Health MANAGEMENT

LEADERSHIP • ECONOMY • TRENDS • TECHNOLOGY • VISION

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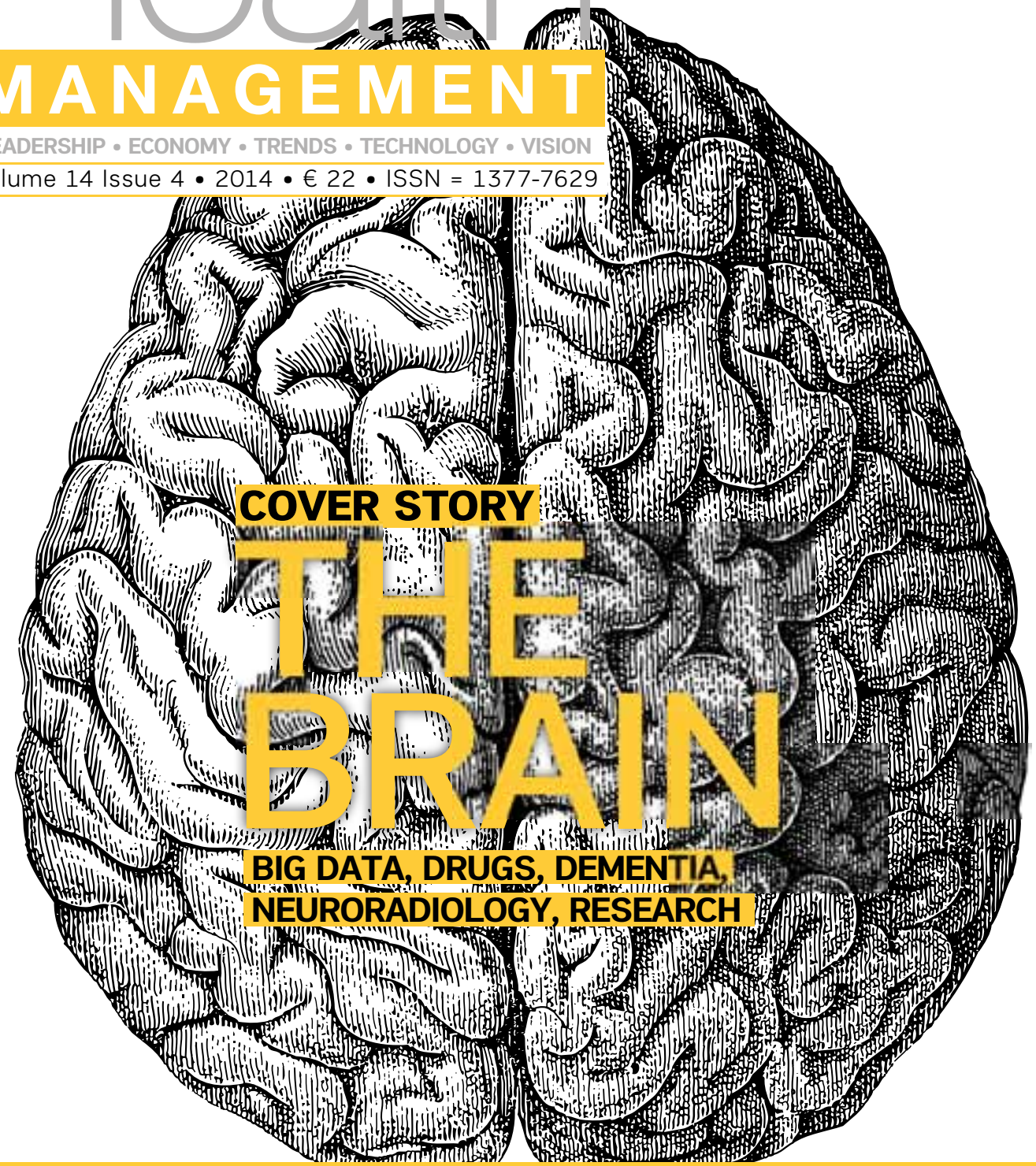

COVER STORY

THE BRAIN

BIG DATA, DRUGS, DEMENTIA, NEURORADIOLOGY, RESEARCH

MANAGEMENT MATRIX
Leadership
Economic Growth Engine
Radiology in 2020
Communicating Radiation Dose
Modern Radiology Department
PET-MR

Universal Image Viewer
Radiology in Europe
Enterprise Imaging Repository
When HIS Lights Go Out
POC Testing

SUPPLEMENT
Safety

INTERVIEW
Prof. D. Sullivan - Chair, QIBA

COMPASS
Dubai Global Healthcare Hub

DATEBOOK
MIR, EAHM, CIRSE

HealthManagement.org

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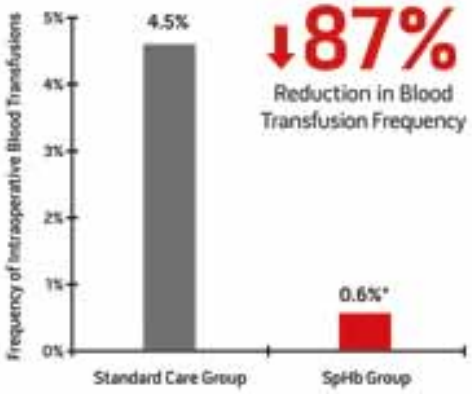
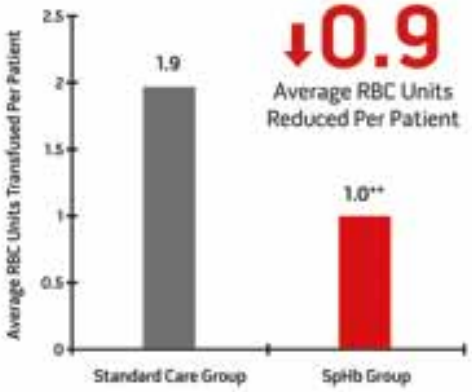
SpHb Impact in Lower Blood Loss Surgery[1]



↓87%
Reduction in Blood Transfusion Frequency

Randomised controlled trial in 327 orthopaedic patients.
**p=0.03 vs Standard Care Group*

SpHb Impact in Higher Blood Loss Surgery[2]



↓0.9
Average RBC Units Reduced Per Patient

Prospective cohort study in 105 neurosurgery patients.
***p<0.001 vs Standard Care Group*

SpHb monitoring is proven to help clinicians reduce blood transfusion in both lower and higher blood loss surgery, and also helps initiate more timely transfusions when they are truly indicated.

To learn more, visit www.masimo.co.uk/hemoglobin/

[1] Ehrenfeld JM, et al. American Society of Anesthesiologists. 2010;LB05. [2] Awada WN, et al. Proceeding of the Society for Technology in Anesthesia Annual Meeting. 2013; p 51.

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THE WORLD FEDERATION OF NEUROLOGY AND THE IMPACT OF NEUROLOGICAL DISEASES

On 22 July 2014, the World Federation of Neurology (WFN) launched World Brain Day, dedicated to bringing more attention to brain health and the prevention of brain diseases. Brain disorders, comprising mental, neurological and substance-use conditions, constitute 13% of the global burden of disease (Collins et al. 2011), surpassing cardiovascular disease and cancer.

Disease Burden

The burden of brain disorders and neurological diseases is underestimated, and under-recognised, with consequent under-resourcing and a lack of comprehensive and coordinated preventive, diagnostic and therapeutic measures. Stroke and traumatic brain injury, the two most important causes of neurological disability around the world, are often not appreciated as neurological disorders.

The WFN promotes high quality brain health worldwide: political and funding priorities need to shift, and governments and international organisations need to prioritise brain health (Anon 2011).

Neurological diseases are a major cause of death. Worldwide, stroke is the second commonest cause of death after ischaemic heart disease (Lozano et al. 2012). One to two percent of the global population suffers from a disability related to traumatic brain injury. Neurological diseases are responsible for 4.5-11% of all disease burden, depending on whether one looks at low- or high-income economies (WHO 2004). Lower-middle-income countries are hit the hardest.

As with stroke the incidence of neurological conditions, such as dementia, Parkinson's disease and other neurodegenerative disorders increases with age, and the ensuing disability adds to the burden of care, management and cost. Ageing is combined with an increase of cognitive disorders and dementia in developed countries, whereas neurological infection and epilepsy are dominant in the developing world.

The number of disability-adjusted life years (DALYs) attributable to neurological illnesses – years lost due to premature death combined with the equivalent years of healthy life lost through poor health or disability – is expected to rise from 92 million worldwide in 2005 to 103 million by 2030. Several chronic diseases such as diabetes cause peripheral neuropathy leading to neurological disability. Infectious diseases such as leprosy are still an important issue, and poliomyelitis still causes disability in some countries.

Access to Healthcare

Although considerable progress has been made in diagnosis and therapy, great disparities in the availability of treatment persist. According to the World Health Organization (WHO), less than 9 percent of the world's population has access to more than one neurological hospital bed per 10,000 inhabitants. In developed countries there is an average of three neurologists for every 100,000 people; in low income countries the number is only 0.03 per 100,000. For many neurological disorders, inexpensive but effective treatments are available (WHO 2004): up to 70 percent of people with epilepsy could become seizure-free with antiepileptic drug treatments, but more than 80 percent of patients remain untreated in most low income countries (Birbeck et al. 2014).

Cost

Brain disorders are costly: in Europe the annual costs of brain diseases for EU economies are estimated to be €798 billion, 60% attributable to direct costs and 40% to lost productivity. Neurological disease alone accounts for €336 billion (Gustavsson et al. 2011; Olesen et al. 2012).

The World Federation of Neurology

The WFN has 117 member organisations, and fosters quality neurology worldwide, through cooperation, education and biennial world congresses. WFN teaching centres have been established in Africa, and more are planned for Asia.

The WFN actively promotes research, and cooperates with neurological specialist societies worldwide, acting in partnership with a range of committed international neurological specialty organisations, such as the World Stroke Organization, the Movement Disorder Society, the International League Against Epilepsy, the Peripheral Nerve Society and others. The WFN awards grants for educational and scientific projects annually, and neurologists from member states can apply for junior travelling fellowships. The WFN, as a global society, promotes the best neurological training for neurologists worldwide (Steck et al. 2013), and supports the great efforts made by neurologists worldwide to improve the lives of patients with neurological diseases. The WFN is actively cooperating with WHO, and is involved in the development of the new ICD 11.

The WFN provides a website, actively uses social media, and publishes an online newsletter *World Neurology* (free to download on the WFN website-http://www.wfneurology.org/) and a scientific monthly publication *Journal of the Neurological Sciences*.

For references

Available on the website or on request

R Shakir
President

W Carroll
First Vice-President

W Grisold
Secretary-Treasurer General

World Federation of Neurology
London, United Kingdom

www.wfneurology.org

@wfneurology

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Operational Headquarters:
166 Agias Filaxeos
CY-3083 Limassol, Cyprus
Tel: +357 25 822 133
Fax: +32 2 2868508
E-mail: office@healthmanagement.org

Brussels Liaison Office:
Rue Villain XIV 53-55
B-1000 Brussels, Belgium
Tel: +32 2 2868500
Fax: +32 2 2868508
E-mail: eu@healthmanagement.org

Project Director
Iphigenia Papaioanou
i@healthmanagement.org

Managing Editor
Claire Pillar
cp@healthmanagement.org

Managing Web Editor
Carine Khoury
ck@healthmanagement.org

Editors
Kelly Ann Callahan
kc@healthmanagement.org

Americas Region Editor
Samna Ghani
sg@healthmanagement.org

APAC Region Editor
Dran Coronado
dc@healthmanagement.org

Editorial Assistant
Dana Ungureanu
office@healthmanagement.org

Project Managers
Luiza Kudelka
luiza@healthmanagement.org

Derek Lainsbury
dl@healthmanagement.org

Katya Mitreva
katya@healthmanagement.org

Art Director
Marilena Patatini
art1@mindbyte.eu

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REGULAR CONTRIBUTORS

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GUEST AUTHORS

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Tel.: +43 1 5337100

Cserni Hamburg
Mittelweg 175, D-20148 Hamburg
Tel.: +49 40 38037264

www.cserni.at, office@cserni.at

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COMPASS 83

MEDICA PREVIEW

The Conferences

The Forums

Globally the largest trade fair and forum for medical technology and products, this year's Medica will welcome the world of healthcare as of November 12. For four consecutive days, Germany's Düsseldorf Fairground will be the place to be, with organisers looking to top last year's impressive numbers: 132,000 trade visitors from 120 countries, and 4,641 exhibitors from 66 nations.

Taking place alongside the industry exhibition and an integral part of Medica, the planned special shows, sessions, forums and conferences will provide the academic, scientific and interdisciplinary training component of the fair.

Who Is Who

The Medica online portal offers unique features, which take congress networking to another level. New this year, 'Who is Who' allows registered trade fair visitors to use the website in order to create their profile and search for other members by certain criteria, enabling the easy finding of suitable contact partners.

Matchmaker

'Matchmaker', the congress' contact and cooperation forum, is a complimentary communication platform. Designed to allow the anonymous submission of questions or offers directly to an exhibitor ahead of the congress, users' identity remains confidential. Only after receiving an answer from an exhibitor can the user decide if they wish further personal contact.

Medica in the Mobile World

The exclusive Medica smartphone app offers an organisational tool that makes trade fair visit preparation extremely easy. Offline search, GoogleMaps link and the interactive fairground hall map allow users to access the database of exhibitors and products, and tailor-make their itinerary of stands and halls they plan to visit. The trade fair information software 'marks the spot', making the exact location of each exhibitor visible.

The Conferences

The Medica Education Conference

The MEC is targeted at medical practitioners and professional groups with an interest in specialised medicine, whether in the areas of research, development, manufacturing or buying of innovative medical technology.

Structured in a manner that allows the visitor to attend many diverse and entertaining sessions, the educational programme features 90-minute symposia, discussion forums and interactive case studies, seminars, training courses and plenary sessions, all centred around four themes:

Infection and Inflammation – causes, principles of pathogenesis, treatment.
Telemedicine and Robotics – possibilities of computer-assisted surgery.
Gastrointestinal Oncology – progress, new biomarkers, personalised treatment.
Interventional Medicine – technical innovations, new procedures.

German Hospital Conference

The congress of the German Hospital Conference Association 'Kongress der Gesellschaft Deutscher Krankenhaustag DKT' is the leading communication platform for hospital decision makers, medical professionals and area experts.

Further conferences are:

- **Medica Medicine + Sports Conference**
- **Medica Physio Conference**
- **DiMiMED – The 2nd International Congress on Emergency, Disaster and Military Medicine**

The Forums

A global, trendsetting and essential platform for interchange of know-how as well as demonstrations of the latest technologies.

- **Health IT Forum**
- **Connected Healthcare Forum**
- **Tech Forum**
- **Econ Forum by Techniker Krankenkasse**
- **Physio Forum**
- **Wound Care Forum**
- **Compamed High-Tech Forum by Ivam**
- **Compamed Suppliers Forum by DeviceMed**

The Medical App Competition

For the 3rd time consecutive year, Medica will host a live competition for the best Medical App for use in the daily routine of a doctor or in the hospital. App submission criteria include:

- to be exclusively targeting the doctor/the doctor's assistant hospital team,
- to optimise processes and raise efficiency,
- to provide secure and reliable functionality,
- to have been launched in minimum one app store (Android, Blackberry, iOS, Windows Phone).

The App does not have to necessarily comply with the EU Medical Device Directive or have obtained FDA Approval. This competition is being held within the Connected Healthcare Forum.

RSNA TURNS 100

ANNUAL MEETING PREVIEW

RSNA's centennial celebrations begin at the 100th Annual Meeting and Scientific Assembly, 30 November – 5 December.

Centennial Showcase

The Centennial Showcase will be presented "virtually" by Wilhelm Roentgen, who will share an account of the events that sparked a specialty - and how RSNA changed the way we practise medicine. The showcase will also include exhibits on the history of radiology and the RSNA, art exhibits, and invite radiologists to tackle cases of the century with the equipment available at the time.

Plenary Sessions

Sun 30 Nov: 8:30 - 10:15, Arie Crown Theater
President's Address: Reflect on the Past, Prepare for the Future NR Dunnick

Mon 1 Dec: 1:30 - 2:45, Arie Crown Theater
New Horizons Lecture: Future of Ultrasound JM Rubin

Tue 2 Dec: 1:30 - 2:45, Arie Crown Theater
Annual Oration in Diagnostic Radiology: Transitioning from Volume-Based to Value-Based Practice: A Meaningful Goal for All Radiologists or a Meaningless Platitude? DC Levin

Wed 3 Dec: 1:30 - 2:45, Arie Crown Theater
Annual Oration in Radiation Oncology: 'Error Bars' in Medical Imaging: Stealth and Treacherous LB Marks

Thu 4 Dec: 1:30 - 2:45 PM, Arie Crown Theater
RSNA/AAPM Symposium: Radiomics: From Clinical Images to Omics
- **The Radiology Reading Room of the Future** RJ Gillies
- **Radiomics in Oncology: Pathway to Precision Medicine** H Hricak

Country Presents

Korea Presents: Exploring Evidence in Cardiovascular Imaging
Mon 1 Dec: 10:30-12 | SPCP21 | E353C

Canada Presents—Beyond Diagnosis: How Cardiovascular Imaging Research in Canada is Improving Clinical Outcomes
Tue 2 Dec: 10:30 – 12 | SPCP31 | E353C

Keynote Speakers

Breast Imaging (Ultrasound Screening)
Sun 30 Nov: 10:45-12:15 | SSA01 | Arie Crown Theater
State of the Art-Ultrasound for Breast Cancer Screening RJ Hooley

Physics (Computed Tomography I: New Techniques/Systems)
Sun 30 Nov: 10:45-12:15 | SSA19 | S403B
State of the Art, Recent Advances and Applications of CT WA Kalender

Physics (Diagnostic X-ray Imaging I: New Techniques/Systems)
Mon 1 Dec: 10:30-12:00 | SSC11 | S504CD
New X-Ray Imaging Technology in Established and New Clinical Applications
A Karellas

Health Service, Policy and Research (Quality)
Mon 1 Dec: 10:30-12:00 | SSC06 | S102D
- **Defining Quality in Radiology** CP Hess
- **Practicing Quality in Radiology** AJ Johnson

Informatics (Enterprise Integration)
Mon 1 Dec: 10:30-12:00 | SSC07 | S402AB
Enterprise Integration-Enterprise Imaging Nuggets RB Shrestha

Emergency Radiology (Forensic Imaging)
Mon 1 Dec: 3:00-4:00 | SSE06 | N227
What's Up in Forensic Radiology? MJ Thali

Health Service, Policy and Research (Evidence-based Radiology)
Mon 1 Dec: 3:00-4:00 | SSE12 | S102D
Meta-analysis of Diagnostic/Imaging Test Accuracy PP Cronin

Chest (Radiation Dose Reduction)
Mon 1 Dec: 3:00-4:00 | SSE05 | S404CD
Approaches to Radiation Dose Reduction and Image Optimization for Thoracic CT NS Paul

Health Service, Policy and Research (Economic Analyses)
Tue 2 Dec: 10:30-12:00 | SSG06 | S102D
Value in Diagnostic Imaging JM Lee

Breast Imaging (CT/Contrast)
Tue 2 Dec: 3:00-4:00 | SSJ02 | E450A
Contrast Mammography JM Lewin

Health Service, Policy and Research (Guidelines/Outcomes)
Tue 2 Dec: 3:00-4:00 | SSJ12 | S102D
Standardization and Guidelines in Radiology JV Rawson

Gastrointestinal (CT Colonography)
Wed 3 Dec: 10:30-12:00 | SSK08 | E351
Present and Future of CT Colonography AH Dachman

Informatics (Quality and Safety)
Wed 3 Dec: 10:30-12:00 | SSK12 | S405AB
Quality Metrics-It's Time to Do It Right W Kim

Health Service, Policy and Research (Medical and Practice Management)
Wed 3 Dec: 10:30-12:00 | SSK11 | S102D
The Current Status of the Choosing Wisely Initiative and Its Implications for Radiologists DC Levin

Emergency Radiology (Neurologic Emergencies)
Wed 3 Dec: 3:00-4:00 | SSM07 | S403B
Update on the MR Imaging of Acute Stroke WS Kubal

Molecular Imaging (Prostate Cancer/ Bone Metastases)
Thu 4 Dec: 10:30-12:00 | SSQ12 | S504CD
PET and/or MR Imaging of Bone Metastases AJ Beer

Nuclear Medicine (Cardiovascular Imaging)
Thu 4 Dec: 10:30-12:00 | SSQ15 | S505AB
New PET Cardiovascular Biomarkers-Beyond Perfusion and Viability
RJ Gropler

Hot Topics

Breast Imaging (Tomosynthesis Diagnostics)
Mon 1 Dec: 3:00-4:00 PM | SSE02 | E450A

Breast Imaging (Quantitative Imaging)
Tue 2 Dec: 3:00-4:00 PM | SSJ01 | Arie Crown Theater

Breast Imaging (Tomosynthesis Screening)
Wed 3 Dec: 10:30-12:00 PM | SSK01 | Arie Crown Theater

Breast Imaging (Breast Density and Risk Assessment)
Thu 4 Dec: 10:30-12:00 PM | SSQ01 | E450A

Chest (Lung Cancer Screening)
Sun 30 Nov: 10:45-12:15 PM | SSA04 | S404CD

N Reed Dunnick

RSNA President
www.rsna.org

WHAT'S NEW AT ARAB HEALTH 2015

The statistics are impressive: in its 40th year, the second largest healthcare congress and exhibition in the world, and the largest in the Middle East, will be host to 4,000 exhibitors, who will attract close to 95,000 visitors. Scheduled alongside the exhibition, the Arab Health Congress programme is packed with 18 conferences that will be attended by over 11,500 delegates from 151 nationalities.

Taking place from January 26 to 29 at the Dubai International Convention & Exhibition Centre, Arab Health 2015 promises to be the region's most important date for anyone in the healthcare industry. It includes the world's second largest general healthcare exhibition, a specialised MEDLAB exhibition, a multi-track medical congress and the Arab Health Awards.

52,000 Continuing Medical Education (CME) Points

Each scientific conference at the Arab Health congress is provided by the Cleveland Clinic Centre for Continuing Education, and by attending a CME accredited conference, delegates can be certain that the content offered has been well researched to ensure its relevance and suitability for the target audience. This year's listing includes the premiere of the Gulf Hypertension Conference.

MEDLAB

The main medical laboratory and technology event in the Middle East, MEDLAB forms an integral part of Arab Health. Providing a platform for leading manufacturers, traders, service providers and researchers to meet and develop business contacts, MEDLAB has its own schedule of accredited conferences offering Laboratory Management, Clinical Chemistry, Molecular Diagnostics, Haematology, Histopathology and Microbiology.

Future of Surgery Centre

With a constant stream of new data from clinical trials, new therapies, technology and treatments constantly emerging, it is critical to stay current in the real-world application of evidence-based medicine. The Future of Surgery Centre offers healthcare professionals the unique opportunity to try out dedicated hands-on training from top specialists on the most innovative surgical equipment and current surgical techniques including:

- Minimally invasive devices & techniques
- Robotics
- Bloodless surgeries
- Laser applications
- Implantable devices & systems (orthopaedic implants/cochlear implants/cardiovascular/mechanical circulatory support)
- Imaging & image guiding technologies (endoscopy/ultrasound/medical x-ray/surgical navigation system)
- Tissue engineering & regenerative medicine
- OR integration systems
- Backend Support

Enquiries regarding Future of Surgery Centre can be submitted by scanning the QR code above

8th Arab Health Innovation & Achievement Awards

Designed to recognise the outstanding institutional and individual achievements that have contributed to the growth and development of the healthcare industry in the Middle East, the Arab Health Awards are open for the following categories:

- Cleveland Clinic Young Clinician Award
- Excellence in Radiology
- Excellence in Surgery Services
- Excellence in Patient Centred Care
- Outstanding Contribution of an Individual to the Middle East Healthcare Industry
- Roche Excellence in Laboratory
- Young Surgeon of the Year Award

The award winners will be announced and presented at a prestigious Awards Ceremony, which will be attended by leading healthcare professionals and companies, speakers and attendees of Arab Health Congress, senior government officials and special VIP industry guests.

Anaesthesia Conference	28 - 29 January
Big Data Conference	28 - 29 January
Biomedical Engineering Forum	28 January
Cardiovascular Disease and Intervention Conference	28 - 29 January
Complementary, Alternative and Integrative Medicine	28 January
Diabetes Conference	26 - 27 January
Gastroenterology Conference	28 - 29 January
Hypertension Conference	26 - 27 January
Leaders in Healthcare Conference	29 January
MEDLAB Congress	26 - 29 January
Orthopaedic Conference	26 - 27 January
Paediatrics Conference	26 - 28 January
Public Health Conference	26 - 27 January
Quality Management Conference	26 - 27 January
Respiratory, Critical Care and Sleep Disorders	28 - 29 January
Surgery Conference	27 - 29 January
Total Radiology Conference	26 - 29 January
Update in Urology Conference	26 - 27 January

CIRSE 2014

SHOWCASING THE BEST IN INTERVENTIONAL RADIOLOGY

Cardiovascular and Interventional Radiology Society of Europe (CIRSE)

Vienna, Austria

www.cirse.org

www.esir.org

@cirsesociety

CIRSE's Annual Meeting, Europe's premier interventional radiology (IR) congress, attracted over 6,400 delegates from 78 countries this year. The scientific programme again focused on six core themes, but sessions ran parallel for the first time, making it easier for delegates to seamlessly follow the clinical tracks. As always, all tracks – vascular interventions, interventional oncology, transcatheter embolisation, non-vascular interventions, neurointerventions and IR management – featured a variety of session formats, including lectures, discussions and hands-on workshops.

Scientific Programme Highlights

This year's Hot Topic Symposium on *Treatment of DVT and PE: paradigm shift?*, which brought together leaders in endovascular blood clot treatment to discuss the relevance of newly available techniques, drew the biggest crowd, with 1,275 attending. Another such session offered insights into high-intensity focused ultrasound, addressing various aspects of the modality, including whether it may offer benefits beyond those provided by more established treatment options.

New EVAR devices and techniques are being developed at a dizzying pace. The Abdominal Aorta Evidence Forum addressed the most up-to-date research on endovascular aneurysm sealing and iliac sidebranch grafts for aorto-liliac aneurysms, different techniques for pararenal aortic aneurysms, and provided an update on relevant trials. The Thoracic Aorta Evidence Forum focused on the rapidly evolving use of endovascular stent grafts to treat thoracic aortic aneurysms.

The Amazing Interventions session, a feature premiered at CIRSE 2013 and a highlight of the event, showcased innovative solutions to a variety of challenging situations. The *Controversies* series also proved highly popular, with eminent experts debating specific concerns in transcatheter, ablative and embolic care.

A broad range of issues, ranging from revascularisation in acute stroke and embolisation in iatrogenic bleeding to back pain treatment, was covered in this year's Interactive Case Sessions, which aim to help practitioners learn about how to best approach difficult cases and possible complications.

Neurointerventions Track

With the further development of devices used for stroke treatment, interventional radiologists play an important role in the diagnosis and treatment of stroke, both ischaemic and haemorrhagic. For several years now, the CIRSE meeting has included a dedicated neurointerventions track, providing the most up-to-date information on image-guided stroke therapies.

For the first time, studies and trials were a crucial component of the Neurointerventions Track, with a Special Session on *Interventional acute stroke treatment: trials update and outlook* evaluating both completed and ongoing trials, as well as closely examining patient selection. Placing these in a broader clinical context was guest lecturer Hugh Markus (Cambridge, UK), who delivered the neurologist's view on the future of acute stroke care and detailed the questions that remain.

In order to allow delegates to actively participate in the education programme, an Interactive Case Session *Revascularisation in acute stroke: technical problems and solutions* was held, allowing audience members to test themselves and learn from their peers. Participants were able to further enhance their knowledge at two Hands-on Workshops and at three case-based discussion workshops. The annual Morbidity and Mortality Conference, held on the last day of the congress, also featured an exciting presentation entitled *Is the brain the target organ of any life-threatening complication during carotid stenting?*

Radiation Protection

The Radiation Protection Pavilion, which made its debut in Glasgow, was a huge success. Prominently located in the Exhibition Hall, the Pavilion offered practical tips and informational material, as well as tailored industry exhibits showcasing relevant products. To raise awareness of the risk of cataracts faced by interventional radiologists, complimentary eye check-ups (vision testing and lens opacity screening) were available for registered members. Available slots were fully booked, with almost 100 members getting their eyes checked.

New Technologies

Many new innovations were showcased at the Technical Exhibition, which offered 8,500 m^2 of exhibition, learning centre and meeting space. Over 100 industry partners participated, launching a total of 14 new products. A wide variety of Satellite Symposia were held, covering topics such as ablation of liver tumours, drug-eluting technologies, SFA interventions, and liquid embolic systems.

Learn More

The comprehensive educational programme of CIRSE 2014 will be repeated and augmented at next year's congress, to be held in Lisbon, Portugal from September 26-30.

Presentations from all tracks, including neurointerventions, are available on the CIRSE educational database, ESIRonline, www.esir.org.

MANAGEMENT IN RADIOLOGY

ANNUAL SCIENTIFIC MEETING 2014

Bologna in Italy was the setting for this year's Management in Radiology (MIR) annual gathering. A roster of distinguished speakers from Europe and the United States discussed, debated and mulled over key topics for radiology leaders and managers, including value, quality, strategy, globalisation, imaging biobanks and communication. Delegates went away encouraged to try something new in their own radiology department.

Prof. Moshe Graif (Israel) set the scene by looking into the future prospects of radiology in 2020 [see page 44 for an article based on this presentation].

Value

The value of radiology and radiologists was discussed from the viewpoint of the U.S. and the UK, by Dr. Geraldine McGinty and Prof. Erika Denton respectively. Prof. Denton is the National Clinical Director for Diagnostics, NHS England, and she argued, with examples from the NHS England Diagnostic Imaging Dataset, that data is essential to effect change and monitor results. Denton observed that strategic thinking is needed to manage the overwhelming sense that radiologists are being overworked. It is important to count what radiologists do, and count the impact of what radiologists do, beyond the "technological silo" that radiology can tend to focus on.

McGinty, Chair, American College of Radiology (ACR)'s Commission on Economics, outlined the ACR's Value 3.0 proposition, and urged delegates to start demonstrating value. She listed six actions, which radiologists could do right now:

1. Maximise reimbursement under the current system;
2. Maximise participation in quality programmes;
3. Get educated about your wider world;
4. Educate your community about what you do;
5. Get involved in system governance;
6. Find a way to connect differently with your patients.

Communication

Prof. Charles Kahn and Prof. Leonard Berlin discussed the technical, ethical and medicolegal aspects of reporting "actionable findings". Kahn served on the ACR's Actionable Findings Work Group, and he took delegates through the categories: communication within minutes, within hours and within days, as well as discussing where IT can assist. Berlin had a plethora of legal cases at his fingertips, where the radiologist was held liable for not communicating findings. Failures occur when the information exists, but is not communicated. Berlin recommended that direct communication of findings, whether in person or by phone, be documented at the time. He asked, "Wouldn't the radiologist, if he/she did not communicate findings, not only be liable to legal consequences, but feel guilty?"

Berlin also spoke about disclosing and apologising for patient errors. Surveys show a gap between aspiration and practice: physicians believe they should disclose errors, but few do. An apology has four parts, explained Berlin: acknowledge, explain, express remorse, reparation. Ineffective apologies involve a failure of one of those elements, e.g by saying, "Mistakes were made" vs. "I made a mistake". Berlin advised radiologists, when apologising, not to speculate about cause, blame others, disclose information prematurely or clutter an apology with excuses. Berlin's presentation prompted some lively discussion around the difference between errors and complications, and the influence of the increased workload of radiologists.

Social Media

Social media can make radiologists more visible, according to Dr. Pablo Rodriguez (Spain), Dr. Lorenzo Faggioni (Italy) and Dr. Jon Bell (UK), who encouraged delegates to get involved in social media, and take advantage of the educational and communication benefits, while being careful to separate the personal and professional. Dr. Peter Pokieser (Austria) described an innovative course at the Medical University of Vienna, which uses social media in blended learning in an interdisciplinary course on emergency medicine.

EHealth in Europe

Dr. Stephan Schug, Chief Medical Officer of the European Health Telematics Association (EHTEL) spoke about the widespread deployment of telemedicine in Europe from the perspective of an eHealth stakeholder. Key actions of the European Commission's Digital Agenda for Europe include to "propose a recommendation defining a minimum common set of patient data for interoperability of patient records", undertaking pilot actions to equip Europeans to secure electronic access to their electronic health record. There are several models of teleradiology: a single facility uses it for home-based radiologists or to obtain second opinions; multi-professional care teams support patients at home, facilitate self-management and patient empowerment. The Association recommends that patient access be

part of the standard set up, and that digital literacy and training in eHealth tools is needed for all health professionals. In addition the identity of a health professional providing a service should be transparent, systematic monitoring of the value of the telemedical service should be monitored before inclusion in guidelines, and telemedia should not replace human encounters.

Celine Deswarte, from the European Commission, outlined the legal approach to telemedicine in Europe: the focus is on licensing, registration, professional qualifications, data protection and reimbursement. Physicians don't necessarily have to move to the country of their patient, but have to comply with authorisation and registration requirements of their member state. There is a project to produce a "European professional card", to accelerate recognition procedures and validation by the host state. Regarding data protection, it is prohibited to process health data except in case of patient consent, to protect vital interests, for health purposes or research purposes (data must be pseudonymised). As to reimbursement, the member state decides what to reimburse.

Dr. Remy Demuth (President, European Union of Medical Specialists (UEMS) Radiology Section) explained the UEMS' views on free movement and training requirements - "quality in mobility". Objectives are to promote free movement, with the vision of setting standards for specialist medical training and quality assurance. As different specialities have reached different levels of quality, harmonisation should aim higher than the highest achieving entity. To modernise training requirements, medical training should be duration- and competence-based.

Promoting Safety

Safety in radiology has many facets, including appropriate imaging and decision support, communication with patients about radiation dose and implementation of European Union directives.

Professor James Brink (U.S.) Mass General spoke about decision support for radiologists and referring physicians. He noted that algorithms have been published for incidental findings, but doctors don't always use them. These algorithms need to be tuned to patient populations.

Communicating with Patients

Professor Davide Caramella spoke about communicating about radiation dose and contrast media (see article on page 48). Dr. Jurgen Jacobs (Belgium) outlined how his department is implementing the European directive on radiation protection, which requires justification, optimisation and limitation of radiation exposure. Exams must be justified, based on evidence-based guidelines. In his department they constructed a generic framework. The next step will be working on its implementation and integration in workflows which currently exist. The data collected will contribute to business intelligence for statistical analysis, etc. Jacobs urged radiologists to start harmonising protocols. Clinical audits should assess care quality and resources effectiveness. Information is there, but is not closely analysed. Jacobs pointed out that the same dataset is of different value to people, depending on their interest and specialities. Tools should save time ultimately, unless they are only seen as a compliance tool. For improving quality, the investment is beneficial. It simplifies the optimisation process. Prof. Caramella pointed out that by using tools passively (disregarding alerts and malpractice), you are collecting evidence against yourself in the case of litigation!

Discussion revolved around how to bring referring physicians on board. Prof. Brink said that they need to understand that the new system will not be punitive – at his hospital (Massachussetts General) they have incentivised physicians to participate. Local variations will of course require modification to suit local practice patterns. That's the only way to keep referring physicians on board. Prof. Caramella noted that a potential weak point is that adverse events could come from following guidelines from new decision support systems. ■

Prof. Peter Mildenberger (Chair, MIR) with Dr. Geraldine McGinty

Prof. Leonard Berlin, Prof. Charles Kahn

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EAHM CONGRESS REVIEW

Heinz Kölking

President of the EAHM

Mr. Eric de Roodenbeke

CEO of the International Hospital Federation (IHF)

The European Association of Hospital Managers' 25th congress was held September 10-13 in Berlin. Moderated by Dr. Ralf Michael Schmitz, EAHM Education and Training, the ceremonial opening began with an outline of this year's theme 'Health Sector: Our role and responsibility'. Achieving a balance between the ethical responsibilities of healthcare and the economic factors in evidence represents a daily challenge, and as Dr.Schmitz explained, this congress aims to provide the opportunity for discussion and a platform for the exchange of ideas.

He then introduced Dr. Josef Düllings, President of the German Association of Hospital Managers (VKD), who in turn welcomed and thanked the participants, organisers and sponsors of the congress. As this EAHM congress was being held on a European level, Dr. Düllings pointed out that Europe got its name from Greek mythology, Europa meaning 'wide-gazing', and he suggested that the emphasis of the event be placed on looking ahead and identifying solutions for improved quality of care in the years to come.

Heinz Kölking, President of the EAHM, then took to the stage and highlighted the fact that this year's congress is the 25th, an anniversary shared with the fall of the Berlin Wall. Europe has undergone significant changes in recent years, and the past five years have shown a fundamental shift in the general direction of European politics. EU regulations and institutions are being increasingly criticised by the member states. The current political constellation opens an increased role for the EAHM association, and Mr. Kölking sees opportunities towards change of the current structure of healthcare. National and EU standards are responsible, and a balance needs to be found between the influencing factors such as the EU working time directives, the patient mobility directives, and local competitive factors. Within this context of change, each hospital needed strategies and strong management to achieve this, Mr. Kölking concluded.

He handed over to Mr. Eric de Roodenbeke, CEO of the International Hospital Federation (IHF), who presented 'Hospitals: Facing Austerity and Ageing'. The OECD perspective of austerity for healthcare will remain in place for the foreseeable future, which makes management ever more important. Current healthcare trends are not sustainable, and the major reason in the change of pattern of care and age is the upcoming big 'Silver Tsunami' wave. Ageing and multichronic conditions are impacting healthcare and creating a burden of disease in the developed world. The role of hospitals in healthcare expands across multiple dimensions, and according to Mr. de Roodenbeke, there is no one-size-fits-all solution, as location, culture and infrastructure play a significant role in each individual country's challenges.

The next speaker was Mr. Lutz Stroppe, Secretary of State, Federal Ministry of Health, Germany, who pointed out that the healthcare industry had an increasing responsibility for quality and economic efficiency in the country's economy. Ageing factors are influencing future dynamics, however, and to sustain the current high standards and extensive catalog of services, Germany needed to concentrate on three tasks: defining the true need for patient-centred care, allocating financial means efficiently, and embracing innovative framework and digital technologies. There was a need to keep the focus on people and not to divert the attention to technology, as was frequently the case.

Mario Czaja, Senator for Health and Social Affairs, Berlin, followed Mr. Stroppe's presentation with an overview of the role that healthcare plays in Berlin. In recent years, Berlin has grown in importance for this sector, with an increasing number of pharmaceutical and medical companies establishing a base in the city. Due to differences prevalent in each locality in Germany, discussions on a nationwide level made very little sense with government allocated hospital investment varying between €60 and €18 per inhabitant, depending on the city, and concluded that geriatric care would need to become the focus in the years to come.

It was then the turn of renowned independent scientist Leo A. Nefiodow to present his work on 'The Sixth Kondratieff – The New, Long Wave of the Economy', a contribution which is included in the Management Matrix section of this issue in the article 'Health – The Economic Growth Engine of the 21st Century' (see page 40).

The afternoon was dedicated to presentations outlining the status quo in Europe and included a podium discussion on economic efficiency. The World Health Economic Forum (WHEF) organised by Entscheiderfabrik was held simultaneously, exploring policy-making and IT, economics and IT and other topics, while the satellite events included a psychiatry workshop with contributions from Germany and Belgium.

The theme of lectures held on the following morning was 'Responsibility for Patients and Staff'. Among them was Dr. Áine Carroll's contribution on quality in healthcare, and her article 'Clinical Leadership and the Challenge of Change' can be found in the Management Matrix of this issue (see page 38).

In the afternoon the focus shifted to the responsibility of the health industry, with presentations on the importance of the healthcare ecosystem and sustainable healthcare. The WHEF continued in parallel, business and IT, medical engineering as well as infrastructure and IT were discussed, while the workshop was held on the challenge of infection prophylaxis.

The congress closed with the EAHM's general meeting, during which elections were held for the period 2014-2018. Gerry O'Dwyer was voted incoming president, taking over from Heinz Kölking, who has successfully led the association over the past four years. ■

TREATING THE BRAIN WITH FOCUSED ULTRASOUND

Dr. Neal Kassell
Chairman, Focused Ultrasound Foundation
Charlottesville, Virginia, USA

info@fusfoundation.org

www.fusfoundation.org

@fusfoundation

Why is high-intensity focused ultrasound being explored to treat the brain?

For a number of brain disorders focused ultrasound (FUS) will represent a treatment that is either superior to best current therapy, or fulfils an unmet clinical need. The driving factor is a validation of the technology. It doesn't take an enormous leap of faith to appreciate that if you can treat something deep in the brain in an awake patient, through the intact scalp and skull with extreme precision and accuracy, if that technology works for the brain it will also work more easily for things outside the brain in more forgiving locations, such as breast or liver tumours.

It is a new field, and it is very important to increase awareness. Everyone is interested in how the brain works, and concerned about brain disorders, such as stroke, Alzheimer's disease or brain tumours and other disorders related to the brain, even though they may not numerically or epidemiologically be the largest disease category. These are certainly the ones that garner most attention from the general population. We are working on increasing awareness and validating the technology in addition to providing better outcomes at lower cost.

> ***"FUS can reversibly open the blood brain barrier that will allow drugs to get into the brain"***

What are the most promising applications for the brain, and how soon could these be implemented into clinical practice?

The full spectrum of what we're looking at pretty much has equal priority in terms of ultimate importance, including movement disorders, such as essential tremor, Parkinson's disease and dystonia; epilepsy, brain tumours and psychiatric disorders, such as obsessive compulsive disorder and depression. They are all important, but in terms of rolling out technologies that can be rapidly adopted, the movement disorders are good, because the patients enter the MRI machine, and come out a couple of hours later and we know the result. We don't have to wait a period of time like you have to for either epilepsy or psychiatric disorders. The movement disorders are like the tip of the spear: essential tremor was a predicate for treating Parkinson's disease. Parkinson's disease numerically is not very different from essential tremor in terms of how many patients could be treated, but Parkinson's disease has much greater disability. My hope is that in two years' time FUS for essential tremor will have U.S. Food and Drug Administration (FDA) approval, and that treatment will be reiumbursed in the next 3-4 years. It is already available with the CE mark in the UK.

What are the main challenges and barriers to wider use of focused US, especially for brain treatment?

The technology currently is only useful for the central part of the brain, but the engineering is being improved so that it can treat basically the entire volume of the brain, and by the end of 2015 we expect that technical hurdle will be overcome.

The main barrier is the evidence. You have to have the evidence, and we are gathering evidence on safety, efficacy, outcomes and cost. Once we have that evidence, it will lead to regulatory approval, reimbursement, and persuasion of the medical community that FUS is better than current treatments.

The potential benefits of focused US are many (quality of life, longevity, decreased costs, shorter treatment time), but are there any potential drawbacks?

It is a major step forward in treatment of a broad spectrum of brain disorders, but it is not a panacea. There are some drawbacks. For example, treatment of large brain tumours may take a long time, but on the other hand there is no other treatment currently. For some tumours e.g. with 10-20 brain metastases, patients are better served with stereotactic radiosurgery, the gamma knife or whole brain radiation therapy.

Focused US can cross the blood brain barrier. What potential new treatments might that facilitate?

