to others, and it was working with HIV or AIDS to areas with suitable medical services.

# Childhood leukaemia

## International scientific conference

**UK** - A large number international and renowned experts are set to converge on London's Westminster Hall to examine environmental and other factors affecting the incidence of leukaemia and other childhood cancers, as well as their mechanisms of action and interaction across a range of scientific disciplines.

Topics, in this September conference, will include the effects of ionising and non-ionising radiation, air and foodborne pollutants, infections and modern lifestyles. The conference will also compare how the precautionary principle is applied to different hazards.

Future research priorities will be identified. Along with this, to encourage new research, 'Children with Leukaemia Paul O'Gorman' research grants, from a £1 million budget, will be awarded. Lead authors of the best conference posters will be invited to submit research proposals for funding.

Sir William Stewart FRS, Chairman of the UK Health Protection Agency, formerly UK Chief Scientist then Chair of the UK Independent Expert Group on Mobile Phones and Health will open the event.

[www.leukaemiaconference.org](http://www.leukaemiaconference.org)

EHFG pointed out. 'Currently there is a huge gap between the demand for treatment and the services actually available. Even in economically advanced states with well-developed health systems, 44-70 % of patients with mental disorders receive no treatment, this figure being as much as 90% in developing countries. As it is often the case in the health sector, however, it would be economically sound to invest more into mental health, and in particular in preventive measures. The cost of mental diseases in EU Member States is estimated at 3-% of the GDP. In many developed countries, 35-45% of work absenteeism is attributable to mental problems.

In a parallel forum the OECD will present its latest study 'Towards high-performing health systems' (based on experiences in different countries) and in another parallel forum the focus will be on pharmaceutical policy in the enlarged Europe, as well as on technology assessment. Indeed, October's EHFG meeting will examine almost all frontline issues in healthcare today - delivery, finance, politics - even the effects of our changing weather will have on healthcare in our united Europe.

Full details: [www.ehfg.org](http://www.ehfg.org)

# Nurse receives £354,000 compensation

**Wales** - Forced to stop nursing seven years ago, due to asthma and anaphylactic attacks and skin problems that were blamed on her sensitivity to dust from latex gloves, nurse Alison Dugmore received £240,000 in compensation for personal injury, loss of future earnings and loss of pension.

## Cross-border health summit

**Czech Republic** - Health leaders from 20 countries will gather in Prague for three days (5-8 September) to explore trends and innovations effecting the development of new cross-border health services and insurance. James A Rice PhD, President of the International Health Summit, said this would be a good opportunity '... for good networking and discussions about challenges and solutions for cost-effective healthcare and health gain'.

The faculty in the Prague symposium includes: Sir Alan Langlands, former CEO of the UK's NHS; David Fine, University of Alabama Medical Centre, USA; Andy Black, UK, and several other insurance, disease management, hospital and medical technology leaders from Germany, Spain, Czech and Slovak Republics and Poland.

Programme details: [www.ihsummit.com/article.cfm?id=80](http://www.ihsummit.com/article.cfm?id=80).  
Email contact: [jrice@ihsummit.com](mailto:jrice@ihsummit.com).

## CleanMed Europe

**Austria - 6-8 October**

CleanMed Europe, the first international healthcare congress on ecologically sustainable healthcare in Europe will take place in Vienna. With healthcare experts from Europe and the US, the congress aims to highlight the significance of environmental protection in all areas of the healthcare industry. Environmentally sound hospital products and services will also be exhibited.

Details: [www.cleanmed.org](http://www.cleanmed.org)

## Food threat to health congress

Globally, about two million people die each year after consuming spoiled food, according to the World Health Organisation (WHO). In Germany alone, about 200,000 cases of illnesses resulting from food are reported annually - over 60,000 caused by salmonellae - and experts believe cases might be 10-20 times higher. The EU estimated that salmonellae infections cost the healthcare system about three billion euros annually.

Professor Andreas Hensel, President of the BfR, speaking at the 5th World Congress Foodborne Infections and Intoxications, said: 'Food infections are a global problem. Only if we impose uniformly high hygiene requirements around the world, will we be able, in the long term, to prevent new pathogens from gaining ground and diseases that had been eradicated in some regions, from flaring up once again.'

400 people from over 50 countries attended the congress, staged every six years. Organised by the Federal Institute for Risk Assessment in its capacity as a Collaborating Centre for Research and Training in Food Hygiene and Zoonoses of the World Health Organisation and the Food and Agriculture Organisation, it serves as a forum for the exchange of scientific findings on the causes and spread of foodborne infections and intoxications as well as for the sharing of practical experience in their prevention and control. Details : [www.bfr.bund.de](http://www.bfr.bund.de)

## NEW

### Fraud and corruption conference

**18-19 October 2004** -The first conference to focus on tackling fraud and corruption in EU healthcare is being organised by the NHS Counter Fraud and Security Management Service (CFSMS), and partner organisations from five other EU countries, having secured funding from AGIS, an EU Commission programme to help EU member states co-operate in criminal matters.

Over £600 billion is spent on the provision of healthcare across the EU. The conference will aim at ensuring the best possible protection of those funds.

CFSMS is organising the conference to examine problems and solutions in healthcare fraud and corruption within the 25 EU member states, with a view to encouraging joint working, developing common standards and sharing best practice.

Although the CFSMS is the lead organisation for this initiative, the application to the European Commission' AGIS programme for funding was a result of a joint working group with counter fraud and corruption representatives from five other European Union countries, such as the Polish Ministry of Health; Official College of Pharmacists of Madrid; Dutch Association of Health Insurers (ZN); The Bureau of Fight against Corruption (Ministry of Interior - Slovakia).

**Actual savings on fraud** £478million (enough to pay for 60,000 kidney transplant operations or 100,000 hip replacements) has been saved by the CFSMS while investigating fraud in the UK's National Health Service (NHS). The CFSMS, which employs more than 400 fraud specialists, reported that the savings were made in their first five years of work, in its ten-year plan. Every single NHS trust, primary care trust and other health bodies are to be investigated during that decade.

A special 'Fraud and Corruption Reporting Line' (08702 400 100) was set up for those who suspected fraud in their workplace. (However, the NHS emphasised that the majority of employees are honest).

By making claim forms 'fraud proof', the reduction in fraud by patients was 49% (false free medicine claims, etc), and by NHS staff (lies about hours worked) was 46%.

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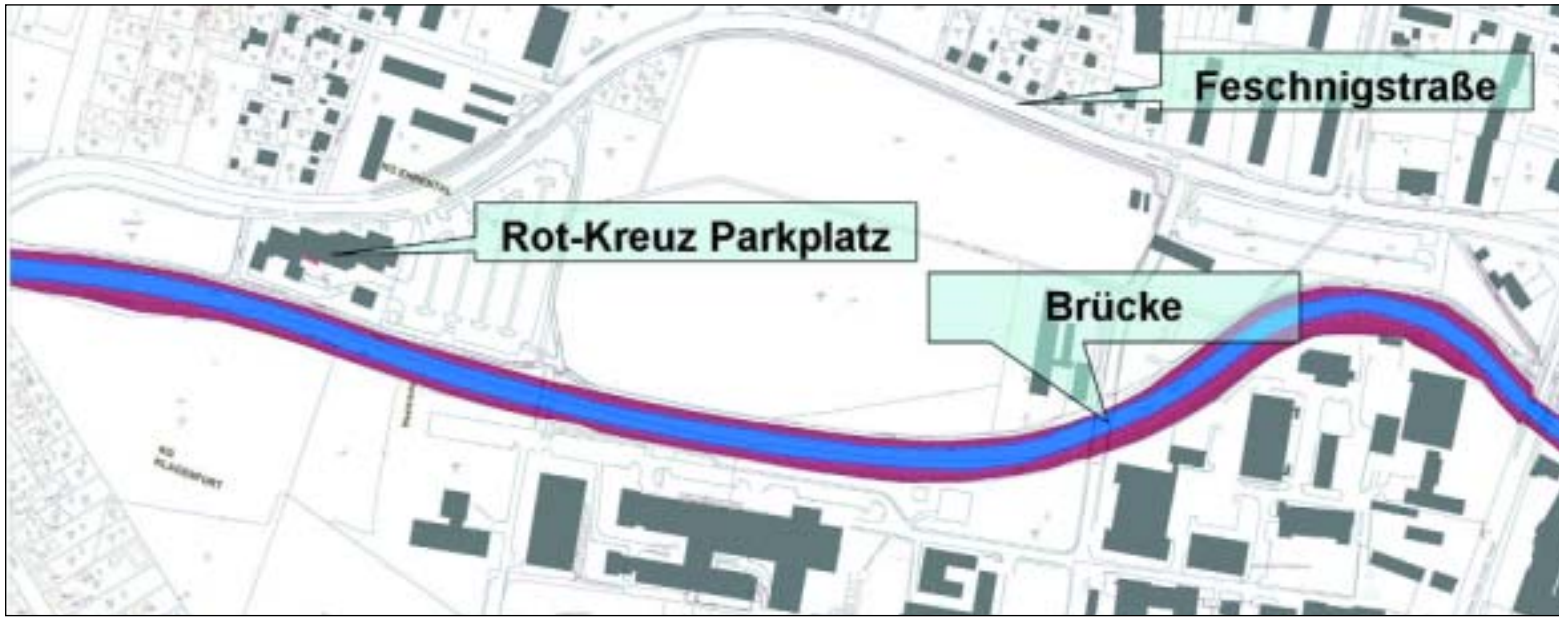
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closer together and working more closely with each other, more efficient use of expensive equipment - these are just some of the ideas that, in total, offer enormous savings potential.

Copenhagen's Rijk Hospital is a role model for the new approach to hospital building and management, and its consultants were involved in the development of the Klagenfurt project.

In 2010, after all departments and wards have moved in to their new quarters, the vacated site will be returned to the city of Klagenfurt, which has plans for its future use.

# River shifts for a streamlined hospital

**Austria** - A new hospital is rarely a groundbreaking enterprise for urban planners and engineers. Recently, however, a whole river had to be re-routed to make way for a new medical centre at Klagenfurt, capital of Bundesland Carinthia. Indeed, in late July, the river Glan was diverted along a stretch of about 850 metres and 106 000 m<sup>3</sup> of ground was shifted, creating a six-hectare site where the new hospital will be built, and all this without interrupting operation of the existing hospital, without costly temporary quarters and without having to settle for architectural compromises.

Designed by Austrian architect Dietmar Feichtinger, the €316 million project promises not only to be progressive in terms of earthworks, but also for hospital technology, quality and service. Feichtinger has a proven track record of tailor-made structural solutions: the new access to the Mont Saint Michel, France, and a new bridge over the Seine in front

of the National Library, Paris, were conceived on his drawing-board.

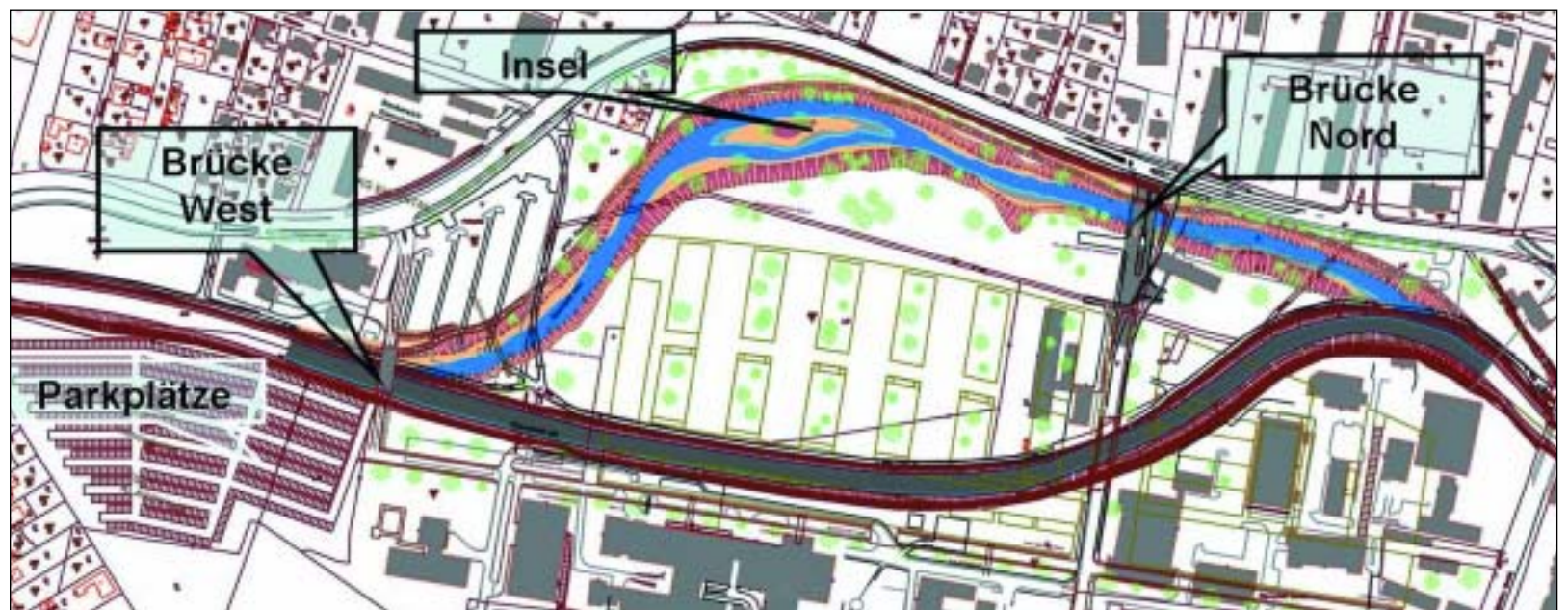
For the Klagenfurt hospital, Feichtinger has designed a flat ensemble that will not dwarf surrounding buildings. Glass will

make this, Austria's second-largest hospital, open, airy and transparent, and more like a hotel than the traditional medical institution. Lots of green, small units and easy orientation also will help make patients more at home.

**Improved logistics reduce costs** - Shorter lengths of stay mean fewer beds; indeed, the new hospital will have 200 beds less than the current one. However, this requires sophisticated logistics. Shorter routes, less staff, departments

By **Christian Pruszinsky**  
EH Austrian Correspondent

Above: 2003 Red Cross parking  
Feschnigstrasse Bridge  
Below: 2004 Parking, Western bridge  
Island, Northern bridge



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OPEN MINDS

## Virtual visits with neonates

Although parents are allowed in neonate ICU units, family members and friends are barred. To meet this need, Innsbruck Medical University recently launched the project 'Babywatch' in its neonatology ICU. Installed in an incubator, a webcam relays images to the website [www.babywatch.at](http://www.babywatch.at). Parents can then supply their user names and passwords to log on, via the internet, for a virtual visit with their infants, at any time, as well as show them off to friends and family.

