EUROPEAN HOSPITAL

THE EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

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Smile please, nurse!

UK – Following a 6-month inquiry in 2007 on how to improve the National Health Service (NHS) (and patients' organisations urging action over an apparent decline in nursing care since the domination of the hospital matron was curtailed) one of the proposals put in a Downing Street Cabinet meeting was that doctors and nurses should smile more.

Now a pioneering pilot training scheme is underway in Stockport Hospital, Greater Manchester, which aims to put smiles on nurses' faces when working with patients – and more. Under a new edict, nurses are to be banned from discussing personal matters, except during breaks, or to speak loudly during night shifts. Another point: Never promise a patient 'I'll be back in a minute' if you cannot return do that.

The Patients' Association (PA) reported that patients felt nurses had lost the 'caring touch'. Many, for example, claimed to be 'too busy' to properly feed the elderly, resulting in malnutrition, whilst others refused to take on cleaning tasks.

However, the reaction of the Royal College of Nursing was that it is insulting to suggest that nurses do not smile enough.

Also on the side of nurses, Michael Summers, Vice-Chair of the PA's Board of Trustees, pointed out that they now work under considerable pressure, so can lose touch with some patients' needs. 'Nurses also qualify in primarily academic degree courses,' he pointed out, 'so when they start nursing many lack day-to-day nursing skills.'

Switzerland to adopt DRGs system

The Swiss hospital system is facing a radical change. Billing by Diagnosis Related Groups (DRGs) is about to be introduced. *European Hospital's* correspondent in Switzerland, *Dr André Weissen*,* approached Dr Carlo Conti (above), President of SwissDRG AG to discuss some of the controversial issues involved in the switch to DRGs

Switzerland's hospital system is highly complicated because the 26 cantons each have different regulations. Nonetheless, they all have one common feature, i.e. billing is calculated on a per diem basis, which means that medical insurers simply pay an agreed amount per day spent in hospital – independent of a patient's diagnosis. Any further costs are covered by the hospital, meaning the state or private hospital operators pay.

Dr Carlo Conti, President of SwissDRG AG, based in Basle, will organise the switch to DRGs. 'There can be no doubt that the current billing systems in Switzerland contain some misguided incentives and are therefore causing a conflict when it comes to achieving more efficiency for hospitals. The partners in the healthcare sector and the world of politics agree that a system change to DRGs would result in real improvements. National, standardised tariffs would also make it easier to achieve comparability and to promote the exchange of healthcare services between different geographical areas within Switzerland,' he told *European Hospital*.

What do they hope to achieve? 'The introduction of DRG case-based lump sums is to achieve two things: More transparency of all medical services offered and provided in a hospital and ideally a performance-based kind of remuneration. In our Federal structure, the DRGs will provide a prerequisite for more competition between the service providers because services and products delivered by hospitals can be compared, regarding cost as well as quality.'

Switzerland is to adopt the German case-based system, for example, although this has now fall-

continued on page 2

LEGIONELLA

Insurer initiates preventive hospitals inspection

UNIQA, Austria's leading health insurer* recently initiated a preventive inspection of the technical water lines and systems at around 40 of the hospitals it insures, to identify any possible contamination by Legionella bacterium. Following the inspections many of the hospitals opted to undergo TÜV certification. Their motivation is not only medical concern, but also economic and legal issues.

According to the World Health Organisation about 10,000 people die from Legionnaire's disease annually. Because an institution, rather than water supplier, is held responsible for the quality of its drinking water, an outbreak is not only a health risk, but has legal repercussions.

'The authorities are currently extremely active in this area. Upon suspicion of an illness caused by Legionella contamination, facilities are closed and can only be opened again when it can be verified that a risk no longer exists,' Dr Johannes Hajek, CEO of UNIQA Sachversicherung, pointed out. 'For this reason we decided to assist all hospitals insured through us in the fight against Legionella by covering the inspection and expert consultation costs.'

Following these, the hospitals can receive a *Legionellae-Free Facility* TÜV certificate.

The inspections and sharing of the expertise were handled by HWC (Hygienic Water Consulting), a long-term partner of UNIQA in this area.

In the event of contamination, necessary measures are discussed and implemented. In almost all cases, it is possible to get the system under control through adaptation of the usage patterns, UNIQA reports.

** In May, Uniqa Versicherungen AG announced its intention to acquire the entire shareholding of Unita Vienna Insurance Group (transaction due for completion this autumn). With 70 companies under its umbrella in Austria and 15 in CEE countries (Germany, Poland, Switzerland, Italy, Lichtenstein, Hungary, Serbia, Bosnia and Herzegovina, Croatia, Czech Republic, Slovakian Republic, Slovenia, Ukraine and Romania), in 2005 employees numbered 10,000.*

Cancer care advances – but at what cost?

Half a million dollars for one extra month of life

Although incremental improvements in cancer care were unveiled at the 44th Annual Meeting of the American Society of Clinical Oncology held in Chicago, USA, – the world's largest gathering of cancer specialists, our correspondent **Ian Mason** writes that, even as new study results were being reported, their cost implications for stretched healthcare budgets were questioned.

Professor Robert Pirker, Medical University of Vienna, Austria, announced results from the FLEX study (Abstract #3) showing that combining the targeted therapy cetuximab with platinum-based chemotherapy improved overall survival compared to chemotherapy alone, when used as a first-line treatment for patients with advanced non-small cell lung cancer – which accounts for more than 80% of all lung cancers.

The addition of cetuximab boosted overall survival from 10.1 months to 11.3 months, a result that Professor Pirker described as 'setting a new standard' for the first-line treatment of this dreadful malignancy.

However, **Professor Thomas J Lynch**, Harvard School of Medicine, pointed out that this modest survival benefit – just 1.2 months – came at a cost per life year gained of $540,000 to $622,080.

The eye-watering cost of such interventions underscored the importance of pharmacogenomics – another major theme at this year's ASCO. 'This exciting field gives us new tools to identify the most appropriate treatment for each patient,' said **Dr Julie Gralow**, associate professor of medicine at the University of Washington.

In one such study, **Professor Eric Van Cutsem**, University Hospital, Leuven, Belgium reported results

continued on page 2

contents

Cancer care advances – but at what cost?

continued from page 1

from the CRYSTAL trial (Abstract #2) showing that patients whose tumours contain the normal form (wild-type) of the gene KRAS are most likely to benefit from the addition of cetuximab to chemotherapy as part of first-line treatment of metastatic colorectal cancer, compared to patients who have a mutation in the KRAS gene. He suggested that KRAS testing now be routinely conducted in all colorectal cancer patients immediately after diagnosis. This was supported by other speakers who said that patients with KRAS mutations should not be given cetuximab or panitumumab.

In testicular cancer, results were reported (Abstract#1) showing that a single dose of carboplatin chemotherapy is as effective and less toxic than radiation therapy (the current standard of care) in preventing recurrence after surgery for early-stage testicular cancer – the most common solid tumor diagnosed in young men. 'Personal preference is becoming a more important factor in determining the best treatment for patients with testicular cancer,' said **Dr Tim Oliver**, St. Bartholomew's Hospital, London. 'This study establishes surgery followed by carboplatin chemotherapy as a safe new alternative for patients who have early-stage seminoma and would prefer a treatment that lasts a shorter period of time.'

There were also promising results for gynaecological malignancies, including results showing that vaginal brachytherapy is as effective as external beam radiation therapy at preventing the recurrence of endometrial cancer (Abstract # LBA5503). In this novel approach, a radioactive cylinder inserted into the vagina proved as effective at preventing the recurrence of higher-risk endometrial cancer as external beam radiation therapy, with fewer side effects and a better quality of life for patients. 'Based on this study, we expect that vaginal brachytherapy will be adopted as the new standard of care for patients with this type of endometrial cancer,' said **Dr Remi Nout**, Leiden University Medical Centre.

In breast cancer, a study found that giving zoledronic acid (Zometa) – a drug used to treat bone metastases and recently approved to treat osteoporosis – to premenopausal women undergoing ovarian suppression and hormone therapy, significantly reduces the risk of recurrence in early-stage breast cancer. 'It's very exciting to find that in addition to preventing bone loss in women undergoing adjuvant endocrine therapy for breast cancer, zoledronic acid can also reduce the likelihood that breast cancer will return in some women,' said **Professor Michael Gnant**, Medical University of Vienna, and President of the Austrian Breast and Colorectal Cancer study group (Abstract # LBA4). Another study reported that adding bevacizumab (Avastin) to docetaxel (Taxotere) slows disease progression for patients newly diagnosed with locally advanced or metastatic breast cancer (Abstract # LBA1011).

A further study (Abstract #9509) with potential cost implications for budget holders was the finding that many survivors of childhood cancers are five to ten times more likely than their healthy siblings to develop heart disease in early adulthood. The massive Childhood *Cancer Survivor Study* (CCSS) showed that various types of heart disease were two to five times greater in survivors who had anthracycline drugs (such as doxorubicin) or radiation therapy to the heart as part of their cancer treatment, compared with survivors who did not undergo these treatments.

** Full ASCO abstracts: www.asco.org/*

Switzerland to adopt DRGs system

André Weissen MD, of MedConsult (a medical consulting company based in Riehen, Switzerland) is trained in medicine and surgery and is an internal medicine specialist and diabetologist.
Dr Weissen is also a member of the Verband Schweizer Fachjournalisten, and a correspondent for the Swiss Medical Tribune.
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continued from page 1

en into disrepute. Why is it in the plan? 'We looked at all available options and came to the conclusion that the German system best meets our needs technically. The problems in German hospitals arise for different reasons,' he explained. 'The negative effects are less to do with the billing system, they are more to do with the type of overall hospital financing and budgeting.'

German university hospitals are considered the big losers in terms of DRGs. How are all the Swiss hospitals – large, small, public and private – to be treated in the same way? 'In Germany, other than in Switzerland, no investment allowances are included in the case-based sums. This led to an investment backlog in public hospitals,' Dr Conti pointed out. 'The new system means that all hospitals included on a Canton hospital list are put on a par. This does away with the difference between public and private hospitals. For the public hospitals it means the discontinuation of the governmental deficit guarantee and equated, performance-based financing for all hospitals. The rules of the game will be the same for everyone, i.e. a significant improvement to the status quo.'

Apart from the treatment costs, hospitals also have to undertake investments to keep up to date and remain competitive. Is the introduction of DRGs not actually counterproductive in this case? 'I think the connection you outline here is less rigid,' Dr Conti responded. 'The right investments will need to continue in the future, enabling us to provide our services. However, as I said before, other than in Germany, the investment costs are treated as chargeable costs and paid through the DRG case-based lump sum. This increasingly links the investment to the actual amount of services provided. We hope to guard against a financing gap for investments in this way.'

* In 2007, the Swiss Parliament passed the new Hospital Financing Draft. This stipulates the introduction of a national, standardised tariff structure (SwissDRG). The SwissDRG is due to be introduced nationwide by 1 January 2012 at the latest.

Re-inventing the hospital

During recent years hospitals have had to face constantly new challenges. So far, the solutions offered in Germany are not sufficient. On the contrary – rather than solving problems, they tend to create new ones. A change of paradigm in the organisation of hospitals is imminent and hospitals have to change radically, argues economist **Holger Richter MA** (right), Managing Director of Bremerhaven Hospital

Medical services

About 90% of hospital income is generated in the 35 weekly working hours of regular day shifts. However, due to new work time regulations fewer and fewer physicians are available for these productive shifts and much of the work time is spent in the 133 working hours of the 'unproductive' night shifts.

Albeit, medical services efficiency is a crucial factor in a hospital's survival strategy. This means, in view of the shortage of physicians and of funds to pay additional medical staff, there is only one solution: capacities should be redefined. Medical capacities need to be concentrated in those shifts in which most medical services are delivered. In turn the level of healthcare services provided in late, night and weekend shifts must be reduced.

Many administrative or low-skill tasks, e.g. taking blood samples or document management, can be performed by clerical staff and medical assistants, freeing doctors to concentrate on their core tasks: diagnosis and therapy.

However, hospitals will not be prepared to finance increasing personnel costs without proper assurance that the work time paid is used sensibly. The management is thus asked to control workflow effectively and efficiently.

A well-structured work environment can help to increase efficiency. However, a prerequisite, namely standardisation of medical processes, has not yet been realised. Organisation still happens by rule of thumb, despite the fact that the introduction of DRGs and the concomitant financing problems should have created sufficient pressure to reconsider internal structures.

Technical approaches to identify, measure and calculate major and minor processes in hospitals are very promising. Frequently only a few major processes need be standardised to realise significant efficiency gains. The crucial, in essence cultural, precondition to bring about this change is the willingness and discipline to follow these standards.

Medical career

The traditional career path – specialised medical training that leads either to a high-status private practice or to a hospital 'tenure track', i.e. to positions as assistant medical director and eventually medical director – seems a decreasing option for young physicians who are well aware of the financial and the reform pressure burdening the healthcare system. A new generation of physicians is therefore prepared to consider career alternatives. Consequently, hospitals should offer attractive, adequately paid jobs below the medical director level, which come with status, long-term perspectives and allow a decent work/family balance. One option is to create a new medical middle-management level for physicians – so-called functional assistant

The Aachen-Maastricht Alliance

International experts in hospital management and business will speak at the MCC Hospital World 2008 (Berlin, 8-9 September). Here, **Dr Guy Peeters**, CEO of Academic Ziekenhuis Maastricht, and **Dr Robert Bider**, CEO of the Hirslanden Private Hospital Group, summarise their presentations on the creation of a European University Medical Centre

The RWTH Aachen University Hospital and the Maastricht University Hospital with their corresponding medical faculties are located centrally in the EU region Meus-Rhine. Because of their similar structures and range of medical services their synergetic potential regarding research, teaching and patient care is very high.

With their partnership the university hospitals strive to establish a common leading position: a European Centre of Reference.

With the cooperation agreement, signed on June 8, 2004 in the Land Parliament of Maastricht, the Executive Boards of both hospitals confirmed their intention to intensify the co-operation. Meanwhile, both medical faculties have joined in this project. Such a (transnational) co-operation agreement is unique in the European hospital sector and in university medicine in Europe.

Dr Robert Bider

Dr Guy Peeters

Objectives and opportunities of further intensifying the co-operation

Since spring 2007, the Executive Boards of Maastricht UMC and the University Hospital Aachen have carried out an ongoing feasibility study that examines the objectives and opportunities to create a leading European University Centre for top medicine.

The combination of the two individual forces will significantly improve the corresponding national position. A stronger profile development will be facilitated. In addition, the strategic alignment and excellent positioning of RWTH Aachen University and Maastricht University will offer the best possible outline conditions to become a European and worldwide leading institution in growth sectors such as medical technology and life sciences. Due to the increased attractiveness of hospitals and faculties in Aachen and Maastricht it will be possible to engage international outstanding and capable institutions and scientists. Further benefits will result from the achievement of an internationally competitive critical mass, complementarities and synergies in scientific resources, teaching capacities, management competence and machinery equipment.

MEDI-CLINIC STEPS INTO EUROPE

Last August, when the South African hospital group Medi-Clinic Corporation acquired Hirslanden, Switzerland's biggest private hospital group, the company not only took its first step into Europe, but progressed its strategy for the geographical expansion of its core business – acute medicine 'in conjunction with superior nursing care'.

'Hirslanden has found a long-time strategic partner that has the same focus as us,' said Dr Robert Bider, Hirslanden's CEO since 1990. 'We are convinced that this partnership holds great potential for the future.' The patients are unaware of a change in ownership; the logo has been retained; the hospitals are characterised by the local market and legislation and the same, as well as enhanced, level of care, with no effects on the staff. There are no plans to sell off any of the hospitals.

Robert Bider said interest in further Swiss acquisitions is keen, but Medi-Clinic wants to tackle international growth systematically. 'Concepts are currently being developed. Structures and processes must be compatible so that the synergy can be exploited, and experience and knowledge exchanged. Access to teaching and research is essential for private institutions, but difficult where the university landscape is dominated by the state. Thanks to today's modern means of communication the establishment of an international private university-related organisation appears absolutely realistic. For example, Medi-Clinic is strongly rooted in a university-linked sector. The group is directly involved in the training of specialists and in research at five medical faculties. Moreover, it is responsible for the first privately managed university medical centre in South Africa.'

Dr Edwin Hertzog, President of the Administrative Board of Medi-Clinic Corp. Ltd, and Hirslanden CEO Dr Robert Bider will report on this development at MCC Hospital World 2008 *(www.hospitalworld.info)*.

medical directors who are specialised and manage their specialised field. While this would increase personnel costs it also – and more importantly – would increase hospital performance.

Nursing services

Since the early 90s, nursing staff is increasingly skilled and trained. While many nurses acquire additional qualifications and specialisations, the majority of their tasks are housekeeping, self organisation and messenger services, which account for 75% of their work time – yet are tasks for which most nurses are overqualified. To improve cost efficiency, simple tasks can be allocated to other functions. There are already successful pilot projects underway in which nurses' assistants, housekeeping, service and hotel staff are employed.

On the other hand, highly qualified nurses could assume more responsibility and perform both medical and case management tasks. It remains to be seen, though, whether nursing staff are willing to assume medical assistant tasks and whether doctors are prepared to hand over case and process management tasks to nurses.

Key issue: logistics

Hospital traffic is immense: Hospital hallways buzz with staff, permanently on the move. They accompany patients to examinations, hand carry reports, files and images because the electronic patient record (EPR) is still not a reality. Long distances between diagnostic, treatment, surgery and care facilities, scattered all over a hospital complex, force staff to spend more time in transit than in the workplace where they belong. These superfluous logistical processes generate superfluous costs of around 20%. Today, PACS, digital ordering, EPRs and electronic scheduling, as well as electronic stock and purchase management, are all possible and should be minimum standard. The core work areas of a hospital must be restructured. With short routes and short waiting times, staff will perform better and patients will be more satisfied.

Data management to support decisions

Hospital management has many possibilities to optimise the economics of medical treatment. Over the last few years, the 'profit accounting centre' at the Institute for the Hospital Remuneration System (Institut für Entgelt-kalkulation im Krankenhaus – InEK) has gained wide acceptance as a decision-making support tool. It provides benchmark-oriented profit and loss accounting as well as continuous DRG calculation, which generates actual cost data for each case. Excess costs as well as shortfalls are identified and their causes can be analysed.

All required data are automatically culled from the overall hospital information system and from functional sub-systems. For hospitals a professional software solution is as indispensable as the above-mentioned standardisation of processes.

Empathy

A major success factor of any hospital is the level of empathy patients receive. But today, in the face of organisational and structural weaknesses, empathy far too often falls by the wayside – a fact deplored by patients and staff alike. In modern society the avoidance of suffering plays an enormous role and, in addition to any pain therapy, human-centred emphatic care can work wonders. If we conclude that, in the current system, empathy has become almost impossible, we need to ask who can serve as a model and how can we improve the situation. The organisational and structural changes suggested above are not merely technocratic, on the contrary, they all aim for one goal: to make empathy possible again.

Implementation example: Vascular Surgery

The European Vascular Centre Aachen-Maastricht serves as a leading example for the development of collaboration in cardiothoracic surgery, cardiology and interventional radiology.

The partners established a joint Centre for Vascular Surgery: Each hospital has fully employed physician and nursing staff, whereas the director of the centre, Professor Michael Jacobs, travels between both locations. Communication with staff is possible by video conferencing. Moreover, corresponding technological solutions enable Maastricht UMC to retrieve information, e.g. patient files stored in Aachen and vice versa. An IT system has been developed to enable neurophysiologists to monitor top-level thoraco-abdominal aorta aneurysma (TAAA) surgery in Aachen from their department at Maastricht UMC. The European Vascular Centre Aachen-Maastricht was accredited recently.

More details of this project can be heard at the MCC Hospital World 2008 (www.hospitalworld.info) meeting in September.

Medi-Clinic, the S. Africa-based private hospital group, was founded in 1983 by Dr Edwin Hertzog, its present Administrative Board President, with the support of the Rembrandt Group. The corporation unites 50 hospitals (c. 7,000 beds; 13,000 staff) most of which operate the affiliated doctor system.

The Swiss Hirslanden private hospital group, established in 1990 by a Hirslanden Clinic merger with four clinics owned by the American Medical International (AMI) Group. The group now owns 13 hospitals (c. 1,300 beds; 4,500 employees). Dr Robert Bider has been CEO since 1990. In 2007, Hirslanden changed hands from the private equity group BC Partners to the South African corporation Medi-Clinic.

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EH 3/08

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Also, despite body size – 93.6 high x 60.9 wide x 21.3 mm deep – and weight, 136g (without battery and card), this 8 megapixel camera, with 3 x optical zoom, provides another reason for our choice: languages. It will suit most of our *very* international readers because the menu comes in 38! (EU, Greater European and Far Eastern languages, of course, but also Hebrew, Persian and Arabic and more).

So, no matter where you plan to take a break, why not see if you will be the one to pack this prize?

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The three winners of the European Hospital issue 2/08 competition are:

Dr Marta Eva Tatar
Head of Cardiology, Spitualul de Cardiologie Covasna, Romania

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Dr Corinna Hauff
Radiology Department, Hull Royal Infirmary, United Kingdom

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Restructuring in the hospital sector

MERGER CONTROL AND OTHER PITFALLS UNDER COMPETITION LAW

The hospital sector has recently faced increased competition law scrutiny, particularly in Germany. In recent years the German Federal Cartel Office (FCO) has made it clear, on numerous occasions, that mergers between hospitals (private and public) are as much subject to competition law provisions as any other merger cases. Here, **Marc Besen** analyses a few recent German merger cases to provide an overview of the impact of competition law provisions on hospitals – and on hospital mergers in particular

The restructuring process in the hospital sector has accelerated over the last couple of years. For example, since 2005 the FCO, has reviewed over 50 hospital merger notifications.