There are a couple of mechanisms of action that FUS can be used for. Firstly, to destroy tissue either by heating it or by breaking up the cells. Secondly, delivering drugs with microbubbles to a precise part of the body or brain where needed, to minimise the systemic side-effects. Importantly, there are many drugs that are very effective, but they don't get into the brain because of the blood brain barrier. FUS can reversibly open the blood brain barrier that will allow drugs to get into the brain that are otherwise excluded, and these drugs can be used for treating tumours, be they chemotherapy agents, or in future genes, growth factors or even stem cells – to treat the Parkinson's disease itself not just the symptoms, and even Alzheimer's disease. The first patient to have chemotherapy agents delivered by FUS across the blood brain barrier to treat a brain tumour is expected in Canada in the next few weeks.

Immunomodulation is another exciting

area: treating tumours with ultrasound unleashes the body's immune response, which is an area of potential.

With brain, where should research be prioritised in your view?

FUS can stimulate or block neural activity, so it can be used to map the brain, to help plan surgery so you avoid eloquent areas of the brain or to confirm the target for doing treatments for movement disorders.

Is the cost of the technology within reach of the average tertiary hospital?

For applications outside the brain, the short answer is yes. The long answer is that in the next couple of years there'll be solid evidence that FUS is not only advantageous in reducing procedural costs, but it will also have a high impact on societal cost, which is important in the new affordable care organisation model where the emphasis is on value-based purchasing.

Who should be using this technology? Are there enough trained physicians who can use the technology?

It depends on the organ. For brain treatment, I personally believe that it should be within the purview of neurosurgery. For uterus treatment, FUS can be carried out by gynaecologists, radiation oncologists or interventional radiologists. For the prostate, by radiation oncologists or urologists.

In the future, I think we will have physicians from a variety of specialities, who are trained, certified and credentialed to use the technology. The training needed is not nearly as challenging as it is to learn to perform minimally invasive or open surgical procedures. So I don't anticipate a shortage.

The Focused Ultrasound Foundation is a very innovative organisation (to quote the website: "tax-exempt, high-performance entrepreneurial service organisation with a global reach." Why is this set-up needed to accelerate adoption of focused US?

The development and adoption of any new therapeutic technology occurs at a glacial pace. For example, the Gamma Knife technology was invented in 1950. The first research device was installed at the Karolinska Institute in 1968, the first unit was commercially available in 1987, and it didn't become mainstream until 1995 – 45 years later. The process of accelerating adoption involves a large number of steps from concept to widespread utilisation, and involves the dynamic interaction of a huge number of organisations that represent the stakeholders or the ecosystem. Is there a way to shorten the process? Every day that goes by translates into unnecessary death and disability and suffering for countless people. It needs to be faster. We needed this new model and it can be used to implement other disruptive technologies. ■

ESAOTE'S LONG TERM VISION FOR ULTRASOUND

INTERVIEW WITH CARLOS FAUSTMANN, CHIEF GLOBAL MARKETING

Carlos Faustmann

Chief Global Marketing & Domestic Sales Officer - Esaote

carlos.faustmann@esaote.com

On the occasion of Esaote's recent launch of their latest mobile ultrasound diagnostic systems MyLab™ Gamma and MyLab™ Six, HealthManagement sat down with Carlos Faustmann to talk about Esaote's approach and strategy in the highly competitive ultrasound market.

Congratulations on the launch. It appears these new machines are the perfect diagnostic tools at an affordable price. Please tell us more.

We have been redeveloping our products over the past few years into a portfolio of ultrasound systems designed to run with software and probes specific to each specialty application. This has allowed us to design for different price points and budgets. Recently there has been a lot of concern within healthcare systems globally with regards to the cost of imaging modalities and subsequent reimbursements. Compared to the other imaging modalities, ultrasound is one of the most affordable modalities available today, and at Esoate we bring over 30 years of experience to our designs and engineering. Not only have we been in this business for a long time, but we manufacture our own probes and design our own software. Now, for the first time, we offer common software that is usable across all our platforms.

Ergonomic Design Minimises Operator Strain

Our customers can custom make their own ultrasound systems and configurations according to their needs. When the workload is high, and the ultrasonographers are manually scanning many patients every day, ergonomics is an important factor. To explore this further, we conducted a study in an Italian University Hospital, and collaborated with a university hospital in the USA, to look at the strain placed on operators of ultrasound machines. We gathered information via detectors on arms, wrists and the neck to determine how they reached out for the screen and so on. Based on this study we have slowly and continuously improved our machines with design engineering.

Extended Range Suits Customer Budgets

To meet the needs of smaller practices, we took the same software used in the MyLab™Seven, and built a new system with the right features for smaller private practices busy with routine examinations, with no compromise on image quality.

"Esaote's ergonomically designed carts are unique, the probes are innovatively versatile"

Upgrades for Legacy Systems

Esaote is a leader in portable systems. We have a very large installed customer base still using legacy systems. They asked for more modern replacement versions. Our strategy is to continue taking care of our loyal customer base, while offering the latest technology.

Eco-Friendly

With this launch we are also introducing our very first green ultrasound diagnostic tool. It emits a barely audible fan noise, has low power consumption, and uses all the latest electronic advancements to comply with low power consumption and battery operation.

Multidisciplinary Use

Hospitals who practise cross-departmental collaboration and who wish to share imaging equipment can use our system and adapt it with the software and probe required at that moment, extending their capability to diagnose patients while keeping costs low. This in turn allows us to address not only cardiologists or gynaecologists or other specific healthcare centres, but to provide solutions to shared service providers.

If you are constantly developing your product you must constantly have new software versions. Do you customers have to purchase these?

These are offered free of charge for purchased applications and allow additional purchases of new capabilities or probes. Our current portfolio is entirely upgradable by software. Every year we have a software update, and since all of the MyLab™ Seven, Six, Alpha and Gamma systems run on the same software, there is an annual performance update available for these four models.

What is the Esaote customer experience?

Our products are made for the long term. We do not compromise; all our ultrasound product ranges offer productivity, efficiency and value:

- Value: the device can be used for many applications.

- Efficiency: the machine can be programmed to suit the way each user wants it to work.
- Productivity: enabled through ease-of-use.

For example, to promote productivity, we also offer Wi-Fi connectivity in our latest generation of systems. Wi-Fi allows the users to connect to the establishment's network and to easily transfer images, use the printer and send data in DICOM industry standard format, giving total flexibility. It also allows remote service diagnostics in case of maintenance issues, to minimise downtime.

We have worked relentlessly to make our products comfortable for the user and for the patient. We recognise that the faster the diagnosis is made, the better.

Now the Esaote customer simply needs to invest in one ultrasound system, equip it with the software and probes of their choice, and be assured of investment protection with our free upgrades. We believe in producing systems that can be easily upgraded, thus ensuring reliability and quality.

Can the data still be given to the patient via CD or memory stick?

Yes. Images can also be transferred from the ultrasound system onto an external PC or network, with appropriate security in place of course.

What is the Esaote philosophy?

We consider ourselves as a partner to our customers. We are aware that customers may have issues, such as the need for faster diagnosis, or the need to solve a workflow issue. Nowadays, we all have to do more with less. Healthcare organisations have fewer people and have to care for more patients. At Esaote we want to continue to figure out how we can make our systems help improve the workflow. We have a physician in our leadership team to ensure that the clinical solutions our customers are looking for are accommodated in our designs.

An important part of our team is the Voice of the Customer, a group of people in marketing, who listen to customers' needs and feedback. They pass the information to our Research & Development (R&D) team to look at the solution. For example, if a customer says to me: 'I have a problem. I cannot see the needle very well when I do this procedure". I will then talk to R&D, who will work on that issue, and in the next release we will have new needle visualisation software.

Carlos Faustmann joined the Esaote Board of Directors in Feb 2011 as a Non Executive Director. In October 2013, he was appointed to the new current position of Chief Global Marketing & Domestic Sales Officer responsible for Domestic Italy Sales and Global Marketing of Ultrasound, Dedicated MRI, Interventional Solutions, Veterinary, Technical Service and Healthcare IT. Carlos has over 30 years Diagnostic Imaging industry experience having held international management & board positions in multinational imaging companies like Aloka, Siemens, and Acuson.

Carlos holds a Bachelor of Science Degree in Electronics Engineering from University of Santo Thomas, Philippines and Management of High Technology Companies Program of the American Electronics Association at Stanford University Executive Institute of California, USA. ■

For further information contact

Carlos Faustmann
Chief Global Marketing &
Domestic Sales Officer
Esaote S.p.A
Italy
Tel: +39 010 6547.1.
Email: carlos.faustmann@esaote.com

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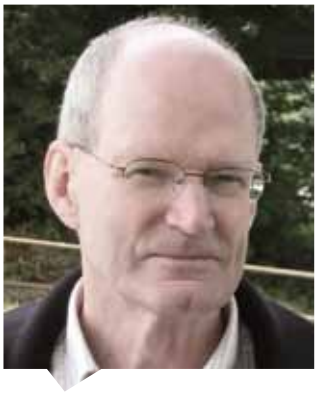
FIGHTING THE RISING TIDE OF DEMENTIAS

THE IN-SILICO MEDICINE APPROACH TOWARDS EARLY DIFFERENTIAL DIAGNOSIS AND TREATMENT



Prof. Karl A. Stroetmann

empirica Communication & Technology Research
Bonn, Germany

School of Health Information Science
University of Victoria, BC, Canada

Dr. Rainer Thiel

empirica Communication & Technology Research
Bonn, Germany

rainer.thiel@empirica.com

Dr. Veli Stroetmann, *MD*

empirica Communication & Technology Research
Bonn, Germany

Tom DeBaggio's Alzheimer's Journey

Tom DeBaggio is less sure of himself these days. He fears a recurrence of an incident over a year ago in which he got lost while driving to the family-run nursery outside Washington, D.C. "I didn't really know where I was," he says. And "I still talk. I still stand up on both feet. I still look the same. And maybe [customers] go out of here and say, 'You know, doesn't look like there's anything wrong with him.' And, of course, you don't see it." And when he was asked "Is that distressing?" he responded: "Actually, no. It relieves me of a whole lot of things. You know, when you don't remember what you did yesterday, you can't feel bad about it or good about it, you know? It's just not there. And you're really living in the moment" (NPR 2005).

Recently, in the New York Times, Roger Cohen noted that while attending services at a Reform synagogue during the High Holy Days in London "I heard sermons of great worthiness from British rabbis. One was about Alzheimer's and dementia among the elderly and the need to honour the 'fragment of the divine in everyone'." (Cohen 2014)

Dementia has arrived in the middle of our societies.

What is Dementia? The Medical and Economic Dementia Tsunami

Dementia is a syndrome in which there is deterioration in memory, thinking, behaviour and the ability to perform everyday activities. It is a broad category of brain diseases that is nowadays used to describe a syndrome that results, firstly, in cognitive function impairment and in many cases, since effective treatment remains elusive, eventually in death.

The most common form of dementia is Alzheimer's disease (60% - 75%). (WHO 2012). Other forms include vascular dementia (20-30%), frontotemporal dementia (5-10%), Lewy body dementia (<5%), as well as other rare forms of dementia.

Dementia is not a normal part of ageing, but it is more common with age. While only 3% of people between the ages of 65-74 have dementia, 47% of people over the age of 85 have some form of dementia (Wikipedia 2012). As more people are living longer, dementia is becoming more common. Worldwide, by now probably almost 40 million people have dementia, and there are some 8 million new cases every year. The prevalence is expected to nearly double to 66 million by 2030 (Wikipedia 2012) and 115 million people by 2050 (ePractice 2013).

This disease is one of the major causes of disability and dependency among older people worldwide. And it has a huge cost burden: "The total monetary cost of dementia [in the USA] in 2010 was between $157 billion (€124 billion) and $215 billion (€170 billion)" (Hurd 2013). The global cost was estimated at about US$ 600 billion (€474 billion) for the same year – about 1% of the world gross domestic product (ePractice 2013).

European Support for Brain Research and the Virtual Physiological Human (VPH) Initiative

Ten years ago 11 German researchers published a Manifesto on "Brain Research in the 21st Century" {Elger at al 2004) – forecasting that within 10 years they will understand and therefore be able to better predict, perhaps avoid, or at least much better treat diseases like Alzheimer's and Parkinson's.

Unfortunately this has not happened, but the European Union continues to support a very significant number of research and innovation projects related to neurological disorders, mental illnesses, brain injuries and related conditions. The seventh EU framework programme for research, FP7 (2007-2013), provided more than €1.9 billion for 1,268 projects for brain research with 1,515 participants from the EU and beyond (European Commission 2013). Within the collaborative research programme, brain research was mainly supported by the 'Health' programme and the 'Information Communication Technology' (ICT) programme. The projects supported by the ICT programme have some common theoretical grounding and objectives:

- Provide specialists with a functional framework to work on;
- Exploit intelligent tools and objects that facilitate health and especially eHealth delivery;
- Promote better diagnosis and treatment;
- Facilitate patients' everyday life.

The "Virtual Physiological Human: DementiA Research Enabled by IT" (VPH-DARE@IT 2013)" project is one of them. It has a budget of €18 million, and receives EC support of €13.5 million. It runs for 48 months, from 2013 to 2017.

It has been funded in the context of the European Virtual Physiological Human (VPH) Initiative, a European response to and support for the Global Physiome Project (Fenner et al 2008). These activities are also known as "in silico" medicine, complementing "in vitro" and "in vivo" medicine. In silico is by now a core part of the wider field of integrative systems biology, which pays tribute to the fact that "at each level of the organism, its various components are imbedded in an integrated

network or system. Each such system has its own logic. It is not possible to understand that logic merely by investigating the properties of the system's components" (Noble 2006). Whereas the genome, proteome, and morphome all concern structure, which is necessary but not sufficient for explaining function, we also need to know about the dynamics, kinetics, and functioning of those structures and how they interact. In other words, we need more than statistical descriptions of associations among physiological variables; "we need models that include mechanisms and distinguish mere association from cause and effect." This type of mathematical modelling and simulation research responds to the macro-ethical imperative to minimise risk for people/patients while at the same time fundamentally advancing biology and medical science: prediction, prevention, personalisation, diagnosis and therapy (Bassingthwaighte 2002).

The European Union research support "Framework Programme 7 (FP7)" running from 2007 to 2013, allowed Europe to gain global leadership in this field and closely cooperate with similar research communities in the USA, Japan, New Zealand and elsewhere. Support continues in the new so-called "Horizon 2020 Programme" (2014-2020). Initially, this work concerned predominantly the development of ICT technologies supporting multi-scale modelling and simulation of human organs or systems, thereby aggregating information from multiple biological levels. Building on this fundament, recently a particular focus has been put on the clinical and personal use of VPH or in silico technologies, aiming also at the clinical proof of concept of person-specific computer-based models. The clinical objectives in using person- specific computer based models are to allow for early diagnosis, prediction of disease behaviour and evolution and treatment outcomes.

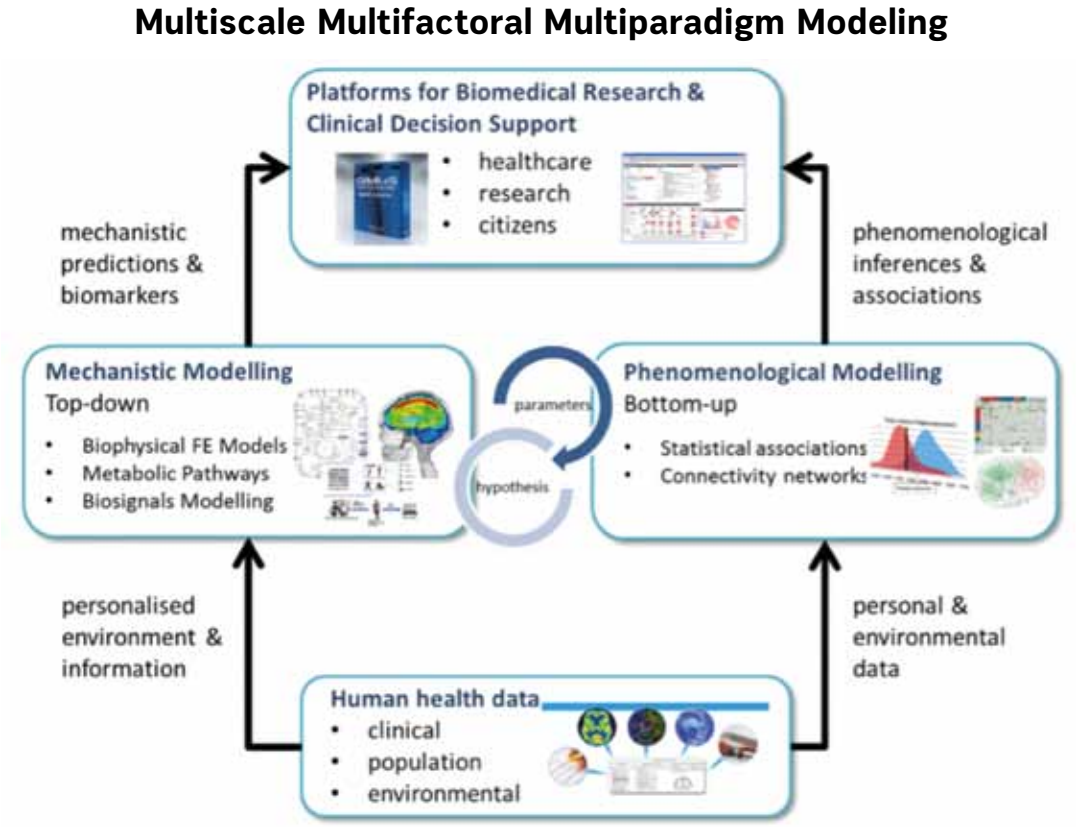
Meeting the Challenge – The DARE@IT Project

The scientific and medical vision of this endeavour is based on the fact that an early and unambiguous diagnosis of dementias will have dramatic benefits for the individual, but also for healthcare systems as a whole: delaying the onset of dementias by *a mere one year leads to a 10% reduction* in symptomatic cases – (VPH-DARE@IT 2013) with dramatic consequences on the quality of life for the subjects, but also with very significant savings for the healthcare system. Unfortunately, both early and differential diagnoses, but also robust methods to predict the evolution of these diseases in a patient-specific manner, and thus decisions on suitable care and hopefully treatment, still elude the medical profession.

It is exactly these challenges that the VPH DARE@IT project addresses. It tackles the most pressing unmet clinical needs in this syndrome and responds to the brief to provide early and differential diagnosis and management of the onset and progression of dementias, by integrating, in a truly multidisciplinary manner, heterogeneous data from individuals and populations, genetic, biochemical and metabolic pathway models, mechanistic and phenomenological multiscale imaging/modelling paradigms and sophisticated information processing tools to deliver highly innovative clinical decision support systems.

> ***"dementia has arrived in the middle of our societies"***

By bringing together new knowledge and innovative methods in these fields, it will deliver the first ever model that can account simultaneously for the patient-specific multiscale biophysical, biochemical and biomechanical brain context, as well for a number of heterogeneous genetic, clinical, demographic, lifestyle



Graph 1: The VPH-DARE@IT concept in a nutshell: combining the appropriate modelling paradigms

and other environmental factors. According to a new World Alzheimer Report 2014, the "strongest evidence for possible causal associations with dementia (plausible, consistent, strong associations, relatively free of bias and confounding) are those of low education in early life, hypertension in midlife, and smoking and diabetes across the life course". VPH DARE@IT will help shed light upon such causal relations by investigating a number of observed and speculated links, including the effect of metabolic syndrome, diabetes, dietary habits, exercise, pulmonary conditions, and how the effect these conditions have on the ageing brain influences onset and evolution of dementias.

This distinctive conceptual approach and the integration of innovative data analysis and modelling methods are illustrated in the following graph, which depicts the VPH-DARE@IT concept of combining the appropriate modelling paradigms in a nutshell: (see Graph 1)

The final objective is to turn know-how and methods into an innovative, integrative and objective clinical decision support platform for the early and differential diagnosis of memory disorders based on principles of evidence-based medicine.

The resulting integrated clinical decision support platform will be validated/tested by access to patient data contained in a dozen databases of international cross-sectional and longitudinal studies, including exclusive access to a population study that has tracked brain ageing in more than 10,000 individuals for over 20 years (Rotterdam Study [14]).The project will also quantify the benefits and costs of using the VPH-DARE@IT platform by both clinicians and industry, and contribute to the competitiveness of European industry active in the in silico domain.

Expected Results and Impact

VPH-DARE@IT's aim is to support researchers and enable clinicians to arrive at earlier, predictive and individualised diagnoses and prognoses of dementias to cope with the challenge of an ageing European society. Amongst others, this requires to identify and/or develop:

- Novel biomedical dementia biomarkers;
- Personalised, multi-factorial brain models, taking into account genetics, metabolism, biophysics, physiology and environmental influences;
- Advanced brain image analysis tools;
- An integrative and personalised modelling platform to support clinical research in dementia;
- A validated clinical platform for the personalised diagnosis of dementia and assessment of treatment efficacy;
- A framework and infrastructure for gathering, semantically coding, sharing and integrating patient and other data from large, often heterogeneous databases.

The impact of VPH-DARE@IT achievements will range across the scientific, clinical and industrial communities of Europe and globally, and uppermost improve prevention and care of dementia patients. Its results will

- Provide for an earlier personalised prognosis, diagnosis and treatment onset, meaning reduced suffering for the individual and their relatives;
- Integrate lifestyle and other environmental factors and data with clinical, biological, and physiological factors and determine their impact on disease progression and prevention;
- Facilitate the earlier risk assessment before a patient's memory is already severely affected, i.e. before it tends to be too late for starting some of the presently available treatment options;
- Provide cost-efficient approaches for detecting high-risk patients and channelling them to detailed diagnostics studies at an early phase;
- Ensure greater equality between citizens through systematic and objective diagnoses (quality of healthcare currently depends on where someone is living and the capacities of their local hospital);
- Provide also for estimates of anticipated healthcare cost reductions based on state-of-the-art impact assessment models. Substantial cost reductions will require, in addition to earlier diagnosis, a delay in the progress of dementia achievable with new prevention and treatment options;
- Foster industrial progress, resulting from the availability of the ICT tools and systems, and the expertise to apply them in the context of clinical applications. For example, the pharmaceutical industry will be able to develop new products as a result of a more accurate understanding of disease progression and clinical interventions. Picture archiving and communication, radiology, electronic health records, and general clinical information, as well as decision support systems (PACS, RIS, EHR, etc.) are also likely to benefit from these products and impact on European eHealth industry leadership;
- Enable biomedical researchers to investigate the influence of environmental factors on dementias through specialised modelling software frameworks, which will be made available to the general community as Open Source platforms.

"citizens should be empowered and supported to screen and assess their own health and risk for certain diseases"

References

Bassingthwaighte JB (2002) The physiome project: the macroethics of engineering toward health. The Bridge 22(3): 24-29.

Cohen R (2014) The community of expulsion. New York Times, 7 October. [Accessed: 22 October 2014] Available from http://www.nytimes.com/2014/10/07/opinion/roger-cohen-for-israel-a-time-of-self-scrutiny.html

Elger CE et al. (2004) Hirnforschung im 21. Jahrhundert: Das Manifest - Elf führende Neurowissenschaftler über Gegenwart und Zukunft der Hirnforschung. Gehirn und Geist, 6: 30-7.

epractice.eu (2013) eHealth and the brain – ICT for neuropsychiatric health: background document for discussion. [Accessed: 22 October 2014] Available from http://www.epractice.eu/files/Background%20Document%20-%20Brain.pdf

European Commission (2013) €150 million for brain research launches EU 'Month of the brain.' [press release] IP/13/380, 30 April. [Accessed: 22 October 2014] Available from http://europa.eu/rapid/press-release_IP-13-380_en.htm

Fenner JW et al. (2008) The EuroPhysiome, STEP and a roadmap for the virtual physiological human. Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences 366(1878): 2979-99.

Hurd MD et al. (2013) Monetary costs of dementia in the United States. N Engl J Med, 368(14): 1326-34

National Public Radio (NPR) (2005) Tom Debaggio's Alzheimer's journey continues, 19 May. [audio] [Accessed: October 2014] Available from http://www.npr.org/2005/05/19/4658784/tom-debaggios-alzheimers-journey-continues

Noble D (2006) The music of life: biology beyond genes. Oxford: Oxford University Press.

Prince M et al. (2014) World Alzheimer report 2014: dementia and risk reduction - an analysis of protective and modifiable factors. London, Alzheimer's Disease International (ADI). [Accessed: 22 October 2014] Available from: http://www.alz.co.uk/research/world-report-2014

Ruitenberg A et al. (2002) Alcohol consumption and risk of dementia: the Rotterdam study. The Lancet, 359(9303): 281-6.

VPH-DARE@IT (2013) The "Virtual Physiological Human: DementiA Research Enabled by IT" project. [Accessed: 22 October 2014] Available from http://www.vph-dare.eu/

Wikipedia (2014) Dementia [Accessed: 22 October 2014] Available from https://en.wikipedia.org/wiki/Dementia

World Health Organization (WHO) and Alzheimer's Disease International (2012) Dementia: a public health priority. Geneva: WHO.

Technology Solution – The VPH-DARE@IT Platforms

The final outcome of VPH-DARE@IT - including its decision support platform - will integrate the tools, models and workflows developed during the life time of the project as well as relevant other open source tools and sub-models that focus on dementia research. This will enable a single framework which not only provides for dementia-related decision support, but also permits to create a new generation of research and development workflows focusing on further as well as totally new multiscale patient specific treatment options for dementia. The specific results expected are to:

- Develop a workflow-oriented and extensible framework for clinical dementia research;
- Implement and make globally available a workflow-oriented and extensible framework for in silico modelling researchers in dementia;
- Specify interoperability mechanisms for leveraging functionality from other open source frameworks in dementia research;
- Define and implement integrative pipelines for data acquisition, curating and processing in the VPH-DARE@IT environment;
- Support the interaction and integration of such frameworks with the in silico and clinical data sharing eInfrastructure under development in related European projects ;
- Support data-provision centres of VPH-DARE@IT partners to federate their databases through this European infrastructure. (see Graph 2)

The VPH-Dare@IT project will deliver the first integrative and validated multiscale modelling platform for biomedical brain research and clinical decision support.

Outlook and Benefits

A functional, clinically validated decision-support system for prediction, diagnosis, and treatment of dementias is not yet available, in spite of predictions made at the start of our century. There is a strong need for an in silico modelling platform that is able to assemble and integrate the biological and medical knowledge on dementia as well as the heterogeneous information and data measured from individual patients and patient populations. It must be able to generate information (e.g. from biomarkers & other clinical and environmental measures) relevant for diagnostics and monitoring of disease progression.

VPH-DARE@IT develops a modelling and analysis system that will be used for supporting early differential diagnostics of dementias. A prime application target is to estimate reliably a predictive risk score for individual patients to become dement. The lack of such clinical support has been identified as a major challenge. Considering the enormous social and economic costs for individuals and society expected for the coming decades, such a solution will have a very high impact –both for individual patients and our health systems. A better selection and stratification of individual persons with respect to their respective risk will, as a next step, permit the much better targeting of preventive interventions and, where and when possible, treatment options.

In order to enter clinical practice, the tool will be easy to use and provide information that is immediately relevant for making diagnostic decisions in routine clinical practice. In other words, clinical user requirements are equally central to the tool's design and implementation.

In addition to expensive dementia screening programmes financed from national health systems or public insurance funds, citizens should be empowered and supported to screen and assess their own health and risk for certain diseases. This project will also demonstrate the use of a portal designed for citizens to evaluate their risk for dementia and ways to integrate such a portal into research as well as clinical platforms. ■

Graph 2:
Analysing brain images

Project Information

VPH-DARE@IT
Virtual Physiological Human: DementiA Research Enabled by IT
Project Identifier:
FP7-ICT-2011-9-601055
Timetable: April 2013 to March 2017
Co-ordinator: Alejandro Frangi - The University of Sheffield

Contact

Dr. Rainer Thiel
Empirica Gesellschaft für Kommunikations- und Technologieforschung mbH
Oxfordstr. 2
D-53111 Bonn
Email: rainer.thiel(at)empirica(dot)com

Key Points

- As more people live longer, dementia is becoming more common. The prevalence is expected to double to 66 million by 2030 and 115 million people by 2050.
- The global cost was estimated at US$ 600 billion (€475 billion) for 2010 – about 1% of the world gross domestic product.
- An early and unambiguous diagnosis of dementias will have dramatic benefits for the individual, but also for healthcare systems as a whole: delaying the onset of dementia by a mere one year may lead to a 10% reduction in symptomatic cases.
- The European Virtual Physiological Human (VPH) Initiative supports the mathematical modelling of human organs and diseases. Also known as "in silico" medicine, it complements "in vitro" and "in vivo" medicine. In silico is by now a core part of the wider field of integrative systems biology.
- The VPH DARE@IT project develops an in silico modelling platform that enables the assembly and integration of biological and medical knowledge on dementia as well as heterogeneous data from individual patients and patient populations. It will help shed light upon causal relations by investigating a number of observed and speculated links.
- VPH-DARE@IT supports researchers and enables clinicians to arrive at earlier, predictive and individualised diagnoses and prognoses of dementias to cope with the challenge of an ageing European society.
- A better selection and stratification of persons with respect to their individual risk will permit a much better targeting of preventive interventions and, where and when possible, treatment options.

BIG DATA AND THE BRAIN

GLOBAL INITIATIVES FOR BIG DATA IN ALZHEIMER'S DISEASE RESEARCH

Kelly Callahan
Editor, HealthManagement

A big opportunity exists to meet the big challenge of Alzheimer's Disease: big data. With hundreds of organisations involved in dementia research around the world, vast amounts of information already exist which, if optimally organised and linked, will provide a better understanding of the condition, its causes and paths of progression. So-called "deep" data from academic and clinical research is now being combined with "broad" data from health records (Ontario Brain Institute 2014).

Strategies for prevention and interventions are urgently needed as the global population ages, with associated costs fast outpacing each devastating diagnosis. Current estimates starkly state that 35 million people are affected by dementia, with estimated annual costs exceeding US$604 billion (€478 billion) (OECD 2013a). Socio-economic costs for affected families are more difficult to calculate, since many caregivers are relatives who must limit or stop working to provide care.

In many ways, Alzheimer's Disease is an ideal candidate for capitalising on the powers of big data. At a June 2013 expert consultation organised by the Organisation for Economic Cooperation and Development (OECD), Lefkos Middleton, a professor of Neurology, Neuroepidemiology and Ageing at Imperial College London's School of Public Health elegantly described the case: "The aetiology and pathophysiology of AD are neither linear nor additive but like a ballet choreographed interactively over time, involving genetic, gene expression, epigenetic and multitude of environmental factors" (OECD 2014).

Data Organisation: The Brain is Big Data

One of the most important discoveries in neuroscience is that brain functions, which were once thought to have localised correlates, actually depend upon functional networks. A stroke or other brain injury in the "language area" of the left hemisphere can cause predictable problems with speech and language comprehension, for example, but focal brain damage seldom results in a single functional deficiency. The brain itself is big data; only powerful with networks intact. The complexity of the brain and its disorders makes it essential that numerous sets of heterogenous data can be combined.

Thus, the importance of networks extends to big data and its potential for advancing the understanding of Alzheimer's Disease and other forms of dementia. Bigger volumes of data, even if quality keeps pace with quantity, are worthless to AD researchers and patients until coordinated efforts can improve efficient analysis. Disconnected systems must be organised so that data can be shared and interpreted with innovative methods and results. Biomedical advances can aid in the prevention and diagnosis of dementia, and in the pharmaceutical treatment and care delivery for those who live with the disease. But existing research and development processes are disconnected, expensive and not always efficient. New models are needed to generate new insights (OECD 2014).

Data Sharing: Connectivity and Creativity

There are two levels of data sharing in dementia research. Participants or patients must consent to share their personal, private data before it can be collected for specific projects. Academic, clinical, commercial and government organisations must also collaborate to share their findings across the borders of companies and countries. Of course, it is not a simple matter involving the mutual agreement of patients and scientists that data sharing is a valuable endeavour. There are big challenges in big data sets, stemming less from their size than from the heterogeneity of records. Variation in formats and structure across entities complicate the task of data sharing.

The blending and sharing of data must take place on at a global level, which entails additional practical and legal concerns. Just as discussions of big data often refer to the "V"s (volume, velocity, variety, veracity, value) the OECD's work on the information economy examines three "C"s: connectivity, creativity and confidence. Regional, national and international calls for access and sharing of data should be synchronised/integrated to ensure open access, while also protecting patient privacy and safety as well as data security. Without compatible frameworks for data governance, it is not possible to verify the value of data for sharing (OECD 2013b).

Projects are gaining momentum around the globe.

OECD

In September 2014, an international meeting convened in Toronto for a discussion of how big data can bring value to dementia research. The workshop provided a platform for the perspectives of more than 50 doctors, data experts, patient advocates and politicians to share their diverse concerns and ideas for new approaches. It was held by the OECD in partnership with the not-for-profit Ontario Brain Institute (OBI) and the University of Toronto's Institute of Health Policy, Management and Evaluation (IHPME). The purpose of the event was to identify ways in which government, industry and scientific entities could streamline goals, optimise investment efforts, and ultimately link data resources to advance dementia research (Grant 2014).

The OECD continues to bring together the perspectives of government and non-government viewpoints to address the dementia challenge. It aims to inform healthcare systems about the adaptations required to address the crisis, and to recommend ways to use big data and information technology as tools for innovative dementia prevention and treatment. In a 2013 paper, "Unlocking Global Collaboration to Accelerate Innovation for Alzheimer's Disease and Dementia", the OECD identified five areas of urgent coordination among stakeholders in policy development for data governance:

- Ensure functional and financial sustainability of large, linked research networks;
- Facilitate timely data exchange and access, compliant with risk assessment standards;
- Link complementary datasets at regional, national and international levels;
- Identify the tech and management tools that make databases efficient;
- Incentivise education and training to extend expertise and build capacity (OECD 2013b).

Big Data for Advancing Dementia Research

Between July 2014 and March 2015, a project commissioned by the OECD and coordinated by the University of Oxford's Oxford Internet Institute (OII) will evaluate best practices in data sharing, based on the following four case studies. Each of the "Big Data for Advancing Dementia Research" studies will firstly provide an analysis of records comprising documentation, websites, policies, consent and other legal forms. Such data will be supplemented by interviews with key decision makers and users. The aim of the project is to advance dementia research by recommending best practices, with results due to be reported to an OECD advisory board and the World Dementia Council next year.

- AddNeuroMed is a data repository funded by the EU and pharmaceutical partners, designed to detect biomarkers for AD.
- The Kungsholmen/Swedish National Study on Ageing and Care (SNAC) links multiple longitudinal studies; datasets include care information.
- The UK Biobank, while not focused exclusively on dementia research, comprises data from 500,000 people. It is a model for patient/participant consent of private data.
- World Wide Alzheimer's Disease Neuroimaging Initiative (WW-ADNI) is an umbrella organisation for regional and national partners focused on neuroimaging in AD (Oxford Internet Institute 2014].

The VPH Dare@IT Project

Within the European Virtual Physiological Human (VPH) Initiative, the VPH Dare@IT project acknowledges that dementia is far from a "one size fits all" disease. Its models of the human body and its disorders take into account individual risk profiles and clinical presentations, stratifying patients in a way that will optimise preventive and therapeutic interventions. The "in silico" modelling platform of the program permits data from diverse sets of medical and biological information to be integrated. The advantage of such integration is that the human body's complex physiological systems are considered, rather than their isolated components. The links between heterogenous data sets, in turn, allows for investigation of speculated links between disease causes and outcomes. The project runs from 2013 to 2017 with a budget of €18 million. More details about the project can be found in "Fighting the Rising Tide of Dementias" in this issue of Health Management.

UK Dementia Research Platform

In June 2014, the Medical Research Council (MRC) launched the UK Dementias Research Platform (UKDP). The program was announced at the Global Dementia Legacy Event in London, where Prime Minister David Cameron affirmed his country's pledge to dementia drug discoveries and development. The platform is a partnership between public and private entities, including pharmaceutical companies and leaders in biotechnology. The UKDP is uniquely positioned to benefit from a number of research initiatives in the UK, with 22 studies amassing a total research population of almost two million people. (Davenport 2014] The combination of smaller and larger studies will permit researchers to explore the significance of smaller studies in bigger populations, or conversely to take a finding

"we are committed to this new scientific environment where open data creates a space for greater innovation and faster translation into treatment"

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SEMANTIC TECHNOLOGY ENABLES SMART COMPUTERS

INTERVIEW WITH DIRK COLAERT, CHIEF MEDICAL OFFICER, AGFA HEALTHCARE

Dirk Colaert, *MD*

Chief Medical Officer
AGFA Healthcare
Mortsel, Belgium

www.agfa.com

@AgfaHealthCare

As healthcare faces up to the promises and challenges of big data, HealthManagement spoke to Dr. Dirk Colaert, Chief Medical Officer at Agfa Healthcare, on the evolution of healthcare against the background of big data.

Big data is an abstract term, but in healthcare the data represent very personal information. Do you see this as a paradox?

Big data is a buzzword without concrete meaning. It refers to both abstract and personal data, so I don't see a paradox. Very soon all healthcare applications will have to deal with huge amounts of both personal and more generic, abstract data. There is patient personal data, but also data, such as measurements from devices and sensors, that can be about one specific patient. There are also examples of abstract data in healthcare, such as generic medical knowledge - scientific databases, medical articles and clinical trials outcomes. In healthcare abstract big data and personal big data are more complementary.

Some administrators, decision-makers and physicians are reluctant to recognise big data's potential. How do you demonstrate its necessity in the future of care delivery?

This is like evidence-based medicine (EBM). Sometimes evidence is contra-intuitive. EBM uses an abstraction of the patient, and doctors may think that their patient is a little bit different, and the suggestions given by EBM systems don't apply to that specific patient. What we have to do with big data is to capture contextual information and take that into account in the analysis. Then the suggestions to the healthcare provider will be much more accurate, and the systems and ultimately the decisions we suggest will be better accepted by doctors and healthcare providers.

Which "V" of big data (volume, velocity, variety, veracity, value) do you think is the biggest challenge for healthcare and why?

All of them are a challenge. Volume and velocity are somewhat interdependent; velocity is a challenge, because of the huge data volumes, and speed has always been a challenge for any application used by healthcare providers.

Variety is a challenge, because we want to combine multiple sources of information into a comprehensible view on the patient's record. By definition you will need some semantic alignment of the different sources. This is a problem, because different systems use different ways to store data, and have different standards. This can be overcome, but the semantic underpinning of these standards is still something to be worked on.

Which attribute has the greatest potential for improving healthcare delivery if the challenges can be overcome?

I think variety has the biggest challenge and the biggest potential. Semantic technology can mitigate this variety. Ultimately it will give the doctor a complete view of the patient records, the electronic health record (EHR), which is the life-long capture of the clinical data of a patient. This is needed to organise integrated care. To me integrated care is the ultimate thing we need in healthcare - organisation across stakeholders, including the patient. It is not only curing diseases, but also preventive medicine etc. Unless we have this global view on the data, we will not get there, but if we get there, and we can cope with this variety, it will enable EHRs and integrated care, which is what we really need in healthcare.

What skills will healthcare IT professionals need for big data?

Healthcare IT professionals should have skills to deal with semantic technologies, standards, vocabularies, terminologies etc., knowledge of clinical data exchange standards and knowledge of patient big data tools, such as databases. They will need to be familiar with more analytical tools, that go beyond the classical dashboard to tools that really let people explore data. They also need medical knowledge. I think IT work will be more and more generic, and the specificity of applications will come from the data and the formalised context. Understanding this context will be very important for anybody in healthcare IT.

Who do you feel should drive the semantic angle?

It is a slow process. Companies do not commit to standards when they are not globally accepted. On the other hand, something is only accepted when companies have made real-life implementations. So this is a chicken-egg situation. We all have to work on it, and

authorities could, for example, say, "In the next five years we will expect any vendor or hospital information system to be able to exchange data in this format". We see less appetite for proprietary standards and more openness, but authorities could maybe enforce it more.

Medical technology is continuously improving, but healthcare systems adopt technology at different rates. Will this help or hinder the sharing of big data?

The slow IT adoption in hospitals so far will not help the sharing of big data. We have the technologies, but many are only sparsely implemented. There is still a psychological barrier to sharing clinical data at all, even anonymised. We have to prove, with good news and success stories, that there is additional value in it.

How is the ideal model for cross-border cooperation of big data architects and archives?

Scalability on an international level can only be achieved by ending established approaches. For example, what I would call "All the knowledge is contained here": there are still people trying to put everything in one computer, so they feel safe and in control. This is not sustainable: we have to move to distributed systems, which allow you to collect the necessary data just in time and fit for purpose. Otherwise we will never achieve the scalability we need on an international, cross-border level. No single database structure, whether it is big data or not, will fulfil the needs of all applications. An operational system storing data in its own local database should be able to fulfil data requests from authorised applications externally. We should have a kind of ad-hoc accessibility of data. For example, "I need data, I know where to find it, I perform this request, I assemble my dataset for analysis for instance, and I don't count on the fact that I have this already on my computer, because I cannot have the whole world on my computer." This is a fundamental change we have to work on. I'm not saying that technologically everything is solved here, but I am sure we cannot solve scalability on an international level by putting everything on one big database. We have to work on distributed systems.

In the future we will need some smart agents that work as brokers for people who need data and don't know where to find it. There will be broker services alongside security services and real data access services, and they will have to collaborate. Instead of having one application doing all, there will be some kind of collaboration or choreography of these different services working like one system, so the computer will be the network.

Patients are increasingly empowered to be active participants in their care through mobile technology and remote monitoring. Do you see any downsides?

There are downsides, but they probably do not outweigh the benefits. If the patient is part of the whole ecosystem, the data coming from the patient is unsure and not controlled, so people may doubt the value of this data.

Another concern is where the balance is between supporting the healthcare IT environment and "Big Brother". If you connect to the patient's room you can capture data from sensors etc., but then we are close to a "Big Brother" that is controlling everything. We will have to find the right balance there.

The informed patient is not a downside, and health professionals will have to change roles, and be guides in the patient's healthcare.

What can healthcare learn from other industries about the potential of big data?

If I buy something on the Internet, I can see what others have bought. The motivation is commercial, but it brings additional value to the customer. We can translate that to healthcare. Imagine a doctor seeking the best treatment for his patient: the system looks at the data, and presents a list of patients with the same symptoms, the treatments that were applied to these patients and the outcomes. This could help the doctor adapt the treatment if necessary. There are limits to what you can do, but having more information is always a great advantage.

What role will Agfa play here?

At Agfa Healthcare we have a close connection with our customers. We are very aware that healthcare is going towards integrated care. For integrated care, you need EHR that combine data from multiple sources, and you need EBM, looking at and analysing the data. Solutions for integrated care encompass all these technologies from big data, big data analytics and decision support. This will be core for Agfa Healthcare, and we are well placed, because we are so close to the data. ■

For further information contact

Dirk Colaert
Chief Medical Officer
Agfa HealthCare
Septestraat 27; B-2640
Mortsel, Belgium
T +32 3444 8408
Email: dirk.colaert@agfa.com

NOTE:

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Key Points

- The brain itself is "big data": coordinated systems, which continually process and produce voluminous information.
- Alzheimer's Disease and other forms of dementia disrupt neural systems with devastating consequences. Fortunately, big data can offer preventive, diagnostic and therapeutic healthcare solutions.
- A number of projects around the world are being coordinated for dementia research.
- Open data that can be safely shared across borders will facilitate research success.
- New models are needed for new insights.

from a large sample size and zoom in on specific data that can only be found in more targeted projects. If structured to promote open access and sharing, the data will allow scientists to ask and answer big questions, according to Dr. Craig Ritchie of Imperial College London (ICL)'s Department of Medicine, a member of the UKDP steering committee. "It will enable the research community to move seamlessly between different levels of data, which simply could not happen if we worked in our own separate research groups and areas" (Davenport 2014).