Doctors also can use Babywatch to make unscheduled virtual ward rounds and monitor their tiny patients. 'The off-limits rule in ICUs is something that is often hard to understand or accept for relatives and friends. It's great that for everyone with internet access this is now a thing of the past,' said Professor Georg Simbruner, Head of clinical neonatology at Innsbruck University, who developed the project in co-operation with Chello broadband nv, a Europe-wide broadband provider, and Telesystem Tirol.

Christian Pruszinsky



The Pillpick system packs tablets, suppositories, phials, syringes, etc. into small plastic bags

# New hospital automates drugs distribution

Boxpicker units in its pharmacy, and a medicine cabinet with password-protected access in the emergency ward.

A pneumatic tube system (compressed air), also being installed by Swisslog, based in Buchs/Aarau, Switzerland, will transport test tube samples from the emergency department to the lab, alleviating the need for manual transportation.

The Pillpick system packs individual tablets, suppositories, phials, disposable syringes and other med-

ications into small plastic bags. Depending on the chosen method of drug therapy, the system picks all medications to be administered to the individual patient on a given day. Tied on plastic rings these drugs are then delivered to the right wards in transport carts. About 70% of all the drugs supplied by the pharmacy to in-patients can be handled in unit doses by Pillpick, which marks the bags with barcodes and assigns them to each patient. The system

also manages the return of drugs not administered by the hospital pharmacy.

Boxpickers - With these space-saving, automated cabinets, drugs that cannot be packaged in unit dose, e.g. multi-dose and large volumes can be handled and dispensed easier and better, Swisslog pointed out. 'For secure storage of drugs that must be available at short notice in the emergency ward, the hospital management in Forlì decided to use Medihive, our

medicine cabinet that can only be opened by doctors and care personnel subject to prior identification. Access is granted only for one specific drawer. The metal slot is unlocked automatically, so that the operator can take out the medication requested. Through centralised storage and standardised processes Medihive helps to prevent dispensing expired drugs.'

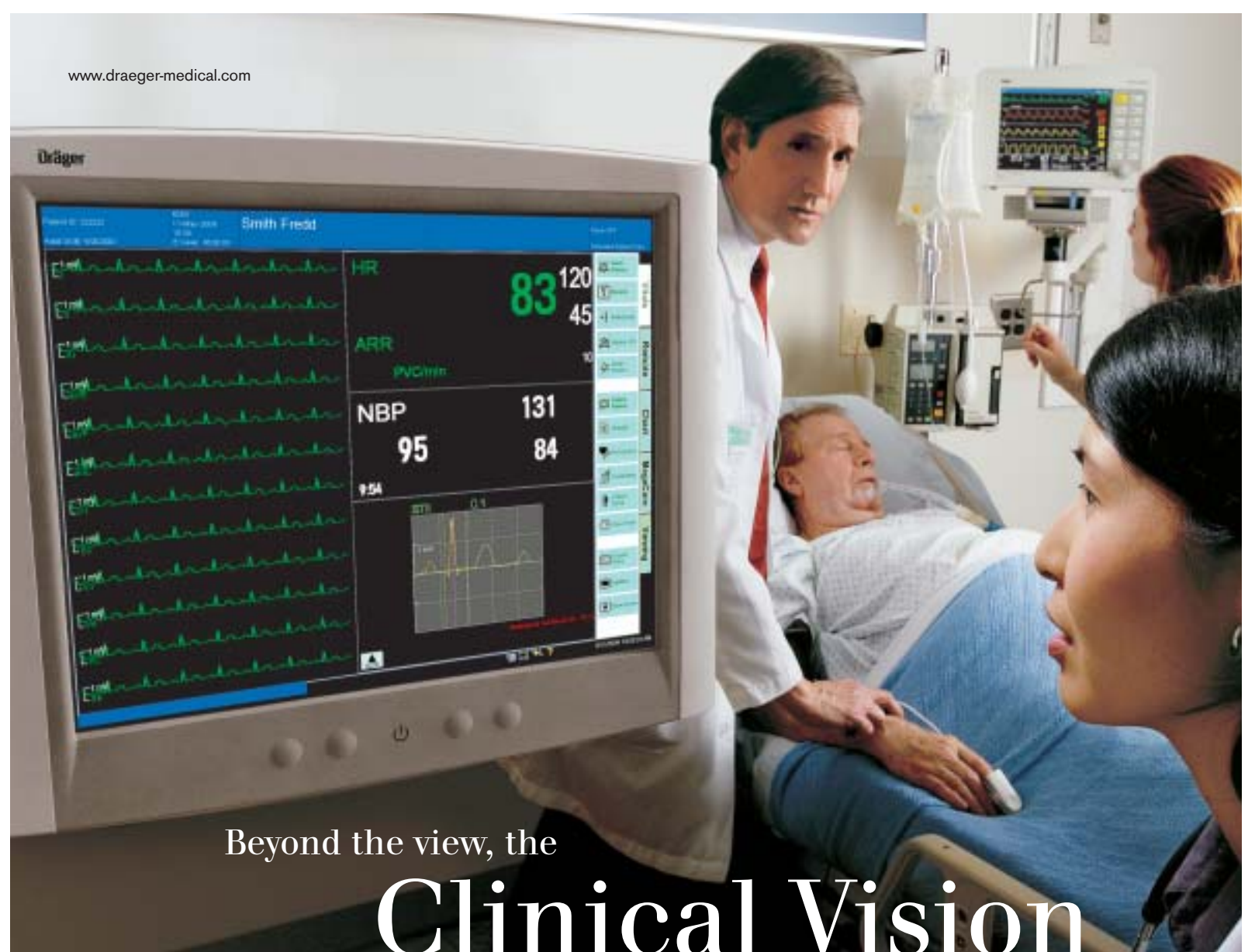
In the next few months this wholly automated drugs system will be fully operational.

**Forlì, Italy** - With construction almost completed, the 550-bed Ospedale Nuovo G B Morgagni can now provide state of the art services for the community it serves.

Among advances at the new hospital are an automated storage and distribution system for pharmaceuticals and a pneumatic tube system to deliver laboratory samples.

Dr Patrizia Grementieri, Project Manager at the new hospital, said: 'One of our top priorities is to supply patients with appropriate drugs, safely and efficiently. The Pillpick system lets us reduce errors remarkably when issuing drugs. The new drug management solution also saves costs and time compared with manual medication selection and distribution.'

As well as the Swisslog Pillpick system - used for patient/individual medication selection, supporting pharmacy staff in their dispensing and care personnel in administering the correct doses to each patient - the hospital has installed two



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## Prion filter for red cells

Scientists at biopharm firm Pathogen Removal and Diagnostic Technologies Inc\* (PRDT) recently confirmed their identification of lead ligands capable of specifically targeting certain 'challenging' viruses. PRDT has also reported that its prion removal ligands - successful in recent preliminary studies - are the only products that specifically address the selective adsorption of infectious prion proteins.

Now, with the American Red Cross, PRDT has announced a strategic alliance with MacoPharma, which distributes blood collection bag sets, to market and further develop products for the selective adsorption of prions and viruses from blood and blood-derived products. PRDT said this product line extension might ultimately target viruses by on-site filtration of donor blood supplies in blood transfusion centres, to reduce potential transmission risk of various viruses, e.g. West Nile virus and Hepatitis C (flavivirus and parvovirus families).

Over 40 million blood units are collected annually, so such filters would find a significant market. The American Red Cross alone collects over six million units a year, to supply around 3,000 hospitals across the States, via its 36 Blood Services regions.

The European launch of first commercially available prion filter for red blood cells is expected next year. \* PRDT is a joint venture of Canada-based ProMetic Life Sciences Inc.

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# Cardiovascular disease

**Europe** - Every year, 4 million people die from cardiovascular disease (CVD) in Europe as a whole (as many as 800,000 of them under 65 years old) and, in the EU Member States, over 1.5 million people die annually from CVD. Many of those deaths were caused by unhealthy lifestyles so could have been avoided, says The European Heart Network, based in Brussels. EHN also points out:

- CVD is the main cause of death in women in all countries of Europe and is the main cause of death in men in all countries except France.
- CVD is the main cause of years of life lost in early death in Europe and the EU.
- Nearly 30% of years of life lost in Europe are due to CVD (over 30% in the EU).
- CVD mortality, incidence and case fatality are falling in most Northern, Southern and Western European countries but rising in Central and Eastern European countries.
- Each year smoking kills about 1.2 million people in Europe (430,000 from CVD) and about 500,000 people in the EU (130,000 from CVD).
- Smoking has declined in many European countries but that rate is now slowing. Women now smoke almost as much as men in many European countries and girls often smoke more than boys.
- Diets are generally improving in Northern and Western European countries but deteriorating in Southern, Central and Eastern European countries.
- Dietary patterns across Europe - once very different - are now converging.
- Levels of obesity are increasing across Europe.
- The prevalence of diabetes is increasing across Europe.

**Economic Costs** - Coronary heart disease is not only the single most common cause of death in the UK, for example, but it also imposes a huge annual burden on its economy. The costs of healthcare alone are over £1.7 billion a year. However, the majority of the costs of CVD fall outside the healthcare system and are due to illness and death in those of working age and the economic effects of their families and friends who care for them.

## Prioritising EU heart health

The Council of Ministers of the European Union (EU) recently acknowledged not only that cardiovascular disease in Europe is 'the largest cause of death of men and women in the European Union' - and is too frequently caused by unhealthy lifestyles - but that these risk factors must be addressed in the development of national and European policy. Professor John Martin, Chairperson of the European Society of Cardiology (ESC) Committee for EU Relations, pointed out that national governments and the medical profession have been working together to bring about an advance, and that the EU move is a 'great step forward for European healthcare'

The EU declaration is a direct consequence of the recent initiatives on cardiovascular health staged by the Irish Department of Health and Children and the ESC

involvement in these, including 'Promoting Heart Health - A European Consensus' (Feb 2004) and the meeting on Cardiology Audit and Registration Data Standards (CARDS) this May.

Professor Martin said the relationship between the ESC and the Irish Department of Health and Children during the Irish Presidency of the EU '... may act as a model for other medical societies in Europe to identify similar problems and advise governments accordingly'.



Professor John Martin

**Sorry statistics from Europe and developing world. EU heart health policy is now a priority**

## The developing world: Soaring CVD hits the young

In developing countries, heart disease and stroke are causing hundreds of thousands of deaths in young people of productive age, according to a report entitled *A Race Against Time*, released in April by Columbia University's Earth Institute. The research, supported by the Initiative for Cardiovascular Health Research in Developing Countries and the Australian Health Policy Institute, University of Sydney, focused on Brazil, South Africa, Tatarstan, India and China.



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Population estimates for the five countries were combined with current death rates and workforce data to calculate the future effects of CVD both on society and on the workforce.

In India, South Africa and Brazil, the researchers found that among working age people mortality rates for cardiovascular disease (CVD) are almost twice those in the more affluent USA. In India, for example, five million people die of CVD each year, and 28% of those people were under 65 years old. In the Russian Republic of Tatarstan, CVD death

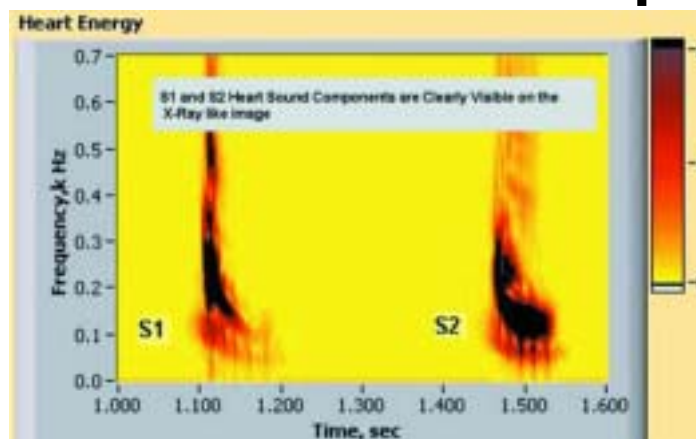
rates for young men have increased in just 20 years by 70% - increased risk factors there include poor diet, smoking, high blood pressure and more sedentary lifestyles.

CVD, the report also points out, is often unrecognised as a cause of impaired health among women, yet, in South Africa, despite HIV/AIDS topping mortality figures, CVD ranks sixth in men's diseases, but a third in women's diseases, and most heavily affects poor women, causing the highest portion of life years lost due to non-communicable diseases (46%). The proportion of deaths occurring among 35 to 44-year-olds

due to chronic disease (mainly CVD) is 12% for men and 17.2% for women.

Australian epidemiologist and Earth Institute Visiting Professor Stephen Leeder, a former dean of the University of Sydney Medical School who led the research team, pointed out that treatment is often unavailable in these countries and lifestyle programmes such as diet/exercise awareness and anti-smoking campaigns, as well as tobacco taxes that have impacted in the US over the past 40 years, have not yet occurred in the countries surveyed.

**NEW** Processing cardiac sounds  
**The electronic stethoscope**



A processing system said to pick up cardiac sounds and correlate these with any related abnormalities, e.g. valve defects, stenosis, fibrillation, septal defect, etc, has been developed by the US firm Biosignetics Corporation. This patent-pending invention, named Heart Energy Signature, is aimed at helping physicians and medical students to identify cardiac problems during routine medical checkups. If defects are present, the cardiac sounds processed through the system prompt on-screen images that indicate what the problem may be.

Reported preliminary results also imply promising possibilities for use in neurology.

'Our research direction is focused on early detection of silent heart diseases, so that they can be treated using less invasive methods,' said Dr Vladimir Polyshchuk, President and Technical Director of Biosignetics, which is registered with the USA's Federal Drug Administration (FDA) as an equipment supplier, and is currently seeking clinical research partners.

The Biosignetics Corporation, founded in January 2004, is a small business start-up located in Exeter, New Hampshire. It was founded to develop an inexpensive and widely available early detection heart diagnosis system. 'We are focused on the cardiovascular market, specialising in cardiac rhythm management, monitoring, and diagnostics. Our short-term product strategy is to focus solely on the developing software applications that will utilise the electronic stethoscope for sound data collection.