The first prohibition of a public hospital merger was issued on 13 December 2006. The FCO prohibited the University Hospital of Greifswald from taking over the Wolgast district hospital. It argued that the merger would further strengthen the dominant position of the Greifswald University Hospital in the relevant market. In its decision, the FCO followed the principles established in the earlier merger case Rhön Klinikum AG/Bad Neustadt (10/3/05). However, despite the basic similarity, the final outcome of the two cases was different. Whereas in its ruling of 16/1/08 on Rhön Klinikum AG/Bad Neustadt, the German Federal Supreme Court upheld[1] the merger prohibition, the merger could be consummated after receiving an exceptional authorisation from the Federal Minister of Economics and Technology on 17 April 2008.

As a lawyer and partner at Clifford Chance, Dusseldorf-based Marc Besen primarily specialises in German and European antitrust law. He advises companies during the implementation of merger control proceedings at the German FCO and EC and co-ordinates worldwide multi-jurisdictional filings. He also has broad expertise in advising interested third parties in successfully intervening proposed transactions within merger control and court proceedings. In addition, he focuses on cartel investigations, issues of compliance systems, contractual implementation of competition and antitrust law requirements, and distribution law across a wide range of industry sectors (in particular healthcare and hospitals).

Relevant provisions

Turnover thresholds

In its ruling on Rhön Klinikum AG/Bad Neustadt the Federal Supreme Court supported the view of the FCO and stated that hospital mergers are subject to merger control provisions in accordance with the provisions of the German Act against Restraints of Competition (ARC). As the ARC does not distinguish between mergers of private and public undertakings, the merger control provisions apply irrespective of the legal status of the hospitals concerned.

Mergers (incl. the acquisition of at least 25% of shares in a company, etc.) must be notified with the FCO if the total global turnover of the parties involved exceeds €500 million and if at least one of the companies involved generates turnover in Germany exceeding €25 million. The fact that such mergers do not normally take place in so-called *de minimis* markets (which are exempt from German merger control provisions) means that merger applications may only be dispensed if a company having generated global turnover of less than €10 million in the last fiscal year (including parent company and subsidiary turnover) merges with another company. Mergers must be notified with the European Commission if the total global turnover of the parties exceeds the threshold laid down in the EU Merger Control Regulation. The turnover thresholds for German merger control were met both by Rhön Klinikum AG/Bad Neustadt and Greifswald/Wolgast. In the latter case the state of Mecklenburg-Western Pomerania argued that its total turnover on the hospital sector does not meet the threshold of €500 million. However, the FCO rejected this assessment arguing that the relevant turnover achieved by the state includes not only the hospital but also any other commercial activities of the state.

Substantive assessment criteria

If a merger is likely to create or strengthen a dominant market position, it will be prohibited by the FCO under sec. 36 (1) of the ARC, unless the parties are able to demonstrate that the merger will have a significant positive effect on competition. A company is regarded as having a dominant market position if it is able to supply or demand certain goods or services on a specific market without having any competitors or being exposed to any substantial competition, or if it has a paramount market position in relation to its competitors (sec. 19 of the ARC). This is presumed to be the case if the company has a market share of at least one third. It is also possible for several companies jointly to hold a dominant market position, if up to three companies have a joint

continued on page 6

continued from page 5

market share of at least 50% or five or fewer companies have a joint market share of at least two thirds. These thresholds are likely to be met on a regular basis in the case of hospital mergers given the overlaps in catchment areas resulting from the regional market set-up.

Market definition

The central issue in both merger cases was the determination of the relevant market and thereby of the relevant market shares.

In both cases the relevant product market was defined as the market for acute hospital services comprising all general hospitals and specialised clinics, but not rehabilitation and other nurse centres.

The geographical scope of the markets was defined regionally by the FCO. The main criteria for the regional delineation was the patient flow, which itself depended on the hospitals in the vicinity of the patients offering a genuine possibility for treatment. In both merger cases the market definition was based on a comprehensive analysis of the market conditions.

This means that, for the purpose of hospital mergers, the market is defined quite narrowly both, in terms of the services offered and the relevant geographical territory. As a consequence, some hospitals will be considered to have a dominant market position in their catchment areas even if they have a relatively low turnover.

In the Bad Neustadt market, in which Rhön Klinikum AG already owns five clinics, Rhön would have – according to the findings of the FCO – increased its market share from 25% to approx. 65%. In the Greifswald market, the FCO concluded that the market share of the Greifswald University Hospital would have increased by 25% to approx. 80% of the overall market and, concerning some specialised departments, such as surgery or gynaecology, to approx. more than 90%. In both cases, the FCO found that a market dominating position would have been created/strengthened and, since the parties had not been able to demonstrate significant positive effects on competition, the mergers were prohibited.

Ministerial authorisation

Under sec. 42 of the ARC, the Federal Minister of Economics and Technology shall, upon application, authorise a concentration prohibited by the FCO, if the restraint of competition is outweighed by advantages to the economy as a whole following from the concentration, or if the concentration is justified by an overriding public interest. Prior to the decision the Federal Minister of Economics and Technology shall obtain an opinion from the Monopolies Commission. The Monopolies Commission constitutes an independent advisory board to the Federal Government concerning merger control and other topical issues of competition policy.

Despite the basic similaritiy between the two merger cases, the ministerial authorisation was rejected in the case Rhön Klinikum AG/Bad Neustadt, but the Greifswald/Wolgast merger was approved by the Federal Minister of Economics and Technology, who basically followed the argumentation of the Monopolies Commission. In Greifswald/Wolgast the Minister argued that the merger can be justified by the overriding public interests in the long term preservation of the medical faculty and the affiliated hospital of Greifswald University. The second overriding interest approved was the further development of the exploratory focus of 'Community Medicine' being a unique selling point of the University of Greifswald. Both aspects are expected to establish an exclusive research region of 'Model Region Eastern Pomerania'.

What conclusions can be drawn from the two merger cases?

First, hospital service providers as well as investors must comply with the merger control law provisions just like any other undertaking. This principle applies irrespective of the legal nature of the hospitals, i.e. for both private and public hospitals. However, not every hospital merger in Germany requires a notification, where the only mergers that trigger a merger filing are still those exceeding the ARC turnover thresholds. Having said that, in cases involving public entities, such as federal states, it must also be taken into consideration that the relevant turnover of the acquirer includes the whole turnover achieved through all its commercial activities. This means that hospital mergers involving a public acquirer are very likely to exceed the thresholds set out in the ARC.

A second, separate issue are the conditions that must be met to obtain FCO clearance. The initial consideration would be whether there is any regional overlap between the catchment areas of the hospitals concerned. The next key factor is whether the merger would create or strengthen a dominant market position on the relevant market.

From Greifswald/Wolgast it can be concluded that mergers between public undertakings in economically underdeveloped German regions probably have better chances to be granted ministerial authorisation under sec. 42 of the ARC. It remains to be seen whether the FCO will adopt a similar legal position.

Risks

If a merger triggering German merger control is not notified before closing at all, or not correctly notified, this may have a number of consequences under civil and regulatory provisions. The first consequence is that the underlying purchase agreement is void according to sec. 41 (1) 2 of the ARC. Moreover, the FCO may impose severe fines on the parties, which can amount to up to 10% of the overall turnover generated in the previous financial year.

There are also other potential forms of cooperation between hospitals in addition to mergers that need careful consideration under an antitrust perspective before being put into practice. The main types of cooperation affected are agreements on specialisation or regional focus and joint purchasing arrangements in particular. The latter can become critical when the joint market share held by the parties involved is 15% or more. Certain risks are also associated with long-term supply agreements including exclusive supply arrangements, non-competition clauses or other exclusivity provisions. In general, there are also considerable antitrust risks related to taking part in meetings held by professional associations or in committees or trade fairs where these involve meeting with competitors. The provisions of the ARC prohibiting the abuse of a dominant market position are also relevant (e.g. discrimination, predatory pricing, etc.). These anti-abuse provisions may also apply to smaller hospitals with a strong market position in their catchment areas.

[1]At the time of the draft of this article, the full statement of grounds was not yet published by the Federal Supreme Court.

Planning pathways to a peaceful end

Annick Chapoy reports on the landscaping of the Centre Hospitalier Emile-Roux in France

People here have reached the end of their lives. After a tour of the vast grounds of the Centre Hospitalier Emile-Roux, just 20 minutes south of Paris, we come upon a familiar scene: two wheel-chairs with three people in attendance, one a nurse. For landscape architect **Olivier Damée**, co-founder of DVA Paysages in Paris, what is more unusual – and so meaningful – is that, each carries a bouquet of lilac, picked to decorate hospital rooms. Olivier planted that lilac and today's gathering signifies the success of his dream.

When, four years ago, he took up his commission to remodel the entire grounds here – all 25 acres – he faced a hospital with history. Apart from a lane leading to Brévannes castle (built 1786) and the green and planted areas in its vicinity, the general visual impression was chaotic. Across this vast area are a great number of buildings, in all styles and sizes (some built in C.17th), as well as much scattered equipment. The more recent buildings appeared – without coherence – during the 20th century. Between these, all the space was reserved solely for vehicles. Departments had to be reached by crossing them, Olivier Damée recalled. This was not just hard on pedestrians but a nightmare for the hospital's multi-handicapped and elderly patients. His diagnosis: anarchic practices, interrupted pedestrian flow and walking generally impractical.

For the design project he decided to adapt the Hospital Emile Roux to contemporary needs as well as emphasise the Brévannes castle history – a rare testimony to neoclassic architecture in this Val de Marne area.

The hospital's clinical requirements presented specific constraints: each handicap has its own characteristics and special needs. Whereas some patients can use a wheel chair or just a helper, others are blind and some multi-handicapped. In remodelling, it was essential to meet all their needs – access, rest along the way, clear directions despite the uniformity of path widths, elimination of obstacles.

Paths – The environmental perception of someone in a wheel chair, whose eye is about 1.20 metres above the ground, was carefully studied. Additionally, the level of fatigue in the elderly was considered before creating circuits for them to walk in different lengths of time, with 'kiosks' in which to rest along the way.

Today, the paths are indeed continuous, firm, neither slippery nor shiny and they are uncluttered. Their colour is also different from the roads for vehicles, and the texture changes at each crossroad for better identification by the walking sticks of the blind – and they are bordered with a material pleasant to the feet or stick. At two metres wide, they can accommodate two wheelchairs side by side.

The décor of the park, kiosks, fountains or ponds helps patients to navigate, without being an obstacle. The kiosks, providing shelter, toilets, benches, and nurse alarms, are placed every 60 or 100 metres.

Benches – Created to retain neither heat nor cold, the benches have back and armrests and the seats incline to resist rain. A metre separates each bench, providing space for a wheelchair.

Not higher than 90 cm, the waste bins can be manipulated with one hand. They also are on the ground to enable the blind to tap and locate them.

Lights – Any sudden change in luminance can lead to orientation problems, especially for the partially-sighted. For patient safety and to avoid any loss of landmarks, lighting equipment must be coherent and continuous. Lights illuminate the paths in areas used at night, as well as at pedestrian crossings over roads. The angles of luminous rays are controlled to eliminate glare and reflection.

Light from lamp post intersect at a height of 2.10 metres minimum. Glare from lower sources of light (under 1.5 metres above ground) does not occur.

Planting – The designer divided the existing large lawn in to four distinct and complementary zones: a forest; valley of flowers; large prairie from which to admire the castle, and a huge orchard.

Various areas focus on the sensory environment – of touch, scents and sounds – particularly valuable for the blind. Woodland of modest height and low density absorb noises, whereas a thick, high hedge acts like a wall. The sound of a fountain is important as a guide for the blind or partially-sighted, for they have less auditory landmarks in a park compared with a street.

Triple rows of linden trees now line the majestic route to the monument, and the orchard planted next to the castle is an ideal attraction for ambulatory patients. In all, there are three kilometres of traffic-free walkways.

Private medicine
A Russian evolution

Olga Ostrovskaya reports on the first St Petersburg medical forum *Private medicine in Russia: Problems and ways of evolution*, which took place in June. Organised by various medical associations, the main goal was to exchange experiences in private medicine and shape proposals to create a productive state policy in this sphere

Sergej Anoufriev, CEO of the St. Petersburg Association of Clinics

The development of private medicine in Russia has reached a new level, according to Sergej Anoufriev, CEO of the St Petersburg Association of Clinics (set up by 13 private clinics two years ago). Private clinics have become a real part of the Russian healthcare system and people increasingly choose private medical services. However, the state and private organisations solve the same problems differently. Thus we must seek and find common ground for the sake of our patients. The Forum was the important step on this road because the state officials, public agents and the private clinics leaders worked together over the three-day event.

Today, in Russia, no one doubts that healthcare will be more qualitative and more effective when private clinics and centres gain state support, and partnership will become the main principle of the relationship between state and private medicine.

Russia has twice the number of hospitals than the European Union. However, about 50% of these cannot provide patients with modern, quality treatment. At the same time, the illegal medical market turns over about US$15 billion annually – i.e. money paid by patients straight into doctors' pockets.

50% of Russians never go to a state hospital – and those are the most actively employed. They pay taxes for state healthcare, yet often seek private treatment.

St Petersburg has about five thousand out- and in-patient hospitals; only about 10% of medical services are provided by private centres. Experts, however, talk about the arrival of several new, big private clinics in the near future.

Generally, private clinics are set up by the most active physicians, Sergej Anoufriev pointed out. They need about US$50,000 to 100,000 to fund a private centre. Today, however, the 'ticket' to a medical business is worth between US$500,000 to 900,000. It's serious business, which needs necessary and serious investments.

The Forum's participants signed a document stating that healthcare system reform will be more successful and more effective if private clinics are included in state healthcare programmes.

Nosocomial infections

NHS survey finds wide variations in control standards


Healthcare Commission CEO Anna Walker

Report: **Mark Nicholls**

UK – The NHS is still suffering from wide variations in infection control standards, according to a survey of health staff in the UK.

The study carried out by the watchdog body the Healthcare Commission, after questioning more than 155,000 NHS staff, indicated that there had been improvements in infection control in several areas.

This was reflected in 82% of staff saying their trust did enough to promote the importance of hand-washing to staff, up from 70% in 2005.

There was also an improvement in the number of staff trained in infection control, up from 68% in 2005 to 71% in 2007.

However, the Healthcare Commission said work still needed to be done in hospitals in parts of the UK to ensure that hand-washing equipment was always available to staff when they needed it. In 2005, 60% of staff said hand-washing equipment was available but in the latest survey, this had only risen to 61% with wide variations between hospital trusts.

Healthcare Commission chief executive Anna Walker said: 'At a time when public concern about healthcare associated infections is so high, I'm pleased to see some improvements in this area. But trusts must make sure that frontline staff always has the necessary equipment to wash their hands. There are trusts that have shown that it is possible to do this well, with as many as 82% of staff saying they always had equipment available. But this fell to as few as 39% at other trusts. Every trust should be aiming to make this 100%.'

In Britain, Prime Minister Gordon Brown ordered a 'deep clean' of every hospital ward last year as a pre-emptive move to halt the spread of nosocomial infections such as MRSA.

Various practices have been introduced in UK hospitals to this end – one, in Plymouth, for example, which had the highest number of MRSA deaths in England with 94 between 2002 and 2006, now has all serious cases of MRSA and clostridium difficile infections reviewed by senior managers.

Another NHS Trust reports it has eliminated MRSA bloodstream infections by stopping the routine practice of administering intravenous injections. *(See page 23 for a roundup of UK approaches to control nosocomial infections.)*

However, although the NHS had experienced a continuous drop in MRSA outbreaks since April 2006, the most recent figures show a slight rise in cases. The Health Protection Agency said cases between October and December 2007 stood at 1,087, up 0.6%, meaning that British government targets on reducing cases may not be met.

The Healthcare Commission will continue to monitor performance of hospital trusts against the Hygiene Code in the UK.

Other findings from the Healthcare Commission survey of NHS staff, which covered 391 NHS trusts, found that staff were generally satisfied in their jobs, that 94% took part in some form of training but that more action is needed to address violence and abuse, which research suggests is relatively high in the health sector compared to other working environments.

Ms Walker said: 'The results show there are a lot of reasons to work in the NHS. But there are challenges to making the NHS a better place to work.'

* In Scotland, a year-long pilot screening programme for MRSA in hospitals was announced by the country's Health Secretary Nicola Sturgeon. Almost one million people will be given nasal swabs to test for the presence of MRSA. If detected, they will receive treatment to clear the infection.

Nurses spend 1.6 million hours weekly on form filling

UK – A plea to hire more 'ward clerks' to free hospital nurses from excessive bureaucracy has been made by the Royal College of Nursing to the government and change NHS targets so as to place more emphasis on patient satisfaction and hygiene standards.

The excessive hours nurses spend on tasks that keep them away from patient care were highlighted at the RCN annual conference this April, based on an ICM poll of over 1,700 staff nurses. This revealed that they spend, on average, 7.3 hours weekly filling in forms; part-time nurses spend some 3.9 hours in this way. Figures for nurses in managerial positions, obviously expected to spend more time on administration, were not included. The total hours of bureaucracy amounted to over a million weekly.

Peter Carter, the RCN general secretary, pointed out that 88% of the poll respondents had experienced an increase, in the last five years, in the amount of bureaucratic tasks that did not need their professional judgment. These include filing, photocopying and ordering supplies. Over 28% pointed out that they had no access to clerical help. Only 22% believed administrative back-up has kept pace with the growth in bureaucratic demands.

Government ministers are being asked by the RCN to introduce new key care quality indicators, including patient satisfaction, complaints, cleanliness, infection rates, food, drug errors, communication and dignity.

DIABETES MANAGEMENT


Professor Antonio Ceriello (left) and Professor Oliver Schnell

During the *2nd European Workshop on Diabetes*, hosted by Bayer HealthCare Diabetes Care, experts called for uncompromising management of diabetes.

Professor Oliver Schnell, of the Diabetes Research Institute, Munich, stressed the value of blood glucose testing. Numerous studies have shown that regular self-testing makes a significant contribution to improving outcomes and management of complications.

The special significance of post-prandial blood glucose values in this was emphasized by **Professor Antonio Ceriello**, of the Clinical Sciences Research Institute, Warwick Medical School, UK. Unlike those of healthy people, the blood glucose levels of people with diabetes fall only slowly and often insufficiently after glucose uptake – a phenomenon that the International Diabetes Federation has taken into account in its Guidelines for the management of post-meal glucose. Professor Ceriello, Chair of the IDF Steering Committee, summarized its recommendations as follows:

- Post-meal hyperglycemia is harmful and should be addressed.
- A variety of both non-pharmacological and pharmacological therapies should be considered to target post-meal plasma glucose.
- Two-hour post-meal plasma glucose should not exceed 7.8 mmol/l (140 mg/dl), as long as hypoglycemia is avoided.
- Self-monitoring of blood glucose (SMBG) should be considered because it is currently the most practical method for monitoring post-meal glycaemia.
- Efficacy of treatment regimens should be monitored as frequently as needed to guide therapy towards achieving post-meal plasma glucose target.

EDUCATION & NETWORKING

ResearchGATE: the first social network for researchers

MOVING TOWARDS SCIENCE 2.0


Ijad Madisch studied medicine and computer science, and was a researcher at Harvard Medical School, Boston, for two years. His doctorate was gained for a thesis on molecular virology

Despite the importance of networking and interaction between researchers and scientists no social networking platform dedicated to researchers existed before ResearchGATE (www.researchgate.net) went online. Designed to facilitate efficient peer-to-peer contact, this network allows researchers to post their profiles, a CV, publication list and research skills. On behalf of *European Hospital*, *Dr Sönke Bartling*, a researcher at the German Cancer Research Centre, Heidelberg, and advocate of Science 2.0, interviewed **Dr Ijad Madisch**, co-founder of ResearchGATE, about the concept and benefits of this social network

What singles ResearchGATE out compared to, for example, using Facebook for social networking?

Dr. Madisch: It's a social network tool adapted to a researcher's needs, i.e. optimized to present yourself in the context of your research. ResearchGATE enables you to get in touch with colleagues internationally; to stay informed about their actual projects and latest publications, as well as their contact information and the literature they read. We want to combine various Science 2.0 applications in order to create a unique collaborative environment.

ResearchGATE can initiate and foster collaboration among researchers in different ways; the platform is increasing efficacy, inter-disciplinary and economic way of collaboration. Through our search engine you can find a researcher specialized in specific fields, so it's easy to find someone who may be a big help. Just search for their research skills. Given the importance of collaboration for researchers we developed a new application: REstoRY (Research Storage History) – a smart file and data sharing application. Several other features are already available. However, driven by ideas and feedback of the scientific community we are continuously developing new applications tailored to researcher's needs.

What is Science 2.0?

We have all heard about this evolution - some people call it revolution – within the internet widely known as Web 2.0. Let us take encyclopaedias. For decades they were hardcovers on the bookshelf, then followed a static online version. Finally encyclopaedias were revolutionized by Wikipedia. Within science – and especially publication within science – we are currently in the static online stage. Science and scientific publication almost completely lacks modern concepts that Web 2.0 offers, which will change through Science 2.0. This is already happening, old fashioned lab notebooks have given way to Wikis, and the amount of open access journals is increasing. Nobody knows how science in the future will look – but with ResearchGATE we want to support that change. ResearchGATE is a part of the Science 2.0 community and will evolve with the community from scientists for scientists.

Cardiology at the Crossroads

This May the Brussels-based *Crossroads Institute for Cardiac and Vascular Medical Education* launched two new educational courses on the prevention of amputation (peripheral vascular disease) and on improving the treatment of women with cardiovascular disease.

These complement the Institute's extensive portfolio of 'hands-on' training for interventional cardiologists, nurses and pharmacists. Over 50 of the Institute's courses are CME-accredited. 'To date, more than 14,000 physicians have participated,' said Prof. Jean Marco MD, course director for the Crossroads Institute.

Virtual simulators and a virtual in-house catheterisation lab enable physicians to practice the latest in cardiac and vascular therapies. Live case broadcasts from hospitals across Europe demonstrate real-time catheterisation lab events.

Programmes offered include the latest stenting techniques (e.g. bioabsorbable stents); revascularisation strategy in diabetics; stenting high risk patients; prevention and management of PCI complications.

The Institute and its education programmes are sponsored by Abbott Vascular, but course content is decided by an independent steering committee.