UK Biobank

By far the biggest project contributing data to the UKDP is the UK Biobank, which is amassing health data on 500,000 people in the UK. The vast and varied collection of open-access data, and the longitudinal nature of the project, will be valuable not only for dementia research but for population health in general. Its Imaging Working Group is chaired by Professor Paul Matthews, head of the Division of Brain Sciences in ICL's Department of Medicine. In May, the group began to collect imaging data from participants at one of its centres, with the goal of performing 18 full sets of brain, heart, bone and blood vessel scans per day for up to 100,000 study participants. The imaging information will powerfully supplement observational data within the Biobank. The team includes experts whose responsibility it is to ensure that the variety of scans comply with protocols and can be stored and shared appropriately.

Neuroimaging in AD is of critical importance. With structural evidence of dementia most apparent in later stages of the disease, single MRI scans are not the most helpful tool on the table. Functional MRI measures changes in blood flow over time, giving analysts greater insight into neural activity and anomalies. However, it is data-intensive: a patient's 20-minute scanning session involves approximately 15,000 voxels per 3D scan, and each voxel examining hundreds of thousands of neurons. It is also time-intensive, requiring manual processing of the scans. An innovative solution for automating fMRI-based methods would improve early detection (OECD 2013a).

Additional value will come from being able to identify which types of markers coincide with dementia onset. The expression of cognitive decline can be indicative of damage already done in the brain, prohibiting the impact of late-stage interventions. Perhaps because the causes and correlates of Alzheimer's Disease are not yet well understood, stubbornly mired in mystery by the neurobiological complexity of the human brain itself, pharmaceutical trials have thus far yielded disappointing results. Based on studies which compare brain imaging and biomarker profiles of people at high risk for developing the disease, some estimates indicate that slow, continuous neuronal deterioration may begin a decade before clinical symptoms appear. Thus, the real potential in opening data sets for sharing and innovation lies in learning how to prevent dementia in the first place.

"it will enable the research community to move seamlessly between different levels of data, which simply could not happen if we worked in our own separate research groups and areas"

Opportunities and Optimism

Despite the daunting task ahead, there is reason to be hopeful. G8 ministers have agreed that international cooperation can lead to innovative solutions to the multifaceted challenge of AD. With collaboration between countries increasing and new relationships developing between private and public partnerships, data sharing will reduce the risks and expenses of the dementia epidemic.

Professor Paul Matthews, who leads the Division of Brain Sciences at ICL, expressed optimism at the opportunities ahead for dementia research based on the capacity of scientists to capitalise on shared knowledge. "We are committed to this new scientific environment where open data creates a space for greater innovation and faster translation into treatment," Prof. Matthews said. In addition to its involvement with the UKDP, ICL recently launched the Imperial Data Science Institute, and hosts the Parkinson's Disease Society brain bank and the MRC-NIHR National Phenome Centre, all of which investigate aspects of dementia (Davenport 2014).

George Vradenburg of the Global CEO Initiative on Alzheimer's Disease addressed the public ahead of the OECD's Toronto event, noting that research funding for dementia lags behind that for other diseases such as cancer, heart disease and HIV-AIDS. One possible reason, he said, is that victims cannot speak for themselves and those who care for them are too exhausted to speak on their behalf. Nonetheless, Mr. Vradenburg is hopeful that a cure or treatment can come from continued and coordinated efforts, reminding the audience, "There wasn't any hope for an HIV-AIDS cure. There wasn't any hope for polio for a long period of time. There wasn't any hope for a lot of these diseases. But at some point people got sufficiently angry that there wasn't anything done that anger turned into mobilisation" (Grant 2014). ■

References

Alzheimer's News Today (2014) Big data: the newest tool in fighting Alzheimer's, dementia. Alzheimer's News Today, 18 September. [Accessed: 24 September 2014] Available from http://alzheimersnewstoday.com/2014/09/18/big-data-the-newest-tool-in-fighting-alzheimers-dementia/

Davenport F (2014) New developments in big, open access data for dementia. Imperial College London, 19 June. [Accessed: 6 October 2014] Available from http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/newssummary/news_18-6-2014-19-12-32

Grant K (2014) Using big data to fight dementia and Alzheimer's. The Globe and Mail, 15 September. [Accessed: 24 September 2014] Available from http://www.theglobeandmail.com/life/health-and-fitness/health/using-big-data-to-fight-dementia-and-alzheimers/article20612097

OECD (2013a) Addressing dementia: the OECD response. [Accessed: 18 October 2014] Available from: http://www.oecd.org/sti/addressing-dementia-the-oecd-response.pdf

OECD (2013b) Unlocking global collaboration to accelerate innovation for alzheimer's disease and dementia: expert consultation [Accessed: 7 October 2014] Available from: http://oe.cd/innovating-against-alzheimers

OECD (2014) Unleashing the power of big data for Alzheimer's disease and dementia research: main points of the OECD expert consultation on unlocking global collaboration to accelerate innovation for alzheimer's disease and dementia, OECD Digital Economy Papers, No. 233, OECD Publishing. [Accessed: 1 October 2014] Available from: http://dx.doi.org/10.1787/5jz73kvmvbwb-en

Ontario Brain Institute (2014) Addressing dementia research and care: Can big data help? OBI, 12 September. [Accessed: 24 September 2014] Available from: http:/www.longwoods.com/newsdetail/4512

Oxford Internet Institute (2014) Big data for advancing dementia research. [Accessed: 6 October 2014] Available from http://bigdatadementia.oii.ox.ac.uk

EUROPEAN SOCIETY OF NEURORADIOLOGY

INTERVIEW WITH PROFESSOR MAJDA THURNHER, PRESIDENT

As the newly installed President of the European Society of Neuroradiology (ESNR), what are your goals for your term of office?

The ESNR is a professional society with more than 3,000 members. A strategic plan and mission for the ESNR was initiated a few years ago. Under my presidency we will expand, improve and update this concept. The ESNR will continue to invest heavily in education, work on a comprehensive European Curriculum for Neuroradiology, and establish standards for neuroradiological knowledge and training in Europe.

What led you to specialise in neuroradiology?

I was interested in neurological sciences already as a medical student, and my first published article was on new therapies in multiple sclerosis. One year as a neurology resident at the University Hospital in Zurich was a great experience, and I had a chance to work with great scientists and clinicians. After completing residency in radiology at the University Hospital Vienna it was more than clear that neuroradiology is my "big love".

Do you see a role for PET/MR in brain imaging?

PET-MR will have a role in evaluation of brain disorders, especially in dementia, stroke, and neurodegenerative disorders.

The ESNR produced a booklet for the 2014 International Day of Radiology (IDoR), looking at the role of radiology in brain tumour, stroke, Alzheimer's disease and dementia, Parkinson's disease, and multiple sclerosis. Do you think neuroradiology is sufficiently recognised?

In the past a radiologist was a person sitting in a dark room looking at plain films, not being involved in patient management. This picture rapidly changed with the introduction of CT and MRI a few decades ago. Nowadays, a radiologist is an important part of clinical boards (tumour board, vascular board), and is heavily involved in the patient´s management. In the IDoR booklet for the general public we have tried to explain who a neuroradiologist is. It is still not broadly acknowledged that a neuroradiologist is not only a specialist trained in performing CT and MR imaging, but also in performing therapeutic procedures in the brain and spine.

There are still many unknowns when it comes to the brain. What has been the greatest breakthrough for neuroradiology, and what research has the greatest promise for the future?

The brain is a fascinating, very well organised organ, but we still don't know enough to understand its functions and subsequently different brain diseases. The first important neuroradiological breakthrough was the discovery of MR; the second was the implementation of the high-field MR units (3.0 T) into the clinical routine. With new MR sequences, we see more anatomical details, we are able to look at the white matter tracts (diffusion tensor imaging [DTI]), at the vasculature (magnetic resonance angiography [MRA], susceptibility weighted imaging [SWI]), brain perfusion, and metabolic peaks in the brain parenchyma.

In the future, interdisciplinary research with all disciplines of neurosciences will be necessary to answer open questions. Ongoing research focusing on multiple sclerosis, healthy ageing and dementia (Alzheimer's disease), neurodegenerative disorders (Parkinson's disease and others) and brain tumours, will continue to improve our knowledge and understanding of brain diseases. ■

"interdisciplinary research with all disciplines of neurosciences will be necessary to answer open questions"

Prof. Majda Thurnher

President, European Society of Neuroradiology

University Clinic for Radiology and Nuclear Medicine
Medical University of Vienna, Austria

majda.thurnher@meduniwien.ac.at

www.esnr.org

PSYCHIATRIC DRUG DEVELOPMENT

A DRY PIPELINE ?

Samna Ghani

Americas Region editor, HealthManagement
sg@healthmanagement.org

Nearly one in five Americans takes at least one psychiatric drug (Medco 2011). Twenty-five percent of Americans suffer from a diagnosable mental illness in a given year (Kaplan 2013). Mental disorders continue to plague people around the globe, and mental illness is a leading cause of impairment and disability across the globe (Greenberg 2013).

However, innovative medications for the treatment of depression, bipolar disorders, schizophrenia and other psychotic disorders are in serious decline. Over the last few years, the pharmaceutical industry has reduced its investment in psychiatric drug development. Big names like GlaxoSmithKline have actually closed down their entire psychiatric laboratories. Others, such as Pfizer and AstraZeneca, have reduced the size of their research programme and/or have closed down their internal research altogether (Hyman 2013).

While the Obama Administration has announced its BRAIN initiative, and the National Institute of Medical Health (NIMH) also promised to renew its efforts to stimulate research on the neurocircuitry of mental disorder, there is nothing significant to report on this front, and the psychiatric drug development pipeline remains relatively dry (Greenberg 2013).

Why Is The Industry Retreating?

The question that arises is this: why are pharmaceutical companies retreating from this particular segment despite the fact that there is clearly an unmet need and there are numerous individuals out there who are struggling with mental disorders, and who remain symptomatic due to ineffective therapeutic options? Despite the fact that this product category is among the most profitable, why are industry leaders closing down their investment and instead diverting their funds into cancer, metabolism, autoimmunity and other disease areas? (Hyman 2013)

The most glaring reason for this retreat is that companies believe that therapeutic development in psychiatry is risky, time-consuming and difficult. They fear that the underlying science for psychiatric drug development remains immature and the path to understanding the very nature of mental disorders is too daunting. That is because most psychiatric disorders are too complicated to understand; their molecular and cellular underpinnings remain unknown and psychiatric diagnoses still remains arbitrary (Hyman 2013).

For companies operating with the goal of earning profits, discovering and developing novel and effective treatments for mental disorders just does not seem the right strategy. The process of drug development is not only time intensive, but it also costs a significant amount of money. It is estimated that the cost to develop a drug (including the cost of any failures) is approximately $1.5 to $2 billion. In addition, according to estimates by the Pharmaceutical Research and Manufacturers of America, it takes an average of ten to fifteen years for a new drug to actually complete the cycle from initial discovery to being available in the market (Kaplan 2013).

No Major Breakthroughs

If one examines drug development in psychiatry, it is evident that most drug development efforts have relied on the recycling of old drugs. Since the 1950s, the primary molecular action of all antidepressants, antianxiety drugs and antipsychotic drugs remains the same. The first antidepressant, imipramine, which was discovered in 1957, altered the serotonin or norepinephrine levels in the brain. The antidepressants that are available today have the same mode of action. Antipsychotic drugs, both old and current, block dopamine D2 receptors (Hyman 2013). The entire psychiatric drug category comprises of "me too" drugs. There are six SSRI antidepressants and ten atypical antipsychotic drugs that perform the same function (Friedman 2013).

In addition, the efficacy level of these drugs has not changed significantly for many years. Whether you use imipramine or a more recent antidepressant, there is no dramatic change in efficacy. Apart from clozapine, all antipsychotic drugs have the same efficacy as chlorpromazine (Hyman 2013). While the drugs may have improved in terms of their safety and tolerability, as far as efficacy is concerned, it seems that goal has somehow become unachievable.

According to Robert H. Lenox, MD, Professor of Pharmacology and Clinical Neuroscience at the University of New England College Of Osteopathic Medicine, the frequency of drug failures in the central nervous system segment is particularly high. Drug candidates entering into Phase III can fail at a rate of 40 to 50 percent. In most cases, the cause of failure is lack of efficacy (Kaplan 2013).

Reasons For The Chronic Shortfall

So where are the breakthrough drugs? Where is that novel treatment that everyone is waiting for? What is the reason for this chronic shortfall in psychiatric drug development?

There are many factors at play here. The central nervous system is excessively complex. The preclinical models of psychiatric disorders are unsatisfactory. Diagnosis of psychiatric

disorders is mainly based on subjective assessments. Disorders like depression have complex aetiology, and large-scale clinical trials of psychiatric drugs have not shown any promising results. How is the industry expected to invest its resources in a segment with so many complications? If one evaluates the point of view of the drug companies, one would realise that they are not entirely to blame. They have spent decades in research and have invested billions of dollars, but have yet to discover a single novel drug within the last thirty years (Fibiger 2012).

Possible Solutions

What the pharmaceutical industry needs is a new paradigm. As Lenox points out, "there is a dearth of valid new targets and novel drug candidates. Pharmaceutical companies often compete on the same poorly validated targets, wasting time and resources in the absence of early stage sharing of lead compounds and data . . . this is unsustainable as a business model" (Kaplan 2013).

What the industry needs to do is to rethink the process of drug discovery in this particular segment. They need to review the type of preclinical models and the classification and selection of patients in clinical trials. They need to make efforts to integrate advances in molecular, cellular and systems level knowledge of psychiatric disorders. Only then could there be any hope for the revitalisation of drug discovery in psychiatry (Psychiatric drug discovery on the couch 2007).

The above discussion in no way gives pharmaceutical companies a free pass as far as the process of drug discovery in psychiatry is concerned. In fact, some believe that it is the big companies who are primarily responsible for this crisis. According to Richard Friedman, MD, a Cornell psychiatrist, "The pharmaceutical industry is making a mistake, by running away from the brain just when things are getting interesting" (Friedman 2013).

However, it is not smart to place the entire weight of drug discovery on pharmaceutical companies. This is mainly because they are driven by profit motives. They are afraid to take financial risks, especially in a category that is significantly complex. However, academic researchers do not have the same fears. They are free to experiment and to take risks. That is why programmes like the Brain Activity Map (Alivisatos et al. 2012) and gene-sequencing technology can help identify genes and circuits that could be linked to mental disorders. If such connections are made, it would be easier to identify new targets for drugs, and would eventually motivate pharmaceutical companies to reinvest in drug development in psychiatry (Friedman 2013).

If innovation is to be achieved, then changes in psychiatry also need to take place, in both the preclinical and clinical domains. Rational drug design for psychiatric diseases can only be achieved if there is more investment in neuroscience. Academic researchers and scientists need to become involved.

Conclusion

Knowledge is the basic ingredient for any drug development process. A perfect example is cancer. Drug development and advancement in cancer was driven by a greater biological understanding of the disease. The same is true for psychiatric disorders. More information is needed about delusions, hallucinations and negative symptoms and more emphasis should be placed on fundamental research.

There needs to be a greater understanding of the psychological, cognitive and behavioural aspects of specific disorders. Knowledge about specific brain circuits and their role should be increased and this knowledge should then be linked to clinical phenomena. What is needed is an acceptance of the fact that the medical world is still quite ignorant about the disorders of the central nervous system. Once this fact is acknowledged, measures can be taken to overcome this ignorance and invest in neuroscience research, which will essentially lead to drug development and therapeutic advancement (Fibiger 2012).

All is not lost, however. A latest report by the Analysis Group highlights that there are potential new medicines in the global pipeline and there are some psychiatry drugs in the preclinical stage. The search for a "blockbuster drug" is being replaced with finding "niche buster drugs" (Kaplan 2013). Hopefully, a change in approach and more specific targeting will start a new phase in psychiatric drug development. ■

Key Points

- Psychiatric drugs are among the most profitable products for the pharmaceutical industry.
- Despite this, investment in psychiatric drug development continues to decline.
- A major reason may be the fact that there has been no major breakthrough in this area of drug development for the last thirty years.
- Several "me-too" products have been launched, but the primary molecular action of psychiatric drugs remains the same since the first discovery of imipramine in the 1950s.

References

Alivisatos PA. et al. (2012) The brain activity map project and the challenge of functional connectomics. Neuron, 74(6): 970-4. [Accessed: 24 October 2014] Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3597383/

Fibiger CH (2012) Psychiatry, the pharmaceutical industry and the road to better therapeutics. Schizophr Bull, 38(4): 649-50.

Friedman RA (2013) A dry pipeline for psychiatric drugs. New York Times, 19 Aug. [Accessed: 24 October 2014] Available from: http://www.nytimes.com/2013/08/20/health/a-dry-pipeline-for-psychiatric-drugs.html

Greenberg G (2013) The psychiatric drug crisis. New Yorker, 3 Sep. [Accessed: 24 October 2014] Available from: http://www.newyorker.com/tech/elements/the-psychiatric-drug-crisis

Hyman S (2013) Psychiatric drug development: diagnosing a crisis. Cerebrum, Mar-Apr: 5. . [Accessed: 24 October 2014] Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3662213/

Kaplan A (2013) Psychiatric drug pipeline. Psychiatric Times, 7 Oct. [Accessed: 24 October 2014] Available from: http://www.psychiatrictimes.com/psychopharmacology/psychiatric-drug-pipeline

Medco Health Solutions Inc. America's State of Mind. A Report by Medco Health Solutions. (2011). [Accessed: 24 October 2014] Available from: http://apps.who.int/medicinedocs/documents/s19032en/s19032en.pdf

Psychiatric drug discovery on the couch. (2007) Nat Rev Drug Discov, 6(3):171.

Honeywell

UZ Leuven improves patient safety with bedside terminals and 2D scanning of medicines

Largest University Hospital in Belgium

Founded 75 years ago, UZ Leuven is the largest hospital in Belgium with some 2,035 beds. It provides high quality medical and paramedical services to ambulant and hospitalized patients in five campuses in the Leuven area. Every day over 8,800 employees and medical professionals provide diverse and specialized patient care. As a leading university medical centre UZ Leuven seeks to maintain and further develop its dominant position by continually improving its quality of care. The essence of the hospital's philosophy is always to work for better and safer patient care. UZ Leuven has put this into practice by gaining accreditation from the internationally recognized Joint Commission International (JCI).

The Business Challenge

Optimizing patient care and patient safety are at the heart of the hospital's mission. Considering the scale its operation, this requires not only advanced medical practice, but also accurate logistics and foolproof systems to ensure that the right information, resources and people are in the right place at the right time. The hospital's IT-department deploys over a 100 IT specialists, of whom 50 are developers working on its proprietary Hospital Information System. When the nurse call system needed replacing some years ago, it prompted the IT department to seek a single technology platform that would enhance patient care and safety. After extensive investigation and evaluation, UZ Leuven decided in 2010 to equip all 2.035 beds with multifunctional bedside terminals. These touch screen terminals give staff access to the Hospital Information System and offer communication and infotainment to each patient. The system also allows for real time tracking of medicines by using a 2D scanner. This innovative concept and the quality-driven culture of UZ Leuven were key to its attaining the internationally acknowledged JCI accreditation in July 2012.

Overview:

Client: UZ Leuven

Country: Belgium

Market: Healthcare

Partner: Nextel

Product Solutions: Honeywell Xenon1m 1900 2D Healthcare version

Greater Personal Care with Reduced Workload

Making sure that each patient receives care and attention is the core objective for nursing staff at the hospital. However, this can be a challenge to deliver while also having to run tight schedules and maintain correct protocols and procedures. Now more personal care can be given to each patient because the tracking of medicines is handled simply by scanning the barcode on the patient's bracelet and a 2D label on their medicine. The Hospital Information System processes the data in real time and an audio alert will automatically warn if an incorrect dose or the wrong medicine is dispensed. This prevents mistakes and ensures seamless and efficient administration. With 2,000 patients receiving multiple medicines three times a day, the system handles an average of 20,000 scans every day.

Seamless Integration

The bedside terminal system was developed and implemented by the Belgian Telecom integrator Nextel. Together with Televic, who developed high-tech communication systems for niche markets like conference systems, nurse call systems or on-board passenger systems, and Lincor, which offers the MEDIvista bedside terminal solution, they tailored the solution to UZ Leuven's needs. The seamless integration of the Honeywell Xenon™ 1900h into their solution made the IT department of UZ Leuven's choice a simple one.

Patient Safety

The Xenon™ 1900h used at UZ Leuven is specifically designed for healthcare environments. The dense population of hospitals and the concentration of infectious diseases, require a strict hospital cleaning policy. Therefore, the scanners come with a disinfectant-ready housing that is resistant to the harsh cleaning chemicals that are applied to it several times a day. This ensures a prolonged product lifecycle despite the demanding environment. These 2D bar code scanners are aimed at the point-of-care, helping healthcare professionals to reduce errors related to bedside medication administration. The limited space on the label of medicines requires 2D scanning as this technology can include much more information than 1D scanning. In the near future, new applications for colour scanning will also be explored at UZ Leuven. With the ability to capture colour images, the Xenon 1900h Color can also support applications such as wound management and patient identification.

Key Benefits

- Effective contribution to patient safety
- Fast and accurate scanning of 1D, 2D, image and colour for future development
- Minimized risk of errors, while reducing the workload of the nursing staff
- Easy wireless handling of 20,000 scans per day
- Disinfectant-ready housing to prevent spreading of infectious diseases

Conclusion

"We are confident that the bedside terminals and the hand-held barcode scanners will drastically improve our patient care and patient safety. To implement this in a fully operational hospital without disrupting key processes or inconveniencing our staff and patients takes several months. Eventually we plan to have all the beds equipped with the new solution", says Reinoud Reynders, IT-manager infrastructure & operations of UZ Leuven. "As we have pioneered and developed the complete information system (KWS) of the electronic patient files that is now being used by a group of hospitals called Nexuz Health, this information-based solution might spread to a total of 6,000 beds in the years to come", concludes André de Deurwaarder, Senior IT Architect of UZ Leuven.

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LEADERSHIP OF STAFF

25 YEARS OF EXPERIENCE

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Medical Centre Director
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Senior Consultant
Department of Radiology, Neuroradiology, Sonography and Nuclear Medicine ('Imaging Centre')
Krankenhaus der Barmherzigen Brüder
Trier, Germany

Senior managers must prepare their organisation for tomorrow's world, in which the quality of the results of holistically designed meta-processes counts. Their remit goes far beyond achieving successful daily management structures, and demands a new set of qualities. These include the capacity to envision future scenarios and be answerable for their implementation. This means exploring unknown territory and confronting new challenges, and such endeavours can only be successful where senior managers can be sure of their ability to take the whole team with them. Pioneers in a competitive environment must be able to rely on the confidence of those they lead. They cannot fall back on any shining examples from the past, for by the time such patterns have established themselves, the competitive lead has already been used up.

The quality and quantity of suitable members of staff, together with their motivation to devote their skills to their organisation, is a decisive factor that determines the difference between success and failure. Senior management, as the driving force that forms the future and greatly influences the working atmosphere through ideas and example, carry personal responsibility for successful development of an organisation, and this cannot be delegated. They must have clear visions and aims, and pursue these consistently with empathy, enthusiasm and the trust of their employees.

Medical and Service Quality and Cost-Effectiveness

Senior management is not required or paid to paint dramatic pictures of current and future problems, but to achieve success within given framework conditions (e.g. health funding, local circumstances, suitability of senior staff).

The current health system demands continuous optimisation of treatment processes and measurable and verifiable success in the areas of medical quality, service quality, economic viability, staff loyalty and staff recruitment. This 'culture of continuous change' challenges senior management in terms of their thinking and their actions.

The physician, as a professional, is free to determine therapies, which may include treatment whose costs cannot be recovered. However, daily compromises in medical, care and administrative dealings are necessary. Unfortunately, the question is not: "What financial resources do I need in order to achieve optimal quality of treatment?", but "How can I achieve the highest possible quality level with the existing resources, obtained either by allocation or through defrayment of costs?" The physician must earn freedom

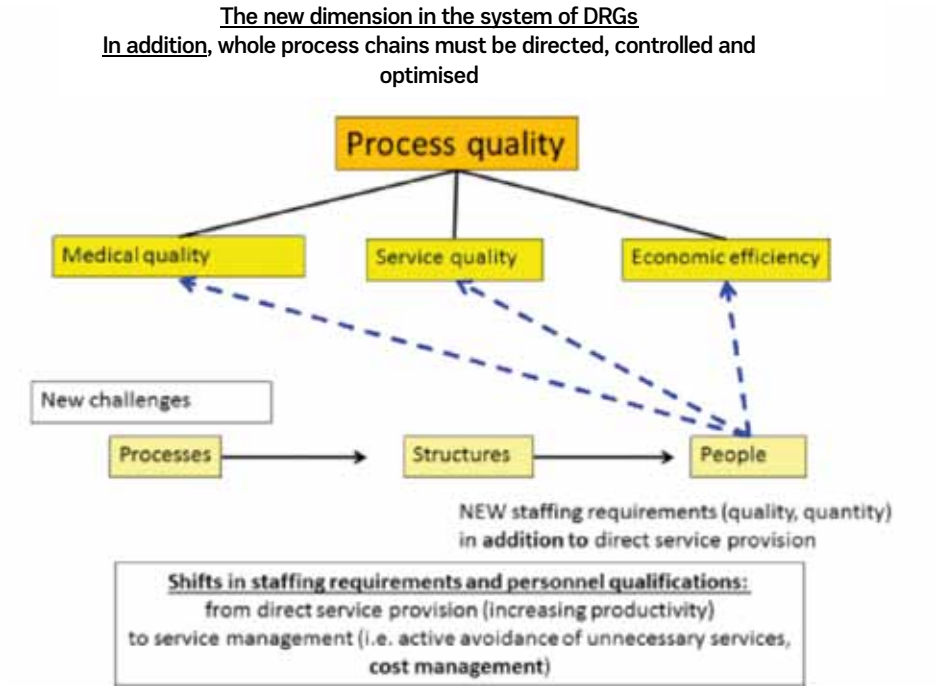


Figure 1.
Process Quality — the New Dimension in Optimisation

in choice of therapy through good housekeeping. It remains a matter of existential importance for a practice or a clinic that costs across the board remain significantly below earnings.

Where are the economic reserves that can increase the degree of therapeutic choice? The answer is to some extent in optimising or re-engineering the processes and structures, and in promoting staff development. Such a strategy will help to achieve an advantageous position in the face of competition, but it will not compensate for all the problems and failings of the health system.

In the context of cost and performance competition, with a guarantee of quality, economic reserves can be mobilised by increasing the efficiency of individual performance items (e.g. more cost-effective examinations with the same quality level), and in hospitals additionally by increasing effectiveness (e.g. by posing questions concerning the medical need for individual items) — in other words, increasing quality levels in interdepartmental, overall treatment processes from admission to discharge. The main thrust of the optimisation should not aim at working more quickly or with greater throughput within the existing structures and procedures, but to develop and work within new structures and procedures. Therefore motivation and reward systems are not concentrated on performance quantity, but on process quality, including the avoidance of medically unnecessary individual items. To date, the consequence of actively avoiding unnecessary individual performance items has been loss of income for practices. In hospitals, despite the advantages for patients and cost savings where diagnostic-related groups (DRG) are applied, the consequence has been job losses. Increasing performance quantity rather than increasing performance and process quality in order to preserve jobs makes for a false incentive.

Staff – the Most Important Factor

The viability of a practice or hospital may be endangered by a lack of medical and service quality, by economic deficits, or by a lack of suitably qualified staff. Anyone who experiences the large number of unsuitable applicants for today's jobs can rest assured that even these applicants will find a position in another clinic or practice that is struggling to survive, and that is liable to become a vicious circle for such organisations. Finding and keeping suitable staff is one of the most important tasks of all members of senior management, irrespective of how unsuitable the framework conditions may be. Competition to obtain qualified and motivated members of staff is fierce.

The parameters of the 'DRG world' require senior management to be prepared to change. Many of the traditional processes and prerogatives that went with the optimisation of (personal) 'operative islands', and may have been sensible as such, will have to be abandoned in the coming world of 'optimisation of overall processes'. The prerequisites of the DRG world are thinking and acting in overall, interdepartmental processes from admission to discharge with a view to optimisation (medical quality, service quality, cost-effectiveness).

Staff members are central to successful development on the basis of their specialist qualifications and their desire, ability and remit to optimise processes and structures, and take on new tasks, roles and responsibilities, thereby making their contribution towards a quality offensive that will secure the survival of the hospital.

An important aspect in the competition to find good staff is the need to combine optimised structures and procedures (medical quality, service quality, economic viability) with improved working conditions (quality of life!) in a way that can be appreciated by the staff. This represents a new challenge.

Capable employees (e.g. qualified specialists) can choose more or less freely where they wish to work. The market conditions that force hospitals actively to entice people by offering clear advantages in terms of working and living conditions (work-life balance) place new demands on the personnel department, the hospital's executive direction, senior management and all staff.

When working conditions are poor, those who have the most attractive alternatives and who take them first are the best members of staff. Good employees tend to attract more good ones; poor employees ...

Both patients and job applicants perceive the quality of the work atmosphere directly, and either stay, or, if they have a suitable alternative, go.

"pioneers in a competitive environment must be able to rely on the confidence of those they lead"

When times are good, it is relatively easy to provide for a good work atmosphere; when they are not, this becomes a vital task for senior management. If senior managers maintain: "We can't do that under these conditions," that is an inadequate and unprofessional response. What is needed are managers who can truly lead, spread optimism and create a positive working atmosphere that is oriented towards change. Only those senior staff who don't spend too much time complaining, who can accept the challenges and the framework conditions associated with them, work towards strategic development in a positive, internal atmosphere of change, and thereby motivate qualified employees with their enthusiasm will enjoy success. This is not just some airy vision for the future, but a necessary precondition to ensure viability.

COMPETENCE	CRITERIA
Methodological knowledge of the way the social and health markets are developing	• Basic knowledge of business economics (at least the terminology) • Knowledge of personnel management • Knowledge of quality management (QM) • Knowledge of personnel development (PD) • Knowledge of organisation development (OD) • Project management • Process management • Strategy development • Methodological competence in analysis (SWOT analysis, market analysis, surveys) • Change management
Strategic	• Capacity to be visionary • Strategy development, conceptual future planning • Understanding of systems • Analytical competence • Capacity to focus on targets • Ability to grasp complexity and reduce it
Social	• Communication skills • Ability to cooperate • Ability to achieve consensus • Willingness to address conflicts • Ability to persuade • Forward thinking • Empathetic skills • Gregariousness • Capacity to reach decisions • Self reflection and self direction • Capacity always to seek and find opportunities and need for action to improve a situation in oneself in the first instance

Table 1.
Requirements for Medical Staff (Social Competence / Management Competence)

Source: Busch 2008

Senior Staff Requirements

Senior managers in a hospital must:

1. Recognise the need for change in processes and structures.
2. Create a change-friendly atmosphere.
3. By means of professional change management and suitable staff development programmes, empower senior staff and other employees to support such change and form the future themselves at the same time.

To achieve this, it is necessary to engage in a systematic process of developing one's own methodological, social and management competence (see table, p. 27). Often there is a lack of methodological competence and experience concerning systematic and sustainable change management, of strategic competence to understand and reduce complexity and of the social competence always to start with oneself in analysing pathways towards improving situations.

Senior management that is used only to thinking within the defining limits of reservations and restrictive framework conditions tends to find the idea of unconditional 'brainstorming' about new forms of hospital organisation completely overwhelming. Often, a process of reawakening creativity amongst lateral thinkers must be initiated first.

Senior managers must render employees capable of dealing with change and prepared to do so.

Staff Development

Generally when top-level senior staff members (senior consultants, medical directors, commercial directors, care directors etc.) are appointed, they consider themselves already to have reached the end of their personal, systematic development of social and managerial competence. This is a pity, as there is often considerable room for useful further development of valuable resources: young senior consultants have often had management training, and there are more and more commercial directors with a medical background. Unfortunately, however, a new senior consultant is usually completely immersed in medical matters by his or her second day of work, and management training is soon forgotten. The assumption is that the new appointment is almost entirely a medical issue. Good management skills are simply expected, somehow, and questions are only asked if there are very obvious negative developments. Then individual consultants are sent to attend senior staff training courses, which are sometimes very good; the consultant comes back full of new ideas. These ideas are viewed with scepticism by the 'boss' and other staff members, with reactions ranging from incomprehension to fear of having to abandon established privileges and procedures. The consultant may wish to improve things, be able to do so, but is then thwarted by not being allowed to. After a short time the ideas go under in the daily routine; the procedures and mindsets remain just as they were before the workshop. The consequences of unsystematic and unsustainable staff development are frustration and loss of motivation to work to the future on the part of all concerned.

In practice staff development is greatly influenced by the examples set by senior managers. In time each senior member of staff is surrounded by employees who he or she has selected and promoted (or 'deserves' as the case may be). ("The apple doesn't fall far from the tree.") However, staff development is not only a 'top down' process, but also takes place from the 'bottom up'. Employees need to persuade their superiors of their own capacities and ideas, and establish personal win-win constellations.

Developing Leadership Skills

There is often a discrepancy between the specialised skills of physicians, care workers and administrators and their leadership skills, albeit such tasks are often allotted to them (by 'recommendation' or 'promotion') as a 'reward' for good work in their areas of expertise. Then, after some time, managers and/or senior members of staff notice that the person concerned is unable to fulfil the new tasks with the desired level of quality, quality of life and motivation. Such situations often arise where those concerned were not sufficiently informed or aware of the requirements in advance and their capabilities and suitability

for the job have not been correctly assessed. There is a world of difference between successful practice as a surgeon working with individual patients and the task of managing a large surgical organ centre, between a consultant's work in the 'sheltered' environment of a hospital and maintaining a practice in competition with commercial enterprises, as well as between successful work in a payroll accounting department and running a modern personnel management centre in a hospital or group of practices. All these positions require specific sets of personal skills, knowledge and experience.

Leadership is more than simply good administration of daily tasks. "Leadership is action, not position" (Donald McGannon, U.S. broadcasting industry executive). Promotion to a new position will not automatically make a good senior consultant manager out of an excellent clinician, nor a good commercial director out of a skilled administrator.

Employees often receive insufficient preparation for senior management tasks. The tension between what is desirable, what is possible and what is allowed generally has left insufficient space for developing social and management skills in parallel with or at least subsequent to medical excellence. The technicalities of the job are, to a certain extent, just a question of learning, whereas traits such as powers of persuasion and empathy tend to extend from a person's basic personality.

Many promoted or supported people fail to devote enough time to critical reflection of their own condition before taking on senior posts. The important questions are: Am I capable of taking on this position — and do I really want to? Have I thought through the consequences for myself, my family and for the organisation? In many cases, it turns out that one's definition of one's own role and the requirements profile of the job are not congruent. From the medical point of view, the following questions arise: Do I want to take on the task of a successful manager in addition to — or perhaps instead of — my job as a successful physician? Am I capable of fulfiling the tasks of a 'conductor' with empathy? The conductor is not the best soloist, but has to be the best team leader, and his or her main responsibility is connected not with individual performance, but with the overall results delivered by the organisation, the team etc. Increased responsibility for results is generally associated with new demands, new problems and the need for more effort. These additional emotional and temporal resources must, at least to some extent, be supplied from the same pool from which one's private life is supplied.

> ***"what is needed - managers who can lead, spread optimism and create a positive working atmosphere oriented towards change"***

According to the 'Peter Principle' (named after Laurence J. Peter):
"In time, every post tends to be occupied by an employee who is incompetent to carry out its duties."
"Work is accomplished by those employees who have not yet reached their level of incompetence."
As a consequence he puts forward the idea that, in that case, it may make more sense to make efforts to avoid embarking on a career (Peter and Hull 1969).

In cases where critical analysis has shed light on serious deficiencies, senior managers and organisations are usually better served by an abrupt end to unpropitious circumstances than a long drawn out demise. So much the better if the person or persons affected can see the wisdom of such a course of action. In practice, however, attempts are often made to save a truly untenable situation (by means of coaching, for instance) for far too long.
"People are less susceptible to being changed than we think. Don't waste your time trying to inculcate something that nature left out. Rather try to extract what is already there. That's already difficult enough."
(Buckingham 1999)

Every organisation has examples of senior managers who, unfortunately, have been promoted beyond the area to which they are best suited. However, there are also examples of staff members who consciously and consistently refuse promotion to senior levels. For them, work tends more to be a means of earning money in order to satisfy their private needs and those of their families. Such an attitude should — and must — be respected, and there is no need to give it a negative image ("Doesn't want to have a successful career"). The organisation has a right to expect employees to place their knowledge and skills fully at its disposal during regular working hours. Any engagement that goes beyond this may be desirable, but it cannot be required. The issue of motivating staff in hospitals to high levels of performance represents one of the main challenges for senior managers. ■

References

Buckingham M, Coffman C (1999) First, break all the rules: what the world's greatest managers do differently. New York: Simon & Schuster.

Busch HP (2008) Management-Handbuch für Radiologen. Stuttgart: Thieme.

Peter LJ, Hull R (1969) The Peter principle. New York, W. Morrow, 1969.

CLINICAL LEADERSHIP AND THE CHALLENGE OF CHANGE

Dr. Áine Carroll

National Director
Clinical Strategy and
Programmes Division
Health Service Executive
Republic of Ireland

nationalcsp@hse.ie

Healthcare is one of the most hazardous industries in the world. A series of large studies and numerous high profile stories of harm and unnecessary death in the services we provide have shown that whilst modern medical advances have been remarkable, hospitals are often unsafe places for patients and staff alike.

It has been recognised for many years that having clinicians involved in managing our healthcare services results in improved efficiencies, effectiveness and improved outcomes for patients. The Kings Fund (2014) in the United Kingdom reported recently that organisations with engaged staff deliver better patient experiences, have fewer errors, lower infection and mortality rates, stronger financial management, higher staff morale and motivation, reduced stress levels and less absenteeism.

Internationally our healthcare systems are currently experiencing unprecedented challenges with constrained budgets, organisational restructuring, hospital centric models of care, workforce challenges and ever increasing demands on our healthcare services as a result of changing demographics (increase in the number of older persons) and chronic diseases (with co-morbidities).

Despite these challenges there are real opportunities to improve services for patients and staff through a partnership approach with clinicians, managers and of course, patients. In many areas we know the right thing to do, but we repeatedly see how difficult it is to do the right thing. Take for example hand washing. In the mid-1800s, Dr Ignaz Semmelweis was the first healthcare professional to demonstrate experimentally that hand washing could prevent infections. Did the healthcare establishment embrace his discovery and implement hand washing as a mandatory component of healthcare? It most certainly did not. About 5 years later he died in a public asylum at the age of 47 having been shunned and discredited by his colleagues.

So why is it so difficult to do the right thing? This question has been the subject of significant study for many years. Many techniques, models and theories have been developed over the years and mini industries have been established in the area of quality improvement. There are clearly risks with not implementing a proven methodology. However, there are also risks with seeking to implement different methodologies that can cause confusion among the very people you wish to implement the change. The million dollar question (often literally) now is 'which model or theory works best?' After the initial enthusiasm of trying something new, can the initial improvement be sustained independent of the initial champion? Unfortunately very often the answer is no.

"in many areas we know the right thing to do, but we repeatedly see how difficult it is to do the right thing"

As a pragmatist, I believe that there are a few simple steps that should be taken. Firstly, identify the aim of the project (often more difficult than it sounds); secondly ensure there is a mechanism of measurement ("In God we trust, everyone else must bring data": quote attributed to Deming) thirdly, use a standardised project management process and lastly, have an implementation plan that has been agreed with all key stakeholders.

In Ireland, we have been seeking to tackle this issue in a novel way. The National Clinical Programmes were initiated in 2010 under the leadership of Dr. Barry White, who was succeeded by me in 2012.

The aim of the programmes is to improve and standardise patient care regardless of geography, by bringing together clinical disciplines and enabling them to share innovative evidence-based solutions in the interest of better patient care.

Clinical leadership is at the core of the National Clinical Programmes. The experience of other health systems around the world has been that the involvement of clinicians in designing and leading improvements in patient care is essential. The core objectives of all the clinical programmes are to improve:

- The quality of care;
- Access to all services;
- Value for money and for the patient.

There are over 30 National Clinical Programmes tasked with improving specific areas within the health service. This is achieved by designing and specifying standardised models of care, guidelines, pathways and associated strategies for the delivery of clinical care. Examples include clinical programmes in Acute Medicine, Acute Surgery, Chronic Obstructive Pulmonary Disease (COPD), Diabetes, Emergency Medicine, Critical Care, Chronic Heart Disease, Stroke and many more.

Each of the Programmes has a Clinical Lead, a multidisciplinary

Working Group (including patient representatives) and a Clinical Advisory Group. The value of having a wide range of clinicians involved is two-fold. Firstly, it is likely that the proposed solutions will be more robust, and secondly will be accepted by colleagues at implementation.

These groups are further enhanced by additional collaboration and consultation with a range of significant stakeholders across the healthcare system.

Some of the achievements attributable to the National Clinical Programmes to date include:

- Reduction in average Length of Stay of medical patients from 8.5 days in 2010 to 6.9 days in 2013
- Increased surgical volume by 9.6% (2010 to 2012)
- Reduced surgical bed day usage by 9.1%. (2010 to 2012)
- The national stroke thrombolysis rate has increased from 3.3% in 2008 to 9.5% in 2012, one of the highest reported in developed countries.
- Access to national neonatal bi-directional inter-facility transfer and retrieval extended to a 24 hour seven day week service as set out in the National Clinical Programme for Transport Medicine Model of Care.
- Asthma clinical practice guidelines developed including Emergency Adult Asthma Guidelines and Emergency Paediatric Asthma Guidelines with a National Education programme now operational in primary and secondary care for asthma.
- Primary Percutaneous Coronary Intervention centers in operation nationally for patients experiencing acute coronary syndrome as set out in the Model of Care.
- 12 COPD Outreach Clinics fully operational, providing an "Early Supported Discharge" programme by a COPD Outreach multidisciplinary team for certain patients with Acute Exacerbations of COPD, that would otherwise require acute in-patient care.
- Identification of 'Preferred Drugs' with the potential to save €19m per annum by getting prescribers to change their prescribing patterns.
- A national model of care to deliver Continuous Subcutaneous Insulin Infusion therapy to children with type 1 diabetes under 5 years of age has been developed and implemented.
- 24 Musculoskeletal Advanced Practice Physiotherapists (6 per Health Service Executive region) in post which has resulted in over 18,000 referrals removed from Orthopaedic and Rheumatology outpatient waiting lists nationally in 2013

The learning over the past three years of the clinical programmes has emphasised the essential need to:

- Maintain and enhance clinical leadership;
- Develop clinical pathways that are truly patient-centred, and seamlessly cross organisational and professional boundaries;
- Align programme design with service priorities;
- Enhance evidence-base and performance and outcome measurement;
- Ensure structured and consistent implementation;
- Align with key enabling functions such as finance, human resources and information & communication technology.

Since their foundation, the National Clinical Programmes have been one of the most significant positive developments in the Irish Health Service. Their success is due to the close collaboration between the Health Service Executive (HSE) and the Medical Colleges, working in partnership with patients, nursing and health and social care professionals. The Programmes have changed and continue to change how care is delivered using evidence-based approaches to system reform.