Biosignetics Corporation has developed patent-pending heart energy signature phonocardiograph (PCG) software.'

Currently the firm sells two software products for educational and non-clinical research, and is working on heart sound databases, as well as on the regulatory approvals with the US Food and Drug Administration.

Details: [www.bsigenetics.com](http://www.bsigenetics.com)

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**PURCHASING**

Germany, Austria, Switzerland GE Healthcare's Prucka CardioLab IT will now be exclusively distributed by Biotronik Vertriebs GmbH & Co KG in these countries. The firms report that their agreement will benefit customers because they can order a comprehensive range of catheters and GE's electro-physiological measuring system from a single source.

25,000 visitors and medical professionals from 47 National Cardiac Societies across central and greater Europe, will attend the 2004 ESC Congress, where 'Diabetes and heart disease' will be the main theme. **Lars Ryden**, ESC Past-President, team member for the Euro-Heart Survey on Diabetes, and Chairman of the 'Guidelines for Diabetes & the Heart', and **William Wijns**, co-chair and Chairman of the Congress Programme Committee, explain why this has become such a central focus for cardiologists

# The ESC Congress

28/8 - 1/9 Munich Germany

Accumulating evidence indicates that the burden of cardiovascular disease in patients with diabetes is growing to such an extent that acknowledging the 'epidemic' growth of the problem represents by no means an exaggeration. This increased cardiovascular risk extends to the many patients with obesity, metabolic syndrome and other conditions that are associated with all too often unrecognised insulin resistance.

For instance, abnormal glucose regulation (defined as previously unknown diabetes and impaired glucose tolerance) is present in 67% of patients admitted for acute myocardial infarction to the Coronary Care Unit. These patients are at increased risk of death, re-infarction and progression to heart failure.

In order to respond to the growing burden of cardiovascular disease in patients with diabetes, the emphasis of the 2004 ESC Congress will be placed on the general theme of 'Diabetes and the Heart'.

Both education and science will be covered. This means that significant parts of the pre-arranged and abstract-based programme will present the latest information on molecular mechanisms, pathophysiology, epidemiology, prevention and treatment of cardiac disorders that are associated with diabetes.

As to the pre-arranged programme, we are introducing the 'Diabetes Track', a series of 12 didactic symposia, or clinical seminars, that will take place continuously during the congress.

In addition, for each major subspecialty topic, issues specifically related to diabetes will be addressed by dedicated lectures in

several sessions.

The final results of the Euro Heart Survey on 'The diabetic state of patients with coronary artery disease' will be presented on 29 August. The overall results as well as a preliminary report of the one-year follow up, conducted during spring and summer 2004, are available.

Practical approaches to the management of the diabetic patient will be illustrated during one of the popular FOCUS Cardiology Practice sessions (on August 30). The topics and patients to be discussed are chosen so that available and upcoming 'Guidelines for Diabetes and the Heart' may be used for commentary.

Even the satellite programme, organised by our industrial partners, will cover many important aspects of this new epidemic, with a special emphasis on the value of prescribing drugs such as ACE inhibitors, angiotensin II receptor blockers, beta-blockers, metformin, moxonidine and others.

Because the European Association for the Study of Diabetes (EASD) will hold its annual meeting in Munich immediately after the ESC Congress, we will take advantage of this opportunity to share a number of initiatives.

We will have a joint main session entitled: 'Caring for patients with type 2 diabetes - a responsibility to be shared between cardiologists and diabetologists'. Be sure to attend this session on August 30.

As for the abstract-based programme, we will hold a prestigious joint session called the EASD-ESC scholarship session. Six abstracts of outstanding quality (half select-



Lars Ryden

ed by each organisation) will be presented at both meetings. Sincere congratulations to the Awardees: N Kraenkel (Leipzig, DE), T Mazurek (Warsaw, PL) and F Cipollone (Chieti, IT) on behalf of the ESC; and W Otter (Munich, DE), C B Kragelund (Frederiksberg, DK), and G Doronzo (Orbassano, IT) on behalf of the EASD.

The regular programme will discuss over 60 abstracts on topics related to Diabetes & the Heart, either during oral or poster presentations.

Last but not the least, some of the trials presented during the Hot Line sessions will release important data for the management of patients with diabetes, for example INTER-HEART (a world-wide study of the impact of risk factors), RIO-EUROPE (a randomised trial on weight reduction with Rimonabant in obese patients) and DETAIL (a trial on the value of Telmisartan & Enalapril in diabetics). Exciting results of Clinical Trial Updates are expected as well, including follow-up data of GAMI and the subgroup analysis of TAXUS VI in patients with diabetes.

## Successfully treating CHD in infancy

By Professor **Boulus Asfour MD**

Assistant Medical Director at the German Children's Heart Centre, Asklepios Klinik Sankt Augustin GmbH

Germany - 0.7% of newborn babies need surgery for congenital heart defects (CHD) - i.e. around 5,000-6,000 children in every 700,000 born. In the entire CHD spectrum, some defects are ideally treated in the first month of life (newborn period), first year of life (infancy) or in childhood before entering school. Indication for surgery depends on symptoms - either cyanosis, congestive heart failure, failure to thrive or haemodynamic reasons. After the introduction of minprostin and the Rushkind procedure almost the only real surgical emergency is for obstructed total anomalous venous return, because oxygenated blood from the lungs does not reach the systemic circulation. The following heart defects are recommended for correction in the first month of life: transposition of the great arteries, critical aortic stenosis and critical coarctation of aorta, interrupted aortic arch, truncus arteriosus, hypoplastic left heart syndrome, anomalous origin of the left coronary artery etc. In the first year of life, the following heart defects should be treated surgically, before irreversible damages to lung and heart occur: persistent ductus arteriosus, ventricular septal defect, atrioventricular septal defect (AVSD), and Tetralogy of Fallot. Before school age, all CHD with no irreversible damage to heart and lung should be corrected e.g. atrial septal defects.



For all CHD one may argue that the earlier the defect is corrected the shorter the heart has to suffer from dysfunction. Furthermore, correction of CHD indicates an anatomical correction and not palliation, such as banding the pulmonary artery for AVSD in order to limit pulmonary blood flow, or placement of an aorto-pulmonary shunt in Tetralogy of Fallot because of cyanosis. After about two years of age, complex CHDs in functionally uni-ventricular hearts are treated by aiming at a perfect Fontan circulation, by early banding of pulmonary arteries in the case of pulmonary hypertension, and implantation of a limited-sized shunt in the case of cyanosis. The ideal Fontan circulation then allows maximal passive blood flow from the superior and inferior vena cava to the pulmonary arteries.

Increasing knowledge in science and physiology and advanced surgical techniques, have led to low mortality even for correction of complex heart defects in infancy, especially in specialised high volume heart centres where over 250 procedures are performed annually. Very few centres in Germany can offer this level of high expertise, thus centralisation of heart centres for congenital disease should be promoted.

Other drugs (e.g. diuretics, digoxin, nitrates) are additionally used for symptomatic reasons. Importantly, therapy must be initiated and up-titrated carefully to increase tolerability. Also, regular controls, particularly of serum creatinine and potassium, are crucial. Since medical therapy of CHF is complex and these patients often have diseases other than CHF, drug interactions must be considered carefully.

Therapy of diastolic CHF (i.e. CHF with preserved EF) is less well defined and mainly aims at reduced symptoms (primarily diuretics). Since arterial hypertension is the most common cause of diastolic CHF, blood pressure control is important. If there is an additional prognostic benefit of medical therapy remains to be investigated.

Congestive heart failure (CHF) is a major healthcare problem with 1-2% of the population affected in Western countries. Because it increases with age, the prevalence of CHF is escalating with our aged populations. Despite improvement in CHF therapy, prognosis is still poor. After hospital discharge, about 50% of patients are readmitted within a year, due to decompensated CHF. Accordingly, healthcare costs are enormous and estimated at about €10,000 / year / patient, of which hospitalisations account for 2/3. Therefore, apart from reducing mortality, a major target of CHF therapy is to reduce the hospitalisation rate.

Dyspnoea is the leading symptom of CHF. However, diagnosis may be difficult. Blood measurement of B-type natriuretic peptide (BNP), which is released by the

## CHF: A major healthcare burden

By Professor **H P Brunner-La Rocca MD**, Cardiology Department, Basel University Hospital

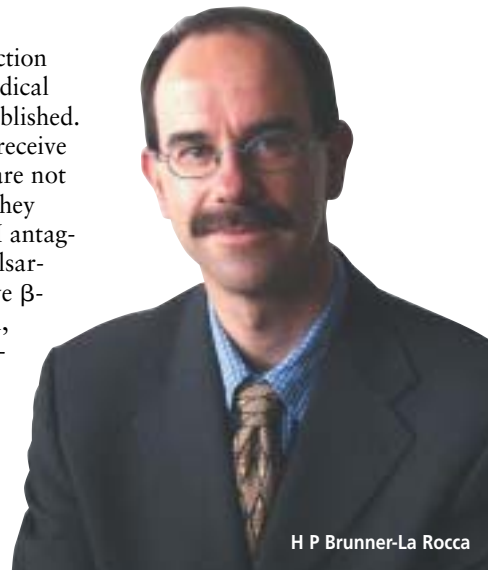
heart in parallel to the severity of CHF, significantly increases the accuracy of diagnosing CHF.

The most important underlying causes of CHF are coronary artery disease and arterial hypertension. Other causes such as valvular heart disease, dilated cardiomyopathy, and other diseases are more seldom. The risk of CHF may be reduced by treating and/or preventing these disorders. Also, even when CHF is established, treatment of the underlying disease may improve outcome.

Therefore, diagnostics should not only define the severity and possible complications, but also

the underlying cause of CHF.

If left ventricular ejection fraction (EF) is reduced (i.e.  $\leq 45\%$ ) medical therapy is well studied and established. Thus, all these patients should receive an ACE-inhibitor, even if they are not symptomatic. If not tolerated, they should receive an angiotensin-II antagonist (candesartan, losartan, valsartan). Patients should also receive  $\beta$ -blockade (bisoprolol, carvedilol, metoprolol) and, if still symptomatic during daily life activities, spironolactone. Recently, the CHARM study showed that angiotensin-II antagonism (candesartan), added to other therapy, might be beneficial.



H P Brunner-La Rocca

Other drugs (e.g. diuretics, digoxin, nitrates) are additionally used for symptomatic reasons. Importantly, therapy must be initiated and up-titrated carefully to increase tolerability. Also, regular controls, particularly of serum creatinine and potassium, are crucial. Since medical therapy of CHF is complex and these patients often have diseases other than CHF, drug interactions must be considered carefully.

Therapy of diastolic CHF (i.e. CHF with preserved EF) is less well defined and mainly aims at reduced symptoms (primarily diuretics). Since arterial hypertension is the most common cause of diastolic CHF, blood pressure control is important. If there is an additional prognostic benefit of medical therapy remains to be investigated.





## BP: A poor indicator for cardiac disease

Blood pressure (BP) screening, either alone or in combination with other cardiovascular risk factors such as cholesterol levels, does not determine a person's chance of having a heart attack or stroke, reports Professor Malcolm Law and colleagues at the Wolfson Institute of Preventive Medicine in the *Journal of Medical Screening*. Although high BP is a proven cause of heart disease and stroke, the authors claim that most heart attacks and strokes occur in people who do not have high levels of blood pressure. Pre-treatment blood pressure measurements identify people who will not suffer from heart disease in addition to those who will. **History of heart disease is best indicator** - 'Identifying patients at the time of hospital discharge following a heart attack or stroke is the most effective screening test to distinguish those who will die of cardiovascular disease,' the authors report. This is supported by the fact that about 50% of deaths caused by heart disease

occur in people who have already had a heart attack. **All people over 55 are at higher risk** - We know that lowering BP decreases the risk of heart attack and stroke, regardless of the patient's existing level of BP. The authors conclude that preventive treatment might as well be offered to everyone above a specified age of 55 '...rather than attempting to discriminate between people using measurements of blood pressure or cholesterol'. **Lower dosage reduces incidents** - Professor Law and colleagues also discuss recent work that has '...shown that blood pressure lowering drugs are in general best used at half the present standard doses, because the resulting reduction in adverse effects outweighs the relatively small loss of efficacy.' Using BP lowering drugs at low dose in persons over 55 would reduce the number of heart attacks by 46% and stroke by 63%. Details: [www.rsm.ac.uk/new/prbody.htm](http://www.rsm.ac.uk/new/prbody.htm)

## Small silent VADs

Powerful tools to beat end-stage HF

Ventricular assist devices (VAD) have been used since the 1980s, primarily to provide support after cardiac surgery for several days during recovery, or more often to keep patients alive until later heart transplantation (HTx). This latter concept, named 'bridge-to-transplantation' (BTT), has saved many patients who otherwise would have died before a donor heart became available.

Organ failure from cardiogenic shock - brain, lungs, kidney, and liver - was reversed by VAD support, which only then made heart transplantation successful. Thus, in experienced teams, the results of HTx after BTT are the same

By **Roland Hetzer MD PhD**, of the German Heart Centre, Berlin

as after primary HTx. However, with BTT the number of possible HTx is not increased.

The waiting time for HTx has now become as long as many months. This has allowed the observation of extended periods on VADs, which has led to two important concepts. First, some patients with acute myocarditis and dilated cardiomyopathy have displayed complete cardiac recovery after weeks and months of unloading of the heart with a VAD, which could then be removed, followed by stable heart function, up to now for over nine years. Such 'bridge-to-recovery' is excitingly



attractive as a treatment concept; however, so far, recovery in the individual patient has remained unpredictable.

Second, long BTT waiting periods, improved VADs, high patient mobility and quality of life on VADs and the discharge of patients to home, then a return to work with a VAD have opened the view to permanent VAD support, and now an increasing number of patients receive VADs as 'destination therapy', either because of contraindications to HTx or due to a patients' own wishes.

Some VADs have now been designed for permanent use and experience with this latter concept shows well-functioning devices in patients up to over six years.

Newly developed devices are smaller, need less energy, are silent and mostly follow the continuous flow principle. Expectations are justified that such VADs will become a powerful routine tool to battle end stage heart failure.