Languages: Mostly English, but other EU language-courses are available.
Details:
www.crossroads-institute.com

WMA gains funding to support TB training course

Pharma company Eli Lilly has increased an existing partnership with the World Medical Association (WMA) by granting c. 646,505 euros to expand online training courses for physicians on multi-drug resistant tuberculosis (MDR-TB), which they have been developed over the past year. The course aims to help physicians to more effectively diagnose, prevent and treat MDR-TB. Clinical guidelines were developed and harmonised with evidence-based material sourced from the WHO, International Council of Nurses and the International Hospital Federation.

The course was tested among physicians in South Africa.

The German Medical Association gave managerial support for the conception of the project, and the Norwegian Medical Association adapted the material to a web-based format and will provide CME credits to course participants.

The new four-year joint partnership agreement was signed in Geneva in May by **Jacques Tapiero**, president of Lilly's intercontinental operations and WMA president **Dr Jon Snaedal**. 'Given adequate healthcare infrastructure and adherence to proper medication regimens, MDR-TB is not only treatable, but indeed curable,' said Jacques Tapiero. 'This online training course is an important addition to the already existing tools and activities of a larger partnership of 16 public and private organisations worldwide dedicated to fighting MDR-TB.'

Dr Snaedal added that the course will now be made more interactive, with more case studies and a progressive learning pattern. 'A TB refresher course is important to get physicians back on track regarding the basic knowledge of standard TB,' he explained.

Currently in English, the online course is being translated into Spanish, French, Chinese and Russian. It will also be published in handbook and CD form.

FREE course access: www.WMA.net/
Or via the Norwegian Medical Association: http://lupin-nma.net/

BMJ gives EU doctors free access to CME

Doctors across Europe now have free access to the British Medical Journal's library of *Continuing Medical Education* (CME) and *Continuing Professional Development* (CPD) content.

With 'revalidation' of medical training becoming a real threat in many EU countries, the availability of unbiased, peer reviewed, accredited CME will become increasingly important, explained Dr Michael Chamberlain, Chairman of the BMJ Group, adding: 'Medical knowledge is changing at such a rapid rate, that a physician's knowledge needs replacing every seven years.'

More than half a million physicians already use univadis, but only now have access to BMJ Learning. Under the new scheme, started in June, EU primary care and hospital physicians can access 350 interactive learning courses from BMJ learning at *www.univadis.com* (sponsored by Merck Sharp and Dohme). Until now, the most popular CME modules have been Childhood Fever, and Avian Flu.

Languages: The courses are being translated first into Spanish, German, French and Italian, to be followed by other EU languages.
Report: Ian Mason

ICELAND'S ADVANCING MEDICAL SERVICES

With two campuses, Iceland's Landspitali University Hospital (LUH) is the largest medical institution in Reykjavik. Both are affiliated with the University of Iceland. While LUH is chartered to serve the entire national population of 313,000, its primary focus has traditionally been on the 178,000 residents in and near the city. LUH is at the forefront of specialized healthcare in Iceland, and is the central base for providing medical services to its citizens as well as educating health professionals. More than 1,100 students are trained at the hospital annually, and nearly all Iceland's physicians received their medical education at LUH.

2008 Medical Design Excellence Award

The Medical Design Excellence Awards competition is organised and presented by Canon Communications LLC (Los Angeles) and is the only awards programme that exclusively recognizes contributions and advances in the design of medical products.

Sectra MicroDose Mammography has been given the 2008 Medical Design Excellence Award. Entries are evaluated on the basis of their design and engineering features, including innovative use of materials, user-related functions that improve healthcare delivery and change traditional medical attitudes or practices, features that provide enhanced benefits to the patient, and the ability of the product development team to overcome design and engineering challenges so that the product meets its clinical objectives.

The independent jury, with expertise in biomedical engineering, human factors, industrial design, medicine and diagnostics, pronounced: 'Sectra MicroDose Mammography with its ultra low-dose radiation output and elegant ergonomics clearly stood out with regard to both the criteria patient safety and ease-of-use. Aesthetics, while not absolutely critical, is also important and the elegant European form factor was another positive.'

Thorgeir Palsson, Clinical Engineering Manager in the Medical Service Department at LUH

Today, Iceland counts 53 personal health clinics, widely scattered across the nation, which, despite its relatively small population, encompass a land area nearly the size of the UK. A combination of hospital-based PACS technology and remote computed radiography (CR) units from Agfa HealthCare will now help many Icelanders receive prompt medical care regardless of location.

LUH had originally installed a basic PACS from Agfa HealthCare in 1997 linking various digital modalities within its radiology department, as well as workstations in other hospital-based locations. A comprehensive CR system was added in 2003. More recently, it upgraded to a newer IMPAX PACS version with an expanded network that included nearby clinical locations outside the main hospital campus.

Thorgeir Palsson, Clinical Engineering Manager at LUH, explained: 'Growing our PACS over the years clearly demonstrated how we could link and archive images from various modalities, as well as make data available to other in-hospital sites. We also saw the speed, workflow improvements, performance reliability and image quality benefits of distributing digital imaging and information. Going digital meant no more film processing, with all the caustic chemicals and strong odors,' he added. 'I also like not having to store and manage chemical supplies, as well as avoiding the huge cost of safely discarding old chemistry. The CR system is very user-friendly, and I'm pleased with all the advantages it offers.'

'LUH physicians and administration agreed it was logical to expand the network using Agfa HealthCare CR systems, since their experience with the original and current IMPAX products was so positive, and deploying the company's CR technology would be an easy, transparent connection,' Agfa pointed out. 'As a result, Agfa HealthCare also deployed CR 35-X and CR 30-X CR systems.'

Performing over 6,000 procedures annually, the Keflavik facility's single CR unit and 11 special cassettes are in constant use.

TRENDS IN IMAGE-GUIDED THERAPY

For the third in his series of articles for *European Hospital*, **Professor Stefan Schönberg** of the Institute of Clinical Radiology and Nuclear Medicine (IKRN), University Hospital Mannheim, Medical Faculty of Mannheim, University of Heidelberg, invited colleagues at the Faculty's Cardiology and Radiology and Nuclear Medicine departments for a round-table discussion on:

Cardiac-CT for guidance of electrophysiologic interventions in patients with cardiac arrhythmias


Rainer Schimpf


Radko Krissak


Christian Wolpert


Tim Süselbeck


Thomas Henzler


Christian Fink

Meet the experts

Rainer Schimpf[1], Radko Krissak[2], Christian Wolpert[1], Tim Süselbeck[1], Thomas Henzler[2], Christian Veltmann[1], Jürgen Kuschyk[1], Martin Borggrefe[1], Stefan Schoenberg[2], Christian Fink[2]

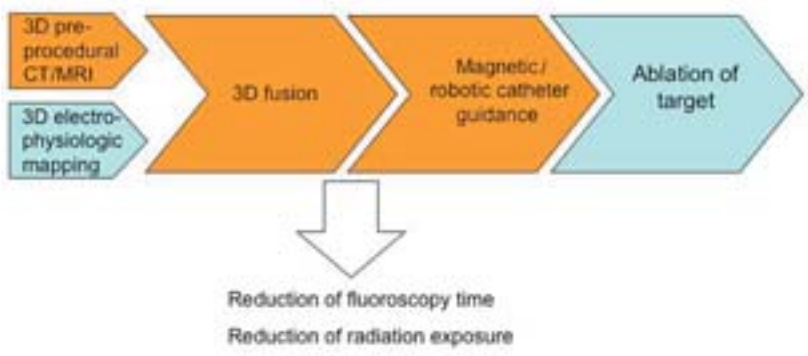
1 *Department of Medicine-Cardiology and*

2 *Department of Radiology and Nuclear Medicine, University Medical Centre Mannheim, University of Heidelberg*

Over the last decades invasive cardiac electrophysiologic studies gained widespread acceptance for the diagnosis and treatment of cardiac arrhythmias. The spectrum of supraventricular and ventricular tachyarrhythmias that can be cured by catheter ablation increased significantly. More complex tachyarrhythmias such as atrial fibrillation (AF) or atrial tachyarrhythmias, premature ventricular contractions (PVC) or ventricular tachycardias in patients with complex congenital heart disease can nowadays be successfully approached.

Electrophysiological studies and ablation procedures are currently performed with manually deflectable catheters under fluoroscopic guidance. The fluoroscopic silhouette of the heart, together with excursions of the catheter during manipulation as assessed by different X-ray angulations as well as the electrical signals recorded by the distal electrode of the electrophysiologic catheter, are the tools to localise the target region for an effective therapy. Some major disadvantages are obvious. Frequent fluoroscopy is needed to control catheter movement which may lead to substantial radiation exposure time for both, the patient and physician. The cardiac anatomy is not visible during conventional procedures.

Improved workflow by using ECG-gated CT for guidance of electrophysiologic cardiac interventions



Therefore, electrical signals recorded from the endocardium by the mapping catheter cannot be directly associated to the individual anatomy in case of conventional fluoroscopy.

However, the last decade has witnessed the development of high-resolution non-fluoroscopic mapping systems and integration of CT or MRI data sets of cardiac anatomy. The three dimensional pattern of electrical activation during the arrhythmia, such as recurrent PVC or regular supraventricular or ventricular tachyarrhythmias can be reconstructed with sequential registration of the electrical activity from different anatomic regions of the heart. Furthermore, continuous non-fluoroscopic control of the tip of the visualised mapping catheter during manipulation in the heart chambers is possible. Thus, movement of the catheter can be performed with less or even without fluoroscopic control. Finally, the new generation electro-anatomical mapping systems offer the possibility to integrate high resolution cardiac CT or MRI images in the electrical map of the heart. Prior to the procedure a contrast-enhanced ECG-gated CT of the heart is performed. The cardiac chamber of interest is then reconstructed using 3-D post-processing algorithms. Therefore, anatomical variations or abnormalities, which may have a significant impact on the outcome of the ablation procedure, e.g. variations of the pulmonary veins in patients with AF, can be detected and visualised prior to ablation (Figure 1). After acquisition of an electro-anatomical map during the invasive procedure the data sets can be merged to visualise both electrical and specific anatomic data (Figure 2). However, morphological information with a preprocedural approach has the disadvantage that it does not account for dynamic changes in anatomical structures and diameters.

Most recent technological developments enable the physician to steer catheters remote either by magnetic navigation or by robotic navigation with a remotely controlled flexible guiding sheath. Highly accurate and reproducible catheter placement and navigation is mandatory for successful and sustained ablation of the target. The knowledge of the individual and often significantly variable anatomy of the patient is essential for a safe and effective therapy. Thus, improved integration of anatomic CT or MRI data of the individual patient during electrophysiological procedures offers the opportunity to increase orientation, safety and efficacy in ablation therapy and to reduce radiation.

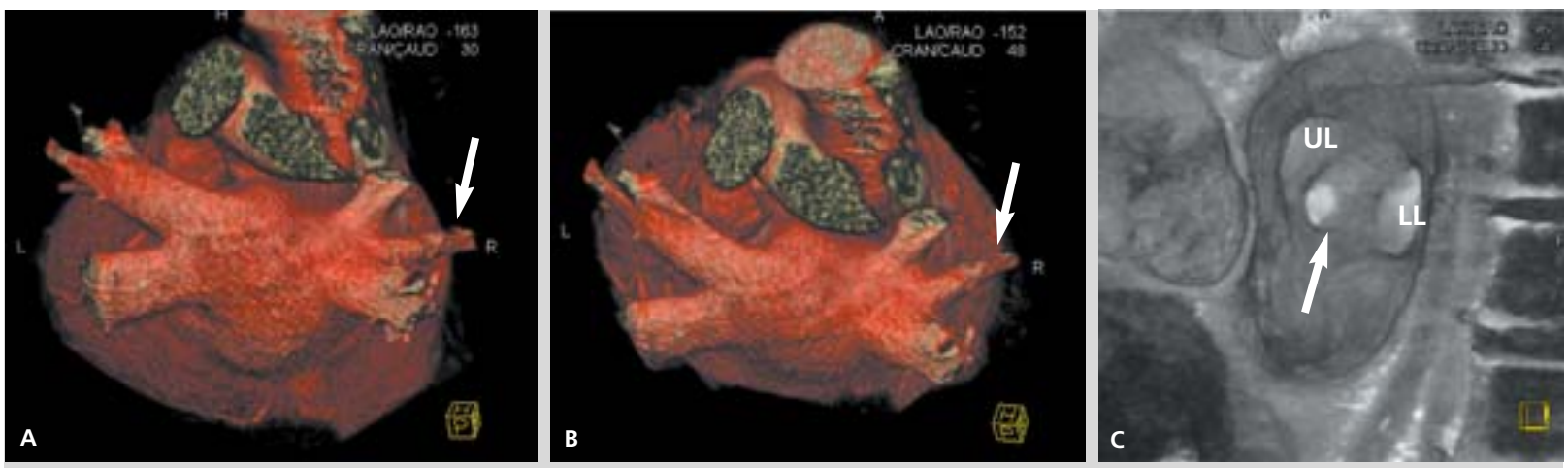


Fig. 1 Pre-interventional ECG-gated Cardiac CT of a patient with atrial fibrillation scheduled for pulmonary vein isolation demonstrating a separate right middle lobe vein (arrows). The pre-interventional identification of the middle lobe vein has direct implications on the therapeutic success, as it is often difficult to identify this small calibre vein at fluoroscopy. **A, B**: 3-D volume-rendering reconstruction with different posterior views. **C**. Virtual angioscopy of the left atrium, view from left side (UL=Vein of upper lobe, LL=vein of lower lobe).

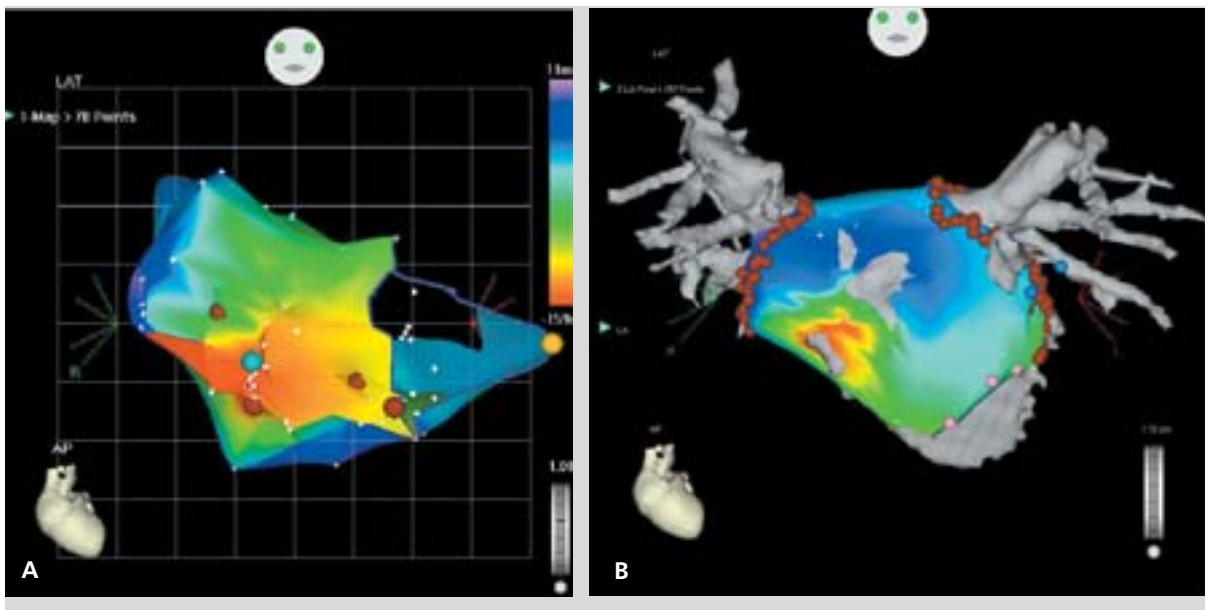


Fig. 2 **A**. Example of an electro-anatomical reconstruction of the right atrium in a patient with focal right atrial fibrillation. **B**. The 3-D fusion of an electro-anatomical map of the left atrium with the pre-interventionally acquired 3-D CT data offers the opportunity to increase orientation, safety and efficacy in ablation therapy and to reduce fluoroscopy time and radiation exposure.

The 2nd National Russian Radiology Congress

Far more than a national event

Drawing together radiologists from all of Russia is a challenge – even more surprising is meeting the president of the *European Congress of Radiology* (ECR) and other well-known radiologists from the rest of Europe writes *Meike Lerner*, of *European Hospital*, who was at the *2nd National Russian Radiology Congress* held in Moscow this May, to report on the hot topics in radiology over the eastern borders.

'This year we except 1,500 congress attendees from all over Russia, which is only possible because we have special approval from the Ministry of Health, otherwise colleagues from other regions could not have participated,' explained **Sergey Ternovoi**, a full member of the Russian Academy of Medical Science and one of the four congress presidents. 'Last year's congress was very successful and this time we tried to broaden the congress topics to include cardiology, pulmonology, urology and some more clinical areas. Our aim is to bring all these specialists to one round table to discuss the latest trends, share experiences and of course talk about education. In Russia, the term radiology does not have as a broad a definition as in Europe. In common use, we say Radiology for Nuclear Medicine and we distinguish between 'Roentgen' and Ultrasound. So at this congress we invite specialists from all those specialties to discuss the problems, in the interest of patients.'

Left: Sergey Ternovoi, Full member of the Russian Academy of Medical Science and one of the four congress presidents

Right: Valentin Sinitsyn, Moscow State University Cardiology Research Complex

Left: Borut Marincek, Director at the Institute for Diagnostic Radiology, University Hospital Zurich and President of the European Congress of Radiology 2009

International experts such as **Professor Matthias Oudkerk**, Head of the European Society of Cardiac Radiology, and **Professor Borut Marincek**, President of the European Congress of Radiology (ECR) 2009, were also invited, and very pleased about the cooperation between East and West European countries: 'Russia and the East European countries in general are becoming increasingly important, something we've noticed just by looking at the turnout at the ECR over the last few years. At the moment, what we can see are differences in imaging technology. In western countries, higher incomes resulted in investments in large medical equipment, such as CTs and MRIs, whereas the eastern countries have mainly used ultrasound scanning. This has not only impacted on costs within the healthcare systems, but also on training, which, in Russia for instance, is much shorter. Understandably, radiology departments are interested in harmonising teaching and training, i.e. they would like to see a convergence of standards from Portugal right across to St. Petersburg. This is, of course, a Sisyphean task, as each of the 47 European countries has different training regulations.' Prof. Marincek expects developments in Russia to take a similar turn to those in the west. 'There will be a shift away from ultrasound towards CT, a method that is always reproducible. The same goes for MRI. The acquisition and use of this equipment obviously always represents a cost issue, and Russia's current situation means that this technology is becoming more widely available in larger cities, whilst rural areas are more or less excluded from those developments.'

His colleague **Professor Valentin Sinitsyn**, Radiology Chair at the Moscow State University, Cardiology Research Complex and a full member of European Society of Radiology, pointed out another problem related to the shift to CT and MR: 'Our government has declared a national health service project and provides money for hospitals for refurnishing and construction. But one problem that remains unsolved is servicing the equipment. The money donated to the hospitals is not enough for equipment maintenance. Sometimes the situation is paradoxical, because it's easier to send an application for a new machine than it is to repair a system that is four or five years old.

'Another problem we face is teaching. If you look at the statistics, we have many radiologists, but the number of them who are active and able to work efficiently with modern equipment is not that high. So we need more specialised training and I agree with Prof Marincek that education has to become more equal across Europe.'

The rush to Russia's booming med-tech market

For medical technology giants such as GE, Philips, Siemens and Toshiba, Russia has become a highly promising market, with the potential further increasing in its growing private hospital sector. During the *Russian Radiology Congress* (26-29 May, Moscow) *Meike Lerner* of *European Hospital* met with company representatives to discuss their presence in Russia and any problems relating to financing in a market that has no great experience of capitalistic structures

Richard di Benedetto

Slava Grischenko

Joost Leeflang

Ilya Gipp

As one of the biggest foreign companies, GE Healthcare has about 200 employees in cities across Russia and, up to now, has supplied around 5,100 units to over 2,900 medical institutions. In 2007, GE´s revenues in Russia/CIS reached US$ 207 million, which is expected to more than double in 2012. According to **Richard di Benedetto**, President and CEO of GE Healthcare's Eastern & Africa Growth Markets (EAGM), which includes Russia, this success is based on strong regional partnerships that introduce GE´s technologies and solutions, as well as its focus on training local medical staff. 'Providing a superb service is one of the most important aspects, if you follow our aim to provide all parts of Russia with medical equipment,' explained **Slava Grischenko**, who heads GE Healthcare in Russia. 'Although our products cover all necessary hospital areas, users need very good training to benefit from the technology. To provide this service we need to establish strong partnerships in manpower within the company itself; this wasn't easy when we began here 20 years ago. Today, GE is very well prepared for that task.' For the near future the priority is to focus more on the private patients sector, he pointed out. 'The middle class is growing exceptionally fast; in just a few years that population will be higher than in China. Consequently, demand for healthcare beyond the basic system will rise. Additionally, compared to the West, Russian health levels are bad: Stroke rates are 20 times higher and the average life expectancy for men is about 56 years. Russia's healthcare market faces a backlog, which is a great opportunity for us.'

Richard di Benedetto believes the Russian situation fits neatly in GE Healthcare's global vision that the future is about *early health*. 'This means moving healthcare delivery to pre-symptomatic and earlier disease detection. The idea of investing today to avoid ever-increasing costs in the future is a powerful and inspiring opportunity. Given the social shift in Russia, we now have the perfect basis for this strategy because people are becoming aware of prevention.'

The biggest challenge: knowledge distribution

For **Joost Leeflang**, Philips CEO for Russia, Belarus, Ukraine & Central Asia, the reasons why investing in Russia has been so interesting in the past five years are clear: 'Russia is an unbelievably large country, with oil producing a very good income and, in general, it has a highly educated workforce and population. In addition, the government structure is stable and it aims to provide high-quality medicine across the country, as well as make it accessible to the entire population. So the government is investing huge sums in the national project for public health services. That's basically why money is not much of an issue for our customers. So, we don't face the same problems as in the UK or Germany, for example, which have huge private sectors and where every cent must be turned twice before spending. Of course, that's something developing in Russia as well, and we expect a strong increase of private hospitals over the next few years. But, as a provider of medical technology equipment, this trend is another opportunity.'