According to Ronda Hughes (in Patient Safety and Quality: An Evidence-Based Handbook for Nurses: Vol. 3) quality improvement requires five essential elements for success: fostering and sustaining a culture of change and safety, developing and clarifying an understanding of the problem, involving key stakeholders, testing change strategies, continuous monitoring of performance and reporting of findings to sustain the change. The Clinical Programmes contain all of these essential elements.

"as clinicians and managers, finding ways to work together is fundamental to the provision of high quality patient care"

Conclusion

As clinicians and managers, finding ways to work together is fundamental to the provision of high quality patient care. We must learn to trust one another and appreciate the richness of skills and perceptions both parties bring to the partnership. Together, we are the stewards of healthcare and together, we have a shared responsibility to make it easy to do the right thing. I am very grateful to the many clinicians and managers who have had the courage to be involved in such a large change initiative. We have also been fortunate to have had ministerial and departmental support for our work. The benefit of having eager hearts and minds is clear and it is with a belief in the endless possibilities of change and a better future that we proceed in our endeavour.

As the poet John O'Donnell says so eloquently in his poem The Lucas Planet No. 33 (in memory of the poet Seamus Heaney) "The consolation that what's well-made endures, and shines on". ■

Key Points

- Having clinicians involved in management improves outcomes for patients and saves money.
- Partnerships between clinicians, professional organisations and managers has allowed spread of innovation at scale in Ireland.
- Clinicians and managers are together the stewards of healthcare.
- "What's well-made endures, and shines on".

References

Amalberti R, Auroy Y, Berwick D et al. (2005) Five system barriers to achieving ultrasafe health care. Ann Intern Med, 142(9):756-64.

Hughes RG, ed. (2008) Patient safety and quality: an evidence-based handbook for nurses. Rockville: Agency for Healthcare and Research Quality.

King's Fund (2014) Improving NHS care by engaging staff and devolving decision-making: report of the review of staff engagement and empowerment in the NHS. London: King's Fund. [Accessed: 5 November 2014] Available from http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/improving-nhs-care-by-engaging-staff-and-devolving-decision-making-jul14.pdf

O'Donnell J (2014) The Lucas planet no.33: in memoriam Seamus Heaney. RTE Radio Sunday Miscellany, 31 August. [Accessed: 5 November 2014] Available at http://www.rte.ie/radio1/sunday-miscellany/programmes/2014/0831/640107-sunday-miscellany-31-august-2014/?clipid=1664425

West MA, Dawson JF (2012) Employee engagement and NHS performance. [Accessed: 17 April 2012] Available from http://www.kingsfund.org.uk/sites/files/kf/employee-engagement-nhs-performance-west-dawson-leadership-review2012-paper.pdf

HEALTH – THE ECONOMIC GROWTH ENGINE OF THE 21ST CENTURY

Leo Nefiodow
Future Researcher

Simone Nefiodow
Scientific Officer / Publicist

Independent Scientists
Sankt Augustin
Germany

nefiodow@kondratieff.net

Is there a correlation between health and economic growth? Can the healthcare sector be an answer to the current weak economic growth in the leading industrial nations?

So far, the economic development of the industrialised nations has been disappointing during the 21st century. And the situation would be even worse, had the administrations not helped the economy by taking on enormous debt and had central banks not flooded the financial markets with practically interest-free money. The industrial nations are obviously not able to leverage their economies with the existing concepts.

The biggest barrier to economic growth is low productivity at the level of society as a whole. Too many resources are being lost on the societal level due to disorder, destructiveness and crime – due to the so-called entropic sector. Entropy is a term taken from physics that describes the disorder of a physical system. Here the term is used to demonstrate the global social disorder.

Disorder has become a worldwide mega problem for the global economy and a mega destructive market. Worldwide money laundering has increased twentyfold from 1990 until 2009 and had almost reached 2,000 billion US dollars (1,568 billion Euros). Corruption and bribery are at a record high all over the world and in 2013 caused at least five percent of all economic costs (4,000 billion US dollars / 3,137 billion Euros). Patent protection and copyrights are systematically being ignored or evaded. Piracy on the world's oceans is increasing, making global commerce more difficult and more expensive. Annual losses from environmental damage make up about 10 percent of the world´s gross national product. Cyber crime is growing by double-digits, computer virus attacks and counterattacks are increasing and have led to a new type of warfare, so-called cyber warfare between companies, institutions and countries. Millions of people all over the world work for illegal organisations (the number of Russians, who are active in criminal organisations is estimated at 300,000). During their lifetime, up to 70 percent of women all over the world become victims of physical, psychological or sexual violence with partially permanent damage to their health. This list could go on and on.

If we add up the damages, losses and costs that accumulate every year in this sector, we get an amount of at least 14,000 billion US dollars (10,979 billion Euros) for the year 2006 (Nefiodow 2014). That was more than the United States gross national product. Based on our own calculations, global entropy has increased to 18,000 billion US dollars (14,116 billion Euros) in 2013.

The entropic sector plays a key role in the global economy, because the enormous losses, damages and costs that incur year after year in this instance have turned this into the most significant barrier for the economic and social development. After all, the free market economy cannot function efficiently without a sufficient number of honest businessmen, public officials and politicians.

Entropy and Health

What are the causes for the entropic sector? They are moral deficits. But these deficits can also be viewed from a different perspective, they can be seen as health deficits (Figure 1).

This becomes apparent if you draw a comparison with the behavior of healthy people. A psychologically healthy person does not cheat. A mentally healthy person does not use drugs. A socially healthy person has a sense of community, advocates well-being of all people and does not harass others. A spiritually healthy person has a trusting relationship with God, strives for reconciliation, truth and peace and does not spread hatred and violence. Inner disturbances and diseases and the social misconduct caused by them are the deeper reasons for global entropy (Figure 1).

At this point, I would like to elaborate on the term health.

The World Health Organization (WHO) definition of health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. In 1997, the Executive Board of the WHO provided some food for thought with a broader definition of health: "Health is a dynamic state of complete physical, mental, social and spiritual well-being and not merely the absence of disease or infirmity." This was once again highlighted in the 2005 Bangkok Charter for Health Promotion in a Globalised World: "Health is one of

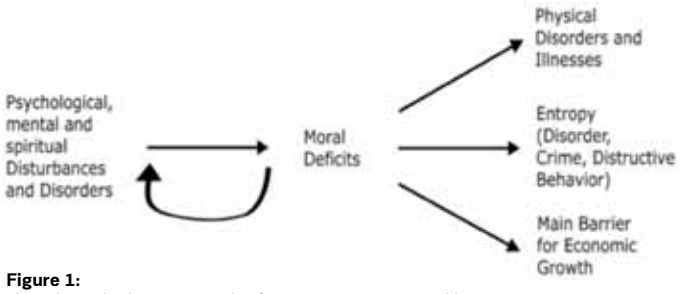


Figure 1:
The Relationship between Moral Deficits – Entropy – Inner Health

the fundamental rights of every human being and encompasses mental and spiritual well-being."

According to the WHO, terms like disease and health are no longer limited to the body. They are systems concepts. There are also sick souls; there are social diseases; there are sick families, companies and societies.

If you apply the WHO definition to the marketplace, we can distinguish between two sectors of the health care system (Figure 2):

The Traditional Health Care

Over the past two centuries, the traditional healthcare sector made tremendous progress. The history of medicine over the past two centuries was a real success story.

But this success story is about to end. Since the late 20th century, the new medical advances are no longer sufficient to adequately deal with the dynamics and complexities of modern life and its high demands on the physical, emotional and mental strength of human beings. As a result of these and other trends (e.g., longer life expectancy of people and the increasing social disarray), the number of diseases and costs in the healthcare sector continuously increase in all countries.

The traditional healthcare system does not provide health based on the definition by the WHO. It is not geared towards holistic healing, but mainly towards the treatment of physical diseases. It is not well prepared for the demands of the 21st century. What we call the traditional healthcare system today is in fact not a healthcare system at all. The correct label would be disease care system, since more than 95 percent of expenditures go towards the research, diagnosis, treatment, administration and management of diseases. In contrast, only limited means are available for prevention, preventive medical checkups and healing.

Dementia is one example. In 2010, the US federal health insurance programs Medicare and Medicaid spent approximately 140 billion US dollars (109,8 billion Euros) to treat dementia, but only 0,5 billion (0,39 billion Euros) to research its causes (Coy 2012). A ratio of 280:1.

The most important source of economic growth in the industrialised nations is productivity. The low productivity level of the traditional healthcare sector is its biggest problem. The productivity is too low, because the costs caused by medical technology advances are not counterbalanced by the cost savings they produce (Schneider, Markus et al.); and because they – as mentioned before – are not geared towards healing, but rather the treatment of disease symptoms. As a result, costs keep increasing. In the meantime, global health expenditures are now 12,000 billion US dollars (9,466 billion Euros) and there are more and more sick people, more and more diseases despite high spending, despite more research, more pharmaceuticals and medical technology, an increasing number of doctors and other healthcare professions and ever more remedies and healthcare products.

How can those two barriers – big losses, expenses and damages of the entropic sector and the high costs and low productivity of the traditional healthcare system – be overcome? In the past, growth barriers were overcome by developing the new Kondratieff cycle.

What is a Kondratieff Cycle?

Kondratieff cycles are economic fluctuations averaging about forty to sixty years. They are triggered by groundbreaking innovations, which are called basic innovations to distinguish them from other innovations. When we summarise the existing studies, so far, six Kondratieff cycles were empirically determined from an economist's point of view (Figure 3):

The 1st Kondratieff cycle begins

THE TRADITIONAL HEALTHCARE SYSTEM

- Medical technology
- Pharmaceutical industry
- Health services
- (Doctors, non-medical practitioners, hospitals, health insurance companies, health insurance funds, pharmacists, public health services, medical care facilities)
- Health spas/sanatoriums
- Company health services
- Health as a competitive factor, training and continuing education (e.g., in people skills), human resource development, health management
- Other (health-related)
- Skilled trades (e.g., for orthopedic products), sporting goods and sports facilities, health publications, medical EDP etc.

THE NEWLY EMERGING HEALTHCARE SECTOR

- Biotechnology
- Naturopathic treatments, natural products, all natural foods
- Complementary/alternative medicine
- Homeopathy, classic acupuncture, electroacupuncture according to Dr. Voll, kinesiology, bioresonance therapy, anthroposophic medicine, magnetotherapy, Dr. Rath's cellular medicine, biofeedback, quantum healing, traditional Chinese medicine, ayurvedic medicine, Reiki etc.
- Environmental protection (predominantly)
- Agriculture, diet, food
- Wellness/fitness, tourism (health tourism)
- Architecture (healthy living), building and construction industry (healthy building materials), textile industry (allergy-free and breathable textiles and clothing), the senses (color therapies, aromatherapies, music therapies),
- Self-medication and self-care
- Participation of illness costs, rising self-care
- Workplace health management
- Company health insurance funds, company sponsored fitness programs, cafeterias, welfare centers, health seminars, preventive medical checkups, good health bonus
- Psychology, psychiatry, psychotherapy, psychosomatic medicine
- Religion/spirituality

Figure 2:
The Health Value Chain of the Sixth Kondratieff
Source: Nefiodow 2014

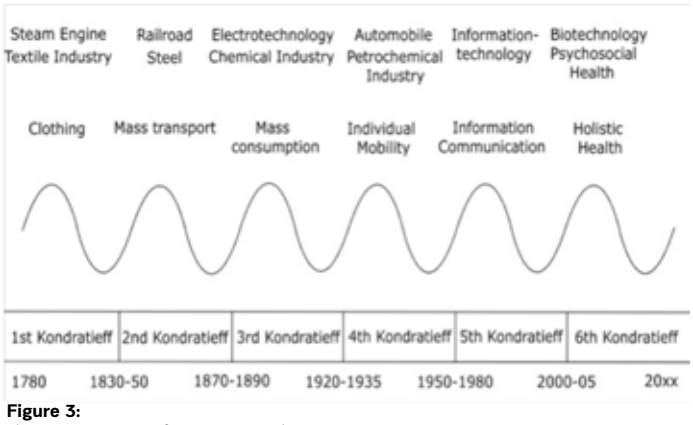


Figure 3:
The Six Long Waves of Economic Development
Source: Nefiodow 2014

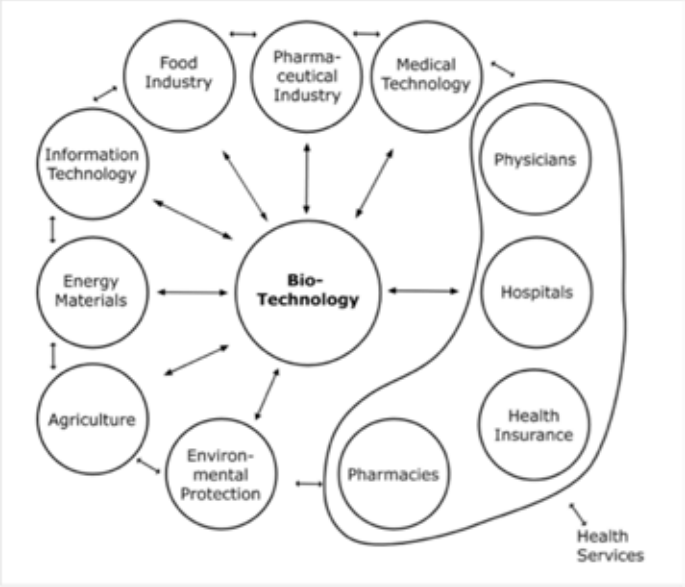


Figure 4:
The Biotechnology Value Chain
Source: Nefiodow 2014

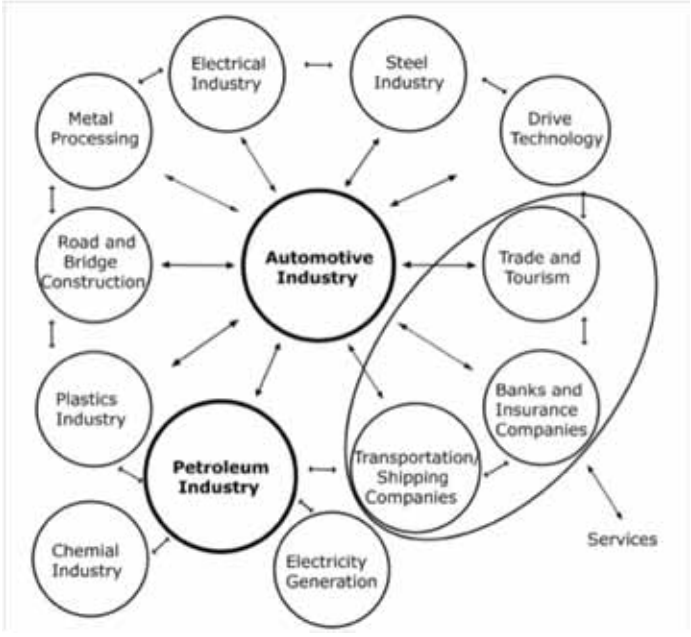


Figure 5:
Value Chain of the fourth Kondratieff
Source: Nefiodow 2014

towards the end of the 18th century. The trigger is the steam engine. The most important application takes place in the textile industry.

The 2nd Kondratieff is the era of big steel and the railroad. Two major new industries develop during the 3rd Kondratieff: the electrotechnical and the chemical industry. The 3rd Kondratieff ends with the world economic crisis of the late 1920s and early 1930s.

The 4th Kondratieff was supported by the automobile and the petrochemical industry. This long cycle drew to an early close due to the massive crude oil price increases of the 1970s.

competence in avoiding diseases and our competence in healing.

Naturopathic treatments, complementary and alternative medicine belong to the new value chain (Figure 2). They have expanded for many years and now play an important role. There is still immense healing potential hidden in this area and a large market for all

"we leave the growth patterns of previous Kondratieff cycles behind. Now the human being takes centre stage"

The 5th Kondratieff is carried by modern information technology. No other technology was able to even remotely exhibit comparable economic dynamics and widespread effect during the second half of the 20th century. This cycle ended with the global recession of 2002-2004. Simultaneously, the sixth Kondratieff began. This long cycle is in its early stages, but is not able to fully develop primarily because of the two mentioned barriers.

The healthcare economy is the carrier of the new, sixth Kondratieff. The weak economic growth in the industrial nations can be overcome by its promotion and extension.

The Newly Emerging Second Healthcare Sector

The main carrier of the sixth Kondratieff will be the new emerging healthcare sector (Figure 2). Biotechnology holds a special position (Figure 4). It is not just a brand-new technology, it is one of the two basic innovations of the sixth Kondratieff, because it will improve productivity in handling physical diseases, it will reduce costs significantly, it will improve our players in the healthcare system.

Big portions of environmental protection are also a part of this new value chain. When you take a closer look, most environmental protection measures only serve the environment at first glance; protecting the health of human beings is the stronger motive.

The wellness industry, fitness studios and health tourism have expanded strongly. Companies increasingly have come to realise that employee health has become a strategic weapon.

Two additional protagonists in the new emerging healthcare sector are psychotherapies and spirituality/religion, which can help in reducing entropy. Psychotherapies could effectively contribute to entropy reduction, if – as established in our book – they could reduce the theoretical deficits. (Nefiodow 2014). Unlike the situation in spirituality where its effectiveness has been scientifically proven. Many studies prove that religious beliefs have a healing effect on the body, soul and spirit. Raphael Bonelli of the University of Vienna and Harold Koenig of Duke University in the US have analysed all studies that were published between 1990 and

2010 on the relationship between health and religion, and concluded that there is a positive correlation between Christian faith and health in 74 percent of these studies (Bonelli and Koenig 2013).

The Kondratieff Cycle as an Economic Engine

To understand why the sixth Kondratieff is going to take on the role of economic growth engine, the example of the fourth Kondratieff is meant to demonstrate how this type of growth engine is built and how it works (Figure 5).

The basic innovation that triggered the fourth Kondratieff was the automobile. Two large new industry sectors developed from its commercialisation: the automotive industry and the petrochemical industry (Figure 5). During the fourth Kondratieff, they were the most important private employers and the largest investors in research, development and production. For more than half a century they significantly defined economic growth and as leading industries, they affected the economic system like a locomotive affects a train: they put all wagons of the train in motion.

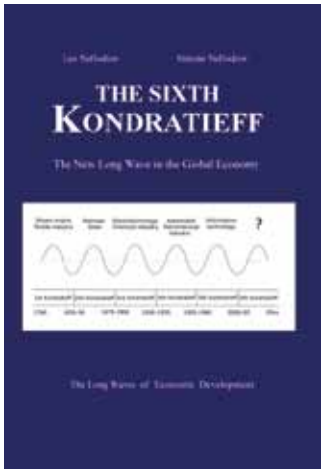
If we stay with the image of a train, the individual wagons represent the sectors of the economy, which benefited from the automobile. This included highway, bridge and road construction companies, steel and tire manufacturers, manufacturers of fuel power stations and gas-fired power plants as well as countless suppliers of metal, electric, electronic and plastic parts. Numerous service providers were also a part of the "wagons" of the train: gas stations, car dealers, repair shops, transport companies, banks, insurance companies, tourism and the leisure industry. All of these "wagons" built a global network of suppliers, customers, retailers and users, which created millions of new jobs. And the entire train in motion illustrated– metaphorically speaking – the fourth Kondratieff. In those countries where the automobile and petrochemical industry boomed, full employment was the result. Every fifth job in the U.S.A. and every seventh job in Germany became dependent on the car during the fourth Kondratieff. The healthcare sector will take on a similar role as a growth engine during the sixth Kondratieff.

Conclusion

We explained that the sixth Kondratieff is a health-related cycle. A detailed analysis of the current growth barriers and growth potential in fact shows that the healthcare system, when it is geared toward the needs of the 21st century and extended to the human being as a whole, can lead to a strong and sustainable upswing (Nefiodow 2014). Outside of the healthcare system there is presently no other candidate through which industrialised nations can achieve full employment. This means that for the first time in history, the focus of economic and social development is not on a machine, a chemical process or hardware technology, but rather the human being with his physical, mental, psychological, social, ecological and spiritual needs, problems and potential. We leave the growth patterns of previous Kondratieff cycles behind. Now the human being takes center stage. This is the message of the 6th Kondratieff: the healing of man is the best program for the future. ■

Editor's note:
Leo Nefiodow has been awarded the Bronze N. D. Kondratieff Medal 2014 by the International Kondratieff Foundation and the Institute of Economics Russian Academy of Sciences. The ceremony was held in Moscow on 12 November 2014.

Further reading:
Leo Nefiodow and Simone Nefiodow 'The Sixth Kondratieff. The New Long Wave in the Global Economy'. Available from Amazon.



Key Points

- The economic and social development of the leading industrialised countries is significantly determined by economic cycles that last between 40 and 60 years.
- In honour of their discoverer Nikolai Kondratieff, these long waves are called Kondratieff cycles.
- A new long cycle, the sixth Kondratieff cycle began around the turn of this past century.
- This article describes why health will develop into a growth engine in the global economy thanks to this new Kondratieff cycle.

References

Bonelli RM, Koenig HG (2013) Mental disorders, religion and spirituality 1990 to 2010: a systematic evidence-based review. J Relig Health, 52(2): 657-73.

Coy P (2012) Cliff isn't the problem: Bloomberg Businessweek opening remarks, 7 December. [Accessed: 5 November 2014] Available from: http://www.bloomberg.com/news/2012-12-06/cliff-isn-t-the-problem-bloomberg-businessweek-opening-remarks.html

Kondratieff ND (1926) Die langen Wellen der Konjunktur. Archiv für Sozialwissenschaft und Sozialpolitik, 56, 573-609.

Nefiodow, L., Nefiodow S (2014) The sixth Kondratieff: the new long wave in the global economy. Amazon.

Schneider, M, Karmann Al; Braeseke G (2014) Produktivität in der Gesundheitswirtschaft. Gutachten für das Bundesministerium für Wirtschaft und Technologie

Schneider M, Karmann A, Braeseke G (2014) Produktivität der Gesundheitswirtschaft: Gutachten für das Bundesministerium für Wirtschaft und Technologie. Berlin: Springer Gabler.

RADIOLOGY IN 2020

OPPORTUNITIES AND CHALLENGES

Prof. Moshe Graif

Director, Imaging Division
The Tel Aviv Sourasky Medical Center
Affiliated to the Faculty of
Medicine, Tel-Aviv University
Tel Aviv, Israel

graif@tasmc.health.gov.il

In the last several centuries the correlation between technological advancements and humanity's wellbeing in terms of life expectancy and world population growth is a well-established reality. A recent article in the Journal of Multidisciplinary Healthcare (Gill 2013), regarding technological innovation and its effect on public health, demonstrated that better technological innovation indicator scores were associated with better public health indicator scores. Furthermore, the study provided preliminary evidence that technological innovation shares causal relation with public health.

Since Josef Schumpeter's paradoxical 'Creative destruction' theory in the 1940s (Schumpeter 1942) to Clayton Christensen (The innovator's dilemma) nowadays (Christensen 1997), there is a trend to classify innovations into two main types. Sustaining or incremental innovations ("Evolution not a revolution") consist of continuous improvements of an existing well-established product, which generally will get increasingly complex and more expensive, and inevitably will hit a point where it will offer more performance than the customers need, want, or can afford. This happens because manufacturers tend to preserve high profit market shares and avoid potential 'cannibalisation' of their own products by a new disruptive development. Disruptive, or radical ("game-changers") innovations on the other hand, are usually introduced by new entrants, and replace an existing product with a simpler and more affordable technology or business model (as personal computers replaced mini and mainframe computers, or the digital camera replaced traditional film-based photography).

A typical innovation cycle is composed of three phases: introduction, growth and maturation. While the growth period is characterised by an exponential curve course, the maturation phase shows a significant slowdown as the technology approaches its physical or fiscal ceiling, or both. In the case of radiology, the 40 year disruptive period that started in the seventies represented the 'golden age' of radiology. Every modality which emerged in those years became a breakthrough in modern medicine. However, the last decade seems to mark the beginning of a shift from the exponential disruptive phase of the current technology into a sustaining phase, which is characterised by the saturation of the innovative momentum of the technology. Ultra-expensive equipment such as the various hybrid technologies is a classic representation of such sustaining innovation trends.

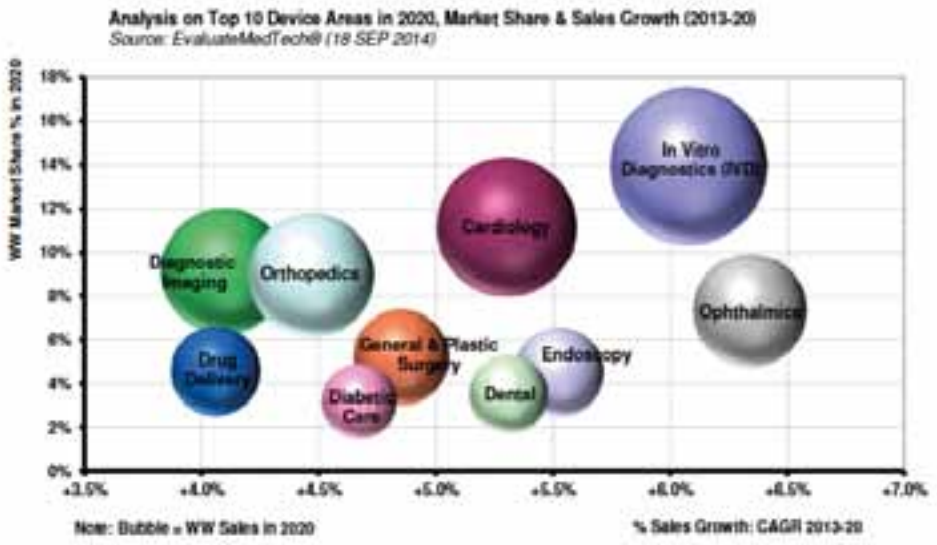
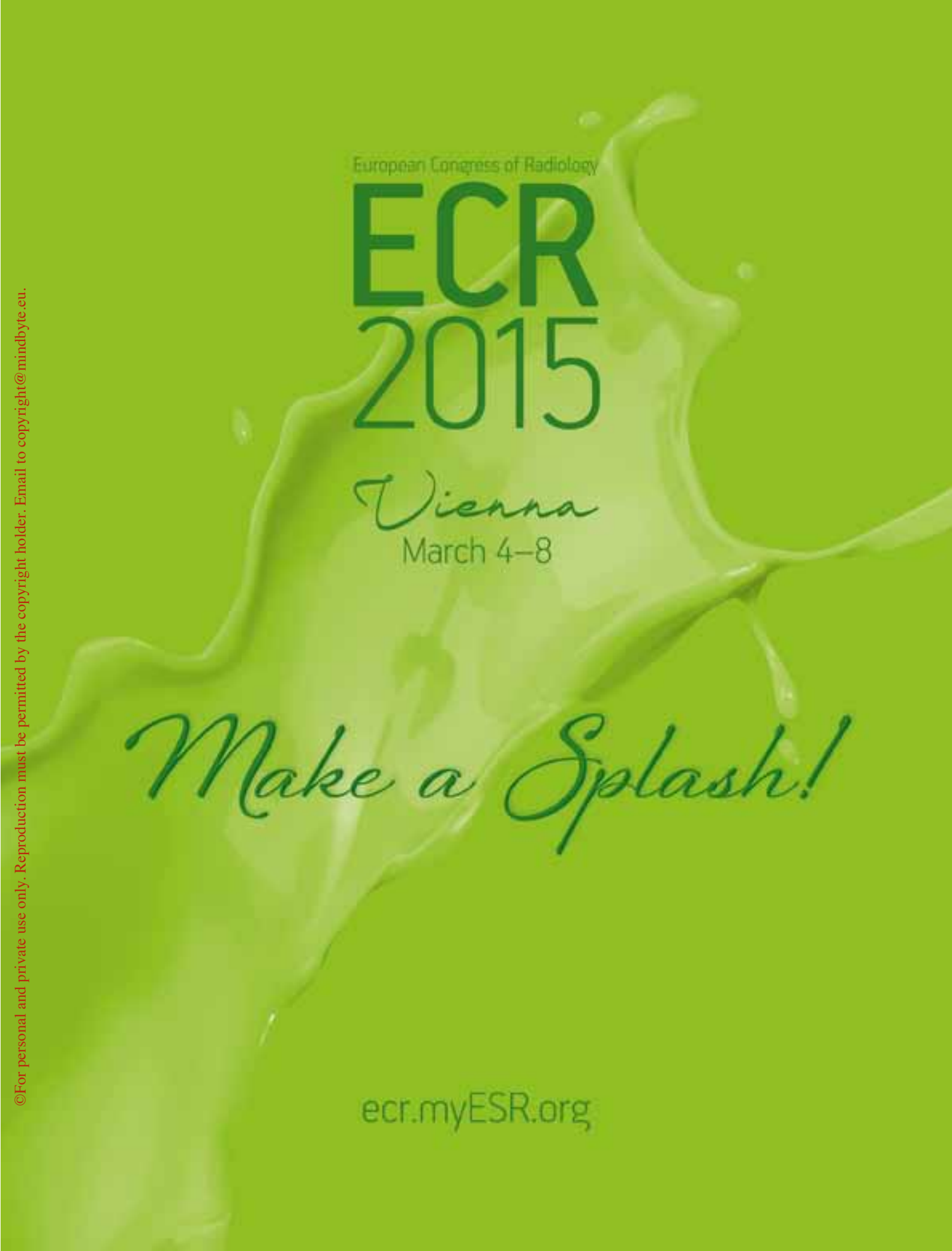


Figure 1



Health
MANAGEMENT
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SPECIAL FEATURE: **SAFETY MATTERS**

More than one million needlestick injuries (NSI) are estimated to occur in the EU each year (EU Commission for Employment 2010). Risks for healthcare workers are omnipresent, but prevention is possible and solutions exist.

As promoter of cross-collaboration, leadership, best practices and patient safety, *HealthManagement* brings you this supplement on safety in collaboration with BD, a leading medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public.

Features include a patient story, considerations about safety-engineered devices and the perspective of the European Union. As the highest frequency of needlestick injuries is in injection, we take a detailed look at that risk area.

Supported by an
Educational Grant from BD

NEEDLESTICK INJURIES: THE AVOIDABLE TRAGEDY

A Patient Story

Unfortunately, needlestick injuries are still among the most common work-related accidents in medical and nursing professions. Experts estimate that each employee cuts or pricks himself at least once every two years. The consequences can be devastating, as in the case of Kurt Wenkenbach* (56), former manager of patient care in a nursing home. While re-capping a used insulin needle he was infected with hepatitis B and hepatitis C. The small injuries cost him his physical and mental health, and in the end his job. However, needlestick injuries and their consequences can easily be minimised by the consistent use of safety devices.

Kurt W. got injured in spring 2001 while re-capping the cannula of an insulin sy-ringe, which he had administered to a diabetic patient of his nursing home. He did not pay much attention to the injury as something like this has happened to him and his colleagues a couple of times before. Dutifully, Kurt W. reported his needlestick injury and made the required blood tests. Then he received the diagnosis that changed everything: chronic hepatitis B and an acute hepatitis C. As a medical professional Kurt W. knew exactly what he would have to face: exhaustion, muscle and joint pain, pressure in the upper abdomen and nausea were only some of the symptoms. But he was more even worried about the possible development of a liver cirrhosis or liver cancer as late sequelae.

The hepatitis of Kurt W. has been developing over the years like a typical case. Initially, Kurt W. coped well with everything at work and even had a training to fill the position of the head of patient care at his nursing home. His responsibilities and tasks at work were growing, the symptoms of his illness became more and more noticeable and he was considered being less reliable. He was permanently tired and weary and his joints ached a lot. The management of his nursing home was displeased: his work and leadership style were repeatedly criticised, colleagues were questioned about him and he very often had to change his work-station internally. At that time, Kurt W. applied for occupational disability. His application was rejected on the grounds that the hepatitis could not obviously be traced back to the infection of the nursing home resident. Kurt W. was in great despair.

In 2007, Kurt W. liver values worsened dramatically. The year after, he decided on a hepatologist's recommendation, to undergo another therapy that unfortunately had severe side effects, such as shortness of breath and nightly tachycardia. Also his old joint discomfort in the lumbar and cervical spine and the sciatica pain flared up again. He was regularly sick. Consequently Kurt W. received a warning from the nursing home management and threats that he would be dismissed. Kurt W. could not sustain the pressure. However, he managed to work at that nursing home until October 2009. Then he fell into a depression. Two years later, with the help of a lawyer, his employment contract was terminated by mutual agreement.

Kurt W. managed to recover slightly and started working part-time in an office. At times he felt physically and mentally very bad and he decided to have a second application for occupational disability. In November 2012 Kurt W. finally received a small disability pension that gave him at least some security. Nevertheless, to this day Kurt W. cannot cope with the fact that he had to give up his job because of a small injury, and that his life changed so much.

It is necessary to ensure the correct disposal of medical sharps, a risk-conscious organisation of the workplace, as well as a safe working environment in order to protect employees. Thus, e.g. vaccination and protective gloves have to be provided. In this way, needlestick injuries can be sustainably avoided.

Still needlestick injuries are played down and not reported. Across his career, Kurt W. got injured by used needles several times and his colleagues are also familiar with that problem. However, needlestick injuries and their tragic consequences can be significantly reduced by the use of safety devices. Fitted with a safety mechanism, these medical instruments make unwanted pricking or cutting after use almost impossible. They offer best protection and should be applied comprehensively and consistently. Furthermore, in order to protect employees, it is necessary to ensure the correct disposal of medical sharps, have a risk-conscious organisation of the work-place, as well as a safe working environment. Thus, e.g. vaccination and protective gloves have to be provided. In this way, needlestick injuries can be sustainably avoided.

"he reported his needlestick injury and made the required blood tests. Then he received the diagnosis that changed everything: chronic hepatitis B and an acute hepatitis C"

About SAFETY FIRST! Germany

The mission of the initiative SAFETY FIRST! Germany is to draw attention to the urgency and relevance of the topic of needlestick injuries and to present strategies to the public on how to avoid injuries from medical sharps as well as infections that result from them. SAFETY FIRST! is supported by BD.

CONSIDERATIONS ON NEEDLESTICK INJURY DEVICES

Luis Mazón Cuadrado
Responsible for Occupational Health
Hospital de Fuenlabrada
Madrid, Spain

The transmission of pathogens through blood and other body fluids represents one of the main risks in the healthcare setting. Although over 20 pathogens can be transmitted in this way, the most important are the hepatitis B (HBV) and C (HCV) viruses and the AIDS virus (HIV).

Since 2006 it has been mandatory in the Madrid Region of Spain to use safety-engineered devices in all healthcare institutions and, on 11 May 2013, the European Directive on the prevention of sharp injuries came into effect. The Directive focuses on two main aspects:

1. Healthcare worker safety and health are essential and are intimately linked to patient health and safety.
2. The key and strategic element of the Directive is the minimisation of exposure risk and reducing the number of injuries, but not the number of infections as a result of exposure.

In our experience, there are several key issues for ensuring the effective implementation of safety-engineered devices. The first is of a strategic nature and consists of the promotion from the Hospital Management of a specific safety culture through the adoption of a general prevention policy encompassing all the workers at risk and all the processes, in which sharp objects are used. This, in turn, inevitably leads us to another aspect, namely the adoption of a method or tool for knowing and evaluating all the processes, in which sharp objects intervene. It is very important to modify the traditional management system and introduce process management. In a very schematic manner, this model offers added value that allows us to integrate and align processes in order to obtain the planned results. Furthermore, it focuses effort on the efficacy and efficiency of processes and fosters operational transparency within the organisation. Lastly, it reduces cycle times and costs through efficient resource use.

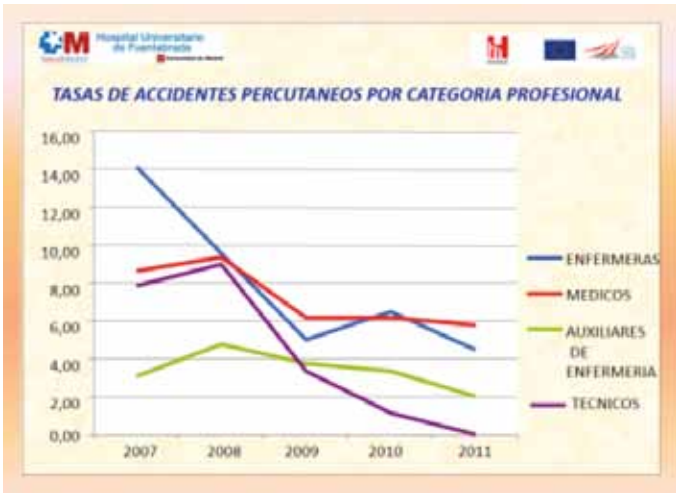
A second key issue is identifying the risk perception of the professionals, their sensitivity to such risk, and their adherence to a new biosafety culture. The greatest infection risk following a percutaneous accident corresponds to hepatitis B (30%), followed by hepatitis C (3%) and HIV infection (0.3%). Such accidents pose a serious occupational health problem due to their high frequency, potential seriousness and associated costs. In this regard, percutaneous accidents represent the most important transmission route. The risk of transmission following exposure clearly depends on the source patient characteristics, the type of exposure, and the serological status of the exposed person (level of evidence II).

Risk is highest when exposure involves extensive contact with blood through deep punctures

PERCUTANEOUS ACCIDENT RATES BY PROFESSIONAL CATEGORY
NURSES
DOCTORS
NURSING ASSISTANTS
TECHNICIANS

Impact Factor Study
Type of study: Cohort. 2007-2011.
Data: Accumulated incidence
Confidence interval: 95.0%

EVOLUTION OF RELATIVE RISK (RR)
(total biological accidents)



or cuts with contaminated hollow needles that had previously been located in an artery or vein (level of evidence III). According to the latest data of our hospital (2014), 68% of all accidents involved hollow needles. Of these, 72% corresponded to small-calibre needles. It is interesting to examine the materials affected after 8 years of biosafety measures. In this respect, subcutaneous, intramuscular and butterfly needles were responsible for 25.7%, 18.5% and 9% of the injuries, respectively, while intravenous catheters accounted for 8.7%, intradermal needles 5.6%, blood gas syringes 3.7%, arterial catheters 0.3%, and central venous catheters 0.3%. This profile is clearly different from that which can be found in a healthcare centre lacking biosafety measures, and, although the results require more exhaustive analysis, we do know that we must not neglect processes such as drug aspiration and injection versus infusion and extraction, as evidenced by our own experience.

Another very important aspect is the adherence by the healthcare professional to the biosafety device and biosafety culture. In this context, the professional should actively participate in the choice of devices through qualitative assessment of the products, once the Occupational Risk Prevention Department in coordination with the Material Resources Unit has determined the technical characteristics after creating the pertinent work groups.

A third key issue refers to effective implementation of the devices. Before deciding on a massive purchase, we recommend conducting a pilot test in sensitised units, with the participation of workers affected in the use of the device, because it must be tested in real-life situations. This will provide very useful information and can serve to identify potential problems.

Once the devices have been chosen, the workers must be trained to use them. In this regard, caution is required to choose devices according to the specific unit in which they are to be used. At the time of actual implementation, no devices with and without safety-engineered features measures for one same procedure should coexist, and systematisation is moreover needed, with the adoption of a logical order. We recommend an analysis to compile data on the frequency of accidents, and the use of a Pareto diagram to know where 80% of the accidents have occurred – thereby, allowing us to establish priorities and ensure effective implementation and investment.

In a fourth stage, we must evaluate the impact factor of the implementation of the devices, answering two crucial questions: Are they effective? How many accidents do we prevent? According to a study carried out in our hospital between 2007 and 2011, we obtained the following results:

1. Adoption of the safety-engineered devices reduced the risk of accidents (DAR -0.45; 95%CI -0.06 to -0.02; p<0.05). Similar conclusions about the efficacy of such devices were drawn by De Carli from the SIROH study between 1997-2010.

2. One accident for every 22 professionals was avoided (NNT 22.2; CI 15.4 – 37.7; p<0.05)

Finally, due to its importance, a cost-efficacy analysis must be carried out. In our study we did not consider estimating the binomial direct – indirect costs. Rather, we aimed to identify the cost of the resources needed to reduce an adverse effect, taking only the product cost into account (analysing the actual product cost and the incremental cost-effectiveness). Clearly, the prices of the devices have decreased considerably with respect to the year 2007 – a fact that favoured our analysis. The results obtained indicate that amortisation of the initial investment is achieved within four years.

A final, but not less important comment, refers to the legal responsibilities and consequences in the European Union, resulting from the seroconversion of an individual secondary to inoculation, considering the existence of a Specific Directive and the availability of safety-engineered devices products on the market.

Cost: Direct cost
HOW MUCH DOES BIOSAFETY COST US?
* Direct gross cost, without considering variations in inflation

Estimated results and global impact upon hospital economy
Estimated number of patients-year candidates to treatment in hospital, estimated annual cost and annual efficacy units

Annual No. patients / Incremental cost per patient / NNT / Annual economic impact / Annual efficacy units
* There was a 10% increase in personnel in 2010 vs 2006.

HOW MUCH DOES EUROPE CARE ABOUT NEEDLESTICK INJURIES?

One of the most common and serious risks to healthcare workers is an infection resulting from a sharp or needlestick injury. In Europe, approximately 8 million healthcare workers are at risk of these injuries. Even though data on the frequency of needlestick injuries differ greatly between different hospitals, as well as between different units of the same hospital, they all show that needlestick injuries happen continuously in the daily work of healthcare workers. It has been estimated that more than one million such injuries occur in the healthcare facilities across the European Union each year. Alarmingly though, approximately 50% are unreported.

Underreporting is one of the major causes of the biased low priority that needlestick injuries have received so far. The extent of this phenomenon has simply been underestimated. Yet, needlestick injuries put the healthcare workers at risk of serious infection from any one of more than 30 potentially dangerous pathogens, including HIV, hepatitis B and hepatitis C.

Another reason why needlestick injuries have been a low priority so far is that in some EU countries, including the Czech Republic, no data are available on a national level. Data collection is carried out sporadically and mostly on the level of a single hospital.

For example, France, Switzerland and Germany give us a clearer indication of the scale of the problem. In France, a survey conducted by the French Group for the Prevention of Occupational Infections in Healthcare Workers found 29,132 cases of occupational exposures to blood and bodily fluids in 2010. Eight out of ten accidents were the result of percutaneous injuries, mainly needlestick. What is significant here is that 43.3% of these could have been avoided through the observance of standard precautions.

In Switzerland and Germany, the focus has centred on the costs of needlestick injuries. A Swiss occupational health physician, Esther Graf-Deuel, estimated that the average cost of a needlestick injury ranges from EUR 355 (for a non-infectious patient) to EUR 3,464 (for an HIV-infected source patient).

According to other research done by Prof. Andreas Wittmann from the University of Wuppertal, the cost of one needlestick injury is EUR 487, of which approximately EUR 150 is not covered by the obligatory accident insurance and must be carried by the employer. Based on the estimated 500,000, needlestick injuries that take place in Germany each year, Prof. Wittman concludes that these injuries cost Germany approximately EUR 47 million per year.

These, as well as numerous other independent studies conclude that, overall, short and long-term benefits, including economic savings, can be achieved by investing in safer working practices and medical devices to prevent needlestick injuries.

Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms.

Acknowledging this wealth of research and recommendations made by experts, the European Union decided to act, and in 2010 it adopted the Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector. The Directive provides for "eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms."