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# Worldwide about 600,000 new cases of breast cancer are diagnosed annually



## THE ON-GOING DEBATE

### Why screen?

Mammography as a diagnostic procedure to evaluate detected tumours is not an issue. But because the technique is performed, in screening programmes, on apparently healthy people, for ethical reasons it becomes an issue. Screening should be based on a sound scientific foundation, so results from several studies of mammographic screening need critical re-evaluation of this procedure, according to Professor I Mühlhauser, specialist in internal medicine, diabetology and endocrinology at Hamburg University, Germany.

Using an evidence-based approach, Danish researchers Peter Goetzsche and Ole Olsen evaluated all available data on mammographic mass screening. They concluded that there is no reliable evidence that regular mammograms reduce breast cancer mortality and argue that six in eight studies showed flawed methodology, questioning the reliability of their results. Two studies that were reliable, i.e. meeting the strict criteria of the Nordic Cochrane Centre, Copenhagen, indicated that mammographic screening does not yield any benefits (*The Lancet* 2001; 358, 1340-1342).

In Sweden, mammographic screening began in the late 80s. The study included 600,000 women aged 50-69. A recently published analysis of the data raised doubts on the usefulness of these expensive screening programmes, because, from 1986-96 breast cancer mortality had not significantly decreased in the region. The number of deaths from breast cancer in the group of women who had undergone mammographic screening was only 0.8 % below the expected value (*British Medical Journal* 1999; 318: 621).

Both findings, published in renowned medical journals, are disquieting in themselves, but worse, Professor Mühlhauser points out, is that screening may have negative effects: wrong results, be they positive or negative. Incorrect positive findings lead to unnecessary interventions and create fear in the women concerned; incorrect negative findings create a false sense of security. In the Swedish study,

100,000 women received an incorrect positive diagnosis and consequently biopsies for further clarification were performed on 16,000 women. 4,000 women underwent unnecessary surgery, in many cases even a mastectomy.

These findings should influence the design of future screening programmes. Comprehensible and objective information for the public must include the possible benefits as well as possible harm. Only then can all findings be evaluated and analysed. One feature of mammographic screening is that many women participate; some benefit and many suffer serious harm. Women can only make an informed decision if they can assess personal benefits in relation to effort and effect.

The primary goal of screening is to achieve a decrease in mortality - while maintaining an acceptable level of quality of life, effort and cost. Data presentation influences the decisions of women and doctors. What does it mean, when mammography allegedly reduces breast cancer mortality by 30%? Most people would assume that, out of 100 women, 30 fewer die from breast cancer. But that is not the case. Absolute figures are far more transparent.

There are different ways to present data in favour of early detection screenings. Often, results are being shown in percentages. Using Swedish data Mühlhauser illustrates the danger inherent in different presentations: **Without** mammography **four** out of 1,000 women die of breast cancer within a 10-year period. **With** mammography, the number is reduced to **three**. In absolute figures: Without mammography 996 women don't die from breast cancer over a period of ten years. With mammography the figure is 997. Or: Out of 1,000 women with mammography one woman benefits by not dying of breast cancer, 999 women have no benefit as they would not have died from breast cancer anyway (996 women) or because they died from breast cancer despite mammography (three women).

Further details:  
[www.mammographie-screening-online.de](http://www.mammographie-screening-online.de)  
[www.gmc-uk.org/standards/CONSENT.htm](http://www.gmc-uk.org/standards/CONSENT.htm)

Report: Christian Pruszinsky

Mammography plays a critical part in diagnosing breast cancer. Although this does not prevent the disease, diagnosing breast cancer as early as possible can save lives. In the past, women who came in with a lump were found to have breast cancer. Nowadays, radiologists find cancer via



mammography early in the disease development, and often before a patient can feel it. Usually, these earlier stages also have far lower lymph node involvement.

While mammograms do not prevent breast cancer, they have been shown to reduce mortality by 35% in women over 50 years old; in women between 40 and 50, studies have shown that mammograms may lower the chance of dying from breast cancer by 25-35%. By using mammography to detect localised breast cancers at an early stage there is less need for surgical breast removal.

Mammograms are far from perfect: breast tissue can conceal a growing cancer and prevent it from showing up on the mammogram (women with breast implants are additionally prone to this). Many health experts agree that the biggest misconception about mammography is that it picks up every breast cancer. However, this is not the case - mammography actually misses at least 10% of all breast cancers. Women should always practice self-examination and bring any lump they feel to their doctor's attention to have it evaluated.

However, mammograms remain one of the most important tools to help doctors to diagnose and evaluate women who have had breast cancer, and leading experts, the National Cancer Institute, the American Cancer Society, and the American College of Radiology

## Screening update

By Karen Dente  
 our USA correspondent

contained aluminium oxide grains, and others were empty, whilst still others contained round lesions with blurred margins to simulate the contours and textures of breast tissue.

When primary dosimetry was completed, the results were compared, using both imaging modalities and X-rays. The five investigators noted their observations for every finding of the 16 wax blocks: 'g' for grains, 'l' for round lesions, 's' for strings and 'e' for empty. Results were then compared with the true arrangements, whereby the test for recognition was planned only for true positive results. In other words the sensitivity of the two systems was proved. For each modality a maximum of 45 true positive results were possible (18 strings, 15 grains, 12 round lesions).

The results showed that using conventional film screen system mammography, a total summary of 191 (average 38.2) of 225 possible details were detected by the five investigators, compared with a summary of 219 (average of 43.8) using digital mammography. Based on these experimental findings, the researchers conclude that, from the two modalities, full-field digital mammography shows better results in the capacity for detection of details, despite lower resolution (7 lp/mm vs. 14 lp/mm). The limit due to lower resolution is compensated in this system by higher DQE (detective quantum efficiency) and signal-to-noise ratio.

The researchers conclude that their phantom study shows the possibility for replacing conventional film screening systems with digital mammography (DR) that includes a newly developed a-Se-detector.

With X-ray technology modernising, as in this new Siemens device, screening women with breast cancer enters a new era. The goal is to have mammography as a highly reliable diagnostic tool for breast cancer, with the potential to become a widespread screening device employed routinely, so that the majority of breast cancers can be detected in their incipient stage.

Pictures courtesy of Siemens

## The UK Ploughing vigorously forward

**The UK** - In the 1990s, the nationally co-ordinated NHS Breast Screening Programme was already saving lives - a 21% fall in breast cancer mortality over the last decade and, with the cervical screening programme, this was viewed as among the best cancer screening programmes in the world. However, in that period, the country's cancer services, as a whole did not match up to those of other European countries.

In September 2000, the government published its NHS Cancer Plan, providing a long-term national strategy that heralded radical reform of cancer services, aimed at reducing mortality from cancers by at least 20% in people under 75 by 2010 (using 1995-97 figures as a baseline).

Between then and 2002 the country's cancer death rate fell by 10.3%, which, by comparison of categories with results from other countries, indicated that Britain had achieved the world's sharpest decrease in premature deaths from breast cancer and had made a substantial decrease in lung cancer deaths. In that period, 1.3 million women had been screened and 8,545 breast cancer cases were diagnosed. Now, new figures published in February 2004 have revealed that breast screening detected 9,848 cancers in 2002/03, over 13% more breast cancers detected by screening than in the previous year.

Because research has shown that two-view mammography could lead to a 42% increase in the detection of small cancers, this was also introduced to the programme, and it is believed this produced the new rise in breast cancer detection. It involves taking two x-ray views of each breast during screening. By December 2003, 86% of local screening services carried out two-view mammographies. (England now has about 80 breast screening units at 87 sites - with some local breast screening programmes creating additional space by undertaking new building projects).

Breast cancer screening programmes were also extended and new programmes and technologies introduced - if proven lifesavers. Additionally, the NHS Breast Screening Programme was extended to include women aged 65-70 years, so that women aged 50-64, formerly invited for five screens, now receive two additional invitations for screening. An additional 400,000 women will be invited for screening annually by the end of 2004.

**Screening staff** - To remedy a dearth in radiographers, training places were doubled. Additionally, the Department of Health (DoH), partnered by the Society and College of Radiographers and the Royal College of Radiologists, developed a programme in which four new roles were created: assistant practitioner, state registered practitioner, advanced practitioner and consultant. Advanced practitioners are radiographers trained to take on some of the tasks of radiologists, i.e. interpreting X-rays and inserting marker wires to identify breast tumour locations. Trained assistant practitioners produce basic breast screening X-rays and can deliver basic radiotherapy to cancer patients.

The NHS reported that this role enhancement attracted more personnel to work for the NHS. By spring last year, 53 assistant practitioners and 158 advanced practitioners were employed and 28% of breast screening units were using assistant practitioners to help deliver the service.

**Equipment** - The DoH allocated £12 million to buy new breast screening equipment, which includes mobile screening units. Purchasing from 2000-2003 included 204 CT Scanners (164 replacements; 40 additional), 88 MRI scanners (51 replacements; 37 additional) and 91 linear accelerators (66 replacements; 25 additional), as well as 44 computers for radiotherapy planning, 23 simulators and over 600 devices for breast screening.

**Patients** - Under the NHS Cancer Plan, new information leaflets about

screening were introduced to explain to patients the potential benefits and harm of screening programmes to help them base their decisions on evidence-based data (information overseen by the Advisory Committees on Breast and Cervical Screening and National Cancer Director). Since 2001, these have been included with the invitations women receive for breast (and cervical) screening.

Following publication of the government's White Paper, 'The new NHS - Modern, Dependable', which

guaranteed anyone with suspected cancer would see a specialist within two weeks of their general practitioner (GP) requesting urgent consultation, from April 1999 this applied to anyone with suspected breast cancer. It was reported that 96.9% of women with breast cancer now receive first treatments within a month of diagnosis. Ways of seeing non-urgent referrals within two weeks have also been investigated by the Cancer Services Collaborative 'Improvement Partnership' (CSC 'IP') breast group.

Rapid access ('one stop') clinics were also established for patients presenting common problems

(including breast cancer symptoms) that might point to an underlying cancer. In addition, in some areas GPs can refer patients directly for diagnostic tests, bypassing the wait for a consultation.

To further streamline diagnoses, significant streamlining of diagnostic tests has also been a focus.

**Peer reviews** - To improve quality of care, assessments of cancer teams have been rigorous, and the value of peer reviews is generally acknowledged. A peer review steering group was established, closely linked to the shadow Commission for Healthcare Audit and Inspection (CHAI), and this summer a three-year peer review programme commenced.

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GE imagination at work

Germany's Federal Committee of Physicians and Statutory Health Insurance Funds set up three model projects, based in Bremen, Wiesbaden and Weser-Ems, to trial the third edition of the European guidelines on healthcare within the German system and to develop the necessary organisational structures to make these work.

GERMANY

# Quality assurance first

Following negotiations over the 'Model Project Mammographic Screening in Bremen', between the Association of Statutory Health Insurance Physicians of the Hanseatic City of Bremen and the national associations of the statutory health insurance funds of the City of Bremen, Dr Hans Junkermann MD, of Heidelberg, was appointed project leader as there was no role model or similar project in any other German city mammographic screening in Bremen oriented itself on examples from the Netherlands, Sweden and England.

The objective was to create conditions to provide quality assured mammography and sufficient information for all women in Bremen aged 50-69 years. The objective of mammographic screening, according to the European guidelines, is to lower the mortality rate from breast cancer by about 30%. According to those guidelines, the main features of mammographic screening should be:

- Organised screening following written invitation to all women aged 50-69, based in the region
- Mammography to be carried out by a qualified radiography assistant who has undergone further training
- Second assessment of each mammographic examination, with both assessments being carried out by practicing radiologists, with further training, who evaluate at least 5,000 images annually
- Assessment based on EU guidelines
- Second diagnosis of all pathology results
- Complete, gapless documentation and publication of results
- Pre-and postoperative, interdisciplinary conferences with compulsory attendance
- Work flow and results based on EU standards
- Internal and external quality assurance

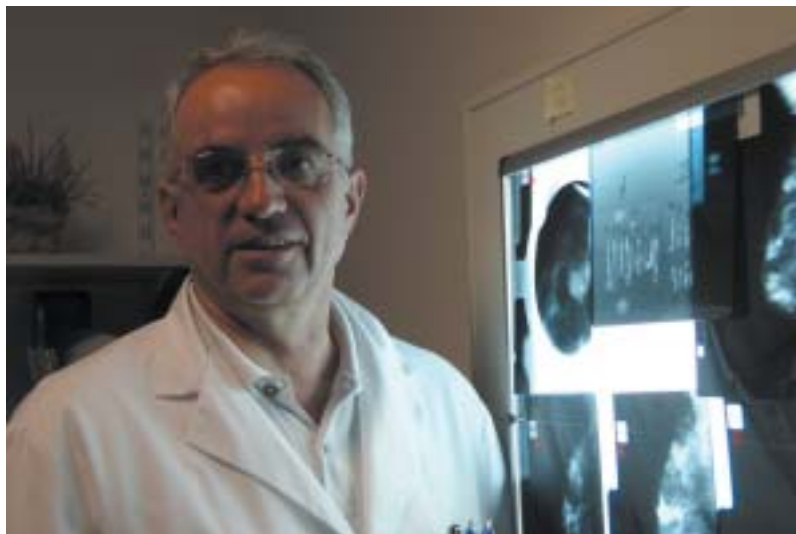
Every step in mammographic screening, from initial invitation to diagnosis, the documentation and possible further assessments right up to surgery (if necessary) must be carried out with quality assurance. Mammographic screening is a

chain of events where each step, plus the whole procedure, must be totally quality assured.

Individual steps

- All women aged 50-69 should receive a written invitation to voluntarily participate in the programme. They can change appointments by phone, fax or email.
- Examinations are carried out in special facilities where specially trained radiography assistants work autonomously and self-dependently

By **Antonia Hanne**, of the mammographic screening unit, Bremen Clinic, describes the lead-up to the adoption of a national breast screening programme



- Each mammogram is assessed by two practicing radiographers, independently
  - Any suspicious images are discussed and assessed with the doctor responsible for the project and patients are then recalled for further assessments
  - Final diagnosis is carried out in the screening centre through clinical examination, ultrasound scan, additional mammography and, if indicated, biopsies
  - All clinical, pathological and radiological results of patients examined are introduced to, and discussed by surgeons, radiologists and pathologists during multidisciplinary, pre-operative conferences. Results of surgery and courses of treatments are discussed during post-surgical meetings.
- The model project in Bremen, the first to be set up, began in July 2001, followed soon afterwards by Wiesbaden, then by Weser-Ems just over a year later.