His colleague **Ilya Gipp**, who is responsible for Philip's CT and MR business added: 'In previous years we have seen the market become more developed and it's growing. But, for us, development of the infrastructure is also important. If we install a MR or CT system in a more rural hospital an infrastructure must be developed for it to be utilised and to allow a sensible patient throughput for the system. Considering this infrastructure, one big issue in Russia is education. Although the doctors' knowledge is incredible, the country has missed the step to the latest diagnostic technologies. Besides technical know-how of the systems, another point is that Russia has very specialised hospitals, based on clinical fields such as oncology or pulmonology. What's important to think about in the near future is that equipment must be used for various treatment areas, which is only possible if there is an infrastructure to support that. In a nutshell: The challenge is to ensure there is the right infrastructure to maximise the benefit of our technology. In geographical terms, getting the knowledge distributed is the biggest challenge.'

For Philips, equipment installation only begins collaboration with customers, training and education programmes are integral. The firm has piloted a CT training programme with Moscow State Medical University, for which certification courses were established.

CT and MR scanner sales are up

At Toshiba's Satellite Symposium on CT and MR, which was held at the congress, **Dr Jörg Blobel**, of Toshiba Medical Systems Corporation, Japan, and **Dr Lucia Kroft**, from the University Medical Centre, Leiden, the Netherlands, described first experiences with the Aquilon ONE 320-slice CT.

Audience interest was keen: Toshiba has already sold some of these scanners to customers around the globe and according to **Mikhail Smirnov**, Product Manger for Toshiba Medical Systems in Moscow, there is more than one potential customer thinking of a purchase in the near future. 'We've had good beginnings with Aquilon ONE in Russia. Along with features such as 4-D dynamic image acquisition, the option for low-dose scanning is of particular interest. In Russia dose regulations are far stricter than in Western Europe,' he explained. 'In the last years, Toshiba has increased its market share, especially in CT (we hope to number one, now). In previous years, a lot of ultrasound systems were installed because they were affordable. Now it is CTs turn, because its clinical value is much appreciated. With Russia's growing economy, the number of CT scanners and MR systems being installed is increasing tremendously.' However, he emphasised that entering the private hospital sector is a huge challenge: 'Private institutions and hospital networks are created by big Russian corporations, such as oil and gas firms, which are eager to equip them with the ultra-modern technology. Our next task is to participate successfully in that sector.'

TOMOTHERAPY SYSTEM TARGETS CANCER MORE PRECISELY

Robert Krempien and tomotherapy system

When tumours are situated in difficult locations, e.g. near the brain, lungs, prostate or abdomen, patients treated with conventional radiation equipment often suffer severe side effects, which include bleeding, chronic infections or organ function limitations. 'This is where tomotherapy opens up new ways of therapy and individually customised treatment,' explained **Professor Robert Krempien**, head of the Radiotherapy Department at the Helios Clinic in Berlin-Buch – among the first German hospitals to use tomotherapy against cancer. 'The new tomotherapy system allows us to treat patients for whom radiotherapy was previously impossible,' he said.

Worldwide, tomotherapy technology – a combination of linear accelerator and computed tomography (CT) – is considered the most advanced procedure in radiation therapy. Whilst a high resolution CT precisely locates a tumour, before each individual radiation dose, the linear accelerator, rotating around a patient, fires at a tumour from all sides. 'We protect sensitive organs by radiating the tumour from many different directions and avoiding these sensitive organs,' Prof. Krempien points out. In addition, the radiation dose that destroys a tumour can be individually customised to the tumour's density (the number of cancer cells).

The tomotherapy system also enables radiation of several tumours and metastases in one day. Adjusting the radiation dose intensity to the extent, strength and type of tumour presents even better protection of healthy tissue and neighbouring organs. Depending on the tumour, radiation lasts 5-20 minutes.

Additionally, although the location of organs and tumours change continuously, tomotherapy adapts to those changes during radiation. The equipment captures slices indicating the current size and location of a tumour with the integrated CT prior to each radiation, so the beams can precisely reach organs that move.

Successful therapy for uterine fibroids using MRgFUS

Magnetic Resonance Guided Focused Ultrasound (MRgFUS) therapy was introduced in June at the Amperklinikum in Dachau, near Munich, the third German site, after Berlin and Bochum for this new technology. **Dr Matthias Matzko**, Head of Radiology at the Dachau Clinic and **Professor Gerlinde Debus**, Head of its Gynaecology Department, presented the advantages of this non-invasive ablation procedure for uterine fibroids. **Bernd von Polheim**, President of GE Healthcare Germany and **Dr Dov Maor**, Vice President Clinical Marketing InSightec, representing the two companies involved in the technical development, were also at the press presentation.

Matthias Matzko (left) with Gerlinde Debus

Dov Maor

MRgFUS, explained Bernd von Polheim, is a particularly gentle procedure. 'Combining focused ultrasound therapy with MRI enables pinpoint accuracy. Real-time efficiency monitoring via thermosensitive sequences facilitates exact positioning with pinpoint accuracy along with permanent monitoring of the temperature distribution in the ultrasonic beam. The surrounding tissue is not damaged by heat and the fibroid is literally melted off through the release of energy. Moreover, the procedure replaces surgery, the patient is not exposed to radiation, there is no need for anaesthetic and the patient can be discharged the same day. In addition the therapy is painless.'

Fibroids are benign and therefore non-hazardous muscle tumours; however, depending on size and location they can cause substantial problems, or prevent pregnancy. Current studies show that patients undergoing MRgFUS have the best chances to have fibroids removed without impairing fertility. As many women want fibroids removed, because they hope to become pregnant, the Dachau Clinic has decided to offer MRgFUS as an alternative to minimally invasive surgery, such as fibroid embolisation.

'The procedure is really fascinating and has great potential,' said Dr Matzko. 'Fibroid therapy is only the beginning. We'd like to be to the fore with this application and further developments from the start. We also hope to treat other diseases, e.g. breast cancer, for which there are already some phase II therapy studies in other hospitals, which have shown malignant breast tumours up to 1.5cm can be melted off with focused ultrasound.'

Is fibroid size significant using MRgFUS?

'Unlike malignant breast tumours, in the uterus we can treat fibroids of any size, but this must be done over several sessions. Two factors are decisive for the success of non-invasive fibroid therapy: location and number of vessels in the fibroid.' He continued. 'If the growth is too saturated with vessels, the blood vessels act as cooling aggregates and heat around our focus point is absorbed. In this case, we can offer a patient hormone therapy prior to ultrasound therapy, to decrease the vessels in the fibroid. We combine the procedures because fibroids only decrease while hormone therapy is given, then they grow back.

'The second factor: We cannot ablate if the position of a fibroid means that the ultrasound beam goes through critical structures, such as the intestine. The danger of burning is too great, as temperatures of 60-80 degrees are reached after only a few seconds.

Therapy for a medium-size fibroid takes 2-3 hours. What of the strain on a patient who must not move in the MR machine? The patient has a light sedation and pain killers, making lying more comfortable. As long as she doesn't move much, nothing can happen. The MR image shows us with a delay of only three seconds what is happening in the body at any given time. Both systems are fine-tuned to each other so precisely that we can repeatedly redirect the US energy right on the fibroid. Moreover, during the planning stage we put *land markers* within the fibroid and exclude the critical structures prior to commencing treatment. However, it is not a problem to interrupt a therapy session, and then carry on in a second session if there is a lot of fibroid tissue, or if the patient requests it.

THE FUTURE OF MRgFUS
'We'll be better than surgery'

Dr Dov Maor is one of the founders of InSightec, a subsidiary of GE Healthcare. AsVice President for Clinical Marketing, he develops and presents the new MRgFUS and its clinical applications to European medical and academic communities.

Seeing that MRgFUS is already successful in the treatment of fibroids, we asked him what other use he foresees for this technology. 'Initially, we began our work with breast cancer research. As physicists and engineers, we assumed that the breast would be easy to treat because the tissue is soft and easily accessible. Then it transpired that this is not the case. Moreover, it was very difficult to carry out studies in this field, which would confirm that malignant tumours can be removed non-invasively. Surgical treatment procedures for breast cancer in its early stages have already been established. It's a long way tocertification of our procedure. However, we remain convinced that we will be able not only to avoid surgery but also be better than surgery. Whereas a surgeon cannot differentiate between tumour tissue and healthy tissue during an intervention, we can trace a tumour's outline very precisely using MRI during a procedure. This saves time and drawn-out follow-up treatment.

'Our next big project will be the therapeutic treatment of metastasising or primary liver cancer. Here we face completely new technological challenges – first, the liver moves position during breathing and second, it is largely obscured by the ribs. In most patients, the liver cancer is situated under the bone. That's why we are working on the development of a special applicator that can aim between the ribs. We hope to start clinical trials for this in about 18 months. We also hope to use the same method for the treatment of kidney tumours, or maybe even pancreatic tumours.

'We have already gathered promising results from our procedure for the palliative treatment of bone metastases, and received the European licence last year. Although bones are not made of soft tissue, which can be focused on as precisely as our other targets, we have been working on a strategy for years to replace radiation with MRgFUS. Radiation is only successful in around 70% of cancer patients in advanced stages of cancer and has strong side effects. We'd like to offer procedures for the palliative treatment of pain that put less strain on the body, particularly for patients with advanced stage cancer

'Additionally, we are currently researching the use of MRgFUS to treat brain problems. This not only focuses on oncological treatment, but also on central nervous system problems, e.g. epilepsy. Sometimes it suffices to destroy just the smallest pieces of brain tissue to rectify malfunctions. This is why we've developed equipment that allows us to focus on the brain through the intact skull. We are working in cooperation with the Neurosurgery and Neuroradiology Departments of the Brigham and Women's Hospital, Harvard University, and University Hospital Zurich, where-doctors have already identified centres in the brain responsible for certain functions. Last month they received clearance from the Ethics Commission to treat the first patients.

'The potential of MRI guided Focused Ultrasound is far from exhausted,' he concluded. 'However, the development processes for these systems are long and it's a long way from a technological concept to clinical application!'

Highlights of the Iranian Society of Radiology

In the 30 years since the overthrow of its last Shah (1979) Iranian radiologists have been welcome speakers and research presenters at the *European Congress of Radiology* (ECR). This year, the *Iranian Society of Radiology*, which represents over 2,000 radiologists, also introduced itself at the congress. There the latest issue of the Society's official radiology journal, the *Iranian Journal of Radiology* (also in English) was also distributed, along with previously published issues and the Society's journal on general medicine.

A R Sedaghat MD (pictured right), *Head of the Iranian Society of Radiology* (ISR), not only presented the Society's work but also congenially invited fellow radiologists to visit Iran.

Speaking with **Daniela Zimmermann** (left) of *European Hospital*, he explained that the Society is run in tandem with the North American Iranian Radiologists Society (NAIRS). Members who are internationally famous specialists include Dr Mahmood Mafi (head and neck); Dr Khalkhali (mammography); Dr Azarkia (central nervous system) and Dr Bonakdarpoor (MSK).

Over 1,000 radiologists and international experts attend the ISR annual congresses. In 2007, the Society also held its first conference on informatics in radiology. Speakers included Dr Huwang (very famous in PACS, Dr Sedaghat pointed out). He emphasised that there are no visa problems for scientific meetings. 'We have not closed our gates against other countries. We know a lot about them -- European, South American, as well as Canada and the USA, but I think the media in the West has closed a lot of windows, so people don't know a lot about us. Today, a lot of tourists visit as well as foreign doctors, scientists and engineers, to work here. **Today, I can call my country the land of peace**, because Afghanistan has war, Iraq has war, the countries of the former Soviet Union are not as economically stable, and some of the Gulf countries are very small and don't want to fight against Iran (KSA is the biggest). KSA is the centre of Islamic pilgrims (Mecca and Medina); at no time would they fight against an Islamic country. So everything is very peaceful.

The way to help a country to advance and grow is not to put money in people's pockets, he said, but by showing them the way to grow by investing the main budget into the economy of the country. 'We have a lot of very big electricity sources, which produce over 40,000 megawatts of electricity, which we export to neighbouring regions, such as Iraq. Also, before the revolution, we had only 11 medical colleges. Now we have 40. Imagine! We also have many highways, bridges, and airports in various cities. Money from gas and oil

in those 30 years was mostly spent in this way. So, though not all the people, but most of the people agree with the government. At the big annual gatherings in our cities celebration the revolution, in Tehran alone, there were more than one million people in the streets this year. The President talked with many, and the event was directly reported by 50 TV companies.' The arguments with the USA, he explained, relate to some $20 billion held in American banks, since 'the time of King Pahlavi, the Shah'.

Dr Sedaghat is no stranger to the ECR, or Austria. He has participated five times, and taken a week-long MRI course there. His main focus is on neuroradiology and muscular skeletal radiology. Additionally, his own radiology practice in Karaj, near Tehran, is the country's biggest private clinic (over 400 patients daily). There the day starts at 8 am, often ending at midnight. It provides offers nuclear medicine and echocardiography, MRI, digital mammography, CT scan, BMD, US, digital radiology, OPG etc, and employs eight radiologists, seven cardiologists, two nuclear medicine specialists and two general practitioners (both women), who compile patients' physical examination results and clinical history, helping the radiologists to write reports and make diagnoses.

Dr Sedaghat is in his second term as ISR president for four years. He explained that such elections are monitored by the Ministry of Health as well as the Ministry of Internal Affairs. 'We have over 85 medical scientific associations in Iran, of which the radiologists' society is among the five biggest societies in the country.' It not only focuses on radiology as a science, but also is responsible for fee setting for various treatments. 'Up to two years ago, the latter was the responsibility of the Ministry of Health; now this task is undertaken by medical associations and Iran's Medical Council,' he explained. (All medical graduates, including midwives, etc. must be registered with the Medical Council, which has about 170,000 members). 'So, part of our responsibility is to set the annual radiology fees, which depends on Iran's budget. We have to increase our fees proportionally to the increased budget rates. But our most important responsibilities are scientific. We hold many small, local conferences annually, around the country. We also have central and annual congresses, e.g. the Iranian Congress of Radiology (ICR) and, since 2007, the Congress for Informatics in Radiology. We also hold workshops, for example on CT, ultrasound and GI, chest etc. and take a very active part in interventional radiology, for embolisation in fibroid tumours in the uterus, aneurismal treatment, RF ablation of tumours and so on, and have published many articles on these in our journals. We work, for example, with gynaecologists: the radiologist embolises a tumour to minimise its size and decrease blood flow; the next day, the surgeon operates on it.' This area sees considerable cooperation with specialists beyond Iran, he added.. 'Tehran has ten 64 slice multi-detector CT scanners and more than 80 MRI machines; most are 1.5T machines -- Philips, GE, Siemens – and smaller machines, 0.3T, come from Japan.

In three decades, improvement and progression in Iranians lives has been very good, he said: 'I'm 49. I remember when the revolution began. At 18 years old, in my first year at Tehran University of Medical Sciences -- over 85% of our villages had no electricity, clean water, or good environment. Now, more than 95% of villages have electricity, clean water, schools, and very good environments. I invite you to come and see one of the most beautiful countries (IRAN).'

Paul M Button

Lean principles applied in path labs

Lean Laboratory **and** ***Lean Automation*** **are vital ingredients for the efficient and productive running of today's modern pathology laboratories. Automation serves as an essential endorsement to Lean, says Paul M Button, Senior Consultant at ValuMetrix, Ortho Clinical Diagnostics***

The underlying principle of Lean – to change the culture, create flow and eliminate waste in all its forms – is logical and readily understandable. It should be no surprise that Lean process improvement is the methodology of choice for the UK's National Health Service (NHS). Considering its outcomes, it is clear that if Lean were a piece of equipment, every laboratory manager would buy one. But Lean is not a piece of equipment; it is a fundamental change in working practices and the thinking behind them. It is an attitude of mind, which constantly seeks to challenge and refine every aspect of working life. It is proven to work, but it can also hurt.

Established practices are demolished in the search for culture change, flow creation and waste elimination. Batch working and specialisation go out; single piece flow and cross training enter. Laboratory workers who are desperate for more space, discover they can work better with significantly less. Managers can discover the factors that really impact on their workflow; biochemists walk less as Lean processes improve laboratory layout.

Johnson & Johnson's ValuMetrix Services group first made its Process Excellence methodologies, which include Lean, available to healthcare organisations in 1999. Its proven success is based on a training and mentoring model that recognises that culture change should not be imposed and that communications and commitment lie at the heart of any successful project. Unlike many consultancy or change management processes, ValuMetrix actually sets out to transfer intellectual capital and knowledge to the client organisation, so that future process improvement projects can be run from internal resources.

The majority of laboratories would benefit from automation, but this should not be incorporated until after lean implementation. Automating a non-Lean process will result in 'automating waste', which is very difficult to rectify. Achieving an efficient flow is usually impossible without some level of automation. The key is to achieve the right level. Too little means lost efficiency; too much means lost reliability and affordability.

ValuMetrix Services offer a combined Lean and Automation approach, whereby the initial phase ensures that the lab implements Lean principles followed by subsequent phases that implement automation at appropriate points in the operations. This is done by a Lean technique known as *Value Stream Mapping*, which moves the lab from the current state through a series of future states to achieve an ideal, world-class laboratory.

The results can be astronomical with substantial reductions in turn-around-times, substantial reductions in error, substantial cost savings and significant increases in productivity thereby allowing business growth without staff increase.

Further details can be obtained via your local Ortho Clinical Diagnostics office.

** A Johnson & Johnson Company*

Automation: a five-year experience

Work procedures have been radically simplified since, over one weekend five years ago, two specialist laboratories owned by Dr Helge Riegel GmbH Medical Supply Centre in Wiesbaden, Germany, installed two Olympus OLA2500 systems. 'The goal was to have one system in routine operation by the Monday. However, we were actually able to put both to work immediately!' exclaimed Dr Patrik Zickgraf, specialist at the Centre's clinical laboratory.

The clinical medicine laboratory serves around 1,100 registered doctors and processes about 5,000 samples a day – roughly five million analytical tests each year.

'The new laboratory electronic data processing system led to changes in our existing procedures, including the introduction of barcode labelling,' Dr Zickgraf told us. 'Our laboratory archives sample tubes for four weeks. Previously we would record the procedure and then divide the samples broadly by departments. Sub-division was performed manually with final distribution to different analytical workstations performed only after this stage. This distribution of samples in the specialist medical laboratory is very complex, resulting in the risk of sample mix up; confusion during

Dr Patrik Zickgraf

accepting and distribution; difficulties in traceability and a high consumption of materials during sub-division. Since we have many workstations, the flow of samples around the laboratory was not optimised. This all highlighted our need for automation.

'The OLA2500 was the only system that covered all our requirements – indeed it still does. It is straightforward and practical. Thanks to the automatic archiving we can now quickly locate samples, traceability is always ensured; we can document and trace the path of the sample from intake up to archiving. We have also reduced turnaround time (TAT) within the laboratory due to enhanced performance in distribution, processing and archiving.

'Finally,' he added, 'we have experienced a significant reduction in serum consumption, since automatic sub-division takes only the volume that is actually required. The OLA systems have given us more time to ensure the quality of our analytical work and also enabled us to redeploy staff from distribution/archiving work to other more productive tasks.'

The Centre's two machines are overseen by just one staff member. How has the equipment affected the lab teams? 'Staff acceptance is high because the reliability and robustness of the OLA2500 systems is so immense; even if a very infrequent fault does stop the system, it can generally be rectified immediately by our experienced staff,' Dr Zickgraf pointed out. 'When the need arises, the excellent training of the Olympus service engineers has brought the machines back into service the very same day. The OLA2500 is a successful system; it's made relaxed operation possible,' he added.

'We now have five years experience with laboratory automation, providing us with a very clear and transparent workflow. This transparency, and the fact that the laboratory staff can see for themselves the advantages that the system brings, generates acceptance. This also allows us to continually optimise our work procedures. Above all, it is essential that everyone understands the "path taken by the sample tube". Only then can they grasp the benefits delivered by automation.'

Machine vision technologies

A group of technologies that can replace human inspection are entering the clinical arena, writes Charles D Hawker PhD MBA FACB, Scientific Director of Automation and Special Projects at ARUP Laboratories and Associate Professor of Pathology (Adjunct), University of Utah School of Medicine in Salt Lake City

Charles D Hawker

In today's clinical laboratory the technical staff performs quality inspections that are separate and distinct from normal laboratory testing quality control. These inspections include checking if the specimen type is correct for the ordered test or at the correct temperature, verifying that it is from the correct patient by comparing the doctor's office label to the laboratory's label, or inspecting specimens for clots, fibrin, haemolysis, icterus, or lipaemia. Systems that have been used in industrial settings for the past two decades are now starting to make their way into clinical laboratory automation. Generally known as *machine vision*, this is a group of technologies that can replace human inspection.

Practically every product you purchase today is assembled and packaged with greater efficiency and quality due to machine vision technology. In pharmaceutical plants, sophisticated optical systems inspect bottles on conveyors to ensure labels are straight and cap seals uniform and tight. They read lot numbers and expiration dates, comparing them to what is expected, and assure there are no red pills in bottles of white pills. In breweries, wineries, and other bottling plants, machines check fill levels, rejecting under-filled cans or bottles on conveyors at speeds 50-100 times faster than today's fastest laboratory automation conveyors.

Depending on the particular plant, fill levels are checked by weight, with gamma rays or X-rays, or other systems. Other systems make sure there are no glass shards in jars of marmalade. The list is endless. These virtually 100% accurate, high speed inspections are simply not possible with human inspectors.