A report by the European Parliament explains why a mandatory obligation to implement prevention and protection measures was chosen by the European legislators. "While the existing legislation [laws such as the Labour Code, Act on Protection of Public Health, Health and Safety at Work Directives] should, theoretically, address the risk of needlestick injuries, in practical terms, this has not been the case. Guidelines, awareness campaigns and other non-legislative initiatives can only make a partial contribution; they should be used in addition to directives."

"eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms."

The strategy is therefore clear; minimise the risk of exposure to sharp objects among healthcare workers by requiring healthcare providers to take suitable prevention and protection steps. Use of safety-engineered devices, vaccination and proper information and training for staff are essential measures to ensure compliance with this strategy and the Directive 2010/32/EU.

And what is your organisation doing to prevent these occupational accidents?

NEEDLESTICK INJURY PREVENTION IN THE DIABETES SETTING

Dr Kenneth Strauss
Endocrinologist and Director of Safety in Medicine, European Medical Association
Global Medical Director, Becton Dickinson (BD)

In the world of diabetes care, most current discussion centres on effective self-administration, accurate insulin dosage, and the avoidance of short-term lipohypertrophy and longer-term health complications resulting from dosage inaccuracies. However, with the advent of a new EU Directive on sharps injury prevention (Council Directive 2010/32/EU), and the impending mandatory implementation deadline of May 2013 in all EU countries, scrutiny has now been focused on the safety and protection of specialist diabetes nurses when they are administering treatment to their patients.

Is the diabetes specialist at risk? And is the risk they face more or less than their colleagues in other healthcare functions? To answer this question requires an objective appraisal of the situation. In our experience, a number of false assumptions about the risk of needlestick injury (NSI) and infection in diabetes treatment have regularly cropped up in conversation with healthcare organisations. This short article reviews the most commonly held misconceptions and offers third party references to refute those misconceptions.

Myth Number One – people with diabetes have a lower prevalence of dangerous viruses than the general population.

This is not true. People with diabetes are at least equivalent to the general population in this regard, if not higher. According to one study (Demir, M, Serin, E, Göktürk, S, et al., 2008), Hepatitis B (HBV) DNA was discovered in 11% of Diabetes type 2 patients, compared to 3% of the control sample, a statistically significant difference. Diabetes specialists working with this group would therefore be at greater risk – in this respect - from NSI and infection than those administering to the general population.

It is not sufficient risk control to rely on the fact that a high proportion of healthcare workers treating people with diabetes will have had the HBV vaccination. The vaccination coverage is far from 100% (De Schryver A, Claesen, B, Meheus, A et al., 2010) and even vaccinated individuals may not be completely protected, because titers of protective antibodies decline over time. Moreover, there are other dangerous viruses, such as HIV and Hepatitis C (HCV), for which there is no vaccination. Looking at infection risk across the board, there are more than 30 viral diseases that a NSI can transmit, of which the most dangerous are HCV and HIV, where their prevalence among people with diabetes is higher than (HCV) (Simó, R, Hernández, C, Genescà J et al., 1996), or equal to (HIV) (Mondy, K, Overton, ET, Grubb, J et al., Mar. 2007) the general population.

Myth Number Two – there are not as many NSIs when treating people with diabetes needles, smaller needles do not carry a significant risk of infection, prophylaxis clears any possible infections, and anyway, diabetes needles and injection devices do not get contaminated.

In fact, the situation is exactly the opposite. NSI with diabetes needles or lancing devices are actually one of the highest frequency sharps injury in the healthcare setting (Kiss, Phillippe, de Meester, et al., Dec 2008). There is no branch of medicine with little or no risk of NSI. Moreover, most people with diabetes are being treated in Internal Medicine, where the highest risks of NSI occur. Some have remarked that people with diabetes inject with tiny needles that, by virtue of their size, represent little risk of injury. Again, this misses the main point. Pen injection devices aspirate human cells back into the cartridge. These potentially infectious cells can then be deposited back into the needle and then transmitted accidentally should a NSI occur. Equally, diabetes needles themselves have been shown to retain traces of blood.

The small size of diabetes needles does not significantly reduce risk either. It takes minute quantities of blood to transmit HBV or HCV, and it is therefore worth dwelling on some simple mathematics, evaluating the number of people who could be infected by the blood in one hollow-bore needle. The average volume of blood inoculated in an associated injury via a 22-gauge needle is approximately 1.0 – 2.0 µL (Mondy, K, Overton, ET, Grubb, J et al., Mar. 2007), which may contain an infectious dose of a blood-borne virus. The viral load in a millilitre of infected blood can be anywhere up to a billion (109) virus particles for HBV (Public Health Agency of Canada) . If we assume a typical load of ten million (107) per millilitre of infected blood, then this would give a load of 10,000 virus particles per µL. This is enough to infect many people with HBV. The load for HCV is lower, but is still enough to infect multiple victims. If we move from risk to actual conversions, the story is significantly worrying, with studies showing HCV conversions running at between one and two in every hundred NSI percutaneous exposures (UK Occupational blood-borne Virus report, Nov. 2008).

What about the impact of prophylaxis on people unlucky enough to sustain an NSI and a subsequent infection? Certainly, the latest prophylactic medications can prevent conversion. However, there is a 'golden hour', in which urgent action must take place for these to be effective. Moreover, even if one receives prophylaxis, there are a number of adverse and unpleasant side effects to therapy – not

just physical, but also occupational and psychological. Affected persons have to change their work routines and duties for periods following injury, often involving a prolonged and extremely stressful period of not knowing whether they have contracted a life-threatening infection (Nursing Times, 2006). Changes in sexual habits also have to be enforced, putting a strain on family life and relationships.

Myth Number Three - people with diabetes recap and safely dispose of their needles; there are no diabetes safety needles; and the new EU Directive on sharps injury prevention specifically excludes diabetes treatment.

It is also a fallacy that people with diabetes scrupulously follow safe disposal procedures, recapping their needles and putting them into a specialised sharps receptacle. In fact, one study (Journal of Diabetes, 2010) has shown that only 33% of used sharps go into containers made specifically for the disposal of sharps. 12% go into an empty bottle or milk carton, 46% go straight into the rubbish after recapping, and 3.5% go in the bin without even being recapped.

Quite apart from the safe disposal of sharps, there are now a number of safety-engineered medical devices on the market, comprising active devices, where the user has to manually activate a needle shield, or passive devices, which shield or retract the needle automatically after it has been deployed. Many people are unaware that these devices even exist. This is tragic, in that numerous studies (Adams, D, Elliott TS., 2006; Jagger J. et al., 2008) have shown that NSIs drop dramatically where safety devices are adopted. Acquisition costs may initially seem off-putting to healthcare organisations, yet a brief look at studies (Armadans, Gil L, Fernandez, Cano MI et al., 2006; Glenngard, Anna H., Persson, Ulf, 2009; NHS Scotland) on the subject reveals that the prevention of injury usually leads to a clear return on investment, especially in mitigating legal, regulatory, financial and reputational risk.

Finally, the new European Directive that has now come into force specifically stipulates that wherever there is risk of sharps injury, the user and all healthcare workers must be protected by adequate safety precautions, including the use of 'medical devices incorporating safety-engineered protection mechanisms' (Council Directive 2010/32/EU).

In conclusion, the treatment of people with diabetes may not be logically excluded from best safety practices. People with diabetes have the same, if not higher, prevalence of dangerous viruses. More needlestick injuries than the norm occur in treating people with diabetes, those injuries are a high risk source of possible infection despite the small size of diabetes needles, and the introduction of readily available safety-engineered medical devices have been clearly shown to reduce the risk of injury and infection. By May 2013, the EU Directive will make it compulsory to use safety devices in all situations, where there is significant risk of sharps injury and infection. In the meantime, many healthcare organisations across the EU are introducing safety devices well in advance of that deadline in order to avoid financial, legal, regulatory, reputational and above all, human damage.

References

Adams, D, Elliott TS. (2006). Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study, J. Hosp Infect.,64(1): 50-5.

Armadans, Gil L, Fernandez, Cano MI et al. (Sep. – Oct. 2006). Safety-engineered devices to prevent percutaneous injuries: cost-effectiveness analysis on prevention of high-risk exposure Gac. Sanit., 20(5): 374-81. [Accessed 2011]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17040646

Council Directive 2010/32/EU, Official Journal of the European Union, L134/71. [Accessed 2011] Available from: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF.

Council Directive 2010/32/EU, Official Journal of the European Union, L134/71 [Accessed 2011]. Available from:http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF

Demir, M, Serin, E, Göktürk, S, et al. (Jul. 2008). The prevalence of occult hepatitis B virus infection in type 2 diabetes mellitus patients. Eur. J. Gastroenterol. Hepatol. , 20(7): 668-73.

De Schryver A, Claesen, B, Meheus, A et al. (Sep. 2010). Department of Epidemiology and Social Medicine, University of Antwerp, Antwerp, Belgium. European survey of hepatitis B vaccination policies for healthcare workers. Eur J Public Health.

Glenngard, Anna H., Persson, Ulf (2009). Costs associated with sharps injuries in the Swedish health care setting and potential cost savings from needle-stick prevention devices with needle and syringe Scandinavian Journal of Infectious Diseases, 4(41): 296 – 302.[Accessed 2011]. Available from: http://informahealthcare.com/doi/abs/10.1080/00365540902780232

Jagger, J et al. (2008, Epub 26 Nov., 2008). The impact of U.S. policies to protect healthcare workers from bloodborne pathogens: The critical role of safety-engineered devices, Journal of Infection and Public Health 1(2): 62-71

Journal of Diabetes (2010) 2(3): 168-79

Kiss, Phillippe, de Meester, Merc, Braeckman, Lutgart . (Dec. 2008). Needlestick Injuries in Nursing Homes: The Prominent Role of Insulin Pens, Infection Control and Hospital Epidemiology, 29(12):1192-4

Mondy, K, Overton, ET, Grubb, J et al. (Mar. 2007, Epub 2007 Jan 22). Metabolic syndrome in HIV-infected patients from an urban, midwestern US outpatient population. Clin. Infect Dis.1;44(5): 726-34.

Mondy, K, Overton, ET, Grubb, J et al. (Mar. 2007, Epub 2007 Jan 22). Metabolic syndrome in HIV-infected patients from an urban, midwestern US outpatient population. Clin. Infect Dis.1;44(5): 726-34.

NHS Scotland, Needlestick Injuries; Sharpen your Awareness, Annex 3, Safer Devices Cost Benefit Assessment. [Accessed 2011]. Available from: http://www.sehd.scot.nhs.uk/publications/nisa/nisa-13.htm

Nursing Times (3 October, 2006), Why we must stop needlesick injuries

Public Health Agency of Canada [Accessed 2011]. Available from: http://www.phac-aspc.gc.ca/msds-ftss/msds76e-eng.php

Simó, R, Hernández, C, Genescà J et al. (Sep. 1996). High prevalence of hepatitis C virus infection in diabetic patients. Diabetes Care. 19(9): 998-1000.

UK Occupational bloodborne Virus report (November 2008)

SHARPS INJURY RISKS IN NURSING HOMES

Background

The everyday activities of workers in nursing homes put them at risk of serious infections with more than 30 potentially dangerous pathogens, including Hepatitis B (HBV), hepatitis C (HCV) and Human Immunodeficiency Virus (HIV), through injuries with contaminated needles and lancets. More than one million needle stick injuries (NSI) are estimated to occur in the EU each year (EU Commission for Employment, 2010), many of them in the nursing home setting.

Nursing Homes and Accidental Sticks

A recent publication from the Netherlands (Vos D, Gotz HM, Richardus JH, 2006), on NSI outside the hospital setting shows that 84% of the NSIs in nursing assistants involved an insulin needle or pen. Worryingly, thirty-five percent of all healthcare workers and 47% of the nursing assistants were not vaccinated against Hepatitis B. In a similar study in Belgium (Kiss P, De Meester M, Braeckman L., 2008), 45 nursing homes were surveyed from the East Flanders region. A total of 162 NSI were reported. Cleaning, technical, or kitchen personnel were involved in 13% of all NSI; registered nurses were involved in 56%, and 28% involved geriatrics helpers. The three sharp devices most frequently involved in NSI were insulin pens (40% of injuries), needles for subcutaneous injection (21%), and lancet needles (20%). All three of these devices are used in the care of patients with diabetes. Therefore, in nursing homes, diabetes treatment is a major source of NSI and should receive priority attention in the development of preventive strategies.

Diabetic Patients and Deadly Viruses

According to one study (Demir M, Serin E, Göktürk S et al. Jul. 2008), HBV DNA was discovered in 11% of type 2 patients with diabetes, compared to 3% of the control sample. The CDC has recently recommended mandatory HBV vaccination for patients with diabetes and has warned that many of them may have been infected in places where they undergo assisted blood glucose monitoring, with more than one person using the monitor (Poll-Hepatatitis B Vaccine Recommended for Adults and Vaccinnes). A worrying proportion of European nurses treating people with diabetes have not had HBV vaccination (De Schryver A, Claesen B, Meheus A et al. Sep. 2010).. The prevalence of HCV (Simó R, Hernández C, Genescà J et al., Sep. 1996) among people with diabetes is also higher than in the general population and the prevalence of HIV (Mondy K, Overton ET, Grubb J et al., Mar. 2007) is approximately equal. For these viruses no vaccination currently exists.

Diabetic Needles and Blood

Furthermore, diabetes needles themselves have been shown to retain traces of blood. It takes very small quantities of blood to transmit HBV or HCV and minute, even invisible, amounts of blood are present on used insulin needles. This can add up to approximately 10,000 virus particles per µL, a number sufficient to infect many people with HBV. The load for HCV is lower, but is still enough to infect multiple victims. If we move from risk to actual conversions, the story is still worrying; there are studies showing HCV conversions are between one and two for every hundred NSI percutaneous exposures with contaminated sharps (UK Occupational Bloodborne Virus Report, November 2008). For HBV this may be as common as one for every three exposures in unvaccinated victims (Denes AE, Smith JL, Maynard JE et al.,1978)..

EU Directive

In June 2010, the EU Council published Directive 2010/32/EU on the prevention of sharps injuries in settings like nursing homes. It requires that all at-risk injections or bloodletting with lancets must be done with safety-engineered devices (Council Directive 2010/32/EU). The Directive must be implemented in all nursing homes in all EU member states by 11 May 2013, at the latest.

WISE Conclusions

The Workshop on Injection Safety in Endocrinology (WISE), sponsored by the European Medical Association, brought together 57 leaders from 13 countries to discuss the application of the new EU Directive to diabetes care. Specific WISE recommendations for safe injections in diabetes have just been published by a leading medical journal, Diabetes & Metabolism (Strauss K, WISE Consensus Group, Jan 2012). These recommendations state that all injections or fingersticks for managing diabetes in nursing homes must be done with safety-engineered devices.

References

Council Directive 2010/32/EU, Official Journal of the European Union, L134/71. Available from:-http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF

Demir M, Serin E, Göktürk S et al. (Jul. 2008). The prevalence of occult hepatitis B virus infection in type 2 diabetes mellitus patients. Eur J Gastroenterol Hepatol., 20(7): 668-73.

Denes AE, Smith JL, Maynard JE et al. (1978). Hepatitis B infection in physicians. Results of a nationwide seroepidemiologic survey. JAMA, 239(3): 210-2.

De Schryver A, Claesen B, Meheus A et al. (Sep. 2010). European survey of hepatitis B vaccination policies for healthcare workers., Eur J Public Health, 1(3): 338-43. Available from: http://www.ncbi.nlm.nih.gov/pubmed?term=European%20survey%20of%20hepatitis%20B%20vaccination%20policies%20for%20healthcare%20workers

EU Commission for Employment, Social Affairs and Inclusion, New legislation to reduce injuries for 3.5 million healthcare workers in Europe, 8th March 2010. Available from: http://europa.eu/rapid/press-release_IP-10-243_en.htm?locale=en

Kiss P, De Meester M, Braeckman L (2008). Needle stick injuries in nursing homes: The prominent role of insulin pens. Infect Control Hosp Epidemiol. 29(12): 1192- 4.

Mondy K, Overton ET, Grubb J et al. (Mar. 2007, Epub. 22 Jan. 2007) Metabolic syndrome in HIV-infected patients from an urban, midwestern US outpatient population. Clin Infect Dis., 44(5): 726-34.

Poll- Hepatitis B Vaccine Recommended for Adults. Available from: http://www.internalmedicinenews.com/single-view/poll-hepatitis-b-vaccine-recommended-for-adults-with-diabetes/7eff3bd28f.html

Simó R, Hernández C, Genescà J et al. (Sep. 1996). High prevalence of hepatitis C virus infection in diabetic patients. Diabetes Care, 19(9): 998-1000.

Strauss K, WISE Consensus Group. (Jan 2012). WISE recommendations to ensure the safety of injections in diabetes. Diabetes Metab. 38 Suppl 1: S2-8.

UK Occupational bloodborne Virus report, November 2008

Vaccines. Available from: http://www.cdc.gov/vaccines/

Vos D, Gotz HM, Richardus JH (2006). Needlestick injury and accidental exposure to blood: The need for improving the hepatitis B vaccination grade among health care workers outside the hospital. Am J Infect Control, 34(9): 610-2.

The Challenges

Two major goals in medical imaging have yet to be met. The first is the problem of the lack of an exact, noninvasive, image-based, tissue characterisation, and the other is microresolution, which will enable an earlier detection of a lesion, a microscopic metastasis (less than 0.2mm) or the exact edges of a detected lesion.

In Vitro Diagnosis

In vitro diagnosis is a major challenge. An early diagnosis can make a big difference in survival rates. It is known that the process of tumour formation can be picked up in the bloodstream before being sizeable enough to be detected by conventional methods. In vitro diagnostics (genomics, proteomics) therefore have the potential to provide a disruptive solution to earlier diagnosis of a disease and its follow-up. Furthermore, in vitro testing will be less expensive and more accessible (being based on a simple blood test), which will increase the compliance of larger populations for screening purposes. It will simplify medical research in terms of costs and timeliness. Thanks to advances in molecular diagnostics, and to drugs becoming increasingly linked to diagnostic tests, the field of in vitro diagnostics continues to grow more swiftly than the med-tech and devices market (see Figure 1).

Upon clinical maturation of in vitro diagnostics, current radiological screening policy will change profoundly. Screening by radiology will practically vanish, but radiology in general will be far from losing ground. In vitro diagnosis (due to its highly sensitive nature) will generate an immense volume of positive cases (both true and false). Every case will necessitate an investigation for a tumour or disease of 'unknown origin'. Once detected it will require workup for further clinical approaches, such as operability, total tumour burden, and guidance to further diagnosis and therapy.

Affordability

Another major forthcoming challenge is affordability. Although imaging accounts for just 5% of the total healthcare expenditure, yet it is the fastest growing medical service and therefore raises concern about future costs. Unaffordability is driven by the increasing cost of imaging technology, fast growing utilisation, and overutilisation.

The golden age of radiology was characterised by focusing on the "flashy technology". The operational mode was lagging behind. Radiology today, although digital, doesn't operate as a quantitative tool. Interpretation is a subjective art based on intuition, and is still using manual scoring. It was more convenient to pick the 'low hanging fruit' than to provide robust quantitative reporting (limited software and shortage of radiologists have contributed their share to this).

"upon clinical maturation of in vitro diagnostics, current radiological screening policy will change profoundly"

Opportunities

Quantitative imaging, improved communication technology and interventional radiology represent the areas with major growth potential.

Quantitative Imaging

Quality imaging is about precision and evidence-based medicine. It requires standardisation and reduction of variability across devices, patients and time. Objective and quantitative metrics will allow the phenotyping and "personalisation" of a disease by imaging, in an individual or population.

Improved Communication Technology

Improved networking and communication will offer active sharing of databases (data availability anytime, anywhere), such as Picture Archiving and Communication Systems (PACS), Radiological Information Systems (RIS) and Integrating the Healthcare Enterprise (IHE). Decision support technology will improve utilisation management by enabling better justification, appropriateness, and economically responsible 'value-based radiology' in the spirit of 'accountable care.'

Telemedicine offers better use of human resources by recruiting and employing radiologists independent of geographical location and time zone. Workflow management will have improved analytic tools to assist in clinical prioritisation, and the pre-detection of abnormal cases, with faster reporting of urgent findings.

Interventional Radiology

Interventional radiology is a great opportunity as it retains two major disruptive elements, i.e. minimising invasiveness and lowering costs. Newer techniques that will reduce radiation to both patient and physician, and smarter semi-automated guidance software will shorten the procedure time and improve safety. This may also carry mixed feelings whether it is a challenge or opportunity from the radiological point of view, as it will fuel the ongoing turf battles with

other clinicians, and may change the current operational model, which will become increasingly interdisciplinary.

Connected Devices

By 2020 there will be more than 50 billion devices connected to each other and to the internet, with medical devices being the third largest component. Medical and healthcare aspects of the "internet of things" include telemonitoring, emergency notification systems, and portable laboratory testing. Radiology-related "i" features include e-health data exchange, teleradiology and actual devices with U.S. Food and Drug Administration (FDA) clearance, such as smartphone ultrasound, and displays for remote radiological reading and accessibility. Portable devices such as handheld ultrasound machines utilised by operators from disciplines with limited training in medical imaging are supposed to revolutionise the diagnostic approach (Topol 2012). However, the use of low level handheld equipment by operators with limited skill and training will generate a trail of imaging follow-up studies performed by experienced radiologists using high-end equipment to sort out the true from false positive.

The "Invisible" Radiologist

Another current issue considered as a challenge concerns the 'invisible role' of the radiologist in the modern medical practice. The prevailing image is that of a radiologist situated in the 'back office', secluded in a dark small cubicle, with minimal contact with the patients. This is not surprising when considering that many radiologists have chosen their medical specialty, fully realising the lack of patient contact it entails. Samuel Shem articulated this notion well in his renowned novel *House of God*, by describing radiology as an N.P.C. (No Patient Care) specialty (Shem 1978). Nevertheless, modern clinicians are on their way to becoming invisible as well. Virtual Skype visits, robotic surgery, robotic rounds and telemonitoring are becoming part of the digitalised practice of medicine.

The' invisible doctor' and 'faceless patient' represent the identity crisis of modern medicine, based on reductionism, objectivism and digitalisation, which is induced by the "purely scientific" approach. This was also well summarised by Eric Topol in his book *The Creative Destruction of Medicine* (Topol 2012): "Reliance on remote monitoring and avoiding hospitalisation or in-person office visits can be tempting physicians into "treating the digital information instead of the individual".

"Wireless wellness" will generate an overwhelming amount of imaging volume, and as radiology is basically an "intuitive art", it will initially increase dependency on radiologists. Nevertheless, automated autonomous reading systems that will be developed to "help" the interpretation process, thus simplifying interpretation of a significant portion of the work, may have a mixed impact on radiology, as non-radiologists may have the opportunity to take an increasing role in supervising and providing interpretation, rendering some of the radiologists redundant. This will also make radiologists more invisible, and the risk is that radiologists may lose their say and influence on imaging healthcare policies and decision-making processes.

The automation and digitalisation of the medical art is a huge challenge. Automation is at its best when employed upon "textbook" cases, but it cannot perform tasks that involve perception and manipulation, creative and social intelligence, and dealing with emotional situations.

Although changes in radiological practice may occur, as in the case of screening for cancer, the bottom line is increased demand for imaging services, despite economic restraints and the advent of new in vitro diagnostic tools.

Factors increasing the future demand for radiology include the ageing population, and the growing prevalence of chronic diseases and cancer survivors. In vitro testing will create demand for imaging workups through its increased sensitivity and potential overdiagnosis. Last but not least, changing geopolitics will generate a growing demand for imaging devices and services in the unsaturated growing economies, which hold a vast untapped potential for expansion in patient care.

Key Points

- Radiological technology is shifting from a "disruptive" period to a sustaining phase.
- Challenges include tissue characterisation and microresolution, affordability and the "invisible" radiologist.
- Opportunities include quantitative imaging and interventional radiology.
- In vitro diagnostics will change radiological screening policy.
- Automation may have a mixed impact on radiology.
- Demand for radiology will continue to increase due to ageing population, and growing prevalence of chronic disease and cancer survivors.

References

Christensen CM (1997) The innovator's dilemma: when new technologies cause great firms to fail. Boston: Harvard Business School Press.

EvaluateMedTech® (2014) World preview 2014, outlook to 2020. Evaluate Ltd., www.evaluate.com

Schumpeter JA (1942) Capitalism, socialism, and democracy. New York: Harper.

Shem S (1978) The house of God. New York: Richard Marek.

Singh PS (2013) Technological innovation and its effect on public health in the United States. J Multidiscipl Healthc, 6: 31-40. http://www.ncbi.nlm.nih.gov/pubmed/23378771

Topol E (2012) The creative destruction of medicine: how the digital revolution will create better health care. New York: Basic Books.

HOW TO COMMUNICATE RADIATION DOSE AND CONTRAST MEDIA INFORMATION

Prof. Davide Caramella, *MD*

Diagnostic and Interventional Radiology
University of Pisa, Italy

HealthManagement Editorial Board Member

davide.caramella@med.unipi.it

Public awareness and concern about radiation safety has grown in the last few years, and concerns have been voiced about radiation dose, for example in breast imaging, across a wide range of media. People are worried; they receive conflicting, sometimes confusing information, and they come to the radiology department with these concerns.

Legal Requirement

The new European directive, 2013/59/Euratom, requires communication to patients. Article 57 states:

"Prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure" (Council Directive (EC) 2013/59/EURATOM).

In the past, informed consent was usually limited to the administration of contrast material. Now, even for a chest x-ray, to take the directive literally, the radiologist or doctor who requires the examination should explain before the examination that exposure to the x-ray may entail some radiation-related risk to the patient.

After the examination, the new directive requires that the radiologist include in the report information about radiation dose: "information relating to patient exposure forms part of the report of the medical radiological procedures" (Council Directive (EC) 2013/59/EURATOM). The radiologist has to write down how much radiation dose was given to the patient during that specific examination. Already, in most PACS systems, together with the diagnostic images, secondary capture images are also stored that give information about the radiation dose and contrast media associated with each examination. In an age of full transparency, in a sense there is a lot of information that can be misinterpreted and be a source of worries to patients.

How to Communicate

It is a truism, but the choice is never between communicating or not communicating, but between communicating well or badly. When the radiologist does not communicate, it encourages the patient to find information on the web, for example on websites that provide a risk calculator where the patient can input data for each study (gender, age, number of exams performed, associated absorbed dose), and the software calculates the effective dose and additional cancer risk. This is very worrisome for patients, because they think, for example, that they are going for a screening examination to ensure early diagnosis of cancer, but at the same time it increases the chances of getting cancer.

When the communication is there, it can be bad, and it may even have the effect of inducing the patient not to accept the examination that is actually useful for his or her health. Radiologists have to control the "scattering" of information, by avoiding use of confusing acronyms and physical dimensions, such as absorbed, equivalent and effective dose that are familiar to professional staff, but may be confusing for the layperson.

Some departments communicate the risk associated with radiation exposure during the medical procedure by using metaphors. Instead of saying that the patient is getting so many millisieverts (mSv), which are associated with a certain increase in health problems, they propose metaphors that take into consideration risky situations that are more familiar to the patient, such as smoking or driving.

Communication Strategy

Patients do not need to be frightened. I have heard patient groups reacting to the new directive, saying, "We don't want to know the technical details, we're not interested in millisieverts". Most have this reaction, because they trust doctors. They say, "I will go and have the x-ray, because you assure me that I need the examination." They want to be assured that when they go to a hospital to have an examination, they will receive state-of-the-art service. Radiology departments have to develop an appropriate communication strategy that does not

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frighten or confuse the patient, and is compliant with the regulation.

Following the new directive, departments will have to record in the radiology report the radiation dose given to the patient. However, radiologists can mitigate this information, which might be threatening or incomprehensible to the patient, by adding information about the department where the examination has been performed and the procedures that are in place to ensure that variations which are not clinically justified are reduced to a minimum, thereby ensuring reproducibility, consistency and quality of all examinations.

Marketing Strategy

Radiology departments need a marketing strategy. Yes, x-rays may be dangerous, but patients have an x-ray exam because it is justified. It is useful to have decision support systems that justify the examination, and patients must be given the information that guarantees that the department is committed to quality service also in terms of radiation dose. Radiology departments should be very clear in their mission statement that in their daily practice they aim for the right diagnoses after the right exam performed at the right time with the right protocol for each patient, with respect to different ages, sex and sizes.

Radiology departments need to measure, and they have to systematically use the quantitative approach in order to improve, where there is a margin to improve. Departments have to show that they are performing meticulous dose tracking for the exams most frequently performed in their department, and show that variation, when it is there, is in examinations that are in principle valuable to the clinical conditions of patients that are inherently different.

Information can be more in-depth: for example, histograms are a way of benchmarking the individual examination with respect to the same type of examinations performed in a department. Histograms that show radiation dose can reassure the patient that he/she is in the group of examinations that are associated with the least amount of radiation dose. It is a subtle way of benchmarking the individual examination. Histograms can also benchmark data with other radiological groups. Patients having repeat examinations may want to have information about accumulated dose, and departments must be prepared to produce this.

Another marketing opportunity in Europe is to promote the radiology department as a Friend of EuroSafe Imaging. Friends of EuroSafe are committed to supporting the EuroSafe objectives:

- Promoting appropriateness;
- Maintaining radiation doses within diagnostic ref erence levels (DRL);
- Promoting the use of up-to-date equipment;
- Use the As Low As Reasonably Achievable (ALARA) principle;
- Improve communication with patients.

EuroSafe's Imaging Action Plan includes as Action 11: "Improve information for and communication with patients regarding radiological procedures and related risks in order to ensure empowerment of patients". EuroSafe Imaging is preparing tools to help radiologists to communicate with patients.

Get Ready

Radiology departments have to prepare for the implementation of the European directive by carrying out rigorous preliminary housekeeping. Marketing efforts are counterproductive, if departments do not work in a very controlled way, and examinations are associated with doses that vary quite randomly. If the line of a patient's examination is on the wrong side of the histogram without a valid clinical reason, this is not good for the department's image. Radiology departments will be increasingly transparent, and when numbers will be on the report they have to be absolutely ready.

There are many commercially available radiation dose and contrast medium tracking software solutions. There is healthy competition, and the radiological community can choose the tool that is best suited for their local situation, IT infrastructure and PACS system. In my opinion, the adoption of radiation dose and contrast medium tracking software solutions is not avoidable. IT is going to be very useful for fine-tuning radiological activities aiming at total quality. Departments need to make sure that variations in contrast media usage and radiation doses are all clinically justified, that there is no random deviation, and that all variations can be explained to patients. Dose tracking is needed to ensure systematic, comprehensive and shared collection of data, and the radiology department must act on it in order to improve.

In our department we started this work some time ago, and it is a lot of additional work. We established a dose team, including our chief technologist, three junior technologists, a medical physicist, an engineer and a medical student. They help me to make sure that this software provides data, and that these data do not contain errors, because sometimes the raw extracted data may need to be analysed further.

It is not easy to obtain additional help in a time of cost-containment, but careful planning should be put in place before embarking on a project of radiation dose and contrast medium tracking, because this will certainly be an additional activity for already busy radiological departments. ■

Key Points

- Radiology departments need to communicate with patients about radiation dose and contrast media to confirm with the new European directive.
- Departments must track radiation dose, and be prepared for the additional workload this requires.
- Radiation dose information and quality assurance can be a marketing tool for departments.

References

Council Directive (EC) 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives89/618/Euratom, 90/641/Euratom. [Accessed: 30 October 2014] Available from: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013L0059

EuroSafe Imaging a. Friends of EuroSafe. [Accessed: 30 October 2014] Available from: http://www.eurosafeimaging.org/friends-of-eurosafe

EuroSafe Imaging b. EuroSafe Imaging Call for Action. [Accessed: 30 October 2014] Available from: http://www.eurosafeimaging.org/about/call-for-action

Miniati F, Paolicchi F, Caramella D (2014) Dose monitoring softwares: new tools for radiology quality. HealthManagement, 14(3): 49-50.

RADIOLOGY DOSE MONITORING SOLUTIONS 2014

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USA

+1-800-920-4109

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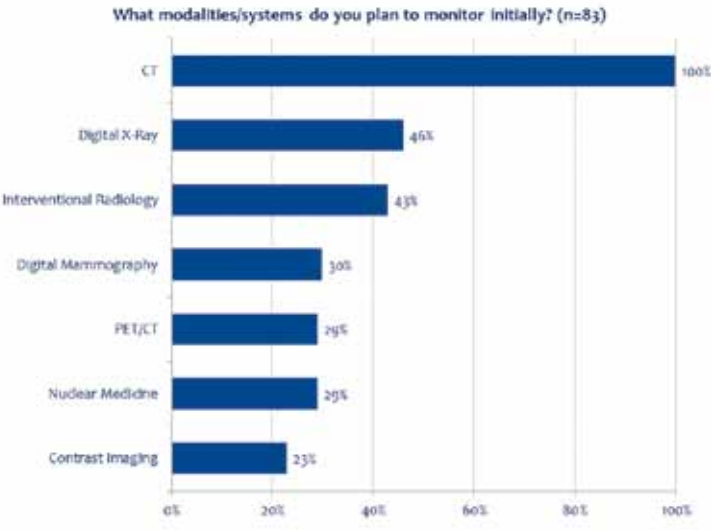
Awareness of radiation dose is a key concern for radiologists and patients on both sides of the Atlantic. A number of dose monitoring solutions are available from vendors. But what informs healthcare providers' purchase decisions and how do they intend to use them? KLAS has issued a report *Radiology Dose Monitoring Solutions 2014: Provider Strategies in an Evolving Market.*

The KLAS report is based on the opinions of 100 healthcare providers, chosen randomly, of which 83 are looking to purchase a dose monitoring solution.



16 vendors offer dose monitoring solutions (alphabetical order):

- ACR
- Agfa Healthcare
- Bayer (Radimetrics)
- Bracco (PACSHealth partnership)
- DR Systems
- GE Healthcare
- Imalogix
- Infinitt
- McKesson (Bayer & PACSHealth partnership)
- Novorad (PACSHealth partnership)
- Radiance
- PACSHealth
- Philips (Bayer partnership)
- Scannerside
- Sectra
- Siemens (Bayer partnership)

The healthcare providers surveyed predominantly had Bayer and GE Healthcare 'top of mind'. They had either considered or already purchased from these vendors. Bayer had the greater share of solutions already purchased.

Purchasing Criteria

Healthcare providers consider functionality, integration, price tag and company recognition and company size.

Low Awareness of Vendor Offerings

From the sample, it would appear that PACS/RIS vendors are not communicating well about their dose monitoring offerings. Some healthcare providers were not considering a particular dose monitoring solution offered by a vendor they already had a relationship with. 45% of the providers surveyed were not aware of any vendor offering apart from their top three choices.

Other Findings

All the healthcare providers surveyed planned to monitor CT dose. Only two planned to monitor dose for all modalities.

The full report *Radiology Dose Monitoring Solutions 2014: Provider Strategies in an Evolving Market* is available from KLAS Research, www.klasresearch.com

About KLAS Research

KLAS works with over 30,000 people in 5,000 hospitals and nearly 3,000 ambulatory organisations. KLAS sources its information predominantly from the United States. KLAS conducts just under 30,000 interviews a year. Provider interviews are conducted at director level and above. Each respondent answers a standard set of questions that require a numeric answer (one-to-nine scale) or a yes/no answer. All evaluations are followed up with a confidential interview, which allows detailed follow up on scores.

THE MODERN RADIOLOGY DEPARTMENT

OPPORTUNITIES AND CHALLENGES IN THE MULTIDISCIPLINARY ENVIRONMENT

Prof. Christoph D. Becker

Professor of Radiology
Chairman, Department of Imaging and Medical Information Sciences
University Hospitals of Geneva
Switzerland

Christoph.Becker@hcuge.ch

The close relationship between the evolution of information technology and advanced biomedical engineering leads to a constant, strong innovative drive for radiologic imaging. Modern advanced imaging offers unprecedented medical information. Cross-sectional imaging techniques, especially magnetic resonance imaging (MRI) and computed tomography (CT) are generally considered to be among the most important innovations in modern medicine (Fuchs and Sox 2001), and have a central role for patient care in every major hospital. Due to the increasing role and unique opportunities of these powerful technologies, and the high cost related to imaging equipment for the hospital, the question may be raised: which is the optimal organisational form for implementation of these powerful technologies, and what is required in terms of knowledge and skills in order to serve the patient best?

The Central Radiology Department: Opportunities

The optimal form of the radiology department depends on a variety of factors, including architectural layout of the hospital, available space for imaging equipment, logistics for inpatients and outpatients and distribution of medical specialties within the campus. A central hospital imaging platform organised in the form of an integrated radiology department, including all biomedical imaging services offers many synergistic effects (Krestin 2009). These include long-term planning and investment strategy for heavy equipment, medical, technical and administrative staff, IT systems such as Radiological Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) for the entire service chain from scheduling to reporting, risk management, quality management, logistics and ergonomics.

Providing 24/7 coverage for diagnostic and interventional radiology in a large general hospital or tertiary referral centre hospital requires a large team of radiologists trained in several subspecialised areas, such as interventional radiology, neuroradiology or paediatric radiology, but also sufficient "allround capabilities". This is more easily provided by a large central imaging department than by small delocalised and subspecialised medical units.

Using imaging equipment for all indications and all patients of an institution may allow optimisation of processes for patient care, cost-effective use of resources, and offer adequate training for medical, technical and administrative personnel. Most biomedical imaging procedures require risk management related to safety aspects of ionising radiation, contrast agents, magnetic fields, intravascular procedures, etc. The quality processes, which are needed in order to guarantee safe imaging to the patients, are best implemented in a common management structure.

Postgraduate training programmes and acquisition of expertise in subspecialised fields of radiology are easier to plan and implement in unified imaging departments with access to all modalities and subspecialties than in decentralised structures, in which imaging is integrated into different clinical departments and postgraduate training programmes.

Finally, professionals providing expertise in areas that support the activities of the radiologist such as MR physics, informatics, image processing or quality management can usually only be afforded by larger structures where they can create synergistic effects.

Challenges: Performance criteria

The performance of a modern radiology department can be measured by a variety of criteria:

- The patient wishes for timely and personalised scheduling, a "smooth and safe" experience in the department and access to information whenever needed.
- The referring physician requires an easy, quick referral process, clear information regarding risk management (contrast agents, radiation, MR safety), timely turnaround of reports, and radiologic medical expertise, including 24-hour coverage.
- Residents look for a complete, didactic postgraduate training programme and interesting career plans; their satisfaction may be surveyed by central authorities.
- Hospital administrators tend to look mainly at indicators for process efficiency or for quality, such as patient satisfaction, team management and return on investment.
- Academic departments are in addition measured by their contribution to undergraduate training, their third-party research funds

and scientific output, and the academic careers and visibility of their staff on a national and international level.

A successful radiology department should meet all of the above performance criteria - a challenge for leadership.

Challenges and Opportunities: Digitisation and "Commoditisation"

Because PACS are now widely used in hospitals, images acquired in the radiology department can be immediately made available to the referring physician for visualisation. The traditional flow of information in the hospital has, therefore, become considerably accelerated, and referring physicians may be tempted to self-interpret images that are not accompanied by a radiology report immediately, albeit a preliminary interpretation. Decentralised or even remote post-processing of standard diagnostic images is possible in many institutions by means of web-based or dedicated post-processing software. Specialised clinicians may make use of these tools for various purposes, such as treatment planning, quantitative image evaluation, or scientific or didactic applications, without involving the radiology department.

The term commoditisation refers to imaging being regarded as a relatively undifferentiated technical service that can be offered anywhere, in a competitive fashion, thus undervaluing the expertise of the radiologist for imaging protocol management and interpretation (Forman et al. 2011). Certain referring physicians may even choose to self interpret or re-interpret imaging studies.

Image communication outside the hospital opens up a variety of opportunities for the radiology department. These include the creation of intra- and inter-institutional networks, improved availability of previous imaging studies, expert consultation for difficult imaging studies or second opinion services. On the other hand, teleradiology services also offer the possibility to economise on local radiology staff by sending locally produced images to distant radiology services for interpretation.

Challenges: Increasing Medical Subspecialisation

The trend towards subspecialisation in internal medicine and surgery related to organ or disease entities often provides the referrer with increased knowledge with regard to the indications for imaging, radiologic anatomy and expected pathologic findings. Radiologists working in multidisciplinary teams or disease-related "centres" thus require additional knowledge in the fields of their clinical counterparts and in-depth knowledge of their needs.

Some imaging procedures and image-guided interventions are the object of "turf wars" between nonradiologist physicians such as cardiologists, neurologists or vascular specialists. Several reasons may explain the interest of nonradiologists physicians in "owning" an imaging procedure: (1) the knowledge acquired in a given field may make the nonradiologist physician believe that he or she can or must do without a radiologist, especially in situations where the radiology department does not or cannot provide trained and skilled staff radiologists in the respective field; (2) ownership of an advanced imaging technology may appear to a subspecialised nonradiologist physician as an advantage to his or her field as a research tool and for promoting careers; (3) self-referral offers the opportunity to confirm the physician's own diagnosis, and also gives financial incentives, although it has been shown that the practice of self–referral results in overuse of imaging procedure and increased cost for the health system as compared with radiologist referral (Hillman et al. 1990). Self-referral requires direct access to imaging technology. Although this may be easily obtained in the case of ultrasonography, different forms may apply in the case of CT, MRI or nuclear medicine. Nonradiologists may obtain imaging privileges for certain indications on certain equipment of the radiology department, with the radiology technician reporting directly to the clinician, or both imaging equipment and technical staff may be integrated in nonradiology departments, thus leading to decentralisation of imaging services. Whatever solution is preferred, the radiologist will always end up in an unfavourable position if his referrer chooses to become a competitor for a given procedure.

> ***"image communication outside the hospital opens up a variety of opportunities for the radiology department"***

Radiology departments providing adequate subspecialised imaging services in the relevant clinical fields of the hospital are much less at risk of being involved in "turf wars" as described above than departments who are staffed by general radiologists. The concept of radiologic subspecialisation must correspond to the local referral patterns, workload and needs in a hospital with regard to clinical fields that may be organ-related, patient-related or pathology-related. At least 2-3 radiologists with subspecialty training are usually required for full coverage of a relevant field with regard to clinical services, teaching and research. This

number increases to 4-5 for subspecialty areas where 24 hour services are to be provided, e.g., for interventional radiology. Depending on the local situation, a matrix system may often appear useful, in which some staff radiologists may be integrated in more than one subspecialty.

Fellowship training positions can be established in relevant subspecialties; advanced training usually requires a minimum of two years, depending on the local spectrum. This concept provides interesting career opportunities for senior radiologists, provided that sufficient staff positions are available in the radiology department, and organisation in the form of subspecialty units can be created. The structural and financial requirements may represent a leadership challenge, because the hospital administration needs to be convinced to invest in the central radiology department, and rely on its organisational structure.

Clinical Relevance of the Radiologist

In order to make radiologic medical expertise valuable in the modern multidisciplinary environment, radiologic services need to be fast, accurate, accessible and relevant (Forman 2011). This includes competent guidance with regard to imaging indications, adequate risk management and protocol selection for individual imaging studies, quality and timeliness of reporting, active participation in the definition of clinical pathways, availability for second opinions on external images (role of consultant) and regular participation in subspecialised clinical rounds and tumour boards. The subspecialised radiologist remains attached to his or her department, but works closely with his clinical counterparts, and ensures advanced postgraduate training and research activities in his field. He or she may also have a key role representing radiology in disease–related multidisciplinary centres (Reekers 2014). This form of organisation places the patient in the centre of the multidisciplinary team of specialists (see Figure 1). It has been shown in tertiary cancer care centres that radiologic consulting leads to important changes in patient management. However, the average daily work volume for second opinions and reinterpretation of external images may add up to almost 20% of the workload of a senior radiologist (Brook et al. 2011; DiPiro et al. 2002).