Up to 31/12/2001, a small number of women due for examination were invited on a daily basis, while the facilities for the clinical aspects of the mammographic screening (assessment, first and second pathology examination, stereotactic biopsy) were being set up. Simultaneously, further training was carried out for staff; guidelines for regular, ongoing training were developed, and external quality assurance was finalised with the reference centre in Nijmegen, Netherlands. Medical documentation programmes were selected and tested and the final data protection concept completed. Around this time, the Goetsche and Olsen's Meta study was published by the Cochrane Institute, which took a clear stance against mammographic screening, causing confusion in Bremen as much as elsewhere.

Since 1/1/2002 Bremen's mammographic screening unit has worked to full capacity. In May of that year, the WHO contradicted Goetsche and Olsen's interpretation with the Lyon IARC (International

Agency for Research on Cancer) statement and clarified: *Quality assured mammographic screening reduces mortality rates from breast cancer by up to 35%*. On one hand, this ended the emotionally heated discussion on disadvantages or benefits of mammographic screening. However, it also made it clear that only quality assured, organised mammographic screening lowers mortality, as opposed to the opportune (grey) type of screening, then widespread in Germany.

In October 2002, Germany's *National Cancer Institute* published the 'Shanghai-Study', which declared that manual examination

of the breast was not a suitable method for early detection of breast cancer. So, from a scientific point of view, only organised mammographic screening can be considered as a suitable tool of early detection that can lower mortality significantly.

In the first two years, 83,102 women across the three model project regions were invited for screening. 44,934 women from the target groups participated in mammographic screening. 6% of participants were recalled for further assessments. 2% of participants had tissue removed through needle biopsies. Breast cancer was discovered in more than 9 (9.6) in a 1,000 women, and in 17% of cases the cancer was still at the in situ stage. The proportion of invasive carcinomas of less than 10mm in diameter was 36%. There were no significant differences between the three model projects. With the exception of the participation rate, all EU guidelines

were achieved or exceeded. Three times as many cases of breast cancer were detected in Bremen and Wiesbaden, with intensive medical care, compared with the period before the screening programme began.

Dealing with external quality assurance is a new and unusual concept in the German healthcare system and was initially considered to be limiting, strange and controlling by staff involved in the mammographic screening programme. However, today external quality assurance is regarded as a natural safeguard and a check on one's own work to ensure efficiency, benefits and evidence.

Experiences gathered from the model projects provide the foundations for the national programme for quality assured mammographic screening, based on EU guidelines, which was recently adopted in Germany.

AUSTRIA

## Weighing up the way to go

Austria is the only 'old' EU Member State that has not implemented a national breast cancer screening programme. That, plus an increasing public debate surrounding hormone replacement therapy (HRT), prompted the country's Health Minister to commission a study, from the Federal Institute of Health (ÖBIG), to examine parameters for such a programme. This set in motion a pilot project, based in Vienna and Vorarlberg, that offered mammographic screening to 70,000 women aged 50-69. A second research programme targets women with genetic breast cancer risk, and a third examines women on HRT over a long period of time.

4,500 Austrian women are diagnosed with breast cancer annually, and about 1,600 women die of it. A systematic screening programme is expected to reduce the mortality rate by a third. By comparison, in the EU-15: 220,000 breast cancer diagnoses and 75,000 deaths from breast cancer, means 25,000 women could be saved through screening. Both the EU Commission and the WHO expect, based on research findings in Sweden and Finland, a reduction of the mortality rate by 30%, if all member States implement a high-performance screening system that includes second diagnosis and follow-up examinations when necessary.

The authors of the ÖBIG report, Mammographic Screening Austria, conclude that a widespread national early detection programme could save the lives of 500 women annually, but they also point out that the Austrian health system currently lacks basic preconditions for a quality-based screening programme that complies to EU guidelines such as training, technical and equipment-related quality assurance or a breast cancer register. The maximum costs of such a programme, not taking into account synergy effects on space, equipment and personnel resources, are estimated at about 22 million euros per annum.

Details: [www.oebig.at](http://www.oebig.at) Report: Christian Pruszinsky

THE NETHERLANDS

## Mobile mammography goes digital

Financed by the Ministry of Health, nine regional screening organisations arrange and implement the Dutch national breast cancer screening programme, in which, every two years, all women from 50-75 years of age are invited for a free mammogram at one of the 62 screening points, of which 56 are mobile vans.

With nine vans, including a new digitally equipped van, BBNN is responsible for the country's northern area. About 80% (84 % in the BBNN region) of all women have registered at one of the screening points in their neighbourhood.

The Dutch BBNN (Breast Cancer Screening Organization) added the new mobile mammography van to its fleet of eight mobile breast cancer screening vans that visit 229 screening points in the country's northern region. This van is equipped with Agfa's Embrace DR system, which sends mammograms in DICOM format to a central PACS database for diagnosis in one of three regional reporting units.

Herman H Meerholz, General Manager of BBNN said that Agfa's Embrace DR system, which combines selenium detector technology with Agfa's MUSICA2 image processing software, covers the complete workflow of the organisation's mobile screening programme. 'Using GPRS (General Packet Radio Service, the latest mobile telephony generation) technology, the radiology technician in the van will retrieve a customer list from a central database for each screening point. During an examination the technician can annotate and prepare images on the Agfa Embrace viewing station and store the images in DICOM format on a removable hard disk, storing 80 examinations. Each day, this is transported to a nearby reporting unit for integration on the central PACS server. The exams can then be accessed for diagnosis from one of the three reporting units in our region.'

Further enhancements, such as CAD (Computer Assisted



Detection) technology, will be integrated in future releases. Using the Agfa Embrace DR system will result in a more consistent image quality, a more reliable workflow and noticeable labour cost savings, Agfa points out. Results from this pilot project, which commenced in June, will be assessed at the end of the year.

UK age and mortality research

Aiming to assess the clinical value and cost-effectiveness of routine breast screening for under 50-year-olds, the UK's 'age' study, begun in 1991, recruited some 160,000 women aged between 40-50 years. Results from this £1 million per annum trial are expected in 2005.

FRANCE

# No reimbursement for digital screening

Interviewed by Daniela Zimmermann, Executive Director of EH,  
**Jean Hooks, General Manager, Global Mammography at GE Healthcare**, examined reasons behind the slow uptake of digital technology in some European countries, comparing this with its early adoption in the USA

**Jean Hooks:** Let me begin by saying that digital mammography offers proven benefits to clinicians and patients including reduced patient examination time and reduced waiting time; lower call-back rates; simplified management of past mammograms; and opportunities for advanced applications including computer-aided detection (CAD) and better access to a broader range of populations with greater use of tele-mammography and tele-radiology.

France was one of the earliest adopters of mammo-technology, and particularly digital technology. But there is still no established digital screening and quality control programme. We see some hesitation about moving to a digital environment.

**DZ:** Is this because digital images are not yet as good as film images?

**JH:** I'm not sure how you formed that opinion. Hopefully I can share information from clinical partners who have shown the benefits of digital mammography.

About 300 hundred studies have been published - not by GE, but by clinicians around the world using GE systems, who describe what they've learned from using digital mammography - recall rates, cancer detection, improved lesion and calcification detection.

Regretfully today, there is some confusion about performance related to digital mammography, for example with CR, which is one of the hot topics in France. In many European countries, the hardest aspect is scepticism and the relatively low level of digital mammography education. Yet France was the place where clinicians took up

Jean Hooks BA has worked for GE for 16 years. Entering the firm's Healthcare division in 2001, she became General Manager of the Global Mammography business in 2003, and is based in Paris



digital mammography very quickly. They believed that, by carrying out studies, they could show the clinical benefits and outcomes in this technology. A lot of our French customers know that it gives them far more information about the breast than can be obtained from film. With image processing you can work through the image in much more detail, and algorithms allow certain features to be highlighted, such as micro-calcifications or instant contrast, from skin-line to the chest wall, without window levelling.

A great deal of French clinicians know that digital mammography gives them far more information about the breast than can be obtained from film. With image processing you can work through the image in much more detail, and algorithms allow certain features to be highlighted, such as micro-calcifications or instant contrast, from skin-line to the chest wall, without window levelling.

**DZ:** Do the French have a screening programme?

**JH:** Screening, reimbursement and quality control are three armaments that go hand in hand in any market. France has screening programmes but no reimbursement for digital screening. One key reason

for this is that, as yet, there is no established quality control programme for digital mammography. We are supporting regulatory bodies efforts towards that objective.

**DZ:** You have to convince politicians?

**JH:** With the French Minister of Health and the former Minister of Health, we have discussed this technology's capabilities and how to introduce it. There is also quite an open and positive dialogue between our safety regulatory group and the French regulatory body. It is critical to ensure that they have the information they need to make very good decisions for putting programmes in place. Technology without screening and regulatory quality control programmes can't benefit anyone.

**DZ:** In France, as in Germany, digital mammography is for women who can afford it.

**JH:** Right now that's the challenge and that's why we are working on education in three areas: first on government and regulatory bodies, then on the physicians, radiologists and technologists - the people who use the technology.

These specialists have a learning curve going fully digital, as is illustrated by the confusion regarding performance of some CR systems compared to other digital mammography devices. If people don't understand the difference, at the end of the day they think it's all digital, all soft copy. But this is not about soft copy; it's about getting very good images through digital mammography.

The third area covers educating patients, for which GE has done a lot of work in various European countries - where we have published around 1.5 million brochures dealing with patient education. If women do not understand breast cancer, how can they detect it earlier? They need to learn the procedures for self-examination, not just mammography, to

gain knowledge about their own bodies. They also need to understand some of the benefits they gain by having mammograms on a regular basis - digital or film - it doesn't matter. We're trying to educate women so that they can get on a screening programme and detect cancer early on. 95% of stage one and stage two cancers are curable. Patient education is as important as that of a radiologist, doctor, technologist and government regulatory body.

At GE Healthcare, we're commit-

ted to better breast cancer care for women. Among the many reasons we've led the industry is because of innovation - we listen to clinicians worldwide and have incorporated their needs and the needs of their patients in advanced breast imaging technologies.

We will continue to work with clinicians and government organisations in the effort to bring better mammography and overall breast care to patients in Europe and worldwide.

## Automated screening & reduced biopsies

Although X-ray mammography can detect small cancers before they have spread. However, because abnormalities can only be identified non-specifically, percutaneous or surgical breast biopsy must follow - but less than 20% of women recalled for biopsies have cancer.

Now, research on the use of scattered X-rays has highlighted the potential for creating an automated process for breast cancer screening and reducing the need for biopsies. This work is among the many projects undertaken by the Synchrotron Radiation Department at the CLRC Daresbury Laboratory, UK, which span physics, chemistry, materials science, structural biology, engineering, environmental science, and novel applications to medicine and archaeology.

'Invasive tumour expansion in breast carcinomas affects the collagen scaffold structure, a major component of breast tissue. Using small-angle X-ray scattering (SAXS), such changes in collagen structure are now detectable, and may lead to the characterisation of fea-

tures in X-ray scatter distributions that show potential as disease markers,' Daresbury Synchrotron explains. 'If the molecular structure of the collagen is intact, the fraction of X-rays that pass through it appear in the form of peaks or rings, representing the effects of coherent interference caused by the diffracted rays. Peaks that are strong demonstrate healthy normal tissue, whereas peaks that are weak or diffuse indicate degraded tissue. The peak intensities have been shown to indicate conclusively which of the collagen specimens were cancerous and which were healthy.'

Preliminary results suggest that this technique can be used to make accurate assessments of cancerous versus normal breast tissue, and also for the detection of benign tumours,' the lab points out. 'There is also scope for in vivo application, which would both eliminate the need for breast tissue removal and greatly reduce the analysis time compared to that of current methods.' Details: [www.srs.dl.ac.uk](http://www.srs.dl.ac.uk)

## PET and recurrent cancer

More sensitive dissemination tests are needed for patients with locoregionally recurrent (LRR) breast cancer, according to a paper by Dutch researchers published online by the *European Journal of Cancer* (Volume 40, Issue 10, 7/2004).

The study aimed to describe the extent and yield of daily clinical practice when staging LRR breast cancer patients and to explore prospects for positron emission tomography (PET). Using the population-based Eindhoven Cancer Registry to select all breast cancer patients in the country's southeast, with a first episode of LRR between 1/1/1994 and 30/6/2000, it was found that, on LRR presentation, 16% of the 175 patients

had distant metastases and a further 24% were diagnosed with distant metastases within 18 months.

Additional data concerning staging procedures and follow-up were collected from medical records, and 77 physicians were also approached with a questionnaire seeking their opinions on staging procedures and actual treatment policy. Of the 75% of physicians who responded to the questionnaire, 33% thought the sensitivity of conventional imaging techniques was too low. The study team said it tended to conclude that '...in daily clinical practice there is a need for more sensitive dissemination tests for patients with a LRR of breast cancer.'

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## World's lowest radiation doses



The Swedish firm Sectra reports that its digital MicroDose Mammography system reduces radiation by 80%, compared with traditional film-based systems, and that its completely new detection technology allows this without compromising image quality. The MicroDose, developed in co-operation with mammography specialists to optimise ergonomic features and workflow, has been used to examine over 7,000 women since installation at Helsingborg Hospital in autumn 2003. Since April, the system also has been fully operational at Klinikum Krefeld, the municipal hospital of Krefeld and academic teaching hospital for the University of Düsseldorf. This hospital is now one of the first fully digitised mammography departments in Germany, producing breast images at the diagnostic workstation seconds after they are taken. The Sectra PACS for Breast Imaging is used for image review, communication and storage. 'This combination facilitates efficient review and thus faster diagnosis,' says Sectra. 'The direct digital system makes the cumbersome handling of cassettes and chemicals a thing of the past.'

Klinikum Krefeld has 19 clinics, 29 departments and over 1,100 beds, and provides all medical specialties for some 500,000 inhabitants of the Linker Niederrhein region, where the hospital has currently been commissioned to conduct a disease management programme against breast cancer.

With its roots in Linköping Institute of Technology, Sectra (which recently received the 2004 Frost & Sullivan Medical Imaging Company of the Year Award) is one of Sweden's fastest growing high-tech companies in IT and has over 500 installations worldwide. Recently the company also became 100% owner of Mamea Imaging AB.

## Ultrasound CT for early diagnosis



### 3D images with 10x higher res

**Karlsruhe, Germany** - A new type of ultrasound computed tomography (CT) system promising to improve diagnosis significantly is currently being developed at the Research Centre Karlsruhe. The procedure delivers three-dimensional (3D), reproducible images with a resolution ten times higher than conventional ultrasound images. The centre, part of the Helmholtz Community ([www.fzk.de](http://www.fzk.de)) reports that the first 3D-demonstrator will shortly be available to carry out first examinations on live tissue.