Laboratory automation manufacturers are beginning to employ machine vision to improve quality and replace human inspection. Some optical systems inspect tubes for cap colour, height, and diameter. Some inspect through the open side of a tube (if it is not completely covered with a label) and determine presence and degree of haemolysis, lipaemia, or icterus. At least two systems can 'peer' through the labels on a closed tube, determine the height of packed red cells, and calculate the volume of serum or plasma above the cells. This information can be used to verify correctness of the specimen for an ordered test, prompt a report comment, or set aside the tube for manual intervention. The latter step is more valuable than it sounds. If 95% of tubes pass an automated inspection, then the technologist only has to handle 5% instead of 100% to determine the next step.

Two decades after automobile assembly plants and other manufacturers began to use automation robotics, Japanese laboratorians began to apply automation concepts, but it was another decade before early Japanese automation ideas for clinical laboratories appeared in systems from laboratory equipment vendors. Similarly, machine vision systems have now been in place in industrial settings for at least two decades, although much faster and more sophisticated today than in the early years. Nevertheless, it seems interesting to this observer that, once again, the clinical laboratory is roughly 20 years behind in applying industrial technologies that could have real value in the laboratory setting.

David Loshak outlines the impact of rapidly increasing mechanisation on the work of hospital lab technicians, researchers and industry

21st Century lab automation

Laboratory automation of the 21st century demonstrates, every second, that in the 30 years since labs took their first tentative steps towards automation it has advanced by orders of magnitude – and moved far beyond the ambitions of its progenitors. Driven by the imperatives of greater efficiency, more precision and round-the-clock operation, ever more sophisticated forms of automation are now widely applied in discovering new medicines, enhancing productivity, reducing error, accelerating research, standardising processes, improving safety.

Innovations in robotics and information technology have transformed research. In the search for new medicines, automated laboratories use robots to manipulate, store and retrieve titre plates; in cell culturing and pharmaceutical research, they undertake specialised forms of material handling with the loading and unloading of test tubes in autoclaves as well as liquid-filled vials, flasks and bottles. Robots in hospitals fill prescriptions, improve the security of pharmaceuticals and reduce mistakes in preparing prescriptions.

Automation also helps to meet stringent demands for rapid patient testing without compromising safety – the laboratory staff has minimal contact with specimens. Tests that require 17 steps in conventional laboratories take nine with system-based automation, five with discrete automation and three with integrated automation. Laboratory directors can justifiably claim that at least three quarters of clinical decisions hinge on good lab information. 'And we have eliminated the unpredictability of our lab service,' adds Dr Kenneth Blick, director of clinical oncology at Oklahoma University Medical Centre. 'We have gone from 18% outliers on our turnaround time targets to less than 5%.'

An iconic instance of modern laboratory automation is provided by liquid handling, a key to drug discovery because most experiment entails definite volumes of reagents. Handling low volumes, calibration, integration and liquid detection are key features of automated liquid handling systems. Hand-held automation devices, such as single and multi-channel pipettes, have hugely affected lab productivity because they permit dispensing into microtitre plates, or microplates, the standard tool in analytical research and clinical diagnostic testing, best known for its use in the enzyme-linked immunosorbent assay (ELISA), the basis of most modern medical diagnostic testing.

Efficient automated liquid handling systems have led directly to miniaturisation of assays. Today's drug discovery is based on HTS – high-throughput screening – which uses robotics, data processing, liquid handling devices and sensitive detectors so that researchers can conduct millions of biochemical, genetic and pharmacological tests that rapidly identify active compounds, antibodies or genes that modulate particular biomolecular pathways.

'The ability to do half a million test points in only one day has opened up new strategies in exploring drugs,' says Kevin Hrusovsky, CEO of the US corporation Caliper Life Sciences. He notes that because plate formats can lower the volumes of samples needed to sub-microlitre amounts, the cost of reagents is much less. Although moving and measuring small quantities of fluids presents challenges, automated liquid handling does allow precise measurement of amounts as little as one nanolitre (a hundred millionth of a litre). 'That not only permits scientists to use tiny quantities but means that fewer repeat tests are needed because the equipment confirms when the right quantities are dispensed.'

The results of such experiments provide starting points for drug design and for understanding the interaction or role of particular biochemical processes. Following genome sequencing and the emergence of genomics, life scientists have developed proteomics, the new science of the complex structures of living cells and how they function. This has disclosed huge numbers of new targets which have potential as drugs, far too many for researchers to study with old manual methods. Thus, HTS has become a key element in modern drug discovery. No wonder the laboratory automation equipment market in Europe alone is now worth some €200 million.

Effective HTS relies on efficient information management systems to deal with the data it generates. 'Typical large pharmas today are generating 20 terabytes of data daily and that will soon rise to 100 terabytes,' according to John Helfrich of Massachusetts-based NuGenesis Technologies Corporation. A good data system, he explains, handles the capturing, loading, sorting, querying and viewing of information from both biological and chemical perspectives and also needs the flexibility to scale up with increasing HTS capacities. 'Our scientific data management system is an application-independent, web-enabled platform for collecting, storing and managing scientific information. The system captures the essence of reports,' he adds. 'We put a print driver on the instruments and capture the contents of their information. The value of that is that it is information source independent. A scientist does not need mass spectrometry or chromatographic software to capture the data from those instruments. Any scientist at the lab bench who has security approval can look at those reports, extract what he or she needs from them and send them on.' The system thus fosters high levels of teamwork and drives up the pace of decision-making in many areas of drug R&D.

Although there are laboratories that still need to work out how best to use automation most efficiently, such problems are minor compared to the potential of lab automation, declares Tony Beugelsdijk, chairman of America's Association of Laboratory Automation. 'Integrated library management is coming along – we will probably see formats that enable libraries to become part of an HTS system, miniaturised beyond what we see today.' The results of screening enabled by lab automation would become available to more scientists than in the past. Manual scoring of crystallisation experiment images would be replaced by computational scoring.

Indeed, the automation of X-ray crystallography provides a paradigm of how laboratory automation evolves.

First come efforts to automate manual procedures. While these often work well, they do not always translate well enough, so processes are re-engineered to take better advantage of automation. Then, other snags and challenges emerge and are addressed.

But the bottom line, as Americans, who lead the world in laboratory automation are fond of saying, is that lab automation increasingly gives scientists authentic freedom. 'Scientists do science best; instrument companies do instruments,' says Joan Stevens, of Gilson Inc. of Wisconsin, US, makers of automation instrumentation and chromatography systems. 'Together, we make a very nice package.'

Companion diagnostics and more

Siemens and LabCorp to co-develop clinical tests

Possibilities to co-develop new clinical diagnostic tests for companion diagnostics, metabolic syndrome, oncology and diabetes, are being explored by Siemens Healthcare and Laboratory Corporation of America Holdings (LabCorp).

Companion diagnostics are tests designed to identify the suitability between patients and a particular drug therapy. The tests can be used in personalised medicine to improve the safety and efficacy of therapeutic drugs and in some cases, may help determine optimal dosing for individual patients.

Metabolic syndrome is becoming more common and is characterised by a person having multiple risk factors that may include high blood pressure, heart disease, obesity and diabetes, among others. It is estimated that more than 50 million people are affected by this syndrome in the USA alone.

LabCorp is a reference laboratory with over 220,000 clients in the US. The new strategic cooperation, said Dave Hickey, Senior Vice President Strategic Planning and Business Development, Siemens Healthcare Diagnostics, 'establishes a framework that gives both companies the opportunity to offer new diagnostic tests to laboratories, physicians and their patients more quickly and effectively than either could do alone.'

Myla P Lai-Goldman MD, executive vice president, chief scientific officer and medical director for LabCorp, added that the firm is '… excited about this strategic collaboration and its impact on our companion diagnostics efforts. Alliances, such as this between developers and providers of new tests, are critical in translating emerging biomarkers from research into clinical practice.'

Siemens – special events at Booth #507

AACC/ASCLS Clinical Lab Expo

Washington DC
29-30 July 2008

Siemens Healthcare Diagnostics will showcase the combined strengths of Diagnostics Products Corporation (DPC), Bayer HealthCare Diagnostics and Dade Behring.

As a leading global clinical diagnostic company, Siemens will demonstrate its wide portfolio of workflow solutions and customer-centred services for today's laboratories. These products include automation, chemistry, immuno-assay, haemostasis, haematology, microbiology, molecular, blood gas, urinalysis, diabetes, IT and customer care.

A variety of 15-minute presentations will be conducted in the Siemens booth, including:

- Monitoring Metastatic Breast Cancer: The Serum HER-2/neu Test
- Paediatric Allergy and Asthma
- Sepsis: 'Can Emerging Markers Improve Survival Rates?'
- MRSA and Beyond
- Liver Disease: Evolving Perspectives on Diagnosis and Management
- Point of Care Testing

30 July: Educational workshops

- Trends in Immunosuppressive Drug Use and Cost Effective Monitoring of Immunosuppressive Drugs at the Local Community Level
- High Sensitivity Troponin: Delivering Value for Chest Pain Management
- Trends in Infectious Disease Testing: A Conversion of Technologies to Meet the Emerging Threat
- The A, B, C's of In Vitro Allergy Testing
- Non-Invasive Markers of Liver Fibrosis – Why are they Needed?

In addition, Siemens will sponsor five AACC awards for excellence and over 37 scientific posters throughout the week.
Full details: www.siemens.com/AACC2008.

Why European laboratorians benefit from the AACC Annual Meeting

AACC
27-31 July 2008
Washington DC

By Mario Plebani MD (left), Professor of Clinical Biochemistry and Clinical Molecular Biology at the University of Padova, Italy, and winner of the AACC's Outstanding Clinical Laboratory Contributions to Improving Patient Safety Award, to be presented at American Association for Clinical Chemistry's 2008 Annual Meeting to be in Washington, DC (27-31 July)

"When asked to write a brief note on why I found it 'important to attend the AACC Annual Meeting, particularly from the European perspective', my mind returned to the first time I attended an AACC meeting. It was in New York, and provided my first opportunity to visit the USA. I was very excited at the idea of seeing the 'New World' and the 'Big Apple' and, of course, attending a scientific event organised by the most influential scientific society for clinical chemistry worldwide.

My expectations were amply met, and I greatly admired the outstanding Congress organisation, despite the incredible number of delegates. I was also impressed by the high standard of the scientific sessions and quality of presentations, many of which were delivered by 'icons' of modern medicine, such as J D Watson (1962 Nobel Prize in Physiology or Medicine for discoveries on the molecular structure of nucleic acids). Another aspect that I appreciated was the time dedicated to discussing all the presentations and the quality of these discussions. At the Poster session, I was particularly impressed by the high level of scientific discussion and the exchange of ideas that took place in front of each poster. This was, and still is, quite unusual in Italy and other European countries. However, I confess that I was really surprised to learn that seminars and scientific presentations would take place at 7.00 a.m., and was shocked to see these being made while people were having breakfast!

Throughout the years my reasons for attending the AACC Annual Meeting have changed, but some fundamental points remain. First, the plenary sessions provide a unique opportunity to look at the future not only of the discipline but, more importantly, of healthcare systems and the global environment in which laboratory services are delivered. The Symposia and Interactive workshops (although I prefer to remember the 'Edu-Tracks') have always been interesting, but have also contributed to changing the delivery of laboratory services. For example, the story of cardiac markers is a paradigm of the change and improvements that laboratory medicine has brought in the management of acute coronary syndrome.

The Exposition, on the other hand, is always interesting, with its display of equipment, diagnostic systems and laboratory devices, but its importance to an 'old' laboratory professional like me has, in a way, decreased over time because there are always other opportunities to see and 'touch' innovative systems. However, it remains an important attraction and meeting point, particularly for people attending this event for the first time. From my perspective, however, the importance of attend the AACC Congress has increased, since it provides a unique opportunity to meet many scientists and colleagues from different countries. In an era of globalisation, the 'de visu' exchange of ideas and experiences is becoming increasingly important, and this meeting is, and will remain, a unique opportunity, as demonstrated by the number of meetings of the Scientific Boards of journals and organisations that occur year by year, before, during and after the AACC Meeting itself.

Let me conclude with another personal anecdote. The first time I was invited to deliver a lecture in a session of this meeting, I had mixed feelings, because there was no way of escaping criticism – or low scores in questionnaires completed by participants! Although I felt honoured to be invited, I was not that open to criticism. 'The world is flat'– of this we are sure and there is no doubt about this – but there are still many good reasons for European laboratorians, including Italians like me, to continue to attend the AACC Annual Meeting!"

Having attended this event for nearly 20 years, Mike Hallworth (below), Consultant Clinical Scientist at the Royal Shrewsbury Hospital, UK, and President of the European Federation of Clinical Chemistry and Laboratory Medicine, agrees with Dr. Plebani: 'The AACC Meeting is unquestionably the major annual event in global laboratory medicine, delivering unrivalled networking opportunities, a world-class exhibition with everything that is significant in laboratory diagnostics, and a scientific programme with something for everyone and some truly excellent plenary lectures. After almost 60 years, it continues to develop its pre-eminent position in our discipline and provides laboratory medicine professionals with a consistently rewarding experience.'
2008 AACC details:
http://www.aacc.org/events/ann_meet/Pages/default.aspx

New sequencing tech for the 1000 Genomes Project

Three companies that have pioneered development of new sequencing technologies have joined the *1000 Genomes Project* – the international research consortium, announced in January, aiming to build the most detailed map of human genome that will provide a view of biomedically relevant DNA variations at a resolution unmatched by current resources.

The new participants: 454 Life Sciences (Roche, Branford, USA); Applied Biosystems (Applera Corporation, Foster City, USA) and Illumina Inc., of San Diego, USA.

Organisations already committed to major support: Beijing Genomics Institute, Shenzhen, China; the Wellcome Trust Sanger Institute, Hinxton, Cambridge, UK, and the National Human Genome Research Institute (NHGRI), part of the National Institutes of Health.

The NHGRI-supported work is being done by the institute's Large-Scale Sequencing Network, which includes the Human Genome Sequencing Centre at Baylor College of Medicine, Houston; the Broad Institute of MIT and Harvard, Cambridge, Mass., and the Washington University Genome Sequencing Centre at Washington University School of Medicine, St. Louis.

Previous studies, such as the International HapMap project, have identified genetic variants that are present at a frequency of 5% or greater. The catalogue produced by the 1000 Genomes Project will map many more details of the human genome and how it varies between individuals, identifying genetic variants that are present at a frequency of 1% across most of the genome and down to 0.5% or lower within genes. The 1000 Genomes Project's high-resolution catalogue will serve to accelerate many future research studies of people with specific illnesses.

The full-scale project will involve sequencing the genomes of at least 1,000 people, drawn from several populations globally, though that number could become 1,500 or more. The project will use samples from donors who have given informed consent for their DNA to be analyzed and placed in public databases. Most of these samples have already been collected, and any additional samples will come from specific populations. The data will contain no medical or personal identifying information about the donors.

**** 454 Life Sciences develops and commercialises the innovative Genome Sequence System for ultra-high-throughput DNA sequencing. Specific applications include de novo sequencing and re-sequencing of genomes, metagenomics, RNA analysis, and targeted sequencing of DNA regions of interest. 'The hallmarks of 454 Sequencing are its simple, unbiased sample preparation and long, highly accurate sequence reads, including paired reads,' the firm reports. This has enabled peer-reviewed studies in diverse research fields, e.g. cancer and infectious diseases and drug discovery etc.***

**** Source: www.roche-applied-science.com/sis/sequencing***

Details: http://www.454.com

30-minute Chlamydia test

An estimated 92 million *Chlamydia trachomatis* infections occur annually. Often, this disease presents no clear symptoms.

Inverness Medical reports that its Clearview Chlamydia MF test can provide a diagnosis in as little as 30 minutes, so that, during a single visit, a patient can also begin treatment.

The test detects the antigen using either female endocervical swabs or male urine samples, so is suitable for male or female patients. 'The easy-to-use lateral flow test has in-built procedural controls which reliably confirm the test has worked correctly. It uses a unique heating step in the testing process which gives Clearview Chlamydia MF its high sensitivity, meaning clinicians can be confident in the test results,' Inverness reports.

Acinetobacter baumannii genome sequence determined

Italy – The genome sequence of Acinetobacter baumannii has been determined by scientists at the Istituto di Tecnologie Biomediche, the Dipartimento di Malattie Infettive at the Istituto Superiore della Sanità and the Dipartimento di Biologia at Roma Tre University. In Italy alone this antibiotic resistant pathogen causes 4,500 to 7,000 deaths annually.

Genome sequencing is the foundation for rapid diagnosis and targeted therapy approaches, said project manager Gianluca de Bellis. 'Sequencing was made possible by a further improved technique which can generate more than 100 million DNA bases within a few hours. This translates into a significant time and cost advantage over the previous methods.' Using this sequencing method the Italian scientists hope to identify new substances for the development of new antibiotics. The phenomenon of antibiotic resistance will be examined from a basic and applied research angle.

This genetic sequence is available free, via www.itb.cnr.it/genome-project.

KNOW YOUR ENEMY

High throughput sequencing technology enables analysis of protective intestinal flora that could combat *Clostridium difficile*

Christoph Högenauer

Along with MRSA and ESBL bacteria, Clostridium difficile is causing a growing problem. Epidemics of a new C. difficile strain have already occurred in hospitals in North America, England and the Benelux countries. Although in its inactive state it is not harmful to humans, C. difficile can abruptly proliferate in the gut if the protective flora is disturbed due to antibiotic therapy; and then the toxins released by C. difficile can cause severe infections that can only be treated with special antibiotics. In some cases, this can lead to lasting damage to the gut flora, with subsequent recurrences of the infection.

One approach to prophylaxis and therapy would be treatment with the same intestinal bacteria that protect against C. difficile proliferations and release of toxins.

In Austria, a study is underway to identify the protective bacteria and consistency of intestinal flora, using high throughput sequencing technology. At the Graz Medical University, *Meike Lerner* of *European Hospital* asked **Professor Christoph Högenauer MD**, in the Clinical Department for Gastroenterology and Hepatology, University Clinic for Internal Medicine, why this identification has not been made before and what his expectations are for this year-long pilot study.

'The normal gut flora is made up of around 10^4 bacteria and around 500 different types of bacteria in each individual,' the professor explained. 'With the technology available up till now, identification of the different types and their functions has only been possible in a very superficial way, because most types cannot be cultured or are only cultured with difficulty. This is why the role of the intestinal flora has so far been relatively unexplored. The Medical University Graz has recently installed the Genome Sequencer FLX System, which has high throughput as well as improved reading length and sequencing accuracy. We are now able to identify the intestinal bacteria via their DNA and map their consistency and functionality.'

Currently, patients are being evaluated and the researchers are examining the bacteria with the help of stool samples. 'The samples are then sequenced and compared with a database. The objective is to find out which groups of bacteria in the gut have a protective effect against infection. If we achieve this we can then separate and culture just those bacteria and use them for therapeutic purposes. So far some patients with frequent, therapy-refractory relapses had to be treated with enemas that supplied the intestinal flora with the appropriate bacteria for the elimination of C. difficile. This is not particularly comfortable for patients. The development of new approaches to therapy and prophylaxis is becoming more pressing as C. difficile infections are an increasing problem for hospitals. The reason is the longevity of the spores, which often settle on the surfaces of bed frames, bedside tables and toilets and which cannot be eradicated with normal disinfection agents such as alcohol.

'For the first time, this new technology offers us the prerequisites for mapping the intestinal flora,' Prof. Högenauer pointed out. 'Apart from C. difficile infection, we also expect to be able to put a name against some other "white spaces" on the map. The study is only the beginning of the research that we will carry out over the next few years.'

AWARDS FOR TB STUDY ORGANISATION

Dr Timo Ulrichs, head of the TB section of the Koch-Metchnikov-Forum, reports on the fight against infectious diseases and a strengthening of international ties

From left: Vice-Chairman of the Koch-Metschnikow-Forum Heinz Zeichhardt with Chairman Helmut Hahn and Timo Ulrichs

In 2005, former German Chancellor Schröder and Russian President Putin agreed on a strategic partnership to give infectious disease control the highest priority. To fulfil this agreement, the 5th Petersburg Dialogue (co-ordinators: Prof. Bergmann, German Academic Exchange Council; Prof. Hahn, Charité and Berlin Medical Association; Prof. Verbitskaya and Prof Trojan, St Petersburg State University) decided to transfer the execution of this agreement to a German/Russian working party of infection specialists – named the Koch-Metchnikov-Forum, after bacteriologist Robert Koch, who described *Mycobacterium tuberculosis* as the etiologic agent of tuberculosis (TB), and immunologist Ilya Metchnikov, whose work on macrophages forms the basis of the understanding of infection immunology. In October 2006, the Koch-Metchnikov-Forum was officially founded and mandated on the occasion of the 6th Petersburg Dialogue in Dresden, attended by President Vladimir Putin and Chancellor Angela Merkel.

The Koch-Metchnikov-Forum, a non-governmental organisation (NGO), is politically mandated and welcomed and there is close and valued interaction with German and Russian governments within the framework of the Petersburg Dialogue.

Koch-Metchnikov-Forum specific aims

- Exchange of humans, ideas and resources between both countries
- Furthering of scientific, clinical and social projects in the fight against infectious diseases
- Organisation of TB-related symposia, congresses, workshops
- Furthering of young scientists and physicians from both countries
- Furthering continuous medical education of physicians and healthcare workers in both countries
- Advice for the governments.

Already existing TB projects were integrated into the Forum: Since 2001, collaborative projects in basic science (mainly infection immunology in human TB) are ongoing, with partners in Moscow (Central TB Research Institute), St. Petersburg (Institute for Phthisiopulmonology), and Tomsk (Siberian State Medical University).

With basic science TB immunology projects being extended by joint projects in microbiological diagnostics and TB epidemiology, the number of scientific partners enlarged. Already, studies in TB control have resulted in several scientific publications in high-ranked peer-reviewed journals. The TB section is now accompanied by sections specialised in HIV/AIDS, hepatitis, transfusion medicine, e-health and hospital management. In addition, a central secretariat co-ordinates intersectional projects and is the contact address for German/Russian partners and institutions. Besides partners in the Russian Federation, institutions in Moldova, Uzbekistan and Kazachstan are now Forum members.