Role of Nuclear Medicine

Although the role of traditional scintigraphy has diminished significantly over the past decade, new imaging modalities combining MR and CT with modalities such as positron emission tomography (PET) or single – photon emission computed tomography (SPECT) have been successfully introduced in clinical medicine. Because the implementation and interpretation of PET-CT, MR-PET and SPECT-CT requires technical and medical skills related to both radiology and nuclear medicine, these combined imaging modalities are also referred to as "hybrid imaging techniques", and play an increasing role in clinical fields such as oncologic imaging, neuroimaging or musculoskeletal imaging. Hybrid imaging may also have an increasing role in the future with regard to new molecular imaging techniques in the context of "personalised medicine"and "theranostics" (European Society of Radiology 2011).

It appears obvious that the organisational structure of a modern imaging department should allow for training curricula that enable some trainees of these disciplines to acquire certification in both disciplines, so that subspecialists eventually can interpret all relevant imaging modalities that are relevant in their respective fields. Clearly, this can be best achieved in structures where nuclear medicine is integrated with radiology in the same department. Although this is the case in many North American institutions, organisational structures in Europe are currently still quite variable, as are the training programmes for dual specialists in many European countries. However, change is likely to occur over the years to come. ■

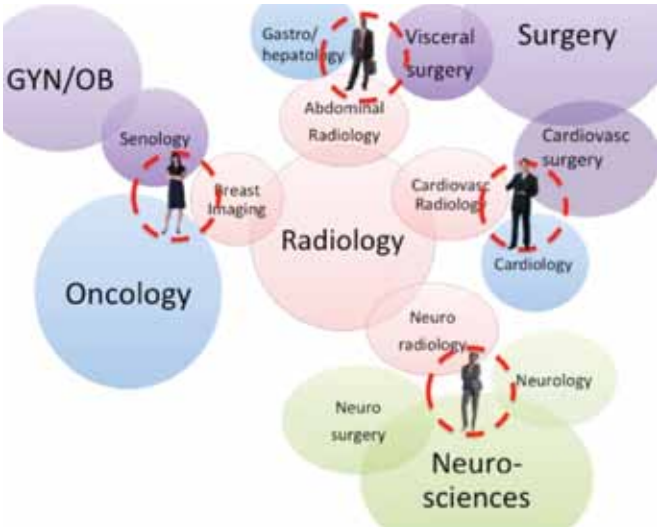


Figure 1. Organisational Structure Placing the Patient in the Centre of Multidisciplinary Medical Teams.

The diagram reflects only some of the possible participating disciplines for each pathology.

Key Points

- A central, integrated radiology department offers many opportunities with regard to quality, 24/7 coverage, logistics, economics, management and specialised logistic support compared to decentralised imaging structures.
- Subspecialisation related to clinical fields and continuous participation in multidisciplinary activities in the hospital are key factors contributing to the radiologist's clinical relevance to patients and colleagues.
- Implementation of the evolving hybrid imaging modalities requiring knowledge and skills in both radiology and nuclear medicine can best be accomplished when both disciplines are integrated in a central imaging department.

References

Brook OR, Hakmon T, Brook A et al. (2011) The effect of a radiology conference consultation on cancer patients management Ann Oncol, 22: 1204-8.

DiPiro PJ, vanSonnenberg E, Tumeh SS et al. (2002) Volume and impact of second-opinion consultations by radiologists at a tertiary care cancer center: data. Acad Radiol, 9(12): 1430-3.

European Society of Radiology (2011) Medical imaging in personalized medicine: a white paper of the research committee of the European Society of Radiology (ESR). Insights Imaging, 2:621-30.

Forman HP, Larson DB, Kaye AD et al. (2011) Masters of radiology panel discussion: the commoditization of Radiology AJR Am J Roentgenol, 196; 843-7.

Fuchs VR, Sox HC (2001) Physician's views of the relative importance of thirty medical innovations. Health Affairs, 20(5): 30-42.

Hillman BJ, Joseph CA, Mabry MR et al. (1990) Frequency and costs of diagnostic imaging in office practice - a comparison of self–referring and radiologist-referring physicians. N Engl J Med, 323: 1604-8.

Krestin GP (2009) Maintaining identity in a changing environment: the professional and organizational future of radiology. Radiology, 250: 612-7.

Reekers JA (2014) The spider model for clinical involvement in radiology. Insights imaging, 5: 403-5.

PET-MR

CHALLENGES AND NEW DIRECTIONS

Prof. Mathias Goyen
Executive Medical Director
GE Healthcare

Adjunct Associate Professor
University Medical Center
Hamburg-Eppendorf
Germany

Industry Adviser, HealthManagement
Editorial Board

mathias@goyen.de

The combination of clinical MR and PET scanners has received increasing attention in recent years. The information provided by MR enables PET-MR to go far beyond simple anatomical registration of PET molecular imaging, while the simultaneous acquisition of PET and MR data opens up new opportunities impossible to realise using sequentially acquired data. This combination of MR and PET technology has proven to be very challenging due to the detrimental effect of the scanners on each other's performance. Significant progress has been made in the last 10 years to solve various technical issues, leading to the recent release of clinical whole-body hybrid scanners.

Technical Aspects

As PET lacks the spatial resolution offered by MRI, which in turn lacks sensitivity, the combination of PET and MR technology is highly complementary. While PET-CT scanners have quickly been integrated into clinical routine, the development of combined PET and MR has been much slower, because of numerous technical challenges on both sides (Catana et al. 2013). MR cannot simply replace the CT part of a PET-CT scanner, as a whole-body PET-MR system requires technical modifications of both the PET and MR part. Details of the physics of these challenges (Quick 2014) are beyond the scope of this article. One major challenge of PET technology in an MR environment is the presence of a magnetic field causing spatial distortion in photomultiplier tubes (PMT), which are the scintillation light detectors for PET scanners. Advances in photon-detector technology have led to silicon-PMTs, which are insensitive to magnetic fields.

PET, on the other hand, can be challenging for MR technology (image artefacts or decreased signal-to-noise ratio, susceptibility effects etc.). Moreover, the issue of accurate MR-based methods for attenuation correction of the measured PET data, particularly important for quantitative PET, needs to be addressed. Different methods for deriving attenuation maps from MR have been proposed (Catana et al. 2013; Pace et al. 2013). One of the main challenges, i.e. the limited space available inside the bore of standard MR systems, has been solved by introducing larger, 70 cm bore diameters providing enough space to integrate the PET camera (Catana et al. 2013).

"more research is needed to determine the cost-effectiveness of PET-MR technology"

PET-MR Scanners for Clinical Use

Following the installation of the first head-only PET-MR scanner in 2007 (Schlemmer et al. 2008), whole-body PET-MR scanners have been introduced into clinical routine by the major medical equipment manufacturers (Siemens Healthcare, Philips Healthcare, GE Healthcare), proposing different PET-MR designs. As only a few whole-body PET-MR systems are already operating, the challenge is to understand the clinical potential of this new imaging modality. Although still limited in numbers, several studies show a better performance in those indications requiring high soft tissue contrast.

Clinical Applications

Whole-body PET-MR imaging has the potential to supplement or even replace combined PET-CT imaging in selected clinical indications. When discussing the immediate benefits of combined PET-CT examinations, the issue of patient exposure must be taken into account. As shown in a multicentre study, whole-body PET-CT examinations result in an effective dose to patients in the order of 25 mSv, and thus mandate a thorough medical justification for each individual patient. Up to 70% of the total radiation exposure is contributed by CT (Brix et al. 2005). It would thus be very welcome if PET-MR could replace PET-CT whenever possible, as soon as the methodological challenges of this new imaging modality have been overcome.

In various paediatric malignancies PET-CT has significantly improved diagnostic accuracy. However, due to the increasing consideration of radiation risk, especially to the paediatric population, prospective studies are limited, because whenever a PET scan is needed in these patients a CT scan is also required for attenuation correction or for anatomical correlation. MR in PET-MR scanners could replace CT for attenuation correction in these

patients, thereby significantly reducing radiation exposure compared to a PET-CT study (Catana et al. 2013).

Radiation exposure is also of concern in adult patients in need for multiple PET-CT scans, such as lymphoma patients. Here PET-MR is a highly attractive alternative imaging modality, providing accurate anatomic localisation without any radiation exposure associated with CT scanning (Drzezga et al. 2012; Platzek et al. 2012).

In patients with head and neck malignancies, MR is superior to CT in terms of accurate staging of tumour extent, involvement of soft tissue structures and nodal involvement. Therefore, PET-MR will likely improve the assessment of tumour extent, involvement of bony structures and bone marrow (Catana et al. 2013).

MR is also the modality of choice to assess and stage prostate cancer. It can reliably diagnose extracapsular extent and neural invasion (see Figure 1) and can improve the accuracy of the assessment of the primary tumour (Jambor et al. 2012; Beer et al. 2011).

In breast cancer MR has been shown to be very useful for local staging and treatment monitoring, and it has greater sensitivity even than conventional imaging methods. Currently there is insufficient data from larger patient cohorts available regarding the performance of combined PET-MR in imaging primary breast cancer and determining local tumour extent. Initial experience with a combined PET-MR approach for the evaluation of the primary tumour suggests that adding FDG-PET information to MR mammography leads to improved information regarding local tumour extent (Buchbender et al. 2014; Pace et al. 2014).

PET/CT is increasingly used for monitoring the effectiveness of therapy in patients with malignant diseases. Use of quantitative measurements of tracer uptake is preferable to use of visual assessment in determining accurately and objectively the degree of tumour response. Combined PET/MR measurements could help quantify precisely how tumour vascular properties (assessed by functional MR methods), proliferation and anti-tumour effects (assessed with PET) occur and interact (Catana et al. 2013) (see Figure 2).

A future application where PET-MR may change how we practice is to assess patients with suspected Alzheimer's disease (AD). The combination of PET and MR imaging will lead to an earlier and more definitive diagnosis as PET and MR provide complementary information (Jack 2008): PET can characterise local upload of amyloid, whereas MR depicts neuronal degeneration.

Costs and Reimbursement

The applicability and recognition of PET-MR as an imaging modality in diagnostic oncology is affected by several factors, of which reimbursement seems to be a major obstacle for the diffusion of PET-MR in a clinical setting. Comparative clinical benefits for existing PET-MR approaches need to be established, as well as the caseload and case mix required for effective utilisation of a hybrid PET-MR-scanner. PET-MR has developed and matured over the last decade. The technology's cost remains a significant obstacle. Integrated PET-MR scanners carry a price tag of approximately US $7 million. Similar to PET-CT scanners, which were very expensive when they first came out, and dropped in price as the technology became more available, PET-MR-scanners

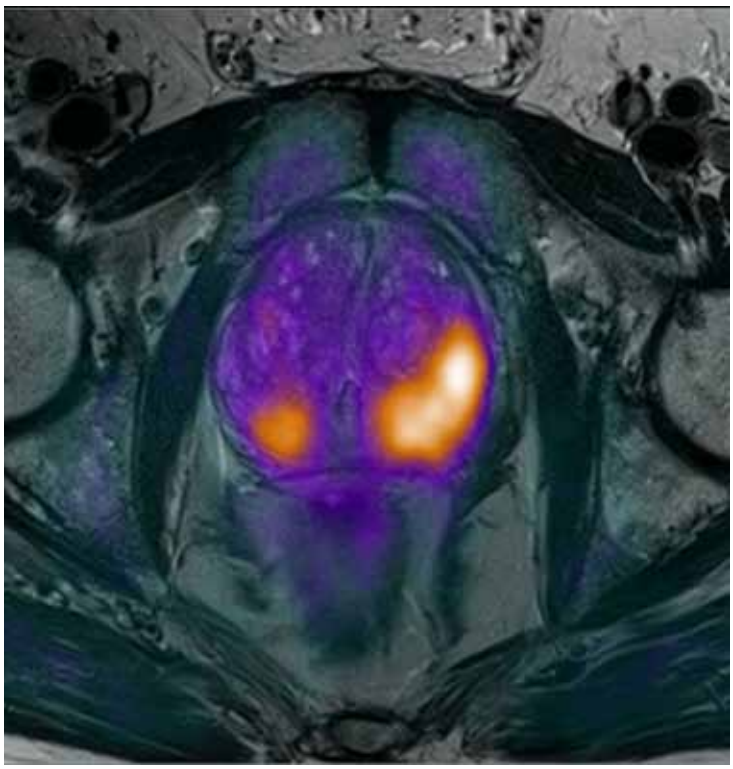


Figure 1.
PET-MR image of the prostate in a patient with suspected prostate cancer showing both lobes are affected (left > right). By combining PET and MRI data, a more accurate delineation of prostate cancer is possible
Image credit: Prof. Dr. med. Thomas Lauenstein, Dept. of Radiology, University Medical Center Essen/Germany)

will also decline in price. More research is needed to determine the cost effectiveness of PET-MR technology (Goyen 2014).

Conclusion

PET-MR is an exciting imaging technology with great potential, paving the way for increased diagnostic power in several clinical scenarios, but the main indication for PET-MR in oncology remains to be defined. PET-MR definitely has the potential to significantly increase our knowledge in vivo of cancer physiology. Many factors will decide the ultimate role of PET-MR systems within the overall healthcare system, not the least of which is the cost of such systems, and the degree to which the benefits accrued match the resources required to perform and interpret these studies in the clinic, as PET-MR will demand interdisciplinary training and a truly multidisciplinary set up involving physicians, physicists and technologist from both the field of nuclear medicine and PET as well as MR imaging and radiation therapy (Catana et al. 2013). If the future of clinical practice is precision medicine, where therapeutic decisions are designed around specific molecular pathological events at the earliest possible stage (Goyen 2014), then PET-MR systems will dramatically impact the expanding field of molecular imaging in the future. ■

"PET-MR will demand interdisciplinary training and a truly multidisciplinary set up"

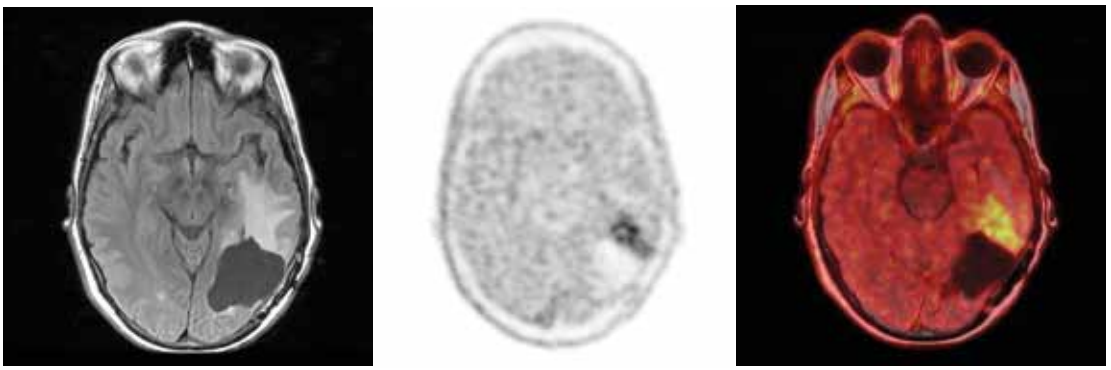


Figure 2.
PET-MR image (18F-FET, tyrosine) in a patient with known glioblastoma (GBM) (a: axial FLAIR, b: PET only, c: PET-MR) showing recurrence of GBM with FET-uptake

Image credit: Priv.-Doz. Dr. med. Patrick Veit-Haibach, Dept. Medical Radiology, University Hospital Zürich, Zürich/Switzerland)

Key Points

- The combination of PET and MR technology is highly complementary.
- The issue of accurate MR-based methods for attenuation correction of the measured PET data needs to be addressed.
- PET-MR imaging is clinically indicated for certain paediatric cancers, lymphoma, breast and prostate cancers and head and neck tumours, with the benefit of reduced radiation exposure. Future applications may include imaging the brain for Alzheimer's disease.
- Few clinical studies are published, but several show a better performance in indications requiring high soft tissue contrast.
- Use of quantitative measurements of tracer uptake is preferable to visual assessment in determining accurately and objectively the degree of tumour response.
- Factors affecting uptake include cost, reimbursement, establishing clinical benefits, caseload and case mix.

References

Beer AJ et al. (2011) Radionuclide and hybrid imaging of recurrent prostate cancer. Lancet Oncol, 12(2): 181-91.

Brix G et al. (2005) Radiation exposure of patients undergoing whole-body dual-modality 18F-FDG PET/CT examinations. J Nucl Med, 46(4): 608-13.

Buchbender C et al. (2014) MR-PET in breast cancer. In: Carrio I, Ros P, eds. PET/MRI: methodology and clinical application. Heidelberg: Springer, pp. 53-70.

Catana C et al (2013) PET and MR imaging: the odd couple or a match made in heaven? J Nucl Med, 54(5): 815-24.

Drzezga A et al. (2012) First clinical experience with integrated whole-body PET/MR: comparison to PET/CT in patients with oncologic diagnoses. J Nucl Med, 53(6): 845-55.

Goyen M (2014): Health Care Costs and Impact. In: In: Carrio I, Ros P, eds. PET/MRI: methodology and clinical application. Heidelberg: Springer, pp. 153-8.

Goyen M. (2014) Radiogenomic imaging-linking diagnostic imaging and molecular diagnostics. World J Radiol, 6(8): 519-22.

Jack CR (2008) 11C PiB and structural MRI provide complementary information in imaging of Alzheimer's disease and amnestic mild cognitive impairment. Brain, 131(Pt 3): 665-80.

Jambor I et al. (2012) Improved detection of localized prostate cancer using co-registered MRI and 11C-acetate PET/CT. Eur J Radiol, 81(11): 2966-72.

Pace L et al. (2013) Whole-body PET/MRI in oncology: current status and clinical applications. Clin Transl Imaging, 1: 31-44.

Pace L et al. (2014) Comparison of whole-body PET/CT and PET/MRI in breast cancer patients: lesion detection and quantitation of 18F-deoxyglucose uptake in lesions and in normal organ tissues. Eur J Radiol, 83(2): 289-96.

Platzek I et al. (2012) PET/MR for therapy response evaluation in malignant lymphoma: intitial experience. MAGMA, 16: 16.

Quick HH (2014) Integrated PET/MR. J Magn Reson Imaging, 39(2): 243-58.

Schlemmer HP et al. (2008) Simultaneous MR/PET imaging of the human brain: feasibility study. Radiology, 248(3):1028-35.

THE UNIVERSAL MEDICAL VIEWER

In today's rapidly evolving healthcare environment, the need for cross-department and cross-enterprise information sharing is greater than ever before. This is particularly true for diagnostic images. A universal medical image viewer meets this need by enabling viewing of any medical image, imaging report and related patient data anytime and anywhere outside of a PACS environment. At last digital image access is no longer confined to the department that created the data.

However, all universal viewers are not created equal. This article examines the attributes of a universal viewer, viewing use cases, and the features and functionalities available in the technology today.

The nature of image viewing is changing. The concept of dedicated technology residing on a single workstation and tied to a particular departmental solution is rapidly becoming history. As the need—and legislative mandate—to share images across departments, multi-site enterprises and entire communities expands, a more flexible vendor-neutral viewing system that provides anywhere, anytime image access is rapidly becoming an expectation.

What is a universal image viewer? To some extent this depends on who you ask and what universe they inhabit. Essentially, a universal viewer is a single platform supporting the visualisation of medical images in any format—both DICOM and non-DICOM—and imaging reports that can run on any off-the-shelf computer or universal device in any location to support the workflow of any physician, as the enterprise requires. In other words, it makes images available wherever, whenever and to whomever needed. The solution eliminates the need for users to log into a specialised radiology PACS or other departmental system to view imaging data, as well as the patchwork of specialised solutions often used to provide image access beyond the department that created the imaging data. Such a viewing solution may replace or coexist with a traditional PACS viewer, and may be integrated with a vendor-neutral archive (VNA) or electronic health record system (EHR).

Not surprisingly, the requirements of a universal viewer for a small hospital are often relatively modest compared to the needs of a large, multi-site institution operating in an expansive imaging environment with digital radiology, cardiology, laboratory, ophthalmology and wound care files, a broad network of consulting clinical specialists and referrers covering a large geographic area. To satisfy all their needs and make the most of their budget, hospitals must truly understand their full image distribution requirements before they begin a search for a solution.

Attributes of a Universal Viewer

Today, hospitals can easily find a high-quality image viewing system that is feature-rich, easy-to-use, versatile, secure, and affordable. Some systems actually deliver performance similar to a standard standalone PACS viewer—with all the bells and whistles. But not all viewers are created equal. So a hospital must understand its needs, survey the marketplace and make its choice carefully.

Best of Breed Solution

The best universal viewing solutions provide a range of advanced functionalities that will enable versatile image communication now and as a hospital's needs expand in the future. These include:

- Zero-footprint browser-based technology to view all standard and less common DICOM files for every imaging modality.
- Viewing of all standard and non-standard DICOM images from other medical specialties, such as cardiology and pathology.
- Display of additional image formats, such as jpeg, tiff, avi, mpeg, often used for laboratory, ophthalmology and other images.
- Viewing textual reports.
- Support for the Integrating the Healthcare Enterprise Cross-Enterprise Document Sharing (IHE XDS) profile.
- Server-side image processing.
- Support of a full range of hardware and platforms, including PC and MAC, as well as Android, BlackBerry, iOS, and Windows.
- Support for all standard Web browsers, including legacy technology.
- Streaming technology to make the most of available bandwidth.
- Application Programming Interface (API) for easy integration in other clinical systems.
- Scalability to accommodate a large user base.

Universal Viewing Use Cases

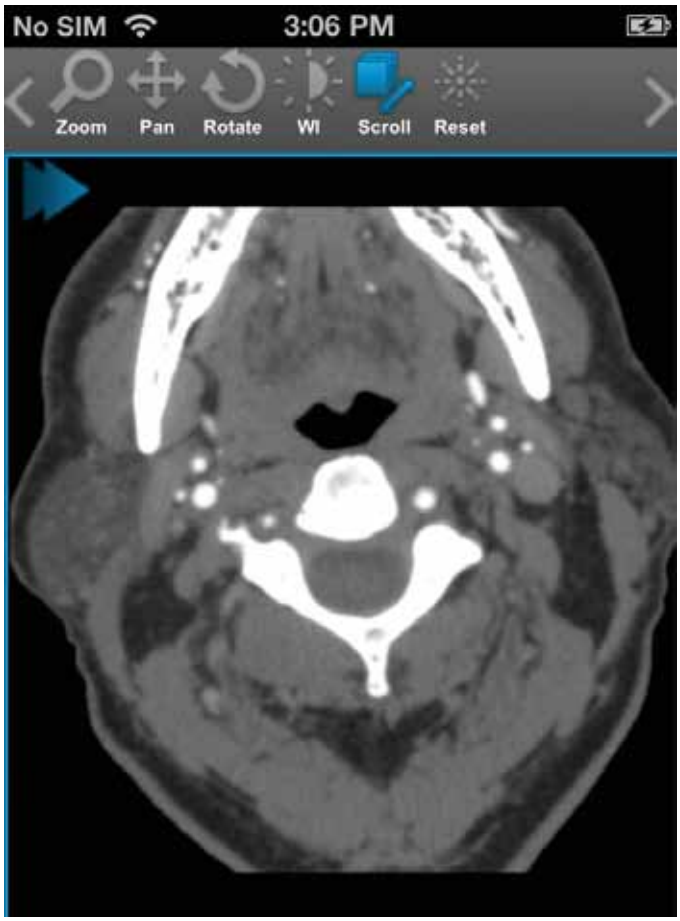
- A universal viewer enables radiologists and clinicians to access patient images and reports when needed, realising

Tom Tilmans

Sales Director, EMEA
Claron Technology

tom.tilmans@clarontech.com

www.clarontech.com



faster diagnoses, therapy decisions and enhanced patient care. The technology supports a variety of other important use cases. These include:

- Image viewing across the enterprise outside of a PACS solution through a VNA or other enterprise-class archive.
- Image-enabling an electronic medical record (EHR) solution.
- Cross-enterprise image sharing for collaboration and second opinions.
- Cross-enterprise image sharing for trauma transfers and other emergency cases, enabling decision-making on a case before the patient is transferred.
- Referring physician image access, typically through a physician web portal.
- Image viewing across a health information exchange (HIE).

images, streamlining hospital processes and procedures. They play a large role in enhancing communication with referring physicians.

Technology Overview

Most universal viewers are browser-based, employing some form of thin-client or zero-footprint technology that downloads from a central server or off-site cloud environment, which is part of the system. This enables use on a wide range of devices in multiple locations with minimal or no updates on these devices. Images to be accessed can be either cached on a universal viewer server or streamed to the server directly from archiving systems like a PACS or a VNA. Users then access the server through a web browser and interact with the application and imaging data remotely—the computing power lies on the server hardware, not the local device. The best viewers do not download images to the device, minimising security concerns. When viewing an image, an authorised user will log into the application with secure authentication protocols, find the desired image and continue from there. The device's connection, whether wired or wireless, is also an important ingredient in the mix. Secure and fast connections are a must for high performance.

Although web-based viewers may use a browser for image display, they can still employ proprietary technology, limiting the usefulness of the images. At times, vendors are less than literal with their descriptions—so buyer beware.

"a universal medical image viewer is becoming a necessity in today's healthcare environment"

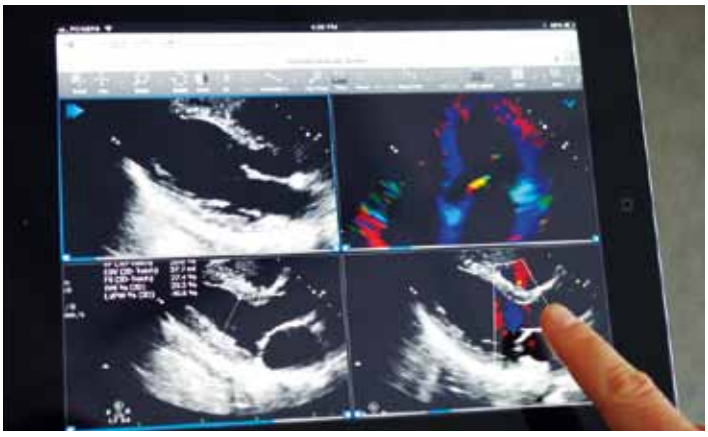
Not every viewer is the best selection for every one of these use cases, and technology choices must be predicated on every site's needs. Hospitals should be sure to identify a system robust enough to meet all their demands today, with an eye towards future needs. Users can also make the most of their budgets by making wise choices and not paying for features they will never need.

Benefits of a Universal Viewer

By providing immediate access to all physicians who need images, a universal viewer can significantly enhance patient care by speeding up diagnosis and increasing treatment efficiency and precision. These viewers also provide convenience and efficiency to all staff involved in using or facilitating access to

Key Points

- A universal image viewer enables viewing of images across departments and enterprises, thus enhancing patient care.
- A universal viewer may replace or coexist with a PACS viewer, and may be integrated with a vendor-neutral archive or electronic health record system.
- Universal viewers offer a number of advanced functionalities, including viewing of DICOM and non-DICOM images and more, server-side image processing, streaming technology and scalability.
- There may be a trade-off between having a zero-footprint solution and availability of advanced features. Few solutions require absolutely no software on the viewing device.



Thin Client vs. Zero-Footprint

The early wave of universal viewers was based exclusively on thin-client technology, with most of the viewing applications running from a server. A plug-in or download of various sizes on the viewing hardware was required. Today, many universal viewers continue as thin client applications. During the past few years, some vendors have progressed to a flavour of zero-footprint technology that still requires installing Adobe Flash software on the device. Few solutions require absolutely no software on the viewing device.

From an IT perspective, thin client technology can create a complex and difficult to maintain IT environment. IT departments need to support the portions of the viewing solution running on remote devices in what is often an uncontrolled operating environment—an iPhone or tablet, which may be treated casually. Therefore, a zero-footprint solution offers tangible advantages over thin-client technology. But on the downside, it can demand a compromise on advanced features. The issue, in part, is the ability of the user interface on a local device to control an application running on a remote server quickly and efficiently to manipulate images as desired. Some vendors have invested significant efforts in making the most of wireless bandwidth to enhance performance and to integrate the most sophisticated viewing functionalities into their systems. Therefore, these viewers deliver the best of both worlds

Conclusion

A universal medical image viewer is becoming a necessity in today's healthcare environment with its emphasis on information sharing and abundance of multiple mobile devices used in healthcare. A wide range of universal viewers are available with significantly different capabilities, from simply providing access to non-diagnostic access to images beyond a PACS to highly sophisticated support for diagnostic quality viewing with a full range of image manipulation tools and the ability to transmit data files in real time. A medical facility should carefully assess its imaging needs beyond the radiology department and the enterprise to determine what features and functionalities it needs in a universal viewer today and in the foreseeable future. It should also carefully examine the capabilities of a full spectrum of such viewers to find the technology that meets its specific needs. ■

QUANTITATIVE IMAGING

BUILDING THE FOUNDATIONS

Prof. Daniel Sullivan

Chair, Quantitative Imaging Biomarkers Alliance

www.rsna.org/qiba

The Quantitative Imaging Biomarkers Alliance (QIBA) was set up by the Radiological Society of North America (RSNA) in 2007 to unite researchers, healthcare professionals and industry stakeholders in the advancement of quantitative imaging and the use of biomarkers in clinical trials and practice. HealthManagement spoke to QIBA's Chair, Professor Daniel Sullivan, about QIBA's progress.

What are the current priorities for QIBA?

Our main priority is developing QIBA Profiles. A Profile consists of one or more claims, which tell a user what quantitative results can be achieved by following the Profile. The details tell a vendor what must be implemented in their product; and tell a user what procedures are necessary. QIBA is working on finishing up Profiles from those committees working on them.

QIBA also works on compliance checklists for manufacturers and vendors. With a scanner manufacturer, for example, the simplest and easiest way to achieve compliance is to have self-certification, as against test objects and phantoms. That way engineers at the factory can run those tests to see if their machine meets specifications. This is a straightforward process for reproducibility. For an individual scanner the physician or physicist can do this test on their own site. We are also looking at this process being part of site compliance. We anticipate that most current scanners will be in compliance. However, there is an installed base of older scanners in the U.S., and many of these will not comply. The compliance process will need a test set of cases, and the challenge is to get a representative set. QIBA would like this process to be part of an existing certification scheme, such as the American College of Radiology Imaging Network (ACRIN™)'s scheme for clinical trials accreditation. There have been preliminary discussions.

In general QIBA is continuing to obtain data about precision for all modalities so that we can get reproducible measurements for all modalities. Collecting data to understand reproducibility has not been well studied or evaluated.

What role will quantitative imaging play in clinical practice in future?

The overarching issue for all physicians is the flood of information they have access to, more than one person can deal with, for example from electronic health records, decision support systems and appropriateness criteria. Ideally all of these systems need objective data. Qualitative reports do not lend themselves to objective data. As physicians more and more expect information to be quantitative and objective, they will demand more of these data from imaging. In addition co-payers will need this kind of information.

Does QIBA facilitate reporting of errors/ variability currently?

Not currently, as the Profiles have not yet been disseminated into clinical practice. They could play such a role in the future, but would need to be more widely disseminated. Third party payers might collect such information. There is little incentive for radiologists to collect such information at present.

Please tell us more about the Uniform Protocol for Imaging in Clinical Trials (UPICT) that QIBA has developed.

This is for use in clinical trials. The idea behind it was to improve consistency of data across multiple sites. Consistent and reproducible numbers within a specified range result from a QIBA Profile. The UPICT protocol, on the other hand, focuses on getting consistent results, whether qualitative or quantitative. A QIBA Profile includes clear specifications that cannot be altered by the user. In the UPICT protocol, because there are often legitimate reasons to alter image acquisition protocols, it is acceptable to edit acquisition parameters, for example in a phase 1 pharmaceutical clinical trial in a few sites trial, as opposed to phase 3 trials in multiple countries. So the standards will be looser in a large phase 3 trial.

Does the standardisation work have implications for costs and management in imaging centres, for example when conducting clinical trials?

It will be important in reducing costs. When the standard is not tight, there is more variety in data collection, more "noise" in the data. So with standardisation we will see a shift from larger studies to smaller trials.

Will this standardisation assist in reconciling the requirements of imaging in clinical trials and imaging in clinical practice?

This is the goal. Some contract research organisations in the United States are promoting use

of QIBA Profiles to their clients. For example, the market leader in transmitting scans from sites to laboratories has developed software that automatically determines if scans meet the QIBA Profile criteria or not.

Is it fair to ask why the development of quantitative imaging biomarkers has taken so long? What are the potential obstacles?

It is fair to say that the development of biomarkers has taken a long time. They all (both imaging and specimen biomarkers) face the same hurdles. There is a lot of anguish about this. For imaging there are even more acute problems in development.

The factors affecting development are: firstly, the science is difficult. Secondly, the business case is weak. There are so many alternatives that it is hard to know what the best payoff will be. It's a gamble.

It is a challenge to get a single protein or the imaging phenotype to uniquely reflect a complex disease. Obtaining data from clinical trials to prove that is difficult and expensive, and clinical trials take a long time.

The cost of doing scans is much higher than a laboratory specimen test. This is an impediment for companies to invest in imaging biomarkers in clinical trials. There has been relatively little commercial sector investment in research in biomarkers. The business case is unfavourable. The cost to develop a PET scan agent, for example, could be several hundred million dollars. The revenue stream is not there to justify that investment in many cases.

Technological improvement is a hindrance also. Technology gets obsolete very quickly. There is not the same benefit from patent protection as there is for a drug. Technology turns over in just 2-3 years.

At the 2013 QIBA working meeting delegates were asked: how do we estimate the value of quantitative imaging before it is implemented and measure its value after implementation? What was the progress?

This is not core work for QIBA. However, it is important that the imaging industry be interested in looking at the value to them, co-payers and clinicians. The biggest impediment is the clinical utility issue. Relatively few treatment decisions currently are driven by quantitative imaging results. It's a chicken and egg situation. You cannot effectively evaluate the clinical utility of an imaging biomarker, because the numbers are not reproducible. QIBA's work is foundational, establishing the threshold for quantitative imaging. For example, in heart disease, with several different treatments now available for congestive heart failure, if physicians could accurately measure a small change in ejection fraction it might trigger a change in therapy. For that to happen you might have to provide the ejection fraction at 5% precision. For chronic obstructive pulmonary disease, you might have to be able to measure a 1% change sufficient for pulmonologists to make a change in therapy. In Alzheimer's a very small (3-5%) change in the volume of the amygdala or hippocampus region might trigger a change in therapy. We don't have the ability to make those precise measurements at the moment, however.

Given current controversies in the U.S. regarding reimbursement for CT screening for lung cancer, will quantitative imaging assist in gaining more support for this?

Leaving aside the issue that Centers for Medicare & Medicaid Services (CMS) decision-making is influenced by political issues as well as scientific ones, QIBA is developing a Profile for CT screening for lung cancer. Marshalling and gathering the evidence for using objective volumetric measurements will, we believe, address the CMS concerns about the lack of consistency and should also reduce false positives. ■

NOTE:
RSNA recently announced an additional $1.27 million of funding from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to support research by the Quantitative Imaging Biomarkers Alliance (QIBA). The funding will be used towards the development of a Quantitative Imaging Data Warehouse, research to characterise the sources of bias and achievable precision associated with quantitative imaging, and to further develop and test phantoms and digital reference objects.

RADIOLOGY IN EUROPE

A SNAPSHOT

Fabio Pinto, MD
Radiologist
Dept. of Radiology
Marcianise Hospital, ASL CE,
Marcianise, Italy

fpinto1966@libero.it

Paolo Sartori, MD
Radiologist
Dept. of Radiology
SS. Giovanni Paolo Castello
Hospital, ULSS 12 VE
Venice, Italy

p.sartori@aliceposta.it

Key Points

- Demand increasing for medical imaging
- Few unemployed radiologists
- Teleradiology and outsourcing lack national legislation
- Other healthcare professions are encroaching on radiology "turf"

Today, European radiology lies at the centre of the healthcare chain. Nevertheless, we don't know very much about how this profession may evolve: what will it be in the future? What is the European perspective? In this era of economic restraints as well as rapidly evolving geo-political factors, what viewpoints are there in different EU countries? For this article, the first author designed a questionnaire, which *HealthManagement* sent to member national associations and societies of the European Society of Radiology (ESR), to gauge the state of health of the radiological world, providing details as to the trends of medical imaging services in forthcoming years. What is likely to be the impact on this profession of new scenarios, such as teleradiology, outsourcing, robotic technologies and other professional competitors?

HealthManagement Survey

HealthManagement sent a 15-question survey to all institutional member societies of the European Society of Radiology, as well as to the radiological society in Iceland.

Fifteen national associations returned the survey: Belgium, Bosnia-Herzegovina, Bulgaria, Iceland, Ireland, Israel, Italy, Netherlands, Norway, Romania, Serbia, Slovak Republic, Slovenia, Spain, and the United Kingdom.

Results

The range of radiologists working in each distinct country varies from a minimum of 1 radiologist to 23,501 inhabitants in Bosnia-Herzegovina, up to a maximum of 1 radiologist vs. 3,972 inhabitants in Romania (see Figure 1).

2. (Un)Employment

The majority of the interviewed associations replied that there are no unemployed radiologists in their countries: in Bulgaria, moreover, they claim a shortage of radiologists. Unemployment was mentioned in Romania (less than 1%), in Spain (1-3%), in Italy (4%), in Belgium, and in the Netherlands (about 10%).

3. Demand for Medical Imaging Services

All the associations, except for Belgium, replied that there is a significant increase in demand.

4. Teleradiology

Teleradiology is widely used in the UK and in Belgium, whereas it has limited use in the remaining countries. Ranschaert and Barneveld published a survey in 2013, which looked at how teleradiology is used in Europe (see Table 1).

Our questionnaire asked if teleradiology was regulated by specific laws. The answer was no, there is a lack of specific laws in all of the involved countries. In a few cases (Belgium, Ireland and Italy), general guidelines have been provided. This appears to be a critical weak point.

5. Outsourcing

Outsourcing is performed only to a small extent in all the countries. In all the enrolled countries, public hospitals use radiology services outside the hospital very seldom. Private hospitals are inclined to use more often radiology services outside the hospital (particularly in countries such as Bosnia-Herzegovina, Israel and the UK, where this percentage exceeds 50%, but also in other places such as the

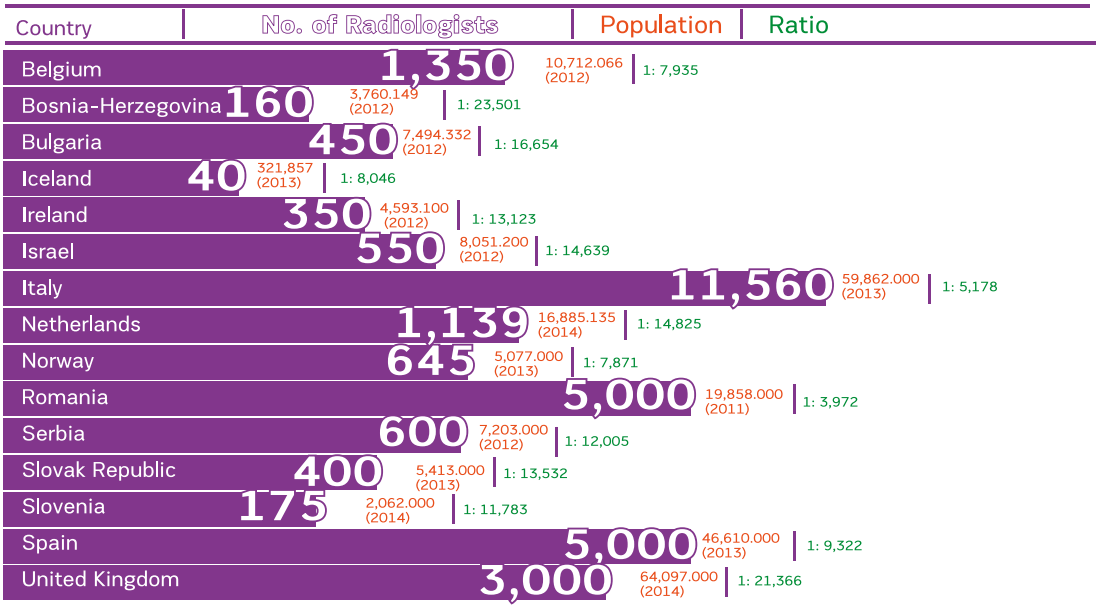


Figure 1.

References

European Society of Radiology (ESR) (2013) Organisation and practice of radiological ultrasound in Europe: a survey by the ESR Working Group on Ultrasound. Insights Imaging, 4(4): 401-7.

Ranschaert ER, Binkhuysen FH (2013) European Teleradiology now and in the future: results of an online survey. Insights Imaging, 4(1): 93-102.

OECD (2013), Health at a glance 2013: OECD Indicators, OECD Publishing. [Accessed: 30 October 2014] Available from: http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf

Acknowledgements

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Appendices

Please visit the HealthManagement website for:
Appendix 1: Respondent Associations and Societies
Appendix 2: Questionnaire

Slovak Republic and Slovenia the range is quite high, between 33 and 50%). There are only a few national laws regulating the outsourcing practice: in Bosnia-Herzegovina, radiologists can have only 30% overtime working hours; in Bulgaria some restrictions apply; in Spain there are some regional and national laws on this matter.

Reasons for outsourcing to teleradiological services have recently been included in the survey by Ranschaert and Barneveld (2013) (see Table 2).

6. Competition

Asked if radiologists in their country were currently threatened by other competitors, the large majority of the interviewed associations replied that radiologists feel currently threatened by other competitors, represented by vascular surgeons, cardiologists, gynaecologists, gastroenterologists, and less frequently by neurosurgeons, emergency physicians, urologists, paediatricians, rheumatologists, neurologists, general physicians, and nuclear physicians. Moreover, in Italy, there is also a turf battle with radiographers.

Who Performs Ultrasound Examinations?

Respondents were asked what percentage of the overall ultrasound examinations is performed by certified radiologists in their country. Here the range is very wide. The peaks are seen in Belgium and in Spain, where about 80% of overall US exams are performed by radiologists. On the other hand, in other countries such as Italy and Bulgaria, only about 40% of US exams are carried out by radiologists (this means that competitors handle the majority of the US workload). Table 3 shows responses to a survey by the ESR Working Group on Ultrasound.

Who Performs MRI Examinations?