The new system makes it possible to capture even capillary structures with good contrast. In trials, objects such as straws and nylon threads were embedded in gelatine and measured with the tomograph. 'Even structures of 0.1mm in size with gaps of 0.5mm between them could clearly be recognised,' said Rainer Stotzka, head of the project. Experts agree that ultrasound CT could soon become the preferred method for early diagnosis, particularly for younger women, because this new system does not share the harmful side effects of X-ray mammography.

Describing the interdisciplinary project, Hartmut Gemmeke, head of the Institute for Data Processing and Electronics (IPE) at the research centre, said: 'In the development of the ultrasound CT system we have combined innovative concepts from the worlds of sensor technology, microelectronics, high-performance computing and algorithm development.' The Institute developed a method for the inexpensive production of thousands of miniaturised ultrasound converters required for the production of 3D tissue images. The control logic for the tomograph was also developed and manufactured at the IPE, along with high-performance computers with several gigabytes per second for the processing of large volumes of data.

## All-in-one digital mammography

Siemens Medical Solutions reports that the first installations have been completed in France, Germany, Italy and Sweden of its new all-in-one system for digital full-field mammography, named Mammomat Novation. This new system provides screening, diagnosis, digital biopsy in a single unit, enabled by the 'Flying Wing', used in Mammomat Novation's forerunner, the analogue model Mammomat 3000.

The unit includes the most up-to-date full-field detector technology based on amorphous selenium (a-Se). A photoconductor that directly converts X-rays to electric signals without any intermediate steps prevents scattered light effects that might occur with other technologies and impair the resulting image quality. Siemens Med points out that, in combination with the proven molybdenum/tungsten anode, this direct detector technology yields maximum image quality whilst minimising dose exposure.

A large detector of 24x29cm allows imaging of almost all breast sizes, including the pectoral muscle. A new compression plate enables central positioning of the breast for all projections without readjustment of the X-ray arm. The Opcomp function ensures that the breast is only compressed as long as it is soft and



pliable and automatically stops at the point of maximum image quality.

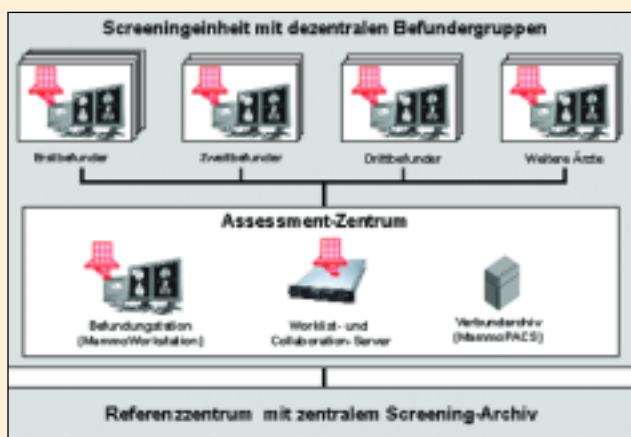
The system has a MammoReport<sup>Plus</sup> reporting station and dedicated AWS Acquisition Workstation, which is operated via Siemens' standard syngo user interface, an intuitive software platform suitable for all imaging modalities and systems. MammoReport<sup>Plus</sup> enables adaptable reporting to meet individual needs, and features ultra-short image loading time: one case with 8 images in under a second. Findings or evaluations previously obtained with other modalities can also be displayed in the shortest possible time.

The firm also points out that it can provide a wide spectrum of individual archiving solutions for its mammography systems.

'Thanks to a combination of a-Se detector technology and our X-ray tube with a molybdenum/tungsten anode, both image quality and dose exposure reduction achieve an optimum level. The acquisition and reporting stations have been optimised for a smooth and trouble-free workflow,' said Holger Schmidt, Head of Special Systems at Siemens Medical Solutions in Erlangen, Germany.

# Efficient screening programmes

Engineer **Dr W Schneider**, of *image diagnost GmbH* discusses digital screening networks and multi-centre co-operation, based on automated DICOM communication. Along with its mammography solutions, image diagnost also specialises in developing concepts for regional and national digital screening networks



Modern methods and technology make it possible to combine out- and inpatient treatment through comprehensive, overlapping systems and to standardise and optimise early diagnosis, therapy and aftercare for malignant diseases of the female breast regionally.

The introduction of standardised documentation and the opportunity to implement quality assurance programmes require the set up of suitable networks to complement the development of digital networks. They are of particular importance in mammography screening where multiple diagnoses are required and where a network significantly eases the workflow. The harmonisation and acceleration of processes, avoidance of information loss and the resulting effects, as well as the stimulation of a close co-operation between everyone involved, open up the opportunity to implement patient-oriented and, in the medium term, cost-effective medicine.

Mammography screening networks can only be successful if suitable measures for quality assurance are introduced. The enormous volume of data generated through a quality assured diagnosis process can only be supported effectively through integrated technical concepts. Solutions based on the sending of images and results by post are no longer acceptable for mammography screening programmes; in fact they are counterproductive from an economic and quality assurance point of view.

Organisational structures, and networking concepts matched to them, should take into consideration geographical factors as well as available expertise and technical equipment. Image diagnost GmbH of Munich therefore developed a concept for multiple diagnosis that is adaptable to these different concepts and is suitable for a central facility, as well as the development of networks linking outpatient and inpatient units.

Graphically, a digital network with complete and standardised data recognition, which consists of a digital screening centre with several participating diagnosis groups, is sketched in an exemplary manner. The system can facilitate first, second and third diagnoses, assessment and central screening data collation and archiving, using the Worklist- and Collaboration Server developed by image diagnost. All digital diagnosis consoles, used instead of alternators, are equipped with a user-interface that can be used to monitor all data input and automated processes.

The Worklist- and Collaboration Server has been especially developed for screening networks. It generates different types of work lists based on adaptable rules and makes these accessible to all partner groups and partners within the network. This makes it possible to set up multi-locational workflow scenarios that allow for a patient and the person carrying out the diagnosis to remain anonymous.

Image- and diagnosis data are centrally stored for a screening network and are additionally backed up in a superordinate centre. Access permissions are monitored by the Collaboration Server and also can be manually

manipulated via the diagnosis workstation. This makes it possible to make images and results temporarily accessible to other colleagues. The Collaboration Server guarantees consistent access to all data. A particular advantage for screening scenarios is that copies of data sets do not need to be stored in an archive file when mammography images are made accessible to other locations, thus saving on storage resources and avoiding unnecessary conflict situations.

The Dutch Breast Cancer Screening Programme BBNN is already using a version of the Collaboration Server developed by image diagnost in its mobile screening units (MammoBuses).

Other products from Image Diagnost include the MammoWorkstation, with possibilities for integration into existing infrastructures supplied by various manufacturers; the CAD-Server (Computer Aided Detection) for automated marking of potential malignant structures in a mammography image, and the Digitising Workstation for the secondary digitisation of film mammographies, based on EUREF guidelines.

The system is an inexpensive first step into the world of digital mammography and the DICOM-shuttle as the key element for automated image and results transmission with high quality image compression.

### A workflow scenario with different rules

Rule	Result of first diagnosis	Result of second diagnosis	Final diagnosis made by
1	+	-	Third specialist
2	-	+	Third specialist
3	+	+	Third specialist
4	-	-	Second specialist

When carrying out a diagnosis, if the first and second person differ, or if both diagnose a positive result, a third person has to compile a diagnosis and summarising report. If the third specialist then makes a negative diagnosis, no further measures are required. However, if the third assessment also results in a positive diagnosis, the patient is definitely referred to an assessment centre, where further investigations are carried out. If the first and second diagnosis are both negative, the specialist carrying out the second diagnosis is responsible for concluding the case.

Despite advances in magnetic resonance imaging (MRI) that have revolutionised diagnostic possibilities, e.g. for functional imaging (fMRI), motion artifacts are still extremely detrimental in multi-slice 3D sequences, often used in fMRI or with uncooperative patients (children, elderly, accidents, stroke...).

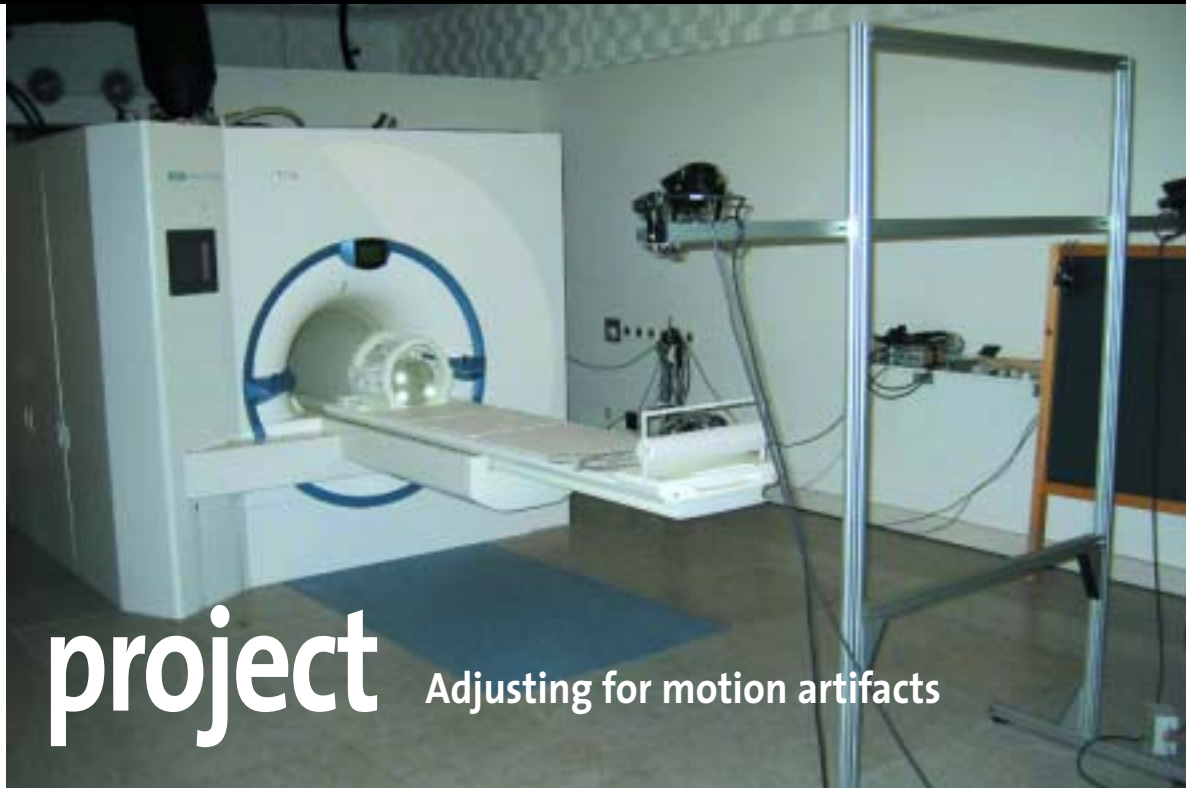
However, Philips has succeeded in compensating breathing artifacts by using data from 'pencil navigators', which can measure diaphragm movement in just 10ms. This technique went into clinical use this year.

In brain imaging, however,

although some procedures have been developed to remove artifacts caused by patients' head movements, their disadvantages include increased image acquisition time and a negative influence on scanner performance.

The EU project MRI-MARCB is aiming to produce an integrated solution to reduce motion effects in brain and cardiac imaging. Working within this project Christian Dold, research engineer at the Fraunhofer Institute of Computer Graphics in Darmstadt, Germany, explained: 'The problem of motion compensation in MRI technology deals with

# The MRI-MARCB project

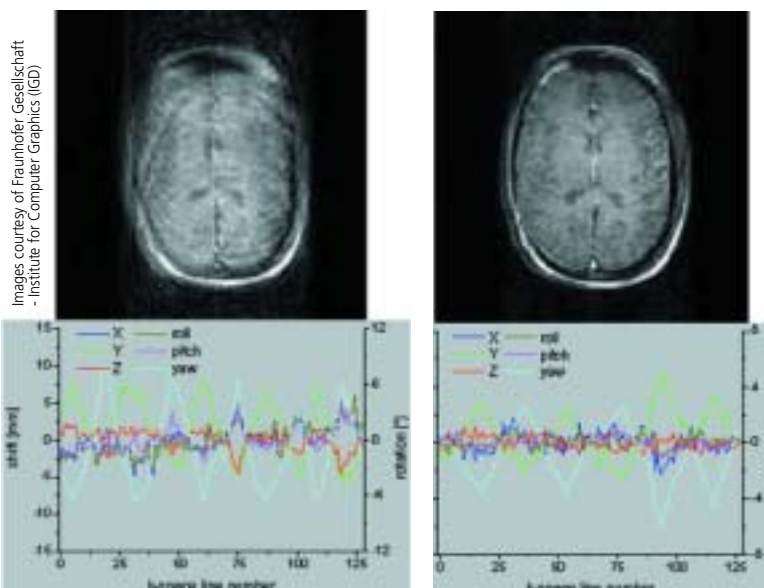


## Adjusting for motion artifacts

capturing the source and pattern of motion; obtaining a mathematical model of motion, using this to identify and compensate for the motion effects, further for optimising the image acquisition sequence so as to minimise, or even eliminate, the effect of motion.'

In its research the Fraunhofer IGD is using an infrared optical tracking system with high precision (RMS about 0.1mm, FOV = 50x50x50cm) to track patients' movements. By capturing ca. 20 movements per second in real-time - with parameters of six degrees of freedom (6DOF)- a volume-to-volume or a slice-to-

slice prospective correction is made in the MR-tomograph during the scan and just before the next slice is captured to translate these movements into new gradients, so that the acquisition of each new volume/image corresponds to the new direction of the head. As Christian Dold explained: 'At the end of each volume/slice acquisition the MR scanner reads the co-ordinates from the tracking system and changes prospective the 3 MR field gradients and frequencies in the sequence prior of acquiring the next volume/slice. The result is a real-time prospective compensation for the complete head movement. This is



Left: Original uncorrected image of the human head with corresponding CDOF.