The TB projects, and subsequently the foundation and organisation of the Forum, are funded by the International Office of the German Federal Ministry of Education and Research (IB-BMBF) and the German Academic Exchange Council (DAAD). In January 2006, there was also project-oriented funding by private companies (mainly medical and diagnostics).

In 2005, the Robert Bosch Foundation awarded it prize for civil engagement to the Russian TB control studies. During the TB Symposium held on World Tuberculosis Day 2008, the Koch-Metchnikov-Forum received the innovation award 'Selected Landmark 2008 in Germany – Land of Ideas'.

Morbid obesity in Europe

By **Martin Fried MD PhD**, Professor of Surgery at the Clinical Centre for Minimally Invasive and Bariatric Surgery, ISCARE-Lighthouse, 1st Faculty of Medicine, Charles University, Prague, Czech Republic

Prevalence of adult obesity has increased three-fold since 1990. The prevalence of childhood obesity has increased ten times since 1970. In Europe, almost 50% of adults and over 20% of children are overweight. A third of these are obese. Conservative estimates show that, in Europe, about 100 million adults and 10 million children are obese. Obesity is accountable for c. one million deaths annually.

Costs – Over 6% of direct EU healthcare expenditures are attributable to obesity, and obesity related co-morbidities (i.e., type 2 Diabetes Mellitus). Indirect costs, e.g. loss of productivity, obesity related unemployment, etc., are twice as high as direct healthcare expenditures. All this underlines the seriousness of obesity as a rapidly spreading epidemic disease.

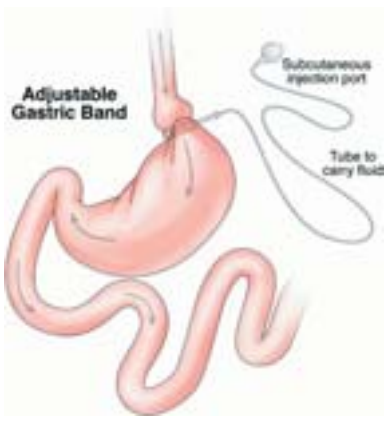


Fig. 1 Adjustable gastric banding: restricting stomach volume (food accommodation capacity) by creating a small upper gastric pouch

Prevention Measures – These are important, e.g. promoting healthy lifestyle. Healthy food should be promoted and available. So should physical exercise, with more opportunities created for this, e.g. safer roads for cycling/walking.

Already obese adults – Ideally, obesity management should be concentrated in specialized centres, thus a multi-disciplinary, scientific medical approach to obesity treatment is one of the key movements in long-term treatment success.

Bariatric surgery – From the long-term treatment perspective, the severely obese (Body Mass Index > 35), can be effectively treated through bariatric surgery only. Bariatric surgery (either limiting food intake by decreasing stomach volume – e.g. adjustable gastric banding, Fig 1, 2, or limiting the absorption of nutrients and energy by bypassing certain length of small bowel from digestion of food – such as 'gastric bypass' or 'biliopancreatic diversion' Fig 3, 4) carries low risks and is significantly beneficial. It not only decreases weight, but also substantially improves and/or resolves serious metabolic disorders and obesity related co-morbidities (such as type 2 Diabetes Mellitus, hypertension, and others) in over 80% of obese patients with these comorbidities. It also prevents new onset of metabolic diseases.

In 2007, an outstanding breakthrough occurred. After almost two years' work, Interdisciplinary European Guidelines for Surgery of Obesity were finalised and published. For the first time in Europe a Bariatric Scientific Collaborative Group (BSCG) panel was appointed through the joint effort of major European Scientific Societies that are active in obesity management.

Fig. 2 Adjustable gastric band device, placed around the upper stomach, creating an 'hour glass' shape, with small upper gastric pouch connected with the rest of the stomach by a narrow channel

Published Guidelines encourage effective collaboration in obesity management not only across medical specialties, but also help to standardise management of severely obese patients in Europe. Recent remarkable progress is reported in NOTES (Natural Orifice Transluminal Endoscopic Surgery). NOTES stands on the borderline of endoscopy and surgery. Although still experimental, it may open new opportunities in the near future in obesity treatment, indeed in a minimally invasive way – NOTES accesses the body through the natural orifices thus providing 'scarless' surgical treatment. In the future this approach may enable some surgeries to be performed on out-patients in a few hours.

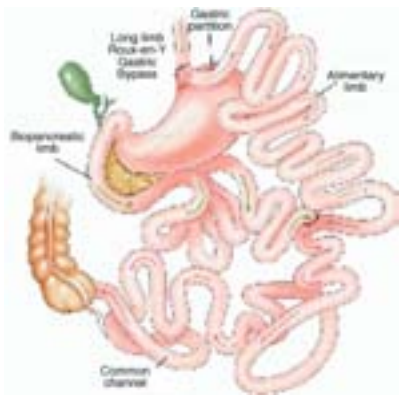


Fig. 3 Gastric bypass operation, affecting both stomach capacity and digestion by diverting food from one part of the small bowel, which decreases food digestion, restricting capability to absorb energy

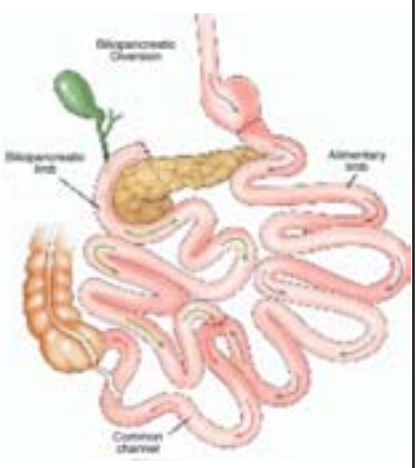


Fig. 4 Biliopancreatic diversion, substantially decreases food digestion by bypassing (diverting) food from contact with part of small bowel, thus decreasing food energy absorption

NEW

The Worldwide Mesh Technology Centre

Cornelia Groehl (left) meeting with Daniela Zimmermann of European Hospital

This was it, 15th May, the big day: Johnson & Johnson's Worldwide Mesh Technology Centre was officially opening in Norderstedt near Hamburg, Germany. 'This is a milestone in our company history,' said **Gary J Pruden**, CEO of the Johnson & Johnson subsidiary Ethicon Products, his presence at the Norderstedt ceremony signifying the importance of this centre to the company.

For **Cornelia Groehl**, president of Ethicon Deutschland, this inauguration was the successful conclusion of laborious negotiations. With enormous commitment she had convinced her US employers that Germany was the only logical choice in which to base an international mesh technology centre. The company-owned European Surgical Institute, with excellent contacts with top surgeons throughout Europe, ultimately may have helped to tip the scales in favour of Norderstedt.

The team of the new Mesh Technology Centre will focus on research, development and production of meshes for surgery and gynaecology. The meshes allow minimally invasive interventions – a reason for Cornelia Groehl to consider the 1.7 million building project as 'an investment in the future' since the implant market records double-digit growth.

The new lightweight meshes are high-tech artworks, barely resembling their unwieldy predecessors. The new generation of material integrates with weakened tissue, at the same time providing support without harming surrounding tissue or causing excessive pain. This technology, which offers immense benefits to the patients, is used about four million times a year globally to repair hernias and other soft tissue defects as well as in plastic and pelvic floor surgery.

Cornelia Groehl is proud that, with the Mesh Centre, the company clearly signals its commitment to the German site: 'It is a recognition for our work and the innovative potential of our staff. It's also a logical decision, because Germany has been the leader in mesh technology for years – and this is no coincidence: Physicians are innovative, and particularly German physicians.' The fact that Norderstedt also offers certain synergies was clearly also significant. On site are Europe's most important production facilities for suture material, needles and absorbable implants from biomaterials, including the firm's European Surgical Institute (ESI) training centre, where every year over 10,000 physicians from all over Europe learn to use the instruments and MIS techniques. Along with training, they also provide feedback to the trainers, a crucial input to Johnson & Johnson's R&D.

It's no surprise that the surgeons themselves gave the decisive drive for the development of the new meshes. In 1993, **Professor Volker Schumpelick**, head of surgery at University Hospital Aachen, and colleagues discussed the idea of flexible, lightweight and wide-meshed devices that could meet the body's needs. They were certain that such a mesh would reduce infections and rejections and help patients to maintain full mobility. 'People bend and bow and move, they exercise, they gain weight and women bear children. Our connective tissues offer enormous stability combined with impressive flexibility – and the materials that replace and support weakened tissues should ideally do the same,' said Dr Schumpelick. Ethicon Products was then the only manufacturer prepared to risk investment in the development of such materials. 'That was courageous,' Prof Schumpelick observed. 'As it went against the trend. I think it's exactly this kind of courage that is the hallmark of a truly innovative company.' Today, flexible high-tech meshes are an international standard.

Top right: Professor Volker Schumpelick

Right: Gary J Pruden, CEO of Johnson & Johnson subsidiary Ethicon Products

Left: Finesse in modern meshes

In the future, the machines at the Worldwide Mesh Technology Centre will annually create over half a million surgical meshes, such as Vypro and Ultrapro. Different designs and combinations of materials will be offered for a wide range of functions: some implants meant to stay in tissue forever, others to dissolve in a set period.

The next generation of meshes envisaged are bioactive meshes that offer more than mere mechanical support for tissue. Cornelia Groehl and Dr Schumpelick have no doubts: the application potential of mesh technology in healthcare is far from exhausted – that is why they know the research to be conducted at the Worldwide Mesh Technology Centre will prove immensely important.

20 years of MIS

By **Professor Ferdinand Köckerling MD**, President of the DGVC, Head of the Clinic for Surgery, Visceral and Vascular Surgery, at the Centre for Minimal Invasive Surgery, Vivantes Hospital Spandau, Berlin

Scientific studies confirm that after 20 years of minimally invasive surgery (MIS) most of these operations have advantages over the equivalent, conventional surgical procedures. For example, minimally invasive removal of the gall bladder, the method chosen in Germany for about 85% of cases, results in less pain and a shorter hospital stay by comparison, even if the conventional removal is performed with only a very small incision. Endoscopic appendix removal compared to the conventional surgical procedure also involves less pain, shorter hospital stay and earlier return to full activity. Due to the lower rate of complications even in complicated cases, this also means lower treatment costs for endoscopic appendix removal. Despite this, minimally invasive appendix removal is currently only performed in around 50% of cases, because an experienced surgical team is not always available, particularly at night and during weekends.

Meta-analysis shows that endoscopic hernia operations carry lower risks of wound infection, fewer haematomas and injuries to nerves and earlier return to normal activity for the patient. The same rates of success also apply to bilateral hernia operations, which occur in up to 30% of cases. Despite these advantages only around 35% of hernia operations are carried out in Germany with MIS – again due to the lack of highly trained surgeons in MIS.

The majority of laparoscopic fundoplication procedures for reflux are now carried out minimally invasively. 10 years after minimally invasive fundoplication, the quality of life for patients is significantly better than that achieved with medicinal therapy. The use of MIS for tumour removal must still be viewed with criticism, although it has now been proven that, for patients with cancer of the large intestine, endoscopic surgery can achieve comparatively good long term results if the right patients are chosen for the procedure.

The key problem for the further MIS development is the long learning curve, i.e. surgeons need to have performed a certain endoscopic operation very frequently until they have mastered it in all situations. To meet this requirement the Surgical Working Group for Minimally Invasive Surgery (CAMIC) of the German Society for Visceral Surgery (DGVC) has instigated certification procedures for surgeons and reference centres. These certificates are only awarded if a surgeon or a hospital meets certain conditions (case numbers, equipment, training) and passes an audit by experts. As the responsible scientific associations, the DGVC and the CAMIC hope for quality assurance and quality improvements in training and therapy for the benefit of patients.

For the world's children – from Russia with love

For 20 years a unique paediatrics team from Russia has provided a significantly welcome presence at natural and man-made disasters worldwide. During our interview with **Professor Leonid Roshal MD**, Executive Director and Chief of the Scientific and Research Institute for Children's Emergency Surgery and Traumatology, in Moscow, he recollected areas in which the team's assistance provided medical aid and pointed out ways in which countries worldwide could improve disaster care for the children of today and those of the future. Journalists have dubbed him 'The Children's Doctor of the World'

'Our institute for Children's Emergency Surgery and Traumatology, which also includes neurotrauma, trauma, resuscitation, intensive care and others, has a unique character,' Prof Roshal explained. 'There are no others of its kind, either in Russia or, actually, the rest of the world. Our equipment is state-of-the-art; we have at our disposal CT and MR tomography with imaging at 3-tesla. We examine traumas using all functional methods. We devote particular attention to problems concerning severe traumatic pathologies. We also treat acute diseases in children, for example peritonitis. In 98% of these cases we use laparoscopy. We have achieved a very high level in treating craniocerebral trauma, and know a lot about crush syndrome, having accumulated a profound experience in the treatment of this condition.'

The institute could and should become a centre of education and training for emergency medical assistance for children, not only in Russia, but also for personnel in countries worldwide, he suggested. 'We can carry out seminars and conferences on all these subjects. I have already started on this endeavour. Within the framework of the World Association for Disaster and Emergency Medicine (WADEM) congress, held every two years, we hold specialised sessions to consider and discuss related problems. Called *Children in Disasters and Wars*, these sessions have been held for many years on our initiative. We began with one session, now there are two. Nevertheless, to my mind the initiatives taken are far from sufficient to solve the problems existing in this specialised field. Focused education and training is needed, and we are ready to provide such training; we are available and have top-rank experts at the Institute. The bulk (99%) of the international medical team who assist at disaster sites are our specialists. Because this is part of our Institute's activity, we have several emergency teams. Practically every day we deal with emergency cases in Moscow; it is our routine work and we have enough staff on the spot to carry it out. In the meantime our medical teams set off to give help at emergency sites anywhere. Their complement varies; perhaps 10 or maybe 14 people. We also replace people if necessary. For example one group returns and another departs for the emergency site.'

The Institute first provided assistance following an earthquake in Armenia in 1988. Since then it has been a notable presence at disaster and earthquake sites in Georgia, Russia, Algeria, Egypt, Turkey, Iran, India, Pakistan, Japan, three times in Afghanistan, and for a month recently was present in Indonesia. 'We have actually walked the whole equator from west to east,' Prof. Roshal remarked. 'At first, it was only my hypothesis. Then I came to a firm opinion that highly skilled paediatric specialists could help children more efficiently compared with physicians for adults. Children have particularities that need special attention. In treating them, our experience has totally demonstrated that the death toll as well as disablements is approximately twice lower when our paediatric team is doing the relief work.'

For many years, Prof Roshal has been on the Board of the WADEM. 'It is from this position that I engage in providing assistance to children whenever emergencies arise. And it has become clear to me that we need a united, efficient structure that can organise emergency aid for children throughout the world. We do not have this. I would prefer this structure to be created under the aegis of the World Health Organisation. The WHO has its specific features; all participating countries pay for the implementation of its concrete programmes. To my regret, a programme to render services to children in emergency situations is not provided for. Nonetheless, I hope that possibilities can be found in this direction. I'm not even contemplating this problem from the point of view of financing the scheme. The main thing is the overall organisational work – throughout the world.

'Teams to provide medical service to children should be formed on the national basis, for which the Russian experience could be put to good use. A team can include neurosurgeons, traumatologists, specialists in burns, plastic surgeons, intensive care and reanimation and paediatric surgeons as well as paediatricians, but it should be staffed according to the nature and scale of a disaster. Such are the principles under which our mobile teams work. That practical experience has proved the expediency of forming emergency teams of this kind at a national level.' When a disaster occurs, particularly on a large-scale, he pointed out, '… we are confronted by a deficiency in highly qualified personnel.'

The Russian team does not engage directly at an emergency site, he added. 'We don't stand near houses waiting for our patient to be rescued from the debris. This important and hard task is accomplished by pre-hospital relief teams, by mobile clinics, not to forget Medicines sans Frontières, the Red Cross, and so on. We concentrate our efforts at the hospital stage of children's treatment. For example, after the Pakistan earthquake, we arrived by air in Islamabad, settled down in the major children's hospital there and began to collect the children with the gravest problems, such as crush syndrome, crush kidney, and craniocerebral trauma, to tend these small patients in hospital.'

Along with his belief that specialised emergency medical teams for children should be organised at a national level, he also believes it necessary to form such emergency teams on the basis of geographical regions, taking advantage of their resources. 'In the case of an extremely large number of injured in a certain country and its own insufficient resources, medical aid ought to be covered at a regional level. Besides this, a special international structure should exist; teams of physicians should be able to arrive by air in the disaster site – and here, the coordination of efforts among different organisations involved is the crucial point. Additionally, in a medical emergency it is essential to evaluate the number of injured and the scale of devastation. The kind of specialists needed at the scene needs to be clear in order to deploy the staff adequately – perhaps five or 10 traumatologists should be sent, but no neurosurgeons or reanimation specialists are needed. It is of major importance that information comes very quickly and is precise. At present, there is no effective information on the necessary medical aid for children at emergency sites; this is a weak point.'

Meike Lerner from European Hospital met Prof Roshal, Executive Director and Chief of the Scientific and Research Institute for Children's Emergency Surgery and Traumatology, in Moscow

There is another highly important point: 'There are always many volunteers who wish to help, but not everyone who comes to a site with a kind heart is qualified enough to cope with the tasks. It's the skilled personnel who are needed, with licenses and a good training. Only a professional workforce can really help.' He emphasised two principal factors as to children necessary to manage disaster medical care to children: *timely* intervention of *high-skilled* personnel.

Four days before our interview, the team had applied to China's government (via the Chinese Embassy in Russia) to enter the country's earthquake region and join the medical teams there. 'The Russian Embassy in China has also applied to China's Ministry of Foreign Affairs,' Prof Roshal said. 'From our experience and calculations we can expect 80,000 injured from the death toll of 20,000. Hence, based on the adult/children ratio, we can calculate the number of injured children; we can also estimate the rate of injured children who definitely need hospital treatment – it should be 20%. We also expect among hospitalised patients a number of children suffering very severe conditions, such as crush syndrome, craniocerebral trauma as well as extensive wounds. We have physicians at our disposal who specialise in treating extensive wounds complicated by fractures. If we can go to the site, how it should be handled will be clear to us. However, we have not received any answer from the Chinese authorities. Meanwhile time flows away; in ten days we shall be hardly any use: amputations will already have been performed, and it is probable that a number of children could already have died.

'Actually, reviewing in my memory of the emergency cases in which we provided medical assistance, I cannot recollect a single occasion when a country accepted our offer to give help at once. National peculiarities connected with sovereignty come to the fore. At first, we are always confronted by refusals. This has been the case everywhere – Japan, India, Indonesia. They said they preferred to manage by themselves. But once we were at the site and working it usually took only an hour or two to clarify who was who, if I may put it that way; our role changed rapidly – we became leaders of fashion. Our work done, we've been rewarded with gratitude from each government.'

Children have physiological as well as psychological peculiarities that must be considered when treating them, he stressed. 'Proceeding from this assumption, the necessity of building up a structure for an emergency medical service exclusively for children really does exist.'

Asked how long he has worked for children we discovered this is a landmark year for Prof Roshal. After graduating in paediatrics 50 years ago he worked for some time as a paediatrician before becoming a paediatric surgeon. 'I've mainly engaged in emergency paediatric surgery, always based in Moscow, but I have worked throughout the world.'

Fifty years of dedication to saving children. We congratulated him and expressed hope for his good health to continue.

'Thank you for your good wishes,' replied Prof Roshal. 'As far as my jubilee is concerned, I'd say 75 is no age at all.'

Wound management in practice

A question of authority between doctor and nurse

Marie-Luise Müller is President of Deutscher Pflegerat e.V. (German Care e.V) Council, and Chair of its Congress, which was held alongside the *Capital Congress on Medicine and Health 2008* in Berlin this June. During our interview, we asked her whether there is too little German medical and political recognition of nursing as a health profession in its own right. In agreement, Marie-Luise Müller pointed out that this is mainly to do with the social insurance system and the basic understanding among the medical fraternity. 'The Social Welfare Code volume V does not recognise care services, which means care is always listed as a sub-item under medical services. It's a long-standing problem from which the structures of our medical fraternity have evolved and they are completely set. This goes hand in hand with the general German mentality, which is always initially very skeptical about change of any kind. German doctors fear a de-professionalisation of their rank, so they cling to their personal position of power.'


Marie-Luise Müller

Whilst the doctor's role and image has been established for over 150 years, the nursing profession is only now questioning it, she added, and this very much involves the transfer of responsibilities, particularly for wound care. A surgeons guideline stipulates that they must apply the first wound dressing after surgery, as well as the last i.e. before hospital discharge. 'However, this only refers to wounds *caused* by surgeons, where they know the exact anastomosis or the surgical thread used, and where they can assess whether any endogenous infection is present. In this case, it is understandable that the doctor wants to take personal responsibility. We do not dispute this. Our main concern is in the broad spectrum of chronic wounds, such as diabetic foot etc. These are all widespread diseases where we need to observe the patient as a whole. Specialist doctors are only concerned with their field of specialisation. Moreover, wound care requires certain capacities and resources. Sometimes there are 10 nurses to every doctor. That's why I believe it is right that in certain areas there should not only be a division of labour but also an actual transfer of tasks and responsibility.'

Asked about the opportunities for nurses that result from the new *Law on Further Developments in Care*, under which they can practice certain aspects of medicine under certain conditions, she believes this has paved the way for academic concepts. 'I can foresee there will be nurse practitioners with an MBA qualification in Germany no later than 2012. In 2009 the first German universities will start running the respective degree courses in nursing care. In the Netherlands and in all Anglo-Saxon countries this academic qualification is already available. In the USA there are already 106,000 nurse practitioners, working under various conditions of employment, and some are self-employed. For chronic wounds, they take over the complete anamnesis and investigation. They are informed about current wound care studies, carry out therapy or delegate it to a nurse, something that the doctor used to do. They also use IT. They document wounds with photographs and send these to specialists, consult with them and then return to the patients. I believe nurse practitioners are the drivers here, because they work right where it is happening, with broad access to patients. They can help them, for instance, to change their diet, or discuss questions about hygiene or sexuality. Usually there is not the same scope for this when patients talk to doctors. A nurse practitioner would have far more training in leading such conversations. So, I believe we should approach patients not only clinically but in consideration of their general environment, circumstances and health.'