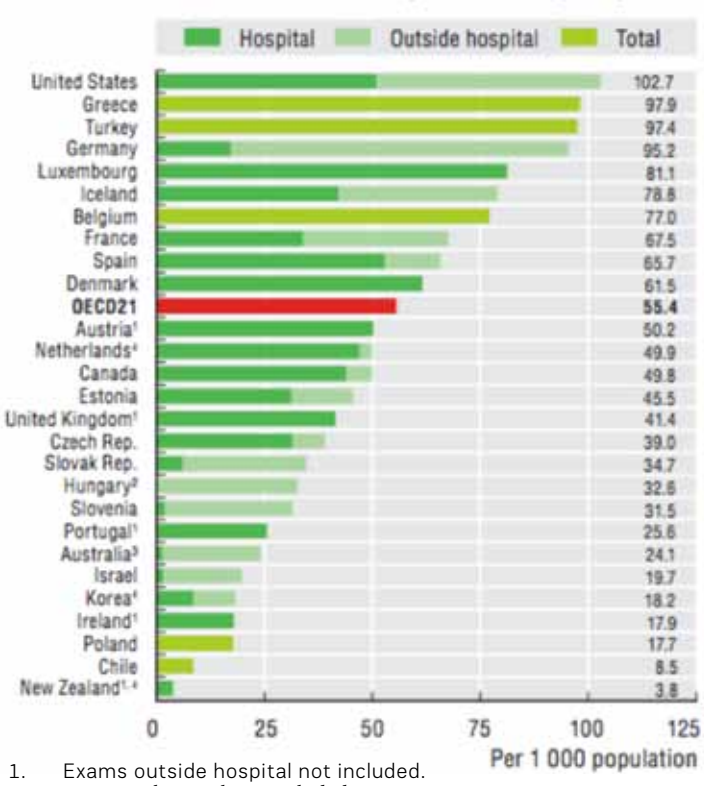
Respondents were asked what percentage of the overall MRI exams is performed by certified radiologists in their country. MRI remains a radiological domain everywhere. In Spain and in Italy less than 5% of the exams are performed by nonradiologists. In the large majority of the respondent countries the percentage performed by radiologists rises up to 100%. Finally, the overall number of MRI exams that were performed in 2011 is shown in Figure 2.

Automation

Respondents were asked if robotisation/automated scanning systems are being used in their country. These innovative systems are seldom used in Europe at the moment. There is limited use in Belgium, Israel, the UK and in Italy (as an example, computer-aided diagnosis (CAD) in mammographic screening).

Future Trends

The questionnaire asked for the respondents' thoughts about the future trends of the radiological profession in Europe as well as in their own country. In general there is an optimistic view about the future of this discipline. In the last few decades, the radiological world has dramatically changed after the introduction of the Radiological Information System (RIS) and Picture Archiving and Communication System (PACS). Thus we have to perform an important role within different multidisciplinary teams. In order to succeed, a high scientific profile has to be kept, together with the ability to understand the evolving needs of the referring physicians.



1. Exams outside hospital not included.
2. Exams in hospital not included.
3. Exams on public patients not included.
4. Exams privately-funded not included.

Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en.
StatLink http://dx.doi.org/10.1787/888932917294

Figure 2.
MRI Exams by Country, 2011 or Nearest Year (OECD 2013)

	Percentage	Number
As part of regular workflow	49%	33
For a second or expert opinion	41%	28
When on call (nights)	40%	27
On a temporary basis (i.e. capacity problems)	19%	13
Other	6%	4

Note: 68 respondents answered the question; 302 skipped the question.
Source: Ranschaert ER and Barneveld FH (2013) European teleradiology now and in the future: results of an online survey. Insights Imaging (2013) 4(1): 93-102.

Table 2. Reasons for Outsourcing

	Percentage	Number
Within hospital (cross-enterprise work list sharing)	71%	144
At home when on call	44%	90
Other	20%	40

Table 1. Use of Teleradiology
Note: 203 respondents answered the question; 167 skipped the question.
Source: Ranschaert ER and Barneveld FH (2013) European teleradiology now and in the future: results of an online survey. Insights Imaging (2013) 4(1): 93-102.

% of hospital US exams performed by radiologists	No. of radiology departments
≥ 90%	25 (20.32%)
70-90%	37 (30.09%)
10-70%	57 (46.35%)
≤10%	4 (3.25%)

Source: European Society of Radiology (ESR) (2013) Organisation and practice of radiological ultrasound in Europe: a survey by the ESR Working Group on Ultrasound. Insights Imaging, 4(4): 401-7.

Table 3. US Examinations Performed by Radiologists

THE ENTERPRISE IMAGING REPOSITORY

NSW'S JOURNEY TO PURSUE SHARING OF IMAGING INFORMATION ACROSS ORGANISATION AND SYSTEM BOUNDARIES

Freeman Wong

Program Manager
Enterprise Imaging Repository
eHealth NSW
Sydney, NSW, Australia

freeman.wong@hss.health.nsw.gov.au

Background

The Australian state of New South Wales (NSW) is the most populous state in Australia. It is situated on the east coast, covering an area of 809,444 square kilometres. NSW has an estimated population of 7.4 million people with just under two-thirds of the state's population (4.6 m) living in the metropolitan areas. Over one-third of the population (2.8 m) is spread out in a fairly large rural and regional geographic area. (see figure 1)

New South Wales Health (NSWH) oversees 15 Local Health Districts (LHD), one Children's Hospitals Network and a Justice Health Network. These LHDs and Health Networks are responsible for providing health services in a wide range of settings within their boundaries. (see figure 2)

In 2013-14 the NSW Health recurrent expenditure budget was $17.9 billion, an increase of $884 million or 5.2% more than the 2012-13 revised budget. This equates to around $49 million spent across all LHDs and the two Health Networks each and every day. NSW Health employs more than 100,000 staff and has around 2,300 beds across 220 hospitals. In any given day, the health system admits 5,600 patients, responds to 6,500 cases in emergency departments, and carries out 1,000 operations.

Strategic Drivers

Like most countries with an ageing population, there are increasing demands on public health resources as hospital activities continue to increase at a rampant pace. As a result, the pressure for a more efficient health system is greater now than ever before. eHealth NSW's Medical Imaging Program is part of a wider investment in the overall e-health strategy, as NSW Health embarks on its journey to the seven stages of the Healthcare Information and Management Systems Society (HiMSS) maturity model (HIMSS Analytics). Its aim is to improve patient outcomes by providing critical key infrastructure as a cornerstone for integrated care for patients in both metropolitan cities as well as rural and regional areas (see figure 3).

Goals and Objectives

As part of eHealth NSW's Medical Imaging Program, the Enterprise Imaging Repository (EIR) is a centralised store that allows digital radiology images and reports to be shared across public hospitals in NSW. The EIR is made possible by utilising existing medical imaging infrastructure as part of a state-wide Picture Archiving and Communications System (PACS)

Figure 1

and Radiology Information System (RIS) implemented by the Medical Imaging Program.

Based on a state-wide federated model, the EIR connects to 10 different RIS PACS supplied by four different vendors, utilising a combination of HL7 and DICOM standards. At the heart of the EIR is the Imaging Repository, utilising a Vendor-Neutral Archive solution and an Enterprise Patient Registry (EPR), based on a proprietary healthcare master person index solution, responsible for reconciling different patient identities across different juristictions. Implementation of the solution was overseen by a global ICT solution provider as the primary contractor.

The overall solution is connected to the National Medicare Health Identifier (HI) service, where EPR searches and retrieves the Individual Health Identifier (IHI), a unique patient identifier across the whole of Australia. IHI is an enabler for a broader national e-health strategy in a comprehensive patient electronic health record, known as Personally Controlled Electronic Health Record (PCEHR).(see figure 4)

NSW is currently producing around 4 million studies per annum across all public hospitals, around two-thirds of which are generated within metropolitan cities. One of the key challenges that faces NSW are the vast regional areas, which account for the remaining one-third of all state-wide diagnostic imaging. Patient transfers and referrals to tertiary hospitals are common occurrences, as many specialty services are located in the metropolitan cities.

By allowing images and reports stored in the EIR to be accessed by clinicians via a patient's Electronic Medical Record (eMR) or via the hospital's RIS/PACS, not only does it allow clinicians the ability to obtain a more comprehensive picture of the patient's condition and medical history, clinicians are also empowered to make

Figure 2

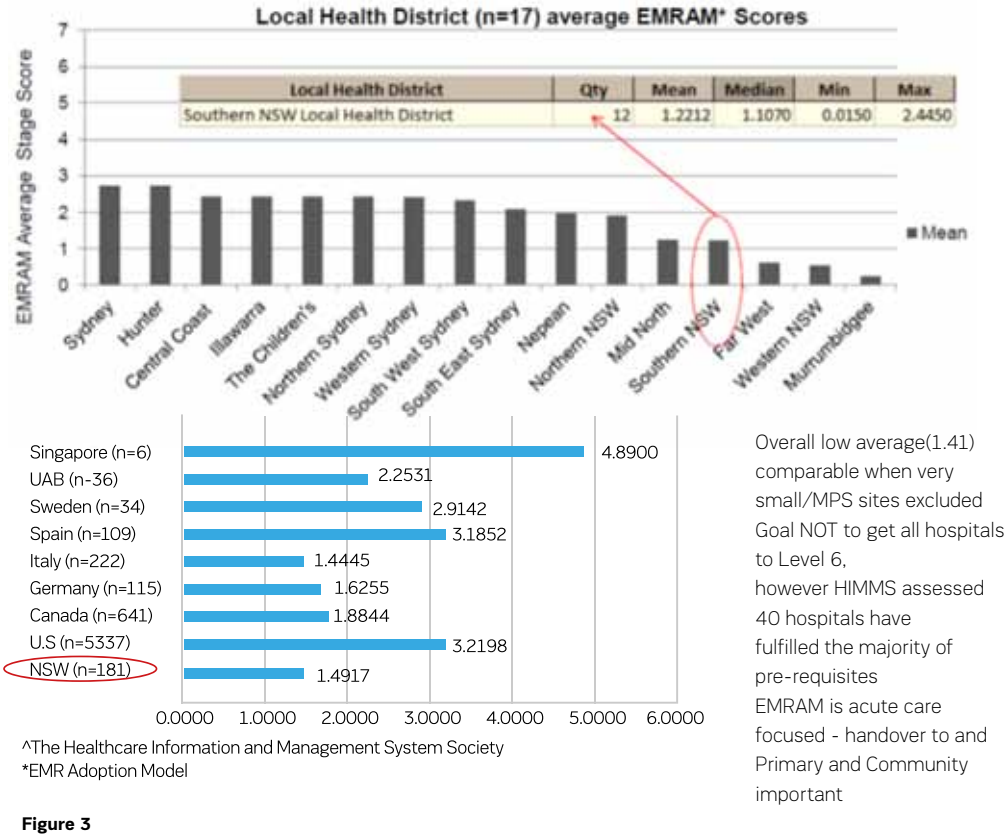


Figure 3

faster and more accurate diagnostic decisions and treatment plans, leading to better patient outcomes. Between January and June 2014, there were approximately 600,000 eMR links posted across NSW. Dr. Allan Kerrigna, a paediatrician at the Orange Base Hospital in rural Western New South Wales, commented that "Being able to share an image with another clinician and discuss and evaluate the same image at the same time adds a new level of collaborative care that we are all working in the same direction. In some instances, it avoids the need to transfer patients to tertiary centres."

Implementation Challenges and Critical Success Factors

Like many ambitious large-scale health ICT projects, there were a number of challenging factors influencing the success of the EIR project. Not least was the size and the complexity of the integration. Although there are other large-scale VNA implementations around the world, none of these involve multiple instances of health information systems linking patient demographics and radiological information. The EIR solution integrates four different RIS/PACS products, two different PAS and eMR vendors across 16 different LHDs and health networks. In addition, there are over 10 different interface engines, each involving multiple interfaces in and out of the solution. One of the great challenges is the standardisation of different code domains into a state-wide common data model; the exercise involved mapping hundreds of codes (and in some instances thousands of codes) across the state, in order to provide a foundation for interoperability between systems.

Another key challenge that the project needed to overcome was to ensure interoperability of the solution across all connecting systems. Even though the solution is governed by industry standards such as HL7 and DICOM protocol, each vendor and indeed each system had a slightly different intepretation of the standards. Initially, the project anticipated a degree of "cookie cutter" approach for sites with similar systems, business processes and clinical workflow. This was certainly not the case as the project progressed through the pilot stage and to the general deployment stage. This not only made the integration effort more difficult, but it also meant that at times changes to the architecture design were warranted. For example, initially the solution was designed to distribute radiology results in the form of a DICOM Structure Report (SR). However, during system integration testing, it became apparent that although DICOM SRs could be received by destination PACS, the content could not be displayed to end users. As a result, changes were made to the solution design in order to utilise HL7 result messages so they are viewable by clinicians in their systems. It is therefore incredibly important to ensure each vendor partner has the flexibility required to accommodate changes as the project matures in its system development lifecycle.

Lastly, efforts to manage both change and clinical engagement within local radiology departments were greater than originally anticipated. With the introduction of the state-wide repository, the LHDs had to work more closely with each other than before, in order to ensure accessibility of the clinical information. For example, the QA workflow now plays a more important role, as incorrect data stored to the EIR could potentially be accessed by clinicians, affecting patient care outcome. With the implementation of the state-wide repository, it introduces an opportunity for standardisation across NSW in terms of administrative processes, such as merging and unmerging radiology studies and the state-wide catalogue of radiology procedures and body parts. eHealth NSW

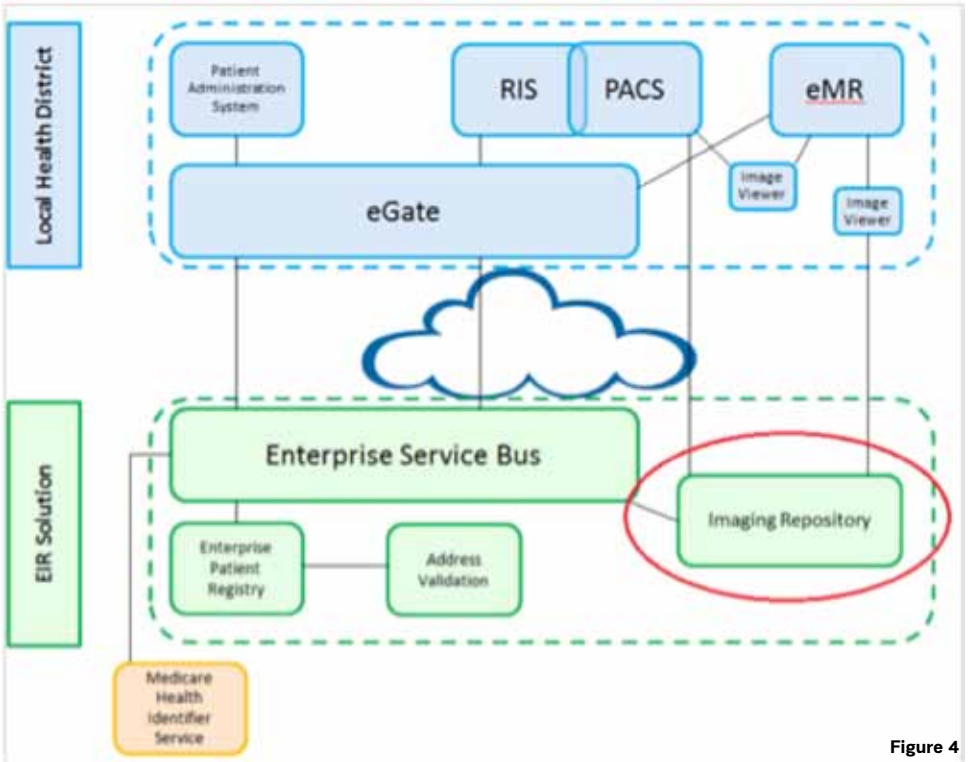


Figure 4

continues to work with local PACS administrators to improve existing processes across the LHDs as the EIR solution matures, whilst maintaining a level of local flexibility to cater for specific clinical workflow.

Given that the EIR introduces a level of operational overhead, the LHDs initially raised questions about operating expenses. As part of the stakeholder engagement, the Medical Imaging Program was able to articulate a number of tangible benefits that could translate to potential cost savings for the LHDs, such as performing fewer repeated imaging requests and unnecessary hospital transfers, as well as a reduced local PACS archive footprint. Operating expenses are based on the number of full-time equivalent clinical employees working in each LHD; therefore, LHDs such as those in the metropolitan cities with larger hospitals pay a larger share of total operational expenses for the EIR.

Benefit Realisation

One of the direct outcomes of allowing instant access to imaging information is the reduction of costly and time-consuming repeat tests. This also reduces radiation to patients, who would otherwise require extra imaging procedures. As the EIR project was only recently implemented, ongoing measurement and benchmarking of the associated benefits are to be reported by the LHDs.

Given that the benefits associated with the EIR project are largely clinical, it is difficult to translate into monetary terms without looking at trends and statistics after the period of normalisation post-EIR implementation.

By enabling the seamless transfer of clinical information between systems and health district boundaries, there is an opportunity to close the gap in the quality of patient care between rural and metropolitan facilities by having access to the same clinical specialists, frequently located in the larger metropolitan facilities, for the one-third of NSW patients in rural and regional areas.

In addition, the EIR also has potential future benefits. It could be utilised by other imaging specialities, such as cardiology, breast screening and endoscopy, to store their clinical data. Given the high costs for storing data and maintaining databases, there is a great deal of value in consolidating data into a single repository.

Having a central repository also paves the way for future improvements in efficiency for radiologists reporting on studies. By making studies available outside current boundaries, the EIR could act as an enabler for cross-district reporting. This would provide cost and efficiency benefits, and could help drive a more innovative way of diagnostic imaging across NSW.

"it is important to ensure each vendor partner has the flexibility required to accommodate changes as the project matures in its system development lifecycle"

Conclusion

As NSW continues to mature with its e-health investments and initiatives, repositories such as the Enterprise Imaging Repository are critical in providing a comprehensive picture of patients' clinical information. Other clinical contents such as discharge summaries are stored in a separate repository that is in the process of being implemented across the state. With the recent successful upload of the National Health Identifiers into the State Patient Registry, NSW is leading the way as the nation's largest consumer of the Individual Health Identifier (IHI). This establishes a very solid foundation for exchange of patient information across public and private sectors through national e-health strategies such as the Personally Controlled Electronic Health Record (PCEHR). ■

Key Points

- Background and context to the Enterprise Imaging Repository in New South Wales, Australia
- Strategy of eHealth NSW
- Enterprise Imaging Repository goals and objectives
- Implementation challenges and critical success factors
- Benefit realisation
- Next step

Reference

HIMSS Analytics. Continuity of care maturity model. [Accessed: 12 September 2014] Available from http://www.himssanalytics.org/emram/continuity.aspx

WHEN THE HIS LIGHTS GO OUT

OFFLINE OPERATION CONTINGENCY IN CASE OF TOTAL HIS OUTAGE

Miroslav Madjaric, PhD

Vice-President
European Association of Healthcare IT Managers, Brussels, Belgium

CIO, Advisor to CEO
University Hospital Center Zagreb (KBC Zagreb), Croatia

Miroslav.Madjaric@kbc-zagreb.hr

Borislav Bogner

Head of Applications Department
University Hospital Center Zagreb (KBC Zagreb), Croatia

Borislav.Bogner@kbc-zagreb.hr

Any discussion of information security is based on three pillars, mnemo-technically described with the notorious acronym CIA (ISO 2013):

- Confidentiality
- Integrity
- Availability

and while the integrity and confidentiality of patient information is of crucial importance in healthcare information systems, relatively little attention is paid to availability issues.

The ISO/IEC standard 27799 (ISO 2008) defines an electronic health record in the health information system as follows:

"repository of information regarding the health of a subject of care in computer-processable form, stored and transmitted securely, and accessible by multiple authorized users"

The terms "availability" and "accessibility" are used interchangeably and with similar meaning. "Availability" is somehow broader term, again defined in ISO/IEC 27799 (ISO 2004):

"the property of being accessible and usable upon demand by an authorized entity"

The lack of availability is always a nightmare for an organisation, whose operation relies heavily on core business information systems. This applies 100% for the considerations on Hospital Information Systems (HIS) within a hospital organisation.

The common sense evaluation question for any HIS functionality scope is:

"What happens in your hospital when HIS is down?"

If this is answered with "the hospital operation stops for non-emergency patients and procedures", evaluation shows that this hospital runs an integrated HIS with a broad scope of functionalities, covering most vital hospital processes. The word "stops" signifies that the HIS is a business-critical system for that hospital.

If so, very high standards for system availability are to be implemented in relation to the infrastructure (central hardware and computer network), as well as to some vital application and system software functionalities. Typical examples of HIS outages root causes are:

- Failures in non-redundant HW or network components;
- External and environmental causes (power supply, physical agents);
- Severe database locks or application errors;
- Adverse activities caused by malware.

ISO/IEC 27799 identifies 25 information security threats in the healthcare information systems, with some of them relating exclusively to confidentiality and integrity of information.

Following are to be taken into account as root causes of threats to availability:

1. Introduction of damaging or disruptive software
2. Misuse of system resources
3. Communications infiltration
4. Connection failure
5. Embedding of malicious code
6. Accidental misrouting
7. Technical failure of the host, storage facility or network infrastructure
8. Environmental support failure
9. System or network software failure
10. Application software failure (e.g., of a health information application)
11. Operator error
12. Maintenance error
13. Willful damage by insiders
14. Willful damage by outsiders
15. Terrorism

Despite awareness of these root causes and implementation of corrective measures, residual risk of failure, which cause outages of unacceptable duration, is sometimes unavoidable.

Services to patients in hospitals represent a vital business function as defined in the ITIL ® framework (ITIL 2007) and therefore must be treated as the most important function within hospital institutions. Upgrading availability in order to get a fraction of a percentage better availability in most cases represents a high growth in costs. Thus, the natural question imposed by this zero downtime demand is "how can the desired availability be achieved?". Even mirrored systems can have a downtime.

System operators tend to prevent most of these risks mentioned with redundancy and proper support. Both cost money, which in times of crisis are to be carefully examined and held within acceptable limits. Because of the fact that no risk mitigation program can reduce the risk to zero, hospital management interprets costs associated with improved security as a means of insurance.

In this situation, the guaranteed number of "9" in availability percentage has always to end with the question: "What do we do if and when the event of residual risk happens?". Ceasing the hospital's IT operation due to an HIS outage is not acceptable, so what is the alternative?

The answer in the University Hospital Centre Zagreb (Croatia) is: "Off-HIS operation!".

Generic architecture of this proposal is described in figure 1. This concept tackles three groups of processes:

Regular HIS operation;

Off-HIS operation during the HIS outage;

Restoration of information system after HIS recovery.

During on-HIS operation the "Ark" is automatically filled in with all HIS documents generated in the PDF form.

During "off-HIS" operation:

The archived documents for patients treated are retrieved from the HIS-Ark.

New documents and orders are generated in off-HIS manner (local templates) and stored in the HIS-Ark or locally in case of catastrophic network failure.

After restoring HIS operation, new documents from HIS-Ark are restored to HIS database for regular usage.

Aimed to be able to work with reasonable efficiency and patient safety during the HIS outage, some contingency of medical document management is to be established. This does not imply redundancy in system components (avoiding SPOFs – single points of failure), but rather the entire ongoing operation of a hospital during an unplanned HIS outage longer than a defined period of time, such as 30 minutes or 1 hour. Furthermore, this is not about a manual mode of operation: fetching existing patient information from the paper archive and recording new patient data on paper (by pen or by means of local word processing).

The University Hospital Centre Zagreb's concept is to generate an external document storage facility named "Ark" (as in Noah's Ark). This can be a standard Document Management System (DMS) outside of the hospital IT infrastructure and maintain a somewhat lesser version of HIS user roles.

This ark is filled in with all documents generated in HIS for every patient in real time. This procedure is feasible and economic, because in any case all documents are visible as PDF versions, and export to a distant location such as cloud based storage is related to a moderate cost.

Two issues are to be taken into account:

- Patient identification
- Confidentiality

In the often elaborated healthcare information installations that are in place, the HIS cannot be easily replicated where access rights are granted according to department attributions and time elapsed after last visit, as well as the permanent logging of every access to patient documentation is assured.

In an emergency operation through "HIS-Ark" some compromises are to be made, and in that case all users within the hospital will be able to get to all patient documents, with access logging over DMS system, and still be able to treat the patients.

The most important issue in an off-HIS situation remains the identification of the patient in order to allow for the storing of documents in the proper "container", as well as the retrieval of the documents during a downtime. In Croatia, citizens are given a unique citizen ID, this will be used for primary identification. Search mechanisms through name and DoB (date of birth) are available.

The structure of the document storage facility is organized by patient, with PDF standard navigation panes according to the documents' originating medical departments. Other relevant EHR information can be stored in PDF metadata, depending on capabilities of source HIS system.

This structure enables the productive part of the off-HIS operation. Thus, when outage occurs, and it is likely to last longer than an acceptable period of time, HIS users can manually switch to the off-HIS operation and perform the following four main functions:

1. Identification of the patient and her/his documents container in the Ark;
2. Retrieval of already stored medical documentation for a selected patient;
3. Entering of medical documentation newly produced during the HIS outage;
4. Communication with other off-HIS users related to the patient's management.

The first two processes have been outlined in the previous considerations. New documents are entered in locally stored templates that are similar to the corresponding online documents, but less sophisticated and

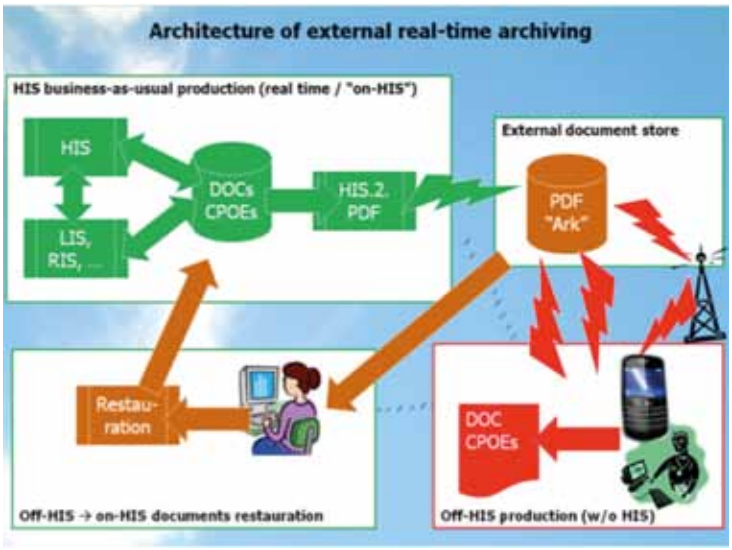


Figure 1:
Off-HIS operation (On-HIS, Off-HIS, store/restore)

specific to different medical specialties (e.g. automatic pasting of selected lab results in the discharge letter will not be possible).

These are simple text documents requiring more effort from the users, however this is necessary trade-off to keep the off-HIS system as simple as possible. These documents are stored in the patient document container after having been completed locally. They are accessible to other off-HIS users immediately.

Additionally, rudimentary clinical procedures order entry (CPOE) can also be performed. Similar to the new document entry, these orders can also be entered in the Ark and viewed by different service departments within the hospital (radiology, laboratory, pharmacy, kitchen, etc).

This part can be equipped with an order repository, which means that these orders are not stored solely in the patient PDF container, but also in service departments folders. This represents in fact the department's simple work-list, and the user can deposit their findings in patients' containers, from which the healthcare providers can view and retrieve the information required.

Once HIS service operation is restored, interim stored documents are to be integrated in the HIS database. This is a semi-automated procedure, which consists of taking text based documents from the Ark and storing them in the standard manner into the HIS documents repository. Criteria include the patient visit category (out-patient or hospital admission), as well as the coding of structured data (HIS documents templates, drugs, diagnoses etc). This task can be performed by hospital clerks or residents. This proposed HIS outage solution provides for a separate part of case-related document storage called "External findings", where the documents from the HIS-Ark can be automatically stored.

More advanced re-synchronisation methods can include automatic data retrieval from the Ark according to the timestamp at which the system failure occurred, in conjunction with the Ark document generation timestamps. Those documents that were generated during the downtime are sent to the HIS, while all others are ignored. The system can utilise the metadata to automatically return the documents to HIS system with all or the most relevant data intact, bypassing the need of manual data retrieval or additional data inputs.

In case of computer network outage, off-HIS operation can be conducted via smartphones, tablets and/or laptops connected to an independent public mobile network.

Special considerations are to be made to business-critical subsystems, such as lab or x-ray departments, in the following three issues:

Retrieval of previous findings: this has to be solved through regular findings' communication in on-HIS functioning (subsystem HIS);

Subsystem back-office operation during outage: in modern integrated systems this is a tricky issue that has to be analysed separately for each and every subsystem;

Off-HIS operation: if autonomous functioning can be continued, the communication with HIS is to be taken into consideration (CPOE and direct findings transmission to PDF Ark).

"what happens in your hospital when your information system is down?"

Conclusion

University Hospital Centre Zagreb strives to mitigate the residual risk of HIS outage by means of off-HIS operation. This system has minimal functionalities, but has to provide functionality that is:

- Safe for patients;
- Feasible for HIS users and
- Acceptable in terms of costs.

The basis for off-HIS operation is an external cloud-residing document storage facility, which contains all HIS documents related to the patients. During HIS outage the users can retrieve and enter patient documentation, as well as communicate with each other. Off-HIS is intended solely for the time period of an HIS outage. After HIS operation restoration, these documents are entered manually in the HIS document repository.

KBC Zagreb plans to implement such a solution in 2015, in collaboration with the HIS solution manufacturer IN2 and Croatian Telecom providing communication and cloud service. ■

Key Points

- Article discusses the contingency measures envisioned in KBC Zagreb in case of total or partial HIS outage
- Important issues highlighted in case all technical risk mitigation measures failed
- Scenarios described: total HIS outage or subsystem failures/disconnections for short and longer period of time
- Procedures for off-HIS operation taken into account: full off-line mode, document archive availability, off-HIS medical documentation, information restoration after HIS recovery, communication with subsystems (lab, x-ray, pharmacy, kitchen etc)
- Special case of off-HIS documentation proposed: external PDF archive

References

ISO (International Organization for Standardization) (2013)ISO/IEC 27001:2013 standard on Information technology: security tecHniques: information security management systems: requirements. Geneva: ISO.

ISO (International Organization for Standardization) (2008) ISO/IEC 27799 Health informatics: Information security management in health using ISO/IEC 27002. Geneva: ISO.

ITIL® (2007) Glossary of terms, definitions and acronyms [Accessed: 9 October 2014] Available from http://www.best-management-practice.com/gempdf/itil_glossary_v3_1_24.pdf

Swanson M, Bowen P, Wohl Phillips A et al. (2010) Contingency planning guide for federal information systems. Washington, DC: National Institute of Standards and Technology, U.S. Department of Commerce. [Accessed: 3 October 2014] Available from http://csrc.nist.gov/publications/nistpubs/800-34-rev1/sp800-34-rev1_errata-Nov11-2010.pdf

QUALITY ASSURANCE IN RADIOLOGY

INTERVIEW WITH THOMAS SCHÖNBECK, VICE PRESIDENT OF GLOBAL SALES & MARKETING AT RTI ELECTRONICS, SWEDEN

One of the major challenges faced by today's healthcare is quality assurance, and radiology is no exception. *HealthManagement* spoke with Thomas Schönbeck, Vice President of Global Sales, Marketing and Service at RTI Electronics, who gave us an insight into how x-ray quality assurance can be made faster and repeatable.

What does RTI do?

RTI is a leading provider of Quality Assurance solutions for x-ray. The company was established in 1981 and has its headquarters in Gothenburg, Sweden and its U.S. office in Towaco, New Jersey.

The founders of the company invented a device and method that use semiconductors instead of ion chambers. RTI has continued the development of this kind of equipment since the beginning of the 1980s.

Current RTI product offerings include the Black Piranha QA multimeter for any X-ray modality and the single modality easy to use Cobia and Cobia Flex meters. RTI also features Ocean 2014 database software for collection, real-time analysis and reporting of standard and customized QA measurements.

What is the key to effective x-ray Quality Assurance?

RTI is all about making the work process more efficient. What we usually hear from our customers is that they want to work faster, due to time and budget constraints. Yet they need to make sure they do the job right. They also want to make sure the same procedure is applied each time. What we do is offer a system for their measurements that makes sure that when they leave the x-ray room, they are done. They are ready with their analysis and report – no need for time-consuming back office work.

In this way you make x-ray Quality Assurance faster as well.

Exactly, I attended a demonstration at a hospital recently, and they observed that the whole process took half the time it would have done otherwise.

Built-in Bluetooth in the Black Piranha and connectivity to Ocean 2014 software provide the foundation. With our wireless solutions the user is up and running instantly.

"the most important part is making the work process more efficient"

How does Ocean work?

Everything is stored in our devices; you don't need cables or anything. All the data that are measured pop into the Ocean software, then Ocean gives you a real-time analysis of the measurements. All measurement data is saved in the database, so if you need to look at these measurements again, and compare them with previous data to see trends, everything is easily retrievable. For every measurement an automatically generated report is also generated and saved in the database. With a couple of clicks in the Ocean software this report is sent to the customer. For efficiency reasons we see more and more customers abandoning the old way of working and looking for a more efficient option. We think the Black Piranha with Ocean provides this.

Do your solutions bring other advantages?

Yes, quite a few, actually. Repeatability is very important to our customers. Following the test templates in our Ocean application you are able to use the same procedure every time. We want to make sure you can trust the measurements you are doing. We offer a longer lifecycle compared to our competitors: after the second year we offer an extended warranty of up to 10 years on our equipment. We recommend a 2 year calibration cycle instead of the more common 1 year. The Piranha is also upgradable: a customer only needs to buy looking at current need, but can upgrade later on if a need for more functionality occurs.

Are demonstrations available?

Yes, that's one of the most important things that we do. We like to meet the customers, show them the equipment before the purchase, to get a feel for how it works. It is also possible in some cases for the customers to borrow the equipment for a short period of time to do their own tests at their own pace. ■

Thomas Schönbeck

Vice President Of Global Sales & Marketing at RTI Electronics, Sweden

For further information contact

Thomas Schönbeck,
Vice President Sales & Marketing
RTI Electronics
SE-431 37 Mölndal, Sweden
Tel: +46 31 746 36 15
Email: thomas.schonbeck@rti.se

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INTEGRITY AND THE PERSONAL HEALTH RECORD

HOW TO STORE, ACCESS AND EXPLORE INTEGRATED HEALTH RECORDS AND ENSURE THEIR PRIVACY

Luís A. Bastião Silva,*MSc,*
PhD Student

Carlos Costa
Assistant Professor

José Luis Oliveira
Associate Professor

University of Aveiro, DETI / IEETA, Aveiro, Portugal
BMD Software Lda

bastiao@ua.pt

What is a Personal Health Record?

Personal health data is being generated in many distinct points of care and in many different formats. Medical tests such as blood pressure, medical imaging, electrocardiogram and others, are being gathered regularly, contributing to the patient's medical history and providing a valuable insight for future diagnostics. There are several definitions of personal health record (PHR), most of them share the idea of an electronic application through which individuals can access, manage and share information in a secure and confidential environment (AHIMA e-HIM Personal Health Record Work Group 2005). The PHR is a self-contained registry controlled by the subject of care, which allows accessing and consolidating health information, making it available to the ones with the right access credentials. There are several types of PHR instances, such as portable data devices, web entities, or integrated electronic health records.

The PHR is intended to be an electronic individual record maintained by the consumer and can be obtained by several Electronic Health Records (EHR) from different medical healthcare providers. However, considering this dual way of information feeding, the information supplied by the PHR can be factual or subjective. For instance, daily monitoring results (e.g. glucose), periodic weight monitoring, and measurements generated by home monitoring devices, is information that the healthcare professionals can rely on. Subjective information is not fully trustable, is related to its own assessment and could include details such as illness symptoms or fitness information.

"while the privacy of patient data is a requirement, it also creates new barriers to research"

Privacy and Confidentiality Concerns

With the explosion of health information technologies, citizens are becoming increasingly concerned about their personal information, as it is increasingly accessible and exposed to disclosure. These concerns about privacy and confidentiality can only be addressed if they control the process related to their medical records, including the control of access to registries, control of transfers and processing, and control of information deletion. However, citizens cannot be confident and secure about this process if they do not have access to the information themselves.

The public's concern has been raised by disclosures and violations of confidential medical information. Patients with chronic diseases and other severe medical conditions are a perfect example of a patient group, whose sensitive health information may be vulnerable to misuse. That could affect not only their job status but also their quality of life in the case of certain insurance denials. Moreover, with the advances in gene research, even young and healthy adults may be concerned about the disclosure of genetic information.

An Approach to Dealing with Security and Privacy Issues

While technology advances have created new equipment and devices to help medical doctors to diagnose specific pathologies, they have also generated more patient data as a natural consequence. The storage of these records has been supported through new technologies such as cloud computing services. Moving personal health data to the cloud is already a reality in several medical institutes around the world, including for instance medical imaging, clinical reports, vital signals, laboratorial tests and many other data sources. Figure 1 depicts key components and data flows. Currently, a significant part of companies in the EHR/PHR industry are claiming their products to be supported over the cloud, and are developing Software-as-a-Service, such as PHR, over the web. Clearly, these approaches bring benefits to healthcare institutions, since they no longer need to scale their own IT infrastructure. Nevertheless, a major issue is to guarantee the privacy of the patient and medical staff. In order to solve the privacy and confidentiality concerns, HIPAA (The Health Insurance Portability and Accountability Act) have defined privacy rules that should be covered by the PHR providers.

The first, and one of the most important issues to address when outsourcing health data storage to third party solutions, is the SLA (Service Level Agreements) with cloud providers. The SLA should clearly define the access level by the infrastructure maintainers, and specify if they are or not HIPPA compliant. While the cloud providers should respect the data ownership, there are no guarantees that special monitors are looking to the data for

any special purposes. In order to minimise the problem, the developed solutions should rely on a system authentication, authorisation and accountability. Moreover, researchers are studying strategies to grant privacy and confidentiality of the data and to avoid data tamper (Ribeiro et al.; Silva et al. 2012).

Trends in Personal Health Data

There are successful initiatives such as MyHealtheVet or Microsoft HealthVault, which are offering PHR for patients to update their own health and fitness information. Nonetheless, in recent years, other platforms such as PatientLikeMe have also been gaining momentum. These kind of platforms have the main goal of sharing some of the patient health conditions in order to find similar patients and thus, figure out an adequate treatment or ways to compare treatment outcomes with other subjects. While this can help the patients, they need to be aware that exposing their health problems publically can be risky (see Figure 1).

Personal Health Data Exploration: How to Maintain Patient Privacy and Utilise Data to Answer Research Questions

The confidentiality of patients' records is a social and medico-legal issue. Personal health data is considered valuable information for many entities including hospitals, doctors, researchers and insurances companies. However, to biomedical research communities they are key in the discovery of new and better treatments and drugs. To achieve outstanding results, access to many already existing EHR and PHR is a major necessity. However, access to clinical data depends on patient authorisation, countries' laws, ethical and legal issues, bureaucracy, and several other social, commercial and scientific issues.

While the privacy of patient data is a requirement, it also creates new barriers to research. Recently, new approaches have been used to create distributed environments, which allow research questions to be performed over a set of databases without exposing patient-level data. The Electronic Health Records for Clinical Research (EHR4CR) and EMIF (EMIF 2014) are two such examples. European Medical Information Framework (EMIF) aims to construct a socio-technological platform to promote the efficient reuse of existing patient data. The patient privacy needs to be kept in safeguard, and in most cases the information cannot flow outside the institution. Moreover, several strategies are being investigated to allow summarising information and extracting aggregated data to answer specific research questions. The analysis of large populations' healthcare data is performed inside the health centre, within their own control, and data never flows outside their safeguard.

While there still exist many issues and controversies about scaling these processes, which are mostly executed in a manual way by the researchers, the ethical and legal aspects will continue to be the major constraint in this path.

Conclusion and Future Perspectives

New technologies have created new opportunities for the integration and centralisation of patient health data. In many cases, moving data is a major requirement in order for the patient or medical staff to access these data everywhere, if they are authorised to do so. Thus, many concerns related to the mobility and data privacy have been raised. Technological solutions already exist to tackle these challenges, allowing to have the data over third party providers, and to access it without losing privacy while ensuring further data exploration. In the coming years, several efforts will be made to create an integrated view of patient records, i.e. to explore patient level data without exposing their privacy. There are still several gaps in the integration of data because, besides the security problems, clinical databases rely on proprietary solutions, distinct languages and terminologies, raising semantic interoperability issues. So, it is fundamental that both ICT and biomedical researchers work together to create new and advanced techniques that help improving patient treatments and general healthcare. ■

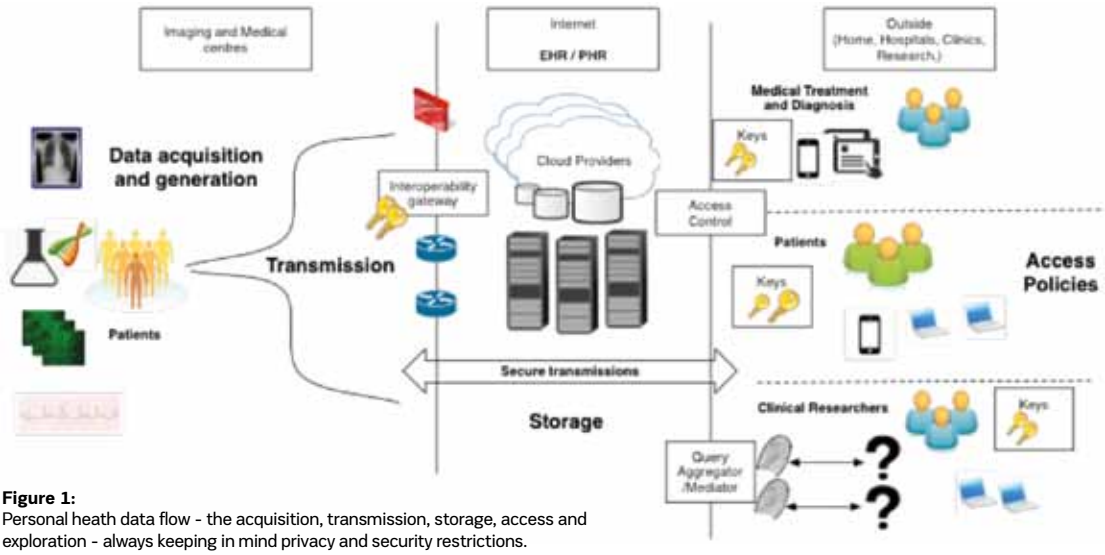

Figure 1:
Personal heath data flow - the acquisition, transmission, storage, access and exploration - always keeping in mind privacy and security restrictions.

Key Points

- Citizens are becoming increasingly concerned about their personal health information.
- Personal health records (PHR) put the control of these data in their own hands.
- However, the utilisation of existing patient data (EHR, PHR) is a crucial step towards new research outcomes.

References

AHIMA e-HIM Personal Health Record Work Group (2005) Practice brief. The role of the personal health record in the EHR. J AHIMA, 76(7: 64A-64D.

Electronic Health Records for Clinical Research (EHR4CR) (2014) Electronic Health Records for Clinical Research [Online] [Accessed: 4 October 2014] Available from: http://www.ehr4cr.eu/

European Medical Information Framework (EMIF) (2014) European Medical Information Framework [Online] [Accessed: 4 October 2014] Available from: http://www.emif.eu

Ribeiro L, Viana-Ferreira C, Oliveira JL et al. (2013) XDS-I outsourcing proxy: ensuring confidentiality while preserving interoperability. IEEE Journal of Biomedical and Health Informatics, 18(4): 1404-12.

Silva LA, Costa C, Oliveira JL (2012). A PACS archive architecture supported on cloud services. Int J Comput Assist Radiol Surg 7 (3): 349-58.