Right: An on-line, real-time corrected image of the head movement shows only small artifacts depending on the latency time of the current implementation to measure the 6DOF and update the MRI gradients. Soon, in the new implementation, this latency time will be significantly reduced

repeat scanning and will, he said, '... improve the quality and speed by imaging uncooperative patients and increase the efficiency of functional MRI, which is beneficial for surgical planning and neuroscience research.' By compensating for patients' restlessness during imaging (e.g. children, Parkinson's patients, etc) this technique should also increase patient throughput and 'reduce measurement redundancy'. Details: [www.mri-marcb.org](http://www.mri-marcb.org)

based on the fact that the time needed to acquire a single k-space line is very much shorter than the time needed between acquiring subsequent k-lines. Hence, motions of the head during acquisition of a

single k-line are negligible and effects of motion are visible between subsequent lines.'

The technique promises a significant reduction in imaging time by lowering the need for

## BREAST THERAPIES

### Balloon Brachytherapy

Balloon brachytherapy is an acceptable alternative to external beam radiation for selected operable breast cancers, and this one-week treatment time allows working women and those living some distance from radiation centres to choose breast conservation rather than mastectomy, according to a paper published in *Arch Surgery* in June\*.

'Partial-breast irradiation for carcinoma by a single source of radiation placed in the centre of a balloon inserted in the lumpectomy cavity is an effective method of treating breast cancer. Previous interstitial radiation therapy using iridium seeds placed within multiple catheters has been shown to be effective but impractical and cosmetically unacceptable to women,' said the research team, who work at the Departments of General Surgery and Radiation Oncology, Rush University Medical Centre, Chicago; the Alabama Breast Centre and Department of Radiation Oncology, Montgomery Cancer Centre, Alabama, and the Lanshe Breast Centre and Centre for Cancer Care, Sacred Heart Hospital, Allentown, PA.

Women aged 40 years plus, who had been diagnosed with in situ and invasive T1 through T2 and N0 or N1 breast cancer and treated with lumpectomy and axillary node sampling, took part in the study to evaluate immediate and short-term complications, their acceptance of the treatment, and cosmetic outcome.

'Of the 129 patients taking part, 112 completed the treatment. 28 experienced transient skin erythema; three had localized oedema and nine showed skin blisters adjacent to the balloon. Seven developed infection, which needed drainage and antibiotic treatment. In ten, ultrasound indicated seromas had developed after removal of the device, which were aspirated percutaneously. In four patients, punctured or ruptured balloons had to be replaced before treatment could be completed. The team reported that patients quickly adjusted to breast distension caused by the balloon, and their acceptance of the procedure was good. The cosmetic outcome was rated high. There were no recurrences during this very short follow-up.'

\* *Arch Surgery* Vol. 139, June 2004. 603-608. Authors: Kambiz Dowlatshahi MD; Howard C Snider MD; Mark A Gittleman MD; Cam Nguyen MD; Phillip M Vigneri DO; Robert Lee Franklin MD.

### Effective drug combination

Combining the molecularly targeted therapy Herceptin with a specific chemotherapy combination has resulted in significant tumour response rates and longer relapse-free periods in women suffering an aggressive form of advanced breast cancer, according to two studies carried out at the Jonsson Cancer Centre, University of California Los Angeles, which were published recently in the *Journal of the National Cancer Institute*. The first study was carried out on cell lines in the laboratory and the second focused on over 120 patients in two Phase II clinical trials.

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## THE EUROPEAN RESPIRATORY SOCIETY (ERS) 14TH ANNUAL CONGRESS

### Céad Mile Fáilte!

'Céad Mile Fáilte!' said ERS President Walter McNicholas (right), to greet those about to attend this the 14th Annual Congress of the ERS, (Glasgow, Scotland, 4-8 September 2004). English translation from the Gaelic greeting: 'A hundred thousand welcomes!'

Each successive year of the ERS sets new records in terms of attendance and scientific presentations, he pointed out. Last year 15,000 people from over a hundred countries attended the congress in Vienna - an over two-third rise in numbers compared with 5 years ago.'

Whilst the congress is the highlight of the year for the Society, the ERS is increasingly active in many other areas, ranging from education to advocacy, he pointed out. 'The ERS School has become a vital and vibrant part of the Society, particularly in terms of external educational courses, and this year alone eight such courses are planned for various venues around Europe, on topics ranging from cystic fibrosis to non-invasive ventilation.'

Political advocacy, a particular focus of activity this year, is now supported, particularly at the EU, due to a new office being established in Brussels. Active efforts are also underway to increase interaction and cooperation with National Respiratory Societies, he added.

Among new offerings from ERS is clinically oriented journal, aimed primarily at practitioners, and revised membership options that offer reduced membership fees to those in poorer regions of Europe and beyond.



Breathlessness, the most common symptom in patients with chronic obstructive pulmonary disease (COPD), greatly reduces their ability to participate in day-to-day activities. Inhaled bronchodilator therapy is the first step in the management of the breathless COPD patient. By achieving sustained improvements in airway function, long-acting bronchodilators, e.g. salmeterol, can achieve superior symptom relief compared with traditional short-acting bronchodilator therapy.

The evaluation of bronchodilator effi-

cacy has evolved considerably in recent years. New information suggests that improved breathlessness after bronchodilator therapy is principally related to reduced air trapping.

In COPD, the inability to expel air from the lungs during expiration through abnormally narrowed and collapsible airways results in air trapping and lung over-inflation. This, in turn, puts the muscles of breathing under a major mechanical disadvantage. Breathing, therefore, requires much greater effort and the patient senses this as breathlessness.

By improving airway function and lung emptying, bronchodilators reduce lung over-inflation, thereby relieving breathlessness.

A current study\*, undertaken by Denis O'Donnell and colleagues at the Dept of Medicine, Queen's University, Kingston, Ontario, Canada, examined the impact of salmeterol, a long acting bron-

chodilator, on breathlessness measured during a standardised task (cycle exercise) and to explore possible mechanisms of benefit.

Twenty-three symptomatic patients with advanced COPD participated in this placebo controlled, crossover study. Breathlessness, exercise performance, and various physiological measures were compared during salmeterol and placebo.

The authors found that during salmeterol therapy the intensity of breathlessness (measured by a validated scale), during a standardised physical task, fell significantly compared with placebo, and that symptom-limited exercise endurance time significantly improved by 58%.

These improvements in breathlessness and in exercise performance correlated strongly with the extent of salmeterol-induced lung deflation (i.e. inspiratory capacity increased by 18% on average). Salmeterol, by reducing lung over-inflation, also improved the patient's ability to increase their breathing capacity to higher levels during exercise than was previously possible and to do so with substantially less breathing discomfort.

The researchers concluded that salmeterol therapy provides effective symptom relief for sufferers of COPD and enhances their ability to undertake physical activity. Pub: *European Respiratory Journal*. 7/04. Vol. 24, No. 1)



## Relieving breathlessness in COPD

### Agent may treat PHT

Sildenafil, an active agent used in the impotence drug Viagra, has been administered to seven young mountaineers on an Everest expedition, to test its effect on the lungs. Seven other men on the expedition are receiving a placebo.

Leading the research, Friedrich Grimminger, from the Centre for Internal Medicine, University of Giessen, Germany, was at the base camp to carry out heart, lung and blood tests on the volunteers. He explained that sildenafil might improve the quality of life of pulmonary hypertension (PHT) patients significantly.

In PHT patients blood vessels in the lung constrict, and they suffer breathlessness and cardiac strain during strenuous activities. If the condition is not diagnosed, heart failure (HF) can result. Current therapies are said to be risky, because they reduce general blood pressure and this can lead to circulatory collapse. Dr Ardeschir Ghofrani, another Giessen study team member, reported that the drug reduced PHT without causing a dangerous reduction in blood pressure elsewhere. Because a biochemical similarity exists between the penis and lungs - both contain large amounts of the enzyme phosphodiesterase - it limits penis erection and has been found to constrict blood vessels around lungs. Sildenafil blocks that enzyme, which then allows sustained erection. Similarly, in the lung walls, it appears to improve blood circulation.

# Viagra tested on Everest



In 2003, the healthy young mountaineers were chosen for this test because their lungs undergo rapid change in a matter of weeks when staying at high altitudes. Professor Grimminger explained that they suffer pulmonary hyper-

Changes caused by lack of oxygen can serve as a model for numerous heart and pulmonary diseases. While the process in the mountaineers' systems is reversible this is not the case for the disease process in patients,' he added.

Although the study results, published in the *Annals of Internal Medicine*, concluded that sildenafil reduced arterial pressure and improved oxygen transport, Professor Grimminger has stressed that the drug would not receive regulatory approval as a treatment for PHT until worldwide tests are completed.

Viagra was invented to treat a range cardiovascular problems but is only licensed to treat impotence. This possible new use is early stage research, said a spokesman for Pfizer, the manufacturer of Viagra, adding, by the by, that this year marks the 50th anniversary of the conquest of Everest, and it is five years since Viagra was launched.



Ardeschir Ghofrani & Friedrich Grimminger tension due to a lack of oxygen, which is only partly resolved by acclimatisation. 'A stay at heights above 5,500 metres cannot be survived in the long run. In the death zone, at levels of above 7,000 metres, survival without an additional oxygen supply is only possible for a few hours to a few days.

## Clinical quality ventilator for home use



NEW

Camena, an innovative ventilator that provides clinical-quality ventilation for patients at home, will be launched, at the European Respiratory Society (ERS) annual meeting (4-8 September 2004, Glasgow, UK), by Dräger Medical AG & Co KGaA, of Lübeck, Germany.

With the support of patients and a six-member scientific team of international experts, Dräger Medical's team based in the Netherlands created the new device in just one-and-a-half years. The result is an advanced mechanical ventilator designed particularly for long-term ventilation in a domestic environment.

**Patient-oriented system technology** - Camena provides both invasive and non-invasive ventilation. A new feature, Volume Guarantee, safeguards gas exchange by assuring the target tidal volume range. The device offers pressure-supported and pressure-controlled ventilation. Modes such as CPAP, Bi-Level and PCV further provide versatile ventilation performance. The AutoSlope software feature automatically adjusts the respective inspiration curve to provide comfortable,

patient-specific ventilation.

Ideally sized for the home, Camena weighs just 4.8 kg and measures 385 mm x 175 mm x 275 mm (L x W x H). It is also extremely quiet and operates at 10 mbar with <29 dB(A) and at 18 mbar with <32 dB(A). The display provides additional convenience - automatically going blank after two minutes.

**The user interface** - This has two levels: a professional user interface displays pressure and flow curves, and the patient interface displays settings and alarm information in case of an event. The number of alarm occurrences, their causes, as well as trends, can be stored internally for up to a year.

Set values can only be set and changed by physicians. In addition, specific parameters can be 'tagged' so that, if necessary, patients can adjust settings themselves - also via the optional remote control. The integrated Rescue Mode ensures that ventilation continues even in the unlikely case of a pressure sensor failure.

**Mobility and service** - Camena also

supports patient mobility. For example, the system could be used in a car, boat or ambulance, due to the 12 V - 24 V power connection. Camena is also ideal for use with wheelchairs. A built-in battery serves as a power backup supply for up to two hours of ventilation, and an optional external battery can add another 20 hours of backup power.

To ensure that the delivered gas is clean, the system includes a highly effective particle absorption (HEPA) filter that removes dust particles and bacteria. Service and maintenance is covered by remote service and diagnosis and backed by DrägerService. This saves time and money, and makes patient location no problem.

'Fifty years ago, Dräger's



Poliomat revolutionised the market for home mechanical ventilation,' said Bas Dirksen, General Manager at Dräger Medical BV, in Best, the Netherlands, and Head of the Business Unit Pre & Post Hospital Care. 'Based on this technology, which was first developed by Dräger in 1906, we have combined today's scientific knowledge with patient requirements, to find a solution that not only meets our standards for innovation but also elevates the quality of care.'



# Non-invasive lung diagnosis

Magnetic resonance imaging (MRI) as a non-invasive diagnostic method has been evolving into an attractive alternative to methods associated with radiation exposure. In a recent issue of the journal *Radiology\**, Dr Christian Fink and colleagues at the Radiology Department of the German Cancer Research Centre also pointed out that this development is beginning to manifest itself in lung perfusion imaging.

Diagnosis of numerous lung diseases requires precise perfusion imaging. The standard method, perfusion scintigraphy, involves injecting a radioactive substance into the bloodstream to scan its distribution in the lungs. Now the equally precise and completely radiation-free method for evaluating lung perfusion turns out to be a MRI scan.

In a comparative study of seven healthy pro-bands and 20 patients with suspected lung cancer, the researchers compared MRI with perfusion scintigraphy. MRI showed a higher temporal and spatial resolution in lung perfusion imaging and provides the additional advantage of 3D image data,

which makes it easier to recognise blood circulation changes. Perfusion defects caused by tumours were recognised with high accuracy. In direct comparison with the standard method, MRI was found to be at least equally good.

It is too early yet for MRI to become a routine clinical method of lung perfusion imaging. The value of the new method first needs to be assessed in larger studies. But the investigators are optimistic that the radiation-free option may turn into the method of choice: 'Image resolution in MRI is about twice as high as in perfusion scintigraphy so that we expect a higher detail precision compared to the standard method,' Dr Fink said. Along with evaluation of perfusion, MRI also provides additional information, e.g. about the anatomy of blood vessels in the lungs and the temporal process of lung perfusion. Thus it provides insight about both vessel organisation and function of blood circulation down to the tiniest branches of the lungs.

The method can be used not only in diagnostics and surgery planning for lung tumour patients. It may, in the future, also be beneficial in non-

invasive diagnoses of other lung diseases, such as pulmonary embolism, emphysema, and chronic bronchitis. For now, however, MRI is substantially more expensive than the standard method (approx. 300 euros v. 75 euros per examination), since the remuneration system does not yet take adequate account of innovative methods of this kind.

\* Christian Fink et al.: Regional Lung Perfusion: Assessment with Partially Parallel Three-dimensional MR Imaging; *Radiology* 2004; 231: 175-184.

Source: Deutsches Krebsforschungszentrum, Heidelberg. [www.dkfz.de](http://www.dkfz.de)



Dr Christian Fink

## The UK's National Lung Cancer Forum for Nurses

With increasing numbers of nurses specialising the care of lung cancer patients, The National Lung Cancer Forum for Nurses (NLCFN) was established in 1997 to offer them a network for information exchange and to support nurses working in 'isolation' due to their changing and different roles. Membership is open to specialist nurses whose work, or clinical activities, focused on lung cancer amounts to over 50% of their employment. Seven years ago the NLCFN had about 40 members. By last year the number had increased to over 200 specialist nurses.