How would wound care specialists be integrated into the daily life in hospital? 'Many hospitals already use good wound experts. Large hospitals in particular tend to have specialist wound care departments, where in- and outpatients can be treated. There is already good dialogue between specialists and wound experts in those departments. Out-patient care is a little more involved; for this nurses have taken many training courses so are often better informed than doctors. The problem in hospitals revolves around the transfer of responsibility. The transfer management writes a comprehensive wound care report for the patient's general practitioner (GP). This is often ignored by many GPs because they lack knowledge. Obviously it makes sense to do something about that. The public is increasingly aware that we live in an ageing society as well as a society which calls for more autonomy and personal responsibility when it comes to health. This is why people are entitled to have their wound dressings changed by somebody who is highly specialised and qualified to do it.'

RUSSIA'S SPECIALIST WOUND SURGEON

Street fights, earthquakes or simply everyday life frequently produce infected wounds that only specialist surgeons can treat. EH Correspondent *Olga Ostrovskaya* interviewed **Valerij Mitish**, whose expertise borders on the unique

A meeting with Dr Valerij Mitish was difficult to arrange – every day he's at a different Moscow hospital. Yesterday he carried out a complicated wound procedure in a children's hospital; today he's at the Military Institute, tomorrow it will be the Endocrinology Centre. He also heads the department of wound infection and wound surgery at the Moscow Research and Clinical Institute of Emergency Children's Surgery and Trauma. In addition, Dr Mitish heads a team of Russian surgeons that helps in other countries following disasters, and is professor of disaster medicine at the Russian University of National Friendship. Between procedures at the Endocrinology Centre, we finally met.

Asked why he must change locations so often and whether the healthcare system is short of surgeons for infection he explained that specialists in infection surgery are a rarity. Why? Mainly due to the complexity of this kind of surgery: several phases (2, 3, 4 etc.) are required. 'First we excise the wound; next plastic surgery must be implemented.'

Is he also a plastic surgeon? 'Sure. To gain the best results in wound treatment, we believe the same doctor should stay with the same patient. 50% of our surgical work is plastic surgery. My colleagues totally manage the plastic skills – from simple ones to tissue micro transplantation. We must not only reconstruct the


Dr Valerij Mitish

organ, but also its function and aesthetics.'

This is great! But why are do few surgeons want to become wound infection specialists? 'Traditionally, in the Russian healthcare system, doctors regard this kind of surgery as a punishment – for poor studies, for bad work. Our specialty usually had the oldest equipment and patients are treated for several months – so it's impossible to be paid big money here… And often you have to work with blasted tissue, stuffed with pus.'

So why is he a wounds surgeon? 'It's a very interesting specialty! I think I'm lucky to understand this. This was the USSR when I began to operate. I worked at the Vishnevskij Institute of Surgery, which was oriented towards military and disaster wounds. It was there, in the beginning of 70s, that the first wounds and wound infection department was set up. A strategy for active surgery was created – the surgeons didn't wait for "ripening" of the wound to treat an abscess; they operated without wasting time. We also had a special air medical service and I flew to the furthest areas of Russia to treat the most complicated cases. As a result, I've gained great experience.' Dr Mitish speaks with sadness. 'We had an excellent system for treating difficult cases in every area of the country. We could get these patients to Moscow for follow-up treatment. We had 20-30-40 most interesting cases at the same time. It's really sad that this system has now been destroyed.'

What can be done in the circumstances? 'We try to share our experience with our colleges in different Russian locations, at congresses and in universities. In 2000, I lectured French surgeons in Paris about the treatment of osteomyelitis after trauma. A lot of surgeons come to my operations. Now we use the most advanced medical technologies to treat wounds. When we go to countries after earthquakes (in Pakistan, for example) our colleges from other countries can use our experience.'

This interests them? 'Sometimes they say they can't do such complex surgery back home, they say "you can do everything without us". I think we have such rich experience because we have a lot of difficult cases after various situations in Russia: regional wars, explosions in our cities, knife and gun wounds delivered on the streets – a lot of really small disasters. And we can use this experience in treating fight wounds to treat common ones.'

Hair helps chronic wound healing

BIOTECH FIRM GENERATES SKIN FROM MOTHER CELLS IN PATIENTS' HAIR FOLLICLES

Hair follicles, long disregarded by researchers, except in the cosmetic industry, may turn out to be 'the fountain of youth', according to **Andreas Emmendörffer**, CEO of German biotech firm Euroderm. The use of a few hairs can help to heal chronic wounds, Euroderm reports.

Just a few years ago scientists discovered a surprising detail in the hair follicle: It contains not one but three kinds of adult stem cells. Even more interesting, these are not only part of hair regeneration but also play an important role in skin repair.

Usually, hair stem cells are involved in hair growth and pigmentation. The lifetime of a hair lasts two to six years and goes through three stages, which recur continuously. For most of the lifecycle the hair is in the active stage, followed by a transitional stage that lasts only three weeks, then a resting phase of four further months after which the hair is shed. Then a new hair is built up.

However, the story does not end there. In addition to the melanocyte stem cells, which are responsible for hair colour, researchers also found the mesenchymal and epithelial types of these 'mother cells'. 'It was very well known, that mesenchymal turn into different kinds of tissues, for example, the inner organs, whereas epithelial ones are able to regenerate skin,' Andreas Emmendörffer explained. Scientist discovered that both kinds of stem cells are activated by damaged skin and connective tissue. While the skin stem cells migrate to the skin surface, the mesenchymal are involved in healing deeper wounds. These findings triggered the idea of growing skin from hair.

Euroderm adopted a method introduced by Professor Thomas Hunziker and team at the Dermatological University Hospital in Bern, Switzerland, and developed it into to a therapy for patients. The procedure sounds simple: The patient provides a few hairs, depending on the size of the wound. The hair is immersed in a solution that contains a cocktail of growth factors, including epithelial growth factor. These stimulate the proliferation of the skin stem cells. 'First they grow in one layer, but once the number of cells exceeds a critical amount, we stimulate them to build up further layers – or simple to make the epidermis thicker,' Andreas Emmendörffer explained. After two to three weeks the new skin is ready to be grafted onto the wound. 'We stabilise the thin plaster on a plastic film, which makes it easier for doctors to transfer it to a wound,' he pointed out. Surprisingly it is not necessary to cover the entire wound with the new grown skin. The patches tend to expand and connect with one another.

The new treatment has proved successful, he said: 'In a clinical trial, 60-80% of the patients had closed wounds or benefited at least from a significant reduction in the size in a few weeks.' Equally important, he added, to date no critical side effects have appeared.

Pressure ulcers

Heidi Heinhold, of the German League for Decubitus Ulcers, sums up physiological basics and practical care issues

Physiology is the science concerned with the processes and functions of an organism. Profound knowledge of physiology allows us to recognise states that deviate from the norm and decide whether these anomalies should be classified as diseases or disorders and thus require care. The initial instrument to assess a patient is the care history. The second mandatory step is the definition of realistic care objectives, the planning and implementation of care measures and the assessment of the results in terms of quality control and nursing science.

Pressure ulcer stages revision

USA – Following five years of work, which began with the identification of deep tissue injury in 2001, the National Pressure Ulcer Advisory Panel (NPUAP), in Washington DC, has redefined the definition of a pressure ulcer and the stages of pressure ulcers, including the original four stages, and adding two stages on deep tissue injury and unstageable pressure ulcers.

The staging system was defined by Shea in 1975 and provides a name to the amount of anatomical tissue loss. The original definitions were confusing to many clinicians and lead to inaccurate staging of ulcers associated or due to perineal dermatitis and those due to deep tissue injury.

The proposed definitions were refined by the NPUAP with input from an online evaluation of their face validity, accuracy clarity, succinctness, utility, and discrimination. This process was completed online and provided input to the Panel for continued work. The proposed final definitions were reviewed by a consensus conference and their comments were used to create the final definitions.

** Source/details: npuap@npuap.org*

Care history is risk assessment

The assessment of a pressure ulcer risks encompasses (beyond a patient's age and sex) the following:

- biological age and state of hydration of local cells, particularly in skin and subcutaneous tissue
- state of deep tissue
- state and functioning of blood vessels
- state and functioning of the lymphatic system.

A patient can rarely provide information on these aspects because, while he probably remembers recent injuries or thromboses, embolisms or known vascular or lymphatic diseases, he is probably not aware of the effects of such injuries or conditions on tissue. The skin turgor (elasticity) provides a first indication of hydration. Pressure on the tissue allows a general assessment of the micro-circulation: if the tissue blanches and the vessels do not refill after a few heartbeats, a circulation disorder is present which can be further differentiated:

- bluish-grey colour indicates a venous disorder of the micro-circulation
- if the site where the pressure was applied remains white for some time and is even cooler than the adjacent tissue an arterial disorder of the micro-circulation has to be suspected.

In the first case the flow of blood and interstitial fluid is disturbed; in the second, the tissue is inadequately supplied with blood. Moreover, there is an as yet unverifiable lymphatic drainage problem. Mechanical obstacles, such as occluded venules or insufficient or overburdened lymph precollectors, cause fluid build-up between cells. This fluid contains, for example, proteins, fats, anaerobe bacteria, cell toxins and other substances that need to be removed through the lymphatic system as quickly as possible, but which cannot be removed since an interstitial oedema blocks the way.

Interstitial oedema are tissue alterations that the most recent NPUAP classifications describe as induration, oedema, painful, soft, exuding, warmer but also cooler than the adjacent tissue. These symptoms indicate a deep tissue disorder that, if untreated, can develop into pressure ulcers. Ideally, a differential diagnosis with the help of imaging methods provides answers to such phenomena. From a physiological point of view, these tissue alterations require the patient to be moved, to activate the venous flow and enable the lymphatic pre-collectors to remove the interstitial liquid. Frequent repositioning is necessary for the local liquid accumulations to dissolve spontaneously, which is still possible in this early stage.

Rubefacient ointments, heating or cooling and massages must be avoided, because such measures increase the arterial inflow to the regions at risk. Consequently even more liquid is released into the interstitial spaces, which means the oedema grows and aggravates the situation. Thus the risk of infectious decubitus stage I as a disease stage would be heightened rather than reduced.

Nurses should be trained to recognise palpable superficial tissue changes and in turn train family carers, since this effectively and significantly increases early detection and prevention of pressure ulcers.

What makes bedsores tick?

By **Friedhelm J Baisch PhD** (med. Eng.) of the Institute for Aerospace Medicine*, Cologne, Germany

According to a study by the German Aerospace Centre, bedsores are mainly induced by a combination of gravity and immobility. Gravity exerts skin pressure and tissue shearing stress, which in turn provoke pathological changes if patient mobility is not encouraged.

Non-invasive, in vivo detection of intra-tissue pressure and tension

Previous calculations regarding the pathological effects of pressure on biological tissue were realised in animal models. Such investigations gave rise to findings such as the Kosiak postulates, which were extrapolated from investigations of tissue pathologies. These postulates allowed investigators, for the first time, to measure stress on human soft tissue using a non-invasive self-constructed pressure stamp and, at the same time, to observe and document the physiological processes in the terminal vessels of the skin and musculature non-invasively.

In this process, erythrocyte movement in the capillary bed was measured in the force direction of the pressure stamp using a Doppler laser, while at the same time the erythrocytes were counted and the oxygen load was measured using a white light spectrometer.

In the gluteal region, the pressure stamp was pointed directly at the ischium. The force was then increased in defined increments until erythrocyte movement ceased in the tissue under the stamp. Up to 50 Newtons were exerted on the skin, with peak pressure ranging as high as 100 mmHG. The deformation was then stepped down using the same increments.

Findings

The force exerted during the various pressure stages was not constant. The force was higher at the beginning of each deformation and then declined to a lower level. The tissue reacted plastically.

The number, oxygen saturation and movement of the erythrocytes decreased as force and deformation lessened. However, substantial numbers of erythrocytes were trapped in the capillary bed when they stopped moving. The oxygen saturation of these erythrocytes was initially high, but decreased as long as the pressure remained constant.

Conclusions

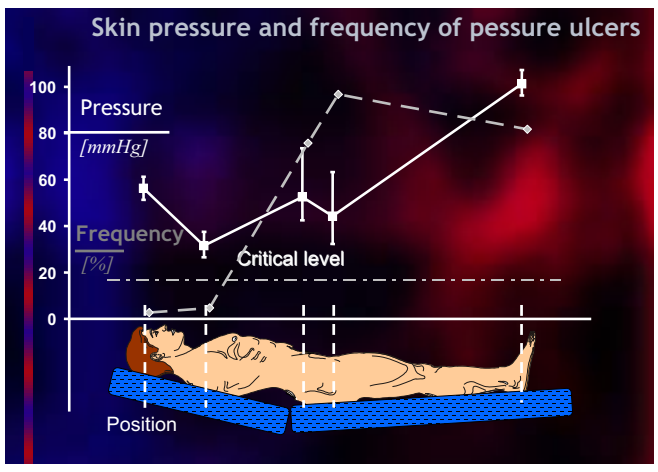
Kosiak's hyperbola model should be expanded, as this would allow the effects of altered hydration status to be brought into play.

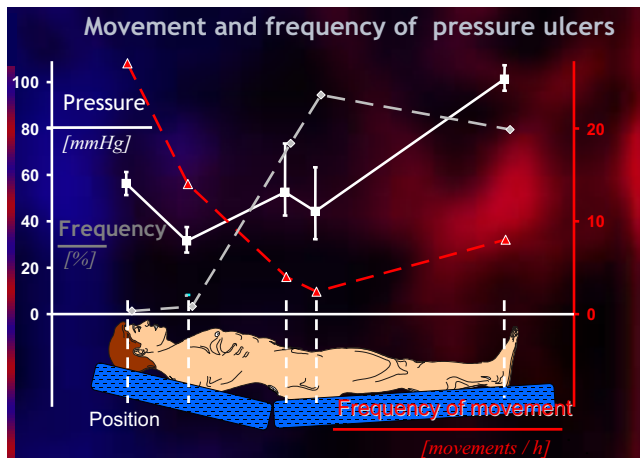
Although tissues tolerate pressure peaks for brief periods, pathologies are provoked by erythrocyte oxygen depletion, i.e. in

continued on page 20

Key parameters for prophylactic mobilisation in cases of bedsores:
Fig. 1 Pressure level (continuous white line) in regions at risk for bedsores (occiput, shoulder blades, coccyx, ischium and heels). It has been shown that bedsores always develop around the coccyx and ischium, even though the pressure exerted on these regions is not particularly high. However this pressure does exceed the critical threshold (gray dot-dash line). On other hand, it is curious that bedsores do not always develop on the heels, where the highest pressure values occur. Moreover, by rights bedsores should be as prevalent on the occiput as in the coccyx region, since the surface pressure there is nearly the same as in the gluteal region. The critical threshold for surface pressure in this region is slightly under 20 mmHG, which is based on the pressure collapse values for older, cachectic patients in a reduced hydration state. This level is age dependent, and varies inter-individually and according to body region.

Fig. 2 The red curve shows the movement frequency of the various areas and parts of the body. The head and upper body move more frequently (or are mobilised, e.g. during food intake). More movement occurs even in the heel region than in the coccyx. Movement and position are the key parameters for bedsore prophylaxis.





continued from page 19

cases where tissue deformation accompanied by flow stasis remains unchanged for an unduly long period.

The amount of oxygen consumed by maintenance metabolism indicates that tissue deformation is tolerated by nerve tissue for only a few minutes, by skin and inactive musculature by approximately 60 minutes, and by cartilage for several hours. This process of deformation provokes erythrocyte stasis owing to the weight exerted on the surrounding capillary bed.

Kosiak showed that a small amount of pressure can result in a critical weight threshold being crossed, which in turn provokes tissue subsidence if the deformation remains unchanged.

Enlargement of the contact surface via softness does not solve the problem, since softness is habit forming and undermines the patient's already diminished desire to move autonomously. Hence softness indisputably promotes both immobility and a negative body image. In this respect, it is essential that immobile patients be mobilised several times daily by a nurse, physiotherapist and/or the family caregiver. Only in this way can bedsores be avoided.

The current annual social cost of bedsore treatment is about 0.8 billion euros (2006 figures), which is likely to reach two 2 billion euros in coming years due to increasingly aged populations.

** Institut für Luft- und Raumfahrtmedizin, Deutsches Zentrum für Luft- und Raumfahrt e.v. Article based on a lecture delivered before the German Bedsore Association (Deutsche Dekubitus Liga) in Berlin in May 2007.*

Optimising chronic wound care

Process optimisation is a major issue in any healthcare facility, say **Ellen Schaperdoth**, **Claudia Roland**, **Rudolf Pape**, **René A. Bostelaar**. Some organisations have already come a long way, others are just about to attempt the first steps

Process optimisation concerns all primary and secondary processes in a hospital. Case management is a tool that supports the implementation of comprehensive optimisation efforts. The *Cologne Case Management Model* is designed as a process of interdisciplinary cooperation in patient care. It encompasses assessment, planning, documentation, coordination, organisation and evaluation of healthcare services. During assessment and during the extended process monitoring by the case manager the wound manager identifies patient needs and initiates agreed solution-oriented actions such as wound management.

At University Hospital Cologne central wound management has been implemented in the context of introducing case management.

There are several treatment strategies for the care of chronic wounds. New research highlights the complex processes involved in wound healing. Industry seems to exploit this trend to present ever more complex products. However, for the user it is increasingly difficult to gain an overview over the broad range of available wound care products. Moreover, clinicians adhere to different theories and practices regarding wound care, making this issue a bone of contention that leads to unnecessary distress. In everyday hospital life many patients are subjected to changing treatment methods, which means a lack of continuity of care. Different materials with widely differing time requirements, and above all uncontrolled costs, are applied with uneven success.

Wound management goals

- Standardisation of wound care (following established guidelines),
- Process optimisation
- Economic use of products.

Wound managers' tasks are to

- advise and care for patients with chronic wounds
- develop guidelines that ensure standardised and consistent wound treatment
- reduce and standardise wound care products by removing unsuitable materials and medication
- train medical and nursing staff
- ensure the continuity of care by appropriate data collection and harmonisation of IT-based wound documentation.

Milestones achieved:

The hospital board adopted guidelines for the treatment of decubitus, diabetic foot syndrome and ulcus cruris. The stock of wound care products was updated and restructured in order to make all procedure-relevant materials immediately available to the staff. Pharmaceuticals of questionable effectiveness were removed. Consignment stock was established for vacuum therapy material.

The first training courses for wound managers began in November 2004 and were completed in February 2005. Additional courses took place from September 2006 to March 2007 and from April 2008 to July 2008. The course contents were supported by bedside teaching on wards. All new members of staff receive training for new products.

To improve and harmonise documentation, the internal IT system was modified and is currently being tested in some clinics.

The first wound manual was published in July 2006.

Responsibilities

Upon admission of a patient with chronic wounds, e.g. decubitus, diabetic foot syndrome, ulcus cruris or secondary healing wounds, wound management should be paged during assessment by the case manager(s). During joint wound assessment (case physician, the nurses and wound manager) photo documentation is created and the therapy concept designed. The agreed therapy is documented on the wound documentation form or the temperature chart.

Monitoring, changing of dressings and the concomitant documentation on the wound documentation form are the responsibility of the nurses and/or medical staff. Support and advice during treatment are the responsibility of the trained wound manager.

The treatment plan is reviewed in regular and previously agreed intervals by the physician in charge and the wound management team. The plan is modified as needed. The case manager is informed.

To facilitate scheduling, the different departments are offered a fixed 'visit day'. Defined procedures facilitate treatment of chronic wounds and ensure continuity of care.

Further guidelines, for example regarding decubitus prevention, are currently being developed.

Roughly every six months a wound colloquium is scheduled where internal and external staff members present their results and undergo additional training.

Process optimisation ensures that problems are identified early and that appropriate solutions can be immediately initiated.

Further details: rudolf.pape@uk-koeln.de

BEST therapy for chronic wounds

The recently launched KFH Novo from Kingfisher Healthcare (KFH) is a non-invasive medical device that utilises Bio-Electric Stimulation Therapy (BEST) to deliver extremely low levels of current to chronic wounds. This does not interfere with standard conventional therapy; the electrodes are placed some way from the wounds, beyond the normal treatment areas.

Kingfisher reports that the therapy has been shown to heal different types of chronic wounds such as venous ulcers, pressure sores and diabetic ulcers, even if open for longer than a year. Professor Raf Meesen, of Limburg University College, Belgium, said: 'The initial results with KFH Novo appear to be very promising. Some wounds that we could not get closed with standard treatments healed completely when this was applied.'

BEST works by enhancing the physiological processes of wound healing; documented effects include:

- **Attracting the right cells to the wound area, e.g. keratinocytes (cells which make up 90% of the outer layer of skin called the epidermis)**
- **Stimulating fibroblast cells to activate wound healing**
- **Increasing the production of ATP, providing energy to restart tissue healing**
- **Increasing the blood and oxygen supply to wound beds**

'KFH Novo is a very cost-effective solution, and we expect significant demand from wound care professionals,' Dr Henk Snyman, the firm's CEO, pointed out.

Distributors wanted: **'There is a great deal of interest from the medical community,' Marc Dauwe, Director of Medical Affairs, confirmed, adding that KFH is looking for specialist distributors (contact: info@kfhealth.com).**

DEVELOPMENTS IN DRESSINGS AND BEDDING

RESEARCH

Investigating new wound healing approaches

Little research has been carried out into new therapies for wound healing. As chronic wounds tend to be classed as side effects of other diseases, e.g. diabetes, they are often treated as trivial. However, the body's capacity to heal itself often does not set in for weeks.

Still the most important initial choice of treatment, wound dressings not only protect an open wound from further infection, but also the active substances they contain encourage healing, which can be effective particularly at the early stage. However, conventional dressings are manufactured from collagen — made from human or animal connective tissue – so cannot guarantee germfree hygiene. Lack of oxygen due to wound covering can cause further problems. The quality of materials is therefore decisive for successful therapy.