TRENDS IN POINT-OF-CARE TESTING

Anthony Kurec MS, H(ASCP). DLM

Clinical Associate Professor
SUNY Upstate Medical University.
Syracuse, NY, USA

kureca@upstate.edu

Point-of-care testing (POCT), also known as near-patient testing, alternate-site testing, decentralised testing, or bedside testing, is defined as the ability to provide patient testing outside of the central laboratory. POCT is not only performed at a patient's hospital bedside, but in the operating theatre, critical care unit, maternity unit, emergency department, prisons, nursing homes, physician's office, on emergency vehicles (ambulances), at health fairs, or at home. More recently, local pharmacies have adopted the technology to provide a one-stop service.

The overall intent of POCT is to make critical laboratory tests available to the care and management of patients in a timely and accessible manner. This patient-centred focus moves healthcare toward the early detection, prevention, and better management of the patient. From the early descriptions of point-of-care testing in 1984 (Hruszczyk 1998), its implementation has grown exponentially and is recognised as an independent section of the clinical laboratory. The worldwide growth of POCT has been estimated to be about 12% to 15% a year compared to the 6% to 7% growth rate of central laboratories (Wagar 2008). Other estimates put the POCT worldwide diagnostic market's worth at around $27.5 billion (€21.6 billion) by the year 2018 (ABC12 2014).

How it Works

There are three types of laboratory POCT instruments currently in use: (Price 2008).

(1). Single-use devices incorporate qualitative strips or cartridges such as dipsticks, complex strips, and immunostrips. An example would be the single-use glucose urine dipstick. Complex strips contain several layers for each pad on the stick, of which the top layer is semi-permeable keeping red blood cells from the reaction sites. Examples would be the common 10-parameter dipstick strip used for urinalysis and a strip that measures haemoglobin and glucose. Immunostrips utilise an antibody that recognises a specific analyte. Detection can be visual with the use of an immunosensor device.

(2). Single-use quantitative strip or cartridge utilises a charge-coupled device (CCD) camera that provides a quantitative value. The most frequently measured analyte is glucose. Some other analytes that have been adapted to this kind of technology are cardiac markers, electrolytes, coagulation tests, fertility tests, allergy tests, drugs of abuse, and blood gases.

(3). Multi-use cartridges are similar to the single-use device differing in its capacity to analyse more than one sample that uses a single cartridge that contains adequate amounts of reagents and calibrators for a fixed number of patient analyses.

These devices are based on technology developed in the 1950's. Using a technique borrowed from the newspaper industry that promoted quick drying of

Common Point-Of-Care Testing Analytes

Acetaminophen	Haematocrit
ACT (Activated Clotting Time)	Haemoglobin
Alcohol (Ethanol)	Lactate
ALT	Leukocyte esterase
Albumin	Nitrite
Bilirubin	Occult blood (Fecal & gastric)
Blood gases	Potassium
BNP	Protein
BUN	Prothrombin/INR
CKMb	RSV
Chloride	Sodium
Cholesterol	Specific gravity
Creatinine	Strep A
Glucose	Tuberculosis
Haemoglobin	Troponin
Haemoglobin A 1c	Uric acid
HCG	Urinalysis
HIV	Urobilinogen
Hepatitis C	
H. pylori	
Influenza	
Ketones	

Table 1.

ink, a reagent-impregnated paper pad was laminated to a plastic strip that was used in testing urine (College of American Pathologists Point of Care Testing Committee 2013). Over the following several decades, a number of additional reagents were developed.

Technological advances in microfluidics, optical readers, and miniature computerisation have lead to the development of compact, efficient, and affordable POCT devices. Wireless connectivity to a Laboratory Information System (LIS) provides a smooth and prompt transmission of test results to a healthcare provider and the patient's medical record. It is anticipated that these portable devices will eventually incorporate the same technologies used in smartphones (SHE'D – 'shrink, hide, eliminate, and define') making POCT an even more powerful testing modality, especially as the test menu for POCT grows (College of American Pathologists 2013). Table 1 lists some of the more common analytes used in point-of-care testing.

Benefits

The main benefits of POCT are its portability and rapid turnaround time (TAT) for results. In one study (Kendall 1998), haematology, chemistry, and blood gas testing TATs were reduced by 74 minutes, 86 minutes, and 21 minutes, respectively. Based on quicker TATs, decision making was significantly altered in only 7% of patients in the cohort, yet these changes in management were critical to patient care.

In addition, use of whole blood samples saves time by not having to wait for clotting and centrifuging; samples do not have to be transported to the central laboratory; and no loss of specimen integrity due to processing delays. POCT requires smaller blood samples (generally a fingerstick), thus a benefit in testing neonatal patients and difficult-draw or elderly patients. Subsequently, smaller reagent volumes are used.

With improved TATs, monitoring of certain patient conditions may also be improved leading to greater patient satisfaction (Crocker 2013; Modern Humanities Research Association 2013). In non-hospital settings, follow-up office/clinic visits and phone calls may not be necessary when laboratory results are readily available (Lewandrowski 2013). This is particularly helpful with young patients and the elderly who otherwise might have to have a return office visit. When clinicians receive timely results, the length-of-stay (LOS) for patients in the emergency department may also be reduced (Hortin 2014). This can avoid unnecessary treatment or additional testing, saving time and costs (Kendall 1998). Many devices are linked wirelessly to the LIS, thus avoiding transcription errors, quicker availability of results, and appropriate documentation for billing purposes.

"main benefits of POCT are its portability and rapid turn-around time"

Disadvantages

POCT has had its share of detractors over the years, mostly regarding the reliability of results when compared to a central laboratory. Though technology has significantly improved POCT quality, there are still many opportunities for errors to occur. The Ontario Laboratory Accreditation body declared that POCT errors were a major source of error compared to other laboratory errors, generally in the analytic phase of testing, accounting for 65% of errors (Kendall 1998). While some POCT manufacturers claim that quality control practices similar to those found in a central laboratory are not necessary, it is clear that a quality systems management protocol for POCT needs to be in place (Kee 2014).

A particular concern with ensuring quality practices with POCT is training. Often times, POCT is performed by non-laboratorians who may have received only a cursory introduction as to how a particular device is to be used. Even for those that have been trained, the infrequency of performing POCT can lead to procedural errors. Use of POCT in some developing countries has faced their own difficulties due to inconsistent electrical power, lighting, refrigeration, and high staff turnover (Hortin 2014).

Improper care of the devices, including infection control, can result in serious problems. The Centers for Disease Control and Prevention (CDC) issued a warning when a shared glucose meter was improperly decontaminated resulting in an outbreak of viral hepatitis (Centers for Disease Control and Prevention 2012). Deploying multiple types/makes/models of devices to various hospital departments, clinics, and physician offices compounds this situation. With different devices, different procedures are needed of each type. Initial training and recurring competency assessments are critical to maintaining a quality systems POCT program (Ford 2010; Kee et al. 2014; Wagar 2008).

Conclusion

One cannot avoid talking about POCT without addressing the cost-benefit of such a program. The initial outlay for equipment purchases is greater for a central laboratory compared to POCT, however, the cost per test is generally higher for POCT due to a lower economy of scale (Hruszczyk 1998). Yet, looking at expenses at a macro-level, other savings may be appreciated by shortening patient LOS. In other studies, savings (in equipment,

Cont. p 80

TRINITY BIOTECH

meritas® | POC Analyzer

TOM PARENTEAU
VP of Cardiovascular Products

IMAGE
Courtesy of Keeley Parenteau

There has been a lot of talk at the ESC Congress about sustainable cardiology and meaningful innovations. How does your product fit into this conversation?

There are a couple of key issues in emergency medicine today, where chest pain patients are coming into overcrowded emergency rooms, experiencing long waits and are not getting the timely care they require. Because of the need to transport samples to the lab, current in-house lab methods are time consuming, with test results often not available for an hour or more. However, healthcare institutions have historically been hesitant to adopt POC testing due to concerns about its performance. With new testing guidelines, existing point-of-care platforms in use by hospitals are simply not good enough. Their use can lead to too many healthy patients being admitted, or too many sick patients mistakenly being sent home. Our state of the art troponin test is guideline compliant, which makes it better than the vast majority of existing central laboratory platforms. The Meritas POC Analyzer and the cTnI test deliver results within 15 minutes, right at the patient's bedside..

What is the competitive advantage of your product and what are the benefits for patients and physicians?

This fast turnaround time is paramount to improved decision-making and rapid intervention in the emergency room. We are the only POC Troponin assay to meet the new heart attack diagnosis guidelines, which places us in a unique position. Our innovative technology allows for exceptional flow control at every point, resulting in unprecedented test precision and sensitivity within the shortest possible timeframe. This leads to better patient outcomes and patient satisfaction, improves waiting times, reduces costs associated with needless additional testing, and because of

MERITAS TROPONIN I: GUIDELINE COMPLIANT PERFORMANCE

- First and only true POC test able to provide results consistent with the Third Universal Definition of Myocardial Infarction
- <10% CV at the 99th percentile Upper Reference Limit (URL)
- Only 200µl Whole Blood or Plasma required
- One step procedure – no sample preparation required: simply add sample
- Results available in just 15 minutes

Guideline compliant high sensitivity Troponin and BNP tests

What have customers and key opinion leaders had to say about the Meritas system?

There is a great deal of excitement about the platform and its ability to allow physicians to make better informed decisions about patient care sooner. One prominent thought leader, **Frank Peacock**, **MD, FACEP, Professor, Emergency Medicine Associate Chair and Research Director Baylor College of Medicine Houston, Texas,** summarized that excitement with the following:

"The Meritas® Troponin test outperforms most historical central laboratory tests, is on par with some of the latest high sensitivity laboratory assays only available in Europe and does it all at the point-of-care in just 15 minutes. Its availability resolves a longstanding critical need and serves as an inflection/pivotal point in improving patient care."

the combined power of the device precision/sensitivity, allows for faster patient disposition algorithms and decisions.

What is your target market?

We obtained the CE mark for our high sensitivity Troponin I product in January 2014 and for our BNP product just this August. We are currently performing clinical trials for our FDA submissions. We expect this to be completed early next year. The Meritas is perfectly suited for emergency rooms and some primary care settings. The products will be made available worldwide.

Dealing with patient data comes with responsibility. How do you handle issues of data transmission and security?

Each specific healthcare facility has its own data protection protocols and firewall. Our data transmission happens securely via Ethernet cable. The cloud is not used in the current process. At no point does our company store patient data. Data is collected and remains within the institution at all times.

What is your company's vision, and do you integrate the opinions of clinical thought leaders and hospital management experts into the company goals?

Yes, they are vital to success in today's evolving healthcare environment. At Trinity Biotech we strive to provide an all-encompassing turnkey solution to medicine's toughest and most critical issues with our diagnostic tools, software and cutting edge technology, which in turn enables our customers to better manage their patients and be leaders in their field. In collaboration with many of the world's top clinical thought leaders, we have already won CE marking for our first and second Meritas tests; Troponin, for diagnosing heart attacks and BNP, for diagnosing heart failure. Beyond that, we have begun working on the next generation analyzer and are in the process of developing additional tests for pulmonary embolism, D-dimer, along with other tests for a host of other critical conditions. We are solely focused on delivering high value critical tests for the fast-paced emergency room. ■

reagents, and labour) were seen when several satellite stat laboratories were closed once POCT was implemented (Pearlman 2007). Patients that can be discharged sooner open time slots for other patients, thus increasing workload, improving patient workflow, and limiting additional expenses seen with longer patient stays.

POCT has come a long way in the past 20 years. With improved technology the test result accuracy for most POCT devices is comparable to those from a central laboratory under the proper user conditions. Quicker TATs allow clinicians to make faster medical decisions and perhaps limit unnecessary treatments and/or other procedures (Kendall 1998; Nichols 2000). It should be noted that POCT does not necessarily mean better patient outcomes, only that results are available sooner. Also, POCT currently has limited test menus, thus clinicians may have to wait for other, more complex laboratory tests that can be performed only in a central laboratory before further patient action can be taken.

Point-of-care testing can be a tremendous asset to many types of healthcare providers and healthcare settings. Critical to having a successful POCT program is to ensure quality practices are in place and are faithfully followed. Poor training, improper care of equipment, and lack of quality control is detrimental to the program. The best programs are based on inter-disciplinary team work with the laboratory taking a lead role in managing the program. Each site that provides patient care must carefully evaluate the need for POCT, the equipment to be used, and the personnel performing the tests to ensure accurate and useful data are generated. ■

Sources of Potential Errors in Point-Of-Care Testing

(Kee et al. 2014; Ford 2010; U.S. Food and Drug Administration 2013)

1. Inadequate training and retraining
2. Large number of devices with an equally large number of users
3. Use of different device brands or models
4. Wide distribution of reagents/materials
5. Different reference intervals (from central lab & different models)
6. Malfunctioning instrument/low battery
7. Loss of connectivity with LIS
8. Dirty optical reader
9. Uncalibrated device
10. Improper strip insertion
11. Inadequate amount of sample
12. Improper fingerstick collection (squeezing of finger)
13. Interferences (maltose, galactose, xylose for glucose testing)
14. Expired, contaminated, or deteriorated reagents
15. Ambient temperature fluctuations
16. Different methodologies from central laboratory testing
17. Different specimen types (blood, serum, plasma)
18. Failure to document results
19. Inaccurate patient identification
20. Patient dehydrated/in shock
21. Patient is anemic/polycythemic

Table 2

Key Points

- Point-of-care testing, with the advances in technology and connectivity in the last 20 years, has become a prominent laboratory service.
- Point-of-care testing can significantly improve laboratory turn-around times by shortening pre- and post analytical times.
- Point-of-care testing can offer easier access for patients at remote locations and other off-site areas.
- Point-of-care testing requires an inter-disciplinary effort to ensure that quality results are obtained.
- Cost-effectiveness of point-of-care testing can be realised under controlled conditions.

References

ABC12 (2014). Point-Of-Care diagnostic market worth $27.5 Billion by 2018, 12 September. [Accessed: 6October 2014] Available from http://www.abc12.com/story/26516997/point-of-care-diagnostic-marketworth-275-billion-by-2018

Centers for Disease Control and Prevention(CDC) (2012) Diabetes and viral hepatitis: important information on glucose monitoring, 31 July. [Accessed: 6 October 2014] Available from http://www.cdc.gov/hepatitis/settings/glucosemonitoring.htm

College of American Pathologists Point of Care Testing Committee (2013) Point of care testing toolkit. [Accessed: 6 October 2014] Available from http://www.cap.org/apps/docs/committees/pointofcare/poct_tool_kit.pdf

Crocker B, Lewandrowski EL, Lewandrowski N et al (2013) Patient satisfaction with point-of-care laboratory testing: report of a quality improvement program in an ambulatory practice of an academic medical center. Clin Chim Acta, 424: 8-11.

Ford A (2010) Eye the basics, not baubles, for point-of-care testing. CAP Today, January. [Accessed:6 October 2014] Available from http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt{actionForm.contentReference}=cap_today%2F0110%2F0110i_eye_the_basics.html&_state=maximized&_pageLabel=cntvwr

Hortin GL, Doern CD (2014) Management of point-of-care testing. In: Garcia LS, ed. Clinical laboratory Management,2nd ed. Washington, DC: ASM Press. Ch. 25, pp. 471-87.

Hruszczyk V (1998) Point of care testing: a review. Warde Report, 9(1): 1-17. [Accessed: 6 October 2014] Available from http://www.wardelab.com/9-1.html

Kee S, Adams L, Whyte CJ et al. (2014) QC explained 1.0 – quality control for point-of-care testing. Randox Quality Control. [Accessed: 6 October 2014] Available from http://www.randox.com/brochures/PDF%20Brochure/White-paper-Quality-Control-for-Point-of-Care-Testing.pdf

Kendall J, Reeves B, Clancy M (1998). Point of care testing: Randomised controlled trial of clinical outcome. BMJ, 316(7137): 1052-7.

Lewandrowski K, Lee-Lewandrowski E, Croker B et al (2013) Financial viability of point-of-care laboratory testing in a primary care setting in the United States. Am J Clin Pathol,140(Suppl 1): A039.

Medicines and Healthcare Products Regulatory Agency (MHRA) (2013). management and use of IVD point of care test devices. [Accessed: 6 October 2014] Available from http://www.mhra.gov.uk/home/groups/dts-bi/documents/publication/con071105.pdf

Nichols JH, Kickler TS, Dyer KL et al (2000) Clinical outcomes of point-of-care testing in the interventional radiology and invasive cardiology setting. Clin Chem, 46(4): 543-50.

Pearlman ES, Hilkey K, Sprei S (2007) The economics of point-of-care technology. Clin Leadersh Manag Rev, 21(5):E1-E10.

Price CP, St. John A. Point-of-care testing (2008) In: Burtis CA, Ashwood ER, Bruns DE eds. Tietz fundamentals of clinical chemistry. 6th ed. Philadelphia: WB Saunders. Ch. 12, pp. 188-200.

U.S. Food and Drug Administration (FDA) (2013) Common problems with the use of glucose meters at point of care. [Accessed: 6 October 2014] Available from www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109449.htm

Wagar EA, Yasin B, Yuan S (2008) Point-of-care testing: twenty years' experience. Lab Med, 39(9): 560-3.

Accelero - a subsidiary of Zimmer - Identifies Opportunities for European Hospital to Improve Perioperative Efficiency

Standardised perioperative process to improve orthopedic surgical throughput

AT A GLANCE

- Large, academic hospital in Northern Europe
- Over 6,000 orthopedic surgeries annually
- Nearly 1,000 hip fractures per year

ISSUES

- First case starts often delayed
- Low perioperative throughput due to fixed schedules
- Poorly coordinated room turnover procedures

RESULTS

Accelero assessed the orthopedic perioperative process and provided a solution to improve first case on-time starts, reduce room turnover and add one additional joint arthroplasty per OR per surgical day.

Introduction

Accelero Health Partners was hired to evaluate the orthopedic perioperative process for a hospital in a major European city. The hospital is one of the large academic hospitals in Northern Europe with an equally large emergency department. The orthopedic group performs approximately 6,000 surgeries per year, both scheduled and unscheduled, with nearly 1,000 resulting from accidental hip fractures.

The hospital is experiencing a decrease in the average reimbursement rate with a coinciding increase in the number of cases. To more effectively manage the growth, a new unit of OR suites was opened to accommodate the scheduled cases. However, current processes were limiting throughput to three joint arthroplasties per OR per day. Furthermore, staffing guidelines required all procedures to be completed by 4:00 pm.

Accelero was asked to provide insights and recommendations that would enable the hospital to increase orthopedic perioperative throughput and accomodate the budgeted case volume. Accelero team members went onsite to identify inefficiencies via benchmarking, observation of operating room procedures, patient flow review and interviews with key stakeholders.

Findings

The hospital had established a goal of four joint arthroplasties per OR per surgical day. The timing of first case starts and a longer than normal room turnover were seen as the primary reasons the hospital was not meeting this goal. FIGURE 1 shows the first case on-time starts of the hospital versus benchmarking data obtained from Accelero's proprietary database for joint arthroplasty cases.

First case on-time starts were well below the industry calculated based on the Accelero database due to variations in patient arrival times, poor communication, insufficient organization of materials and supplies and unclear expectations.

Inefficient processes that varied by staff members and a lack of clear expectations contributed to average room turnover times of 41 minutes between joint arthroplasty procedures, significantly higher than the average for hospitals in the Accelero database (FIGURE 2).

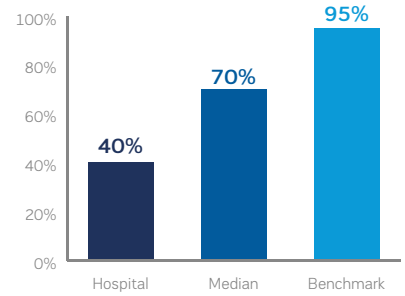

FIGURE 1. First case on-time starts for the hospital v. the Accelero database.

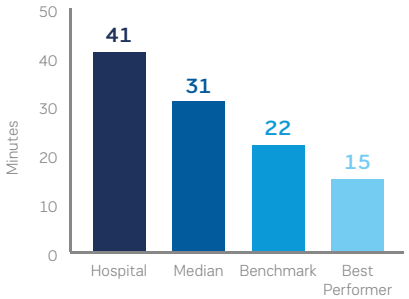

FIGURE 2. Room turnover times for the hospital v. the Accelero database.

Recommendations

At the request of the hospital, Accelero presented a plan to meet current demand and case volume by improving first case on-time starts and room turnover.

First Case On-Time Start

Accelero's solution to meet or exceed the benchmark for on-time starts consisted of:

- Clearly define and communicate the time patients need to arrive in both the pre-op area and the OR
- Develop a process flow document with responsibilities and timing of events for all staff members so they have clear expectations for daily arrival and tasks
- Create protocols to ensure all anesthesia and instrument case carts are fully stocked in advance
- Implement tracking methodology with an action plan for unprepared carts

Room Turnover

The proprietary Accelero hospital database was used to establish a room turnover goal of 22 minutes. The steps required to meet this goal consisted of:

- Clearly define and communicate goals
- Establish a multidisciplinary team of OR staff, management, housekeeping and anesthesia to focus specifically on room turnover process improvement
- Utilize lean methodologies to create standard work and eliminate wasteful efforts for all stakeholders
- Create control documents for monitoring progress with action plans for slow room turnover

Summary

Accelero confirmed that a low percentage of the daily first cases were starting on time. In addition, long room turnover time was identified as a limiting factor in meeting the hospital's joint arthroplasty volume goals. After a thorough analysis, Accelero provided a plan to add one more joint arthroplasty per OR per surgical day during normal operating room hours.

Accelero HEALTH PARTNERS

Accelero Health Partners, a subsidiary of Zimmer Holdings, Inc.
380 Southpointe Boulevard, Plaza II, Suite 400 | Canonsburg, PA 15317
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DUBAI: GLOBAL HEALTHCARE HUB

REAPING THE REWARDS OF HEALTHCARE INFRASTRUCTURE, EDUCATION AND REGULATION DEVELOPMENT

The UAE is one of the most developed healthcare markets in the Gulf Cooperation Council (GCC), with robust infrastructure and the second highest per capita healthcare expenditure in the region. The per capita healthcare spend stood at US$ 1,640 (€1,280) in 2011, which is more than twice that of Saudi Arabia (Alpen Capital 2014). With a growing incidence of lifestyle diseases and rising income level, the per capita spend in the nation, which rose at a compound annual growth rate (CAGR) of 8.1 percent between 2006 and 2011, is expected to expand further (Alpen Capital 2014).

The growing per capita expenditure on healthcare has not been the only reason for the thriving sector in the country. Dubai, recently ranked by Forbes among the world's top 10 most influential cities, has been, for years, seeing double digit growth in the number of inbound tourists, reaching over 11 million in 2013 (Thomas 2014) according to Dubai Department of Tourism and Commerce Marketing (DTCM). The Dubai government is maximising the benefits from its tourist inflow, and is increasingly bolstering its healthcare offering to cater to medical tourists.

To meet the local and regional demand for high-quality, patient-centered healthcare, Dubai Healthcare City (DHCC) was launched in 2002. DHCC is the world's largest healthcare free zone, and has grown in reputation over the past decade to become the region's choice of health and wellness for specialised clinical care and a host of allied services.

Located in the heart of Dubai, DHCC comprises two phases. Phase 1, dedicated to healthcare and medical education, covers 4.1 million square feet. Phase 2, which is dedicated to wellness, will cover 19 million square feet, and is currently being developed.

DHCC, overseen by the Dubai Healthcare City Authority (DHCA) its governing body and regulator, operates in Healthcare, Education and Research, Investment and Regulatory.

Healthcare

Today, DHCC is home to more than 120 medical facilities including JCI-accredited hospitals, outpatient medical centers and diagnostic laboratories with more than 4,000 licensed professionals. It also has 180 non-clinical facilities including healthcare consultancy, clinical research organisations, and patient education services.

In the first half of 2014, patient visits to DHCC crossed 600,000, suggesting 20 percent annual growth in visits from the one million recorded in 2013; visits expected to reach 1.2 million by year end.

Of DHCC patients, roughly 15 percent are medical tourists. The majority represented by patients from GCC, Arab World, Eastern and Western Europe and Asia, seeking procedures, treatments or tests in infertility, cosmetic, dental, cardiac, and orthopaedic.

Dubai has prioritised medical tourism as a key driver of economic growth in the run up to 2020.

Dubai is aiming to attract 20 million tourists as per Dubai Vision 2020, with an increasing percentage of these visitors utilising healthcare services.

DHCC released a survey in August using respondents from its medical facilities. The data collected represented a six-month period, beginning January 2014. (The sample size was weighted for facilities that offer clinical services so that it was representative of medical tourism profile.)

According to the results, the majority of physicians believe that medical tourists come to Dubai for quality of care (80 percent) and experienced physicians (61 percent), closely followed by specialist treatments (48 percent) available and geographic proximity (36 percent).

Education and Research

Education is an integral element of DHCC's operations. The Mohammed Bin Rashid Academic Medical Center (MBR- AMC) is a world-class beacon for medical education and research.

The Mohammed Bin Rashid Academic Medical Center offers clinical training programmes, postgraduate programmes and CME courses. It has collaborations with the Royal College of Surgeons of Edinburgh (RCSE), Royal College of Surgeons in Ireland (RCSI) and American Heart Association, among other healthcare and academic institutions.

The academic complex is home to Al Maktoum Medical Library (AMML), and the Khalaf Ahmad Al Habtoor Medical Simulation Center (KHMSC). The MBR-AMC also oversees the Dubai College of Dental Medicine (DCDM), which offers postgraduate diplomas in periodontics, prosthodontics, endodontics, orthodontics, paediatric dentistry, and oral surgery in collaboration with Royal College of Surgeons of Edinburgh (RCSE)

KHMSC is the first comprehensive clinical simulation training centre in the region and features advanced technology including unique high-fidelity patient simulators. It facilitates hands-on training for both healthcare professionals and students in a simulated, risk-free environment. This year, 612 multidisciplinary healthcare professionals from 22 hospitals were trained from January to June, bringing the total number of trainees to 1,400 since the centre's opening

Marwan Abedin

CEO
Dubai Healthcare City
Dubai, UAE

in November 2012. Courses offered include respiratory, cardiology, diabetes management, anaesthesiology and neonatology.

MBR-AMC supports the medical community at Dubai Healthcare City by providing access to quality and authoritative information resources through its Al Maktoum Medical Library, which provides more than 2,000 print titles, more than 12,000 e-journals and e-books, and more than 15 medical databases.

MBR-AMC also supports the sharing of knowledge and expertise in the healthcare industry by catering to medical education events through its auditorium, education suites, conference centers and lecture halls.

In September this year, DHCC announced the setting up of the Mohammed Bin Rashid University of Medicine and Health Sciences (MBR-UMHS), its first medical university, and the Mohammed Bin Rashid University Hospital, which will be developed in parallel. The Mohammed Bin Rashid University of Medicine and Health Sciences will offer a range of undergraduate and postgraduate degrees for both Emiratis and expatriates, welcoming its first batch of undergraduate medical students in September 2015.

The first phase of the project will include two colleges - the Dubai College of Dental Medicine (DCDM) which is already established and the College of Medicine for undergraduate medical students.

Investment

DHCC offers medical and healthcare providers with comprehensive solutions to set up operations and avail of free zone benefits. Investors have access to a variety of products including clinical, commercial, retail, business centre and freehold land.

The integrated healthcare free zone currently houses some of the world-leading healthcare providers from across the globe. The main buildings at DHCC's of Phase I are 96 percent occupied as of June 2014, and demand on space is on the rise. In the first half of 2014, DHCC attracted nine new medical institutions, with five existing business partners expanding their presence significantly. In January, Mediclinic City Hospital announced its expansion, which will have an advanced oncology unit set to further increase capacity in cancer care and to provide the latest diagnostic technology.

"Dubai has prioritised medical tourism as a key driver of economic growth in the run up to 2020"

Work on DHCC's Phase 2 is ongoing, and a few projects include a wellness luxury hotel and an International Scientific School Educational project that will introduce pre-medical curricula at school level - the first of its kind in the region. The school project is led by one of the most internationally recognised education institutions.

Regulatory

Regulation and licensure are handled by the Center for Healthcare Planning and Quality (CPQ), an independent regulator overseen by Dubai Healthcare City Authority (DHCA), the governing body and regulator of Dubai Healthcare City.

The CPQ was established to set and maintain international best practice in healthcare delivery and patient care at Dubai Healthcare City.

In January 2014, DHCC announced that ISQua, a global leader in assessing the standards in healthcare safety and quality, and the only organisation to 'accredit the accreditors', awarded CPQ the 2nd Edition of the CPQ Outpatient Clinic Quality Standards accreditation, valid from May 2013 to April 2017. Maintenance of this award depends on the submission to ISQua of two progress reports, one at 12 months post survey and the second at 30 months post survey.

In an effort to further strengthen its regulatory standards, Dubai Healthcare City announced in September the introduction of an independent Appeals Board for healthcare professionals and healthcare operators.

This marks a milestone for DHCC's regulatory framework as healthcare professionals or healthcare operators in the Dubai Healthcare City can now appeal against decisions relating to licensing or complaints.

A physician can now file a valid appeal by supporting his/her notice of appeal with new evidence which was not considered at the initial hearing and demonstrating that there is a clear possibility that the initial decision was unreasonable or unfair. An appeal may also be filed if it is supported by any evidence which was not available at the time the original ruling against the professional was made.

The Board comprises leading healthcare and legal experts: Dr Guy Fish, Senior Vice President at Fletcher Spaght, US, who is the current Chairman of the Board; Melanie Ho, Deputy Head of the Specialist & Private Client Dispute Practice, Wong Partnership, Singapore; Dr Alawi Alsheikh-Ali, Chairman, Institute of Cardiac Sciences at Sheikh Khalifa Medical City, Abu Dhabi, UAE; and Dr Matthew Lohn, Senior Partner, Field Fisher Waterhouse, UK.

UAE Statistics (2012)

Total population (2012)	**9,206,000**
Gross national income per capita (PPP international $, 2011)	**41,550**
Life expectancy at birth m/f (years, 2012)	**76/78**
Probability of dying under five (per 1 000 live births, 0)	**8**
Probability of dying between 15 and 60 years m/f (per 1000 population, 2012)	**85/60**
Total expenditure on health per capita (Intl $, 2012)	**1,355**
Total expenditure on health as % of GDP (2012)	**2.8**

Statistics available from:
http://www.who.int/countries/are/en/ [Accessed 22.10.2014]

A region of opportunity

Dubai, already the fifth most visited city in the world (MasterCard 2014), is racing ahead as a global hub for healthcare and wellness. It benefits from its location, and unique social fabric which is constructed with a multicultural community and mix of vacationing, living and business environments. It offers the widest of attractions from luxury urban spots to rugged mountains and tranquil beaches – all connected by state-of-the-art infrastructure and transport. In proximity, Dubai is connected to over a third of the world's population within four hours' flight, and two-thirds within an eight-hour flight.

To contextualise its growth potential, projected figures are: the MENA healthcare market is likely to be worth $144 billion (€112 billion) by 2020, with the GCC accounting for $69 billion (€54 billion) (Al Masah Capital 2014). The International Monetary Fund (IMF) estimates that the region's population would cross the 50 million mark by 2020, providing impetus to the consumption of healthcare services. Research by private management advisory and consultancy firm, Falak Consulting, suggests that the number of people aged more than 65 years old, who are likely to spend more money on common ailments like heart diseases, hypertension and diabetes, is forecast to double by 2020 (Maceda 2014). In addition, the region's healthcare industry will benefit from increased medical insurance penetration as relevant GCC government laws are put into effect in the coming years. ■

Key Points

- *The UAE is one of the most developed healthcare markets in the GCC*
- *Dubai Healthcare City (DHCC) is the world's largest healthcare free zone*
- *Education and research are an integral element of DHCC's operations*
- *Continued investment will ensure phase 2, which includes wellness-focused projects*
- *DHCC was awarded CPQ standards accreditation by the ISQua in January 2014*

References

Al Masah Capital (2014) MENA healthcare sector. [Accessed: 6 October 2014] Available from http://almasahcapital.com/uploads/report/pdf/report_111.pdf

Alpen Capital (2014) GCC healthcare sector report [Accessed: 6 October 2014] Available from http://www.alpencapital.com/

Maceda C (2014) GCC health care market to reach $56 billion. Gulf News, 24 June. [Accessed: 6 October 2014] Available from GulfNews: http://gulfnews.com/business/general/gcchealth-care-market-to-reach-56-billion-1.1351666

MasterCard (2014) Global Destination Cities Index [Accessed: 6 October 2014] Available from http://newsroom.mastercard.com/digital-press-kits/mastercard-global-destination-cities-index-2014/

Thomas B. (2014) Dubai hotels welcome 11 million guests in 2013. Arabian Business, 4 March. [Accessed: 6 October 2014] Available from http://www.arabianbusiness.com/dubai-hotels-welcome-11-million-guestsin-2013-541345.html

HealthManagement.org WEBSITE TOP 5

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Patients who get infected by C. difficile often develop serious complications such as severe diarrhoea, bowel perforation, toxic megacolon, multi-organ failure and even death. In most cases, the onset of disease symptoms from C. difficile occurs within ten to fourteen days.

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2 EMS System Can Improve Survival from Cardiac Arrest

A new emergency medicine system that sent patients to designated cardiac reviving centres increased the survival rate of victims of sudden cardiac arrests dramatically.

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3 Reducing Surgical Site Infections after Heart Surgeries

One of the most common postoperative complications seen after open heart surgeries is an infection at the surgical site.

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4 Healthcare Data Breaches

There have been several news stories recently related to sophisticated data breaches of confidential data in hospitals and healthcare organisations. Early this year, two healthcare organisations lost tens of thousands of data records because of lost USB flash drives and data sticks.

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5 Echometrix Software: New Ultrasound Technique

Ultrasound is widely used today as it is a safe, affordable and non-invasive technique to see the internal structure of the human body, including the human foetus, tendons and ligaments. Ray Vanderby, Professor of Biomedical Engineering and Rehabilitation at the University of Wisconsin-Madison has developed an ultrasound method that could analyse the condition of soft human tissue.

To read the full story scan this QR code

Special K Weight Management

Kellogg's SpecialK has been exploring how digital tools can assist people lead healthier lives. In a recent symposium at the European Congress on Obesity in Sofia, speakers presented the findings of research in the efficacy of MySpecialK.co.uk, a free online weight loss website which provides users with calorie controlled meal plans, healthy lifestyle tips and simple weight loss tracking tools.

Dr David Johns (MRC Human Nutrition Research, Cambridge, UK) presented the National Institute for Health and Care Excellence (NICE) review of Behavioural Weight Loss Programmes (BWMP's) and subsequent recommendations for successful services. In the review, calorie counting, contact with a dietitian and use of behaviour change techniques that compare participants' behaviour with others were associated with greater weight loss. BWMPs using a combination of diet and exercise were more effective than diet only or exercise only.

Dr Margaret Ashwell (Ashwell Associates, Ashwell, UK)) then summarised a UK trial, funded by The Kellogg Company, which tested the hypothesis that promoting breakfast cereal consumption, as part of a web based programme, results in loss of body mass. This trial was set up because there was reasonable evidence from observational studies that adults (de la Hunty and Ashwell 2007) and children(de la Hunty, Gibson et al. 2013) who regularly eat ready to eat cereals (RTEC) are slimmer than those who don't.

Therefore, in a single centre, single blind, randomised parallel study, the test group followed a fully interactive website (B) with 'prescribed' breakfast cereals whereas the control group followed website (A) giving standard advice on weight loss. Study site visits were made at 0, 4, 12 and 24 weeks for measurements of height, weight, skinfolds, body fat, waist and hip circumference. 180 women were randomly allocated to two equal groups. Subjects were in good health, aged 19-50 years, with a BMI ranging from 25-40 kg/m2. At baseline there was no difference in mean age or BMI of the two groups. The programme provided customisable goals based on lifestyle choice linked to a designated and flexible meal plan with detailed recipes and full ingredient information. Next to this, healthy lifestyle tips were provided and progress could be tracked and if wanted shared with friends.

The results showed that the percentage change in body mass loss was greater when following website B (2.4% with SD 4.0%) than website A (1.1% with SD 3.4%). There were 90 in each group and ITT ANOVA repeated measures showed a significant difference (p=0.013). For completers (website A: n=62, website B: n=64), the percentage change in body mass loss was also greater for website B (3.1% with SD 4.5%) than website A (1.5% with SD 3.1%)(p=0.023). The difference in fat mass loss

in the Digital Age

was borderline significance between groups. However this still shows that the body mass loss was not just due to water loss. Dr Ashwell concluded that the advice and motivation offered by an interactive website, including provision and consumption of breakfast cereals, results in significantly greater loss of body mass compared to the use of a standard website.

Dr Francis Bornet (NEALTH, Toulouse, France) then described a similar web-based weight management programme trial, which had been conducted in France. Its purpose was to determine whether the effectiveness of the programme as found in the UK would also be found in a country with a different dietary culture.

Its objective was to assess the efficacy of the weight-loss and weight-loss maintenance website programme in young overweight women without co-morbidity. The French trial was designed to be a single arm study to recruit and examine the effect of a 6m website programme in seventy healthy overweight women. They were asked to follow the recommendations of the website programme that provided nutritionally balanced controlled meal plans to lose weight during the first three months and to maintain their weight loss during the subsequent 3 months. Assessments were at the outset, at three months (3m) and at six months (6m). Main outcome variables were changes in body weight, waist and hip circumferences and fat mass. The main characteristics of women at baseline with mean (SD) were as follows: age (y): 33.4 (8.6); weight (kg): 77.0 (6.9); BMI (kg/m2): 28.4 (0.9); waist and hip circumferences (cm): 92.6 (5.9) and 109.8 (5.9), respectively.

Dr Bornet presented the results, which showed that changes in body weight and body circumferences measured between baseline and 3m, and baseline and 6m for patients in intention-to-treat (ITT) (n = 70) and completer (n = 49) populations were significantly reduced. At 3m, the completer population showed a significant reduction of body weight compared to baseline (2.7 (2.3) kg; t = –7.96, P <0.0001). During the 3m weight maintenance period women maintained their weight, hip and waist circumferences so that 6m measures did not vary significantly from 3m measures.

Dr Bornet concluded that the moderate, but maintained, reduction of body weight and body circumferences suggests that a website programme proposing a nutritionally balanced controlled eating plan can be a good approach to help with weight management in overweight women without any co-morbidities (Bornet F.R.J., Curis E. et al. 2014).

The results of the UK study and the French study suggest that strong differences in dietary culture do not seem to have large impact on the effectiveness of the web-based programme.

After discussion of these two trials, Dr. Nicola Lasikiewicz (James Cook University Australia, Singapore) presented the results of a recent systematic review exploring the psychological benefits of weight loss following participation in behavioural or dietary based interventions with or without exercise (Lasikiewicz, Myrissa et al. 2014). The results of the review demonstrated that improvements in psychological wellbeing, specifically, self-esteem, depressive symptoms, body image and vitality are frequently observed. Of interest, was that improvements in self-esteem and depressive symptoms were not always tied to actual weight loss, meaning that a person may feel better following the intervention, despite losing little or no weight. Dr. Lasikiewicz summarised by saying that understanding the changes a person goes through, psychologically, may be key to understanding successful weight loss following implementation of a weight loss intervention, specifically one that is behavioural in nature. Essentially, if a person feels better about themselves and loses weight following an intervention, then this may promote future weight loss success or weight loss maintenance.

In conclusion, the digital age brings a suite of new tools for people managing their weight and the experts who advise them. Interactive websites, such as MySpecialK.co.uk, can offer the motivation, encouragement and tracking tools required for a success weight loss journey.

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Prof. David Koff – Editorial Board Member Imaging

David Koff, MD, FRPC, is Radiologist-in-Chief, Department of Diagnostic Imaging, Hamilton Health Sciences, Ontario, Canada; Associate Professor and Chair, Department of Radiology, McMaster University; Founder and Director, Medical Imaging Informatics Research Centre, McMaster University; Co-founder of RealTime Medical. We put our seven questions to him recently:

1. What are your key areas of interest and research?
I strongly believe in a world where health data will be communicated seamlessly and securely between multiple platforms, environments and countries, where medical images will be readily available to health professionals and patients on a variety of supports; evidence-based knowledge will be made available to support clinical decisions and treatments. To make the dream come true, we need to promote the use of standards and train a new generation of health informatics professionals, as well as engaging actively in research to invent the tools of tomorrow.

2. What are the major challenges in your field?
Lack of resources, lack of support and interest for research, but also lack of accountability and complacency.

3. What is your top management tip?
Express your vision clearly and don't try to do too much at a time, you'll face major push back. Progress step by step and stay the course.

4. What would you single out as a career highlight?
Reaching a leadership position that has allowed me to craft and implement a vision and strategy for my department. It is so rewarding when you see it working.

5. If you had not chosen this career path you would have become a...?
Diplomat.

6. What are your personal interests outside of work?
Visual arts - mainly painting, travelling, hiking.

7. Your favourite quote?
The true sign of intelligence is not knowledge but imagination (Albert Einstein).

A dual citizen of Canada and France, Professor Koff attained his medical degree and diagnostic radiology qualification at Rene-Descartes University Paris V, France. He began his radiology career in 1982 as Radiologist at the Partner Centre d'Imagerie Médical de Creil, Oise, France, where he expanded the service, and developed innovative delivery and partnership models.

Having worked in France on image exchange over the Internet and wavelet compression solutions, he wanted to bring these products to market. As Europe was not ready at this time for this type of solution, he moved to North America. Following his move to Canada in 1998 he founded Easy Pax, Inc.

The full Zoom On can be found online at **www.healthmanagement.org** or scan **the QR code**

Dr. Áine Carroll - National Director, HSE

Dr. Áine Carroll, MB, BCh, MD, FRCP, FRCPI is the National Director, Clinical Strategy and Programmes Division of the Health Service Executive Directorate in the Republic of Ireland. We recently posed our 7 Questions to Dr. Carroll.

1. What are your key areas of interest and research?
Clinicians in leadership and management, implementation science, computer brain interfaces and disability; the opportunities for technology in facilitating participation and cost effectiveness of rehabilitation

2. What are the major challenges in your field?
Apart from obvious financial challenges, the biggest challenge is the increasing life expectancy and the increased incidence of non-communicable diseases and the need to reverse flow out of hospital and into the community. We also need to be braver and support older people at home as independently as possible and think more about quality of life rather than quantity of life.

3. What is your top management tip?
Be kind and be an active listener.

4. What would you single out as a career highlight?
Seeing patients exceed their personal rabilitation goals.

5. If you had not chosen this career path you would have become a...?
I have never wanted to be anything else but a doctor, apart from a brief notion of being an astronaut when I was around 7 years old.

6. What are your personal interests outside of work?
Spending time with my family, my children, gardening, reading and currently researching my grandfather's army career in the first word war.

7. Your favourite quote?
"Be the change you want to see" - Ghandi

Originally from Northern Ireland, United Kingdom, Dr. Áine Carroll studied medicine at Queens University in Belfast and did a postgraduate MD at Newcastle University, Newcastle upon Tyne. She completed her higher specialist training in Rehabilitation Medicine in Newcastle upon Tyne and came to work in Dublin in 2005.

Dr. Carroll is a Consultant in Rehabilitation Medicine, and was formerly Chair of the Medical Board of the National Rehabilitation Hospital, Republic of Ireland. She is also a former President of the Irish Association of Rehabilitation Medicine and Senior Clinical Lecturer, University College Dublin.

In her current role as the National Director, Clinical Strategy and Programmes Division of the Health Service Executive Directorate in the Republic of Ireland, Dr. Carroll's focus is on the consolidation of the achievements of the programmes to date by supporting regional and local teams with implementation to ensure effective changes. programmes is to improve individual specialty delivery and to promote integrated care and team work across services and specialties.

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