In 2002 a new website, developed by Sequence in conjunction with Astra Zeneca, was set up to offer an updateable online resource for professionals and patients. Along with member contributions to the website, including their experiences in the field, nurses can also access new research studies, news and events, resources and education.

As part of on-going activities, for example, the London and South East Lung Cancer Forum for Nurses (c/o the NHS Trust, Palliative Care Department, Guy's Hospital, London, UK, has drawn up guidelines on the role of the specialist nurse in supporting patients with lung cancer. (Pub: Blackwell Publishing Ltd: *European Journal of Cancer Care* 13, 344-348). The recommendations made in these guidelines are based on Government guidelines, in which the NHS Executive reminds health professionals that, despite the very high mortality figure for lung cancer, 'improved quality of life represents an important therapeutic gain that should not be subsumed by a sense of nihilism or clinical failure'.

On 25-26 November there will be a members-only meeting of the NLCFN, in Chester, UK. However, for our specialist nurse readers in the EU, this information on the forum's activities may offer inspiration for the setting up such help groups elsewhere, and perhaps a greater international sharing of experiences in this difficult nursing field.

NLCFN details: [www.nlcn.co.uk](http://www.nlcn.co.uk)

## NEW Tuberculosis blood test gains EU approval

TB causes three million deaths annually, ranking it higher than any other infectious disease. And TB has resurged in Europe. In August, the British Thoracic Society, British Lung Foundation and TB Alert highlighted its increase in over the last 15 years in the UK alone. During this period, the number of TB cases in London doubled and it has been suggested that the capital is on the brink of an epidemic. Paul Sommerfeld, Chairperson of TB Alert said: 'The importance of having access to accurate and reliable diagnosis cannot be overstated. Accurate testing is vital for effective disease control, especially with the threat of multi-drug resistant TB and the recent increase in incidence of the disease hanging over us.'

Up to now, a century-old skin test (the oldest diagnostic test still in use today) has been used, but this can produce both false-positive and false-negative results and previous BCG vaccination makes it inconsistent, according to a report from the firm Oxford

Immunotec, the international clinical diagnostics company headquartered near Oxford, UK. 'It is also inconvenient, taking 3-7 days before it can be read, and it can cause painful blistering and scarring of the skin,' the firm added.

Now a new blood test has been approved for use in Europe. Named T SPOT-TB, and made Oxford Immunotec, this promises to replace the old TB skin test. Dr Ajit Lalvani of Oxford University, who led the development of this test over the past decade, said: 'The tools we use to diagnose TB are 50-100 years old; this disease has been neglected for decades. I am pleased that we have finally brought the benefits of modern scientific research to the front-line to fight this age-old disease. In contrast to the crude and inaccurate skin test, the new blood test is fast, accurate and convenient. It is a 100-year upgrade for diagnosing TB and I believe it will significantly improve the way we manage tuberculosis.'

The SPOT test works in a unique way, the firm pointed out. 'Whereas conventional diagnostic tests rely on detecting antibodies induced by an infection, such antibodies are not generated by TB infection. However, TB infection induces a strong response by immune cells in the blood called T-cells. It is these T-cells, in a small blood sample, that are detected by T SPOT-TB, which literally counts them as spots on a test plate.'

The T SPOT-TB test has been tested in 16 clinical studies, involving over 4,000 patients in 11 different countries, in both the developed and developing world. 99.9% specificity was shown in healthy unexposed controls, in five separate studies of low-risk subjects. Sensitivity of the test has been shown to be over 96%.

SPOT will be used to screen people who have been in contact with a TB sufferer, so that, if

infected, they could be identified and treated long before they actually develop the disease and infect others. 'Crucially, it is the first test that reliably detects infection in people with weak immune systems, including newborn babies, people with HIV and transplant patients - precisely the people who are most vulnerable to developing full-blown TB,' the firm added.

T SPOT-TB is Oxford Immunotec's first product, which is based on its patented T SPOT technology, a novel platform that opens up new ways of diagnosing and monitoring infections by providing a simple and extremely accurate method of studying a person's cellular immune response to an infection. T-SPOT technology can be applied to diagnose and monitor any major disease driven by a T-cell response, the firm pointed out.

### TB charity

TB Alert, registered in 1998 and launched in London's Houses of Parliament on World TB Day in 1999, was set up by people who believe there should be a greater response to the resurgent threat of TB - already declared a global emergency by the World Health Organisation (WHO) in 1993. TB Alert is the first TB-specific charity in Britain since the 1960s, when earlier organisations, assuming too soon that the disease had been vanquished, faded away or shifted to other interests. TB Alert aims to:

- Raise awareness of TB as a global threat and as a disease resurgent in Britain
- Advocate for greater global spending on TB
- Support TB control programmes overseas, focusing on increasing access to treatment especially for poor and marginalised groups
- Complement the work of the NHS in the UK, supporting public and patient education and information

### TB - the disease and its treatment

The TB bacteria may infect most a third of the world's population, and an estimated eight million people develop the active disease annually.

TB is passed from person to person through the air, but a person exposed to TB does not necessarily develop the disease. Some people are able to clear it from the system through their natural immune response, but most only control it and do not clear it completely, so it remains dormant in their systems. This latent infection can reactivate at any time, to cause the active disease.

TB is usually curable with effective antibiotic treatment. Typically a long course of a combination of four antibiotics is recommended for initial treatment of the active disease. If caught in its latent state, only one drug is usually needed to manage the disease.

Due to poor compliance to therapy over the long period required to completely cure TB and because there have been few new drugs to treat TB over the last 30 years, there has been a substantial increase in the number of strains of TB resistant to current treatments. The rise and spread of multi-drug resistant (MDR) TB is a cause of great concern.



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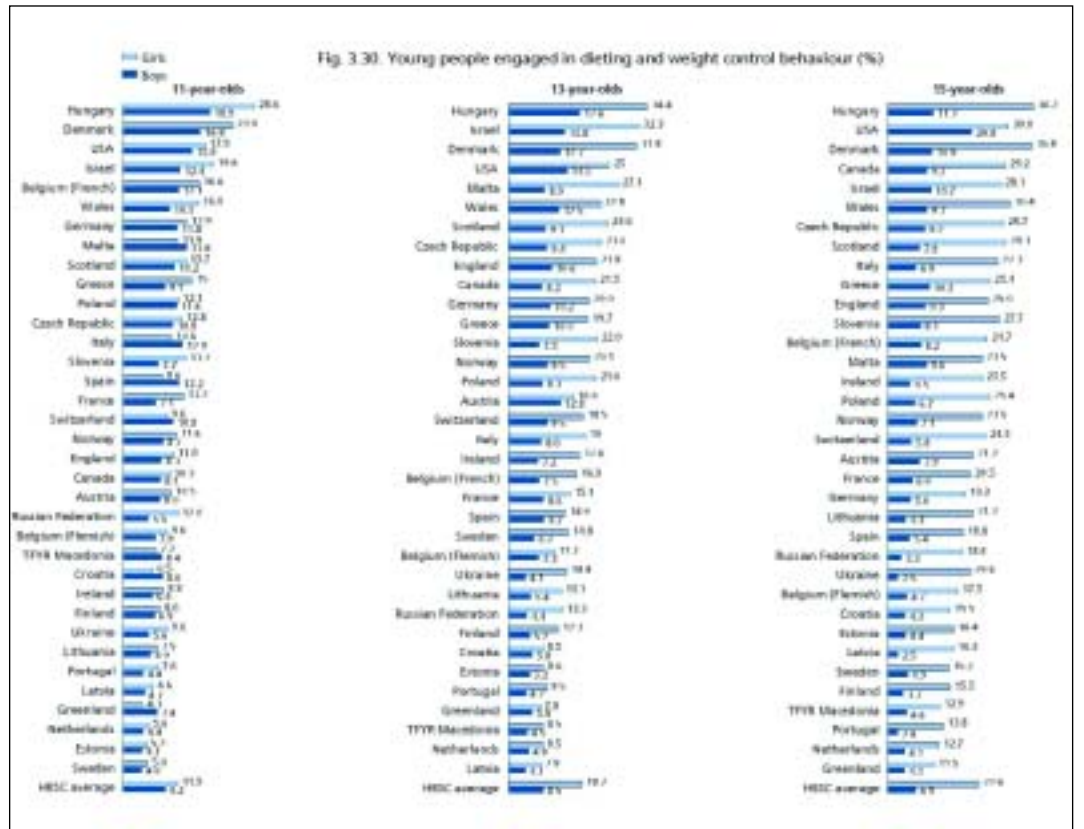
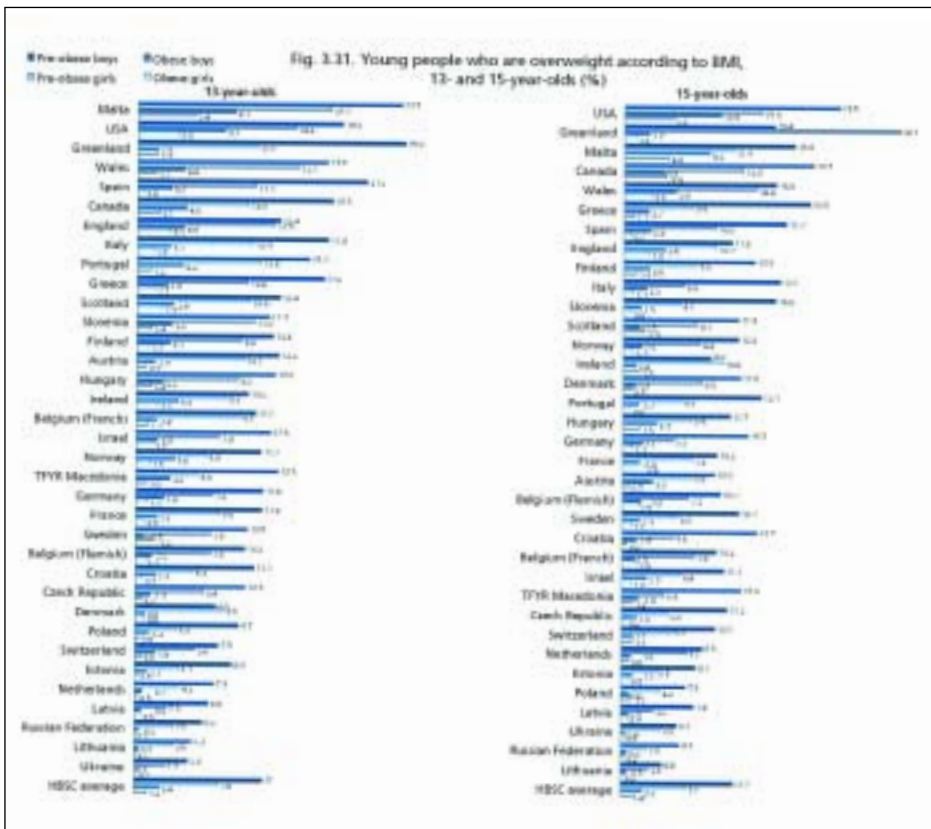
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# Obesity

Study shows increased chronic illness in children and adolescents

The disturbing international comparative study on health behaviour in school children (HBSC), conducted by the World Health Organization (WHO), European regional offices, have been presented by the research director for Germany, Professor Hurrelmann, Dean of the School of

Public Health at the University of Bielefeld, at the 3rd German Congress for Health Services Research. 'Although children and adolescents consider themselves quite healthy, chronic illnesses have continuously increased in that age bracket over the last three decades,' said Professor Klaus Hurrelmann,

President of the congress. One cause is early and uncontrolled consumption of psycho-active substances such as cigarettes, alcohol and illegal drugs. Two further factors are poor eating habits and lack of physical activity - both the underlying cause obesity. In Germany alone, depending on the definition used, 10-20% of children and adolescents are considered obese.

their families have to adapt and adjust to unexpected pressure and often a change in lifestyle. At the congress patient education programmes were presented that were developed with children and adolescents. Such strategies take into account the special needs of young patients, because difficulties in handling chronic illnesses seem to increase after puberty.

In view of these developments it is important that children become health conscious from very early on and learn permanent self management because such chronic - an non-chronic - illnesses often mean a substantial decrease in the quality of life. But these children are not the only ones who suffer, for

Source: *Young people's health in context. Health Behaviour in School-aged Children (HBSC) study: international report from the 2001/2002 survey. Copenhagen, WHO Regional Office for Europe, 2004 (Health Policy for Children and Adolescents, No. 4).*

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## Baby food & meningitis

An extensive international study, presented at the American Society for Microbiology meeting in New Orleans, concludes that baby foods contain worrying levels of disease-causing microbes, including *Enterobacter sakazakii* (linked to some fatal outbreaks of meningitis at children's hospitals in Europe and the USA\*). Although the *E. sakazakii* has been found in powdered infant formula before, findings from the study, which focused on powdered infant formula, dried infant food and milk powder from seven European countries, the US, South Korea and South Africa, have proved that it can be present in those foods.

The team analysed over 200 samples from 110 different products. Stomach bacteria were found in eight out of 82 of the powdered infant formula samples, and in 12 out of 49 of the dried infant food samples. Thirteen of bacteria identified, including *E. sakazakii*, are members of the Enterobacteriaceae, which is associated with hospital-acquired infections.

Although manufacturers do not claim the absence of bacterium in their products, Carol Iversen said there is a misconception among parents and nurses that infant formula powder is a sterile product.

In a separate study, also presented during the New Orleans meeting, the team examined the best ways to prepare and store infant formula made from powder to minimise infection risks. They reported that, when kept in a fridge the number of bacteria in the preparation doubled every 10 hours, but at room temperature this occurred in just 30 minutes. So, any formula left ready for night use could go from containing very few bacteria to harbouring dangerous levels, said Stephen Forsythe, who urges parents to resist the temptation to prepare infant feeds in advance.

Few meningitis cases arise annually, but the death rate can be as high as a third of those affected - particularly putting premature babies and those with weakened immune systems at risk. Survival of the infection can still leave patients brain damaged. 'Very few recover fully,' said Carol Iversen, at Nottingham Trent University.

In 2001, an outbreak of meningitis at a Tennessee neonatal intensive care unit infected nine babies. One died. The infection was traced to a batch of powdered infant formula, and prompted the Centres for Disease Control in Atlanta, Georgia, to warn doctors about potential dangers in powdered formula. The product was recalled by the manufacturer.





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