At the Bayer subsidiary BIG (Bayer Innovation GmbH), project teams working on various innovative wound healing therapies and treatment strategies are researching high-quality substances and modern procedures, Bayer reports. They are using the characteristics of the well-known silica gel based on scientific findings at the Fraunhofer Institute for Silicate Research in Würzburg, Germany. 'Not only does it ensure germfree cleanliness during treatment, but the fibres of the silica gel also have the positive ability to make skin cells stick to them faster and better so that newly developing fibrous tissue has better support,' Bayer explains. 'The natural structure of the wound closure facilitates an optimum supply of nutrients for the newly forming connective tissue. As the wound dressing is processed by the body at a slower pace than other materials this allows for optimum cell proliferation.'

'When the protective bond decomposes too quickly, or is not structured enough, which leads to a large accumulation of skin cells. This in turn leads to an undersupply of these cells with nutrients. In the end the internal cells die and the newly formed tissue collapses into itself,' adds Iwer Baecker, Head of the Project for Bioresorbable Silica Gel.

In the future, the BIG investigation into completely new methods may lead to a move away from conventional wound dressings. One issue is of particular interest. 'At the moment only flat wound dressings are available,' Dr Burkhard Fugmann points out. 'This is why we have tried to find a material that will adapt to the actual shape of a wound in a better way.'

Further optimisation of active substances is another important area of research. Bayer's approaches centre around the addition of growth factors that are lacking within the chronic wound, and inhibitors that prevent the break down of growth factors through protein-decomposing enzymes. Dr Fugmann's long-term goal is the development of a '…building set for chronic wound healing', which brings together the optimum combination of different treatment methods.

Source: Bayer

Dressing changes need not be painful

Chronic wound patients can experience acute pain during dressing changes. Additionally, inappropriate or sometimes aggressive adhesives on dressings can cause trauma to the healing wound bed and surrounding skin.

Clinically significant patient benefits of specific advanced wound dressings have been highlighted in a large multi-national survey of patients (pub: *Wounds UK* journal). The *Pain on Removal Cases* (PORC) survey involved over 3,000 patients with various wounds, from 20 countries. Over 90% of them said they preferred dressings with Safetac* soft silicone adhesive (Mepilex was used in the study) because they suffered less pain during dressing changes than when advanced dressings with traditional adhesives (e.g. polyurethane, acrylic or hydrocolloid-based) were used.

'The PORC survey illustrates the benefits of using dressings with Safetac technology in terms of reducing pain,' commented Dr. Richard White, Professor of Tissue Viability at the University of Worcester in UK. 'Hopefully the results of this preliminary survey will contribute to increased awareness among healthcare providers of the importance of recognising and managing patients' pain during wound dressing related procedures.'

** Safetac dressings are produced by the Wound Care division of Mölnlycke Health Care, manufacturer of single-use surgical and wound care products and services for healthcare.*

Thinsulate Thermal Insulation

Less weight, same warmth

Because the dirt and liquid repellent fibres used in Thinsulate Insulation Type Z are substantially thinner than conventional fibres, less material is needed to store the same amount of heat, its manufacturer 3M reports. 'The bedding is therefore lighter in weight and much more comfortable for patients suffering open ulcers or post-surgical wounds, for example, and yet it still provides soft, cosy protection against the cold. At the same time, the hydrophobic fibres ideally compensate temperature changes and their breathability allows unpleasant perspiration moisture to escape.'

Laundering – The material's compression resistance and quick recovery ensures that the bedding does not become lumpy or fall apart, despite many washing cycles. In addition, its light weight and low volume mean more can be laundered per load and drying is quicker, all resulting in cost saving.

Available in three different lofts (120g, 150g and 250g) for different thermal and comfort requirements, the material is also hypoallergenic and meets the ecological requirements of the Oeko-Tex Standard 100 Classes 1 to 4.

Details: www.3M.com

ESGE-ESGENA

2008 Guideline update on cleaning and disinfection in gastrointestinal endoscopy

Ulrike Beilenhoff, President of the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA)

Endoscopic procedures, which are well established in the diagnosis and therapy of gastrointestinal diseases, not only carry procedural risks but also the risk of endoscopy associated infections. These include:

- Endogenous infections
- Exogenous infections caused by inadequately reprocessed equipment from one patient to another
- Risk of infection to staff working in endoscopy

Appropriate reprocessing of flexible endoscopes and endoscopic accessories is an essential part of safety and quality assurance in gastrointestinal endoscopy.

Since the late 1970s there have been sporadic reports of nosocomial infections linked to endoscopic procedures. These include bacterial infections caused for example by Salmonella spp, *Helicobacter pylori* and Pseudomonas spp, as well as viruses such as Hepatitis B and C . The majority of documented cases were due to non-compliance with national and international reprocessing guidelines.

Since 1994, the ESGE-ESGENA* Guideline Committee has developed a number of guidelines focused on hygiene and infection control in Endoscopy (see *www.esge.com* or *www.esgena.org*).

This year, the Committee has updated the current guideline on reprocessing of flexible endoscopes and accessories. It addresses several important aspects of safety in gastrointestinal endoscopy. In addition to general statements, the guideline provides detailed technical protocols for the daily work of medical staff as there are multiple local variations in the application of general guidelines. The consensus guideline has been prepared by endoscopists, microbiologists, hygienists, endoscopy nurses, and representatives of the biomedical industry.

In 2007, two guidelines were published that also address the necessity of hygiene control in GI Endoscopy:

- ESGE-ESGENA Guideline for process validation and routine testing for endoscope reprocessing in washer-disinfectors, according to the European Standard EN ISO 15883 parts 1, 4 and 5
- ESGE-ESGENA Guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy

These two guidelines must be taken into account when establishing local quality management of hygiene and infection control in Endoscopy.

The ESGE-ESGENA guidelines can be adapted locally to comply with national laws and regulations.

Source: Ulrike Beilenhoff/ESGENA
* ESGE - European Society of Gastrointestinal Endoscopy

The 7th Villacher Hygienetag

Villach, Austria 15-16 October 2008

Experts from almost a dozen European countries – including for the first time Russia, Bulgaria, Serbia and Croatia – will meet at the Villacher Hygienetag (Hospital Hygiene Congress) in October to discuss 'Antibiotic resistance – development, consequences and concepts'.

20 presentations and discussion rounds will try to find answers to why the antibiotics and other agents developed to vanquish viruses and bacteria also made the organisms stronger.

The broad range of topics covers:

- inter alia infection risks after natural disasters
- sources of infections in hospitals, a look at the relationship between nursing staff and physicians from a sociological point of view
- the applicability of aviation safety strategies to healthcare
- the economic aspects of improved hospital hygiene will also be discussed.

Conference languages: German, English, Italian, with simultaneous interpreting.

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NOSOCOMIAL INFECTIONS IN THE USA

By **Cynthia E Keen**

As nosocomial, or healthcare-related infections (HAIs), continue to escalate in the US, and protocols to manage this problem remain complex and confusing, surveillance healthcare IT systems offer hope to gain control of the situation. These offer the potential for data to be uniformly collected, quantified, and assessed. How rapidly they will be implemented enough is unknown.

The Centres for Disease Control and Prevention (CDC) believe that HAIs are one of the top ten causes of unnecessary death in the US. According to a study published in November 2007, infections caused by staphylococcus aureus alone have increased by 7% annually from 1998-2003. In 1998, US hospitals reported approximately 250,000 staph infections; in 2003, nearly 390,000, the equivalent of 1% of hospital in-patient visits. But because no standard methodologies have been established to acquire meaningful data, the numerous studies to quantify the cost of HAIs differ dramatically.

Lead author **Dr Gary Noskin**, of Northwestern Memorial Hospital in Chicago, estimated that the cost to treat staph infections alone increased from $8.7 billion in 1998 to $14.5 billion in 2003. His source of data originated from a National Inpatient Sample Database containing data from seven million annual patient visits.

A study by University of Alabama researchers (pub: Medical Care. 1/08) utilised data from over 1,300,000 hospital admissions to 55 hospitals for a five-year period (2001-2006). The hospitals were representative in size of the mix typical throughout the US, from 50 to 1,000 beds, located in urban, suburban and rural communities.

Data, including actual hospital costs had been uniformly collected by a healthcare IT data analysis company. Using this database, it was possible to determine accurately the number of HAIs and their cost in 2007 dollar values.

A total of 58,381 (4.3% of the total) infections were identified. Out of 99,445 re-admissions of previously hospitalised patients, 7,501 were due to an infection acquired during the previous stay.

The additional average total cost relating to the infection was $7,007 in added variable cost, $12 in added total cost, and 5.4 extra in-patient days. The majority of infections were urinary tract (32.4%) costing $3,936, blood (21.5%) costing $12,774, respiratory (18.3%) costing $24,408 and wound (14.3%) costing $7.059.

Clearly, the cost to treat HAI infections is a huge waste and a travesty as the cost of US healthcare treatment continues to soar. As of October 2008, Medicare, which pays for the healthcare of 43 million people over aged 65, has stated that it will stop reimbursing hospitals for three types of preventable infections, which include urinary and vascular catheter infections. This will have a ripple effect, because US healthcare insurance companies typically follow the lead of Medicare.

New GAO report criticises federal health agencies

In April 2008, the General Accounting Office (GAO), the 'watchdog' over US federal agencies, issued a report about infection control to Congress. This detailed how four different US agencies within the Health and Human Services Department (HHS) all collect data, but collect different types of data about different subsets of patients. About 500 hospitals report data on infection rates. 14 states require that data be reported to HHS and 16 states have legislation pending to do so.

The GAO's very critical report stated that none of these agencies were taking any steps to integrate any of the data from the four huge databases or communicate effectively with each other. The report concluded that 'HHS could not use its databases to provide reliable national estimates of HAI rates, even for the selected types of HAI being monitored, because none of the databases collect data on the incidence of HAI for a nationally representative sampling of patients.'

The GAO identified over 1,200 recommended practices to be followed by hospitals, clinics, and long-term care facilities to prevent infection. 500 of these are strongly recommended. The GAO pointed out that this huge number has hindered efforts to promote their implementation, and recommended that realistic priorities be established that can be reasonably followed.

MRSA

According to the respected Society for Healthcare Epidemiology of America, antibiotic-resistant MRSA acquired in the community is increasingly the cause of infections transferred to hospitals. The drug corporation Pfizer, Inc. estimates the nationwide cost for MRSA-hospitalised patients to be $3.2-$4.2 billion.

In Illinois, New Jersey and Pennsylvania, state legislation requires that high risk patients and those in ICUs be tested for MRSA. At least eight other state legislatures are debating this. Testing of patients is a very contentious issue, and has divided the medical community. Screening is expensive. Opponents do not believe that screening and isolation is preventing the spread of MRSA.

Legislation was introduced in 2007 in the US Congress called the STAAR Act to create an Office of Antimicrobial Resistance, fund research, collect data and establish research. While many hearings have been held, it must be passed by August, due to election year politics, and controversy is associated with animal-related provisions that may cause it to fail.

Surveillance IT

Meanwhile, hospitals with electronic patient records (EPR) are increasingly starting to utilise commercial healthcare IT surveillance services. One such service, from Cardinal Health, uses a Nonsocomial Infection Marker to provide hospitals with a report of HAIs by type and location throughout a healthcare facility and specifically identifies MRSA. By using specialised data mining and artificial intelligence software, it constantly evaluates EPR data in real time, and alerts administrators to issues of concern or abnormal incidents indicative of infection outbreaks.

The software is similar to that used by credit card companies to monitor purchases for fraud, and identifies patterns indicative of specific and correctable quality breakdowns. Cardinal Health states that its software identifies clinically relevant issues that should be investigated, provides situation-specific, evidence-based practice recommendations, and provides follow-up documentation of the corrective action's impact based upon the continuous monitoring.

This IT tool brings hope of an efficient means to fight infection in hospitals at its source. It would not exist without the infrastructure of EPRs, and is still a relatively new technology. Combined with the old-fashioned remedy of repetitive hand washing, it seems to be one of the best tools available to help tackle this huge, expensive and dangerous problem.

The Thermologger

The remote monitoring of the operating status of automatic bedpan washers has become possible with the launch of the Thermologger, made by Meiko. This new technology complements the firm's cleaning and disinfection appliances, which also have integrated control and measuring systems.

Current DIN 15883 standards governing the functional capability of medical devices (the category in which Meiko bedpan washers belong) require tri-annual compliance validation and documentation. Its service package covers this task, Meiko points out. 'A specially-developed process guarantees maximum efficiency and safety with a minimum of effort. A temperature logger is attached by a holder in an optimum position on the sanitised item. During the wash cycle a continuous stream of temperature data is wirelessly transmitted at a logging interval of one second. At the end of each equipment test, a set of DIN-compliant documentation is generated and sent to the customer in PDF file format. Obtaining a validation certificate has never been easier. The service package also provides the customer with all the relevant data for his appliance logbook.'

The logger wirelessly transmits data from inside the machine to a receiver. Should the logger detect an irregularity, e.g. temperature fluctuation, a service technician can remedy the fault immediately.

This new temperature measuring technology, which was developed by Meiko with measurement specialists *ebro*, means that no additional monitoring, including the microbiological inspection of the appliances, is necessary. 'The temperature logger measures and monitors the temperature profile, which correlates with the microbiological destruction of pathogenic organisms,' Meiko explains.

Additionally, data from the machine and logging are stored with the appliance's serial number – providing users with information on the life expectancy of the machine, to meet logbook requirements at all times.
Details: www.meiko.de

Nursing documentation meets legal requirements

Belgium – Since 1988, all general hospitals are legally required to collect quarterly data for a Nursing Minimum Data Set (NMDS). The NMDS was revised from 23 to 78 items in 1997.

Imelda Hospital, in Bondheiden, one of the first hospitals there to implement PACS, was also among the first to implement Agfa Healthcare's Orbis Care system. This went live last November. Since then, over 15,000 nursing documentation forms have been registered electronically in Orbis. In a second phase (completion: end of 2008) the NDMS and the Orbis electronic care workflows will be integrated.

Care Planning is also to be implemented within Orbis, where the captured data from the Nursing Documentation is immediately available for planning processes. Additionally, the patient chart, a tool to evaluate a patient's status and adapt corresponding care planning in Orbis, will provide nurses and physicians with a complete overview of all necessary activities and observations.

BRENDA MARSH PRESENTS JUST A FEW OF THE TECHNOLOGIES AND STRATEGIES USED TO COMBAT DANGEROUS PATHOGENIC RESISTANCE

Britain: The big bug buster

The UK's MRSA rates have been declining since 2006 — and this year could be 50% lower than in 2004. This increasing control over dangerous pathogens has not been achieved without considerable hospital staff efforts, relentless public and government pressures on them, and in-house malcontent about the out-sourcing of cleaning work.

Given the cost of nosocomial infections to patients, the NHS has developed many practices to be followed — for example operation 'deep clean' – and it spends a lot on developing various strategies, promotions as well as equipment to promote more stringent hygiene. Here are just a few measures taken as well as debates currently in the UK news.

French robots join UK battle

A small army of six robots (to be augmented by a cohort of six, in total costing around €106,000) will soon arrive to emit a dry mist to attack any pathogenic micro-organisms in three hospitals in England's Midlands.

A Norovirus outbreak in a ward at Sandwell General Hospital last December subsequently spread throughout the hospital. In April visitors to all adult wards (excluding paediatrics and maternity) had to be banned. Stringent hygiene and a 'deep clean' followed.

After testing a Sterinis Robot on a ward, the NHS Trust responsible for this and two other Midlands hospitals estimated it would take 16 of the robots to clean a single ward in two hours, but they found the robot was also very effective in cleaning side rooms, bays and even ambulances. When the robots arrive, the Trust plans to use them as well as a deep clean.

Made by Gloster Santé, based in Toulouse, France, the Sterinis Robot uses a patented dry-fog diffusion technology to release particles of electrically-charged ultra-high performance hydrogen peroxide (H_2O_2)-based disinfectant. The particles stick to anything, the mist carrying them everywhere, onto curtains, beneath beds, into cupboards, even concealed or inaccessible areas, there to eradicate pathogenic organisms, the firm reports, adding that no room furnishings or equipment need be removed before a robot 'invasion'. Such an onslaught is reported to be effective in destroying MRSA, C Diff, e-coli, Norovirus, listeria, salmonella, etc.

Along with automatic monitoring and operating systems, which require no human presence during the robots work, the equipment also incorporates a traceability system, so that disinfecting operations can be recorded and a log edited via the unit's USB port.

The Sterinis process meets all the requirements of the Biocide Directive CE 98/8, Gloster Santé adds. 'It is neither corrosive nor toxic, and is 99.99% biodegradable.'

Glow and show inspection

Using long wave ultraviolet light the *Hand Inspection Cabinet* (also called the *Glow and Show machine*) highlights hygiene problems after washing, enabling infection control officers to help train staff in correct hand washing or scrubbing techniques. A lotion called Glitter Bug, or a powder, is applied to the hands and then washed off. When placed in the cabinet any remaining lotion on hands fluoresces under the UV lamp.

Recently, Suffolk-based DaRo UV Systems Ltd redesigned this device. The main body is now made in one-piece and is no longer textured black, but now a smooth metallic silver colour to make lotion spills easier to wipe off. 'It also provides better light reflection for greater disclosure of poor hand cleansing,' DaRo says, '…and, it's generally more ascetically pleasing!' adds DaRo. The larger viewing area also makes training easier.

Among users for teaching purposes, Vicki Parkin, Head of Infection Control at York Hospital — reported to have the lowest number of outbreaks of secondary infection (e.g. MRSA) in the UK – believes in the cabinet's valuable. 'Every infection control unit must have it, because it's visually the only way people can see how easily infection can spread.'

Get the message?

The UK's official 2007 MRSA rates showed that the Heart of England NHS Foundation Trust (HENHSF) had reduced MRSA infections more than any other Trust in the country. The HENHSF award-inning Infection Control Team at Heartlands Hospital have certainly neither been short on efforts or of ideas to reduce those numbers.

This May it was commended by Ecolab, which produces Spirigel's alcohol gel, for using more of this product than any other UK clients – 61,000 ml in 2007 compared to 5,000 ml in 2006.

During HENHSF's two-week intensive *Cleanyourhands* campaign, inspired by the film *Ghostbusters*, members of the promotional team (pictured) manned the main entrance of the hospital wearing boiler suits and proton packs. There they gave visitors alcohol hand gel, urging them to use it upon entering the building. Inside, visitors also found posters, life-size cardboard models and eight foot display screens to remind them, as well as patients, of how to combat unwanted pathogens.

CHANGING CONCEPTS

Killing MRSA by curbing cannulae

One highly notable development could find itself a paradigm to be adopted nationally and internationally.

Although in 2007-08 the Winchester and Eastleigh Healthcare NHS Trust had reported 11 bacteraemia infections (the government's maximum 'acceptable' level is 12). Yet, in the last seven months the Trust's two hospitals have reported not one case of MRSA infections, including bacteraemia and wound infections. Why?

Traditionally, new patients were automatically set up with cannulae for intravenous injections. However, last November a new procedure was launched in which only a doctor can prescribe cannula use and its insertion must be performed only by trained specialists. Once in situ the tube is flushed with saline solution and then checked daily by a doctor, who records its appearance and any irregularities.

Outsourcing must be ousted

Despite the government giving hospital cleaning high priority status and its recent implementation of a 'deep cleaning' programme for all NHS hospitals in England, as well as its infection strategy (pub. January) that says quality cleaning is essential, a high number of doctors and nurses are far from satisfied that outsourcing of ward cleaning and instrument cleansing to private companies works.

Instruments - Currently, the government is encouraging NHS Trusts to use private decontamination centres for instrument sterilisation. However, a survey of surgeons, by the Royal College of Surgeons of England (RCS) has revealed country-wide concern that some surgical procedures have to be cancelled due to problems with outsourcing. Two thirds of the 250 respondents said they were unhappy about either the condition of returned instruments (damage) or the lateness of their return — or even non-return — from their out-source centres.

ENT surgeon Professor Richard Ramsden, who worked on the survey, emphasised that the study indicates that '…surgeons working with on-site instrument cleaning facilities are getting a better service, enough to warrant an urgent reassessment of what's best for the NHS'.

Ward cleaning – Back in the 80s, private cleaning firms began to receive hospital contracts. Today they undertake about 40% of NHS hospital cleaning. This is not satisfactory, said participants at the recent Royal College of Nursing Conference, indeed for one the equation looked straightforward: '*There has been an increase in hospital infections and decline in cleanliness. It's quite simple.*'

The nurses blamed poor cleaning results on a higher turnover among company supplied cleaners, their low training level and less commitment to the hospital. In-house cleaners are more committed because they feel 'part of the NHS family' and 'an essential part of the team', nurses pointed out. Another participant reported that NHS Trusts in the north-west has found their own answer: they are bringing cleaning back in-house. The nurses voted 'overwhelmingly' for action to end cleaning contracts with private companies and bring hospital cleaning back in-house generally.

** The Department of Health has pointed out that there is no evidence of a difference in quality, or infection rates, between hospitals with in-house or out-sourced cleaning services.*

Hospitals with only single en suite rooms Is this the answer?

Aneurin Bevan: What would he think today?

Medical professionals are hailing plans for the new £53.7 million hospital in Wales, to be named after the Welsh MP Aneurin Bevan who became known as the 'Architect of the National Health Service' after its launch 60 years ago. Due to open in 2011, the hospital will have 96 en suite single-rooms. It will also provide 11 adult mental health beds, 15 out-patient consulting rooms, a radiology department and a GP out-of-hours and minor injuries unit.

Health Minister Edwina Hart said the single, en suite rooms will help to aid recovery, improve privacy and reduce infection risks. However, the Royal College of Nursing commented that the 'all single rooms' policy would not provide the full answer to infection control.

Last autumn, the Health Minister ordered unannounced inspections of two Welsh hospitals with low hygiene standards. Among other measures, she said a group of health professionals was being established to consider the enhancement and expansion of the role of hospital ward sisters, so that they would have more power over hygiene control.

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